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GlaxoSmithKline Biologicals, SA**Clinical Study Report****1. TITLE PAGE**

Study detailed title: Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status

Study number: 204878 (ZOSTER-064)

Regulatory Agency Identifying Number(s): BB-IND-13857

Development phase: Not applicable

Study Vaccines: GlaxoSmithKline Biologicals SA's (GSK's) lyophilized formulation of the Herpes Zoster subunit (HZ/su) vaccine (GSK1437173A) or Placebo

Indication studied: *Shingrix* is indicated for the prevention of Herpes Zoster (HZ) and HZ-related complications, such as post-herpetic neuralgia (PHN), in adults aged 50 years of age and older

Sponsor name: GlaxoSmithKline Biologicals, SA

Study initiation date: 05 June 2018

Study completion date: 30 April 2019

Date of report: Final: 22 October 2019

Coordinating Investigators Dr. McNeil, MD, FRCPC, and Dr. Andrew, MD, MSc(Ph), FRCPC, Izaak Walton Killam Grace Health Sciences Center, Halifax, Nova Scotia, Canada

Sponsor Signatory: Anne Schuind, Senior Director, Clinical and Epidemiology Project Lead for Zoster, Clinical Research and Development, GSK

This study was performed according to the principles of Good Clinical Practices including the archiving of essential documents.

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2. SYNOPSIS

Name of sponsor: GlaxoSmithKline Biologicals, SA	Name of finished product: HZ/su vaccine	Name of active substance: Varicella zoster virus glycoprotein E (VZV gE)

Study detailed title: Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status

Coordinating investigators: Dr. McNeil, MD, FRCPC, and Dr. Andrew, MD, MSc(Ph), FRCPC, Izaak Walton Killam Grace Health Sciences Center, Halifax, Nova Scotia, Canada

Study centers: ZOSTER-064 was a multicenter study which included 171 of the 198 study centers that participated in ZOSTER-006 and ZOSTER-022. At least 1 study center from all 18 countries in which ZOSTER-006 and ZOSTER-022 were conducted participated in ZOSTER-064: Australia, Brazil, Canada, Czechia, Estonia, Finland, France, Germany, Hong Kong, Italy, Japan, Mexico, Republic of Korea (South Korea), Spain, Sweden, Taiwan, United Kingdom (UK) and United States (US).

Publications: None at the time of the report.

Study period:

Study initiation date: 05 June 2018

Study completion date: 30 April 2019

Phase of development: Not applicable.

Objectives:

The following objectives were assessed in the ZOSTER-064 study population.

Primary:

- To assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022.

Secondary:

- To present the distribution of Short Form 36 questionnaire (*SF-36*) and EuroQol 5D questionnaire (*EQ-5D*) scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.
- To assess vaccine efficacy (VE) against Herpes Zoster (HZ) by frailty status.
- To assess HZ burden of illness (BOI) by frailty status.

- To identify predictive factors for individuals developing HZ.
- To describe safety by frailty status.
- To assess humoral immunogenicity by frailty status.

Tertiary:

- To describe cell-mediated immunogenicity (CMI) by frailty status of subjects enrolled in ZOSTER-006 only.

Methodology: ZOSTER-064 was a multi-country, observational, retrospective study designed to assess the frailty status of subjects who participated in ZOSTER-006 and ZOSTER-022. Subjects were eligible for inclusion in ZOSTER-064 if they had signed an Informed Consent Form (ICF) in ZOSTER-006 and ZOSTER-022 which permitted use of their data in future research.

Data collection: For eligible subjects at sites participating in ZOSTER-064 who did not have a suspected HZ case in ZOSTER-006 or ZOSTER-022: subjects' year of birth and responses to Quality of Life (QoL) questionnaires were encoded in the ZOSTER-064 electronic Case Report Form (eCRF); their medical history, efficacy, immunogenicity and safety data were centrally retrieved from the ZOSTER-006 and ZOSTER-022 databases and linked to the ZOSTER-064 database.

For eligible subjects at sites participating in ZOSTER-064 who had a suspected HZ case in ZOSTER-006 or ZOSTER-022: responses to QoL questionnaires were previously encoded as part of ZOSTER-006 and ZOSTER-022; subjects' year of birth, responses to QoL questionnaires, and medical history, efficacy, immunogenicity and safety data were centrally retrieved from the ZOSTER-006 and ZOSTER-022 databases and linked to the ZOSTER-064 database.

Both sets of subjects constitute the ZOSTER-064 study population.

Data from 2 QoL questionnaires was collected in this study: The *SF-36* is a multi-purpose health survey with 36 questions. The *EQ-5D* is a questionnaire with 5 questions designed as a generic measure of health status that provides a simple descriptive profile and a single index value. The *EQ-5D* defines health in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

Frailty scores for study subjects who participated in ZOSTER-064 were calculated by incorporating the subject's medical history and patient reported outcomes (PROs) from the *SF-36* and *EQ-5D* questionnaires.

Number of subjects (planned and analyzed): Of the 29 305 subjects in the Total Vaccinated cohort (TVC) of ZOSTER-006 and ZOSTER-022, 2329 subjects were excluded as they belonged to centers not participating in ZOSTER-064. Thus 26 976 subjects were eligible for inclusion in ZOSTER-064. Of these, 776 subjects had QoL questionnaires previously entered as part of ZOSTER-006 and ZOSTER-022, as they had a suspected case of HZ, 26 151 subjects had QoL questionnaires encoded in ZOSTER-064 and for 49 subjects QoL questionnaires were not available.

Diagnosis and main criteria for inclusion: Data from all subjects enrolled in ZOSTER-006 and ZOSTER-022 could be included in ZOSTER-064 if the subjects were from centers which agreed to participate (i.e. performed data entry of QoL Questionnaires) in ZOSTER-064 and had signed an ICF which permitted use of their data in future research. Data from centers that did not participate in ZOSTER-064 were excluded from analyses.

Test vaccine, dose, mode of administration and lot number: Not applicable.

Other vaccine(s), dose, mode of administration and lot number: Not applicable.

Duration of study: 11 months between encoding the first and the last data for the study.

Criteria for evaluation:

The following endpoints were assessed in the ZOSTER-064 study population.

Primary endpoint

- Baseline Frailty Status:
 - Frailty Status pre-vaccination Dose 1 as defined by responses to components of the *SF-36* and *EQ-5D* questionnaire at vaccination Day 0 and the subjects' coded medical history.

Secondary endpoints

- *SF-36* and *EQ-5D* scale scores:
 - At Months 0, 14, 26 and 38.
- Confirmed HZ cases:
 - Incidence of HZ cases [during ZOSTER-006 and ZOSTER-022] for subjects in the modified Total Vaccinated Cohort (mTVC).
- HZ BOI:
 - HZ BOI score for subjects in both ZOSTER-006 and ZOSTER-022 as calculated from the Zoster Brief Pain Inventory (ZBPI).
- Solicited local and general adverse events (AEs) collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity of each solicited local AE within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset;
 - Occurrence, intensity and relationship to vaccination of each solicited general AE within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset.
- Unsolicited AEs collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0 - 29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects.

- Serious Adverse Events (SAEs) from ZOSTER-006 and ZOSTER-022:
 - Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in all subjects;
 - Occurrence of SAEs related to study participation or to a concurrent GlaxoSmithKline Biologicals SA (GSK) medication/vaccine during the entire study period in all subjects;
 - Occurrence of any fatal SAEs during the entire study period in all subjects.
- Occurrence of pre-defined AEs collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence and relationship to vaccination of any potential Immune-Mediated Diseases (pIMDs) during the entire study period in all subjects.
- Humoral immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022:
 - Anti-Glycoprotein E (gE) and anti-Varicella-Zoster Virus (VZV) Antibody (Ab) concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.
- CMI of the study vaccine in subset of subjects from ZOSTER-006 (Months 0, 3, 14, 26 and 38):
 - CMI in terms of frequencies of antigen-specific CD4[2+] T-cells;
 - Frequencies of CD4[2+] T-cells following induction with gE with antigen-specific Interferon gamma (IFN- γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF- α) and/or CD40 Ligand (CD40L) secretion/secretion to gE and VZV as determined by intracellular cytokine staining (ICS).

Statistical methods: The analyses were conducted according to the protocol administrative change 3 dated 11 February 2019, Statistical Analysis Plan (SAP) Amendment 1 dated 18 June 2019.

Analysis of Demography and Baseline Characteristics

Demographic characteristics (mean age at first vaccination including median, range and standard deviation (SD), gender, race, geographic ancestry and ethnicity) of each study cohort are tabulated overall and by vaccination group for each study cohort. Demographic characteristics in the TVC are also tabulated overall, by vaccination group and frailty status.

Assessment of frailty status

For the primary objective, the number and percentage of subjects in each frailty category (non-frail, pre-frail, frail and unknown) based on medical history and PROs pre-vaccination Dose 1 are presented by vaccination group, overall, by age group (50-59, 60-69, 70-79 and ≥ 80 years of age (YOA)), by gender and by country in the TVC.

Analysis of Vaccine Efficacy

VE against HZ in the ZOSTER-064 population was estimated separately for each frailty category in the mTVC. Further details of the model used to calculate VE are provided in the SAPs for ZOSTER-006 and ZOSTER-022.

Pooled HZ BOI scores are presented by frailty category in the mTVC. The number of subjects with a confirmed HZ episode, the mean BOI scores and the total follow-up time are presented by frailty status and vaccination group. VE against HZ BOI and 95% confidence intervals (CIs) are presented by frailty status in the mTVC.

Analysis of Immunogenicity

The analysis of immunogenicity in the ZOSTER-064 population was performed on the According to Protocol (ATP) cohort for analysis of immunogenicity.

Humoral immune response was assessed in the Humoral Immunogenicity subset and descriptive statistics of the following parameters are tabulated by vaccination group and frailty status at Months 0, 3, 14, 26 and 38:

- Geometric mean concentrations (GMCs) of anti-gE/anti-VZV Ab with 95% CIs;
- Humoral seropositivity rates with exact 95% CIs;
- Vaccine response rates (VRR) with 95% CIs.

CMI response was assessed in the CMI subset and descriptive statistics of the following parameters (for gE-specific CD4[2+] T-cell frequency and CD4[2+] T-cell frequency following induction with gE) are tabulated by vaccination group and frailty status at Months 0, 3, 14, 26 and 38:

- Descriptive statistics of the frequency of CD4 T-cell secreting at least 2 different cytokines (IFN- γ , IL-2, TNF- α or CD40L in any combination and by specific cytokine) to gE antigens;
- VRR with exact 95% CI at Months 3, 14, 26 and 38 (only in the gE-specific CD4[2+] T-cell frequency).

Analysis of Safety

The analysis of safety data in the ZOSTER-064 population was based on the TVC for safety, and the analysis of reactogenicity was based on the TVC - Diary card subset. Solicited AEs (Days 0-6 post-vaccination), unsolicited AEs (Days 0-29 post-vaccination), unsolicited AEs with medically attended visit from first vaccination up to Month 8, SAEs and causally related SAEs from first vaccination up to Month 14, causally related SAEs, fatal SAEs and pIMDs from first vaccination up to study end were analyzed by vaccination group and baseline frailty status.

Unless otherwise specified, the analyses of AEs included both non-serious and serious AEs. The terms “signs and symptoms” and “symptoms” in tables refer to AEs.

Further details of the statistical analyses are provided in the SAP.

Summary:**Demographics**

Of the 29 305 subjects included in the pooled ZOSTER-006/022 TVC, a total of 26 976 subjects (92%) were included in the TVC of ZOSTER-064 (Table 2.1). Subjects' mean age at baseline was 68.8 years and 58.1% were female. The majority of subjects were White Caucasian (74.6%). Demographic characteristics were well balanced between treatment groups in each frailty category. Completion rates were >99% for both the *SF-36* and *EQ-5D* QoL questionnaires used for assessment of frailty at baseline.

Table 2.1 Study population (Total Vaccinated Cohort)

Number of subjects	HZ/su	Placebo
N (Total Vaccinated Cohort)	13487	13489
Females:Males	7822:5665	7863:5626
Mean Age, years (SD)	68.8 (9.8)	68.8 (9.8)
Median Age, years (minimum, maximum)	71 (50, 96)	71 (48, 95)
White - Caucasian / European Heritage, n (%)	10062 (74.6)	10050 (74.5)
Asian - East Asian Heritage, n (%)	2048 (15.2)	2042 (15.1)
Other, n (%)	637 (4.7)	651 (4.8)

Source : Table 14.1.1.3

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Primary objective:

Baseline frailty status based on QoL questionnaires components and medical history at baseline (TVC)

- In the TVC, 11518 (42.7%) of subjects were classified as non-frail, 12 290 (45.6%) as pre-frail, and 3073 (11.3%) as frail at baseline (Table 2.2). Baseline frailty status was well balanced between the HZ/su (42.9%, 45.0% and 11.7% in non-frail, pre-frail and frail categories, respectively) and Placebo groups (42.5%, 46.1% and 10.9% in non-frail, pre-frail and frail categories, respectively). The percentage of subjects in the frail category in the TVC increased with age from 5.7% of subjects 50-59 YOA to 22.7% of subjects ≥ 80 YOA.

Table 2.2 Frailty status by age group and overall (Total Vaccinated Cohort)

	50-59YOA N = 6542		60-69YOA N = 4000		70-79YOA N = 12819		≥ 80 YOA N = 3615		Total N = 26976	
Frailty Status	n	%	n	%	N	%	n	%	n	%
Non-Frail	4305	65.8	2102	52.6	4457	34.8	654	18.1	11518	42.7
Pre-Frail	1843	28.2	1614	40.4	6719	52.4	2114	58.5	12290	45.6
Frail	375	5.7	268	6.7	1575	12.3	819	22.7	3037	11.3
Unknown	19	0.3	16	0.4	68	0.5	28	0.8	131	0.5

Source : Table 14.1.2.1

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

 ≥ 80 YOA = ≥ 80 years old subjectsNon-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

N in the column header is the total number of subjects in each age group and overall in the total vaccinated cohort.

n=number of subjects in each category by age category and overall.

Percentages are based on the total number of subjects in each age category of the total vaccinated cohort.

Efficacy/Immunogenicity results

Secondary Objectives:

HZ/su VE against HZ and against ZBPI BOI score by frailty status (mTVC)

- HZ/su VE against the first or only episode of HZ was $> 90\%$ in all frailty categories (Synopsis Table 3): 95.81%, 90.40% and 90.17% in non-frail, pre-frail and frail categories, respectively.
- HZ/su VE was shown to be high against ZBPI BOI score in all frailty categories: 98.6%, 92.6% and 85.2% in non-frail, pre-frail and frail categories, respectively. Absolute reduction in ZBPI BOI score between the Placebo (2.330, 1.475 and 1.173 in frail, pre-frail and non-frail categories) and HZ/su groups (0.345, 0.108 and 0.017 in frail, pre-frail and non-frail categories) was higher in subjects in the frail (1.985) than pre-frail (1.367) and non-frail (1.156) categories.

Table 2.3 Vaccine Efficacy: First or only episode of HZ during the entire study period by frailty status using Poisson method (modified Total Vaccinated Cohort)

	HZ/su				Placebo				VE			
									95% CI			
Type	N	n	T(year)	n/T (per 1000)	N	n	T(year)	n/T (per 1000)	(%)	LL	UL	p-value
Non-Frail	5545	8	21802.7	0.4	5551	188	21442.8	8.8	95.81	91.58	98.22	<0.0001
Pre-Frail	5738	18	21842.0	0.8	5969	191	22250.4	8.6	90.40	84.41	94.43	<0.0001
Frail	1449	5	5157.5	1.0	1348	46	4662.8	9.9	90.17	75.36	96.95	<0.0001
Unknown	53	0	186.5	0.0	62	5	194.0	25.8	100.00	14.61	100.00	0.0690

Source : [Table 14.2.1.2](#)

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

N = number of subjects included in each group

n = number of subjects having at least one confirmed HZ episode

T (year) = sum of follow-up period (censored at the first occurrence of a confirmed HZ episode) expressed in years

n/T (per 1000)= Incidence rate of subjects reporting at least one event

LL, UL = 95% Lower and Upper confidence limits

VE (%) = Vaccine Efficacy (Poisson method)

P-value=Two sided Exact P-value conditional to number of cases

Predictive factors for developing HZ (TVC - Placebo subjects only)

- Age was identified as the only significant baseline parameter ($p=0.0229$) when using Model 1 of the final Cox multivariate model for predicting HZ episodes.

Humoral immunogenicity by frailty status (ATP cohort for immunogenicity – Humoral)

- HZ/su elicited a robust anti-gE and anti-VZV antibody responses at 1-month post-dose 2 (Month 3) for all frailty categories i.e. anti-gE GMCs of 53 121 mIU/mL, 52 514 mIU/mL and 44 915 mIU/mL for non-frail, pre-frail and frail, respectively (Synopsis Table 4). Anti-gE and anti-VZV GMCs remained above pre-vaccination levels at least 3 years post-dose 2 (Month 38) for all frailty categories i.e. anti-gE GMCs 12 505 mIU/mL, 11 100 mIU/mL and 8 695 mIU/mL for non-frail, pre-frail and frail, respectively.
- VRR for anti-gE and anti-VZV antibody were highest at Month 3 in the HZ/su group for all frailty categories i.e. anti-gE VRR of 98.0%, 97.9% and 95.7% for non-frail, pre-frail and frail, respectively. At Month 38, VRR for anti-gE antibody in the HZ/su group remained high for all frailty categories i.e. anti-gE VRR of 81.7%, 74.6% and 62.0% for non-frail, pre-frail and frail, respectively.

Table 2.4 Seropositivity rates and Geometric Mean Concentrations (GMCs) of anti-gE antibody at Months 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity - Humoral)

					≥ 97 mIU/mL				GMC				
							95% CI			95% CI			
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
VZV.gE Ab.IgG	Non-Frail	HZ/su	PRE(M0)	603	596	98.8	97.6	99.5	1251.6	1151.7	1360.3	<97.0	49273.2
			P1I(M3)	603	603	100	99.4	100	53120.8	50229.2	56178.8	432.7	252485.3
			P1I(M14)	591	591	100	99.4	100	18628.2	17477.6	19854.6	512.3	150266.5
			P1I(M26)	582	582	100	99.4	100	14502.0	13610.9	15451.4	516.9	171049.4
			P1I(M38)	555	555	100	99.3	100	12505.4	11695.1	13371.8	374.8	121520.7
		Placebo	PRE(M0)	606	604	99.7	98.8	100	1389.1	1286.6	1499.8	<97.0	230579.9
			P1I(M3)	606	599	98.8	97.6	99.5	1314.6	1211.8	1426.2	<97.0	259629.7
			P1I(M14)	586	582	99.3	98.3	99.8	1272.4	1174.4	1378.5	<97.0	85917.5
			P1I(M26)	571	569	99.6	98.7	100	1355.5	1253.2	1466.1	<97.0	47396.8
			P1I(M38)	553	549	99.3	98.2	99.8	1304.3	1203.5	1413.5	<97.0	74603.5
	Pre-Frail	HZ/su	PRE(M0)	653	649	99.4	98.4	99.8	1363.0	1262.1	1471.9	<97.0	233132.9
			P1I(M3)	655	655	100	99.4	100	52514.0	49937.0	55224.0	863.2	308834.6
			P1I(M14)	640	640	100	99.4	100	16689.7	15739.5	17697.2	643.5	160387.0
			P1I(M26)	617	617	100	99.4	100	13344.2	12592.6	14140.6	376.7	87976.9
			P1I(M38)	586	586	100	99.4	100	11099.9	10458.8	11780.4	302.6	85298.8
		Placebo	PRE(M0)	695	688	99.0	97.9	99.6	1325.4	1227.0	1431.7	<97.0	28926.7
			P1I(M3)	697	691	99.1	98.1	99.7	1266.9	1171.6	1369.9	<97.0	82777.8
			P1I(M14)	662	657	99.2	98.2	99.8	1224.7	1129.9	1327.4	<97.0	41611.7
			P1I(M26)	628	625	99.5	98.6	99.9	1320.2	1219.1	1429.6	<97.0	29541.0
			P1I(M38)	588	585	99.5	98.5	99.9	1274.3	1171.4	1386.2	<97.0	29634.7
	Frail	HZ/su	PRE(M0)	138	137	99.3	96.0	100	1450.8	1230.9	1710.1	<97.0	16976.3
			P1I(M3)	138	138	100	97.4	100	44914.9	39734.6	50770.6	2119.1	219362.7
			P1I(M14)	124	124	100	97.1	100	13405.4	11701.3	15357.7	1125.0	80216.2
			P1I(M26)	115	115	100	96.8	100	11060.6	9689.0	12626.3	494.4	44973.4
			P1I(M38)	110	110	100	96.7	100	8694.8	7612.1	9931.6	1407.2	37879.9
		Placebo	PRE(M0)	125	125	100	97.1	100	1457.7	1213.6	1750.8	136.4	19896.0
			P1I(M3)	125	125	100	97.1	100	1310.8	1089.8	1576.7	121.0	12832.4
			P1I(M14)	114	113	99.1	95.2	100	1337.8	1089.7	1642.4	<97.0	19167.0
			P1I(M26)	112	112	100	96.8	100	1431.4	1156.2	1772.2	104.9	25054.3
			P1I(M38)	109	108	99.1	95.0	100	1399.1	1112.6	1759.2	<97.0	54820.5

					≥ 97 mIU/mL				GMC					
							95% CI				95% CI			
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max	
	Unknown	HZ/su	PRE(M0)	4	4	100	39.8	100	1172.9	389.0	3536.5	697.9	3258.9	
			PII(M3)	4	4	100	39.8	100	34703.5	18272.8	65908.6	20943.3	56029.4	
			PII(M14)	4	4	100	39.8	100	9834.3	3469.9	27871.7	4202.3	20391.5	
			PII(M26)	4	4	100	39.8	100	5278.7	1248.8	22313.6	2269.4	15956.7	
			PII(M38)	4	4	100	39.8	100	5128.7	1349.3	19494.2	2223.8	14611.5	
		Placebo	PRE(M0)	4	4	100	39.8	100	836.2	157.6	4434.9	186.8	2035.0	
			PII(M3)	4	4	100	39.8	100	854.8	119.2	6132.2	138.8	1922.7	
			PII(M14)	4	4	100	39.8	100	888.2	270.6	2914.9	349.3	2138.9	
			PII(M26)	3	3	100	29.2	100	712.8	143.6	3538.1	350.8	1237.9	
			PII(M38)	3	3	100	29.2	100	614.9	64.5	5863.9	222.8	1281.0	

Source: [Table 14.2.2.1](#)

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration equal to or above specified value

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

MIN/MAX = Minimum/Maximum

PRE(M0) = Pre-vaccination (Month 0)

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Tertiary Objective:

CMI by frailty status (ATP cohort for immunogenicity - CMI)

- In the HZ/su group, gE-specific CD4[2+] T-cells responses were highest at Month 3 for all frailty categories and remained above pre-vaccination levels during the 3 year follow-up period for all frailty categories.

Safety results:

Safety by frailty status (TVC and TVC - Diary card subset for solicited AEs)

- Solicited AEs within 7 days post-vaccination:** Percentages of solicited AEs (all, grade 3, vaccine-related and grade 3 vaccine-related) by dose and by subject were higher in the HZ/su group than in the Placebo group for all frailty categories (Synopsis Table 5 and Synopsis Table 6). Percentages of solicited AEs (all and vaccine-related) decreased with increasing frailty in the HZ/su group and were similar across frailty categories in the Placebo group. Percentages of grade 3 solicited AEs (all and vaccine-related) increased with increasing frailty in the Placebo group and were similar across frailty categories in the HZ/su group.
- Unsolicited AEs within 30 days post-vaccination:** Percentages of unsolicited AEs (all, grade 3, vaccine-related and grade 3 vaccine-related) by dose and by subject were higher in the HZ/su group than in the Placebo group for all frailty categories.

Percentages of unsolicited AEs (all and grade 3) tended to increase with increasing frailty in the Placebo group and were similar across frailty categories in the HZ/su group. Percentages of vaccine-related unsolicited AEs decreased with increasing frailty in the HZ/su group and were similar across frailty categories in the Placebo group. In the HZ/su group across frailty categories, the most frequently reported unsolicited AEs were injection site pain (25.1%, 22.0% and 18.9% for non-frail, pre-frail and frail, respectively), injection site erythema (10.5%, 8.8% and 7.3% for non-frail, pre-frail and frail, respectively), injection site swelling (7.9%, 6.4% and 5.6% for non-frail, pre-frail and frail, respectively). These events, which are reactogenicity symptoms, were also the most frequently reported vaccine-related unsolicited AEs.

- **Unsolicited AEs with medically attended visits up to Month 8:** Percentages of subjects reporting unsolicited AEs with medically attended visits were in the same range in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups. Across frailty categories, the most reported unsolicited AEs with medically attended visits by Preferred Term (PT) was nasopharyngitis in both groups (2.9%, 3.4% and 3.1% for non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 3.5%, 3.5% and 2.8% for non-frail, pre-frail and frail categories of the Placebo group, respectively).
- **SAEs up to Month 14 and up to study end:** Percentages of subjects reporting SAEs (all and fatal) were in the same range in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups. Few vaccine-related SAEs were reported in both groups and occurrence was balanced across frailty categories.
- **pIMDs up to study end:** Occurrence of pIMDs was balanced between the HZ/su and Placebo groups in each frailty category. No relevant differences in reporting of pIMDs were observed by frailty status in both treatment groups. Few vaccine-related pIMDs were reported in both groups and occurrence was balanced across frailty categories.

Table 2.5 Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period overall subjects and overall doses by frailty status: Frail Subjects only (Total Vaccinated Cohort - Diary Card Subset)

		Frail									
		HZ/su					Placebo				
					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Pain	All	483	276	57.1	52.6	61.6	461	32	6.9	4.8	9.7
	Grade 3	483	20	4.1	2.5	6.3	461	1	0.2	0.0	1.2
Redness (mm)	All	483	119	24.6	20.9	28.7	461	1	0.2	0.0	1.2
	>100	483	6	1.2	0.5	2.7	461	0	0.0	0.0	0.8
Swelling (mm)	All	483	79	16.4	13.2	20.0	461	2	0.4	0.1	1.6
	>100	483	0	0.0	0.0	0.8	461	0	0.0	0.0	0.8
Dose 2											
Pain	All	455	256	56.3	51.6	60.9	442	35	7.9	5.6	10.8
	Grade 3	455	25	5.5	3.6	8.0	442	4	0.9	0.2	2.3
Redness (mm)	All	455	104	22.9	19.1	27.0	442	1	0.2	0.0	1.3
	>100	455	8	1.8	0.8	3.4	442	0	0.0	0.0	0.8

		Frail									
		HZ/su					Placebo				
					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL
Swelling (mm)	All	455	63	13.8	10.8	17.4	442	1	0.2	0.0	1.3
	>100	455	2	0.4	0.1	1.6	442	0	0.0	0.0	0.8
Overall/dose											
Pain	All	938	532	56.7	53.5	59.9	903	67	7.4	5.8	9.3
	Grade 3	938	45	4.8	3.5	6.4	903	5	0.6	0.2	1.3
Redness (mm)	All	938	223	23.8	21.1	26.6	903	2	0.2	0.0	0.8
	>100	938	14	1.5	0.8	2.5	903	0	0.0	0.0	0.4
Swelling (mm)	All	938	142	15.1	12.9	17.6	903	3	0.3	0.1	1.0
	>100	938	2	0.2	0.0	0.8	903	0	0.0	0.0	0.4
Overall/subject											
Pain	All	489	322	65.8	61.5	70.0	468	51	10.9	8.2	14.1
	Grade 3	489	38	7.8	5.6	10.5	468	5	1.1	0.3	2.5
Redness (mm)	All	489	160	32.7	28.6	37.1	468	2	0.4	0.1	1.5
	>100	489	12	2.5	1.3	4.2	468	0	0.0	0.0	0.8
Swelling (mm)	All	489	107	21.9	18.3	25.8	468	3	0.6	0.1	1.9
	>100	489	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8

Source: Table 14.3.1.8

Frail = Subjects with frailty index score > 0.25

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

Table 2.6 Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period overall subjects and overall doses by frailty status: Frail Subjects only (Total Vaccinated Cohort - Diary Card Subset)

		Frail									
		HZ/su					Placebo				
					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1											
Fatigue	All	480	114	23.8	20.0	27.8	461	77	16.7	13.4	20.4
	Grade 3	480	14	2.9	1.6	4.8	461	5	1.1	0.4	2.5
	Related	480	88	18.3	15.0	22.1	461	40	8.7	6.3	11.6
	Grade 3 Related	480	11	2.3	1.1	4.1	461	3	0.7	0.1	1.9
Gastrointestinal symptoms	All	480	38	7.9	5.7	10.7	461	39	8.5	6.1	11.4
	Grade 3	480	4	0.8	0.2	2.1	461	1	0.2	0.0	1.2
	Related	480	21	4.4	2.7	6.6	461	18	3.9	2.3	6.1
	Grade 3 Related	480	2	0.4	0.1	1.5	461	0	0.0	0.0	0.8
Headache	All	480	96	20.0	16.5	23.9	461	70	15.2	12.0	18.8
	Grade 3	480	6	1.3	0.5	2.7	461	7	1.5	0.6	3.1
	Related	480	73	15.2	12.1	18.7	461	47	10.2	7.6	13.3
	Grade 3 Related	480	5	1.0	0.3	2.4	461	4	0.9	0.2	2.2
Myalgia	All	480	113	23.5	19.8	27.6	461	57	12.4	9.5	15.7
	Grade 3	480	13	2.7	1.4	4.6	461	9	2.0	0.9	3.7

		Frail									
		HZ/su					Placebo				
					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL
Shivering	Related	480	90	18.8	15.4	22.5	461	34	7.4	5.2	10.2
	Grade 3 Related	480	11	2.3	1.1	4.1	461	5	1.1	0.4	2.5
	All	480	40	8.3	6.0	11.2	461	23	5.0	3.2	7.4
	Grade 3	480	6	1.3	0.5	2.7	461	0	0.0	0.0	0.8
	Related	480	31	6.5	4.4	9.0	461	11	2.4	1.2	4.2
Temperature/(*) (°C)	Grade 3 Related	480	5	1.0	0.3	2.4	461	0	0.0	0.0	0.8
	All	480	33	6.9	4.8	9.5	461	10	2.2	1.0	4.0
	>39.0	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8
	Related	480	24	5.0	3.2	7.3	461	4	0.9	0.2	2.2
	>39.0 Related	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8
Dose 2											
Fatigue	All	456	120	26.3	22.3	30.6	443	46	10.4	7.7	13.6
	Grade 3	456	13	2.9	1.5	4.8	443	3	0.7	0.1	2.0
	Related	456	104	22.8	19.0	26.9	443	27	6.1	4.1	8.7
	Grade 3 Related	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0
Gastrointestinal symptoms	All	456	44	9.6	7.1	12.7	443	29	6.5	4.4	9.3
	Grade 3	456	2	0.4	0.1	1.6	443	5	1.1	0.4	2.6
	Related	456	34	7.5	5.2	10.3	443	13	2.9	1.6	5.0
	Grade 3 Related	456	2	0.4	0.1	1.6	443	2	0.5	0.1	1.6
Headache	All	456	104	22.8	19.0	26.9	443	43	9.7	7.1	12.9
	Grade 3	456	12	2.6	1.4	4.6	443	4	0.9	0.2	2.3
	Related	456	90	19.7	16.2	23.7	443	24	5.4	3.5	8.0
	Grade 3 Related	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0
Myalgia	All	456	119	26.1	22.1	30.4	443	38	8.6	6.1	11.6
	Grade 3	456	18	3.9	2.4	6.2	443	5	1.1	0.4	2.6
	Related	456	106	23.2	19.4	27.4	443	21	4.7	3.0	7.2
	Grade 3 Related	456	17	3.7	2.2	5.9	443	1	0.2	0.0	1.3
Shivering	All	456	64	14.0	11.0	17.6	443	24	5.4	3.5	8.0
	Grade 3	456	13	2.9	1.5	4.8	443	2	0.5	0.1	1.6
	Related	456	58	12.7	9.8	16.1	443	14	3.2	1.7	5.2
	Grade 3 Related	456	13	2.9	1.5	4.8	443	2	0.5	0.1	1.6
Temperature/(*) (°C)	All	456	48	10.5	7.9	13.7	443	11	2.5	1.2	4.4
	>39.0	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8
	Related	456	43	9.4	6.9	12.5	443	4	0.9	0.2	2.3
	>39.0 Related	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8
Overall/dose											
Fatigue	All	936	234	25.0	22.3	27.9	904	123	13.6	11.4	16.0
	Grade 3	936	27	2.9	1.9	4.2	904	8	0.9	0.4	1.7
	Related	936	192	20.5	18.0	23.2	904	67	7.4	5.8	9.3
	Grade 3 Related	936	23	2.5	1.6	3.7	904	6	0.7	0.2	1.4
Gastrointestinal symptoms	All	936	82	8.8	7.0	10.8	904	68	7.5	5.9	9.4
	Grade 3	936	6	0.6	0.2	1.4	904	6	0.7	0.2	1.4
	Related	936	55	5.9	4.5	7.6	904	31	3.4	2.3	4.8
	Grade 3 Related	936	4	0.4	0.1	1.1	904	2	0.2	0.0	0.8
Headache	All	936	200	21.4	18.8	24.1	904	113	12.5	10.4	14.8
	Grade 3	936	18	1.9	1.1	3.0	904	11	1.2	0.6	2.2
	Related	936	163	17.4	15.0	20.0	904	71	7.9	6.2	9.8
	Grade 3 Related	936	17	1.8	1.1	2.9	904	7	0.8	0.3	1.6
Myalgia	All	936	232	24.8	22.0	27.7	904	95	10.5	8.6	12.7
	Grade 3	936	31	3.3	2.3	4.7	904	14	1.5	0.8	2.6
	Related	936	196	20.9	18.4	23.7	904	55	6.1	4.6	7.8
	Grade 3 Related	936	28	3.0	2.0	4.3	904	6	0.7	0.2	1.4

		Frail									
		HZ/su					Placebo				
					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL
Shivering	All	936	104	11.1	9.2	13.3	904	47	5.2	3.8	6.9
	Grade 3	936	19	2.0	1.2	3.2	904	2	0.2	0.0	0.8
	Related	936	89	9.5	7.7	11.6	904	25	2.8	1.8	4.1
	Grade 3 Related	936	18	1.9	1.1	3.0	904	2	0.2	0.0	0.8
Temperature/(*) (°C)	All	936	81	8.7	6.9	10.6	904	21	2.3	1.4	3.5
	>39.0	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4
	Related	936	67	7.2	5.6	9.0	904	8	0.9	0.4	1.7
	>39.0 Related	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4
Overall/subject											
Fatigue	All	488	164	33.6	29.4	38.0	468	96	20.5	16.9	24.5
	Grade 3	488	22	4.5	2.8	6.7	468	8	1.7	0.7	3.3
	Related	488	139	28.5	24.5	32.7	468	54	11.5	8.8	14.8
	Grade 3 Related	488	19	3.9	2.4	6.0	468	6	1.3	0.5	2.8
Gastrointestinal symptoms	All	488	65	13.3	10.4	16.7	468	56	12.0	9.2	15.3
	Grade 3	488	6	1.2	0.5	2.7	468	5	1.1	0.3	2.5
	Related	488	44	9.0	6.6	11.9	468	26	5.6	3.7	8.0
	Grade 3 Related	488	4	0.8	0.2	2.1	468	2	0.4	0.1	1.5
Headache	All	488	147	30.1	26.1	34.4	468	89	19.0	15.6	22.9
	Grade 3	488	17	3.5	2.0	5.5	468	10	2.1	1.0	3.9
	Related	488	122	25.0	21.2	29.1	468	59	12.6	9.7	16.0
	Grade 3 Related	488	16	3.3	1.9	5.3	468	6	1.3	0.5	2.8
Myalgia	All	488	173	35.5	31.2	39.9	468	75	16.0	12.8	19.7
	Grade 3	488	28	5.7	3.8	8.2	468	12	2.6	1.3	4.4
	Related	488	148	30.3	26.3	34.6	468	47	10.0	7.5	13.1
	Grade 3 Related	488	25	5.1	3.3	7.5	468	6	1.3	0.5	2.8
Shivering	All	488	86	17.6	14.3	21.3	468	41	8.8	6.4	11.7
	Grade 3	488	18	3.7	2.2	5.8	468	2	0.4	0.1	1.5
	Related	488	74	15.2	12.1	18.7	468	22	4.7	3.0	7.0
	Grade 3 Related	488	17	3.5	2.0	5.5	468	2	0.4	0.1	1.5
Temperature/(*) (°C)	All	488	70	14.3	11.4	17.8	468	19	4.1	2.5	6.3
	>39.0	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8
	Related	488	57	11.7	9.0	14.9	468	8	1.7	0.7	3.3
	>39.0 Related	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8

Source: [Table 14.3.1.9](#)

Frail = Subjects with frailty index score > 0.25

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

All = all subjects who have experienced the symptom

*Temperature is measured by oral, axillary, rectal or tympanic routes

Fever is defined as temperature $\geq 37.5^{\circ}\text{C}$ for oral, axillary or tympanic route, or $\geq 38.0^{\circ}\text{C}$ for rectal route

Conclusions:

In the ZOSTER-064 TVC, which included 92% (N=26 976) of the pooled ZOSTER-006/022 TVC, 11.3% (N=3 037) of subjects were classified as frail. Baseline frailty status was well-balanced between treatment groups. The proportion of subjects in the frail category increased with age and tended to be higher in females than males.

HZ/su VE against the first or only episode of HZ was >90% in all frailty categories. HZ/su VE was shown to be high against HZ ZBPI BOI; the absolute reduction in ZBPI BOI score was higher in subjects in the frail than the pre-frail or non-frail categories.

HZ/su elicited a robust anti-gE and anti-VZV antibody responses at 1-month post-dose 2 for all frailty categories. Anti-gE and anti-VZV GMCs remained above pre-vaccination levels at least 3 years post-dose 2 for all frailty categories.

Reporting of solicited and unsolicited AEs was higher in HZ/su group than in the Placebo group for all frailty categories and decreased with increasing frailty in the HZ/su group. Reporting of unsolicited AEs with medically attended visits and SAEs was in the same range in both treatment groups within each frailty category and increased with increasing frailty in both groups. Occurrence of pIMDs was balanced between the HZ/su and Placebo groups in all frailty categories. The safety profile in subjects in the frail category was clinically acceptable and comparable to the known safety profile of HZ/su vaccine. No safety concern specific to subjects in the frail category was identified.

Date of report: Final 22 October 2019

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4. LIST OF ABBREVIATIONS & DEFINITION OF TERMS**List of Abbreviations**

Ab	Antibody
AE	Adverse Event
ATP	According to Protocol
BOI	Burden of Illness
CD40L	CD40 Ligand
CI	Confidence Interval
CMI	Cell-Mediated Immunogenicity
CRO	Contract Research Organisation
CSR	Clinical Study Report
eCRF	electronic Case Report Form
ELISA	Enzyme-linked Immunosorbent Assay
<i>EQ-5D</i>	EuroQol 5D questionnaire
FI	Frailty Index
GCP	Good Clinical Practice
gE	Glycoprotein E
GMC	Geometric Mean Concentration
GSK	GlaxoSmithKline Biologicals SA
HZ	Herpes Zoster
HZ/su	Herpes Zoster Subunit Vaccine (50µg gE/AS01 _B)
HZAC	Herpes Zoster Adjudication Committee
ICF	Informed Consent Form
ICS	Intracellular Cytokine Staining
IEC	Independent Ethics Committee

IFN-γ	Interferon gamma
IL	Interleukin
IRB	Institutional Review Board
MedDRA	Medical Dictionary for Regulatory Activities
mTVC	modified Total Vaccinated Cohort
PBMC	Peripheral Blood Mononuclear Cell
PCR	Polymerase Chain Reaction
PHN	Postherpetic Neuralgia
pIMD	potential Immune-Mediated Disease
PRO	Patient Reported Outcome
PT	Preferred Term
QoL	Quality of Life
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SF-36	Short Form 36 questionnaire
SOC	System Organ Class
SOP	Standard Operating Procedure
TNF-α	Tumour Necrosis Factor alpha
TTO	Time-Trade-Off
TVC	Total Vaccinated Cohort
UK	United Kingdom
US	United States of America
VAS	Visual Analogue Scale
VE	Vaccine Efficacy

VRR	Vaccine Response Rate
VZV	Varicella-Zoster Virus
YOA	Years of Age
ZBPI	Zoster Brief Pain Inventory

Definition of Terms

According-to-Protocol (ATP)	The ATP cohort for analysis of immunogenicity consisted of all subjects in the ATP cohort for analysis of immunogenicity in ZOSTER-006 or ZOSTER-022 from centers participating in ZOSTER-064. In ZOSTER-006 and ZOSTER-022, the ATP cohort included all evaluable subjects meeting all eligibility criteria, complying with the procedures and intervals allowed for the analysis, with no elimination criteria during the study.
Coded:	Data from which personal identifier information has been removed and replaced by a key. These data are not anonymised since a decode listing exists and it is therefore possible to identify the patient under certain circumstances by an authorised or legally appointed third party data custodian, or by the original holder of the data.
Eligible:	Qualified for enrolment into the study based upon strict adherence to inclusion/exclusion criteria.
Epoch:	An epoch is a self-contained set of consecutive timepoints or a single timepoint from a single protocol. Self-contained means that data collected for all subjects at all-timepoints within that epoch allows to draw a complete conclusion. Typical examples of epochs are retrospective data collection and prospective data collection, etc.
eTrack:	GSK tracking tool for clinical/ epidemiological trials.
Frailty:	Frailty is a term used in geriatric medicine to identify older adults who are at increased risk of poor clinical outcomes, such as incident disability, cognitive decline, falls, hospitalization, institutionalization, or increased mortality. Frailty represents a reduction in resistance to stressors leading to increased clinical vulnerability and adverse health outcomes.
modified Total Vaccinated cohort (mTVC)	The mTVC included all subjects in the mTVC in ZOSTER-006 or ZOSTER-022 from centers participating in ZOSTER-064. The mTVC excluded subjects in the TVC who were not administered the second vaccination or who developed a confirmed case of Herpes Zoster (HZ) prior to 1 month after the second vaccination.

Non-interventional (observational) Human Subject Research:	Studies where medicinal products, should they be administered, are prescribed in normal (routine) medical practice. No medical care or medical/scientific procedures as required in a research protocol are administered to participants except as part of routine medical care.
Quality of Life (QoL)	QoL is measured, using 2 patient reported outcomes (PROs) questionnaires (<i>EQ-5D</i> and <i>SF-36</i>). <i>EQ-5D</i> and <i>SF-36</i> provide multi-dimensional evaluation of the health status.
Research protocol:	A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.
Retrospective study:	A study that looks backward in time (e.g., at events that occurred in the past; outcomes and exposure can no longer be influenced), usually using medical records, databases or interviews in order to address 1 or more study objectives.
Study population:	Sample of population of interest.
Subject:	Term used throughout the protocol to denote an individual who has been contacted in order to participate or participates in the epidemiological study or a person about whom some medical information has been recorded in a database.
Subject number:	A unique number identifying a subject, assigned to each subject consenting to participate in the study.
Total Vaccinated cohort (TVC)	The TVC included all subjects in the TVC in ZOSTER-006 or ZOSTER-022 from centers participating in ZOSTER-064. All subjects in the TVC in ZOSTER-006 or ZOSTER-022 who were from centers not participating in ZOSTER-064 were excluded from the TVC.

Trademarks

Trademarks of the GSK group of companies	Generic description
<i>Shingrix</i>	Zoster Vaccine Recombinant, Adjuvanted

5. ETHICS

5.1. Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The study protocol, amendment and administrative changes, and other information that required pre-approval were reviewed and approved by a national, regional, or investigational center IEC or IRB.

5.2. Ethical Conduct of the Study

This study was conducted in accordance with ethical principles that have their origins in the Declaration of Helsinki, the principles of "Good Clinical Practice" (GCP) and all applicable regulatory requirements.

Refer to the ZOSTER-006 and ZOSTER-022 Clinical Study Reports (CSRs, [GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for details of the ethical conduct in these studies.

5.3. Subject Information and Consent

ZOSTER-064 was designed to allow the encoding and analysis of Quality of life (QoL) questionnaires (*SF-36*, *EQ-5D*) previously completed by subjects in ZOSTER-006 and ZOSTER-022. Because QoL questionnaires were only encoded and analyzed for subjects who developed a suspected Herpes Zoster (HZ) episode in ZOSTER-006 and ZOSTER-022, the questionnaires for the remaining subjects were not encoded or analysed during these studies. The purpose of ZOSTER-064 was to allow for the encoding of the remaining questionnaires to assess the baseline frailty of the ZOSTER-006 and ZOSTER-022 study population.

Every subject considered for inclusion in ZOSTER-064 had previously signed an Informed Consent Form (ICF) at the investigational sites of ZOSTER-006 or ZOSTER-022. At the majority of sites, the ICF signed by subjects in ZOSTER-006 and ZOSTER-022 allowed for the use of collected information to plan new studies, other types of research, or other medical purposes.

Since consent had already been obtained in the prior studies (ZOSTER-006 and ZOSTER-022), the Sponsor made available an informed consent waiver which individual sites could submit to the relevant IEC or IRB in ZOSTER-064 for subjects who had signed ICFs which specified that their collected data may be used in new studies.

In 4 ZOSTER-006 and ZOSTER-022 study centers the local ICF did not include wording to allow the use of data in future research and therefore these centers did not participate in the ZOSTER-064 study and data from these centers was not in scope of the ZOSTER-064 analysis.

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

This multicenter study, sponsored by GlaxoSmithKline Biologicals SA (GSK), was conducted in 18 countries: Australia, Brazil, Canada, Czechia, Estonia, Finland, France, Germany, Hong Kong, Italy, Japan, Mexico, Republic of Korea (South Korea), Spain, Sweden, Taiwan, United Kingdom (UK) and United States (US).

From the 171 Principal Investigators involved in the ZOSTER-064 study, the following 2, called Coordinating Investigators, reviewed and signed the CSR: Dr. McNeil and Dr. Andrew (Canada).

GSK sponsored the study and was responsible for coordinating activities, initiating and conducting the study, data management and statistical analyses.

The following activities were performed by Contract Research Organisations (CROs) or vendors:

- Study Delivery Lead, Study Delivery Assistant and Data Management services (Syneos Health, Farnborough, United Kingdom; North Carolina, United States);
- Local Delivery Lead and monitoring support for Sweden and Czechia (Pharmaceutical Product Development (PPD), North Carolina, United States; Stockholm, Sweden; Prague, Czechia);
- Statistical analysis (4Clinics, Waterloo, Belgium).

Study monitoring at the country level, and management of the country monitoring study file were performed by local CROs and/or by GSK Local Operating Companies (GSK LOCs).

7. INTRODUCTION

7.1. Background

Varicella-Zoster Virus (VZV) causes 2 distinct diseases. Varicella (chickenpox) occurs shortly after primary VZV infection and is characterized by systemic illness and a widely disseminated rash. Shingles or HZ occurs when VZV reactivates from latency. Vaccination as a means to reduce risk of HZ has been examined in both older and immunocompromised persons.

HZ is characterized by rash, pain and/or pruritus. The typical HZ rash vesicles in a localized, dermatomal band on 1 side of the body, lasts 2 to 4 weeks and is often accompanied by severe pain that is described as burning, shooting, or stabbing. In some patients, even lightly touching the affected area may cause pain, a phenomenon known as allodynia. Pruritus, which can also be severe, may be as common as pain. Pain that persists after the resolution of the HZ rash is called postherpetic neuralgia (PHN). Notably, PHN can last for months or even years.

The study vaccine, GSK's HZ vaccine (trade name *Shingrix*) is an adjuvanted recombinant VZV envelope glycoprotein E (gE) subunit vaccine, hereafter referred to as Herpes Zoster subunit (HZ/su) vaccine. The study vaccine contains a truncated form of gE and the adjuvant is AS01_B. AS01_B consists of liposomes in combination with 3-O-desacyl-4'-Monophosphoryl Lipid A (MPL) and *Quillaja saponaria* Molina, fraction 21 (QS-21, purified natural saponin molecule extracted from the South American tree, *Quillaja saponaria*). The HZ/su vaccine was first approved for the prevention of HZ in adults 50 years of age (YOA) and older in Canada and the United States in October 2017.

7.1.1. Age and frailty as risk factors for herpes zoster

Several studies have demonstrated that the incidence and severity of HZ increases with age [CDC, 2008]. Half of all HZ cases occur in individuals ≥ 60 YOA. Individuals who reach 85 YOA have a 50% chance of having HZ during their lifetime [Oxman, 2005].

The risk for PHN is also highest in older people with HZ, occurring in 18-50% of those ≥ 70 YOA [Oxman, 2005; Scott, 2006; Dworkin, 2007, Kanbayashi, 2012; Kawai, 2015]. Since the loss of VZV-specific T-cell responses as a result of aging leads to heightened susceptibility to HZ, vaccination is considered as a means to reduce the risk of HZ in older adults [Oxman, 2005; Sperber, 1992].

In addition to an increase in the incidence and severity of HZ with age, frailty increases with age. A recent study explored the frailty status of older subjects who received the HZ/su vaccine. In this study the proportion of subjects defined as frail increased from 3.7% to 17.2% in participants aged 50-59 and ≥ 70 years, respectively [Curran, 2019]. Because frail older adults are at increased risk of poor clinical outcomes, the use of a frailty assessment is important in clinical studies to understand the benefits and harms of interventions.

There is a lack of consensus on how frailty should be assessed, and numerous methods are presented within the literature. Mitnitski *et al.* [Mitnitski, 2001] defined frailty status using a frailty index (FI) based on the accumulation of deficits (e.g. symptoms, signs, functional impairments, and laboratory abnormalities). Curran *et al.* [Curran, 2019] recently developed 2 FIs: (1) a prospectively specified index involving formal tests (e.g. gait speed, grip strength) and instruments and (2) a retrospectively generated index combining medical comorbidities and patient reported outcomes (PROs). Both indices calculate a total deficit score based on the accumulation of deficits to categorize subjects as non-frail, pre-frail and frail. A retrospective FI similar to that developed by Curran *et al.* [Curran, 2019] is applied in ZOSTER-064 (see Section 9.5.1.1 for details)

7.1.2. Studies ZOSTER-006 and ZOSTER-022

The HZ/su vaccine has been evaluated in several studies in adults ≥ 50 YOA in stable health as well as in immunocompromised adults ≥ 18 YOA. The vaccine was shown to be efficacious and elicit strong cellular and humoral immune responses. Furthermore, the safety and reactogenicity profile of the vaccine was acceptable. Overall, the HZ/su vaccine safety data from the clinical development as well as post-licensure safety surveillance data support the acceptable benefit-risk and safety profile of HZ/su vaccine.

Two large pivotal phase III studies ZOE-50 (ZOSTER-006) and ZOE-70 (ZOSTER-022) that enrolled subjects ≥ 50 and ≥ 70 YOA, respectively, evaluated the vaccine efficacy, immunogenicity and safety of GSKs' HZ/su vaccine in elderly adults. These randomized studies together enrolled more than 30 000 subjects who either received the HZ/su vaccine or Placebo on a 0, 2-month schedule.

ZOSTER-006 demonstrated that the vaccine is highly efficacious in adults ≥ 50 YOA, with vaccine efficacy (VE) against HZ of 97.2% overall and between 96.6% and 97.9% for all pre-specified age groups (50-59, 60-69 and ≥ 70 YOA) [Lal, 2015]. ZOSTER-022 demonstrated VE against HZ of 89.8% in subjects ≥ 70 YOA, results consistent with ZOSTER-006 [Cunningham, 2016]. In addition, in a pre-specified pooled analysis of ZOSTER-006 and ZOSTER-022, HZ/su was shown to effectively prevent PHN with a VE of 88.8% (95% Confidence Interval (CI) of 68.7-97.1) in adults ≥ 70 YOA.

The QoL analysis conducted for subjects who experienced a confirmed HZ case in the ZOSTER-006 and ZOSTER-022 studies showed a trend towards lower impact of HZ on QoL in the HZ/su group compared to the Placebo group [Curran, 2018].

7.2. Rationale for the study

As part of the ZOSTER-006 and ZOSTER-022 study procedures, subjects enrolled were asked to complete 2 QoL questionnaires named respectively Short Form 36 questionnaire (*SF-36*) and EuroQol 5D questionnaire (*EQ-5D*) at predefined timepoints, including pre-vaccination baseline. All subjects were asked to complete the questionnaires at baseline to provide relevant information about subjects' QoL (functional status, ability to socialize, mental health, etc.) prior to vaccination (see protocol APPENDIX A and APPENDIX B for samples of the *SF-36* and *EQ-5D* questionnaires). Subjects who developed a suspected HZ episode during the studies were also asked to complete the QoL questionnaires at the study visit for evaluation of suspected HZ and weekly thereafter.

At the time of ZOSTER-006 and ZOSTER-022 study conduct, encoding of QoL questionnaires into the respective study databases was limited to subjects who developed a suspected HZ episode during the studies, to assess the pre-defined endpoint related to impact of HZ on QoL. The purpose of study ZOSTER-064 was to allow for the encoding of the remaining QoL questionnaires from subjects who did not develop a suspected HZ episode during the previous studies. The responses to these QoL questionnaires, along with comorbidities from subjects' medical history, were used to retrospectively attribute frailty scores to subjects who participated in ZOSTER-006 and ZOSTER-022 using a retrospective FI.

This retrospective frailty assessment allowed classification of the study population into different frailty categories (frail, pre-frail and non-frail) in order to provide information about the representativeness of the ZOSTER-006 and ZOSTER-022 study populations to the general population of older adults in terms of frailty. In addition, possible comparison of subjects' baseline *SF-36* and *EQ-5D* scores with normative values for those questionnaires in the general population of the countries participating in the study (where these values are available) could provide further insight in the study population.

In ZOSTER-064, the efficacy, immunogenicity and safety of HZ/su were assessed by frailty category. The same methodology used in ZOSTER-006 and ZOSTER-022 studies to assess efficacy, immunogenicity, and safety was applied in ZOSTER-064. The data collected was further used to assess if certain physical, physiological and/or psychological characteristics reported by the subjects before the onset of HZ could be predictive of HZ, since those have been hypothesized to be predictive factors [Liu, 2015].

8. STUDY OBJECTIVES AND ENDPOINTS

8.1. Objectives

The following objectives were assessed in the ZOSTER-064 study population.

8.1.1. Primary objective

- To assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022.

8.1.2. Secondary objectives

- To present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.*
- To assess VE against HZ by frailty status.
- To assess HZ burden of illness (BOI) by frailty status.
- To identify predictive factors for individuals developing HZ.
- To describe safety by frailty status.
- To assess humoral immunogenicity by frailty status.

* Note that the distribution of *SF-36* and *EQ-5D* scores at baseline by country are presented in the current report.

8.1.3. Tertiary objectives

- To describe the cell-mediated immunogenicity (CMI) by frailty status of subjects enrolled in ZOSTER-006 only.

8.2. Endpoints

The following endpoints were assessed in the ZOSTER-064 study population.

8.2.1. Primary endpoint

- Baseline Frailty Status:
 - Frailty Status pre-vaccination dose 1 as defined by responses to components of the *SF-36* and *EQ-5D* questionnaire at vaccination day 0 and the subjects coded medical history.

8.2.2. Secondary endpoints

- *SF-36* and *EQ-5D* scale scores:
 - At months 0, 14, 26 and 38.
- Confirmed HZ cases:
 - Incidence of HZ cases during the ZOSTER-006 and ZOSTER-022 studies for subjects in the modified Total Vaccinated Cohort (mTVC).
- HZ BOI
 - HZ BOI score for subjects in both the ZOSTER-006 and ZOSTER-022 studies as calculated from the Zoster Brief Pain Inventory (ZBPI).
- Solicited local and general adverse events (AEs) collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity of each solicited local AE within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset;
 - Occurrence, intensity and relationship to vaccination of each solicited general AE within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset.
- Unsolicited AEs collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0 - 29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects.
- Serious Adverse Events (SAEs) from ZOSTER-006 and ZOSTER-022.
 - Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in all subjects;
 - Occurrence of SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period in all subjects;
 - Occurrence of any fatal SAEs during the entire study period in all subjects.

- Occurrence of pre-defined AEs
 - Occurrence and relationship to vaccination of any Potential Immune-Mediated Diseases (pIMDs) during the entire study period in all subjects.
- Humoral Immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022.
 - Anti-gE and anti-VZV antibody (Ab) concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.

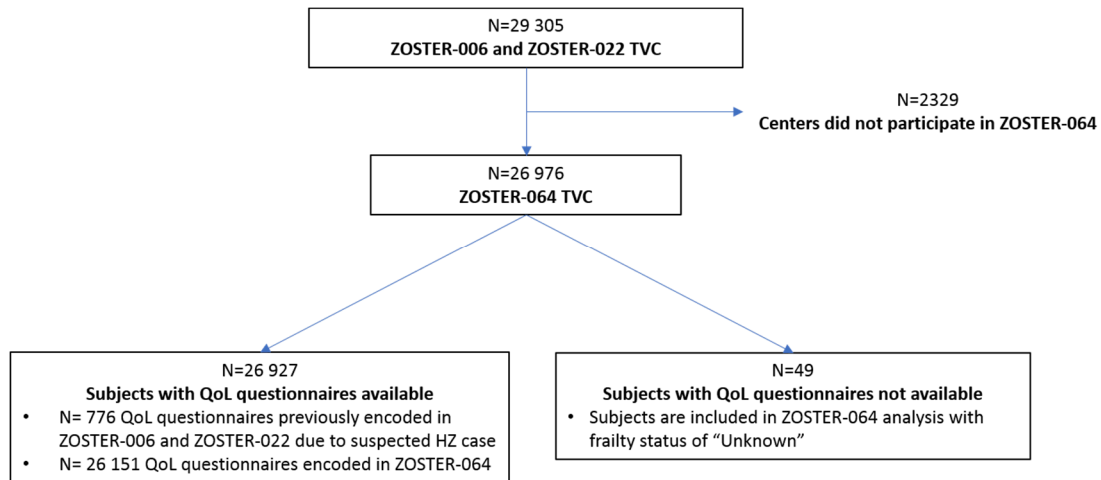
8.2.3. Tertiary endpoints

- CMI of the study vaccine in subset of subjects from ZOSTER-006 (Months 0, 3, 14, 26 and 38):
 - CMI in terms of frequencies of antigen-specific CD4[2+] T-cells;
 - Frequencies of CD4[2+] T-cells (following induction with gE) with antigen-specific Interferon gamma (IFN- γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF- α) and/or CD40 Ligand (CD40L) secretion/production to gE and VZV as determined by intracellular cytokine staining (ICS).

9. INVESTIGATIONAL PLAN

9.1. Overall Study Design and Plan

- **Type of design:** Observational, retrospective study.
- **Study population:** The figure below shows how the ZOSTER-064 study population was derived from the approximately 30 000 adults aged ≥ 50 YOA who participated in either ZOSTER-006 or ZOSTER-022.



Source: ZOSTER-022 CSR Table 80

N = Number of subjects

TVC = Total Vaccinated Cohort

HZ = Herpes Zoster

QoL = Quality of Life

- **Type of study:** QoL questionnaire and baseline data collected in ZOSTER-006 (eTrack 110390) and ZOSTER-022 (eTrack 113077) were analyzed in this study to assess frailty status.
- **Data collection:** electronic Case Report Form (eCRF).
- **Duration of the study:** The time between the first and the last information encoded was 11 months.

9.2. Discussion of Study Design, Including Choice of Control Group

ZOSTER-064 was a multi-country, observational, retrospective study designed to assess the frailty status of subjects who participated in ZOSTER-006 and ZOSTER-022. No new subjects were recruited and subjects were included in ZOSTER-064 if they had signed an ICF in ZOSTER-006 and ZOSTER-022 which permitted use of their data in future research. In studies ZOSTER-006 and ZOSTER-022, encoding of QoL questionnaires (*SF-36*, *EQ-5D*) was only performed for subjects who developed a suspected HZ episode during the study. This was done to assess the QoL of subjects who developed suspected cases of HZ between the vaccine group and the Placebo group. The

remaining study subjects who did not develop suspected cases of HZ completed the questionnaires; however, these questionnaires were not encoded or analyzed as part of studies ZOSTER-006 and ZOSTER-022. The purpose of study ZOSTER-064 was to allow for the encoding of the remaining questionnaires in order to assess the baseline frailty of all the subjects in ZOSTER-006 and ZOSTER-022. Analyses of efficacy, safety and immunogenicity were performed based on subject's baseline frailty status.

9.3. Selection of Study Population

Subjects who had signed an ICF permitting future research at centers participating in ZOSTER-064 were eligible for study inclusion, see Section 5.3.

9.3.1. Inclusion Criteria for Enrolment

All subjects had to satisfy ALL the following criteria at study entry:

- Subjects enrolled in ZOSTER-006 and ZOSTER-022.

9.3.1.1. Inclusion criteria for the study data encoding

- Subjects enrolled in ZOSTER-006 and ZOSTER-022;
- Subjects who died or were lost to follow-up during ZOSTER-006 and ZOSTER-022 were considered for inclusion in ZOSTER-064 and their data/questionnaires up to that point were used.

9.3.2. Exclusion Criteria

The following criterion was checked at the time of study entry. If the exclusion criterion applied, the subject was not to be included in the study:

- Subjects who were excluded from all analyses from ZOSTER-006 and ZOSTER-022. This included any subject eliminated following deviations from GCP compliance.

9.3.2.1. Exclusion criteria for data encoding

- Subjects who developed a suspected HZ case during ZOSTER-006 and ZOSTER-022 (since their QoL questionnaires were encoded during ZOSTER-006 and ZOSTER-022 study conduct).

9.3.3. Removal of Subjects from Vaccination or Assessment

Not applicable.

9.4. Vaccines

No vaccines were administered in study ZOSTER-064. Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for details of vaccines administered in these studies.

9.5. Frailty, Quality of Life, Efficacy, Immunogenicity and Safety Variables

Subjects were identified by the same subject identification number as in studies ZOSTER-006 and ZOSTER-022 with the addition of a prefix to the original subject identification number. Prefix “6” was used for subjects enrolled in ZOSTER-006, and “2” was used for subjects enrolled in ZOSTER-022. This prevented the possibility of having 2 subjects from the 2 different studies having the same identification number.

Sites were provided with a list of subjects for whom questionnaires and data should be encoded. To help the investigator/delegate identify subjects for which data and QoL questionnaires were to be encoded, the list included (but was not limited to) the following information for each subject:

- Subject identification number in ZOSTER-006 or ZOSTER-022;
- New subject identification number to be used in ZOSTER-064;
- Site number;
- Date of birth (year);
- Date of subject’s consent withdrawal, when applicable;
- Occurrence of suspected HZ episode in ZOSTER-006 and ZOSTER-022.

To note: Additional subject’s information related to (but not limited to) medical history, HZ cases, immunogenicity and safety assessments was used to perform the analysis. These data **did not** need to be encoded on the ZOSTER-064 eCRF, but were retrieved centrally from the ZOSTER-006 and ZOSTER-022 databases and linked to perform the required analyses.

9.5.1. Frailty, Quality of Life, Efficacy, Immunogenicity and Safety Measurements Assessed and Flow Chart

An overview of study procedures is given in [Table 9.1](#).

Table 9.1 List of study procedures

Activity	Epoch-001
Check inclusion/exclusion criteria*	○
Encoding of subject's year of birth**	●
Encoding of QoL questionnaires**	●
Study conclusion (Investigator's signature)**	●

QoL: quality of life

● was used to indicate a study procedure that required documentation in the individual eCRF.

○ was used to indicate a study procedure performed by GSK and not documented in the eCRF.

* Performed by GSK.

** Procedure performed for subjects with no suspected HZ episode during ZOSTER-006 and ZOSTER-022. Refer to Section 8.3 of the protocol for details about the study procedures.

9.5.1.1. Definition of Frailty

Frailty status was measured in relation to the accumulation of deficits using a FI adapted from the model proposed by Mitnitski *et al.* [Mitnitski, 2001]. The different aspects of frailty composing the FI were assessed through the medical history and components of the *SF-36* and *EQ-5D* questionnaires recorded pre-vaccination Dose 1.

The FI was scored between 0 and 41 as detailed in [Table 9.2](#). The subject's pre-vaccination questionnaires contributed a max score of 29 and the medical history contributed a max score of 12. Refer to Section 9.7.1.3 for details of FI calculation.

Table 9.2 Detail of frailty index components

Item	Scoring method based on response to questionnaire or medical history assessment	Max Contribution to Frailty Index
SF-36 Q1	Poor=1, Fair=0.5 Good=0, Very good=0 Excellent=0	1
SF-36 Q11A-11D	Q11A, Q11C Definitely true=1 Mostly true=0.5 Don't know=0 Mostly false=0 Definitely false=0 Q11B, Q11D Definitely true=0 Mostly true=0 Don't know=0 Mostly false=0.5 Definitely false=1	4
SF-36 Q3I - Q3J	Limited a lot=1 Limited a little=0.5 Not limited at all=0	10

Item	Scoring method based on response to questionnaire or medical history assessment	Max Contribution to Frailty Index
SF-36 Q9A - Q9I	Q9A, Q9D, Q9E, Q9H: All of the Time=0 Most of the time=0 Some of the time=0 A little of the time=0.5 None of the time=1 Q9B, Q9C, Q9F, Q9G, Q9I : All of the Time=1 Most of the time=0.5 Some of the time=0 A little of the time=0 None of the time=0	9
SF-36 Q2 Compared to one week before, how did the subject rate his / her health in general?	Much worse=1, Somewhat worse=0.5, Same=0 Somewhat better=0 Better=0	1
EQ-5D Mobility	No Problems=0 Some Problems=0.5 Confined to bed=1	1
EQ-5D Anxiety	No Anxiety=0 Moderate Anxiety=0.5 Extreme Anxiety=1	1
EQ-5D Self care	No Problems=0 Some Problems=0.5 Inability to wash or dress himself /herself=1	1
EQ-5D Usual activities	No Problems=0 Some Problems=0.5 Inability to perform usual activities=1	1
Medical history	Cancer	1
	Diabetes Mellitus	1
	High Blood Pressure	1
	Heart Attack	1
	Congestive Heart Failure	1
	Cerebrovascular Disease	1
	Arthritis	1
	Chronic Lung Disease	1
	Stomach or Intestinal Ulcers	1
	Migraine	1
	Cataract	1
	Glaucoma	1
Total		41

The medical history was divided into 12 selected categories; each category contributed a score of 0 or 1 to the FI (Table 9.3). The coded combined medical history database from studies ZOSTER-006 and ZOSTER-022 was searched and subjects with the relevant Preferred Terms (PTs) were assigned to 1 or more of the above categories. If a subject had any of the listed events in a category they were assigned a max score of 1 for that category and a max score of 12 overall.

Table 9.3 Detail of Medical history search items

Category	MedDRA version 18 Search Terms
Cancer	Malignancy related conditions (SMQ) Malignant tumours (SMQ)
Diabetes Mellitus	Diabetes mellitus (incl subtypes) (HLT) Diabetic complications (HLGT)
High Blood Pressure	Hypertension (SMQ)
Heart Attack	Ischaemic heart disease (SMQ)
Congestive Heart Failure	Cardiac failure (SMQ)
Cerebrovascular Disease	Central nervous system vascular disorders (SMQ)
Arthritis	Arthritis (SMQ)
Chronic Lung Disease	Asthma/bronchospasm (SMQ) Interstitial lung disease (SMQ) Pulmonary hypertension (SMQ) Chronic Obstructive Pulmonary Disease (PT) / Infective exacerbation of chronic obstructive airways disease (PT) Bronchiectasis (PT) / Infective exacerbation of bronchiectasis (PT) Cystic fibrosis (PT) / Cystic fibrosis lung (PT) / Infective pulmonary exacerbation of cystic fibrosis (PT) Chronic respiratory disease (PT) Chronic respiratory failure (PT)
Stomach or Intestinal Ulcers	Gastrointestinal ulceration (SMQ)
Migraine	Migraine headaches (HLT) Migraine prophylaxis (PT)
Cataract	Cataract Conditions (HLT) Cataract operation (PT) Cataract diabetic (PT) Cataract operation complication (PT)
Glaucoma	Glaucoma (SMQ)

SMQ: Standardized MedDRA queries. HLGT: High Level Group Term. HLT: High Level Term. PT: Preferred Term

9.5.1.2. QoL Questionnaires

In ZOSTER-006 and ZOSTER-022, the *EQ-5D* and *SF-36* QoL questionnaires were to be completed at Months 0, 14, 26 and 38.

***SF-36* questionnaire**

The *SF-36* is a multi-purpose health survey with 36 questions underlying the construction of 8 scales [Ware, 2001]. All but 1 of the 36 items (self-reported health transition) are used to score the 8 *SF-36* scales (see Table 9.4).

Table 9.4 Construction of the 8 scales generated from the SF-36

Scale	Items	Response Categories Per Item
Physical Functioning (PF)	3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	3
Role Physical (RP)	4a, 4b, 4c, 4d	5
Bodily Pain (BP)	7*, 8*	6, 5
General Health (GH)	1*, 11a, 11b*, 11c, 11d*	5
Vitality (VT)	9a*, 9e*, 9g, 9i	5
Social functioning (SF)	6*, 10	5
Role Emotional (RE)	5a, 5b, 5c	5
Mental Health (MH)	9b, 9c, 9d*, 9f, 9h*	5

* Item Reversed

EQ-5D questionnaire

The *EQ-5D* questionnaire is a generic measure of health status that provides a simple descriptive profile and a single index value [Kind, 1996]. The *EQ-5D* defines health in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The 5 items are combined to generate health profiles.

9.5.1.3. HZ case definition

Classification as a HZ confirmed case was done during ZOSTER-006 and ZOSTER-022, after confirmation of suspected HZ cases by either of the 2 following ways:

- Polymerase Chain Reaction (PCR):
Rash lesion samples were collected from subjects clinically diagnosed as having a suspected case of HZ. The samples were transferred to GSK laboratory using standardized and validated procedures for laboratory diagnosis of HZ by PCR. For more information, please refer to Appendix B of the ZOSTER-006 protocol.
- The HZ Adjudication Committee:
All suspected HZ cases were referred to the HZ Adjudication Committee (HZAC). The HZAC classified all referred cases as either “HZ”, “not HZ”, or “not able to decide”. However, the HZAC classification was to serve as the final case definition only when the case could not be confirmed or excluded by PCR, e.g., when all samples from a given subject were inadequate (i.e. when both VZV and β -actin PCR results were negative), or when no samples were available for a given subject. If the case could not be confirmed or excluded by PCR and the HZAC final outcome was ‘not able to decide’, the overall final outcome was “No possible classification”; for analysis the categories “not HZ” and “No possible classification” were considered as “not HZ”.

9.5.1.4. HZ burden-of-illness score

For confirmed case of HZ in studies ZOSTER-006 and ZOSTER-022, responses to the “worst pain” question in the ZBPI were used to calculate a “HZ burden-of-illness” (BOI) score. Refer to Section 9.7.1.5.2 for details of BOI score calculation .

9.5.1.5. Immunogenicity Measurements

The immunogenicity assessments were performed in ZOSTER-006 and ZOSTER-022.

Specific Ab (anti-gE) measurements

Anti-gE ELISA: Anti-gE Ab concentrations were measured using an anti-gE ELISA. Diluted blood serum samples of study subjects are added to microtiter wells pre-coated with gE antigen. Secondary peroxidase-conjugated anti-human Abs are added, which bind to the primary human anti-gE Abs. After incubation of the microtiter wells with a chromogen substrate solution, the enzymatic reaction is stopped. Optical densities are recorded and anti-gE Ab concentrations are calculated from a standard curve. The assay cut-off is 97 milli-international units (mIU)/mL.

Anti-VZV ELISA: Anti-VZV Ab concentrations were measured using a commercial ELISA kit (Enzygnost/Siemens), which is based on a single point quantification Ab method (sera tested at a 1:231 dilution). The assay cut-off is 25 mIU/mL.

Intracellular cytokine staining (ICS)

CMI response was assessed in a subset of subjects in the ZOSTER-006 study in 3 countries (Czechia, Japan and the US) at designated sites that had access to a Peripheral Blood Mononuclear Cell (PBMC) processing facility within the acceptable time window from sample collection to PBMC processing.

CMI responses were performed by the Center for Vaccinology (CEVAC) on thawed PBMCs by ICS. This assay provides information on the frequency of CD4 T-cells responding to culture medium or antigens (gE peptide pool) by secreting activation marker molecules involved in immunity i.e., cytokines interferon gamma (IFN- γ) and interleukin-2 (IL-2) and tumor necrosis factor alpha (TNF- α), and CD40 Ligand (CD40L)].

Briefly, PBMC collected from the subjects are stimulated for 2 hours using culture medium (for evaluation of the non-specific response), a pool of overlapping peptides covering the entire sequence of the vaccine antigen gE. Then, an intracellular block (brefeldin A) is added to inhibit activation marker secretion for a subsequent overnight incubation. Cells are then harvested, stained for surface markers (CD3, CD4 and CD8) and fixed. The fixed cells are then permeabilized and stained with anti-activation marker Abs, washed and analyzed by cytofluorometry.

The results of ICS assays are expressed as the frequency of specific CD4 T-cells per million total CD4 T-cells.

9.5.1.6. Safety Measurement

The safety assessments were performed in ZOSTER-006 and ZOSTER-022.

Adverse events

The standard definition for AE is provided in the ZOSTER-006 protocol.

The investigator or site staff was/were responsible during the study for the detection and documentation of events meeting the criteria and definition of an AE or SAE as provided in the protocol.

The occurrence of HZ or PHN did not constitute an AE or SAE. However, HZ complications other than PHN were considered as AEs or SAEs.

Solicited AEs were evaluated only in subjects who were part of the 7-day diary card subset. Subjects in the 7-day diary card subset were asked to report daily, from Day 0 to Day 6 (7-day follow-up period) after each dose, the occurrence of local or general solicited AEs on a safety diary card provided by the sponsor. All clinical signs and symptoms were recorded by the investigator on the appropriate section of the eCRF.

The following local (injection-site) AEs were solicited ([Table 9.5](#)):

Table 9.5 Solicited local adverse events

Pain at injection site
Redness at injection site
Swelling at injection site

The following general AEs were solicited ([Table 9.6](#)):

Table 9.6 Solicited general adverse events

Fatigue
Fever
Gastrointestinal symptoms [†]
Headache
Myalgia
Shivering

[†] Gastrointestinal symptoms include nausea, vomiting, diarrhoea and/or abdominal pain

All other AEs were recorded as unsolicited AEs for subjects who were part of the 7-day diary card subset. For subjects not included in the 7-day diary card subset, all AEs were recorded as unsolicited AEs.

Diary cards (30-day diary card) were completed by all subjects for unsolicited AEs (from Day 0 to Day 29 after each vaccination) and any concomitant medication and vaccination taken from Day 0 to Day 29 after each vaccination. All AEs occurring from Day 0 to Day 29 after each vaccination were recorded into the Adverse Event screen in the subject's eCRF, irrespective of intensity and relationship to study vaccines.

Assessment of intensity

Intensity of the following AEs was assessed as described in [Table 9.7](#).

Table 9.7 Intensity scales for solicited AEs

Adverse Event	Intensity grade	Parameter
Pain at injection site	0	None
	1	Mild: Any pain neither interfering with nor preventing normal every day activities.
	2	Moderate: Painful when limb was moved and interfered with every day activities.
	3	Severe: Significant pain at rest. Prevented normal every day activities.
Redness at injection site		Recorded greatest surface diameter in mm
Swelling at injection site		Recorded greatest surface diameter in mm
Fever*		Recorded temperature in °C/°F
Headache	0	Normal
	1	Mild: Headache that was easily tolerated
	2	Moderate: Headache that interfered with normal activity
	3	Severe: Headache that prevented normal activity
Fatigue	0	Normal
	1	Mild: Fatigue that was easily tolerated
	2	Moderate: Fatigue that interfered with normal activity
	3	Severe: Fatigue that prevented normal activity
Gastrointestinal symptoms (nausea, vomiting, diarrhoea and/or abdominal pain)	0	Gastrointestinal symptoms normal
	1	Mild: Gastrointestinal symptoms that were easily tolerated
	2	Moderate: Gastrointestinal symptoms that interfered with normal activity
	3	Severe: Gastrointestinal symptoms that prevented normal activity
Myalgia	0	Normal
	1	Mild: Myalgia that was easily tolerated
	2	Moderate: Myalgia that interfered with normal activity
	3	Severe: Myalgia that prevented normal activity
Shivering	0	None
	1	Shivering that was easily tolerated
	2	Shivering that interfered with normal activity
	3	Shivering that prevented normal activity

*Fever was defined as rectal temperature $\geq 38^{\circ}\text{C}$ (100.4°F)/axillary/oral/tympanic temperature $\geq 37.5^{\circ}\text{C}$ (99.5°F). The preferred route for recording temperature was oral.

The maximum intensity of local injection site redness/swelling was scored at GSK Biologicals using GSK Biologicals' standard grading scale based on the US FDA guidelines for Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers enrolled in Preventive Vaccine Clinical Trials" [FDA, 2007].

0	:	< 20 mm diameter
1	:	≥ 20 mm to ≤ 50 mm diameter
2	:	> 50 mm to ≤ 100 mm diameter
3	:	> 100 mm diameter

Axillary/oral/tympanic temperature was scored at GSK as follows:

0	:	< 37.5°C
1	:	37.5°C to 38.0°C
2	:	38.1°C to 39.0°C
3	:	> 39.0°C

The investigator assessed the maximum intensity that occurred over the duration of the event for all other AEs, i.e., unsolicited AEs, including SAEs reported during the study. The assessment was based on the investigator's clinical judgement.

The intensity of each AE and SAE recorded in the eCRF or SAE screens, as applicable, was assigned to one of the following categories:

1 (mild)	=	An AE which was easily tolerated by the subject, causing minimal discomfort and not interfering with everyday activities.
2 (moderate)	=	An AE which was sufficiently discomforting to interfere with normal everyday activities.
3 (severe)	=	An AE which prevented normal, everyday activities. Such an AE would have, for example prevented attendance at work and would have necessitated the administration of corrective therapy.

Assessment of causality

The investigator used clinical judgement to determine the relationship to study vaccine. Alternative plausible causes, based on natural history of the underlying diseases, concomitant therapy, other risk factors and the temporal relationship of the event to the investigational vaccine were to be considered and investigated. The investigator was also to consult the Investigator Brochure in the determination of his/her assessment.

All solicited local (injection site) reactions were considered causally related to vaccination. Causality of all other AEs was assessed by the investigator using the following question: 'Is there a reasonable possibility that the AE may have been caused by the investigational vaccine?'

NO	:	The AE was not causally related to administration of the study vaccine(s). There were other, more likely causes and administration of the study vaccine(s) was not suspected to have contributed to the AE.
YES	:	There was a reasonable possibility that the vaccine(s) contributed to the AE.

Non-serious and serious AEs were evaluated as two distinct events. If an event met criteria to be determined "serious", additional examinations/tests were performed by the investigator in order to determine ALL possible contributing factors applicable to each SAE.

Possible contributing factors included:

- Medical history.
- Other medication.
- Protocol required procedure.
- Other procedure not required by the protocol.
- Lack of efficacy of the vaccine, if applicable.
- Erroneous administration.
- Other cause (was to be specified).

Assessment of outcomes

The investigator assessed the outcome of all unsolicited AEs (including SAEs) recorded during the study as:

- Recovered/resolved.
- Recovering/resolving.
- Not recovered/not resolved.
- Recovered with sequelae/resolved with sequelae.
- Fatal (SAEs only).

Medically attended visits

The subject was asked if he/she received medical attention defined as hospitalization, an emergency room visit or a visit to or from medical personnel (medical doctor) for any reason, other than routine health care visits, from the first vaccination until Month 8, and this information was recorded in the eCRF.

Follow-up of adverse events and serious adverse events

After the initial AE/SAE report, the investigator was required to proactively follow each subject and provide further information to GSK Biologicals on the subject's condition.

All SAEs documented at a previous visit/contact and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until study conclusion.

All AEs documented at a previous visit/contact and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until 30 days after the last vaccination.

pIMDs [formerly referred to as new onset of autoimmune diseases (NOADs and other immune mediated inflammatory disorders)] documented at a previous visit/contact and designated as not recovered/not resolved or recovering/resolving were reviewed at subsequent visits/contacts until study conclusion.

Investigators followed-up subjects:

- With SAEs or subjects withdrawn from the study as a result of an AE, until the event had resolved, subsided, stabilized, disappeared, or until the event was otherwise explained, or the subject was lost to follow-up.
- Or, in the case of other non-serious AEs, cases of pIMDs, until study conclusion or they were lost to follow-up.

Clinically significant laboratory abnormalities were followed-up until they had returned to normal, or a satisfactory explanation had been provided.

Serious adverse events

The standard definition for SAE is provided in the ZOSTER-006 and ZOSTER-022 protocols.

The standard time period for collecting and recording SAEs began at Day 0 and continued until Month 14 for each subject.

SAEs that were considered by the investigator to be related to the investigational vaccine were to be collected and recorded from the time of the first receipt of study vaccine/placebo until the subject was discharged from the study.

Potential immune-mediated diseases

pIMDs were defined as a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune etiology. AEs that needed to be recorded and reported as pIMDs include those listed in [Table 9.8](#).

In addition, the investigator exercised his/her medical and scientific judgement in deciding whether other immune-mediated diseases had an autoimmune origin (i.e., pathophysiology involving systemic or organ-specific pathogenic autoantibodies) and were also recorded as a pIMD.

The time period for collecting and recording pIMDs started at the first receipt of study vaccine and ended at the study conclusion contact.

Table 9.8 List of Potential immune-mediated diseases

Neuroinflammatory disorders		Musculoskeletal disorders	Skin disorders
• Cranial nerve disorders, including paralyzes/paresis (e.g. Bell's palsy) • Optic neuritis • Multiple sclerosis • Transverse myelitis • Guillain-Barré syndrome, including Miller Fisher syndrome and other variants • Acute disseminated encephalomyelitis, including site specific variants: e.g. non-infectious encephalitis, encephalomyelitis, myelitis, myeloradiculoneuritis • Myasthenia gravis, including Lambert-Eaton myasthenic syndrome • Immune-mediated peripheral neuropathies and plexopathies, (including chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy and polyneuropathies associated with monoclonal gammopathy). • Narcolepsy		• Systemic lupus erythematosus and associated conditions • Systemic scleroderma (Systemic sclerosis), including diffuse systemic form and CREST syndrome • Idiopathic inflammatory myopathies, including dermatomyositis • Polymyositis • Antisynthetase syndrome • Rheumatoid arthritis, and associated conditions including juvenile chronic arthritis and Still's disease • Polymyalgia rheumatica • Spondyloarthritis, including ankylosing spondylitis, reactive arthritis (Reiter's Syndrome) and undifferentiated spondyloarthritis • Psoriatic arthropathy • Relapsing polychondritis • Mixed connective tissue disorder	• Psoriasis • Vitiligo • Erythema nodosum • Autoimmune bullous skin diseases (including pemphigus, pemphigoid and dermatitis herpetiformis) • Alopecia areata • Lichen planus • Sweet's syndrome • Localised Scleroderma (Morphoea)
Vasculitides		Blood disorders	Others
• Large vessels vasculitis including: giant cell arteritis such as Takayasu's arteritis and temporal arteritis. • Medium sized and/or small vessels vasculitis including: polyarteritis nodosa, Kawasaki's disease, microscopic polyangiitis, Wegener's granulomatosis, Churg–Strauss syndrome (allergic granulomatous angiitis), Buerger's disease (thromboangiitis obliterans), necrotizing vasculitis and anti-neutrophil cytoplasmic antibody (ANCA) positive vasculitis (type unspecified), Henoch-Schonlein purpura, Behcet's syndrome, leukocytoclastic vasculitis.		• Autoimmune hemolytic anemia • Autoimmune thrombocytopenia • Antiphospholipid syndrome • Pernicious anemia • Autoimmune aplastic anemia • Autoimmune neutropenia • Autoimmune pancytopenia	• Autoimmune glomerulonephritis (including IgA nephropathy, glomerulonephritis rapidly progressive, membranous glomerulonephritis, membranoproliferative glomerulonephritis, and mesangioproliferative glomerulonephritis) • Ocular autoimmune diseases (including autoimmune uveitis and autoimmune retinopathy) • Autoimmune myocarditis/cardiomyopathy • Sarcoidosis • Stevens-Johnson syndrome • Sjögren's syndrome • Idiopathic pulmonary fibrosis • Goodpasture syndrome • Raynaud's phenomenon
Liver disorders	Gastrointestinal disorders		Endocrine disorders
• Autoimmune hepatitis • Primary biliary cirrhosis • Primary sclerosing cholangitis • Autoimmune cholangitis	• Inflammatory Bowel disease, including Crohn's disease, ulcerative colitis, microscopic colitis, ulcerative proctitis • Celiac disease • Autoimmune pancreatitis		• Autoimmune thyroiditis (including Hashimoto thyroiditis) • Grave's or Basedow's disease • Diabetes mellitus type I • Addison's disease • Polyglandular autoimmune syndrome • Autoimmune hypophysitis

9.5.2. Appropriateness of Measurements

The FI used in ZOSTER-064 was developed based on the frailty assessment used in a previous study [ZOSTER-063, [Curran, 2019](#)] and was deemed appropriate to determine frailty status in the ZOSTER-064 study.

Efficacy, immunogenicity, QoL and safety data from ZOSTER-006 and ZOSTER-022 are the basis for licensure of the HZ/su vaccine in several countries. Therefore, those measurements are deemed appropriate for use in the ZOSTER-064 study.

9.5.3. Primary Efficacy/Immunogenicity Variable

See primary endpoint in Section [8.2.1](#).

9.5.4. Drug Concentration Measurements

This study was not designed to assess pharmacokinetics, and drug concentration measurements were not performed.

9.6. Data Quality Assurance

To ensure that the study procedures conformed across all investigator sites, the protocol and eCRF were reviewed with each investigator(s) and their personnel responsible for the conduct of the study by the Company representative(s) prior to ZOSTER-064 study start. Refer to ZOSTER-006 and ZOSTER-022 CSRs [[GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)] for details of the data quality assurance in these studies.

Adherence to the protocol requirements and verification of data generation accuracy were achieved through monitoring visits to each investigator site. Computer checks and blinded review of subject tabulations were performed to ensure consistency of eCRF completion.

Information regarding CROs that were employed to perform certain activities related to the study are described in Section [6](#).

Local CROs were employed to perform monitoring activities at the country level and/or management of the country monitoring study file according to agreed contracts. The CRO responsibilities were conducted according to GSK Standard Operating Procedures (SOPs) and/or CRO SOPs.

The CRO 4Clinics was employed to perform statistical analyses (see Section [6](#)) according to agreed contracts. The CRO responsibilities were conducted according to GSK SOPs.

No protocol deviations were identified in ZOSTER-064. Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for details of protocol deviations in these studies.

Independent Audit statement: No study specific audits were performed for this study.

9.7. Statistical Methods Planned in the Protocol and Determination of Sample Size

9.7.1. Statistical Analysis Plan

The statistical analyses were performed using the Statistical Analysis Systems (SAS) SAS Drug Development platform Version 4.3.

There was 1 final analysis after completion of the database freeze.

Comparative analyses were descriptive with the aim to characterize the difference between groups in the endpoint related to the objective. No adjustment was done for multiple comparisons (i.e. a 2-sided significance level of 0.05 was used).

These descriptive analyses should be interpreted with caution.

9.7.1.1. Analysis Sets

9.7.1.1.1. *Total Vaccinated cohort (TVC)*

The primary analysis of frailty and safety analysis were performed on the TVC.

TVC: included all subjects from the TVC in ZOSTER-006 and ZOSTER-022 from centers participating in ZOSTER-064. All subjects in the TVC in ZOSTER-006 or ZOSTER-022 from centers not participating in ZOSTER-064 were excluded from the TVC.

The TVC included all vaccinated subjects (at least 1 dose) belonging to the Total Effective Cohort with respect to the vaccine actually administered as described in ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)).

TVC diary card subset for analysis of reactogenicity: included all subjects in the TVC who were included in the diary card subset in either ZOSTER-006 or ZOSTER-022.

9.7.1.1.2. *modified Total Vaccinated Cohort (mTVC)*

The primary analysis of efficacy was performed on the mTVC.

mTVC: included subjects in the mTVC in the ZOSTER-006 and ZOSTER-022 studies from centers participating in ZOSTER-064.

In ZOSTER-006 and ZOSTER-022, the mTVC excluded subjects of the TVC who were not administered the second vaccination or who developed a confirmed case of HZ prior to 1 month after the second vaccination.

9.7.1.1.3. According to Protocol (ATP) cohort for analysis of immunogenicity

The ATP cohort for analysis of immunogenicity included all subjects in the ATP cohort for analysis of immunogenicity in ZOSTER-006 or ZOSTER-022 from centers participating in ZOSTER-064.

Humoral immune response was assessed in a subset of subjects from ZOSTER-006 and ZOSTER-022 and analyzed in the ATP cohort for immunogenicity - Humoral.

CMI was assessed in a subset of subjects from ZOSTER-006 in 3 countries (Czechia, Japan and the US) and analyzed in the ATP cohort for immunogenicity - CMI.

In ZOSTER-006 and ZOSTER-022, the ATP cohort for analysis of immunogenicity included all evaluable subjects from the ATP cohort for analysis of safety (i.e., those meeting all eligibility criteria, complying with the procedures and intervals allowed for the analysis, with no elimination criteria during the study) for whom data concerning immunogenicity endpoint measures were available. Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for specific criteria of the ATP cohort for immunogenicity.

For the immunogenicity tables where different timepoints were presented, the concept of “Adapted ATP cohort for immunogenicity” was used to denote that for each timepoint, the corresponding ATP cohort for immunogenicity was used.

More specifically,

- The analyses on the timepoints Month 0 and Month 3 were based on the ATP cohort for immunogenicity Month 3;
- The analysis on the timepoint Month 14 was based on the ATP cohort for immunogenicity Month 14;
- The analysis on the timepoint Month 26 was based on the ATP cohort for immunogenicity Month 26;
- The analysis on the timepoint Month 38 was based on the ATP cohort for immunogenicity Month 38.

9.7.1.2. Analysis of Demographics

Centers that participated in ZOSTER-064 along with their corresponding center numbers in ZOSTER-006 or ZOSTER-022 are presented. The distribution of subjects across the study centers was tabulated overall, by vaccination group and country.

Demographic characteristics (mean age at first vaccination including median, range and standard deviation [SD], gender, race, geographic ancestry and ethnicity) are tabulated overall and by vaccination group for each of the cohorts defined in Section 9.7.1.1.

Demographic characteristics in the TVC are also tabulated overall, by vaccination group and frailty status.

Frequency tables were generated for categorical variables such as gender. Mean, median and SD were provided for continuous data such as age. No inferential analyses of demographic data or baseline characteristics were performed.

Age was calculated as the number of years between the date of birth and the date of first vaccination. To ensure that the collection of date of birth did not jeopardize the privacy of Personally Identifiable Information (PII), only a partial date of birth (MMYYYY) was collected. Therefore, the 15th of the month was used to replace the missing date. In case the month was missing, the date was replaced by June 30th of the year.

Note that due to incomplete date, the derived age may be incorrect by 1 month when month was missing from the birthdate. This may lead to apparent inconsistency between the derived age and the ZOSTER-006/22 eligibility criteria/the age category used for randomization.

9.7.1.3. Analysis of Frailty

The FI was calculated by combining the accumulation of deficits (Table 9.2) into a score from 0 to 1: $FI = (\text{accumulation of deficits}) / (41 - \text{nmissQoL})$ where nmissQoL was the number of missing components of the 29 items from the *SF-36* and *EQ-5D* questionnaires. If a subject had more than 10 missing QoL components, the FI was not calculated.

Each subject was then assigned to 1 of 3 categories: Non-Frail, Pre-Frail and Frail based on the FI.

If the FI was less than or equal to 0.08, the subject was classified as Non-Frail. If the score was greater than 0.08 but less than or equal to 0.25, the subject was classified as pre-frail. If the score was greater than 0.25, the subject was classified as Frail. Subjects without a FI score were classified as unknown.

For the primary objective, the number and percentage of subjects in each frailty category (non-frail, pre-frail, frail and unknown) based on medical history and PROs pre-vaccination Dose 1 (see definition in Section 9.5.1.1) are presented overall, by vaccination group (HZ/su or Placebo) and by age group (50-59, 60-69, 70-79 and ≥ 80 YOA) in the TVC. Frailty status at baseline is also presented by gender and country.

9.7.1.4. Analysis of Quality of life

For *SF-36* questionnaires, each item is used in scoring only 1 scale. Scale scores are to be constructed following the summated ratings and standardized *SF-36* scoring algorithms. See APPENDIX A of the protocol for a sample of the *SF-36* questionnaire.

For *EQ-5D* questionnaires, a subject who responds 1 (no problem/no symptom) to all 5 items has a profile “11111” and similarly a subject who responds with the highest level of difficulty or symptom to all items has a profile “33333”. These profiles are subsequently converted to a continuous single index utility score using a 1 to 1 matching, e.g. “11111”=1.00, “22222”=0.52 and “33333”= -0.59, using value sets (i.e. matching

profiles to single index utility scores). As suggested by the developers, for international studies, the UK Time-Trade-Off (TTO) value set was used for the main analysis. Note: higher scores represent a better QoL. See APPENDIX B of the protocol for a sample of the *EQ-5D* questionnaire.

For the secondary QoL objectives, descriptive statistics of the 8 components of the *SF-36* Questionnaire (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional and Mental Health) and the *EQ-5D* Utility and Visual Analogue Scale (VAS) scores are presented for each scheduled visit (Months 0, 14, 26 and 38) by gender and age group in the TVC. These analyses are also presented by country to allow for possible comparison with normative values for those questionnaires in the general population of the countries participating in the study. The *EQ-5D* utility was based on country-specific TTO values for the analysis by country. The UK TTO was used for countries for which there is no specific TTO.

Compliance with completion of both *SF-36* and *EQ-5D* questionnaires was summarized by country at each timepoint (Months 0, 14, 26 and 38) and overall in the TVC.

% Completion was defined for each timepoint as follows: % Completion = $100 \times N1 / N2$

Where:

N1 = number of subjects with a completed and newly encoded *SF-36/EQ-5D* questionnaire.

N2 = number of subjects for whom a questionnaire was expected.

9.7.1.5. Analysis of Efficacy

9.7.1.5.1. Vaccine efficacy against HZ by frailty status

VE against HZ (see definition in Section 9.5.1.3) in the ZOSTER-064 population was categorized by baseline frailty status for subjects in the mTVC. VE was estimated separately for each frailty category. Further details of the model used to calculate VE are provided in the Statistical Analysis Plans (SAPs) for ZOSTER-006 and ZOSTER-022.

9.7.1.5.2. Vaccine efficacy against HZ BOI by frailty status

HZ BOI score was defined as the area under the curve of HZ-associated pain plotted against time during the 182-day period after the onset of the case. In subjects who developed HZ, the BOI score could range from 0 to 1820. A score of 0 was recorded for subjects who did not develop HZ during the study period.

Pooled HZ BOI scores are presented by frailty category in the mTVC. The number of subjects with a confirmed HZ episode, the mean BOI scores and the total follow-up time are presented by frailty status and vaccination group. The VE against HZ BOI (see definition in Section 9.5.1.4) and 95% CIs are presented by frailty status in the mTVC.

9.7.1.5.3. Predictive factors for subjects developing HZ

Only subjects in the TVC of the Placebo group were included in the analysis of potential predictive factors. A Cox proportional hazards regression model allowing for time-dependent covariates was fitted to identify which factors were predictive of developing HZ. The model included time to HZ as the outcome variable, and demographic variables age and gender, *SF-36* and *EQ-5D* variables as potential predictors.

Each *EQ-5D* and *SF-36* assessment at a scheduled timepoint was re-classified into timepoints based on the date of assessment relative to date of vaccination: Study day = date of assessment – date of vaccination. The study day was the time component used in the model.

Refer to the SAP for further details.

9.7.1.6. Analysis of Immunogenicity**Humoral immune response**Descriptive statistics:

The following parameters are tabulated by vaccination group and frailty status at Months 0, 3, 14, 26 and 38:

- Geometric Mean Concentrations (GMCs) of anti-gE/anti-VZV Ab with 95% CIs;
- Humoral seropositivity rates with exact 95% CIs;
- Vaccine response rates (VRR) with 95% CIs.

Cell-mediated immune response

To obtain meaningful results, the analysis of CMI by frailty status was only to be carried out if a minimum of 20 subjects in the ATP cohort for immunogenicity - CMI were classified as frail.

Descriptive statistics:

The following parameters (for gE specific CD4[2+] T-cell frequency and CD4[2+] T-cell frequency following induction with gE) are tabulated by vaccination group and frailty status at Months 0, 3, 14, 26 and 38:

- Descriptive statistics of the frequency of CD4 T-cell secreting at least 2 different cytokines (IFN- γ , IL-2, TNF- α , CD40L) to gE antigens;
- Descriptive statistics of the frequency of CD4 T-cell secreting at least IFN- γ and another cytokine (IL-2, TNF- α , CD40L) to gE antigens;
- Descriptive statistics of the frequency of CD4 T-cell secreting at least IL-2 and another cytokine (IFN- γ , TNF- α , CD40L) to gE antigens;
- Descriptive statistics of the frequency of CD4 T-cell secreting at least TNF- α and another cytokine (IFN- γ , IL-2, CD40L) to gE antigens;

- Descriptive statistics of the frequency of CD4 T-cell secreting at least CD40L and another cytokine (IFN- γ , IL-2, TNF- α) to gE antigens;
- VRR with exact 95% CI at Months 3, 14, 26 and 38 (only in the gE-specific CD4[2+] T-cell frequency).

9.7.1.7. Analysis of Safety

The safety analysis was based on the TVC. The analysis of reactogenicity was based on the TVC diary card subset. Solicited AEs, unsolicited AEs, SAEs and pIMDs were analyzed by baseline frailty status.

The following analyses were performed for safety endpoints:

- The percentage of subjects with at least 1 local solicited AE, with at least 1 general solicited AE and with any solicited AE during the solicited 7-day follow-up period was tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation was performed for grade 3; related and grade 3 related AEs;
- The percentage of subjects with at least 1 local AE (solicited and unsolicited), with at least 1 general AE (solicited and unsolicited) and with any AE during the solicited 7-day follow-up period was tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation was performed for grade 3, related and grade 3 related AEs;
- The percentage of subjects reporting each individual solicited local and general AE during the solicited 7-day-follow-up period was tabulated with exact 95% CI. For all solicited AEs, the same tabulation was performed for grade 3 solicited AEs and for solicited general AEs with relationship to vaccination;
- Summary of temperature value by half degree increment reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall doses and subjects. The same tabulation for fever with relationship to vaccination was done;
- The number of days with each individual solicited local and general AE during the solicited 7-day follow-up period was tabulated;
- The percentage of subjects with at least 1 local solicited AE, with at least 1 general solicited AE and with any solicited AE reported during the solicited 7-day follow-up period and lasting beyond this period was tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation was performed for grade 3;
- The percentage of subjects with each individual solicited local and general AE ongoing beyond the 7-day follow-up period was tabulated. The same tabulation was performed for grade 3;
- The percentage of subjects with at least 1 report of unsolicited AE classified by the MedDRA Primary System Organ Class (SOC) and PT and reported up to 30 days after each vaccination was tabulated with exact 95% CI. The same tabulation was performed for grade 3 unsolicited AEs, for unsolicited AEs with a relationship to vaccination and grade 3 unsolicited AEs with a relationship to vaccination;

- The percentage of subjects with at least 1 report of unsolicited AEs classified by MedDRA Primary SOC and PT with medically attended visit, from first vaccination up to Month 8 post first vaccination by frailty status;
- Total number/percentages of doses followed by unsolicited AEs was tabulated;
- The percentage of subjects with at least 1 report of SAE or causally related SAE classified by the MedDRA Primary SOC and PT and reported from first vaccination up to Month 14 was tabulated with exact 95% CI; The same tabulation was performed for related SAEs, fatal SAEs and fatal SAEs with causal relationship to vaccination from first vaccination up to study end;
- The proportion of subjects with at least 1 report of pIMDs classified by the MedDRA Primary SOC and PT and reported during the whole post-vaccination period (from Dose 1 up to study end) was tabulated with exact 95% CI. The same tabulation was performed for pIMDs with causal relationship to vaccination.

9.7.2. Determination of Sample Size

Refer to Section 9.1 for an overview of the ZOSTER-064 study population. Data encoded as part of the ZOSTER-064 study was combined with data from the ZOSTER-006 and ZOSTER-022 studies for frailty, QoL, efficacy, immunogenicity and safety analyses, as appropriate taking into account inclusion/exclusion criteria (Section 9.3) and cohorts for analysis (Section 9.7.1.1).

9.7.2.1. Number of subjects in the Humoral subset

The ZOSTER-064 ATP cohort for immunogenicity - Humoral Month 3 included 2832 subjects from ZOSTER-006 and ZOSTER-022.

9.7.2.2. Number of subjects in the CMI subset

The ZOSTER-064 ATP cohort for immunogenicity - CMI Month 3 included 400 subjects from ZOSTER-006.

9.8. Changes in the Conduct of the Study or Planned Analyses

9.8.1. Protocol Amendments

Study ZOSTER-064 was conducted according to the protocol and its amendments. There was 1 amendment to the study protocol dated 17 October 2018 and 3 administrative changes dated 27 March 2018, 13 November 2018 and 11 February 2019. A summary of the major changes introduced to the study protocol is given below.

9.8.1.1. Administrative change 1 (27 March 2018)

- Trademark table was updated to include *Shingrix*;
- The Sample *EQ-5D* questionnaire in APPENDIX B of the protocol was missing the VAS. Images of pages from a sample *EQ-5D* questionnaire, including the VAS, were provided to replace the *EQ-5D* questionnaire text, to better represent the appearance of the *EQ-5D* questionnaire used in the study;
- To complement the images of an *EQ-5D* sample questionnaire in APPENDIX B, images of pages from a sample *SF-36* questionnaire were provided to replace the *SF-36* questionnaire text in APPENDIX A, to better represent the appearance of the *SF-36* questionnaire used in the study.

9.8.1.2. Amendment 1 (17 October 2018)

- The protocol was amended to include the specific requirements of the Japanese Ministry of Health and Welfare, Labour Ministerial Ordinance on the Standards for Conduct of Clinical Trials of Medicinal Products, dated 27 March 1997.
- The list of medical conditions used to build the Frailty Index, which was based on the comorbidities terminology of ZOSTER-063 study, was clarified.
- Updates to the definition of Cohorts for Analysis were made.

9.8.1.3. Administrative change 2 (13 November 2018)

Typographical errors were corrected.

9.8.1.4. Administrative change 3 (11 February 2019)

The Japan Vaccine Company was no longer in operation as of 01 April 2019. Therefore, the reference to “Japan Vaccine Co., Ltd.” was changed to “GSK Japan”.

9.8.2. Changes to the Planned Analyses

The analyses were conducted according to the protocol administrative change 3 dated 11 February 2019 with the exception of the following changes which are described in the SAP Amendment 1 dated 18 June 2019:

- In the protocol, the secondary objective to present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-064 by country was indicated for assessment at baseline only. However, to align with the corresponding endpoint described in the protocol, this analysis was performed at baseline, Months 14, 26 and 38 by country.
- The definition of the TVC, mTVC and ATP study cohorts were clarified in the SAP amendment dated 18 June 2019, such that these cohorts included only subjects from centers that participated in ZOSTER-064. Subjects with data already encoded as part of the ZOSTER-006 or ZOSTER-022 studies were excluded if the center to which they belonged did not take part in ZOSTER-064.

SAEs and pIMDs are not described in detail as no new safety data was collected in ZOSTER-064 and all SAEs and pIMDs are described in detail in the ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)).

Due to the large number of QoL tables generated as a result of the planned analysis by each questionnaire domain, only the key summary tables giving an overview of the data are presented in the CSR.

The following changes from planned analyses occurred which were not described in the SAP Amendment 1 dated 18 June 2019:

- Analyses of SAEs throughout the entire study period by frailty status were only performed for SAEs considered vaccine-related by the investigator and not for SAEs considered related to study participation or to a concurrent GSK medication/vaccine as described in the protocol. These analyses were previously presented in the ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)).
- CMI analyses were only performed for gE antigens and not VZV antigens as specified in the protocol. As it was observed in ZOSTER-006 that VZV-specific CMI responses in the HZ/su group followed a similar trend compared to the gE-specific CMI responses, the tertiary endpoint for VZV CMI analyses were not performed in ZOSTER-064.

10. STUDY SUBJECTS

10.1. Disposition of Subjects

Of the 29 305 subjects included in the pooled ZOSTER-006/022 TVC, a total of 26 976 subjects (92%) were included in the TVC of ZOSTER-064. Of these, 25 715 were included in the mTVC, 9 141 in the TVC - Diary card subset, 2 832 in the ATP cohort for immunogenicity - Humoral Month 3 and 400 in the ATP cohort for immunogenicity - CMI Month 3 ([Table 10.1](#)).

The study was conducted at 171 centers in 18 countries ([Table 14.1.1.1](#)). The numbers of subjects by country, center and vaccination group in the TVC are presented in [Table 14.1.1.2](#).

Table 10.1 Number of subjects in the various cohorts (Total Vaccinated Cohort)

	HZ/su N = 13487	Placebo N = 13489	Total N = 26976
	n	n	n
Total Vaccinated Cohort	13487	13489	26976
modified Total Vaccinated Cohort	12785	12930	25715
Total Vaccinated Cohort - Diary Card Subset	4570	4571	9141
ATP Cohort for immunogenicity - Humoral Month 3	1400	1432	2832
ATP Cohort for immunogenicity - Humoral Month 14	1360	1366	2726
ATP Cohort for immunogenicity - Humoral Month 26	1318	1314	2632
ATP Cohort for immunogenicity - Humoral Month 38	1255	1253	2508
ATP Cohort for immunogenicity - CMI Month 3	196	204	400
ATP Cohort for immunogenicity - CMI Month 14	187	194	381
ATP Cohort for immunogenicity - CMI Month 26	185	188	373
ATP Cohort for immunogenicity - CMI Month 38	174	180	354

Source : [Table 14.1.1.3](#)

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

ATP = According-To-Protocol

CMI = Cell-mediated immunogenicity

N = total number of subjects

n = number of subjects in the given cohort

10.2. Protocol Deviations

No protocol deviations were identified in ZOSTER-064. Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for protocol deviations reported in those studies.

11. EFFICACY/IMMUNOGENICITY EVALUATION

11.1. Data Sets Analyzed

Frailty status at baseline and QoL scores during the study were determined in the TVC and results are presented in Section [11.2](#). HZ/su VE against HZ and against ZBPI BOI was assessed in the mTVC and results are presented in Section [11.4.1](#). Predictive factors for developing HZ were assessed in TVC Placebo subjects and results are presented in Section [11.4.1.3](#). Humoral immunogenicity was assessed in the ATP cohort for immunogenicity - Humoral with results presented in Section [11.4.2.1](#), and CMI was assessed in the ATP cohort for immunogenicity - CMI with results presented in Section [11.4.2.2](#).

11.2. Demographic and Other Baseline Characteristics

11.2.1. Demographic Characteristics

Demographic characteristics were well balanced between the HZ/su and Placebo groups in the TVC ([Table 11.1](#)). Subjects' mean age at baseline was 68.8 years and 58.1% were female. The majority of subjects were White Caucasian (74.6%). Similar demographic characteristics were seen in the mTVC ([Table 11.2](#)).

Demographic characteristics were also well balanced between the HZ/su and Placebo groups in the TVC - Diary card subset ([Table 14.1.1.8](#)), ATP cohort for immunogenicity - Humoral Month 3 ([Table 14.1.1.9](#)) and ATP cohort for immunogenicity - CMI Month 3 ([Table 14.1.1.10](#)).

Table 11.1 Summary of demographic characteristics (Total Vaccinated Cohort)

		HZ/su N = 13487		Placebo N = 13489		Total N = 26976	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	68.8	-	68.8	-	68.8	-
	SD	9.8	-	9.8	-	9.8	-
	Median	71.0	-	71.0	-	71.0	-
	Minimum	50	-	48	-	48	-
	Maximum	96	-	95	-	96	-
Gender	Female	7822	58.0	7863	58.3	15685	58.1
	Male	5665	42.0	5626	41.7	11291	41.9
Ethnicity	American hispanic or latino	1187	8.8	1189	8.8	2376	8.8
	Not American hispanic or latino	12300	91.2	12300	91.2	24600	91.2
Geographic Ancestry	African Heritage / African American	179	1.3	168	1.2	347	1.3
	American Indian or Alaskan Native	8	0.1	12	0.1	20	0.1
	Asian - Central/South Asian Heritage	6	0.0	7	0.1	13	0.0
	Asian - East Asian Heritage	2048	15.2	2042	15.1	4090	15.2
	Asian - Japanese Heritage	452	3.4	449	3.3	901	3.3
	Asian - South East Asian Heritage	15	0.1	23	0.2	38	0.1
	Native Hawaiian or Other Pacific Islander	2	0.0	4	0.0	6	0.0
	White - Arabic / North African Heritage	78	0.6	83	0.6	161	0.6
	White - Caucasian / European Heritage	10062	74.6	10050	74.5	20112	74.6
	Other	637	4.7	651	4.8	1288	4.8

Source : [Table 14.1.1.6](#)

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

Table 11.2 Summary of demographic characteristics (modified Total Vaccinated Cohort)

Characteristics	Parameters or Categories	HZ/su N = 12785		Placebo N = 12930		Total N = 25715	
		Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	68.7	-	68.7	-	68.7	-
	SD	9.8	-	9.8	-	9.8	-
	Median	71.0	-	71.0	-	71.0	-
	Minimum	50	-	48	-	48	-
	Maximum	96	-	95	-	96	-
Gender	Female	7409	58.0	7543	58.3	14952	58.1
	Male	5376	42.0	5387	41.7	10763	41.9
Ethnicity	American hispanic or latino	1094	8.6	1115	8.6	2209	8.6
	Not American hispanic or latino	11691	91.4	11815	91.4	23506	91.4
Geographic Ancestry	African Heritage / African American	164	1.3	158	1.2	322	1.3
	American Indian or Alaskan Native	8	0.1	12	0.1	20	0.1
	Asian - Central/South Asian Heritage	5	0.0	6	0.0	11	0.0
	Asian - East Asian Heritage	1906	14.9	1924	14.9	3830	14.9
	Asian - Japanese Heritage	428	3.3	434	3.4	862	3.4
	Asian - South East Asian Heritage	14	0.1	21	0.2	35	0.1
	Native Hawaiian or Other Pacific Islander	2	0.0	4	0.0	6	0.0
	White - Arabic / North African Heritage	74	0.6	80	0.6	154	0.6
	White - Caucasian / European Heritage	9608	75.2	9689	74.9	19297	75.0
	Other	576	4.5	602	4.7	1178	4.6

Source : [Table 14.1.1.7](#)

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

11.2.2. Frailty Status at Baseline

Assessment of the primary objective, baseline frailty status of subjects, was determined using a FI based on components of the *SF-36* and *EQ-5D* questionnaires and medical history at baseline.

In the TVC, 42.7% of subjects were classified as non-frail, 45.6% as pre-frail, 11.3% as frail and 0.5% as unknown at baseline ([Table 11.3](#)). Baseline frailty status was well balanced between HZ/su (42.9%, 45.0% and 11.7% in non-frail, pre-frail and frail categories, respectively) and Placebo (42.5%, 46.1% and 10.9% in non-frail, pre-frail and frail categories, respectively) groups. The percentage of subjects in the frail category increased with age from 5.7% of subjects 50-59 YOA to 22.7% of subjects ≥ 80 YOA.

Table 11.3 Frailty status by age group and overall (Total Vaccinated Cohort)

	50-59YOA N = 6542		60-69YOA N = 4000		70-79YOA N = 12819		≥80YOA N = 3615		Total N = 26976	
Frailty Status	n	%	n	%	n	%	n	%	n	%
Non-Frail	4305	65.8	2102	52.6	4457	34.8	654	18.1	11518	42.7
Pre-Frail	1843	28.2	1614	40.4	6719	52.4	2114	58.5	12290	45.6
Frail	375	5.7	268	6.7	1575	12.3	819	22.7	3037	11.3
Unknown	19	0.3	16	0.4	68	0.5	28	0.8	131	0.5

Source : [Table 14.1.2.1](#)

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

≥80YOA = ≥80 years old subjects

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

N in the column header is the total number of subjects in each age group and overall in the total vaccinated cohort.

n=number of subjects in each category by age category and overall.

Percentages are based on the total number of subjects in each age category of the total vaccinated cohort.

There were more female subjects in the frail (64.6%) category than in the overall study population (58.1%, [Table 14.1.2.2](#)). The percentage of subjects in the frail category by country ranged from 3.2% to 18.6% ([Table 14.1.2.3](#)).

The mean age for subjects in the frail category was 73.6 years in the HZ/su group and 73.4 years in the Placebo group compared to 68.8 years in the overall study population ([Table 14.1.2.4](#)).

Frailty status was measured in relation to the accumulation of deficits which were assessed through the medical history and PROs (*SF-36* and *EQ-5D*) recorded at baseline (Section 9.5.1.1). The mean number of deficits per subject increased from 1.60 in the non-frail category to 5.91 in the pre-frail category and 13.43 in the frail category compared to 4.90 in the overall study population ([Table 14.1.2.5](#)).

11.2.3. Analysis of QoL questionnaires

The number of expected and received *SF-36* and *EQ-5D* questionnaires by country and timepoint are presented in [Table 14.1.1.4](#) and [Table 14.1.1.5](#), respectively.

The 8 domain scores of the *SF-36* and the *EQ-5D* utility and VAS scores were analyzed by timepoint, age group and country for the TVC. These results are presented by country in [Table 14.2.4.1](#) to [Table 14.2.4.18](#). The *SF-36* and *EQ-5D* scores tended to decline with age at each timepoint and scores were generally constant over the study period with some decline in older age groups at later timepoints.

11.3. Measurements of Vaccination Compliance

Not applicable.

11.4. Efficacy / Immunogenicity Results and Tabulations of Individual Subject Data

11.4.1. Analysis of Efficacy

11.4.1.1. Vaccine Efficacy for HZ

HZ/su VE against the first or only episode of HZ was > 90% in all frailty categories in the mTVC (Table 11.4). The HZ incidence was highest for subjects in the frail category in the Placebo group (9.9).

Table 11.4 Vaccine Efficacy: First or only episode of HZ during the entire study period by frailty status using Poisson method (modified Total Vaccinated Cohort)

Type	HZ/su				Placebo				VE			
	N	n	T(year)	n/T (per 1000)	N	n	T(year)	n/T (per 1000)	(%)	95% CI		p-value
Non-Frail	5545	8	21802.7	0.4	5551	188	21442.8	8.8	95.81	91.58	98.22	<0.0001
Pre-Frail	5738	18	21842.0	0.8	5969	191	22250.4	8.6	90.40	84.41	94.43	<0.0001
Frail	1449	5	5157.5	1.0	1348	46	4662.8	9.9	90.17	75.36	96.95	<0.0001
Unknown	53	0	186.5	0.0	62	5	194.0	25.8	100.00	14.61	100.00	0.0690

Source : Table 14.2.1.2

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown= Subjects who were not assigned a Frailty category

N = number of subjects included in each group

n = number of subjects having at least one confirmed HZ episode

T (year) = sum of follow-up period (censored at the first occurrence of a confirmed HZ episode) expressed in years

n/T (per 1000)= Incidence rate of subjects reporting at least one event

LL, UL = 95% Lower and Upper confidence limits

VE (%) = Vaccine Efficacy (Poisson method)

P-value=Two sided Exact P-value conditional to number of cases

11.4.1.2. Vaccine Efficacy for ZBPI BOI

For confirmed case of HZ, responses to the “worst pain” question in the ZBPI were used to calculate a BOI score, refer to Section 9.5.1.4 for further details. HZ/su VE was shown to be high against ZBPI BOI: 93.6% overall and > 85% in all frailty categories in the mTVC (Table 11.5). The BOI score increased with increasing frailty in both treatment groups. Absolute reduction in ZBPI BOI score between Placebo (2.330, 1.475 and 1.173 in frail, pre-frail and non-frail categories) and HZ/su groups (0.345, 0.108 and 0.017 in frail, pre-frail and non-frail categories) was higher in subjects in the frail (1.985) than pre-frail (1.367) and non-frail categories (1.156).

Table 11.5 Zoster Brief Pain Inventory (ZBPI) Burden of Illness Score (BOI) by frailty status (modified Total Vaccinated Cohort)

Frailty Status	HZ/su (N= 12785)				Placebo (N= 12930)				Vaccine Efficacy for ZBPI BOI	
	n	m	Total Follow-Up Time (Person Years)	ZBPI BOI score	n	m	Total Follow-Up Time (Person Years)	ZBPI BOI score	Point Estimate	95% CI
Non-Frail	8	5545	21803	0.017	187	5550	21439	1.173	98.6	(97.1, 100.0)
Pre-Frail	18	5738	21842	0.108	190	5968	22248	1.475	92.6	(86.6, 98.7)
Frail	5	1449	5158	0.345	46	1348	4663	2.330	85.2	(62.6, 100.0)
Unknown	0	53	186	0.000	3	60	190	3.303	100.0	NE
Overall	31	12785	48989	0.092	426	12926	48540	1.431	93.6	(88.9, 98.3)

Source : Table 14.2.1.3

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown= Subjects who were not assigned a Frailty category

ZBPI Burden of Illness score is calculated as the sum of the ZBPI worst pain scores for all subjects in the group divided by subject years of follow-up.

95% CI=95% confidence interval using the variance estimate of the vaccine efficacy from the Chang test.

Subjects who did not have a confirmed Zoster episode were assigned a score of 0.

Subjects who had a confirmed Zoster episode but who did not have at least 1 ZBPI assessment were excluded from the analysis.

N=number of subjects in each vaccination group.

n=number of subjects with a confirmed zoster episode.

m=number of subjects with follow-up

11.4.1.3. Predicting HZ episodes

In the TVC Placebo group, 71.3% of suspected HZ episodes were confirmed (Table 14.2.1.1).

No statistically significant *SF-36* or *EQ-5D* scores were identified using Model 1 of the minimally adjusted Cox model (Section 9.7.1.5.3) for predicting HZ episodes in TVC Placebo subjects (Table 11.6).

Age was identified as the only statistically significant baseline parameter ($p=0.0229$) when using Model 1 of the final Cox multivariate model for predicting HZ episodes in TVC Placebo subjects (Table 11.7).

Similar results were obtained using Model 2 and Model 3 of the minimally adjusted Cox model (Table 14.2.1.6 and Table 14.2.1.8, respectively) and final Cox multivariate model (Table 14.2.1.7 and Table 14.2.1.9, respectively) for predicting HZ episodes in TVC Placebo subjects.

Pairwise correlation coefficients of QoL parameters in the TVC Placebo subjects are presented in Table 14.2.1.10.

Table 11.6 Minimally adjusted Cox model predicting HZ episode - Model 1 (Total Vaccinated Cohort - Placebo subjects only)

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
SF-36 Domain Scales	Physical Functioning Scale	0.0007	0.0021	1.001	0.1249	0.7238
	Social Functioning	-0.0001	0.0024	1.000	0.0019	0.9648
	Role Physical	-0.0000	0.0019	1.000	0.0006	0.9799
	Emotional Well Being/ Mental Health Scale	0.0004	0.0026	1.000	0.0215	0.8834
	Vitality	-0.0012	0.0023	0.999	0.2464	0.6197
	Role Emotional	0.0009	0.0021	1.001	0.1738	0.6767
	Bodily Pain	-0.0002	0.0019	1.000	0.0106	0.9178
	General Health	0.0036	0.0024	1.004	2.1559	0.1420
EQ-5D	EQ5D Utility Score (Country Specific)	0.1487	0.2750	1.160	0.2923	0.5887
	VAS Score	-0.0019	0.0030	0.998	0.4216	0.5161

Source: Table 14.2.1.4

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

Event is defined as a HZ episode. This analysis excludes subjects who had a suspected case that was not subsequently classified as a confirmed HZ episode.

SE=Standard Error.

Table 11.7 Final Cox multivariate model predicting HZ episode - Model 1 (Total Vaccinated Cohort - Placebo subjects only)

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
Baseline Parameters	Age	0.0142	0.0063	1.014	5.1753	0.0229
	Gender (Female v Male)	0.0799	0.0949	1.083	0.7080	0.4001
	Study (006 v 022)	0.1473	0.1206	1.159	1.4913	0.2220

Source: Table 14.2.1.5

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

Event is defined as a HZ episode. This analysis excludes subjects who had a suspected case that was not subsequently classified as a confirmed HZ episode.

SE=Standard Error.

A step-down backward variable selection procedure is used to fit the final multivariate model.

11.4.2. Analysis of Immunogenicity

11.4.2.1. Humoral immunogenicity

HZ/su elicited a robust anti-gE and anti-VZV antibody responses at 1-month post-dose 2 (Month 3) for all frailty categories. Anti-gE and anti-VZV GMCs remained above pre-vaccination levels at least 3 years post-dose 2 (Month 38) for all frailty categories.

The GMCs of anti-gE antibody were highest at Month 3 in the HZ/su group for all frailty categories: 53 121 mIU/mL, 52 514 mIU/mL and 44 915 mIU/mL for non-frail, pre-frail and frail, respectively (Table 11.8). At Month 38, the GMCs of anti-gE antibody in the HZ/su group remained above pre-vaccination levels for all frailty categories: 12 505 mIU/mL, 11 100 mIU/mL and 8 695 mIU/mL for non-frail, pre-frail and frail, respectively.

VRRs for anti-gE antibody were highest at Month 3 in the HZ/su group for all frailty categories: 98.0%, 97.9% and 95.7% for non-frail, pre-frail and frail, respectively (Table 14.2.2.2). At Month 38, the VRR for anti-gE antibody in the HZ/su group remained high for all frailty categories: 81.7%, 74.6% and 62.0% for non-frail, pre-frail and frail, respectively.

Table 11.8 Seropositivity rates and Geometric Mean Concentrations (GMCs) of anti-gE antibody at Months 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity - Humoral)

					≥ 97 mIU/mL				GMC				
					95% CI				95% CI				
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
VZV.gE Ab.IgG	Non-Frail	HZ/su	PRE(M0)	603	596	98.8	97.6	99.5	1251.6	1151.7	1360.3	<97.0	49273.2
			P1I(M3)	603	603	100	99.4	100	53120.8	50229.2	56178.8	432.7	252485.3
			P1I(M14)	591	591	100	99.4	100	18628.2	17477.6	19854.6	512.3	150266.5
			P1I(M26)	582	582	100	99.4	100	14502.0	13610.9	15451.4	516.9	171049.4
			P1I(M38)	555	555	100	99.3	100	12505.4	11695.1	13371.8	374.8	121520.7
		Placebo	PRE(M0)	606	604	99.7	98.8	100	1389.1	1286.6	1499.8	<97.0	230579.9
			P1I(M3)	606	599	98.8	97.6	99.5	1314.6	1211.8	1426.2	<97.0	259629.7
			P1I(M14)	586	582	99.3	98.3	99.8	1272.4	1174.4	1378.5	<97.0	85917.5
			P1I(M26)	571	569	99.6	98.7	100	1355.5	1253.2	1466.1	<97.0	47396.8
			P1I(M38)	553	549	99.3	98.2	99.8	1304.3	1203.5	1413.5	<97.0	74603.5
	Pre-Frail	HZ/su	PRE(M0)	653	649	99.4	98.4	99.8	1363.0	1262.1	1471.9	<97.0	233132.9
			P1I(M3)	655	655	100	99.4	100	52514.0	49937.0	55224.0	863.2	308834.6
			P1I(M14)	640	640	100	99.4	100	16689.7	15739.5	17697.2	643.5	160387.0
			P1I(M26)	617	617	100	99.4	100	13344.2	12592.6	14140.6	376.7	87976.9
			P1I(M38)	586	586	100	99.4	100	11099.9	10458.8	11780.4	302.6	85298.8
		Placebo	PRE(M0)	695	688	99.0	97.9	99.6	1325.4	1227.0	1431.7	<97.0	28926.7
			P1I(M3)	697	691	99.1	98.1	99.7	1266.9	1171.6	1369.9	<97.0	82777.8
			P1I(M14)	662	657	99.2	98.2	99.8	1224.7	1129.9	1327.4	<97.0	41611.7
			P1I(M26)	628	625	99.5	98.6	99.9	1320.2	1219.1	1429.6	<97.0	29541.0
			P1I(M38)	588	585	99.5	98.5	99.9	1274.3	1171.4	1386.2	<97.0	29634.7
	Frail	HZ/su	PRE(M0)	138	137	99.3	96.0	100	1450.8	1230.9	1710.1	<97.0	16976.3
			P1I(M3)	138	138	100	97.4	100	44914.9	39734.6	50770.6	2119.1	219362.7
			P1I(M14)	124	124	100	97.1	100	13405.4	11701.3	15357.7	1125.0	80216.2
			P1I(M26)	115	115	100	96.8	100	11060.6	9689.0	12626.3	494.4	44973.4
			P1I(M38)	110	110	100	96.7	100	8694.8	7612.1	9931.6	1407.2	37879.9

					≥ 97 mIU/mL				GMC				
					95% CI				95% CI				
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
		Placebo	PRE(M0)	125	125	100	97.1	100	1457.7	1213.6	1750.8	136.4	19896.0
			PII(M3)	125	125	100	97.1	100	1310.8	1089.8	1576.7	121.0	12832.4
			PII(M14)	114	113	99.1	95.2	100	1337.8	1089.7	1642.4	<97.0	19167.0
			PII(M26)	112	112	100	96.8	100	1431.4	1156.2	1772.2	104.9	25054.3
			PII(M38)	109	108	99.1	95.0	100	1399.1	1112.6	1759.2	<97.0	54820.5
	Unknown	HZ/su	PRE(M0)	4	4	100	39.8	100	1172.9	389.0	3536.5	697.9	3258.9
			PII(M3)	4	4	100	39.8	100	34703.5	18272.8	65908.6	20943.3	56029.4
			PII(M14)	4	4	100	39.8	100	9834.3	3469.9	27871.7	4202.3	20391.5
			PII(M26)	4	4	100	39.8	100	5278.7	1248.8	22313.6	2269.4	15956.7
			PII(M38)	4	4	100	39.8	100	5128.7	1349.3	19494.2	2223.8	14611.5
		Placebo	PRE(M0)	4	4	100	39.8	100	836.2	157.6	4434.9	186.8	2035.0
			PII(M3)	4	4	100	39.8	100	854.8	119.2	6132.2	138.8	1922.7
			PII(M14)	4	4	100	39.8	100	888.2	270.6	2914.9	349.3	2138.9
			PII(M26)	3	3	100	29.2	100	712.8	143.6	3538.1	350.8	1237.9
			PII(M38)	3	3	100	29.2	100	614.9	64.5	5863.9	222.8	1281.0

Source: [Table 14.2.2.1](#)

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration equal to or above specified value

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

MIN/MAX = Minimum/Maximum

PRE(M0) = Pre-vaccination (Month 0)

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

A similar trend in GMCs was observed with anti-VZV antibody with a robust immune response for all frailty categories at Month 3 that remained above pre-vaccination levels at Month 38 ([Table 11.9](#)). A similar trend was observed for VRR to anti-VZV antibody ([Table 14.2.2.4](#)).

Table 11.9 Seropositivity rates and Geometric Mean Concentrations (GMCs) of anti-VZV antibody at Months 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity - Humoral)

					≥ 25 mIU/mL				GMC						
							95% CI			95% CI					
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max		
VZV Ab.IgG	Non-Frail	HZ/su	PRE(M0)	588	584	99.3	98.3	99.8	966.9	893.6	1046.2	<25.0	16807.7		
			PII(M3)	603	603	100	99.4	100	9206.0	8731.3	9706.5	179.9	42412.2		
			PII(M14)	587	587	100	99.4	100	3791.4	3569.3	4027.2	48.0	25510.7		
			PII(M26)	580	580	100	99.4	100	3226.8	3037.6	3427.7	36.4	67488.2		
			PII(M38)	550	550	100	99.3	100	3111.6	2928.2	3306.4	40.6	29699.0		
		Placebo	PRE(M0)	587	587	100	99.4	100	1053.3	981.8	1130.0	36.2	51884.1		
			PII(M3)	594	594	100	99.4	100	989.8	922.5	1061.9	32.6	52454.9		
			PII(M14)	579	579	100	99.4	100	931.4	867.4	1000.1	31.6	27654.0		
			PII(M26)	554	554	100	99.3	100	986.0	918.0	1058.9	41.4	13197.4		
			PII(M38)	526	526	100	99.3	100	1029.2	958.8	1104.8	61.5	19500.2		
		Pre-Frail	HZ/su	PRE(M0)	643	642	99.8	99.1	100	992.9	927.8	1062.7	<25.0	71467.2	
				PII(M3)	655	655	100	99.4	100	9468.9	9046.7	9910.8	323.9	63502.4	
				PII(M14)	636	636	100	99.4	100	3630.9	3450.2	3821.0	59.8	18062.4	
				PII(M26)	615	615	100	99.4	100	3261.7	3094.9	3437.5	39.6	17140.1	
				PII(M38)	578	578	100	99.4	100	2966.3	2813.9	3126.9	34.7	14103.9	
			Placebo	PRE(M0)	676	676	100	99.5	100	1036.9	969.7	1108.7	60.7	51930.7	
				PII(M3)	677	677	100	99.5	100	997.0	933.4	1065.0	37.6	24233.8	
				PII(M14)	649	649	100	99.4	100	945.3	883.8	1011.0	42.1	25730.4	
	PII(M26)			610	610	100	99.4	100	1040.8	973.8	1112.3	73.3	18930.9		
	PII(M38)			575	574	99.8	99.0	100	1068.0	994.7	1146.7	<25.0	31624.8		
	Frail	HZ/su	PRE(M0)	135	135	100	97.3	100	996.6	866.7	1146.1	59.6	8082.1		
			PII(M3)	138	138	100	97.4	100	8162.4	7332.5	9086.2	532.4	44933.7		
			PII(M14)	124	124	100	97.1	100	3034.4	2719.3	3386.1	315.8	13012.9		
			PII(M26)	115	115	100	96.8	100	2759.4	2472.4	3079.8	171.2	8821.9		
			PII(M38)	109	109	100	96.7	100	2462.1	2201.7	2753.4	726.4	9268.0		
		Placebo	PRE(M0)	124	124	100	97.1	100	1054.7	894.9	1243.1	54.7	10020.0		
			PII(M3)	121	121	100	97.0	100	904.2	764.4	1069.4	58.0	7441.6		
			PII(M14)	114	114	100	96.8	100	921.9	769.0	1105.2	60.4	6046.9		
			PII(M26)	112	112	100	96.8	100	1023.0	850.1	1231.1	59.4	10007.3		
			PII(M38)	109	109	100	96.7	100	1098.1	903.3	1334.8	61.5	16765.1		
			Unknown	HZ/su	PRE(M0)	4	4	100	39.8	100	712.3	166.2	3052.9	228.4	1719.8
					PII(M3)	4	4	100	39.8	100	6499.1	4054.7	10417.1	4869.9	9429.8
	PII(M14)	4			4	100	39.8	100	2175.3	1073.6	4407.6	1266.5	3689.1		
	PII(M26)	4			4	100	39.8	100	1909.4	839.1	4344.8	1322.2	4012.4		
	PII(M38)	4			4	100	39.8	100	1928.4	857.8	4335.2	1127.0	3555.9		
	Placebo	PRE(M0)	4	4	100	39.8	100	553.7	63.7	4812.0	94.7	2593.7			
		PII(M3)	4	4	100	39.8	100	601.7	78.7	4601.0	106.3	2314.1			
		PII(M14)	4	4	100	39.8	100	646.9	90.1	4646.3	154.1	3178.2			
		PII(M26)	3	3	100	29.2	100	374.7	48.9	2869.2	145.5	611.0			
		PII(M38)	3	3	100	29.2	100	286.3	33.3	2460.0	108.0	564.9			

Source: [Table 14.2.2.3](#)

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration equal to or above specified value
 95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit
 MIN/MAX = Minimum/Maximum
 PRE(M0) = Pre-vaccination (Month 0)
 PII(M3) = Post-vaccination Dose II (Month 3)
 PII(M14) = Post-vaccination Dose II (Month 14)
 PII(M26) = Post-vaccination Dose II (Month 26)
 PII(M38) = Post-vaccination Dose II (Month 38)

11.4.2.2. Cell-mediated immunogenicity response

The CMI response was highest at Month 3 for all frailty categories in the HZ/su group and remained above pre-vaccination levels at Month 38 for all frailty categories. Note there were few subjects in the frail category of the HZ/su group in the ATP cohort for immunogenicity - CMI.

Mean values of gE-specific CD4[2+] T-cells were highest at Month 3 in the HZ/su group for all frailty categories: 2508, 2156 and 1758 for non-frail, pre-frail and frail, respectively (Table 14.2.3.1). At Month 38, mean values of gE-specific CD4[2+] T-cells remained above pre-vaccination levels for all frailty categories: 1052, 829 and 535 for non-frail, pre-frail and frail, respectively.

VRRs for gE-specific CD4[2+] T-cells were highest at Month 3 in the HZ/su group for all frailty categories: 91.7%, 94.2% and 92.9% for non-frail, pre-frail and frail, respectively (Table 14.2.3.2). At Month 38, the CMI VRR in the HZ/su group was 58.6%, 48.9% and 33.3% for non-frail, pre-frail and frail categories, respectively.

Similar trends were seen for CD4[2+] T-cells following induction with gE at Months 0, 3, 14, 26 and 38 by frailty status in the adapted ATP cohort for immunogenicity-CMI (Table 14.2.3.3). Descriptive statistics of the frequency of CD4[2+] T-cells following induction with gE secreting at least IFN γ , IL-2, TNF α or CD40L are presented in Table 14.2.3.4, Table 14.2.3.5, Table 14.2.3.6 and Table 14.2.3.7, respectively.

11.4.3. Statistical/Analytical Issues

11.4.3.1. Adjustments for Covariates

No adjustment for covariates was performed for analyses of the primary or secondary endpoints.

11.4.3.2. Handling of Drop-outs or Missing Data

For a given subject and a given demographic variable, the missing measurement was not replaced except for age (see Section 9.7.1.2). If any item of the *SF-36* or *EQ-5D* was missing, it was not imputed. The missing endpoint and censoring occurred independently, and the pattern was classified as being either Missing Completely At Random (MCAR) or Missing At Random (MAR) only.

For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements were not replaced. Therefore, an analysis excluded subjects with missing or non-evaluable measurements.

For the analysis of solicited AEs, missing or non-evaluable measurements were not replaced. Therefore, the analysis of the solicited AEs based on the TVC – Diary card subset included only subjects/doses with documented safety data (i.e., symptom screen/sheet completed). For the analysis of unsolicited AEs/SAEs/concomitant medication, all vaccinated subjects were considered and subjects who did not report an event were considered as subjects without an event.

11.4.3.3. Interim Analyses and Data Monitoring

No interim analysis was planned for this study.

11.4.3.4. Multicenter Studies

The distribution of subjects across the study centers was tabulated overall, by vaccination group and country. The analyses of efficacy, immunogenicity and safety were not performed by center.

11.4.3.5. Multiple Comparisons/Multiplicity

No adjustment for multiplicity was applied as the study analyses were descriptive.

11.4.3.6. Use of an “Efficacy/Immunogenicity Subset” of subjects

Refer to Section [9.7.1.1.3](#) for definitions of the subsets used for analysis of immunogenicity.

11.4.3.7. Active-control Studies Intended to Show Equivalence

Not applicable. No active control was used in this study.

11.4.3.8. Examination of Subgroups

Demographic characteristics, VE, immunogenicity and safety were assessed by frailty status. Frailty status was assessed by age group, gender and country, and QoL questionnaires were also assessed by age group and country in this study.

11.4.4. Tabulation of Individual Response Data

Data listings for QoL questionnaires by subject encoded in ZOSTER-064 are provided in Section 16.2. Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for data listings of QoL questionnaires in subjects with HZ and data listings for demographic, immunogenicity and safety in all subjects which were previously encoded in these studies.

11.4.5. Drug Dose, Drug Concentration, and Relationships to Response

Not applicable. The study was not designed to assess dose-response relationship.

11.4.6. Drug-drug and Drug-disease Interactions

Not applicable. The study was not designed to assess drug-drug or drug-disease interactions.

11.4.7. By-subject Displays

Data listings for QoL questionnaires by subject encoded in ZOSTER-064 are provided in Section 16.2. Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for data listings of QoL questionnaires in subjects with HZ and data listings for demographic, immunogenicity and safety in all subjects which were previously encoded in these studies.

11.5. Frailty/Efficacy/Immunogenicity ConclusionsPrimary objective:

Baseline frailty status based on QoL questionnaires components and medical history at baseline (TVC)

- In the TVC, 45.6% of subjects were classified as pre-frail and 11.3% as frail at baseline. Baseline frailty status was well balanced between the HZ/su and Placebo groups. The percentage of subjects in the frail category of the TVC increased with age from 5.7% of subjects 50-59 YOA to 22.7% of subjects ≥ 80 YOA.

Secondary Objectives:

VE against HZ and against ZBPI BOI score by frailty status (mTVC)

- HZ/su VE against the first or only episode of HZ was $> 90\%$ in all of frailty categories: 95.81%, 90.40% and 90.17% in subjects in the non-frail, pre-frail and frail categories, respectively.
- HZ/su VE was shown to be high against ZBPI BOI score in all frailty categories: 98.6%, 92.6% and 85.2% in subjects of the non-frail, pre-frail and frail categories, respectively. Absolute reduction in ZBPI BOI score between the Placebo (2.330, 1.475 and 1.173 in frail, pre-frail and non-frail categories) and HZ/su groups (0.345, 0.108 and 0.017 in frail, pre-frail and non-frail categories) was higher in subjects in the frail (1.985) than pre-frail (1.367) and non-frail (1.156) categories.

Predictive factors for developing HZ (TVC - Placebo subjects only)

- Age was identified as the only significant baseline parameter ($p=0.0229$) when using Model 1 of the final Cox multivariate model for predicting HZ episodes.

Humoral immunogenicity by frailty status (ATP cohort for immunogenicity – Humoral)

- HZ/su elicited a robust anti-gE and anti-VZV antibody responses in terms of GMCs and VRR at 1-month post-dose 2 (Month 3) for all frailty categories. Anti-gE and anti-VZV GMCs remained above pre-vaccination levels at least 3 years post-dose 2 (Month 38) for all frailty categories.

Tertiary Objective:*CMI by frailty status (ATP cohort for immunogenicity - CMI)*

- In the HZ/su group, gE-specific CD4[2+] T-cells responses were highest at Month 3 for all frailty categories and remained above pre-vaccination levels during the 3 year follow-up period for all frailty categories.

12. SAFETY EVALUATION

Safety was assessed in the TVC - Diary card subset for solicited AEs and TVC for all other safety evaluations. Unless otherwise specified, the analyses of AEs included both non-serious and serious AEs. The terms “signs and symptoms” and “symptoms” in tables refer to AEs.

12.1. Extent of Exposure

Subjects were previously vaccinated in ZOSTER-006 and ZOSTER-022 and no study vaccination was administered in ZOSTER-064. From the ZOSTER-064 study population, 95.0% of subjects in the HZ/su group and 96.1% of subjects in the Placebo group had received 2 doses of vaccine in the parent studies (Table 14.3.1.1). In subjects with a known frailty status, the percentage of subjects having received 2 doses of vaccine ranged from 92.2% in the frail to 96.2% in the non-frail categories of the HZ/su group, and from 92.3% in the frail to 97.1% in the non-frail categories of the Placebo group.

12.2. Adverse Events

The following safety results by frailty status are presented in this section:

- Solicited AEs within 7 days of vaccination in the TVC - Diary card subset (Section 12.2.3.1);
- Unsolicited AE within 30 days of vaccination in the TVC (Section 12.2.3.2);
- AEs with medically attended visit up to 8 months after vaccination in the TVC (Section 12.2.3.2.5);
- Fatal SAEs up to study end in the TVC (Section 12.3.1.1);
- SAEs up to 14 months after vaccination and up to study end in the TVC (Section 12.3.1.2);
- pIMDs up to study end in the TVC (Section 12.3.1.3).

12.2.1. Brief summary of Adverse events

Percentages of any, general and local AEs (solicited and unsolicited) were higher in the HZ/su group than in the Placebo group for all frailty categories during the 7-day post-vaccination period following each dose and overall per dose and per subject in the TVC - Diary card subset (Table 14.3.1.6):

- Percentages of any AEs (solicited and unsolicited, Table 14.3.1.6) decreased with increasing frailty in the HZ/su group (86.7%, 83.0% and 72.6% overall/subject for non-frail, pre-frail and frail, respectively) and were similar across frailty categories in the Placebo group (34.9%, 38.4% and 38.8% overall/subject for non-frail, pre-frail and frail, respectively).
- General AEs (solicited and unsolicited, Table 14.3.1.6) were reported by 69.1%, 64.4% and 52.5% of subjects in for non-frail, pre-frail and frail categories, respectively, in the HZ/su group, and 30.4%, 34.2% and 35.7% of subjects in non-frail, pre-frail and frail categories, respectively, in the Placebo group.
- Local AEs (solicited and unsolicited, Table 14.3.1.6) were reported by 83.8%, 77.5% and 67.2% of subjects in non-frail, pre-frail and frail categories, respectively, in the HZ/su group, and 11.3%, 11.6% and 11.4% of subjects in non-frail, pre-frail and frail categories, respectively, in the Placebo group.

Percentages of any, general and local grade 3 AEs (solicited and unsolicited) was higher in the HZ/su group than in the Placebo group for all frailty categories during the 7-day post-vaccination period following each dose and overall per dose and per subject in the TVC - Diary card subset (Table 14.3.1.7):

- Percentages of any grade 3 AEs (solicited and unsolicited, Table 14.3.1.7) were similar across frailty categories in the HZ/su group (18.1%, 14.6% and 15.7% overall/subject for non-frail, pre-frail and frail, respectively) and were higher in the frail than the pre-frail and non-frail categories in the Placebo group (2.2%, 2.9% and 6.4% overall/subject for non-frail, pre-frail and frail, respectively).
- General grade 3 AEs (solicited and unsolicited, Table 14.3.1.7) were reported by 12.7%, 10.0% and 10.7% of subjects in non-frail, pre-frail and frail categories, respectively, in the HZ/su group, and 2.2%, 2.6% and 6.0% of subjects in non-frail, pre-frail and frail categories, respectively, in the Placebo group .
- Local grade 3 AEs (solicited and unsolicited, Table 14.3.1.7) were reported by 9.4%, 8.5% and 9.9% of subjects in non-frail, pre-frail and frail categories, respectively, in the HZ/su group, and 0.2%, 0.4% and 1.0% of subjects in non-frail, pre-frail and frail categories, respectively, in the Placebo group.

12.2.2. Display of Adverse Events

Tables displaying AEs reported during the study are provided in Section 14.

12.2.3. Analysis of Adverse Events

12.2.3.1. Solicited Adverse Events

12.2.3.1.1. Any solicited AE

Percentages of any solicited AE were higher in the HZ/su group than in the Placebo group for all frailty categories during the 7-day post-vaccination period following each dose and overall per dose and per subject in the TVC - Diary card subset (Table 12.1):

- Percentages of any solicited AEs (Table 12.1) decreased with increasing frailty in the HZ/su group (87.3%, 83.4% and 73.5% overall/subject for non-frail, pre-frail and frail, respectively) and were similar across frailty categories in the Placebo group (32.2%, 33.7% and 36.1% overall/subject for non-frail, pre-frail and frail, respectively).
- General solicited AEs (Table 12.1) were reported by 68.2%, 63.0% and 50.8% of subjects in non-frail, pre-frail and frail categories, respectively, of the HZ/su group, and 27.4%, 29.3% and 32.9% of subjects in non-frail, pre-frail and frail categories, respectively, of the Placebo group.
- Local solicited AEs (Table 12.1) were reported by 84.7%, 78.9% and 68.5% of subjects in non-frail, pre-frail and frail categories, respectively, of the HZ/su group, and 11.2%, 11.6% and 10.9% of subjects in non-frail, pre-frail and frail categories, respectively, of the Placebo group.

Similar results were seen for vaccine-related solicited AEs (Table 14.3.1.4) reported during the 7-day post-vaccination period following each dose and overall per dose and per subject by frailty status in the TVC - Diary card subset.

Table 12.1 Incidence and nature of symptoms (solicited only) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom						General symptoms						Local symptoms					
						95% CI					95% CI					95% CI				
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%
Dose 1	Non-Frail	HZ/su	2004	1647	82.2	80.4	83.8	2001	1068	53.4	51.2	55.6	2000	1569	78.5	76.6	80.2			
		Placebo	2032	503	24.8	22.9	26.7	2032	420	20.7	18.9	22.5	2031	168	8.3	7.1	9.6			
	Pre-Frail	HZ/su	1971	1497	76.0	74.0	77.8	1963	965	49.2	46.9	51.4	1970	1393	70.7	68.6	72.7			
		Placebo	1962	502	25.6	23.7	27.6	1960	429	21.9	20.1	23.8	1962	158	8.1	6.9	9.3			
	Frail	HZ/su	483	316	65.4	61.0	69.7	480	186	38.8	34.4	43.3	483	292	60.5	55.9	64.8			
		Placebo	462	134	29.0	24.9	33.4	461	123	26.7	22.7	31.0	461	33	7.2	5.0	9.9			
	Unknown	HZ/su	21	16	76.2	52.8	91.8	20	11	55.0	31.5	76.9	21	15	71.4	47.8	88.7			
		Placebo	18	6	33.3	13.3	59.0	18	5	27.8	9.7	53.5	17	2	11.8	1.5	36.4			
Dose 2	Non-Frail	HZ/su	1943	1558	80.2	78.3	81.9	1942	1098	56.5	54.3	58.8	1941	1457	75.1	73.1	77.0			
		Placebo	1988	367	18.5	16.8	20.2	1988	304	15.3	13.7	17.0	1988	111	5.6	4.6	6.7			
	Pre-Frail	HZ/su	1911	1373	71.8	69.8	73.9	1906	933	49.0	46.7	51.2	1909	1259	66.0	63.8	68.1			
		Placebo	1899	364	19.2	17.4	21.0	1895	315	16.6	15.0	18.4	1899	115	6.1	5.0	7.2			
	Frail	HZ/su	456	294	64.5	59.9	68.9	456	190	41.7	37.1	46.3	455	268	58.9	54.2	63.5			
		Placebo	444	98	22.1	18.3	26.2	443	85	19.2	15.6	23.2	442	35	7.9	5.6	10.8			
	Unknown	HZ/su	18	12	66.7	41.0	86.7	18	5	27.8	9.7	53.5	18	11	61.1	35.7	82.7			
		Placebo	15	3	20.0	4.3	48.1	15	3	20.0	4.3	48.1	15	0	0.0	0.0	21.8			
Overall/dose	Non-Frail	HZ/su	3947	3205	81.2	79.9	82.4	3943	2166	54.9	53.4	56.5	3941	3026	76.8	75.4	78.1			
		Placebo	4020	870	21.6	20.4	22.9	4020	724	18.0	16.8	19.2	4019	279	6.9	6.2	7.8			
	Pre-Frail	HZ/su	3882	2870	73.9	72.5	75.3	3869	1898	49.1	47.5	50.6	3879	2652	68.4	66.9	69.8			
		Placebo	3861	866	22.4	21.1	23.8	3855	744	19.3	18.1	20.6	3861	273	7.1	6.3	7.9			
	Frail	HZ/su	939	610	65.0	61.8	68.0	936	376	40.2	37.0	43.4	938	560	59.7	56.5	62.9			
		Placebo	906	232	25.6	22.8	28.6	904	208	23.0	20.3	25.9	903	68	7.5	5.9	9.4			
	Unknown	HZ/su	39	28	71.8	55.1	85.0	38	16	42.1	26.3	59.2	39	26	66.7	49.8	80.9			
		Placebo	33	9	27.3	13.3	45.5	33	8	24.2	11.1	42.3	32	2	6.3	0.8	20.8			
Overall/subject	Non-Frail	HZ/su	2008	1752	87.3	85.7	88.7	2007	1369	68.2	66.1	70.2	2007	1699	84.7	83.0	86.2			
		Placebo	2034	654	32.2	30.1	34.2	2034	558	27.4	25.5	29.4	2034	227	11.2	9.8	12.6			
	Pre-Frail	HZ/su	1977	1649	83.4	81.7	85.0	1971	1242	63.0	60.8	65.1	1977	1559	78.9	77.0	80.6			
		Placebo	1964	662	33.7	31.6	35.8	1964	575	29.3	27.3	31.3	1964	227	11.6	10.2	13.1			
	Frail	HZ/su	490	360	73.5	69.3	77.3	488	248	50.8	46.3	55.3	489	335	68.5	64.2	72.6			
		Placebo	468	169	36.1	31.8	40.6	468	154	32.9	28.7	37.4	468	51	10.9	8.2	14.1			
	Unknown	HZ/su	21	18	85.7	63.7	97.0	21	11	52.4	29.8	74.3	21	17	81.0	58.1	94.6			
		Placebo	18	7	38.9	17.3	64.3	18	6	33.3	13.3	59.0	17	2	11.8	1.5	36.4			

Source: [Table 14.3.1.2](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

12.2.3.1.2. Grade 3 Solicited Adverse Events

Percentages of any grade 3 solicited AE were higher in the HZ/su group than in the Placebo group for all frailty categories during the 7-day post-vaccination period following each dose and overall per dose and per subject in the TVC - Diary card subset (Table 12.2):

- Percentages of any grade 3 solicited AEs (Table 12.2) were similar across frailty categories in the HZ/su group (17.4%, 14.1% and 15.3% overall/subject for non-frail, pre-frail and frail, respectively) and were higher in the frail than the pre-frail and non-frail categories in the Placebo group (1.8%, 2.2% and 5.1% overall/subject for non-frail, pre-frail and frail, respectively).
- General grade 3 solicited AEs (Table 12.2) were reported by 12.0%, 9.4% and 10.2% of subjects in non-frail, pre-frail and frail categories, respectively, of the HZ/su group, and 1.8%, 2.0% and 4.7% of subjects in non-frail, pre-frail and frail categories, respectively, of the Placebo group.
- Local grade 3 solicited AEs (Table 12.2) were reported by 9.5%, 8.7% and 10.2% of subjects in non-frail, pre-frail and frail categories, respectively, of the HZ/su group, and 0.2%, 0.3% and 1.1% of subjects in non-frail, pre-frail and frail categories, respectively, of the Placebo group.

Similar results were seen for grade 3 vaccine-related solicited AEs (Table 14.3.1.5) reported during the 7-day post-vaccination period following each dose and overall per dose and per subject by frailty status in the TVC - Diary card subset.

Table 12.2 Incidence and nature of grade 3 symptoms (solicited only) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom						General symptoms						Local symptoms					
						95% CI					95% CI					95% CI				
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL			
Dose 1	Non-Frail	HZ/su	2004	180	9.0	7.8	10.3	2001	104	5.2	4.3	6.3	2000	110	5.5	4.5	6.6			
		Placebo	2032	23	1.1	0.7	1.7	2032	22	1.1	0.7	1.6	2031	3	0.1	0.0	0.4			
	Pre-Frail	HZ/su	1971	163	8.3	7.1	9.6	1963	99	5.0	4.1	6.1	1970	99	5.0	4.1	6.1			
		Placebo	1962	27	1.4	0.9	2.0	1960	26	1.3	0.9	1.9	1962	2	0.1	0.0	0.4			
	Frail	HZ/su	483	45	9.3	6.9	12.3	480	27	5.6	3.7	8.1	483	26	5.4	3.5	7.8			
		Placebo	462	14	3.0	1.7	5.0	461	14	3.0	1.7	5.0	461	1	0.2	0.0	1.2			
	Unknown	HZ/su	21	1	4.8	0.1	23.8	20	0	0.0	0.0	16.8	21	1	4.8	0.1	23.8			
		Placebo	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	17	0	0.0	0.0	19.5			
Dose 2	Non-Frail	HZ/su	1943	237	12.2	10.8	13.7	1942	172	8.9	7.6	10.2	1941	118	6.1	5.1	7.2			
		Placebo	1988	18	0.9	0.5	1.4	1988	18	0.9	0.5	1.4	1988	1	0.1	0.0	0.3			
	Pre-Frail	HZ/su	1911	168	8.8	7.6	10.2	1906	112	5.9	4.9	7.0	1909	100	5.2	4.3	6.3			
		Placebo	1899	23	1.2	0.8	1.8	1895	20	1.1	0.6	1.6	1899	4	0.2	0.1	0.5			
	Frail	HZ/su	456	49	10.7	8.1	14.0	456	31	6.8	4.7	9.5	455	33	7.3	5.0	10.0			
		Placebo	444	14	3.2	1.7	5.2	443	12	2.7	1.4	4.7	442	4	0.9	0.2	2.3			
	Unknown	HZ/su	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5			
		Placebo	15	0	0.0	0.0	21.8	15	0	0.0	0.0	21.8	15	0	0.0	0.0	21.8			
Overall/dose	Non-Frail	HZ/su	3947	417	10.6	9.6	11.6	3943	276	7.0	6.2	7.8	3941	228	5.8	5.1	6.6			
		Placebo	4020	41	1.0	0.7	1.4	4020	40	1.0	0.7	1.4	4019	4	0.1	0.0	0.3			
	Pre-Frail	HZ/su	3882	331	8.5	7.7	9.4	3869	211	5.5	4.8	6.2	3879	199	5.1	4.5	5.9			
		Placebo	3861	50	1.3	1.0	1.7	3855	46	1.2	0.9	1.6	3861	6	0.2	0.1	0.3			
	Frail	HZ/su	939	94	10.0	8.2	12.1	936	58	6.2	4.7	7.9	938	59	6.3	4.8	8.0			
		Placebo	906	28	3.1	2.1	4.4	904	26	2.9	1.9	4.2	903	5	0.6	0.2	1.3			
	Unknown	HZ/su	39	1	2.6	0.1	13.5	38	0	0.0	0.0	9.3	39	1	2.6	0.1	13.5			
		Placebo	33	0	0.0	0.0	10.6	33	0	0.0	0.0	10.6	32	0	0.0	0.0	10.9			
Overall/subject	Non-Frail	HZ/su	2008	349	17.4	15.7	19.1	2007	240	12.0	10.6	13.5	2007	190	9.5	8.2	10.8			
		Placebo	2034	37	1.8	1.3	2.5	2034	36	1.8	1.2	2.4	2034	4	0.2	0.1	0.5			
	Pre-Frail	HZ/su	1977	279	14.1	12.6	15.7	1971	185	9.4	8.1	10.8	1977	172	8.7	7.5	10.0			
		Placebo	1964	44	2.2	1.6	3.0	1964	40	2.0	1.5	2.8	1964	6	0.3	0.1	0.7			
	Frail	HZ/su	490	75	15.3	12.2	18.8	488	50	10.2	7.7	13.3	489	50	10.2	7.7	13.3			
		Placebo	468	24	5.1	3.3	7.5	468	22	4.7	3.0	7.0	468	5	1.1	0.3	2.5			
	Unknown	HZ/su	21	1	4.8	0.1	23.8	21	0	0.0	0.0	16.1	21	1	4.8	0.1	23.8			
		Placebo	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	17	0	0.0	0.0	19.5			

Source: [Table 14.3.1.3](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

12.2.3.1.3. Solicited Local Adverse Events

Percentages of each local solicited AE (pain, redness and swelling) were higher in the HZ/su group than in the Placebo group for all frailty categories during the 7-day post-vaccination period following each dose and overall per dose and per subject in the TVC - Diary card subset ([Table 12.3](#)):

- Pain (any grade, [Table 12.3](#)) was the most frequently reported solicited local AE for each frailty category in both treatment groups. Overall/subject, pain decreased with increasing frailty in the HZ/su group (82.5%, 75.6% and 65.8% overall/subject for non-frail, pre-frail and frail, respectively) and was similar across frailty categories in the Placebo group (10.3%, 10.7% and 10.9% overall/subject for non-frail, pre-frail and frail, respectively).
- Pain ([Table 12.3](#)) was the most frequently reported grade 3 solicited local AE in each frailty category in both treatment groups. Overall/subject, reporting of grade 3 pain was similar across frailty categories in both the HZ/su group (5.7%, 6.3% and 7.8% overall/subject for non-frail, pre-frail and frail, respectively) and Placebo group (0.2%, 0.3% and 1.1% overall/subject for non-frail, pre-frail and frail, respectively).
- Similar results were seen for each dose and overall/dose and no increase was observed between Dose 1 and Dose 2 for each solicited local AE in each frailty category in both treatment groups ([Table 12.3](#)). Redness and swelling were reported less frequently than pain in all groups and no grade 3 redness or swelling were reported in the Placebo group.

The number of days with solicited local AEs during the 7-day post-vaccination period by frailty status in the TVC - Diary Card Subset between the treatment groups or across frailty categories is presented in [Table 14.3.1.11](#).

The number of days with grade 3 solicited local AEs during the 7-day post-vaccination period by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.12](#).

Total number of days during the study with solicited local AEs by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.13](#).

A summary of solicited local AEs ongoing beyond the 7-day post-vaccination period by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.14](#).

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Table 12.3 Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort – Diary Card Subset)

		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																																									
Pain	All	2000	1515	75.8	73.8	77.6	2031	154	7.6	6.5	8.8	1970	1315	66.8	64.6	68.8	1962	143	7.3	6.2	8.5	483	276	57.1	52.6	61.6	461	32	6.9	4.8	9.7	21	15	71.4	47.8	88.7	17	1	5.9	0.1	28.7
	Grade 1	2000	1034	51.7	49.5	53.9	2031	133	6.5	5.5	7.7	1970	913	46.3	44.1	48.6	1962	128	6.5	5.5	7.7	483	164	34.0	29.7	38.4	461	29	6.3	4.3	8.9	21	13	61.9	38.4	81.9	17	1	5.9	0.1	28.7
	Grade 2	2000	420	21.0	19.2	22.9	2031	18	0.9	0.5	1.4	1970	335	17.0	15.4	18.7	1962	12	0.6	0.3	1.1	483	92	19.0	15.6	22.8	461	2	0.4	0.1	1.6	21	1	4.8	0.1	23.8	17	0	0.0	0.0	19.5
	Grade 3	2000	60	3.0	2.3	3.8	2031	3	0.1	0.0	0.4	1970	65	3.3	2.6	4.2	1962	2	0.1	0.0	0.4	483	20	4.1	2.5	6.3	461	1	0.2	0.0	1.2	21	1	4.8	0.1	23.8	17	0	0.0	0.0	19.5
Redness (mm)	All	2000	599	30.0	27.9	32.0	2031	18	0.9	0.5	1.4	1970	526	26.7	24.8	28.7	1962	19	1.0	0.6	1.5	483	119	24.6	20.9	28.7	461	1	0.2	0.0	1.2	21	6	28.6	11.3	52.2	17	0	0.0	0.0	19.5
	≥20 and ≤50	2000	284	14.2	12.7	15.8	2031	17	0.8	0.5	1.3	1970	253	12.8	11.4	14.4	1962	15	0.8	0.4	1.3	483	56	11.6	8.9	14.8	461	1	0.2	0.0	1.2	21	2	9.5	1.2	30.4	17	0	0.0	0.0	19.5
	>50 and ≤100	2000	266	13.3	11.8	14.9	2031	1	0.0	0.0	0.3	1970	239	12.1	10.7	13.7	1962	3	0.2	0.0	0.4	483	54	11.2	8.5	14.3	461	0	0.0	0.0	0.8	21	4	19.0	5.4	41.9	17	0	0.0	0.0	19.5
	>100	2000	49	2.5	1.8	3.2	2031	0	0.0	0.0	0.2	1970	30	1.5	1.0	2.2	1962	0	0.0	0.0	0.2	483	6	1.2	0.5	2.7	461	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5
Swelling (mm)	All	2000	383	19.2	17.4	20.9	2031	12	0.6	0.3	1.0	1970	340	17.3	15.6	19.0	1962	15	0.8	0.4	1.3	483	79	16.4	13.2	20.0	461	2	0.4	0.1	1.6	21	5	23.8	8.2	47.2	17	1	5.9	0.1	28.7
	≥20 and ≤50	2000	208	10.4	9.1	11.8	2031	11	0.5	0.3	1.0	1970	183	9.3	8.0	10.7	1962	12	0.6	0.3	1.1	483	40	8.3	6.0	11.1	461	2	0.4	0.1	1.6	21	2	9.5	1.2	30.4	17	1	5.9	0.1	28.7
	>50 and ≤100	2000	161	8.1	6.9	9.3	2031	1	0.0	0.0	0.3	1970	136	6.9	5.8	8.1	1962	1	0.1	0.0	0.3	483	36	7.5	5.3	10.2	461	0	0.0	0.0	0.8	21	3	14.3	3.0	36.3	17	0	0.0	0.0	19.5
	>100	2000	13	0.7	0.3	1.1	2031	0	0.0	0.0	0.2	1970	12	0.6	0.3	1.1	1962	0	0.0	0.0	0.2	483	0	0.0	0.0	0.8	461	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5
Dose 2																																									
Pain	All	1941	1382	71.2	69.1	73.2	1988	106	5.3	4.4	6.4	1909	1187	62.2	60.0	64.4	1899	110	5.8	4.8	6.9	455	256	56.3	51.6	60.9	442	35	7.9	5.6	10.8	18	11	61.1	35.7	82.7	15	0	0.0	0.0	21.8
	Grade 1	1941	936	48.2	46.0	50.5	1988	96	4.8	3.9	5.9	1909	776	40.6	38.4	42.9	1899	93	4.9	4.0	6.0	455	150	33.0	28.7	37.5	442	28	6.3	4.3	9.0	18	10	55.6	30.8	78.5	15	0	0.0	0.0	21.8
	Grade 2	1941	365	18.8	17.1	20.6	1988	9	0.5	0.2	0.9	1909	331	17.3	15.7	19.1	1899	13	0.7	0.4	1.2	455	81	17.8	14.4	21.6	442	3	0.7	0.1	2.0	18	1	5.6	0.1	27.3	15	0	0.0	0.0	21.8
	Grade 3	1941	80	4.1	3.3	5.1	1988	1	0.1	0.0	0.3	1909	78	4.1	3.2	5.1	1899	4	0.2	0.1	0.5	455	25	5.5	3.6	8.0	442	4	0.9	0.2	2.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Redness (mm)	All	1941	583	30.0	28.0	32.1	1988	8	0.4	0.2	0.8	1909	499	26.1	24.2	28.2	1899	12	0.6	0.3	1.1	455	104	22.9	19.1	27.0	442	1	0.2	0.0	1.3	18	6	33.3	13.3	59.0	15	0	0.0	0.0	21.8
	≥20 and ≤50	1941	272	14.0	12.5	15.6	1988	6	0.3	0.1	0.7	1909	225	11.8	10.4	13.3	1899	11	0.6	0.3	1.0	455	54	11.9	9.0	15.2	442	1	0.2	0.0	1.3	18	5	27.8	9.7	53.5	15	0	0.0	0.0	21.8
	>50 and ≤100	1941	271	14.0	12.4	15.6	1988	1	0.1	0.0	0.3	1909	247	12.9	11.5	14.5	1899	1	0.1	0.0	0.3	455	41	9.0	6.5	12.0	442	0	0.0	0.0	0.8	18	1	5.6	0.1	27.3	15	0	0.0	0.0	21.8
	>100	1941	37	1.9	1.3	2.6	1988	0	0.0	0.0	0.2	1909	22	1.2	0.7	1.7	1899	0	0.0	0.0	0.2	455	8	1.8	0.8	3.4	442	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Swelling (mm)	All	1941	364	18.8	17.0	20.6	1988	6	0.3	0.1	0.7	1909	336	17.6	15.9	19.4	1899	9	0.5	0.2	0.9	455	63	13.8	10.8	17.4	442	1	0.2	0.0	1.3	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	≥20 and ≤50	1941	208	10.7	9.4	12.2	1988	5	0.3	0.1	0.6	1909	200	10.5	9.1	11.9	1899	9	0.5	0.2	0.9	455	38	8.4	6.0	11.3	442	1	0.2	0.0	1.3	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	>50 and ≤100	1941	140	7.2	6.1	8.5	1988	1	0.1	0.0	0.3	1909	120	6.3	5.2	7.5	1899	0	0.0	0.0	0.2	455	22	4.8	3.1	7.2	442	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	>100	1941	13	0.7	0.4	1.1	1988	0	0.0	0.0	0.2	1909	9	0.5	0.2	0.9	1899	0	0.0	0.0	0.2	455	2	0.4	0.1	1.6	442	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8

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		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
Symptom	Type	N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI						
Overall/dose																																									
Pain	All	3941	2897	73.5	72.1	74.9	4019	260	6.5	5.7	7.3	3879	2502	64.5	63.0	66.0	3861	253	6.6	5.8	7.4	938	532	56.7	53.5	59.9	903	67	7.4	5.8	9.3	39	26	66.7	49.8	80.9	32	1	3.1	0.1	16.2
	Grade 1	3941	1970	50.0	48.4	51.6	4019	229	5.7	5.0	6.5	3879	1689	43.5	42.0	45.1	3861	221	5.7	5.0	6.5	938	314	33.5	30.5	36.6	903	57	6.3	4.8	8.1	39	23	59.0	42.1	74.4	32	1	3.1	0.1	16.2
	Grade 2	3941	785	19.9	18.7	21.2	4019	27	0.7	0.4	1.0	3879	666	17.2	16.0	18.4	3861	25	0.6	0.4	1.0	938	173	18.4	16.0	21.1	903	5	0.6	0.2	1.3	39	2	5.1	0.6	17.3	32	0	0.0	0.0	10.9
	Grade 3	3941	140	3.6	3.0	4.2	4019	4	0.1	0.0	0.3	3879	143	3.7	3.1	4.3	3861	6	0.2	0.1	0.3	938	45	4.8	3.5	6.4	903	5	0.6	0.2	1.3	39	1	2.6	0.1	13.5	32	0	0.0	0.0	10.9
Redness (mm)	All	3941	1182	30.0	28.6	31.5	4019	26	0.6	0.4	0.9	3879	1025	26.4	25.0	27.8	3861	31	0.8	0.5	1.1	938	223	23.8	21.1	26.6	903	2	0.2	0.0	0.8	39	12	30.8	17.0	47.6	32	0	0.0	0.0	10.9
	≥20 and ≤50	3941	556	14.1	13.0	15.2	4019	23	0.6	0.4	0.9	3879	478	12.3	11.3	13.4	3861	26	0.7	0.4	1.0	938	110	11.7	9.7	14.0	903	2	0.2	0.0	0.8	39	7	17.9	7.5	33.5	32	0	0.0	0.0	10.9
	>50 and ≤100	3941	537	13.6	12.6	14.7	4019	2	0.0	0.0	0.2	3879	486	12.5	11.5	13.6	3861	4	0.1	0.0	0.3	938	95	10.1	8.3	12.2	903	0	0.0	0.0	0.4	39	5	12.8	4.3	27.4	32	0	0.0	0.0	10.9
	>100	3941	86	2.2	1.7	2.7	4019	0	0.0	0.0	0.1	3879	52	1.3	1.0	1.8	3861	0	0.0	0.0	0.1	938	14	1.5	0.8	2.5	903	0	0.0	0.0	0.4	39	0	0.0	0.0	9.0	32	0	0.0	0.0	10.9
Swelling (mm)	All	3941	747	19.0	17.7	20.2	4019	18	0.4	0.3	0.7	3879	676	17.4	16.2	18.7	3861	24	0.6	0.4	0.9	938	142	15.1	12.9	17.6	903	3	0.3	0.1	1.0	39	7	17.9	7.5	33.5	32	1	3.1	0.1	16.2
	≥20 and ≤50	3941	416	10.6	9.6	11.6	4019	16	0.4	0.2	0.6	3879	383	9.9	9.0	10.9	3861	21	0.5	0.3	0.8	938	78	8.3	6.6	10.3	903	3	0.3	0.1	1.0	39	4	10.3	2.9	24.2	32	1	3.1	0.1	16.2
	>50 and ≤100	3941	301	7.6	6.8	8.5	4019	2	0.0	0.0	0.2	3879	256	6.6	5.8	7.4	3861	1	0.0	0.0	0.1	938	58	6.2	4.7	7.9	903	0	0.0	0.0	0.4	39	3	7.7	1.6	20.9	32	0	0.0	0.0	10.9
	>100	3941	26	0.7	0.4	1.0	4019	0	0.0	0.0	0.1	3879	21	0.5	0.3	0.8	3861	0	0.0	0.0	0.1	938	2	0.2	0.0	0.8	903	0	0.0	0.0	0.4	39	0	0.0	0.0	9.0	32	0	0.0	0.0	10.9
Overall/subject																																									
Pain	All	2007	1655	82.5	80.7	84.1	2034	209	10.3	9.0	11.7	1977	1494	75.6	73.6	77.4	1964	211	10.7	9.4	12.2	489	322	65.8	61.5	70.0	468	51	10.9	8.2	14.1	21	17	81.0	58.1	94.6	17	1	5.9	0.1	28.7
	Grade 1	2007	960	47.8	45.6	50.0	2034	180	8.8	7.7	10.2	1977	882	44.6	42.4	46.8	1964	184	9.4	8.1	10.7	489	155	31.7	27.6	36.0	468	43	9.2	6.7	12.2	21	14	66.7	43.0	85.4	17	1	5.9	0.1	28.7
	Grade 2	2007	579	28.8	26.9	30.9	2034	25	1.2	0.8	1.8	1977	483	24.4	22.6	26.4	1964	20	1.0	0.6	1.6	489	129	26.4	22.5	30.5	468	3	0.6	0.1	1.9	21	2	9.5	1.2	30.4	17	0	0.0	0.0	19.5
	Grade 3	2007	115	5.7	4.8	6.8	2034	4	0.2	0.1	0.5	1977	125	6.3	5.3	7.5	1964	6	0.3	0.1	0.7	489	38	7.8	5.6	10.5	468	5	1.1	0.3	2.5	21	1	4.8	0.1	23.8	17	0	0.0	0.0	19.5
Redness (mm)	All	2007	805	40.1	38.0	42.3	2034	25	1.2	0.8	1.8	1977	734	37.1	35.0	39.3	1964	28	1.4	0.9	2.1	489	160	32.7	28.6	37.1	468	2	0.4	0.1	1.5	21	11	52.4	29.8	74.3	17	0	0.0	0.0	19.5
	≥20 and ≤50	2007	336	16.7	15.1	18.4	2034	22	1.1	0.7	1.6	1977	318	16.1	14.5	17.8	1964	23	1.2	0.7	1.8	489	74	15.1	12.1	18.6	468	2	0.4	0.1	1.5	21	6	28.6	11.3	52.2	17	0	0.0	0.0	19.5
	>50 and ≤100	2007	393	19.6	17.9	21.4	2034	2	0.1	0.0	0.4	1977	363	18.4	16.7	20.1	1964	4	0.2	0.1	0.5	489	70	14.3	11.3	17.7	468	0	0.0	0.0	0.8	21	5	23.8	8.2	47.2	17	0	0.0	0.0	19.5
	>100	2007	75	3.7	3.0	4.7	2034	0	0.0	0.0	0.2	1977	46	2.3	1.7	3.1	1964	0	0.0	0.0	0.2	489	12	2.5	1.3	4.2	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5
Swelling (mm)	All	2007	545	27.2	25.2	29.2	2034	18	0.9	0.5	1.4	1977	497	25.1	23.2	27.1	1964	22	1.1	0.7	1.7	489	107	21.9	18.3	25.8	468	3	0.6	0.1	1.9	21	6	28.6	11.3	52.2	17	1	5.9	0.1	28.7
	≥20 and ≤50	2007	285	14.2	12.7	15.8	2034	16	0.8	0.5	1.3	1977	263	13.3	11.8	14.9	1964	19	1.0	0.6	1.5	489	51	10.4	7.9	13.5	468	3	0.6	0.1	1.9	21	3	14.3	3.0	36.3	17	1	5.9	0.1	28.7
	>50 and ≤100	2007	233	11.6	10.2	13.1	2034	2	0.1	0.0	0.4	1977	204	10.3	9.0	11.7	1964	1	0.1	0.0	0.3	489	50	10.2	7.7	13.3	468	0	0.0	0.0	0.8	21	3	14.3	3.0	36.3	17	0	0.0	0.0	19.5
	>100	2007	24	1.2	0.8	1.8	2034	0	0.0	0.0	0.2	1977	19	1.0	0.6	1.5	1964	0	0.0	0.0	0.2	489	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5

Source: Table 14.3.1.8

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

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Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

12.2.3.1.4. Solicited General Adverse Events

Percentages of each general solicited AE (fatigue, gastrointestinal symptoms, headache, myalgia, shivering and temperature) were higher in the HZ/su group than in the Placebo group for all frailty categories during the 7-day post-vaccination period following each dose and overall per dose and per subject in the TVC - Diary card subset (Table 12.4):

- Fatigue and myalgia (Table 12.4) were the most frequently reported solicited general AEs for each frailty category in both treatment groups.

The percentages of subjects reporting fatigue decreased with increasing frailty in the HZ/su group (47.4%, 43.0% and 33.6% in the non-frail, pre-frail and frail, respectively) and tended to increase with increasing frailty in the Placebo group, (14.8%, 17.3% and 20.5%, in the non-frail, pre-frail and frail, respectively).

The percentages of subjects reporting myalgia decreased with increasing frailty in the HZ/su group (47.4%, 42.0% and 35.5% in the non-frail, pre-frail and frail, respectively) and tended to increase with increasing frailty in the Placebo group (10.3%, 11.5% and 16.0% in the non-frail, pre-frail and frail, respectively).

- Fatigue and myalgia (Table 12.4) were the most frequently reported grade 3 solicited general AEs for each frailty category in both treatment groups.

The percentages of subjects reporting grade 3 fatigue was 5.7%, 4.7% and 4.5% in the non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 0.7%, 0.9% and 1.7% in the non-frail, pre-frail and frail categories of the Placebo group, respectively.

The percentages of subjects reporting grade 3 myalgia was 5.0%, 4.5% and 5.7% in the non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 0.4%, 0.4% and 2.6% in the non-frail, pre-frail and frail categories of the Placebo group, respectively.

- Fatigue and myalgia (Table 12.4) were the most frequently reported vaccine-related solicited general AEs for each frailty category in both treatment groups.

The percentages of subjects reporting vaccine-related fatigue decreased with increasing frailty in the HZ/su group (42.3%, 36.3% and 28.5% in non-frail, pre-frail and frail, respectively) and was similar across frailty categories in the Placebo group (11.5%, 11.8% and 11.5% in the non-frail, pre-frail and frail, respectively).

The percentages of subjects reporting vaccine-related myalgia decreased with increasing frailty in the HZ/su group (43.0%, 37.0% and 30.3% in non-frail, pre-frail and frail, respectively) and was similar across frailty categories in the Placebo group (7.5%, 8.8% and 10.0% in the non-frail, pre-frail and frail, respectively).

- Fatigue and myalgia (Table 12.4) were the most frequently reported grade 3 vaccine-related solicited general AEs for each frailty category in both treatment groups.

The percentages of subjects reporting grade 3 vaccine-related fatigue was 5.1%, 3.9% and 3.9% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 0.6%, 0.7% and 1.3% in non-frail, pre-frail and frail categories of the Placebo group, respectively.

The percentages of subjects reporting grade 3 vaccine-related myalgia was 4.6%, 3.9% and 5.1% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 0.3%, 0.3% and 1.3% in non-frail, pre-frail and frail categories of the Placebo group, respectively.

Headache was the next most frequently reported solicited general AE in all groups and gastrointestinal symptoms, shivering and temperature were reported less frequently than fatigue and myalgia in all groups ([Table 12.4](#)).

A summary of temperature value by half degree increment reported during the 7-day post-vaccination period following each dose and overall (no conversion) by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.10](#).

The number of days with solicited general AEs during the 7-day post-vaccination period by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.15](#).

The number of days with grade 3 solicited general AEs during the 7-day post-vaccination period by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.16](#).

Total number of days during the study with solicited general AEs by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.17](#).

A summary of solicited general AEs ongoing beyond the 7-day post-vaccination period by frailty status in the TVC - Diary Card Subset is presented in [Table 14.3.1.18](#).

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Table 12.4 Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort- Diary Card Subset)

		Non-Frail										Pre-Frail										Frail										Unknown										
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI							
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL						
Dose 1																																										
Fatigue	All	2001	650	32.5	30.4	34.6	2032	219	10.8	9.5	12.2	1963	592	30.2	28.1	32.2	1960	237	12.1	10.7	13.6	480	114	23.8	20.0	27.8	461	77	16.7	13.4	20.4	20	4	20.0	5.7	43.7	18	4	22.2	6.4	47.6	
	Grade 1	2001	449	22.4	20.6	24.3	2032	173	8.5	7.3	9.8	1963	399	20.3	18.6	22.2	1960	179	9.1	7.9	10.5	480	68	14.2	11.2	17.6	461	46	10.0	7.4	13.1	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7	
	Grade 2	2001	158	7.9	6.8	9.2	2032	37	1.8	1.3	2.5	1963	147	7.5	6.4	8.7	1960	45	2.3	1.7	3.1	480	32	6.7	4.6	9.3	461	26	5.6	3.7	8.2	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7	
	Grade 3	2001	43	2.1	1.6	2.9	2032	9	0.4	0.2	0.8	1963	46	2.3	1.7	3.1	1960	12	0.6	0.3	1.1	480	14	2.9	1.6	4.8	461	5	1.1	0.4	2.5	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5	
	Related	2001	565	28.2	26.3	30.3	2032	160	7.9	6.7	9.1	1963	482	24.6	22.7	26.5	1960	147	7.5	6.4	8.8	480	88	18.3	15.0	22.1	461	40	8.7	6.3	11.6	20	4	20.0	5.7	43.7	18	4	22.2	6.4	47.6	
	Grade 1 Related	2001	390	19.5	17.8	21.3	2032	124	6.1	5.1	7.2	1963	321	16.4	14.7	18.1	1960	115	5.9	4.9	7.0	480	53	11.0	8.4	14.2	461	23	5.0	3.2	7.4	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7	
	Grade 2 Related	2001	138	6.9	5.8	8.1	2032	29	1.4	1.0	2.0	1963	127	6.5	5.4	7.6	1960	24	1.2	0.8	1.8	480	24	5.0	3.2	7.3	461	14	3.0	1.7	5.0	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7	
	Grade 3 Related	2001	37	1.8	1.3	2.5	2032	7	0.3	0.1	0.7	1963	34	1.7	1.2	2.4	1960	8	0.4	0.2	0.8	480	11	2.3	1.1	4.1	461	3	0.7	0.1	1.9	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5	
Gastrointestinal symptoms	All	2001	219	10.9	9.6	12.4	2032	100	4.9	4.0	6.0	1963	188	9.6	8.3	11.0	1960	117	6.0	5.0	7.1	480	38	7.9	5.7	10.7	461	39	8.5	6.1	11.4	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7	
	Grade 1	2001	162	8.1	6.9	9.4	2032	78	3.8	3.0	4.8	1963	146	7.4	6.3	8.7	1960	84	4.3	3.4	5.3	480	23	4.8	3.1	7.1	461	25	5.4	3.5	7.9	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3	
	Grade 2	2001	44	2.2	1.6	2.9	2032	18	0.9	0.5	1.4	1963	28	1.4	0.9	2.1	1960	25	1.3	0.8	1.9	480	10	2.1	1.0	3.8	461	13	2.8	1.5	4.8	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3	
	Grade 3	2001	13	0.6	0.3	1.1	2032	4	0.2	0.1	0.5	1963	14	0.7	0.4	1.2	1960	7	0.4	0.1	0.7	480	4	0.8	0.2	2.1	461	1	0.2	0.0	1.2	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5	
	Related	2001	166	8.3	7.1	9.6	2032	54	2.7	2.0	3.5	1963	114	5.8	4.8	6.9	1960	62	3.2	2.4	4.0	480	21	4.4	2.7	6.6	461	18	3.9	2.3	6.1	20	0	0.0	0.0	16.8	18	2	11.1	1.4	34.7	
	Grade 1 Related	2001	121	6.0	5.0	7.2	2032	39	1.9	1.4	2.6	1963	87	4.4	3.6	5.4	1960	48	2.4	1.8	3.2	480	15	3.1	1.8	5.1	461	11	2.4	1.2	4.2	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3	
	Grade 2 Related	2001	37	1.8	1.3	2.5	2032	13	0.6	0.3	1.1	1963	18	0.9	0.5	1.4	1960	12	0.6	0.3	1.1	480	4	0.8	0.2	2.1	461	7	1.5	0.6	3.1	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3	
	Grade 3 Related	2001	8	0.4	0.2	0.8	2032	2	0.1	0.0	0.4	1963	9	0.5	0.2	0.9	1960	2	0.1	0.0	0.4	480	2	0.4	0.1	1.5	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5	
Headache	All	2001	538	26.9	25.0	28.9	2032	215	10.6	9.3	12.0	1963	435	22.2	20.3	24.1	1960	214	10.9	9.6	12.4	480	96	20.0	16.5	23.9	461	70	15.2	12.0	18.8	20	5	25.0	8.7	49.1	18	2	11.1	1.4	34.7	
	Grade 1	2001	389	19.4	17.7	21.2	2032	172	8.5	7.3	9.8	1963	327	16.7	15.0	18.4	1960	170	8.7	7.5	10.0	480	66	13.8	10.8	17.2	461	50	10.8	8.2	14.0	20	4	20.0	5.7	43.7	18	1	5.6	0.1	27.3	
	Grade 2	2001	116	5.8	4.8	6.9	2032	38	1.9	1.3	2.6	1963	85	4.3	3.5	5.3	1960	35	1.8	1.2	2.5	480	24	5.0	3.2	7.3	461	13	2.8	1.5	4.8	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3	
	Grade 3	2001	33	1.6	1.1	2.3	2032	5	0.2	0.1	0.6	1963	23	1.2	0.7	1.8	1960	8	0.4	0.2	0.8	480	6	1.3	0.5	2.7	461	7	1.5	0.6	3.1	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5	
	Related	2001	451	22.5	20.7	24.4	2032	151	7.4	6.3	8.7	1963	347	17.7	16.0	19.4	1960	132	6.7	5.7	7.9	480	73	15.2	12.1	18.7	461	47	10.2	7.6	13.3	20	5	25.0	8.7	49.1	18	2	11.1	1.4	34.7	
	Grade 1 Related	2001	324	16.2	14.6	17.9	2032	125	6.2	5.1	7.3	1963	260	13.2	11.8	14.8	1960	107	5.5	4.5	6.6	480	51	10.6	8.0	13.7	461	37	8.0	5.7	10.9	20	4	20.0	5.7	43.7	18	1	5.6	0.1	27.3	
	Grade 2 Related	2001	98	4.9	4.0	5.9	2032	22	1.1	0.7	1.6	1963	69	3.5	2.7	4.4	1960	21	1.1	0.7	1.6	480	17	3.5	2.1	5.6	461	6	1.3	0.5	2.8	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3	
	Grade 3 Related	2001	29	1.4	1.0	2.1	2032	4	0.2	0.1	0.5	1963	18	0.9	0.5	1.4	1960	4	0.2	0.1	0.5	480	5	1.0	0.3	2.4	461	4	0.9	0.2	2.2	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5	

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		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Myalgia	All	2001	682	34.1	32.0	36.2	2032	149	7.3	6.2	8.6	1963	591	30.1	28.1	32.2	1960	152	7.8	6.6	9.0	480	113	23.5	19.8	27.6	461	57	12.4	9.5	15.7	20	4	20.0	5.7	43.7	18	2	11.1	1.4	34.7
	Grade 1	2001	471	23.5	21.7	25.5	2032	127	6.3	5.2	7.4	1963	422	21.5	19.7	23.4	1960	113	5.8	4.8	6.9	480	66	13.8	10.8	17.2	461	37	8.0	5.7	10.9	20	4	20.0	5.7	43.7	18	1	5.6	0.1	27.3
	Grade 2	2001	171	8.5	7.4	9.9	2032	17	0.8	0.5	1.3	1963	123	6.3	5.2	7.4	1960	31	1.6	1.1	2.2	480	34	7.1	5.0	9.8	461	11	2.4	1.2	4.2	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3
	Grade 3	2001	40	2.0	1.4	2.7	2032	5	0.2	0.1	0.6	1963	46	2.3	1.7	3.1	1960	7	0.4	0.1	0.7	480	13	2.7	1.4	4.6	461	9	2.0	0.9	3.7	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	604	30.2	28.2	32.2	2032	106	5.2	4.3	6.3	1963	503	25.6	23.7	27.6	1960	105	5.4	4.4	6.4	480	90	18.8	15.4	22.5	461	34	7.4	5.2	10.2	20	3	15.0	3.2	37.9	18	2	11.1	1.4	34.7
	Grade 1 Related	2001	411	20.5	18.8	22.4	2032	90	4.4	3.6	5.4	1963	359	18.3	16.6	20.1	1960	81	4.1	3.3	5.1	480	50	10.4	7.8	13.5	461	26	5.6	3.7	8.2	20	3	15.0	3.2	37.9	18	1	5.6	0.1	27.3
	Grade 2 Related	2001	156	7.8	6.7	9.1	2032	12	0.6	0.3	1.0	1963	108	5.5	4.5	6.6	1960	19	1.0	0.6	1.5	480	29	6.0	4.1	8.6	461	3	0.7	0.1	1.9	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3
	Grade 3 Related	2001	37	1.8	1.3	2.5	2032	4	0.2	0.1	0.5	1963	36	1.8	1.3	2.5	1960	5	0.3	0.1	0.6	480	11	2.3	1.1	4.1	461	5	1.1	0.4	2.5	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	37	1.8	1.3	2.5	2032	4	0.2	0.1	0.5	1963	36	1.8	1.3	2.5	1960	5	0.3	0.1	0.6	480	11	2.3	1.1	4.1	461	5	1.1	0.4	2.5	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
Shivering	All	2001	317	15.8	14.3	17.5	2032	69	3.4	2.7	4.3	1963	240	12.2	10.8	13.8	1960	75	3.8	3.0	4.8	480	40	8.3	6.0	11.2	461	23	5.0	3.2	7.4	20	3	15.0	3.2	37.9	18	2	11.1	1.4	34.7
	Grade 1	2001	196	9.8	8.5	11.2	2032	58	2.9	2.2	3.7	1963	158	8.0	6.9	9.3	1960	63	3.2	2.5	4.1	480	29	6.0	4.1	8.6	461	20	4.3	2.7	6.6	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Grade 2	2001	83	4.1	3.3	5.1	2032	10	0.5	0.2	0.9	1963	60	3.1	2.3	3.9	1960	8	0.4	0.2	0.8	480	5	1.0	0.3	2.4	461	3	0.7	0.1	1.9	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	Grade 3	2001	38	1.9	1.3	2.6	2032	1	0.0	0.0	0.3	1963	22	1.1	0.7	1.7	1960	3	0.2	0.0	0.4	480	6	1.3	0.5	2.7	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	279	13.9	12.5	15.5	2032	43	2.1	1.5	2.8	1963	206	10.5	9.2	11.9	1960	50	2.6	1.9	3.3	480	31	6.5	4.4	9.0	461	11	2.4	1.2	4.2	20	3	15.0	3.2	37.9	18	2	11.1	1.4	34.7
	Grade 1 Related	2001	168	8.4	7.2	9.7	2032	39	1.9	1.4	2.6	1963	137	7.0	5.9	8.2	1960	42	2.1	1.5	2.9	480	23	4.8	3.1	7.1	461	10	2.2	1.0	4.0	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Grade 2 Related	2001	75	3.7	3.0	4.7	2032	4	0.2	0.1	0.5	1963	52	2.6	2.0	3.5	1960	5	0.3	0.1	0.6	480	3	0.6	0.1	1.8	461	1	0.2	0.0	1.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	Grade 3 Related	2001	36	1.8	1.3	2.5	2032	0	0.0	0.0	0.2	1963	17	0.9	0.5	1.4	1960	3	0.2	0.0	0.4	480	5	1.0	0.3	2.4	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	36	1.8	1.3	2.5	2032	0	0.0	0.0	0.2	1963	17	0.9	0.5	1.4	1960	3	0.2	0.0	0.4	480	5	1.0	0.3	2.4	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
Temperature/(°C)	All	2001	242	12.1	10.7	13.6	2032	24	1.2	0.8	1.8	1963	210	10.7	9.4	12.1	1960	31	1.6	1.1	2.2	480	33	6.9	4.8	9.5	461	10	2.2	1.0	4.0	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	≥37.5 and ≤38	2001	190	9.5	8.2	10.9	2032	18	0.9	0.5	1.4	1963	154	7.8	6.7	9.1	1960	23	1.2	0.7	1.8	480	26	5.4	3.6	7.8	461	9	2.0	0.9	3.7	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	>38 and ≤39	2001	50	2.5	1.9	3.3	2032	3	0.1	0.0	0.4	1963	48	2.4	1.8	3.2	1960	4	0.2	0.1	0.5	480	4	0.8	0.2	2.1	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	>39.0	2001	2	0.1	0.0	0.4	2032	1	0.0	0.0	0.3	1963	3	0.2	0.0	0.4	1960	2	0.1	0.0	0.4	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	213	10.6	9.3	12.1	2032	17	0.8	0.5	1.3	1963	176	9.0	7.7	10.3	1960	16	0.8	0.5	1.3	480	24	5.0	3.2	7.3	461	4	0.9	0.2	2.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	≥37.5 and ≤38	2001	165	8.2	7.1	9.5	2032	15	0.7	0.4	1.2	1963	133	6.8	5.7	8.0	1960	14	0.7	0.4	1.2	480	19	4.0	2.4	6.1	461	4	0.9	0.2	2.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	Related	2001	165	8.2	7.1	9.5	2032	15	0.7	0.4	1.2	1963	133	6.8	5.7	8.0	1960	14	0.7	0.4	1.2	480	19	4.0	2.4	6.1	461	4	0.9	0.2	2.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	>38 and ≤39	2001	47	2.3	1.7	3.1	2032	2	0.1	0.0	0.4	1963	40	2.0	1.5	2.8	1960	2	0.1	0.0	0.4	480	3	0.6	0.1	1.8	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	47	2.3	1.7	3.1	2032	2	0.1	0.0	0.4	1963	40	2.0	1.5	2.8	1960	2	0.1	0.0	0.4	480	3	0.6	0.1	1.8	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	>39.0 Related	2001	1	0.0	0.0	0.3	2032	0	0.0	0.0	0.2	1963	3	0.2	0.0	0.4	1960	0	0.0	0.0	0.2	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5

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Symptom	Type	N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI						
Dose 2																																									
Fatigue	All	1942	711	36.6	34.5	38.8	1988	147	7.4	6.3	8.6	1906	597	31.3	29.2	33.5	1895	192	10.1	8.8	11.6	456	120	26.3	22.3	30.6	443	46	10.4	7.7	13.6	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 1	1942	408	21.0	19.2	22.9	1988	127	6.4	5.4	7.6	1906	360	18.9	17.2	20.7	1895	147	7.8	6.6	9.1	456	68	14.9	11.8	18.5	443	26	5.9	3.9	8.5	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 2	1942	224	11.5	10.1	13.0	1988	14	0.7	0.4	1.2	1906	183	9.6	8.3	11.0	1895	39	2.1	1.5	2.8	456	39	8.6	6.2	11.5	443	17	3.8	2.3	6.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	79	4.1	3.2	5.0	1988	6	0.3	0.1	0.7	1906	54	2.8	2.1	3.7	1895	5	0.3	0.1	0.6	456	13	2.9	1.5	4.8	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	635	32.7	30.6	34.8	1988	120	6.0	5.0	7.2	1906	510	26.8	24.8	28.8	1895	141	7.4	6.3	8.7	456	104	22.8	19.0	26.9	443	27	6.1	4.1	8.7	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	Grade 1 Related	1942	362	18.6	16.9	20.4	1988	103	5.2	4.2	6.2	1906	302	15.8	14.2	17.6	1895	109	5.8	4.7	6.9	456	59	12.9	10.0	16.4	443	14	3.2	1.7	5.2	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	Grade 2 Related	1942	199	10.2	8.9	11.7	1988	12	0.6	0.3	1.1	1906	161	8.4	7.2	9.8	1895	27	1.4	0.9	2.1	456	33	7.2	5.0	10.0	443	10	2.3	1.1	4.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	74	3.8	3.0	4.8	1988	5	0.3	0.1	0.6	1906	47	2.5	1.8	3.3	1895	5	0.3	0.1	0.6	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Gastrointestinal symptoms	All	1942	237	12.2	10.8	13.7	1988	75	3.8	3.0	4.7	1906	201	10.5	9.2	12.0	1895	79	4.2	3.3	5.2	456	44	9.6	7.1	12.7	443	29	6.5	4.4	9.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 1	1942	179	9.2	8.0	10.6	1988	50	2.5	1.9	3.3	1906	139	7.3	6.2	8.6	1895	62	3.3	2.5	4.2	456	27	5.9	3.9	8.5	443	14	3.2	1.7	5.2	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 2	1942	44	2.3	1.7	3.0	1988	17	0.9	0.5	1.4	1906	45	2.4	1.7	3.1	1895	15	0.8	0.4	1.3	456	15	3.3	1.9	5.4	443	10	2.3	1.1	4.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	13	0.7	0.4	1.1	1988	8	0.4	0.2	0.8	1906	17	0.9	0.5	1.4	1895	1	0.1	0.0	0.3	456	2	0.4	0.1	1.6	443	5	1.1	0.4	2.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	200	10.3	9.0	11.7	1988	40	2.0	1.4	2.7	1906	150	7.9	6.7	9.2	1895	41	2.2	1.6	2.9	456	34	7.5	5.2	10.3	443	13	2.9	1.6	5.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 1 Related	1942	149	7.7	6.5	8.9	1988	26	1.3	0.9	1.9	1906	104	5.5	4.5	6.6	1895	33	1.7	1.2	2.4	456	20	4.4	2.7	6.7	443	8	1.8	0.8	3.5	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 2 Related	1942	39	2.0	1.4	2.7	1988	10	0.5	0.2	0.9	1906	34	1.8	1.2	2.5	1895	8	0.4	0.2	0.8	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	12	0.6	0.3	1.1	1988	4	0.2	0.1	0.5	1906	12	0.6	0.3	1.1	1895	0	0.0	0.0	0.2	456	2	0.4	0.1	1.6	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Headache	All	1942	627	32.3	30.2	34.4	1988	131	6.6	5.5	7.8	1906	463	24.3	22.4	26.3	1895	160	8.4	7.2	9.8	456	104	22.8	19.0	26.9	443	43	9.7	7.1	12.9	18	3	16.7	3.6	41.4	15	1	6.7	0.2	31.9
	Grade 1	1942	395	20.3	18.6	22.2	1988	99	5.0	4.1	6.0	1906	309	16.2	14.6	17.9	1895	124	6.5	5.5	7.8	456	55	12.1	9.2	15.4	443	22	5.0	3.1	7.4	18	3	16.7	3.6	41.4	15	1	6.7	0.2	31.9
	Grade 2	1942	184	9.5	8.2	10.9	1988	29	1.5	1.0	2.1	1906	117	6.1	5.1	7.3	1895	29	1.5	1.0	2.2	456	36	7.9	5.6	10.8	443	16	3.6	2.1	5.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	48	2.5	1.8	3.3	1988	3	0.2	0.0	0.4	1906	37	1.9	1.4	2.7	1895	6	0.3	0.1	0.7	456	12	2.6	1.4	4.6	443	4	0.9	0.2	2.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	562	28.9	26.9	31.0	1988	91	4.6	3.7	5.6	1906	413	21.7	19.8	23.6	1895	103	5.4	4.5	6.6	456	90	19.7	16.2	23.7	443	24	5.4	3.5	8.0	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 1 Related	1942	345	17.8	16.1	19.5	1988	69	3.5	2.7	4.4	1906	271	14.2	12.7	15.9	1895	84	4.4	3.6	5.5	456	47	10.3	7.7	13.5	443	12	2.7	1.4	4.7	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 2 Related	1942	171	8.8	7.6	10.2	1988	20	1.0	0.6	1.5	1906	109	5.7	4.7	6.9	1895	18	0.9	0.6	1.5	456	31	6.8	4.7	9.5	443	8	1.8	0.8	3.5	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	46	2.4	1.7	3.1	1988	2	0.1	0.0	0.4	1906	33	1.7	1.2	2.4	1895	1	0.1	0.0	0.3	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Myalgia	All	1942	713	36.7	34.6	38.9	1988	109	5.5	4.5	6.6	1906	587	30.8	28.7	32.9	1895	117	6.2	5.1	7.4	456	119	26.1	22.1	30.4	443	38	8.6	6.1	11.6	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 1	1942	419	21.6	19.8	23.5	1988	91	4.6	3.7	5.6	1906	342	17.9	16.2	19.7	1895	90	4.7	3.8	5.8	456	59	12.9	10.0	16.4	443	19	4.3	2.6	6.6	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 2	1942	220	11.3	10.0	12.8	1988	15	0.8	0.4	1.2	1906	192	10.1	8.8	11.5	1895	24	1.3	0.8	1.9	456	42	9.2	6.7	12.2	443	14	3.2	1.7	5.2	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	74	3.8	3.0	4.8	1988	3	0.2	0.0	0.4	1906	53	2.8	2.1	3.6	1895	2	0.1	0.0	0.4	456	18	3.9	2.4	6.2	443	5	1.1	0.4	2.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	639	32.9	30.8	35.0	1988	82	4.1	3.3	5.1	1906	521	27.3	25.3	29.4	1895	91	4.8	3.9	5.9	456	106	23.2	19.4	27.4	443	21	4.7	3.0	7.2	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8

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		95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI			95 % CI						
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL					
	Grade 1 Related	1942	374	19.3	17.5	21.1	1988	69	3.5	2.7	4.4	1906	300	15.7	14.1	17.5	1895	70	3.7	2.9	4.6	456	53	11.6	8.8	14.9	443	10	2.3	1.1	4.1	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 2 Related	1942	197	10.1	8.8	11.6	1988	11	0.6	0.3	1.0	1906	172	9.0	7.8	10.4	1895	18	0.9	0.6	1.5	456	36	7.9	5.6	10.8	443	10	2.3	1.1	4.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	68	3.5	2.7	4.4	1988	2	0.1	0.0	0.4	1906	49	2.6	1.9	3.4	1895	2	0.1	0.0	0.4	456	17	3.7	2.2	5.9	443	1	0.2	0.0	1.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Shivering	All	1942	500	25.7	23.8	27.8	1988	58	2.9	2.2	3.8	1906	338	17.7	16.0	19.5	1895	47	2.5	1.8	3.3	456	64	14.0	11.0	17.6	443	24	5.4	3.5	8.0	18	0	0.0	0.0	18.5	15	2	13.3	1.7	40.5
	Grade 1	1942	279	14.4	12.8	16.0	1988	48	2.4	1.8	3.2	1906	198	10.4	9.1	11.8	1895	37	2.0	1.4	2.7	456	32	7.0	4.8	9.8	443	16	3.6	2.1	5.8	18	0	0.0	0.0	18.5	15	2	13.3	1.7	40.5
	Grade 2	1942	146	7.5	6.4	8.8	1988	7	0.4	0.1	0.7	1906	99	5.2	4.2	6.3	1895	5	0.3	0.1	0.6	456	19	4.2	2.5	6.4	443	6	1.4	0.5	2.9	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	74	3.8	3.0	4.8	1988	3	0.2	0.0	0.4	1906	41	2.2	1.5	2.9	1895	4	0.2	0.1	0.5	456	13	2.9	1.5	4.8	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	453	23.3	21.5	25.3	1988	44	2.2	1.6	3.0	1906	289	15.2	13.6	16.9	1895	32	1.7	1.2	2.4	456	58	12.7	9.8	16.1	443	14	3.2	1.7	5.2	18	0	0.0	0.0	18.5	15	1	6.7	0.2	31.9
	Grade 1 Related	1942	249	12.8	11.4	14.4	1988	38	1.9	1.4	2.6	1906	166	8.7	7.5	10.1	1895	24	1.3	0.8	1.9	456	30	6.6	4.5	9.3	443	9	2.0	0.9	3.8	18	0	0.0	0.0	18.5	15	1	6.7	0.2	31.9
	Grade 2 Related	1942	136	7.0	5.9	8.2	1988	4	0.2	0.1	0.5	1906	84	4.4	3.5	5.4	1895	5	0.3	0.1	0.6	456	15	3.3	1.9	5.4	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	68	3.5	2.7	4.4	1988	2	0.1	0.0	0.4	1906	39	2.0	1.5	2.8	1895	2	0.1	0.0	0.4	456	13	2.9	1.5	4.8	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Temperature/(°C)	All	1942	335	17.3	15.6	19.0	1988	31	1.6	1.1	2.2	1906	230	12.1	10.6	13.6	1895	25	1.3	0.9	1.9	456	48	10.5	7.9	13.7	443	11	2.5	1.2	4.4	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	≥37.5 and ≤38	1942	234	12.0	10.6	13.6	1988	22	1.1	0.7	1.7	1906	160	8.4	7.2	9.7	1895	19	1.0	0.6	1.6	456	32	7.0	4.8	9.8	443	9	2.0	0.9	3.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	>38 and ≤39	1942	96	4.9	4.0	6.0	1988	5	0.3	0.1	0.6	1906	64	3.4	2.6	4.3	1895	4	0.2	0.1	0.5	456	14	3.1	1.7	5.1	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	>39.0	1942	4	0.2	0.1	0.5	1988	4	0.2	0.1	0.5	1906	2	0.1	0.0	0.4	1895	2	0.1	0.0	0.4	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	306	15.8	14.2	17.5	1988	18	0.9	0.5	1.4	1906	200	10.5	9.2	12.0	1895	13	0.7	0.4	1.2	456	43	9.4	6.9	12.5	443	4	0.9	0.2	2.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	≥37.5 and ≤38 Related	1942	214	11.0	9.7	12.5	1988	13	0.7	0.3	1.1	1906	139	7.3	6.2	8.6	1895	11	0.6	0.3	1.0	456	29	6.4	4.3	9.0	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	>38 and ≤39 Related	1942	88	4.5	3.6	5.6	1988	3	0.2	0.0	0.4	1906	58	3.0	2.3	3.9	1895	2	0.1	0.0	0.4	456	13	2.9	1.5	4.8	443	1	0.2	0.0	1.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	>39.0 Related	1942	4	0.2	0.1	0.5	1988	2	0.1	0.0	0.4	1906	2	0.1	0.0	0.4	1895	0	0.0	0.0	0.2	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8

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Symptom	Type	N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI						
Overall/dose																																									
Fatigue	All	3943	1361	34.5	33.0	36.0	4020	366	9.1	8.2	10.0	3869	1189	30.7	29.3	32.2	3855	429	11.1	10.2	12.2	936	234	25.0	22.3	27.9	904	123	13.6	11.4	16.0	38	6	15.8	6.0	31.3	33	5	15.2	5.1	31.9
	Grade 1	3943	857	21.7	20.5	23.1	4020	300	7.5	6.7	8.3	3869	759	19.6	18.4	20.9	3855	326	8.5	7.6	9.4	936	136	14.5	12.3	17.0	904	72	8.0	6.3	9.9	38	4	10.5	2.9	24.8	33	3	9.1	1.9	24.3
	Grade 2	3943	382	9.7	8.8	10.7	4020	51	1.3	0.9	1.7	3869	330	8.5	7.7	9.5	3855	84	2.2	1.7	2.7	936	71	7.6	6.0	9.5	904	43	4.8	3.5	6.4	38	2	5.3	0.6	17.7	33	2	6.1	0.7	20.2
	Grade 3	3943	122	3.1	2.6	3.7	4020	15	0.4	0.2	0.6	3869	100	2.6	2.1	3.1	3855	17	0.4	0.3	0.7	936	27	2.9	1.9	4.2	904	8	0.9	0.4	1.7	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	1200	30.4	29.0	31.9	4020	280	7.0	6.2	7.8	3869	992	25.6	24.3	27.0	3855	288	7.5	6.7	8.3	936	192	20.5	18.0	23.2	904	67	7.4	5.8	9.3	38	6	15.8	6.0	31.3	33	4	12.1	3.4	28.2
	Grade 1 Related	3943	752	19.1	17.9	20.3	4020	227	5.6	5.0	6.4	3869	623	16.1	15.0	17.3	3855	224	5.8	5.1	6.6	936	112	12.0	10.0	14.2	904	37	4.1	2.9	5.6	38	4	10.5	2.9	24.8	33	2	6.1	0.7	20.2
	Grade 2 Related	3943	337	8.5	7.7	9.5	4020	41	1.0	0.7	1.4	3869	288	7.4	6.6	8.3	3855	51	1.3	1.0	1.7	936	57	6.1	4.6	7.8	904	24	2.7	1.7	3.9	38	2	5.3	0.6	17.7	33	2	6.1	0.7	20.2
	Grade 3 Related	3943	111	2.8	2.3	3.4	4020	12	0.3	0.2	0.5	3869	81	2.1	1.7	2.6	3855	13	0.3	0.2	0.6	936	23	2.5	1.6	3.7	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	111	2.8	2.3	3.4	4020	12	0.3	0.2	0.5	3869	81	2.1	1.7	2.6	3855	13	0.3	0.2	0.6	936	23	2.5	1.6	3.7	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Gastrointestinal symptoms	All	3943	456	11.6	10.6	12.6	4020	175	4.4	3.7	5.0	3869	389	10.1	9.1	11.0	3855	196	5.1	4.4	5.8	936	82	8.8	7.0	10.8	904	68	7.5	5.9	9.4	38	2	5.3	0.6	17.7	33	2	6.1	0.7	20.2
	Grade 1	3943	341	8.6	7.8	9.6	4020	128	3.2	2.7	3.8	3869	285	7.4	6.6	8.2	3855	146	3.8	3.2	4.4	936	50	5.3	4.0	7.0	904	39	4.3	3.1	5.9	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 2	3943	88	2.2	1.8	2.7	4020	35	0.9	0.6	1.2	3869	73	1.9	1.5	2.4	3855	40	1.0	0.7	1.4	936	25	2.7	1.7	3.9	904	23	2.5	1.6	3.8	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 3	3943	26	0.7	0.4	1.0	4020	12	0.3	0.2	0.5	3869	31	0.8	0.5	1.1	3855	8	0.2	0.1	0.4	936	6	0.6	0.2	1.4	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	366	9.3	8.4	10.2	4020	94	2.3	1.9	2.9	3869	264	6.8	6.0	7.7	3855	103	2.7	2.2	3.2	936	55	5.9	4.5	7.6	904	31	3.4	2.3	4.8	38	0	0.0	0.0	9.3	33	2	6.1	0.7	20.2
	Grade 1 Related	3943	270	6.8	6.1	7.7	4020	65	1.6	1.3	2.1	3869	191	4.9	4.3	5.7	3855	81	2.1	1.7	2.6	936	35	3.7	2.6	5.2	904	19	2.1	1.3	3.3	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
	Grade 2 Related	3943	76	1.9	1.5	2.4	4020	23	0.6	0.4	0.9	3869	52	1.3	1.0	1.8	3855	20	0.5	0.3	0.8	936	16	1.7	1.0	2.8	904	10	1.1	0.5	2.0	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
	Grade 3 Related	3943	20	0.5	0.3	0.8	4020	6	0.1	0.1	0.3	3869	21	0.5	0.3	0.8	3855	2	0.1	0.0	0.2	936	4	0.4	0.1	1.1	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	20	0.5	0.3	0.8	4020	6	0.1	0.1	0.3	3869	21	0.5	0.3	0.8	3855	2	0.1	0.0	0.2	936	4	0.4	0.1	1.1	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Headache	All	3943	1165	29.5	28.1	31.0	4020	346	8.6	7.8	9.5	3869	898	23.2	21.9	24.6	3855	374	9.7	8.8	10.7	936	200	21.4	18.8	24.1	904	113	12.5	10.4	14.8	38	8	21.1	9.6	37.3	33	3	9.1	1.9	24.3
	Grade 1	3943	784	19.9	18.6	21.2	4020	271	6.7	6.0	7.6	3869	636	16.4	15.3	17.6	3855	294	7.6	6.8	8.5	936	121	12.9	10.8	15.2	904	72	8.0	6.3	9.9	38	7	18.4	7.7	34.3	33	2	6.1	0.7	20.2
	Grade 2	3943	300	7.6	6.8	8.5	4020	67	1.7	1.3	2.1	3869	202	5.2	4.5	6.0	3855	64	1.7	1.3	2.1	936	60	6.4	4.9	8.2	904	29	3.2	2.2	4.6	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 3	3943	81	2.1	1.6	2.5	4020	8	0.2	0.1	0.4	3869	60	1.6	1.2	2.0	3855	14	0.4	0.2	0.6	936	18	1.9	1.1	3.0	904	11	1.2	0.6	2.2	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	1013	25.7	24.3	27.1	4020	242	6.0	5.3	6.8	3869	760	19.6	18.4	20.9	3855	235	6.1	5.4	6.9	936	163	17.4	15.0	20.0	904	71	7.9	6.2	9.8	38	7	18.4	7.7	34.3	33	3	9.1	1.9	24.3
	Grade 1 Related	3943	669	17.0	15.8	18.2	4020	194	4.8	4.2	5.5	3869	531	13.7	12.7	14.8	3855	191	5.0	4.3	5.7	936	98	10.5	8.6	12.6	904	49	5.4	4.0	7.1	38	6	15.8	6.0	31.3	33	2	6.1	0.7	20.2
	Grade 2 Related	3943	269	6.8	6.1	7.7	4020	42	1.0	0.8	1.4	3869	178	4.6	4.0	5.3	3855	39	1.0	0.7	1.4	936	48	5.1	3.8	6.7	904	14	1.5	0.8	2.6	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 3 Related	3943	75	1.9	1.5	2.4	4020	6	0.1	0.1	0.3	3869	51	1.3	1.0	1.7	3855	5	0.1	0.0	0.3	936	17	1.8	1.1	2.9	904	7	0.8	0.3	1.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	75	1.9	1.5	2.4	4020	6	0.1	0.1	0.3	3869	51	1.3	1.0	1.7	3855	5	0.1	0.0	0.3	936	17	1.8	1.1	2.9	904	7	0.8	0.3	1.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Myalgia	All	3943	1395	35.4	33.9	36.9	4020	258	6.4	5.7	7.2	3869	1178	30.4	29.0	31.9	3855	269	7.0	6.2	7.8	936	232	24.8	22.0	27.7	904	95	10.5	8.6	12.7	38	7	18.4	7.7	34.3	33	2	6.1	0.7	20.2
	Grade 1	3943	890	22.6	21.3	23.9	4020	218	5.4	4.7	6.2	3869	764	19.7	18.5	21.0	3855	203	5.3	4.6	6.0	936	125	13.4	11.2	15.7	904	56	6.2	4.7	8.0	38	7	18.4	7.7	34.3	33	1	3.0	0.1	15.8
	Grade 2	3943	391	9.9	9.0	10.9	4020	32	0.8	0.5	1.1	3869	315	8.1	7.3	9.0	3855	55	1.4	1.1	1.9	936	76	8.1	6.5	10.1	904	25	2.8	1.8	4.1	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
	Grade 3	3943	114	2.9	2.4	3.5	4020	8	0.2	0.1	0.4	3869	99	2.6	2.1	3.1	3855	9	0.2	0.1	0.4	936	31	3.3	2.3	4.7	904	14	1.5	0.8	2.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	1243	31.5	30.1	33.0	4020	188	4.7	4.0	5.4	3869	1024	26.5	25.1	27.9	3855	196	5.1	4.4	5.8	936	196	20.9	18.4	23.7	904	55	6.1	4.6	7.8	38	6	15.8	6.0	31.3	33	2	6.1	0.7	20.2

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		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
		95 % CI			95 % CI		95 % CI			95 % CI		95 % CI			95 % CI		95 % CI			95 % CI		95 % CI			95 % CI		95 % CI			95 % CI		95 % CI									
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL					
	Grade 1 Related	3943	785	19.9	18.7	21.2	4020	159	4.0	3.4	4.6	3869	659	17.0	15.9	18.3	3855	151	3.9	3.3	4.6	936	103	11.0	9.1	13.2	904	36	4.0	2.8	5.5	38	6	15.8	6.0	31.3	33	1	3.0	0.1	15.8
	Grade 2 Related	3943	353	9.0	8.1	9.9	4020	23	0.6	0.4	0.9	3869	280	7.2	6.4	8.1	3855	37	1.0	0.7	1.3	936	65	6.9	5.4	8.8	904	13	1.4	0.8	2.4	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
	Grade 3 Related	3943	105	2.7	2.2	3.2	4020	6	0.1	0.1	0.3	3869	85	2.2	1.8	2.7	3855	7	0.2	0.1	0.4	936	28	3.0	2.0	4.3	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Shivering	All	3943	817	20.7	19.5	22.0	4020	127	3.2	2.6	3.7	3869	578	14.9	13.8	16.1	3855	122	3.2	2.6	3.8	936	104	11.1	9.2	13.3	904	47	5.2	3.8	6.9	38	3	7.9	1.7	21.4	33	4	12.1	3.4	28.2
	Grade 1	3943	475	12.0	11.0	13.1	4020	106	2.6	2.2	3.2	3869	356	9.2	8.3	10.2	3855	100	2.6	2.1	3.1	936	61	6.5	5.0	8.3	904	36	4.0	2.8	5.5	38	2	5.3	0.6	17.7	33	4	12.1	3.4	28.2
	Grade 2	3943	229	5.8	5.1	6.6	4020	17	0.4	0.2	0.7	3869	159	4.1	3.5	4.8	3855	13	0.3	0.2	0.6	936	24	2.6	1.6	3.8	904	9	1.0	0.5	1.9	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	Grade 3	3943	112	2.8	2.3	3.4	4020	4	0.1	0.0	0.3	3869	63	1.6	1.3	2.1	3855	7	0.2	0.1	0.4	936	19	2.0	1.2	3.2	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	732	18.6	17.4	19.8	4020	87	2.2	1.7	2.7	3869	495	12.8	11.8	13.9	3855	82	2.1	1.7	2.6	936	89	9.5	7.7	11.6	904	25	2.8	1.8	4.1	38	3	7.9	1.7	21.4	33	3	9.1	1.9	24.3
	Grade 1 Related	3943	417	10.6	9.6	11.6	4020	77	1.9	1.5	2.4	3869	303	7.8	7.0	8.7	3855	66	1.7	1.3	2.2	936	53	5.7	4.3	7.3	904	19	2.1	1.3	3.3	38	2	5.3	0.6	17.7	33	3	9.1	1.9	24.3
	Grade 2 Related	3943	211	5.4	4.7	6.1	4020	8	0.2	0.1	0.4	3869	136	3.5	3.0	4.1	3855	10	0.3	0.1	0.5	936	18	1.9	1.1	3.0	904	4	0.4	0.1	1.1	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	Grade 3 Related	3943	104	2.6	2.2	3.2	4020	2	0.0	0.0	0.2	3869	56	1.4	1.1	1.9	3855	5	0.1	0.0	0.3	936	18	1.9	1.1	3.0	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Temperature/(*) (°C)	All	3943	577	14.6	13.5	15.8	4020	55	1.4	1.0	1.8	3869	440	11.4	10.4	12.4	3855	56	1.5	1.1	1.9	936	81	8.7	6.9	10.6	904	21	2.3	1.4	3.5	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	≥37.5 and ≤38	3943	424	10.8	9.8	11.8	4020	40	1.0	0.7	1.4	3869	314	8.1	7.3	9.0	3855	42	1.1	0.8	1.5	936	58	6.2	4.7	7.9	904	18	2.0	1.2	3.1	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	>38 and ≤39	3943	146	3.7	3.1	4.3	4020	8	0.2	0.1	0.4	3869	112	2.9	2.4	3.5	3855	8	0.2	0.1	0.4	936	18	1.9	1.1	3.0	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	>39.0	3943	6	0.2	0.1	0.3	4020	5	0.1	0.0	0.3	3869	5	0.1	0.0	0.3	3855	4	0.1	0.0	0.3	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	519	13.2	12.1	14.3	4020	35	0.9	0.6	1.2	3869	376	9.7	8.8	10.7	3855	29	0.8	0.5	1.1	936	67	7.2	5.6	9.0	904	8	0.9	0.4	1.7	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	≥37.5 and ≤38 Related	3943	379	9.6	8.7	10.6	4020	28	0.7	0.5	1.0	3869	272	7.0	6.2	7.9	3855	25	0.6	0.4	1.0	936	48	5.1	3.8	6.7	904	7	0.8	0.3	1.6	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	>38 and ≤39 Related	3943	135	3.4	2.9	4.0	4020	5	0.1	0.0	0.3	3869	98	2.5	2.1	3.1	3855	4	0.1	0.0	0.3	936	16	1.7	1.0	2.8	904	1	0.1	0.0	0.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	>39.0 Related	3943	5	0.1	0.0	0.3	4020	2	0.0	0.0	0.2	3869	5	0.1	0.0	0.3	3855	0	0.0	0.0	0.1	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6

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		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
Symptom	Type	N	n	%	95 % CI			95 % CI			N	n	%	95 % CI			95 % CI			N	n	%	95 % CI			95 % CI			N	n	%	95 % CI			95 % CI						
					LL	UL		LL	UL					LL	UL		LL	UL					LL	UL		LL	UL					LL	UL		LL	UL		LL	UL		LL
Overall/subject																																									
Fatigue	All	2007	951	47.4	45.2	49.6	2034	301	14.8	13.3	16.4	1971	848	43.0	40.8	45.2	1964	339	17.3	15.6	19.0	488	164	33.6	29.4	38.0	468	96	20.5	16.9	24.5	21	5	23.8	8.2	47.2	18	4	22.2	6.4	47.6
	Grade 1	2007	537	26.8	24.8	28.8	2034	237	11.7	10.3	13.1	1971	500	25.4	23.5	27.3	1964	244	12.4	11.0	14.0	488	89	18.2	14.9	22.0	468	53	11.3	8.6	14.6	21	3	14.3	3.0	36.3	18	2	11.1	1.4	34.7
	Grade 2	2007	300	14.9	13.4	16.6	2034	49	2.4	1.8	3.2	1971	255	12.9	11.5	14.5	1964	76	3.9	3.1	4.8	488	53	10.9	8.2	14.0	468	35	7.5	5.3	10.2	21	2	9.5	1.2	30.4	18	2	11.1	1.4	34.7
	Grade 3	2007	114	5.7	4.7	6.8	2034	15	0.7	0.4	1.2	1971	93	4.7	3.8	5.7	1964	17	0.9	0.5	1.4	488	22	4.5	2.8	6.7	468	8	1.7	0.7	3.3	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related	2007	848	42.3	40.1	44.4	2034	233	11.5	10.1	12.9	1971	715	36.3	34.1	38.4	1964	231	11.8	10.4	13.3	488	139	28.5	24.5	32.7	468	54	11.5	8.8	14.8	21	5	23.8	8.2	47.2	18	4	22.2	6.4	47.6
	Grade 1 Related	2007	476	23.7	21.9	25.6	2034	181	8.9	7.7	10.2	1971	415	21.1	19.3	22.9	1964	170	8.7	7.4	10.0	488	75	15.4	12.3	18.9	468	30	6.4	4.4	9.0	21	3	14.3	3.0	36.3	18	2	11.1	1.4	34.7
	Grade 2 Related	2007	269	13.4	11.9	15.0	2034	40	2.0	1.4	2.7	1971	223	11.3	9.9	12.8	1964	48	2.4	1.8	3.2	488	45	9.2	6.8	12.1	468	18	3.8	2.3	6.0	21	2	9.5	1.2	30.4	18	2	11.1	1.4	34.7
	Grade 3 Related	2007	103	5.1	4.2	6.2	2034	12	0.6	0.3	1.0	1971	77	3.9	3.1	4.9	1964	13	0.7	0.4	1.1	488	19	3.9	2.4	6.0	468	6	1.3	0.5	2.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
Gastrointestinal symptoms	All	2007	369	18.4	16.7	20.2	2034	157	7.7	6.6	9.0	1971	325	16.5	14.9	18.2	1964	166	8.5	7.3	9.8	488	65	13.3	10.4	16.7	468	56	12.0	9.2	15.3	21	2	9.5	1.2	30.4	18	2	11.1	1.4	34.7
	Grade 1	2007	265	13.2	11.8	14.8	2034	111	5.5	4.5	6.5	1971	233	11.8	10.4	13.3	1964	122	6.2	5.2	7.4	488	39	8.0	5.7	10.8	468	32	6.8	4.7	9.5	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3
	Grade 2	2007	77	3.8	3.0	4.8	2034	35	1.7	1.2	2.4	1971	64	3.2	2.5	4.1	1964	35	1.8	1.2	2.5	488	20	4.1	2.5	6.3	468	19	4.1	2.5	6.3	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3
	Grade 3	2007	26	1.3	0.8	1.9	2034	11	0.5	0.3	1.0	1971	28	1.4	0.9	2.0	1964	8	0.4	0.2	0.8	488	6	1.2	0.5	2.7	468	5	1.1	0.3	2.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related	2007	298	14.8	13.3	16.5	2034	88	4.3	3.5	5.3	1971	229	11.6	10.2	13.1	1964	86	4.4	3.5	5.4	488	44	9.0	6.6	11.9	468	26	5.6	3.7	8.0	21	0	0.0	0.0	16.1	18	2	11.1	1.4	34.7
	Grade 1 Related	2007	213	10.6	9.3	12.0	2034	59	2.9	2.2	3.7	1971	164	8.3	7.1	9.6	1964	66	3.4	2.6	4.3	488	27	5.5	3.7	7.9	468	15	3.2	1.8	5.2	21	0	0.0	0.0	16.1	18	1	5.6	0.1	27.3
	Grade 2 Related	2007	65	3.2	2.5	4.1	2034	23	1.1	0.7	1.7	1971	45	2.3	1.7	3.0	1964	18	0.9	0.5	1.4	488	13	2.7	1.4	4.5	468	9	1.9	0.9	3.6	21	0	0.0	0.0	16.1	18	1	5.6	0.1	27.3
	Grade 3 Related	2007	20	1.0	0.6	1.5	2034	6	0.3	0.1	0.6	1971	20	1.0	0.6	1.6	1964	2	0.1	0.0	0.4	488	4	0.8	0.2	2.1	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
Headache	All	2007	838	41.8	39.6	43.9	2034	287	14.1	12.6	15.7	1971	676	34.3	32.2	36.4	1964	311	15.8	14.2	17.5	488	147	30.1	26.1	34.4	468	89	19.0	15.6	22.9	21	6	28.6	11.3	52.2	18	3	16.7	3.6	41.4
	Grade 1	2007	514	25.6	23.7	27.6	2034	221	10.9	9.5	12.3	1971	448	22.7	20.9	24.6	1964	239	12.2	10.8	13.7	488	84	17.2	14.0	20.9	468	50	10.7	8.0	13.8	21	5	23.8	8.2	47.2	18	2	11.1	1.4	34.7
	Grade 2	2007	250	12.5	11.0	14.0	2034	58	2.9	2.2	3.7	1971	175	8.9	7.7	10.2	1964	58	3.0	2.2	3.8	488	45	9.2	6.8	12.1	468	29	6.2	4.2	8.8	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3
	Grade 3	2007	74	3.7	2.9	4.6	2034	8	0.4	0.2	0.8	1971	53	2.7	2.0	3.5	1964	12	0.6	0.3	1.1	488	17	3.5	2.0	5.5	468	10	2.1	1.0	3.9	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related	2007	735	36.6	34.5	38.8	2034	202	9.9	8.7	11.3	1971	582	29.5	27.5	31.6	1964	198	10.1	8.8	11.5	488	122	25.0	21.2	29.1	468	59	12.6	9.7	16.0	21	5	23.8	8.2	47.2	18	3	16.7	3.6	41.4
	Grade 1 Related	2007	441	22.0	20.2	23.8	2034	159	7.8	6.7	9.1	1971	380	19.3	17.6	21.1	1964	156	7.9	6.8	9.2	488	68	13.9	11.0	17.3	468	39	8.3	6.0	11.2	21	4	19.0	5.4	41.9	18	2	11.1	1.4	34.7
	Grade 2 Related	2007	225	11.2	9.9	12.7	2034	37	1.8	1.3	2.5	1971	155	7.9	6.7	9.1	1964	37	1.9	1.3	2.6	488	38	7.8	5.6	10.5	468	14	3.0	1.6	5.0	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3
	Grade 3 Related	2007	69	3.4	2.7	4.3	2034	6	0.3	0.1	0.6	1971	47	2.4	1.8	3.2	1964	5	0.3	0.1	0.6	488	16	3.3	1.9	5.3	468	6	1.3	0.5	2.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
Myalgia	All	2007	952	47.4	45.2	49.6	2034	209	10.3	9.0	11.7	1971	828	42.0	39.8	44.2	1964	225	11.5	10.1	12.9	488	173	35.5	31.2	39.9	468	75	16.0	12.8	19.7	21	5	23.8	8.2	47.2	18	2	11.1	1.4	34.7
	Grade 1	2007	551	27.5	25.5	29.5	2034	170	8.4	7.2	9.6	1971	487	24.7	22.8	26.7	1964	166	8.5	7.3	9.8	488	81	16.6	13.4	20.2	468	43	9.2	6.7	12.2	21	5	23.8	8.2	47.2	18	1	5.6	0.1	27.3
	Grade 2	2007	301	15.0	13.5	16.6	2034	31	1.5	1.0	2.2	1971	252	12.8	11.3	14.3	1964	50	2.5	1.9	3.3	488	64	13.1	10.2	16.4	468	20	4.3	2.6	6.5	21	0	0.0	0.0	16.1	18	1	5.6	0.1	27.3
	Grade 3	2007	100	5.0	4.1	6.0	2034	8	0.4	0.2	0.8	1971	89	4.5	3.6	5.5	1964	8	0.4	0.2	0.8	488	28	5.7	3.8	8.2	468	12	2.6	1.3	4.4	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related	2007	864	43.0	40.9	45.2	2034	153	7.5	6.4	8.8	1971	730	37.0	34.9	39.2	1964	172	8.8	7.5	10.1	488	148	30.3	26.3	34.6	468	47	10.0	7.5	13.1	21	4	19.0	5.4	41.9	18	2	11.1	1.4	34.7

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		Non-Frail										Pre-Frail										Frail										Unknown												
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo							
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL			
	Grade 1 Related	2007	495	24.7	22.8	26.6	2034	125	6.1	5.1	7.3	1971	428	21.7	19.9	23.6	1964	132	6.7	5.7	7.9	488	68	13.9	11.0	17.3	468	30	6.4	4.4	9.0	21	4	19.0	5.4	41.9	18	1	5.6	0.1	27.3			
	Grade 2 Related	2007	276	13.8	12.3	15.3	2034	22	1.1	0.7	1.6	1971	225	11.4	10.0	12.9	1964	34	1.7	1.2	2.4	488	55	11.3	8.6	14.4	468	11	2.4	1.2	4.2	21	0	0.0	0.0	16.1	18	1	5.6	0.1	27.3			
	Grade 3 Related	2007	93	4.6	3.8	5.6	2034	6	0.3	0.1	0.6	1971	77	3.9	3.1	4.9	1964	6	0.3	0.1	0.7	488	25	5.1	3.3	7.5	468	6	1.3	0.5	2.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			
Shivering	All	2007	623	31.0	29.0	33.1	2034	111	5.5	4.5	6.5	1971	459	23.3	21.4	25.2	1964	107	5.4	4.5	6.5	488	86	17.6	14.3	21.3	468	41	8.8	6.4	11.7	21	3	14.3	3.0	36.3	18	3	16.7	3.6	41.4			
	Grade 1	2007	336	16.7	15.1	18.4	2034	91	4.5	3.6	5.5	1971	264	13.4	11.9	15.0	1964	87	4.4	3.6	5.4	488	48	9.8	7.3	12.8	468	31	6.6	4.5	9.3	21	2	9.5	1.2	30.4	18	3	16.7	3.6	41.4			
	Grade 2	2007	183	9.1	7.9	10.5	2034	16	0.8	0.5	1.3	1971	138	7.0	5.9	8.2	1964	12	0.6	0.3	1.1	488	20	4.1	2.5	6.3	468	8	1.7	0.7	3.3	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5			
	Grade 3	2007	103	5.1	4.2	6.2	2034	4	0.2	0.1	0.5	1971	57	2.9	2.2	3.7	1964	6	0.3	0.1	0.7	488	18	3.7	2.2	5.8	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			
	Related	2007	559	27.9	25.9	29.9	2034	80	3.9	3.1	4.9	1971	398	20.2	18.4	22.0	1964	74	3.8	3.0	4.7	488	74	15.2	12.1	18.7	468	22	4.7	3.0	7.0	21	3	14.3	3.0	36.3	18	3	16.7	3.6	41.4			
	Grade 1 Related	2007	292	14.5	13.0	16.2	2034	70	3.4	2.7	4.3	1971	229	11.6	10.2	13.1	1964	58	3.0	2.2	3.8	488	41	8.4	6.1	11.2	468	17	3.6	2.1	5.8	21	2	9.5	1.2	30.4	18	3	16.7	3.6	41.4			
	Grade 2 Related	2007	171	8.5	7.3	9.8	2034	8	0.4	0.2	0.8	1971	118	6.0	5.0	7.1	1964	10	0.5	0.2	0.9	488	16	3.3	1.9	5.3	468	3	0.6	0.1	1.9	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5			
	Grade 3 Related	2007	96	4.8	3.9	5.8	2034	2	0.1	0.0	0.4	1971	51	2.6	1.9	3.4	1964	5	0.3	0.1	0.6	488	17	3.5	2.0	5.5	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			
Temperature/(°C)	All	2007	465	23.2	21.3	25.1	2034	52	2.6	1.9	3.3	1971	368	18.7	17.0	20.5	1964	55	2.8	2.1	3.6	488	70	14.3	11.4	17.8	468	19	4.1	2.5	6.3	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5			
	≥37.5 and ≤38	2007	328	16.3	14.8	18.0	2034	38	1.9	1.3	2.6	1971	253	12.8	11.4	14.4	1964	42	2.1	1.5	2.9	488	49	10.0	7.5	13.1	468	16	3.4	2.0	5.5	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5			
	>38 and ≤39	2007	130	6.5	5.4	7.6	2034	8	0.4	0.2	0.8	1971	104	5.3	4.3	6.4	1964	8	0.4	0.2	0.8	488	16	3.3	1.9	5.3	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			
	>39.0	2007	6	0.3	0.1	0.6	2034	4	0.2	0.1	0.5	1971	5	0.3	0.1	0.6	1964	3	0.2	0.0	0.4	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			
	Related	2007	419	20.9	19.1	22.7	2034	35	1.7	1.2	2.4	1971	316	16.0	14.4	17.7	1964	29	1.5	1.0	2.1	488	57	11.7	9.0	14.9	468	8	1.7	0.7	3.3	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5			
	≥37.5 and ≤38 Related	2007	293	14.6	13.1	16.2	2034	28	1.4	0.9	2.0	1971	219	11.1	9.8	12.6	1964	25	1.3	0.8	1.9	488	40	8.2	5.9	11.0	468	7	1.5	0.6	3.1	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5			
	>38 and ≤39 Related	2007	121	6.0	5.0	7.2	2034	5	0.2	0.1	0.6	1971	91	4.6	3.7	5.6	1964	4	0.2	0.1	0.5	488	14	2.9	1.6	4.8	468	1	0.2	0.0	1.2	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			
	>39.0 Related	2007	5	0.2	0.1	0.6	2034	2	0.1	0.0	0.4	1971	5	0.3	0.1	0.6	1964	0	0.0	0.0	0.2	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5			

Source: [Table 14.3.1.9](#)

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

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Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

All = all subjects who have experienced the symptom

*Temperature is measured by oral, axillary, rectal or tympanic routes

Fever is defined as temperature $\geq 37.5^{\circ}\text{C}$ for oral, axillary or tympanic route, or $\geq 38.0^{\circ}\text{C}$ for rectal route

12.2.3.2. Unsolicited Adverse Events

12.2.3.2.1. Any unsolicited AEs

Percentages of any unsolicited AEs within the 30-day (Days 0-29) post-vaccination period were higher in the HZ/su group than in the Placebo group for all frailty categories in the TVC (Table 14.3.1.19 and global summary in Table 14.3.1.22):

- The percentage of subjects reporting at least 1 unsolicited AE (Table 14.3.1.19) was similar across frailty categories in the HZ/su group (51.6%, 49.7% and 47.9% in the non-frail, pre-frail and frail, respectively), and tended to increase with increasing frailty in the Placebo group (29.6%, 32.7% and 35.5% in the non-frail, pre-frail and frail, respectively).
- The percentage of doses with at least 1 unsolicited AE (Table 14.3.1.21) was 39.1%, 35.8% and 34.2% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 17.7%, 20.0% and 22.2% in non-frail, pre-frail and frail categories of the Placebo group, respectively (Table 14.3.1.21).
- Across frailty categories, the most frequently reported unsolicited AEs by SOC (Table 14.3.1.19) were general disorders and administration site conditions in all frailty categories for the HZ/su group (36.6%, 31.0% and 27.9% in non-frail, pre-frail and frail categories, respectively) and infections and infestations in all frailty categories for the Placebo group (11.4%, 11.0% and 11.7% in non-frail, pre-frail and frail categories, respectively).
- Across frailty categories, the most frequently reported unsolicited AEs by PT (Table 14.3.1.20) in the HZ/su group were injection site pain (25.1%, 22.0% and 18.9% in non-frail, pre-frail and frail categories, respectively), injection site erythema (10.5%, 8.8% and 7.3% in non-frail, pre-frail and frail categories, respectively) and injection site swelling (7.9%, 6.4% and 5.6% in non-frail, pre-frail and frail categories, respectively), and in the Placebo group were nasopharyngitis (4.4%, 3.3% and 2.5% in non-frail, pre-frail and frail categories, respectively), headache (3.6%, 2.6% and 2.0% in non-frail, pre-frail and frail categories, respectively) and injection site pain (1.6%, 1.8% and 2.0% in non-frail, pre-frail and frail categories, respectively). Note that these unsolicited AEs are the same as the solicited AEs for reactogenicity assessed within 7 days of vaccination in the TVC - Diary card subset.

12.2.3.2.2. Grade 3 unsolicited AEs

Percentages of grade 3 unsolicited AEs within the 30-day (Days 0-29) post-vaccination period were higher in the HZ/su group than in the Placebo group for all frailty categories in the TVC (Table 14.3.1.23 and global summary in Table 14.3.1.26):

- The percentage of subjects with at least 1 grade 3 unsolicited AE (Table 14.3.1.23) was similar across frailty categories in the HZ/su group (7.4%, 7.1% and 8.5% in non-frail, pre-frail and frail categories, respectively), and tended to increase with increasing frailty in the Placebo group (3.2%, 3.9% and 5.5% in non-frail, pre-frail and frail categories, respectively).

- The percentage of doses with at least 1 grade 3 unsolicited AE (Table 14.3.1.25) was 4.0%, 3.9% and 4.8% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 1.6%, 2.0% and 3.0% in non-frail, pre-frail and frail categories of the Placebo group, respectively (Table 14.3.1.25).
- Across frailty categories, the most frequently reported grade 3 unsolicited AEs by SOC (Table 14.3.1.23) were general disorders and administration site conditions in all frailty categories of the HZ/su group (3.9%, 2.9% and 3.4% in non-frail, pre-frail and frail categories, respectively) and infections and infestations in all frailty categories of the Placebo group (1.2%, 1.0% and 0.8% in non-frail, pre-frail and frail categories, respectively).
- Across frailty categories, the most frequently reported grade 3 unsolicited AEs by PT (Table 14.3.1.24) in the HZ/su group was injection site pain (1.4%, 1.2% and 2.5% of non-frail, pre-frail and frail categories, respectively), and in the Placebo group was back pain (0.1%, 0.2% and 0.3% of non-frail, pre-frail and frail categories, respectively).

12.2.3.2.3. Vaccine-related unsolicited AEs

Percentages of vaccine-related unsolicited AEs within the 30-day (Days 0-29) post-vaccination period were higher in the HZ/su group than in the Placebo group for all frailty categories in the TVC (Table 14.3.1.27 and global summary in Table 12.5):

- The percentage of subjects with at least 1 vaccine-related unsolicited AE (Table 14.3.1.27) decreased with increasing frailty in the HZ/su group (38.4%, 32.3% and 28.5% in the non-frail, pre-frail and frail categories, respectively), and was similar across frailty categories in the Placebo group (6.7%, 6.8% and 6.2% in the non-frail, pre-frail and frail categories, respectively).
- The percentage of doses with at least 1 vaccine-related unsolicited AE (Table 14.3.1.28) was 30.0%, 24.2% and 20.3% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 3.8%, 3.9% and 3.7% in non-frail, pre-frail and frail categories of the Placebo group, respectively.
- Across frailty categories, the most frequently reported vaccine-related unsolicited AEs by SOC (Table 14.3.1.27) were general disorders and administration site conditions in all frailty categories for the HZ/su group (35.5%, 29.8% and 26.3% of non-frail, pre-frail and frail, respectively) and also in the Placebo group (3.5%, 4.1% and 3.1% of non-frail, pre-frail and frail, respectively).
- Across frailty categories, the most frequently reported vaccine-related unsolicited AEs by PT (Table 14.3.1.27) was injection site pain in the HZ/su group (25.1%, 22.0% and 18.9% of non-frail, pre-frail and frail, respectively), and also in the Placebo group (1.6%, 1.8% and 2.0% of non-frail, pre-frail and frail, respectively).

Table 12.5 Global Summary of unsolicited sign and symptoms reported with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	2223	386	1962	420	449	91	16	6	4650	903
Number of doses followed by at least one unsolicited symptom	3399	431	2857	470	613	105	24	6	6893	1012
Number of unsolicited symptoms classified by MedDRA Preferred Term*	7219	598	5640	721	1173	149	41	8	14073	1476
Number of unsolicited symptoms reported**	7291	614	5683	735	1186	153	41	8	14201	1510

Source: [Table 14.3.1.29](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

12.2.3.2.4. Grade 3 vaccine-related unsolicited AEs

Percentages of grade 3 vaccine-related unsolicited AEs within the 30-day (Days 0-29) post-vaccination period were higher in the HZ/su group than in the Placebo group for all frailty categories in the TVC ([Table 14.3.1.30](#) and global summary in [Table 12.6](#)):

- The percentage of subjects with at least 1 grade 3 vaccine-related unsolicited AE ([Table 14.3.1.30](#)) was 4.4%, 3.4% and 4.4% in the non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 0.3%, 0.4% and 0.5% in the non-frail, pre-frail and frail categories of the Placebo group, respectively.
- The percentage of doses with at least 1 grade 3 vaccine-related unsolicited AE ([Table 14.3.1.31](#)) was 2.4%, 1.9% and 2.6% in the non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 0.2%, 0.2% and 0.3% in the non-frail, pre-frail and frail categories of the Placebo group, respectively ([Table 14.3.1.31](#)).
- Across frailty categories, the most frequently reported grade 3 vaccine-related unsolicited AEs by SOC ([Table 14.3.1.30](#)) were general disorders and administration site conditions in all frailty categories for the HZ/su group (3.6%, 2.6% and 3.3% of non-frail, pre-frail and frail categories, respectively) and also in the Placebo group (0.1%, 0.2% and 0.1% of non-frail, pre-frail and frail categories, respectively).
- Across frailty categories, the most frequently reported grade 3 vaccine-related unsolicited AEs by PT ([Table 14.3.1.30](#)) in the HZ/su group was injection site pain (1.4%, 1.2% and 2.5% in non-frail, pre-frail and frail categories, respectively), and in the Placebo group was injection site bruising (1.4% of subjects with unknown frailty status and no subjects in other frailty categories).

Table 12.6 Global summary of grade 3 unsolicited sign and symptoms reported with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	252	18	207	26	69	8	2	1	530	53
Number of doses followed by at least one unsolicited symptom	272	18	223	26	78	8	2	1	575	53
Number of unsolicited symptoms classified by MedDRA Preferred Term*	464	25	367	34	141	9	4	1	976	69
Number of unsolicited symptoms reported**	465	25	367	34	141	9	4	1	977	69

Source: [Table 14.3.1.32](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

12.2.3.2.5. Unsolicited AEs with medically attended visit up to 8 months after vaccination (TVC)

Percentages of subjects reporting unsolicited AEs with medically attended visits were similar in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups ([Table 14.3.1.33](#) and global summary in [Table 12.7](#)).

- The percentage of subjects with at least 1 unsolicited AE with medically attended visit ([Table 14.3.1.33](#)) was 32.4%, 42.7% and 51.9% in the non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 34.1%, 43.1% and 53.4% in the non-frail, pre-frail and frail categories of the Placebo group, respectively.
- The percentage of doses with at least 1 unsolicited AE with medically attended visit ([Table 14.3.1.34](#)) was 19.4%, 26.8% and 34.2% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 20.1%, 26.8% and 34.8% in non-frail, pre-frail and frail categories of the Placebo group, respectively ([Table 14.3.1.34](#) and global summary in [Table 12.7](#)).
- Across frailty categories, the most frequently reported unsolicited AEs with medically attended visit by SOC ([Table 14.3.1.33](#)) were infections and infestations in all frailty categories of the HZ/su group (14.1%, 17.7% and 21.4% in non-frail, pre-frail and frail categories, respectively) and also in the Placebo group (14.5%, 17.7% and 24.2% in non-frail, pre-frail and frail categories, respectively).

- Across frailty categories, the most frequently reported unsolicited AEs with medically attended visit by PT ([Table 14.3.1.33](#)) in the HZ/su group was nasopharyngitis (2.9%, 3.4% and 3.1% in non-frail, pre-frail and frail categories, respectively), and also in the Placebo group (3.5%, 3.5% and 2.8% in non-frail, pre-frail and frail categories, respectively).

Table 12.7 Global summary of unsolicited signs and symptoms with medically attended visit reported from first vaccination up to Month 8 post-first vaccination by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	1872	1957	2590	2680	817	782	20	26	5299	5445
Number of doses followed by at least one unsolicited symptom	2196	2270	3166	3268	1035	979	24	35	6421	6552
Number of unsolicited symptoms classified by MedDRA Preferred Term*	3292	3298	5282	5459	1904	1944	35	54	10513	10755
Number of unsolicited symptoms reported**	3365	3369	5422	5611	1956	2005	35	55	10778	11040

Source: [Table 14.3.1.35](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once **

Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

12.2.4. Listing of Adverse Events by Subject

Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for listings of AEs in these studies.

12.3. Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

12.3.1. Listing of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

Refer to ZOSTER-006 and ZOSTER-022 CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for listings of deaths, SAEs and other significant AEs in these studies.

12.3.1.1. Deaths*Fatal SAEs up to study end (TVC)*

Percentages of subjects reporting fatal SAEs were similar in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups up to study end in the TVC ([Table 14.3.1.42](#) and global summary in [Table 14.3.1.43](#)):

- The percentage of subjects experiencing at least 1 SAE with fatal outcome ([Table 14.3.1.42](#)) was 2.1%, 4.9% and 11.1% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 1.9%, 5.5% and 12.4% in non-frail, pre-frail and frail categories of the Placebo group, respectively.
- Across frailty categories, the most frequently reported fatal SAEs by SOC ([Table 14.3.1.42](#)) were neoplasms benign, malignant and unspecified (incl. cysts and polyps) in the HZ/su group (0.9%, 1.4% and 2.2% of non-frail, pre-frail and frail, respectively) and cardiac disorders in the Placebo group (0.3%, 1.5% and 4.8% of non-frail, pre-frail and frail, respectively).
- Across frailty categories, the most frequently reported fatal SAE by PT ([Table 14.3.1.42](#)) was pneumonia in the HZ/su group (0.1%, 0.4% and 0.6% in non-frail, pre-frail and frail categories, respectively), and death in the Placebo group (0.1%, 0.3% and 1.0% in non-frail, pre-frail and frail categories, respectively).

Vaccine-related fatal SAEs up to study end (TVC)

- One fatal SAE which was considered vaccine-related by the investigator was reported in the HZ/su group: a case of neutropenic sepsis in a subject in the frail category ([Table 14.3.1.44](#) and global summary in [Table 14.3.1.45](#)). Refer to the ZOSTER-022 CSR ([GSK Clinical Report 113077](#)) for further details.

12.3.1.2. Other Serious Adverse Events*SAEs up to Month 14 (TVC)*

Percentages of subjects reporting SAEs were similar in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups up to Month 14 in the TVC ([Table 14.3.1.36](#) and global summary in [Table 12.8](#)).

- The percentage of subjects with at least 1 SAE ([Table 14.3.1.36](#)) was 6.2%, 11.5% and 18.6% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 5.7%, 12.1% and 22.7% in non-frail, pre-frail and frail categories of the Placebo group, respectively.
- Across frailty categories, the most frequently reported SAEs by SOC ([Table 14.3.1.38](#)) were cardiac disorders in the HZ/su group (0.9%, 2.3% and 4.8% of subjects in non-frail, pre-frail and frail categories, respectively) and also in the Placebo group (0.8%, 2.5% and 6.7% of subjects in non-frail, pre-frail and frail categories, respectively).

- Across frailty categories, the most frequently reported SAE by PT ([Table 14.3.1.36](#)) was pneumonia in the HZ/su group (0.3%, 0.6% and 1.4% of subjects in non-frail, pre-frail and frail categories, respectively), and also in the Placebo group (0.2%, 0.5% and 1.6% of subjects in non-frail, pre-frail and frail categories, respectively).

Table 12.8 Global summary of serious adverse events reported from first vaccination up to Month 14 post-first vaccination by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	357	328	697	751	293	332	8	10	1355	1421
Number of doses followed by at least one unsolicited symptom	365	330	719	780	311	349	8	11	1403	1470
Number of unsolicited symptoms classified by MedDRA Preferred Term*	501	465	1075	1248	531	617	9	16	2116	2346
Number of unsolicited symptoms reported**	501	466	1090	1266	547	637	9	16	2147	2385

Source: [Table 14.3.1.37](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Vaccine-related SAEs up to 14 months after vaccination (TVC)

Few vaccine-related SAEs were reported in both groups and occurrence of SAEs was balanced across frailty categories up to Month 14 in the TVC ([Table 14.3.1.39](#)):

- At least 1 vaccine-related SAE ([Table 14.3.1.39](#)) was reported by 14 subjects (6, 6 and 2 in the non-frail, pre-frail and frail categories, respectively) in the HZ/su group, and 10 subjects (2 in the non-frail and 8 in the pre-frail categories) in the Placebo group.
- Across frailty categories, the most frequently reported vaccine-related SAEs by SOC ([Table 14.3.1.39](#)) were infections and infestations in the HZ/su group (2, 1 and 1 subjects in the non-frail, pre-frail and frail categories, respectively) and nervous system disorders in the Placebo group (1 subject in the non-frail and 6 in the pre-frail categories).
- Each vaccine-related SAE by PT ([Table 14.3.1.39](#)) was reported by at most 1 subject in the HZ/su group, and only syncope in the Placebo group was reported by 2 subjects in the pre-frail category.

Vaccine-related SAEs up to study end (TVC)

Few vaccine-related SAEs were reported in both groups and occurrence was balanced across frailty categories up to study end in the TVC (Table 14.3.1.40 and global summary in Table 12.9):

- At least 1 vaccine-related SAE (Table 14.3.1.40) was reported by 14 subjects (6, 6 and 2 in the non-frail, pre-frail and frail categories, respectively) in the HZ/su group, and 12 subjects (3 and 9 in the non-frail and pre-frail categories, respectively) in the Placebo group.
- Across frailty categories, the most frequently reported vaccine-related SAEs by SOC (Table 14.3.1.40) were infections and infestations in the HZ/su group (2, 1 and 1 subjects in the non-frail, pre-frail and frail categories, respectively) and nervous system disorders in the Placebo group (1 subject in the non-frail and 6 in the pre-frail categories).
- Each vaccine-related SAE by PT (Table 14.3.1.40) was reported by at most 1 subject in the HZ/su group, and only syncope (2 in the pre-frail category) and rheumatoid arthritis (1 each in the non-frail and pre-frail categories) were reported by more than 1 subject in the Placebo group.

Table 12.9 Global summary of serious adverse events reported with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	6	3	6	9	2	0	0	0	14	12
Number of doses followed by at least one unsolicited symptom	6	3	6	9	2	0	0	0	14	12
Number of unsolicited symptoms classified by MedDRA Preferred Term*	9	3	6	10	3	0	0	0	18	13
Number of unsolicited symptoms reported**	9	3	6	10	3	0	0	0	18	13

Source: Table 14.3.1.41

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

12.3.1.3. Other Significant Adverse Events*pIMDs up to study end (TVC)*

Occurrence of pIMDs was balanced between the HZ/su and Placebo groups in each frailty category up to study end in the TVC ([Table 14.3.1.46](#) and global summary in [Table 12.10](#)):

- The percentage of subjects with at least 1 pIMD ([Table 14.3.1.46](#)) was 1.3%, 1.3% and 1.0% in non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 1.2%, 1.4% and 1.8% in non-frail, pre-frail and frail categories of the Placebo group, respectively.
- Across frailty categories, the most frequently reported pIMDs by SOC ([Table 14.3.1.46](#)) were musculoskeletal and connective tissue disorders in the HZ/su group (0.4%, 0.5% and 0.3% of subjects in non-frail, pre-frail and frail categories, respectively) and also in the Placebo group (0.3%, 0.6% and 0.9% of subjects in non-frail, pre-frail and frail categories, respectively).
- Across frailty categories, the most frequently reported pIMD by PT ([Table 14.3.1.46](#)) was polymyalgia rheumatica in the HZ/su group (0.2%, 0.3% and 0.1% of subjects in non-frail, pre-frail and frail categories, respectively), and also in the Placebo group (0.1%, 0.3% and 0.3% of subjects in non-frail, pre-frail and frail categories, respectively).

Table 12.10 Global summary of potential Immune-Mediated Diseases reported from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	74	69	76	90	15	27	1	0	166	186
Number of doses followed by at least one unsolicited symptom	74	70	76	91	15	27	1	0	166	188
Number of unsolicited symptoms classified by MedDRA Preferred Term*	75	72	77	99	15	27	1	0	168	198
Number of unsolicited symptoms reported**	75	73	77	99	15	27	1	0	168	199

Source: [Table 14.3.1.47](#)

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Vaccine-related pIMDs up to study end (TVC)

Overall, at least 1 vaccine-related pIMD was reported by 15 subjects (4, 9 and 2 in the non-frail, pre-frail and frail categories, respectively) in the HZ/su group, and 14 subjects (7, 6 and 1 subjects in the non-frail, pre-frail and frail categories, respectively) in the Placebo group (Table 14.3.1.48 and global summary in Table 14.3.1.49).

- Across frailty categories, the most frequently reported vaccine-related pIMDs by SOC (Table 14.3.1.48) were skin and subcutaneous tissue disorders in the HZ/su group (1, 3 and 1 subjects in the non-frail, pre-frail and frail categories, respectively) and musculoskeletal and connective tissue disorders in the Placebo group (3 subjects in the non-frail category and 4 in the pre-frail category).
- The only vaccine-related pIMDs by PT reported by more than 1 subject (Table 14.3.1.48) were psoriasis (1 each in the pre-frail and frail categories) and rheumatoid arthritis (2 in the pre-frail category) in the HZ/su group, and polymyalgia rheumatica (1 in the non-frail and 2 in the pre-frail categories) and rheumatoid arthritis (1 each in the non-frail and pre-frail categories) in the Placebo group.

12.3.2. Narratives of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

Narratives of deaths, other SAEs and other significant AEs that are judged to be of specific interest because of clinical importance were previously reported in the ZOSTER-006 and ZOSTER-022 CSRs (GSK Clinical Report 110390 and GSK Clinical Report 113077).

12.3.3. Analysis and Discussion of Deaths, Other Serious Adverse Events and Other Significant Adverse Events

Deaths, other SAEs and other significant AEs reported are presented in Section 12.3.1.1, Section 12.3.1.2 and Section 12.3.1.3 respectively.

12.4. Clinical Laboratory Evaluations

Not applicable.

12.4.1. Listing of Individual Laboratory Measurements by Subject and Each Abnormal Laboratory Value

Not applicable.

12.4.2. Evaluation of Each Laboratory Parameter

Not applicable.

12.4.2.1. Laboratory Values Over Time

Not applicable.

12.4.2.2. Individual Subject Changes

Not applicable.

12.4.2.3. Individual Clinically Significant Abnormalities

Not applicable.

12.5. Vital Signs, Physical Findings, and Other Observations Related to Safety

There were no vital signs, physical findings or other observations related to safety.

12.6. Safety Conclusions

Descriptive summary of safety data is provided in this section. This data, together with the safety data from other studies will contribute to the safety evaluation of the product. The safety profile in subjects in the frail category was clinically acceptable and comparable to the known safety profile of HZ/su vaccine. No safety concern specific to subjects in the frail category was identified.

Safety by frailty status (TVC and TVC - Diary card subset for solicited AEs)

- **Solicited AEs within 7 days post-vaccination:** Percentages of solicited AEs (all, grade 3, vaccine-related and grade 3 vaccine-related) by dose and by subject were higher in the HZ/su group than in the Placebo group for all frailty categories. Percentages of solicited AEs (all and vaccine-related) decreased with increasing frailty in the HZ/su group and were similar across frailty categories in the Placebo group. Percentages of grade 3 solicited AEs (all and vaccine-related) increased with increasing frailty in the Placebo group and were similar across frailty categories in the HZ/su group.
- **Unsolicited AEs within 30 days post-vaccination:** Percentages of unsolicited AEs (all, grade 3, vaccine-related and grade 3 vaccine-related) by dose and by subject were higher in the HZ/su group than in the Placebo group for all frailty categories. Percentages of unsolicited AEs (all and grade 3) tended to increase with increasing frailty in the Placebo group and were similar across frailty categories in the HZ/su group. Percentages of vaccine-related unsolicited AEs decreased with increasing frailty in the HZ/su group and were similar across frailty categories in the Placebo group. In the HZ/su group across frailty categories, the most frequently reported unsolicited AEs were injection site pain (25.1%, 22.0% and 18.9% for non-frail, pre-frail and frail, respectively), injection site erythema (10.5%, 8.8% and 7.3% for non-frail, pre-frail and frail, respectively), injection site swelling (7.9%, 6.4% and 5.6% for non-frail, pre-frail and frail, respectively). These events, which are reactogenicity symptoms, were also the most frequently reported vaccine-related unsolicited AEs.

- **Unsolicited AEs with medically attended visits up to Month 8:** Percentages of subjects reporting unsolicited AEs with medically attended visits were in the same range in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups. Across frailty categories, the most frequently reported unsolicited AEs with medically attended visits by PT was nasopharyngitis in both groups (2.9%, 3.4% and 3.1% for non-frail, pre-frail and frail categories of the HZ/su group, respectively, and 3.5%, 3.5% and 2.8% for non-frail, pre-frail and frail categories of the Placebo group, respectively).
- **SAEs up to Month 14 and up to study end:** Percentages of subjects reporting SAEs (all and fatal) were in the same range in the HZ/su and Placebo groups across frailty categories; and percentages increased with increasing frailty in both treatment groups. Few vaccine-related SAEs were reported in both groups and occurrence was balanced across frailty categories.
- **pIMDs up to study end:** Occurrence of pIMDs was balanced between the HZ/su and Placebo groups in each frailty category. No relevant differences in reporting of pIMDs were observed by frailty status. Few vaccine-related pIMDs were reported in both groups and occurrence was balanced across frailty categories.

13. DISCUSSION AND OVERALL CONCLUSIONS

13.1. Discussion

ZOSTER-064 was a retrospective observational study to assess the baseline frailty status of subjects from 2 large phase III studies in older adults (ZOSTER-006 and ZOSTER-022 in subjects ≥ 50 YOA or ≥ 70 YOA, respectively) who were to receive 2 doses of Herpes Zoster subunit (HZ/su) vaccine or Placebo. The study also described HZ efficacy, immunogenicity and safety of the HZ/su vaccine by frailty status. As ZOSTER-064 data are derived from the pooled ZOSTER-006 and ZOSTER-022 TVCs, the proportion of subjects ≥ 70 YOA in the ZOSTER-064 TVC is higher than in the general population.

ZOSTER-064 study results are consistent with published literature on frailty indices and the criteria defining a FI [Curran, 2019] i.e. frailty increases with age, a higher proportion of females than males are frail, and serious adverse outcomes increase with frailty. Furthermore, as frailty and age are highly correlated, the results for VE, immunogenicity, reactogenicity and safety by frailty status observed in ZOSTER-064 are consistent with results observed by age group in ZOSTER-006 and ZOSTER-022.

Presentation of the distribution of *SF-36* and *EQ-5D* scores by country would allow for possible comparison with normative values for those QoL questionnaires in the general population of the countries participating in the study.

13.2. Overall Conclusions

In the ZOSTER-064 TVC, which included 92% (N=26 976) of the pooled ZOSTER-006/022 TVC, 11.3% (N=3 037) of subjects were classified as frail. Baseline frailty status was well-balanced between treatment groups. The proportion of subjects in the frail category increased with age and tended to be higher in females than males.

HZ/su VE against the first or only episode of HZ was >90% in all frailty categories. HZ/su VE was shown to be high against HZ ZBPI BOI; the absolute reduction in ZBPI BOI score was higher in subjects in the frail than the pre-frail or non-frail categories.

HZ/su elicited a robust anti-gE and anti-VZV antibody responses at 1-month post-dose 2 for all frailty categories. Anti-gE and anti-VZV GMCs remained above pre-vaccination levels at least 3 years post-dose 2 for all frailty categories.

Reporting of solicited and unsolicited AEs was higher in HZ/su group than in the Placebo group for all frailty categories and decreased with increasing frailty in the HZ/su group; while reporting of unsolicited AEs with medically attended visits and SAEs was in the same range in both treatment groups within each frailty category and increased with increasing frailty in both groups. Occurrence of pIMDs was balanced between the HZ/su and Placebo groups in all frailty categories. The safety profile in subjects in the frail category was clinically acceptable and comparable to the known safety profile of HZ/su vaccine. No safety concern specific to subjects in the frail category was identified.

14. TABLES, FIGURES AND GRAPHS

Demographic Data	Table 14.1.1.1 to Table 14.1.1.10 (Demographics and baseline characteristics) Table 14.1.2.1 to Table 14.1.2.5 (Summary of Frailty status)
Efficacy / Immunogenicity /Quality of Life Data	Table 14.2.1.1 to Table 14.2.1.10 (Vaccine Efficacy) Table 14.2.2.1 to Table 14.2.2.4 (Humoral Immunogenicity) Table 14.2.3.1 to Table 14.2.3.7 (Cell-Mediated Immunogenicity) Table 14.2.4.1 to Table 14.2.4.18 (QoL - SF36 / EQ5D)
Safety Data	Table 14.3.1.1 to Table 14.3.1.49

Narratives of Deaths, Other Serious and Significant Adverse Events

As ZOSTER-064 retrospectively encodes questionnaires from previous studies (ZOSTER-006 and ZOSTER-022), clinical narratives were not generated for this study. Refer to ZOSTER-006 (Section 14) and ZOSTER-022 (Section 20) CSRs ([GSK Clinical Report 110390](#) and [GSK Clinical Report 113077](#)) for full clinical narratives and listings for SAEs (including serious pIMDs) and non-serious pIMDs.

Table 14.1.1.1 Centers taking part in ZOSTER-064 with corresponding center numbers in ZOSTER-006 and ZOSTER-022 (Total Vaccinated Cohort)

Country	ZOSTER-064 Center Number	ZOSTER-006 Center Number	ZOSTER-022 Center Number
Australia	PPD		
Brazil	PPD		
Canada	PPD		
Czechia	PPD		
Estonia	PPD		
Finland	PPD		
France	PPD		

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Country	ZOSTER-064 Center Number	ZOSTER-006 Center Number	ZOSTER-022 Center Number
Japan	PPD		
Mexico	PPD		
Republic of Korea	PPD		
Spain	PPD		
Sweden	PPD		
Taiwan	PPD		
United Kingdom	PPD		

Country	ZOSTER-064 Center Number	ZOSTER-006 Center Number	ZOSTER-022 Center Number
United States	PPD		

Center = GSK Biologicals assigned center number

**Table 14.1.1.2 Number of subjects by country, center and vaccination group
(Total Vaccinated Cohort)**

Region	Country	Center	HZ/su	Placebo	Total	
			n	n	n	%
Australasia	Australia	PPD	131	126	257	1.0
		PPD	42	41	83	0.3
		PPD	17	19	36	0.1
		PPD	37	40	77	0.3
		PPD	21	21	42	0.2
		All	248	247	495	1.8
	Hong Kong	PPD	103	104	207	0.8
		PPD	224	219	443	1.6
		All	327	323	650	2.4
	Japan	PPD	49	51	100	0.4
		PPD	51	49	100	0.4
		PPD	54	55	109	0.4
		PPD	46	50	96	0.4
		PPD	57	53	110	0.4
		PPD	89	87	176	0.7
		PPD	41	40	81	0.3
		All	387	385	772	2.9
	Republic of Korea	PPD	66	67	133	0.5
		PPD	78	77	155	0.6
		PPD	87	88	175	0.6
		PPD	28	29	57	0.2
		PPD	59	61	120	0.4
		PPD	108	107	215	0.8
		PPD	56	57	113	0.4
		PPD	49	50	99	0.4
		All	531	536	1067	4.0
	Taiwan	PPD	161	159	320	1.2
		PPD	529	532	1061	3.9
		PPD	304	302	606	2.2
		PPD	200	201	401	1.5
		All	1194	1194	2388	8.9
Europe	Czechia	PPD	613	613	1226	4.5
		All	613	613	1226	4.5
	Germany	PPD	22	23	45	0.2
		PPD	13	11	24	0.1
		PPD	11	11	22	0.1
		PPD	28	29	57	0.2
		PPD	16	16	32	0.1
		PPD	33	32	65	0.2
		PPD	41	41	82	0.3
		PPD	11	9	20	0.1
		PPD	8	10	18	0.1
		PPD	11	11	22	0.1
		PPD	32	32	64	0.2
		PPD	26	25	51	0.2
		PPD	16	16	32	0.1
		PPD	56	57	113	0.4
		PPD	40	41	81	0.3
		PPD	45	43	88	0.3
		PPD	57	55	112	0.4
		PPD	15	15	30	0.1

Region	Country	Center	HZ/su	Placebo	Total	
			n	n	n	%
		PPD	19	18	37	0.1
		PPD	38	40	78	0.3
		PPD	19	19	38	0.1
		PPD	50	50	100	0.4
		PPD	28	28	56	0.2
		PPD	47	47	94	0.3
		PPD	31	32	63	0.2
		PPD	52	54	106	0.4
		PPD	31	31	62	0.2
		PPD	28	30	58	0.2
		PPD	7	10	17	0.1
		PPD	11	11	22	0.1
		PPD	11	12	23	0.1
		PPD	29	29	58	0.2
		PPD	22	22	44	0.2
		PPD	13	11	24	0.1
		PPD	31	30	61	0.2
		PPD	14	14	28	0.1
		All	962	965	1927	7.1
	Estonia	PPD	885	884	1769	6.6
		PPD	177	179	356	1.3
		All	1062	1063	2125	7.9
	Spain	PPD	59	64	123	0.5
		PPD	58	56	114	0.4
		PPD	41	42	83	0.3
		PPD	49	49	98	0.4
		PPD	97	98	195	0.7
		PPD	70	70	140	0.5
		PPD	55	56	111	0.4
		PPD	33	32	65	0.2
		PPD	5	6	11	0.0
		PPD	35	31	66	0.2
		PPD	29	26	55	0.2
		PPD	468	461	929	3.4
		All	999	991	1990	7.4
	Finland	PPD	1564	1561	3125	11.6
		All	1564	1561	3125	11.6
	France	PPD	34	35	69	0.3
		PPD	8	8	16	0.1
		PPD	37	38	75	0.3
		PPD	32	34	66	0.2
		PPD	29	27	56	0.2
		PPD	48	47	95	0.4
		PPD	34	34	68	0.3
		PPD	43	44	87	0.3
		PPD	34	34	68	0.3
		PPD	21	19	40	0.1
		PPD	37	37	74	0.3
		PPD	48	48	96	0.4
		PPD	105	104	209	0.8
		PPD	34	36	70	0.3
		PPD	23	24	47	0.2
		All	567	569	1136	4.2

Region	Country	Center	HZ/su	Placebo	Total	
			n	n	n	%
	Italy	PPD	28	30	58	0.2
		PPD	27	25	52	0.2
		PPD	26	24	50	0.2
		PPD	10	10	20	0.1
		PPD	6	7	13	0.0
		PPD	41	41	82	0.3
		PPD	2	2	4	0.0
		All	140	139	279	1.0
	Sweden	PPD	53	55	108	0.4
		PPD	133	134	267	1.0
		PPD	97	96	193	0.7
		PPD	75	76	151	0.6
		PPD	60	59	119	0.4
		PPD	83	84	167	0.6
		PPD	63	63	126	0.5
		PPD	98	102	200	0.7
		PPD	152	153	305	1.1
		PPD	63	62	125	0.5
		All	877	884	1761	6.5
	United Kingdom	PPD	19	19	38	0.1
		PPD	200	202	402	1.5
		PPD	100	96	196	0.7
		PPD	66	66	132	0.5
		PPD	96	97	193	0.7
		PPD	41	44	85	0.3
		PPD	131	132	263	1.0
		All	653	656	1309	4.9
Latin America	Brazil	PPD	110	110	220	0.8
		PPD	72	69	141	0.5
		PPD	162	163	325	1.2
		PPD	125	131	256	0.9
		PPD	50	47	97	0.4
		PPD	108	110	218	0.8
		All	627	630	1257	4.7
	Mexico	PPD	253	255	508	1.9
		PPD	212	211	423	1.6
		All	465	466	931	3.5
North America	Canada	PPD	18	20	38	0.1
		PPD	12	13	25	0.1
		PPD	82	84	166	0.6
		PPD	108	111	219	0.8
		PPD	19	17	36	0.1
		PPD	40	37	77	0.3
		PPD	41	40	81	0.3
		PPD	38	39	77	0.3
		PPD	112	110	222	0.8
		PPD	33	33	66	0.2
		PPD	74	76	150	0.6
		PPD	29	31	60	0.2
		PPD	34	32	66	0.2
		PPD	53	56	109	0.4
		All	693	699	1392	5.2

Region	Country	Center	HZ/su	Placebo	Total	
			n	n	n	%
	United States	PPD	18	18	36	0.1
		PPD	69	74	143	0.5
		PPD	43	44	87	0.3
		PPD	52	51	103	0.4
		PPD	73	74	147	0.5
		PPD	17	19	36	0.1
		PPD	23	24	47	0.2
		PPD	21	21	42	0.2
		PPD	17	17	34	0.1
		PPD	43	43	86	0.3
		PPD	30	31	61	0.2
		PPD	83	80	163	0.6
		PPD	115	117	232	0.9
		PPD	68	66	134	0.5
		PPD	58	59	117	0.4
		PPD	48	49	97	0.4
		PPD	25	24	49	0.2
		PPD	50	53	103	0.4
		PPD	70	70	140	0.5
		PPD	31	26	57	0.2
		PPD	74	71	145	0.5
		PPD	83	76	159	0.6
		PPD	95	92	187	0.7
		PPD	48	45	93	0.3
		PPD	62	61	123	0.5
		PPD	62	62	124	0.5
		PPD	31	34	65	0.2
		PPD	35	36	71	0.3
		PPD	21	20	41	0.2
		PPD	44	44	88	0.3
		PPD	36	36	72	0.3
		PPD	33	31	64	0.2
		All	1578	1568	3146	11.7
All	All	All	13487	13489	26976	100

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

n = number of subjects included in each group or in total for a given country/region and center, for all centers in a given country/region or for all countries/regions

All = sum of all subjects in each group or in total (sum of all groups) in a given country/region or for all countries/regions

 $\% = (n/\text{All for all countries/regions}) \times 100$

Table 14.1.1.3 Number of subjects in the various cohorts (Total Vaccinated Cohort)

	HZ/su N = 13487	Placebo N = 13489	Total N = 26976
	n	n	n
Total Vaccinated Cohort	13487	13489	26976
modified Total Vaccinated Cohort	12785	12930	25715
Total Vaccinated Cohort Diary Card Subset	4570	4571	9141
ATP Cohort for immunogenicity - Humoral Month 3	1400	1432	2832
ATP Cohort for immunogenicity - Humoral Month 14	1360	1366	2726
ATP Cohort for immunogenicity - Humoral Month 26	1318	1314	2632
ATP Cohort for immunogenicity - Humoral Month 38	1255	1253	2508
ATP Cohort for immunogenicity - CMI Month 3	196	204	400
ATP Cohort for immunogenicity - CMI Month 14	187	194	381
ATP Cohort for immunogenicity - CMI Month 26	185	188	373
ATP Cohort for immunogenicity - CMI Month 38	174	180	354

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

ATP = According-To-Protocol

N = total number of subjects

n = number of subjects in the given cohort.

Table 14.1.1.4 Number of expected SF-36 Questionnaires and number received by country and timepoint (Total Vaccinated Cohort)

	Month 0			Month 14			Month 26			Month 38		
	n1	n2	%	n1	n2	%	n1	n2	%	n1	n2	%
Australia	481	495	97.2	437	441	99.1	413	415	99.5	403	405	99.5
Brazil	1255	1257	99.8	1151	1170	98.4	1118	1133	98.7	1095	1103	99.3
Canada	1386	1392	99.6	1341	1349	99.4	1292	1301	99.3	1252	1260	99.4
Czechia	1226	1226	100	1210	1214	99.7	1199	1201	99.8	1177	1179	99.8
Estonia	2125	2125	100	2059	2061	99.9	2032	2032	100	1994	1994	100
Finland	3113	3125	99.6	2979	2990	99.6	2903	2928	99.1	2864	2874	99.7
France	1121	1136	98.7	1091	1113	98	1014	1025	98.9	997	1009	98.8
Germany	1921	1927	99.7	1818	1835	99.1	1773	1778	99.7	1704	1713	99.5
Hong Kong	648	650	99.7	622	624	99.7	604	613	98.5	595	599	99.3
Italy	278	279	99.6	264	266	99.2	251	253	99.2	243	244	99.6
Japan	771	772	99.9	738	740	99.7	723	727	99.4	702	708	99.2
Republic of Korea	1066	1067	99.9	940	943	99.7	906	907	99.9	863	863	100
Mexico	929	931	99.8	819	830	98.7	785	793	99	749	755	99.2
Spain	1987	1990	99.8	1850	1869	99	1795	1813	99	1745	1760	99.1
Sweden	1753	1761	99.5	1684	1691	99.6	1659	1665	99.6	1630	1634	99.8
Taiwan	2382	2388	99.7	2246	2266	99.1	2188	2205	99.2	2106	2116	99.5
United Kingdom	1303	1309	99.5	1238	1252	98.9	1189	1211	98.2	1166	1177	99.1
United States	3139	3146	99.8	2829	2855	99.1	2685	2702	99.4	2530	2551	99.2
Total	26884	26976	99.7	25316	25509	99.2	24529	24702	99.3	23815	23944	99.5

n1 = number of SF-36 questionnaires received per timepoint.

n2 = number of SF-36 questionnaires expected per timepoint.

% = n1/n2 x 100

Table 14.1.1.5 Number of expected EQ-5D Questionnaires and number received by country and timepoint (Total Vaccinated Cohort)

	Month 0			Month 14			Month 26			Month 38		
	n1	n2	%	n1	n2	%	n1	n2	%	n1	n2	%
Australia	479	495	96.8	434	441	98.4	412	415	99.3	402	405	99.3
Brazil	1252	1257	99.6	1149	1170	98.2	1117	1133	98.6	1095	1103	99.3
Canada	1385	1392	99.5	1340	1349	99.3	1292	1301	99.3	1252	1260	99.4
Czechia	1226	1226	100	1210	1214	99.7	1199	1201	99.8	1177	1179	99.8
Estonia	2123	2125	99.9	2059	2061	99.9	2031	2032	100	1994	1994	100
Finland	3088	3125	98.8	2970	2990	99.3	2895	2928	98.9	2861	2874	99.5
France	1118	1136	98.4	1083	1113	97.3	1008	1025	98.3	997	1009	98.8
Germany	1915	1927	99.4	1811	1835	98.7	1769	1778	99.5	1703	1713	99.4
Hong Kong	648	650	99.7	622	624	99.7	604	613	98.5	595	599	99.3
Italy	277	279	99.3	262	266	98.5	251	253	99.2	243	244	99.6
Japan	771	772	99.9	738	740	99.7	723	727	99.4	702	708	99.2
Republic of Korea	1066	1067	99.9	941	943	99.8	906	907	99.9	861	863	99.8
Mexico	929	931	99.8	819	830	98.7	785	793	99	749	755	99.2
Spain	1986	1990	99.8	1847	1869	98.8	1795	1813	99	1745	1760	99.1
Sweden	1746	1761	99.1	1678	1691	99.2	1654	1665	99.3	1624	1634	99.4
Taiwan	2382	2388	99.7	2245	2266	99.1	2188	2205	99.2	2103	2116	99.4
United Kingdom	1298	1309	99.2	1238	1252	98.9	1188	1211	98.1	1167	1177	99.2
United States	3135	3146	99.7	2823	2855	98.9	2673	2702	98.9	2523	2551	98.9
Total	26824	26976	99.4	25269	25509	99.1	24490	24702	99.1	23793	23944	99.4

n1 = number of EQ-5D questionnaires received per timepoint.

n2 = number of EQ-5D questionnaires completed per timepoint.

% = n1/n2 x 100

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Table 14.1.1.6 Summary of demographic characteristics (Total Vaccinated Cohort)

		HZ/su N = 13487		Placebo N = 13489		Total N = 26976	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	68.8	-	68.8	-	68.8	-
	SD	9.8	-	9.8	-	9.8	-
	Median	71.0	-	71.0	-	71.0	-
	Minimum	50	-	48	-	48	-
	Maximum	96	-	95	-	96	-
Gender	Female	7822	58.0	7863	58.3	15685	58.1
	Male	5665	42.0	5626	41.7	11291	41.9
Ethnicity	American hispanic or latino	1187	8.8	1189	8.8	2376	8.8
	Not american hispanic or latino	12300	91.2	12300	91.2	24600	91.2
Geographic Ancestry	African Heritage / African American	179	1.3	168	1.2	347	1.3
	American Indian or Alaskan Native	8	0.1	12	0.1	20	0.1
	Asian - Central/South Asian Heritage	6	0.0	7	0.1	13	0.0
	Asian - East Asian Heritage	2048	15.2	2042	15.1	4090	15.2
	Asian - Japanese Heritage	452	3.4	449	3.3	901	3.3
	Asian - South East Asian Heritage	15	0.1	23	0.2	38	0.1
	Native Hawaiian or Other Pacific Islander	2	0.0	4	0.0	6	0.0
	White - Arabic / North African Heritage	78	0.6	83	0.6	161	0.6
	White - Caucasian / European Heritage	10062	74.6	10050	74.5	20112	74.6
	Other	637	4.7	651	4.8	1288	4.8

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

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Table 14.1.1.7 Summary of demographic characteristics (modified Total Vaccinated Cohort)

		HZ/su N = 12793		Placebo N = 12953		Total N = 25746	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	68.7	-	68.7	-	68.7	-
	SD	9.8	-	9.8	-	9.8	-
	Median	71.0	-	71.0	-	71.0	-
	Minimum	50	-	48	-	48	-
	Maximum	96	-	95	-	96	-
Gender	Female	7416	58.0	7559	58.4	14975	58.2
	Male	5377	42.0	5394	41.6	10771	41.8
Ethnicity	American hispanic or latino	1094	8.6	1116	8.6	2210	8.6
	Not american hispanic or latino	11699	91.4	11837	91.4	23536	91.4
Geographic Ancestry	African Heritage / African American	164	1.3	158	1.2	322	1.3
	American Indian or Alaskan Native	8	0.1	12	0.1	20	0.1
	Asian - Central/South Asian Heritage	5	0.0	6	0.0	11	0.0
	Asian - East Asian Heritage	1907	14.9	1928	14.9	3835	14.9
	Asian - Japanese Heritage	428	3.3	436	3.4	864	3.4
	Asian - South East Asian Heritage	14	0.1	21	0.2	35	0.1
	Native Hawaiian or Other Pacific Islander	2	0.0	4	0.0	6	0.0
	White - Arabic / North African Heritage	74	0.6	80	0.6	154	0.6
	White - Caucasian / European Heritage	9615	75.2	9705	74.9	19320	75.0
	Other	576	4.5	603	4.7	1179	4.6

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

Table 14.1.1.8 Summary of demographic characteristics (Total Vaccinated Cohort – Diary Card subset)

		HZ/su N = 4570		Placebo N = 4571		Total N = 9141	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	67.4	-	67.3	-	67.3	-
	SD	9.8	-	9.8	-	9.8	-
	Median	69.0	-	69.0	-	69.0	-
	Minimum	50	-	48	-	48	-
	Maximum	96	-	95	-	96	-
Gender	Female	2742	60.0	2667	58.3	5409	59.2
	Male	1828	40.0	1904	41.7	3732	40.8
Ethnicity	American hispanic or latino	428	9.4	416	9.1	844	9.2
	Not american hispanic or latino	4142	90.6	4155	90.9	8297	90.8
Geographic Ancestry	African Heritage / African American	69	1.5	59	1.3	128	1.4
	American Indian or Alaskan Native	6	0.1	2	0.0	8	0.1
	Asian - Central/South Asian Heritage	3	0.1	2	0.0	5	0.1
	Asian - East Asian Heritage	731	16.0	725	15.9	1456	15.9
	Asian - Japanese Heritage	150	3.3	159	3.5	309	3.4
	Asian - South East Asian Heritage	7	0.2	11	0.2	18	0.2
	Native Hawaiian or Other Pacific Islander	0	0.0	1	0.0	1	0.0
	White - Arabic / North African Heritage	22	0.5	25	0.5	47	0.5
	White - Caucasian / European Heritage	3352	73.3	3368	73.7	6720	73.5
	Other	230	5.0	219	4.8	449	4.9

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

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Table 14.1.1.9 Summary of demographic characteristics (ATP cohort for immunogenicity - Humoral Month 3)

		HZ/su N = 1400		Placebo N = 1432		Total N = 2832	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	67.5	-	67.8	-	67.7	-
	SD	9.5	-	9.5	-	9.5	-
	Median	70.0	-	70.0	-	70.0	-
	Minimum	50	-	50	-	50	-
	Maximum	94	-	95	-	95	-
Gender	Female	818	58.4	839	58.6	1657	58.5
	Male	582	41.6	593	41.4	1175	41.5
Ethnicity	American hispanic or latino	98	7.0	93	6.5	191	6.7
	Not american hispanic or latino	1302	93.0	1339	93.5	2641	93.3
Geographic Ancestry	African Heritage / African American	31	2.2	25	1.7	56	2.0
	American Indian or Alaskan Native	1	0.1	3	0.2	4	0.1
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	250	17.9	245	17.1	495	17.5
	Asian - Japanese Heritage	99	7.1	102	7.1	201	7.1
	Asian - South East Asian Heritage	3	0.2	6	0.4	9	0.3
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	4	0.3	6	0.4	10	0.4
	White - Caucasian / European Heritage	980	70.0	1011	70.6	1991	70.3
	Other	32	2.3	34	2.4	66	2.3

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

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Table 14.1.1.10 Summary of demographic characteristics (ATP cohort for immunogenicity - CMI Month 3)

		HZ/su N = 196		Placebo N = 204		Total N = 400	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	64.0	-	64.4	-	64.2	-
	SD	9.0	-	8.8	-	8.9	-
	Median	63.0	-	64.0	-	63.0	-
	Minimum	50	-	50	-	50	-
	Maximum	88	-	90	-	90	-
Gender	Female	100	51.0	113	55.4	213	53.3
	Male	96	49.0	91	44.6	187	46.8
Ethnicity	American hispanic or latino	1	0.5	4	2.0	5	1.3
	Not american hispanic or latino	195	99.5	200	98.0	395	98.8
Geographic Ancestry	African Heritage / African American	17	8.7	14	6.9	31	7.8
	American Indian or Alaskan Native	0	0.0	1	0.5	1	0.3
	Asian - Central/South Asian Heritage	0	0.0	0	0.0	0	0.0
	Asian - East Asian Heritage	1	0.5	0	0.0	1	0.3
	Asian - Japanese Heritage	56	28.6	61	29.9	117	29.3
	Asian - South East Asian Heritage	0	0.0	0	0.0	0	0.0
	Native Hawaiian or Other Pacific Islander	0	0.0	0	0.0	0	0.0
	White - Arabic / North African Heritage	0	0.0	0	0.0	0	0.0
	White - Caucasian / European Heritage	122	62.2	128	62.7	250	62.5
	Other	0	0.0	0	0.0	0	0.0

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

Table 14.1.2.1 Frailty Status by age group and overall (Total Vaccinated Cohort)

	50-59YOA N = 6542		60-69YOA N = 4000		70-79YOA N = 12819		≥80YOA N = 3615		Total N = 26976	
Frailty Status	n	%	n	%	n	%	n	%	n	%
Non-Frail	4305	65.8	2102	52.6	4457	34.8	654	18.1	11518	42.7
Pre-Frail	1843	28.2	1614	40.4	6719	52.4	2114	58.5	12290	45.6
Frail	375	5.7	268	6.7	1575	12.3	819	22.7	3037	11.3
Unknown	19	0.3	16	0.4	68	0.5	28	0.8	131	0.5

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

≥80YOA = ≥80 years old subjects

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

N in the column header is the total number of subjects in each age group and overall in the total vaccinated cohort.

n=number of subjects in each category by age category and overall.

Percentages are based on the total number of subjects in each age category of the total vaccinated cohort.

Table 14.1.2.2 Frailty Status by Gender (Total Vaccinated Cohort)

	Non-Frail N = 11518		Pre-Frail N = 12290		Frail N = 3037		Unknown N = 131		Total N = 26976	
Gender	n	%	n	%	n	%	n	%	n	%
Male	5021	43.6	5141	41.8	1076	35.4	53	40.5	11291	41.9
Female	6497	56.4	7149	58.2	1961	64.6	78	59.5	15685	58.1

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

N = total number of subjects.

n/% = number / percentage of subjects in a given category.

Table 14.1.2.3 Frailty Status by Country (Total Vaccinated Cohort)

Country	Frailty Status	n	%
Australia	Non-Frail	153	30.9
	Pre-Frail	258	52.1
	Frail	70	14.1
	Unknown	14	2.8
Brazil	Non-Frail	443	35.2
	Pre-Frail	608	48.4
	Frail	200	15.9
	Unknown	6	0.5
Canada	Non-Frail	486	34.9
	Pre-Frail	752	54.0
	Frail	147	10.6
	Unknown	7	0.5
Czechia	Non-Frail	675	55.1
	Pre-Frail	473	38.6
	Frail	78	6.4
	Unknown	0	0.0
Estonia	Non-Frail	681	32.0
	Pre-Frail	1163	54.7
	Frail	281	13.2
	Unknown	0	0.0
Finland	Non-Frail	1831	58.6
	Pre-Frail	1126	36.0
	Frail	140	4.5
	Unknown	28	0.9
France	Non-Frail	442	38.9
	Pre-Frail	532	46.8
	Frail	142	12.5
	Unknown	20	1.8
Germany	Non-Frail	625	32.4
	Pre-Frail	962	49.9
	Frail	332	17.2
	Unknown	8	0.4
Hong Kong	Non-Frail	332	51.1
	Pre-Frail	280	43.1
	Frail	35	5.4
	Unknown	3	0.5
Italy	Non-Frail	179	64.2
	Pre-Frail	84	30.1
	Frail	15	5.4
	Unknown	1	0.4
Japan	Non-Frail	459	59.5
	Pre-Frail	287	37.2
	Frail	25	3.2
	Unknown	1	0.1
Mexico	Non-Frail	391	42.0
	Pre-Frail	412	44.3
	Frail	126	13.5
	Unknown	2	0.2
Republic of Korea	Non-Frail	326	30.6
	Pre-Frail	542	50.8
	Frail	198	18.6
	Unknown	1	0.1

Country	Frailty Status	n	%
Spain	Non-Frail	813	40.9
	Pre-Frail	918	46.1
	Frail	256	12.9
	Unknown	3	0.2
Sweden	Non-Frail	1078	61.2
	Pre-Frail	588	33.4
	Frail	85	4.8
	Unknown	10	0.6
Taiwan	Non-Frail	967	40.5
	Pre-Frail	1194	50.0
	Frail	220	9.2
	Unknown	7	0.3
United Kingdom	Non-Frail	484	37.0
	Pre-Frail	583	44.5
	Frail	233	17.8
	Unknown	9	0.7
United States	Non-Frail	1153	36.6
	Pre-Frail	1528	48.6
	Frail	454	14.4
	Unknown	11	0.3

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

Percentages are based on the total number of subjects in that country

Table 14.1.2.4 Summary of demographic characteristics by frailty status (Total Vaccinated Cohort)

		Non-Frail				Pre-Frail			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	65.0	-	64.9	-	71.2	-	71.3	-
	SD	9.5	-	9.5	-	8.9	-	8.9	-
	Median	66.0	-	66.0	-	72.0	-	72.0	-
	Minimum	50	-	48	-	50	-	50	-
	Maximum	91	-	92	-	94	-	95	-
Gender	Female	3226	55.8	3271	57.0	3540	58.3	3609	58.0
	Male	2558	44.2	2463	43.0	2531	41.7	2610	42.0
Ethnicity	American hispanic or latino	461	8.0	467	8.1	541	8.9	555	8.9
	Not american hispanic or latino	5323	92.0	5267	91.9	5530	91.1	5664	91.1
Geographic Ancestry	African Heritage / African American	70	1.2	53	0.9	73	1.2	80	1.3
	American Indian or Alaskan Native	4	0.1	3	0.1	3	0.0	7	0.1
	Asian - Central/South Asian Heritage	2	0.0	2	0.0	2	0.0	4	0.1
	Asian - East Asian Heritage	831	14.4	789	13.8	979	16.1	1029	16.5
	Asian - Japanese Heritage	269	4.7	240	4.2	169	2.8	187	3.0
	Asian - South East Asian Heritage	7	0.1	9	0.2	7	0.1	14	0.2
	Native Hawaiian or Other Pacific Islander	0	0.0	1	0.0	2	0.0	2	0.0
	White - Arabic / North African Heritage	25	0.4	34	0.6	36	0.6	40	0.6
	White - Caucasian / European Heritage	4313	74.6	4333	75.6	4522	74.5	4572	73.5
	Other	263	4.5	270	4.7	278	4.6	284	4.6

		Frail				Unknown			
		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	73.6	-	73.4	-	70.7	-	72.4	-
	SD	9.1	-	9.1	-	8.4	-	9.6	-
	Median	75.0	-	75.0	-	72.0	-	73.0	-
	Minimum	50	-	50	-	53	-	50	-
	Maximum	96	-	93	-	87	-	94	-
Gender	Female	1020	64.8	941	64.3	36	61.0	42	58.3
	Male	553	35.2	523	35.7	23	39.0	30	41.7
Ethnicity	American hispanic or latino	183	11.6	161	11.0	2	3.4	6	8.3
	Not american hispanic or latino	1390	88.4	1303	89.0	57	96.6	66	91.7
Geographic Ancestry	African Heritage / African American	36	2.3	34	2.3	0	0.0	1	1.4
	American Indian or Alaskan Native	1	0.1	2	0.1	0	0.0	0	0.0
	Asian - Central/South Asian Heritage	2	0.1	1	0.1	0	0.0	0	0.0
	Asian - East Asian Heritage	234	14.9	217	14.8	4	6.8	7	9.7
	Asian - Japanese Heritage	13	0.8	21	1.4	1	1.7	1	1.4
	Asian - South East Asian Heritage	1	0.1	0	0.0	0	0.0	0	0.0
	Native Hawaiian or Other Pacific Islander	0	0.0	1	0.1	0	0.0	0	0.0
	White - Arabic / North African Heritage	16	1.0	9	0.6	1	1.7	0	0.0
	White - Caucasian / European Heritage	1175	74.7	1087	74.2	52	88.1	58	80.6
	Other	95	6.0	92	6.3	1	1.7	5	6.9

		Total			
		HZ/su N = 13487		Placebo N = 13489	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%
Age (years) at vaccination dose: 1	Mean	68.8	-	68.8	-
	SD	9.8	-	9.8	-
	Median	71.0	-	71.0	-
	Minimum	50	-	48	-
	Maximum	96	-	95	-
Gender	Female	7822	58.0	7863	58.3
	Male	5665	42.0	5626	41.7
Ethnicity	American hispanic or latino	1187	8.8	1189	8.8
	Not american hispanic or latino	12300	91.2	12300	91.2
Geographic Ancestry	African Heritage / African American	179	1.3	168	1.2
	American Indian or Alaskan Native	8	0.1	12	0.1
	Asian - Central/South Asian Heritage	6	0.0	7	0.1
	Asian - East Asian Heritage	2048	15.2	2042	15.1
	Asian - Japanese Heritage	452	3.4	449	3.3
	Asian - South East Asian Heritage	15	0.1	23	0.2
	Native Hawaiian or Other Pacific Islander	2	0.0	4	0.0
	White - Arabic / North African Heritage	78	0.6	83	0.6
	White - Caucasian / European Heritage	10062	74.6	10050	74.5
	Other	637	4.7	651	4.8

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = total number of subjects

n/% = number / percentage of subjects in a given category

Value = value of the considered parameter

SD = standard deviation

Table 14.1.2.5 Summary statistics of number of deficits per subject of each frailty sub-category and overall (Total vaccinated cohort)

		Non-Frail N = 11518	Pre-Frail N = 12290	Frail N = 3037	Unknown N = 131	Total N = 26976
Frailty Category	Parameters	Value	Value	Value	Value	Value
SF36	N	11518	12290	3037	131	26976
	Mean	0.79	3.45	9.37	0.40	2.97
	SD	0.743	1.867	2.767	0.958	3.077
	Minimum	0.0	0.0	2.0	0.0	0.0
	Q1	0.00	2.00	7.50	0.00	0.50
	Median	0.50	3.00	9.00	0.00	2.00
	Q3	1.00	4.50	11.00	0.00	4.50
	Maximum	3.0	10.0	22.0	4.0	22.0
EQ5D	N	11518	12290	3037	131	26976
	Mean	0.05	0.30	1.06	0.05	0.28
	SD	0.161	0.426	0.659	0.185	0.484
	Minimum	0.0	0.0	0.0	0.0	0.0
	Q1	0.00	0.00	0.50	0.00	0.00
	Median	0.00	0.00	1.00	0.00	0.00
	Q3	0.00	0.50	1.50	0.00	0.50
	Maximum	2.0	4.0	3.5	1.0	4.0
Comorbidities	N	11518	12290	3037	131	26976
	Mean	0.8	2.2	3.0	1.8	1.6
	SD	0.77	1.29	1.62	1.31	1.40
	Minimum	0	0	0	0	0
	Q1	0.0	1.0	2.0	1.0	1.0
	Median	1.0	2.0	3.0	2.0	1.0
	Q3	1.0	3.0	4.0	2.0	2.0
	Maximum	3	8	9	6	9
Total	N	11518	12290	3037	131	26976
	Mean	1.60	5.91	13.43	2.24	4.90
	SD	0.971	1.906	2.928	1.725	4.049
	Minimum	0.0	2.5	8.5	0.0	0.0
	Q1	1.00	4.50	11.50	1.00	2.00
	Median	1.50	5.50	12.50	2.00	4.00
	Q3	2.50	7.50	15.00	3.00	7.00
	Maximum	3.0	10.0	28.5	7.0	28.5

Non-Frail = Subjects with frailty index score ≤ 0.08 Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25 Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

SF36 = 25 components of the SF-36 questionnaire.

EQ5D = 4 components of the EQ-5D questionnaire.

Comorbidities = 12 medical history components

Table 14.2.1.1 Distribution of confirmed HZ episodes amongst suspected HZ episodes (Total vaccinated cohort Placebo Subjects)

		Placebo									
		50-59YOA N = 141		60-69YOA N = 114		70-79YOA N = 318		≥80YOA N = 88		Total N = 661	
Characteristics	Categories	n	%	n	%	n	%	n	%	n	%
Confirmed HZ episode	YES	100	70.9	82	71.9	217	68.2	72	81.8	471	71.3
	NO	41	29.1	32	28.1	101	31.8	16	18.2	190	28.7

Placebo = Placebo

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

≥80YOA = ≥80 years old subjects

N = number of suspected episodes

n = number of episode in a given category

% = n/N x100

Table 14.2.1.2 Vaccine Efficacy: First or only episode of HZ during the entire study period by frailty status using Poisson method (modified Total Vaccinated Cohort)

		HZ/su				Placebo				VE			
										95% CI			
Type	N	n	T(year)	n/T (per 1000)	N	n	T(year)	n/T (per 1000)	(%)	LL	UL	p-value	
Non-Frail	5545	8	21802.7	0.4	5551	188	21442.8	8.8	95.81	91.58	98.22	<0.0001	
Pre-Frail	5738	18	21842.0	0.8	5969	191	22250.4	8.6	90.40	84.41	94.43	<0.0001	
Frail	1449	5	5157.5	1.0	1348	46	4662.8	9.9	90.17	75.36	96.95	<0.0001	
Unknown	53	0	186.5	0.0	62	5	194.0	25.8	100.00	14.61	100.00	0.0690	

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of subjects included in each group

n = number of subjects having at least one confirmed HZ episode

T (year) = sum of follow-up period (censored at the first occurrence of a confirmed HZ episode) expressed in years

n/T (per 1000)= Incidence rate of subjects reporting at least one event

LL, UL = 95% Lower and Upper confidence limits

VE (%) = Vaccine Efficacy (Poisson method)

P-value=Two sided Exact P-value conditional to number of cases

Table 14.2.1.3 ZBPI Burden of Illness Scores by Frailty Status (Modified Total Vaccinated Cohort)

	HZ/su (N= 12785)				Placebo (N= 12930)				Vaccine Efficacy for ZBPI Burden of Illness	
Frailty Status	n	m	Total Follow-Up Time (Person Years)	ZBPI Burden of Illness score	n	m	Total Follow-Up Time (Person Years)	ZBPI Burden of Illness score	Point Estimate	95% CI
Non-Frail	8	5545	21803	0.017	187	5550	21439	1.173	98.6	(97.1, 100.0)
Pre-Frail	18	5738	21842	0.108	190	5968	22248	1.475	92.6	(86.6, 98.7)
Frail	5	1449	5158	0.345	46	1348	4663	2.330	85.2	(62.6, 100.0)
Unknown	0	53	186	0.000	3	60	190	3.303	100.0	NE
Overall	31	12785	48989	0.092	426	12926	48540	1.431	93.6	(88.9, 98.3)

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown= Subjects who were not assigned a Frailty category

ZBPI Burden of Illness score is calculated as the sum of the ZBPI worst pain scores for all subjects in the group divided by subject years of follow-up.

95% CI=95% confidence interval using the variance estimate of the vaccine efficacy from the Chang test.

Subjects who did not have a confirmed Zoster episode were assigned a score of 0.

Subjects who had a confirmed Zoster episode but who did not have at least 1 ZBPI assessment were excluded from the analysis.

N=number of subjects in each vaccination group.

n=number of subjects with a confirmed zoster episode.

m=number of subjects with follow-up

Table 14.2.1.4 Minimally adjusted Cox model predicting HZ episode - Model 1 (Total Vaccinated Cohort - Placebo Subjects only)

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
SF-36 Domain Scales	Physical Functioning Scale	0.0007	0.0021	1.001	0.1249	0.7238
	Social Functioning	-0.0001	0.0024	1.000	0.0019	0.9648
	Role Physical	-0.0000	0.0019	1.000	0.0006	0.9799
	Emotional Well Being/ Mental Health Scale	0.0004	0.0026	1.000	0.0215	0.8834
	Vitality	-0.0012	0.0023	0.999	0.2464	0.6197
	Role Emotional	0.0009	0.0021	1.001	0.1738	0.6767
	Bodily Pain	-0.0002	0.0019	1.000	0.0106	0.9178
	General Health	0.0036	0.0024	1.004	2.1559	0.1420
EQ-5D	EQ5D Utility Score (Country Specific)	0.1487	0.2750	1.160	0.2923	0.5887
	VAS Score	-0.0019	0.0030	0.998	0.4216	0.5161

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

Event is defined as a HZ episode. This analysis excludes subjects who had a suspected case that was not subsequently classified as a confirmed HZ episode.

SE=Standard Error.

**Table 14.2.1.5 Final Cox multivariate model predicting HZ episode - Model 1
(Total Vaccinated Cohort - Placebo Subjects only)**

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
Baseline Parameters	Age	0.0142	0.0063	1.014	5.1753	0.0229
	Gender (Female v Male)	0.0799	0.0949	1.083	0.7080	0.4001
	Study (006 v 022)	0.1473	0.1206	1.159	1.4913	0.2220

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

Event is defined as a HZ episode. This analysis excludes subjects who had a suspected case that was not subsequently classified as a confirmed HZ episode.

SE=Standard Error.

A step-down backward variable selection procedure is used to fit the final multivariate model.

Table 14.2.1.6 Minimally adjusted Cox model predicting HZ episode - Model 2 (Total Vaccinated Cohort - Placebo Subjects only)

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
SF-36 Domain Scales	Physical Functioning Scale	0.0007	0.0021	1.001	0.1165	0.7329
	Social Functioning	-0.0001	0.0024	1.000	0.0027	0.9585
	Role Physical	-0.0000	0.0019	1.000	0.0007	0.9789
	Emotional Well Being/ Mental Health Scale	0.0004	0.0026	1.000	0.0206	0.8858
	Vitality	-0.0012	0.0023	0.999	0.2513	0.6162
	Role Emotional	0.0009	0.0021	1.001	0.1685	0.6814
	Bodily Pain	-0.0002	0.0019	1.000	0.0127	0.9101
	General Health	0.0036	0.0024	1.004	2.1616	0.1415
EQ-5D	EQ5D Utility Score (Country Specific)	0.1455	0.2750	1.157	0.2798	0.5968
	VAS Score	-0.0020	0.0029	0.998	0.4434	0.5055

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

Event is defined as a HZ episode.

The second analysis includes subjects who had a suspected case that was later proven not to be a HZ episode.

These subjects are censored at their latest available assessment and are considered not to have had the HZ event.

SE=Standard Error.

**Table 14.2.1.7 Final Cox multivariate model predicting HZ episode - Model 2
(Total Vaccinated Cohort - Placebo Subjects only)**

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
Baseline Parameters	Age	0.0142	0.0063	1.014	5.1641	0.0231
	Gender (Female v Male)	0.0770	0.0949	1.080	0.6574	0.4175
	Study (006 v 022)	0.1488	0.1206	1.160	1.5217	0.2174

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

Event is defined as a HZ episode.

The second analysis includes subjects who had a suspected case that was later proven not to be a HZ episode.

These subjects are censored at their latest available assessment and are considered not to have had the HZ event.

SE=Standard Error.

A step-down backward variable selection procedure is used to fit the final multivariate model.

Table 14.2.1.8 Minimally adjusted Cox model predicting HZ episode - Model 3 (Total Vaccinated Cohort - Placebo Subjects only)

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
SF-36 Domain Scales	Physical Functioning Scale	-0.0001	0.0018	1.000	0.0032	0.9549
	Social Functioning	0.0006	0.0021	1.001	0.0812	0.7756
	Role Physical	0.0002	0.0016	1.000	0.0189	0.8906
	Emotional Well Being/ Mental Health Scale	0.0008	0.0023	1.001	0.1328	0.7156
	Vitality	-0.0009	0.0020	0.999	0.1830	0.6688
	Role Emotional	0.0018	0.0019	1.002	0.8855	0.3467
	Bodily Pain	0.0005	0.0017	1.000	0.0856	0.7699
	General Health	0.0022	0.0021	1.002	1.0892	0.2967
EQ-5D	EQ5D Utility Score (Country Specific)	0.3128	0.2435	1.367	1.6496	0.1990
	VAS Score	-0.0002	0.0026	1.000	0.0090	0.9242

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

The third analysis includes all subjects. The event is defined as a suspected HZ episode.

SE=Standard Error.

**Table 14.2.1.9 Final Cox multivariate model predicting HZ episode - Model 3
(Total Vaccinated Cohort - Placebo Subjects only)**

Category	Parameter	Parameter Estimate	SE	Hazard Ratio	Chi-Square	P-Value
Baseline Parameters	Age	0.0094	0.0055	1.009	2.9614	0.0853
	Gender (Female v Male)	0.1693	0.0829	1.184	4.1683	0.0412
	Study (006 v 022)	0.0682	0.1059	1.071	0.4149	0.5195

Each Quality of Life parameter was included as a time dependent covariate in a model with the baseline parameters age, gender and original study (ZOSTER - 006 or 022)

Analysis was performed on subjects from the Placebo group only.

The event is defined as a suspected HZ episode.

SE=Standard Error.

A step-down backward variable selection procedure is used to fit the final multivariate model.

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Table 14.2.1.10 Pairwise Correlation coefficients of QoL Parameters (Total vaccinated Cohort Placebo Subjects)

			Correlation coefficient / P-Value									
			SF-36								EQ-5D	
	LABEL1	N	PF	RP	BP	GH	VT	SF	RE	MH	UTIL	VAS
SF-36	Physical Functioning (PF)	13385	1.000	0.588 / <.0001	0.501 / <.0001	0.439 / <.0001	0.493 / <.0001	0.347 / <.0001	0.377 / <.0001	0.287 / <.0001	0.489 / <.0001	0.418 / <.0001
	Role Physical (RP)	13409	0.588 / <.0001	1.000	0.495 / <.0001	0.449 / <.0001	0.537 / <.0001	0.496 / <.0001	0.617 / <.0001	0.397 / <.0001	0.412 / <.0001	0.413 / <.0001
	Bodily Pain (BP)	13396	0.501 / <.0001	0.495 / <.0001	1.000	0.406 / <.0001	0.463 / <.0001	0.388 / <.0001	0.345 / <.0001	0.327 / <.0001	0.561 / <.0001	0.398 / <.0001
	General Health (GH)	13436	0.439 / <.0001	0.449 / <.0001	0.406 / <.0001	1.000	0.529 / <.0001	0.381 / <.0001	0.362 / <.0001	0.453 / <.0001	0.396 / <.0001	0.583 / <.0001
	Vitality (VT)	13407	0.493 / <.0001	0.537 / <.0001	0.463 / <.0001	0.529 / <.0001	1.000	0.496 / <.0001	0.486 / <.0001	0.612 / <.0001	0.407 / <.0001	0.477 / <.0001
	Social Functioning (SF)	13416	0.347 / <.0001	0.496 / <.0001	0.388 / <.0001	0.381 / <.0001	0.496 / <.0001	1.000	0.558 / <.0001	0.521 / <.0001	0.317 / <.0001	0.327 / <.0001
	Role Emotional (RE)	13400	0.377 / <.0001	0.617 / <.0001	0.345 / <.0001	0.362 / <.0001	0.486 / <.0001	0.558 / <.0001	1.000	0.517 / <.0001	0.291 / <.0001	0.309 / <.0001
	Mental Health (MH)	13406	0.287 / <.0001	0.397 / <.0001	0.327 / <.0001	0.453 / <.0001	0.612 / <.0001	0.521 / <.0001	0.517 / <.0001	1.000	0.301 / <.0001	0.377 / <.0001
EQ-5D	Utility	13291	0.489 / <.0001	0.412 / <.0001	0.561 / <.0001	0.396 / <.0001	0.407 / <.0001	0.317 / <.0001	0.291 / <.0001	0.301 / <.0001	1.000	0.425 / <.0001
	VAS	13299	0.418 / <.0001	0.413 / <.0001	0.398 / <.0001	0.583 / <.0001	0.477 / <.0001	0.327 / <.0001	0.309 / <.0001	0.377 / <.0001	0.425 / <.0001	1.000

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N is the number subjects with a non-missing value of the particular QoL variable.

Each Quality of Life parameter was measured at Month 0.

Analysis was performed on subjects from the Placebo group only.

Table 14.2.2.1 Seropositivity rates and Geometric Mean Concentrations (GMCs) of anti-gE antibody at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-Humoral)

					≥ 97 mIU/ml				GMC				
							95% CI			95% CI			
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max
VZV.gE Ab.IgG	Non-Frail	HZ/su	PRE(M0)	603	596	98.8	97.6	99.5	1251.6	1151.7	1360.3	<97.0	49273.2
			PII(M3)	603	603	100	99.4	100	53120.8	50229.2	56178.8	432.7	252485.3
			PII(M14)	591	591	100	99.4	100	18628.2	17477.6	19854.6	512.3	150266.5
			PII(M26)	582	582	100	99.4	100	14502.0	13610.9	15451.4	516.9	171049.4
			PII(M38)	555	555	100	99.3	100	12505.4	11695.1	13371.8	374.8	121520.7
		Placebo	PRE(M0)	606	604	99.7	98.8	100	1389.1	1286.6	1499.8	<97.0	230579.9
			PII(M3)	606	599	98.8	97.6	99.5	1314.6	1211.8	1426.2	<97.0	259629.7
			PII(M14)	586	582	99.3	98.3	99.8	1272.4	1174.4	1378.5	<97.0	85917.5
			PII(M26)	571	569	99.6	98.7	100	1355.5	1253.2	1466.1	<97.0	47396.8
			PII(M38)	553	549	99.3	98.2	99.8	1304.3	1203.5	1413.5	<97.0	74603.5
	Pre-Frail	HZ/su	PRE(M0)	653	649	99.4	98.4	99.8	1363.0	1262.1	1471.9	<97.0	233132.9
			PII(M3)	655	655	100	99.4	100	52514.0	49937.0	55224.0	863.2	308834.6
			PII(M14)	640	640	100	99.4	100	16689.7	15739.5	17697.2	643.5	160387.0
			PII(M26)	617	617	100	99.4	100	13344.2	12592.6	14140.6	376.7	87976.9
			PII(M38)	586	586	100	99.4	100	11099.9	10458.8	11780.4	302.6	85298.8
		Placebo	PRE(M0)	695	688	99.0	97.9	99.6	1325.4	1227.0	1431.7	<97.0	28926.7
			PII(M3)	697	691	99.1	98.1	99.7	1266.9	1171.6	1369.9	<97.0	82777.8
			PII(M14)	662	657	99.2	98.2	99.8	1224.7	1129.9	1327.4	<97.0	41611.7
			PII(M26)	628	625	99.5	98.6	99.9	1320.2	1219.1	1429.6	<97.0	29541.0
			PII(M38)	588	585	99.5	98.5	99.9	1274.3	1171.4	1386.2	<97.0	29634.7
	Frail	HZ/su	PRE(M0)	138	137	99.3	96.0	100	1450.8	1230.9	1710.1	<97.0	16976.3
			PII(M3)	138	138	100	97.4	100	44914.9	39734.6	50770.6	2119.1	219362.7
			PII(M14)	124	124	100	97.1	100	13405.4	11701.3	15357.7	1125.0	80216.2
			PII(M26)	115	115	100	96.8	100	11060.6	9689.0	12626.3	494.4	44973.4
			PII(M38)	110	110	100	96.7	100	8694.8	7612.1	9931.6	1407.2	37879.9
		Placebo	PRE(M0)	125	125	100	97.1	100	1457.7	1213.6	1750.8	136.4	19896.0
			PII(M3)	125	125	100	97.1	100	1310.8	1089.8	1576.7	121.0	12832.4
			PII(M14)	114	113	99.1	95.2	100	1337.8	1089.7	1642.4	<97.0	19167.0
			PII(M26)	112	112	100	96.8	100	1431.4	1156.2	1772.2	104.9	25054.3
			PII(M38)	109	108	99.1	95.0	100	1399.1	1112.6	1759.2	<97.0	54820.5
	Unknown	HZ/su	PRE(M0)	4	4	100	39.8	100	1172.9	389.0	3536.5	697.9	3258.9
			PII(M3)	4	4	100	39.8	100	34703.5	18272.8	65908.6	20943.3	56029.4
			PII(M14)	4	4	100	39.8	100	9834.3	3469.9	27871.7	4202.3	20391.5
			PII(M26)	4	4	100	39.8	100	5278.7	1248.8	22313.6	2269.4	15956.7
			PII(M38)	4	4	100	39.8	100	5128.7	1349.3	19494.2	2223.8	14611.5
		Placebo	PRE(M0)	4	4	100	39.8	100	836.2	157.6	4434.9	186.8	2035.0
			PII(M3)	4	4	100	39.8	100	854.8	119.2	6132.2	138.8	1922.7
			PII(M14)	4	4	100	39.8	100	888.2	270.6	2914.9	349.3	2138.9
			PII(M26)	3	3	100	29.2	100	712.8	143.6	3538.1	350.8	1237.9
			PII(M38)	3	3	100	29.2	100	614.9	64.5	5863.9	222.8	1281.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration equal to or above specified value

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

MIN/MAX = Minimum/Maximum

PRE(M0) = Pre-vaccination (Month 0)

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.2.2 Vaccine response rates for anti-gE antibody ELISA concentrations at Month 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-Humoral)

					Vaccine response				
					95% CI				
Test description	Sub-group	Group	Timing	N	n	%	LL	UL	
VZV.gE Ab.IgG	Non-Frail	HZ/su	PII(M3)	603	591	98.0	96.5	99.0	
			PII(M14)	578	522	90.3	87.6	92.6	
			PII(M26)	570	485	85.1	81.9	87.9	
			PII(M38)	546	446	81.7	78.2	84.8	
		Placebo	PII(M3)	606	10	1.7	0.8	3.0	
			PII(M14)	578	20	3.5	2.1	5.3	
			PII(M26)	563	20	3.6	2.2	5.4	
			PII(M38)	545	14	2.6	1.4	4.3	
	Pre-Frail	HZ/su	PII(M3)	653	639	97.9	96.4	98.8	
			PII(M14)	626	527	84.2	81.1	87.0	
			PII(M26)	604	463	76.7	73.1	80.0	
			PII(M38)	575	429	74.6	70.8	78.1	
		Placebo	PII(M3)	695	13	1.9	1.0	3.2	
			PII(M14)	652	22	3.4	2.1	5.1	
			PII(M26)	615	21	3.4	2.1	5.2	
			PII(M38)	579	17	2.9	1.7	4.7	
	Frail	HZ/su	PII(M3)	138	132	95.7	90.8	98.4	
			PII(M14)	121	97	80.2	71.9	86.9	
			PII(M26)	112	80	71.4	62.1	79.6	
			PII(M38)	108	67	62.0	52.2	71.2	
		Placebo	PII(M3)	125	5	4.0	1.3	9.1	
			PII(M14)	113	6	5.3	2.0	11.2	
			PII(M26)	110	6	5.5	2.0	11.5	
			PII(M38)	107	8	7.5	3.3	14.2	
	Unknown	HZ/su	PII(M3)	4	4	100	39.8	100	
			PII(M14)	4	3	75.0	19.4	99.4	
			PII(M26)	4	2	50.0	6.8	93.2	
			PII(M38)	4	2	50.0	6.8	93.2	
		Placebo	PII(M3)	4	0	0.0	0.0	60.2	
			PII(M14)	4	0	0.0	0.0	60.2	
			PII(M26)	3	0	0.0	0.0	70.8	
			PII(M38)	3	0	0.0	0.0	70.8	

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Vaccine response defined as :

For initially seronegative subjects, antibody concentration at post-vaccination ≥ 4 fold the cut-off for Anti-gE (4x97 mIU/ml)

For initially seropositive subjects, antibody concentration at post-vaccination ≥ 4 fold the pre-vaccination antibody concentration

N = Number of subjects with pre- and post-vaccination results available

n/% = Number/percentage of responders

95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.2.3 Seropositivity rates and Geometric Mean Concentrations (GMCs) of anti-VZV antibody at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-Humoral)

					≥ 25 mIU/ml				GMC					
					95% CI			95% CI						
Antibody	Sub-group	Group	Timing	N	n	%	LL	UL	value	LL	UL	Min	Max	
VZV Ab.IgG	Non-Frail	HZ/su	PRE(M0)	588	584	99.3	98.3	99.8	966.9	893.6	1046.2	<25.0	16807.7	
			PII(M3)	603	603	100	99.4	100	9206.0	8731.3	9706.5	179.9	42412.2	
			PII(M14)	587	587	100	99.4	100	3791.4	3569.3	4027.2	48.0	25510.7	
			PII(M26)	580	580	100	99.4	100	3226.8	3037.6	3427.7	36.4	67488.2	
			PII(M38)	550	550	100	99.3	100	3111.6	2928.2	3306.4	40.6	29699.0	
			Placebo	PRE(M0)	587	587	100	99.4	100	1053.3	981.8	1130.0	36.2	51884.1
				PII(M3)	594	594	100	99.4	100	989.8	922.5	1061.9	32.6	52454.9
				PII(M14)	579	579	100	99.4	100	931.4	867.4	1000.1	31.6	27654.0
				PII(M26)	554	554	100	99.3	100	986.0	918.0	1058.9	41.4	13197.4
				PII(M38)	526	526	100	99.3	100	1029.2	958.8	1104.8	61.5	19500.2
		Pre-Frail	HZ/su	PRE(M0)	643	642	99.8	99.1	100	992.9	927.8	1062.7	<25.0	71467.2
				PII(M3)	655	655	100	99.4	100	9468.9	9046.7	9910.8	323.9	63502.4
				PII(M14)	636	636	100	99.4	100	3630.9	3450.2	3821.0	59.8	18062.4
				PII(M26)	615	615	100	99.4	100	3261.7	3094.9	3437.5	39.6	17140.1
				PII(M38)	578	578	100	99.4	100	2966.3	2813.9	3126.9	34.7	14103.9
			Placebo	PRE(M0)	676	676	100	99.5	100	1036.9	969.7	1108.7	60.7	51930.7
				PII(M3)	677	677	100	99.5	100	997.0	933.4	1065.0	37.6	24233.8
				PII(M14)	649	649	100	99.4	100	945.3	883.8	1011.0	42.1	25730.4
				PII(M26)	610	610	100	99.4	100	1040.8	973.8	1112.3	73.3	18930.9
				PII(M38)	575	574	99.8	99.0	100	1068.0	994.7	1146.7	<25.0	31624.8
	Frail	HZ/su	PRE(M0)	135	135	100	97.3	100	996.6	866.7	1146.1	59.6	8082.1	
			PII(M3)	138	138	100	97.4	100	8162.4	7332.5	9086.2	532.4	44933.7	
			PII(M14)	124	124	100	97.1	100	3034.4	2719.3	3386.1	315.8	13012.9	
			PII(M26)	115	115	100	96.8	100	2759.4	2472.4	3079.8	171.2	8821.9	
			PII(M38)	109	109	100	96.7	100	2462.1	2201.7	2753.4	726.4	9268.0	
			Placebo	PRE(M0)	124	124	100	97.1	100	1054.7	894.9	1243.1	54.7	10020.0
				PII(M3)	121	121	100	97.0	100	904.2	764.4	1069.4	58.0	7441.6
				PII(M14)	114	114	100	96.8	100	921.9	769.0	1105.2	60.4	6046.9
				PII(M26)	112	112	100	96.8	100	1023.0	850.1	1231.1	59.4	10007.3
				PII(M38)	109	109	100	96.7	100	1098.1	903.3	1334.8	61.5	16765.1
		Unknown	HZ/su	PRE(M0)	4	4	100	39.8	100	712.3	166.2	3052.9	228.4	1719.8
				PII(M3)	4	4	100	39.8	100	6499.1	4054.7	10417.1	4869.9	9429.8
				PII(M14)	4	4	100	39.8	100	2175.3	1073.6	4407.6	1266.5	3689.1
				PII(M26)	4	4	100	39.8	100	1909.4	839.1	4344.8	1322.2	4012.4
				PII(M38)	4	4	100	39.8	100	1928.4	857.8	4335.2	1127.0	3555.9
			Placebo	PRE(M0)	4	4	100	39.8	100	553.7	63.7	4812.0	94.7	2593.7
				PII(M3)	4	4	100	39.8	100	601.7	78.7	4601.0	106.3	2314.1
				PII(M14)	4	4	100	39.8	100	646.9	90.1	4646.3	154.1	3178.2
				PII(M26)	3	3	100	29.2	100	374.7	48.9	2869.2	145.5	611.0
				PII(M38)	3	3	100	29.2	100	286.3	33.3	2460.0	108.0	564.9

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n/% = number/percentage of subjects with concentration equal to or above specified value

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

MIN/MAX = Minimum/Maximum

PRE(M0) = Pre-vaccination (Month 0)

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.2.4 Vaccine response rates for anti-VZV antibody ELISA concentrations at Month 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-Humoral)

					Vaccine response				
					95% CI				
Test description	Sub-group	Group	Timing	N	n	%	LL	UL	
VZV Ab.IgG	Non-Frail	HZ/su	PII(M3)	588	489	83.2	79.9	86.1	
			PII(M14)	560	251	44.8	40.6	49.0	
			PII(M26)	554	198	35.7	31.7	39.9	
			PII(M38)	528	174	33.0	29.0	37.1	
		Placebo	PII(M3)	578	6	1.0	0.4	2.2	
			PII(M14)	558	9	1.6	0.7	3.0	
			PII(M26)	531	7	1.3	0.5	2.7	
			PII(M38)	511	8	1.6	0.7	3.1	
	Pre-Frail	HZ/su	PII(M3)	643	546	84.9	81.9	87.6	
			PII(M14)	613	271	44.2	40.2	48.2	
			PII(M26)	592	222	37.5	33.6	41.5	
			PII(M38)	558	184	33.0	29.1	37.0	
		Placebo	PII(M3)	663	10	1.5	0.7	2.8	
			PII(M14)	628	13	2.1	1.1	3.5	
			PII(M26)	587	12	2.0	1.1	3.5	
			PII(M38)	555	14	2.5	1.4	4.2	
	Frail	HZ/su	PII(M3)	135	110	81.5	73.9	87.6	
			PII(M14)	120	42	35.0	26.5	44.2	
			PII(M26)	111	30	27.0	19.0	36.3	
			PII(M38)	105	21	20.0	12.8	28.9	
		Placebo	PII(M3)	121	0	0.0	0.0	3.0	
			PII(M14)	112	2	1.8	0.2	6.3	
			PII(M26)	109	3	2.8	0.6	7.8	
			PII(M38)	106	7	6.6	2.7	13.1	
	Unknown	HZ/su	PII(M3)	4	3	75.0	19.4	99.4	
			PII(M14)	4	2	50.0	6.8	93.2	
			PII(M26)	4	2	50.0	6.8	93.2	
			PII(M38)	4	2	50.0	6.8	93.2	
		Placebo	PII(M3)	4	0	0.0	0.0	60.2	
			PII(M14)	4	0	0.0	0.0	60.2	
			PII(M26)	3	0	0.0	0.0	70.8	
			PII(M38)	3	0	0.0	0.0	70.8	

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Vaccine response defined as :

For initially seronegative subjects, antibody concentration at post-vaccination ≥ 4 fold the cut-off for Anti-VZV (4x25 mIU/ml)

For initially seropositive subjects, antibody concentration at post-vaccination ≥ 4 fold the pre-vaccination antibody concentration

N = Number of subjects with pre- and post-vaccination results available

n/% = Number/percentage of responders

95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.3.1 Descriptive statistics of the frequency of gE-specific CD4[2+] T-cells at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

Immune marker	Sub-group	Group	Timing	N	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
CD4[2+]	Non-Frail	HZ/su	PRE(M0)	83	15	170.94	219.51	1.0	9.3	106.9	241.2	1364.6
			PII(M3)	79	19	2507.93	1609.35	483.9	1332.5	2301.8	3130.9	8583.1
			PII(M14)	86	10	1080.56	980.20	1.0	501.0	810.1	1353.4	6018.8
			PII(M26)	82	14	1108.08	920.47	1.0	471.3	930.7	1473.8	5007.6
			PII(M38)	79	15	1052.02	993.56	1.0	503.7	797.6	1325.5	5412.0
		Placebo	PRE(M0)	92	19	124.10	186.22	1.0	4.4	68.0	166.0	1310.6
			PII(M3)	91	20	141.88	167.85	1.0	9.5	111.0	190.0	1002.1
			PII(M14)	91	16	128.25	167.23	1.0	1.0	80.6	164.4	1104.6
			PII(M26)	91	13	149.65	254.21	1.0	18.3	83.3	212.5	2129.3
			PII(M38)	79	22	111.30	128.46	1.0	1.0	66.6	195.5	697.3
	Pre-Frail	HZ/su	PRE(M0)	63	17	132.25	143.79	1.0	1.0	91.0	208.7	660.4
			PII(M3)	58	22	2155.92	1514.20	350.8	1052.0	1612.1	2692.9	6830.0
			PII(M14)	60	15	908.66	687.87	81.3	428.6	672.5	1186.8	3305.3
			PII(M26)	62	12	896.13	631.42	1.0	417.0	711.7	1202.5	2687.7
			PII(M38)	52	15	829.29	679.05	1.0	303.3	662.9	1249.2	3190.2
		Placebo	PRE(M0)	65	14	166.63	192.07	1.0	19.5	108.5	249.6	928.6
			PII(M3)	66	13	118.46	160.14	1.0	1.0	57.9	157.2	738.3
			PII(M14)	68	9	154.61	185.43	1.0	1.0	101.0	229.6	853.4
			PII(M26)	55	16	149.95	200.09	1.0	1.0	90.6	192.5	952.1
			PII(M38)	49	18	109.94	126.78	1.0	1.0	71.2	173.0	539.4
	Frail	HZ/su	PRE(M0)	15	3	63.77	59.84	1.0	1.0	72.8	115.9	165.1
			PII(M3)	15	3	1757.64	1025.95	576.4	1120.3	1504.6	1943.4	4204.8
			PII(M14)	13	3	689.39	511.26	149.1	302.2	523.2	870.6	2057.4
			PII(M26)	14	1	604.37	564.35	15.6	240.6	538.3	762.1	2247.7
			PII(M38)	11	2	534.86	437.31	92.2	124.9	493.7	737.3	1440.5
		Placebo	PRE(M0)	11	3	124.90	150.71	1.0	5.5	93.7	161.1	451.5
			PII(M3)	11	3	73.81	74.47	1.0	1.0	46.2	149.7	201.2
			PII(M14)	7	3	154.53	102.63	1.0	90.2	142.0	280.2	286.5
			PII(M26)	11	2	122.33	115.56	1.0	20.6	105.7	162.6	416.9
			PII(M38)	9	3	136.66	272.93	1.0	1.0	1.0	196.0	828.7

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of subjects with available results

Nmiss = number of subjects with missing results

SD = Standard Deviation

Q1, Q3 = First and third quartiles

Min/Max = Minimum/Maximum

PRE(M0) = Pre-vaccination (Month 0)

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.3.2 Vaccine response rates for gE-specific CD4[2+] T-cells frequencies at Month 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

				Vaccine response				
				95% CI				
Test description	Sub-group	Group	Timing	N	n	%	LL	UL
CD4[2+]	Non-Frail	HZ/su	PII(M3)	72	66	91.7	82.7	96.9
			PII(M14)	79	48	60.8	49.1	71.6
			PII(M26)	74	47	63.5	51.5	74.4
			PII(M38)	70	41	58.6	46.2	70.2
		Placebo	PII(M3)	81	0	0.0	0.0	4.5
			PII(M14)	84	1	1.2	0.0	6.5
			PII(M26)	80	0	0.0	0.0	4.5
			PII(M38)	71	0	0.0	0.0	5.1
	Pre-Frail	HZ/su	PII(M3)	52	49	94.2	84.1	98.8
			PII(M14)	52	26	50.0	35.8	64.2
			PII(M26)	53	30	56.6	42.3	70.2
			PII(M38)	45	22	48.9	33.7	64.2
		Placebo	PII(M3)	60	0	0.0	0.0	6.0
			PII(M14)	60	0	0.0	0.0	6.0
			PII(M26)	53	0	0.0	0.0	6.7
			PII(M38)	47	0	0.0	0.0	7.5
	Frail	HZ/su	PII(M3)	14	13	92.9	66.1	99.8
			PII(M14)	11	5	45.5	16.7	76.6
			PII(M26)	12	4	33.3	9.9	65.1
			PII(M38)	9	3	33.3	7.5	70.1
		Placebo	PII(M3)	10	0	0.0	0.0	30.8
			PII(M14)	5	0	0.0	0.0	52.2
			PII(M26)	9	0	0.0	0.0	33.6
			PII(M38)	7	1	14.3	0.4	57.9

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

Vaccine response defined as :

For initially subjects with pre-vaccination T cell frequencies below the LLL, at least a 2-fold increase as compared to the LLL ($2 \times < 320 >$ Events/ 10^6 CD4+ T cells)

For initially subjects with pre-vaccination T cell frequencies above the LLL, at least a 2-fold increase as compared to pre-vaccination T cell frequencies

N = Number of subjects with pre- and post-vaccination results available

n/% = Number/percentage of responders

95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.3.3 Descriptive statistics of the frequency of CD4[2+] T-cells following induction with gE at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

Immune marker	Sub-group	Group	Timing	N	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
CD4[2+]	Non-Frail	HZ/su	PRE(M0)	83	15	503.92	348.09	50.8	202.7	414.3	699.8	2071.7
			PII(M3)	79	19	2873.54	1660.26	552.8	1753.4	2476.3	3697.9	9184.9
			PII(M14)	86	10	1405.26	1002.23	279.1	798.8	1200.8	1711.5	6296.6
			PII(M26)	82	14	1417.93	955.71	134.1	820.0	1210.3	1775.9	5464.3
			PII(M38)	79	15	1383.61	1034.90	144.4	830.6	1112.4	1561.1	5985.3
		Placebo	PRE(M0)	92	19	450.05	333.20	45.0	235.4	347.6	595.9	2103.1
			PII(M3)	91	20	487.23	310.01	44.8	271.5	418.1	681.3	1788.2
			PII(M14)	91	16	419.78	274.40	62.0	230.5	377.1	548.3	1843.9
			PII(M26)	91	13	471.58	393.65	74.4	236.5	377.1	589.9	3064.8
			PII(M38)	79	22	393.69	234.04	28.6	238.5	328.5	515.8	1109.0
	Pre-Frail	HZ/su	PRE(M0)	63	17	442.15	266.31	50.5	217.9	410.9	554.1	1112.9
			PII(M3)	58	22	2476.52	1519.38	700.8	1482.0	1921.6	3136.3	7085.9
			PII(M14)	60	15	1226.38	690.51	163.3	698.1	1151.6	1486.7	3477.6
			PII(M26)	62	12	1178.10	639.47	238.7	688.2	956.2	1564.6	3056.6
			PII(M38)	52	15	1107.22	674.34	259.7	572.5	912.9	1476.5	3208.8
		Placebo	PRE(M0)	65	14	471.85	279.24	60.0	245.0	459.8	583.5	1231.6
			PII(M3)	66	13	461.42	269.46	50.5	270.0	420.2	597.9	1587.0
			PII(M14)	68	9	443.61	272.87	0.0	232.3	413.3	607.0	1220.9
			PII(M26)	55	16	426.77	254.10	85.7	253.1	369.2	572.0	1285.5
			PII(M38)	49	18	418.97	252.60	57.1	263.8	365.5	481.4	1113.1
	Frail	HZ/su	PRE(M0)	15	3	351.70	144.77	165.6	193.0	345.1	450.5	595.3
			PII(M3)	15	3	2050.90	1015.48	684.5	1492.1	1727.1	2410.2	4323.4
			PII(M14)	13	3	927.78	550.24	185.4	549.6	976.5	1091.4	2228.3
			PII(M26)	14	1	920.09	642.85	152.5	456.4	938.7	1082.9	2679.2
			PII(M38)	11	2	869.49	629.87	130.5	414.7	795.3	1159.2	2224.8
		Placebo	PRE(M0)	11	3	334.00	322.73	55.4	137.7	218.0	602.5	1106.6
			PII(M3)	11	3	344.66	301.97	32.4	92.5	220.2	664.7	909.2
			PII(M14)	7	3	326.74	159.91	155.0	168.9	320.3	459.6	596.4
			PII(M26)	11	2	354.33	200.49	75.6	190.1	325.3	515.5	772.0
			PII(M38)	9	3	381.45	291.03	118.8	254.9	272.3	397.8	1104.7

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of subjects with available results

Nmiss = number of subjects with missing results

SD = Standard Deviation

Q1, Q3 = First and third quartiles

Min/Max = Minimum/Maximum

PRE(M0) = Pre-vaccination (Month 0)

PII(M3) = Post-vaccination Dose II (Month 3)

PII(M14) = Post-vaccination Dose II (Month 14)

PII(M26) = Post-vaccination Dose II (Month 26)

PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.3.4 Descriptive statistics of the frequency of CD4 T-cells secreting at least IFN γ and another activation marker (IL-2, TNF α , CD40L) following induction with gE at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

Immune marker	Sub-group	Group	Timing	N	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
CD4.IFN γ (+)+ Other activation marker	Non-Frail	HZ/su	PRE(M0)	83	15	168.79	208.35	0.0	55.8	105.4	184.3	1350.2
			PII(M3)	79	19	1374.73	941.73	132.5	710.4	1109.8	1780.6	6288.6
			PII(M14)	86	10	649.98	661.38	21.6	288.4	545.9	838.8	5045.8
			PII(M26)	82	14	791.72	675.78	14.3	360.8	657.9	1034.6	4679.0
			PII(M38)	79	15	798.59	750.01	14.9	349.9	634.6	952.9	5027.7
		Placebo	PRE(M0)	92	19	132.95	162.24	0.0	38.6	87.2	167.8	1155.8
			PII(M3)	91	20	140.96	126.74	0.0	51.5	98.4	186.7	547.1
			PII(M14)	91	16	119.90	100.56	0.0	49.7	88.1	174.0	485.4
			PII(M26)	91	13	189.18	237.02	0.0	86.2	135.8	234.8	2117.2
			PII(M38)	79	22	149.55	112.46	0.0	64.3	131.9	204.5	563.1
	Pre-Frail	HZ/su	PRE(M0)	63	17	131.57	122.47	0.0	51.9	91.1	166.9	515.0
			PII(M3)	58	22	1143.98	944.75	62.0	446.0	853.5	1404.0	4175.9
			PII(M14)	60	15	495.97	370.17	51.0	218.6	403.5	634.9	1928.0
			PII(M26)	62	12	605.22	459.69	63.0	268.8	474.0	855.1	2190.4
			PII(M38)	52	15	594.57	441.30	94.4	240.1	467.3	900.6	2191.8
		Placebo	PRE(M0)	65	14	144.61	143.74	0.0	51.1	100.6	200.1	712.0
			PII(M3)	66	13	124.45	109.96	0.0	45.7	99.0	160.4	614.4
			PII(M14)	68	9	121.76	125.83	0.0	44.8	79.6	127.9	732.5
			PII(M26)	55	16	176.61	175.18	0.0	57.9	135.0	231.6	1003.3
			PII(M38)	49	18	150.46	138.02	0.0	73.7	114.2	189.2	710.8
	Frail	HZ/su	PRE(M0)	15	3	93.20	66.36	22.3	48.2	64.5	155.5	243.7
			PII(M3)	15	3	1030.33	723.30	155.6	557.9	847.4	1298.7	2891.3
			PII(M14)	13	3	396.66	329.18	37.1	186.9	347.1	544.9	1290.0
			PII(M26)	14	1	452.86	415.67	29.1	142.9	390.8	600.1	1655.7
			PII(M38)	11	2	441.13	345.21	14.5	165.9	289.8	732.1	1142.1
		Placebo	PRE(M0)	11	3	101.31	102.18	10.3	39.4	56.7	118.6	344.3
			PII(M3)	11	3	83.30	83.40	0.0	28.9	53.7	182.7	243.2
			PII(M14)	7	3	88.80	62.14	15.5	44.7	83.6	99.9	213.5
			PII(M26)	11	2	128.72	68.71	29.2	48.6	132.6	188.0	228.8
			PII(M38)	9	3	99.29	88.70	0.0	39.5	83.2	102.8	295.9

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Non-Frail = Subjects with frailty index score ≤ 0.08
Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25
Frail = Subjects with frailty index score > 0.25
Unknown = Subjects who were not assigned a Frailty category
HZ/su = Herpes Zoster subunit vaccine
Placebo = Placebo
N = number of subjects with available results
Nmiss = number of subjects with missing results
SD = Standard Deviation
Q1, Q3 = First and third quartiles
Min/Max = Minimum/Maximum
PRE(M0) = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M14) = Post-vaccination Dose II (Month 14)
PII(M26) = Post-vaccination Dose II (Month 26)
PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.3.5 Descriptive statistics of the frequency of CD4 T-cells secreting at least IL-2 and another activation marker (IFNg, TNFa,CD40L) following induction with gE at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

Immune marker	Sub-group	Group	Timing	N	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
CD4.IL2(+)+ Other activation marker	Non-Frail	HZ/su	PRE(M0)	83	15	308.20	238.06	50.8	138.5	231.4	411.7	1401.7
			PII(M3)	79	19	2386.47	1486.84	420.9	1311.9	2109.5	3059.5	7568.7
			PII(M14)	86	10	1145.05	896.66	237.7	595.0	893.8	1361.7	5585.2
			PII(M26)	82	14	1190.22	910.14	117.3	572.5	974.7	1487.6	4896.0
			PII(M38)	79	15	1180.89	967.21	101.1	645.2	940.9	1261.5	5530.4
		Placebo	PRE(M0)	92	19	255.89	230.26	0.0	139.8	208.7	287.5	1743.2
			PII(M3)	91	20	278.31	172.48	14.9	162.9	229.3	364.4	884.8
			PII(M14)	91	16	234.44	142.34	34.9	131.7	200.3	294.2	910.1
			PII(M26)	91	13	313.30	312.63	40.4	140.9	222.2	378.6	2620.6
			PII(M38)	79	22	248.19	163.73	0.0	131.9	214.2	340.8	724.0
	Pre-Frail	HZ/su	PRE(M0)	63	17	290.65	188.81	42.3	156.2	263.6	381.9	965.7
			PII(M3)	58	22	2082.35	1367.70	577.1	1209.3	1624.4	2642.9	6313.2
			PII(M14)	60	15	1005.81	650.31	142.8	524.1	851.1	1266.9	3315.4
			PII(M26)	62	12	1025.62	615.05	173.6	543.1	857.0	1429.7	2747.3
			PII(M38)	52	15	940.36	651.45	44.0	446.5	740.6	1319.2	3051.0
		Placebo	PRE(M0)	65	14	288.98	185.44	0.0	164.1	257.0	370.5	865.2
			PII(M3)	66	13	265.72	155.81	28.2	164.6	250.2	321.9	963.8
			PII(M14)	68	9	265.99	177.64	0.0	144.6	225.5	331.3	976.7
			PII(M26)	55	16	273.72	191.62	22.8	146.4	229.2	325.6	1081.7
			PII(M38)	49	18	269.73	174.67	42.8	146.9	234.7	341.4	778.4
	Frail	HZ/su	PRE(M0)	15	3	238.36	102.06	101.9	160.8	246.8	295.5	498.1
			PII(M3)	15	3	1753.17	939.22	643.0	1163.1	1432.6	2019.9	4026.2
			PII(M14)	13	3	770.05	459.70	160.7	492.9	746.0	929.5	1951.1
			PII(M26)	14	1	762.39	568.28	91.5	373.1	744.8	871.6	2393.2
			PII(M38)	11	2	697.60	490.12	116.0	359.4	672.5	1006.6	1705.7
		Placebo	PRE(M0)	11	3	168.67	120.29	33.2	94.7	113.5	207.5	387.3
			PII(M3)	11	3	178.44	114.74	0.0	92.5	173.2	275.6	379.4
			PII(M14)	7	3	163.57	72.30	93.0	97.6	138.2	239.8	284.7
			PII(M26)	11	2	215.50	154.61	18.9	120.1	180.9	236.6	571.3
			PII(M38)	9	3	185.97	66.69	79.2	153.0	177.7	191.0	298.3

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Non-Frail = Subjects with frailty index score ≤ 0.08
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Frail = Subjects with frailty index score > 0.25
Unknown = Subjects who were not assigned a Frailty category
HZ/su = Herpes Zoster subunit vaccine
Placebo = Placebo
N = number of subjects with available results
Nmiss = number of subjects with missing results
SD = Standard Deviation
Q1, Q3 = First and third quartiles
Min/Max = Minimum/Maximum
PRE(M0) = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M14) = Post-vaccination Dose II (Month 14)
PII(M26) = Post-vaccination Dose II (Month 26)
PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.3.6 Descriptive statistics of the frequency of CD4 T-cells secreting at least TNFa and another activation marker (IFNg, IL-2,CD40L) following induction with gE at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

Immune marker	Sub-group	Group	Timing	N	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
CD4.TNFa(+)+ Other activation marker	Non-Frail	HZ/su	PRE(M0)	83	15	356.45	275.78	30.5	131.9	301.6	479.2	1442.9
			PII(M3)	79	19	1640.94	1207.59	296.5	834.8	1265.9	2225.2	7872.8
			PII(M14)	86	10	907.39	765.77	75.7	490.8	693.7	1118.9	5387.0
			PII(M26)	82	14	913.68	733.17	83.8	501.8	796.4	1129.8	4891.7
			PII(M38)	79	15	893.33	804.17	72.2	498.5	712.0	949.4	5314.9
		Placebo	PRE(M0)	92	19	336.02	285.26	0.0	148.4	244.3	480.8	1743.2
			PII(M3)	91	20	359.19	275.62	26.8	167.7	308.3	465.0	1661.9
			PII(M14)	91	16	306.54	240.97	18.8	140.6	247.5	407.4	1644.0
			PII(M26)	91	13	312.54	331.73	27.7	115.3	220.2	417.6	2620.6
			PII(M38)	79	22	263.41	188.74	0.0	128.7	223.2	365.4	836.0
	Pre-Frail	HZ/su	PRE(M0)	63	17	309.79	216.39	12.6	146.1	256.6	431.5	979.9
			PII(M3)	58	22	1393.24	895.19	173.4	706.8	1207.2	1620.9	4537.6
			PII(M14)	60	15	769.69	476.81	112.2	415.1	648.8	1012.8	2414.5
			PII(M26)	62	12	729.68	461.05	63.0	381.7	604.1	1080.0	2070.9
			PII(M38)	52	15	657.27	457.65	109.5	288.5	576.8	889.9	2244.4
		Placebo	PRE(M0)	65	14	342.87	235.56	30.0	132.6	307.0	444.3	964.5
			PII(M3)	66	13	343.18	244.56	12.9	157.5	288.6	468.0	1432.1
			PII(M14)	68	9	327.76	236.52	0.0	140.6	310.6	454.3	1090.6
			PII(M26)	55	16	296.66	225.47	42.8	126.6	247.8	381.4	1008.1
			PII(M38)	49	18	284.62	205.51	33.6	142.3	228.3	386.7	1038.9
	Frail	HZ/su	PRE(M0)	15	3	224.25	115.19	89.2	153.9	201.9	315.9	509.7
			PII(M3)	15	3	1167.13	652.20	342.2	748.3	918.6	1635.1	2729.2
			PII(M14)	13	3	594.94	422.28	123.6	230.8	556.1	747.9	1577.9
			PII(M26)	14	1	564.79	528.67	45.7	207.3	517.4	600.1	2167.4
			PII(M38)	11	2	528.41	535.17	58.0	82.9	397.7	701.1	1765.0
		Placebo	PRE(M0)	11	3	256.87	321.30	44.3	61.6	137.9	373.0	1106.6
			PII(M3)	11	3	270.25	260.43	0.0	78.0	180.1	502.2	793.8
			PII(M14)	7	3	245.05	159.85	76.8	139.5	177.9	339.7	551.7
			PII(M26)	11	2	243.87	156.43	37.8	146.2	207.0	390.4	525.0
			PII(M38)	9	3	263.05	305.62	79.2	116.5	178.4	232.0	1056.7

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Non-Frail = Subjects with frailty index score ≤ 0.08
Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25
Frail = Subjects with frailty index score > 0.25
Unknown = Subjects who were not assigned a Frailty category
HZ/su = Herpes Zoster subunit vaccine
Placebo = Placebo
N = number of subjects with available results
Nmiss = number of subjects with missing results
SD = Standard Deviation
Q1, Q3 = First and third quartiles
Min/Max = Minimum/Maximum
PRE(M0) = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M14) = Post-vaccination Dose II (Month 14)
PII(M26) = Post-vaccination Dose II (Month 26)
PII(M38) = Post-vaccination Dose II (Month 38)

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Table 14.2.3.7 Descriptive statistics of the frequency of CD4 T-cells secreting at least CD40L and another activation marker (IFN γ , IL-2, TNF α) following induction with gE at Month 0, 3, 14, 26 and 38 by frailty status (Adapted ATP cohort for immunogenicity-CMI)

Immune marker	Sub-group	Group	Timing	N	Nmiss	Mean	SD	Min	Q1	Median	Q3	Max
CD4.CD40L(+)+ Other activation marker	Non-Frail	HZ/su	PRE(M0)	83	15	445.83	315.65	35.1	181.4	378.1	625.4	1875.8
			PII(M3)	79	19	2609.03	1569.29	372.3	1492.5	2224.8	3423.7	8752.8
			PII(M14)	86	10	1293.70	964.17	270.2	707.8	1067.8	1604.2	5969.7
			PII(M26)	82	14	1320.56	953.10	100.6	689.0	1123.4	1610.8	5382.5
			PII(M38)	79	15	1297.58	1014.34	130.0	771.2	1029.6	1492.2	5889.5
		Placebo	PRE(M0)	92	19	406.70	296.10	30.0	189.3	319.4	541.1	1686.3
			PII(M3)	91	20	436.68	292.52	44.8	216.0	377.3	568.8	1767.1
			PII(M14)	91	16	377.88	264.51	52.4	193.0	310.3	512.5	1799.5
			PII(M26)	91	13	418.19	353.60	59.5	214.1	318.6	552.1	2813.1
			PII(M38)	79	22	340.80	205.83	17.4	187.8	299.9	484.9	989.1
	Pre-Frail	HZ/su	PRE(M0)	63	17	391.26	231.83	50.5	190.0	357.9	508.5	1028.1
			PII(M3)	58	22	2225.69	1416.57	546.2	1258.7	1767.9	2716.1	6806.4
			PII(M14)	60	15	1110.29	656.94	142.8	603.6	1013.2	1372.6	3423.5
			PII(M26)	62	12	1116.72	628.38	195.3	648.3	916.2	1437.0	3002.0
			PII(M38)	52	15	1057.40	666.80	154.0	540.1	824.6	1425.7	3173.7
		Placebo	PRE(M0)	65	14	429.22	256.41	60.0	221.0	418.2	558.1	1201.0
			PII(M3)	66	13	417.25	261.87	28.2	233.1	375.3	536.6	1535.4
			PII(M14)	68	9	399.92	249.84	0.0	205.9	377.7	574.4	1186.0
			PII(M26)	55	16	390.27	239.48	85.7	219.3	342.3	495.3	1269.8
			PII(M38)	49	18	384.32	242.03	42.8	222.9	329.9	463.1	1098.2
	Frail	HZ/su	PRE(M0)	15	3	307.20	135.11	128.7	161.3	320.6	418.3	550.1
			PII(M3)	15	3	1805.91	964.57	611.9	1280.9	1403.1	2276.9	4093.8
			PII(M14)	13	3	803.18	469.11	185.4	520.3	735.2	982.9	1759.2
			PII(M26)	14	1	881.75	634.30	152.5	441.7	905.3	1024.9	2649.1
			PII(M38)	11	2	808.82	618.48	116.0	414.7	536.1	1143.9	2195.2
		Placebo	PRE(M0)	11	3	287.28	303.19	22.2	92.8	173.7	516.5	1049.8
			PII(M3)	11	3	295.49	299.29	31.2	92.5	128.0	599.9	909.2
			PII(M14)	7	3	241.42	178.03	62.0	92.2	195.2	399.7	536.8
			PII(M26)	11	2	306.94	159.94	56.7	180.1	286.4	471.3	586.7
			PII(M38)	9	3	366.07	277.37	99.0	254.9	256.7	381.2	1056.7

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Frail = Subjects with frailty index score > 0.25
Unknown = Subjects who were not assigned a Frailty category
HZ/su = Herpes Zoster subunit vaccine
Placebo = Placebo
N = number of subjects with available results
Nmiss = number of subjects with missing results
SD = Standard Deviation
Q1, Q3 = First and third quartiles
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PRE(M0) = Pre-vaccination (Month 0)
PII(M3) = Post-vaccination Dose II (Month 3)
PII(M14) = Post-vaccination Dose II (Month 14)
PII(M26) = Post-vaccination Dose II (Month 26)
PII(M38) = Post-vaccination Dose II (Month 38)

Table 14.2.4.1 SF-36 and EQ-5D components by time point, age group and country - Australia (Total Vaccinated Cohort)

			50-59YOA N = 109	60-69YOA N = 84	70-79YOA N = 234	80-89YOA N = 63	≥90YOA N = 5	Total N = 495
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	105	83	227	61	5	481
		Mean	84.23	81.57	74.17	59.64	45.00	75.50
		SD	18.234	20.496	23.705	23.600	17.321	23.366
	SF36 RP	N	105	83	227	61	5	481
		Mean	86.25	87.65	79.71	66.29	43.75	80.43
		SD	22.707	20.682	23.021	28.258	36.443	24.521
	SF36 BP	N	105	83	227	61	5	481
		Mean	73.19	80.34	75.07	67.20	67.20	74.49
		SD	23.435	20.743	22.949	27.670	23.124	23.545
	SF36 GH	N	105	83	227	61	5	481
		Mean	79.24	78.97	74.84	71.38	82.60	76.15
		SD	17.304	15.852	17.058	17.094	8.473	17.016
	SF36 VT	N	105	83	227	61	5	481
		Mean	65.06	72.52	68.36	61.99	71.25	67.58
		SD	21.065	16.534	16.750	20.036	12.960	18.344
	SF36 SF	N	105	83	227	61	5	481
		Mean	90.60	92.32	92.18	86.27	92.50	91.11
		SD	18.162	17.222	15.040	17.486	11.180	16.485
	SF36 RE	N	105	83	227	61	5	481
		Mean	88.97	92.37	88.91	83.61	80.00	88.76
		SD	22.002	15.021	19.108	22.718	32.596	19.879
	SF36 MH	N	105	83	227	61	5	481
		Mean	82.43	86.20	84.15	83.61	90.00	84.12
		SD	16.729	11.883	13.270	14.293	6.124	13.975
	EQ5D Utility	N	104	83	227	60	5	479
		Mean	0.8042	0.8681	0.8094	0.7248	0.7516	0.8072
		SD	0.21343	0.20193	0.19377	0.17068	0.14363	0.19966
	EQ5D VAS	N	104	83	226	60	5	478
		Mean	85.41	87.73	85.65	81.08	89.40	85.43
		SD	14.100	11.079	12.722	14.259	9.788	13.031
Month 14	SF36 PF	N	91	75	210	55	5	436
		Mean	80.45	78.75	71.85	59.90	24.00	72.78
		SD	21.254	18.552	25.841	21.098	19.812	24.472
	SF36 RP	N	91	75	210	55	5	436
		Mean	80.70	81.00	76.25	64.66	63.75	76.39
		SD	26.981	22.048	26.670	25.550	34.347	26.339
	SF36 BP	N	91	75	209	55	5	435
		Mean	67.29	72.73	71.60	68.98	62.60	70.46
		SD	25.266	22.806	24.646	23.928	35.104	24.483
	SF36 GH	N	91	75	211	55	5	437
		Mean	73.23	73.67	71.64	67.22	68.80	71.73
		SD	21.213	17.237	17.560	16.669	15.498	18.227
	SF36 VT	N	91	75	209	55	5	435
		Mean	61.13	67.58	65.51	61.10	53.75	64.26
		SD	22.024	20.542	22.342	22.255	3.423	21.926
	SF36 SF	N	91	75	210	55	5	436
		Mean	82.55	90.00	87.14	84.09	55.00	85.92
		SD	26.866	20.652	22.109	24.231	31.375	23.581

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			50-59YOA N = 109	60-69YOA N = 84	70-79YOA N = 234	80-89YOA N = 63	≥90YOA N = 5	Total N = 495
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	91	75	210	55	5	436
		Mean	85.99	88.67	87.46	78.94	68.33	86.07
		SD	22.148	19.836	21.572	27.351	34.055	22.532
	SF36 MH	N	91	75	209	55	5	435
		Mean	79.01	82.68	83.60	83.09	63.00	82.18
		SD	19.554	16.825	15.540	16.344	14.405	16.909
	EQ5D Utility	N	91	74	206	55	5	431
		Mean	0.7839	0.7931	0.7642	0.7323	0.5770	0.7671
		SD	0.22269	0.17936	0.18980	0.18599	0.16268	0.19586
	EQ5D VAS	N	89	73	203	54	5	424
		Mean	81.26	84.77	81.61	77.93	70.60	81.48
		SD	14.262	11.537	14.877	16.519	13.667	14.544
Month 26	SF36 PF	N	82	74	201	51	4	412
		Mean	83.37	78.58	71.18	58.65	32.50	73.01
		SD	19.952	20.077	24.984	24.682	8.660	24.468
	SF36 RP	N	82	74	201	51	4	412
		Mean	83.61	82.18	75.34	60.05	54.69	76.12
		SD	23.419	22.108	24.892	27.188	21.875	25.386
	SF36 BP	N	82	74	201	51	4	412
		Mean	71.00	72.55	68.97	69.63	69.25	70.10
		SD	25.400	21.654	24.095	26.551	24.622	24.188
	SF36 GH	N	82	74	202	51	4	413
		Mean	71.54	72.73	70.39	64.90	72.75	70.38
		SD	20.899	18.632	17.823	19.175	16.500	18.815
	SF36 VT	N	82	74	201	51	4	412
		Mean	59.98	66.13	63.74	54.90	48.44	62.18
		SD	22.903	18.564	20.832	22.407	31.198	21.385
	SF36 SF	N	82	74	201	51	4	412
		Mean	85.06	91.72	88.56	80.39	71.88	87.26
		SD	24.724	15.521	19.913	26.369	32.874	21.499
	SF36 RE	N	82	74	201	51	4	412
		Mean	85.47	90.20	86.44	77.94	83.33	85.84
		SD	23.563	18.213	21.643	27.071	33.333	22.472
	SF36 MH	N	82	74	201	51	4	412
		Mean	76.95	84.05	82.88	78.24	71.25	81.22
		SD	19.241	13.591	15.976	18.677	34.490	17.017
	EQ5D Utility	N	82	74	201	51	4	412
		Mean	0.7753	0.8036	0.7531	0.6895	0.7030	0.7582
		SD	0.24471	0.18867	0.19173	0.21733	0.22467	0.20781
	EQ5D VAS	N	82	74	199	51	4	410
		Mean	81.23	84.05	81.59	76.78	69.00	81.24
		SD	17.453	16.301	15.130	15.855	21.463	16.066
Month 38	SF36 PF	N	81	74	198	47	3	403
		Mean	82.59	78.04	69.71	55.17	28.33	71.83
		SD	20.188	23.318	26.158	26.107	20.817	25.972
	SF36 RP	N	81	74	198	47	3	403
		Mean	82.33	79.39	72.94	58.51	50.00	74.16
		SD	22.703	24.409	27.895	27.474	47.186	27.235
	SF36 BP	N	81	74	198	47	3	403
		Mean	70.27	71.08	70.13	68.83	53.33	70.06
		SD	22.211	23.884	24.287	25.166	35.796	23.919

			50-59YOA N = 109	60-69YOA N = 84	70-79YOA N = 234	80-89YOA N = 63	≥90YOA N = 5	Total N = 495
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	81	74	198	47	3	403
		Mean	71.86	72.64	70.66	67.06	63.00	70.79
		SD	21.082	19.275	19.551	19.753	7.937	19.777
	SF36 VT	N	81	74	197	47	3	402
		Mean	65.05	65.96	64.33	56.12	45.83	63.68
		SD	21.028	18.995	21.696	21.234	28.183	21.220
	SF36 SF	N	81	74	198	47	3	403
		Mean	84.10	88.18	87.12	82.98	75.00	86.14
		SD	22.098	20.679	22.065	21.560	33.072	21.822
	SF36 RE	N	81	74	198	47	3	403
		Mean	86.42	89.30	86.15	76.24	77.78	85.57
		SD	20.601	19.483	22.502	26.121	38.490	22.371
	SF36 MH	N	81	74	197	47	3	402
		Mean	79.63	81.69	83.62	82.87	68.33	82.26
		SD	18.520	14.365	14.706	16.244	28.431	15.807
	EQ5D Utility	N	81	74	197	47	3	402
		Mean	0.7621	0.8019	0.7592	0.6989	0.5217	0.7589
		SD	0.22216	0.18339	0.19734	0.16134	0.19029	0.19839
	EQ5D VAS	N	81	74	197	46	3	401
		Mean	82.40	84.04	80.76	74.48	65.00	80.86
		SD	14.577	12.032	16.001	14.984	10.000	15.135

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.2 SF-36 and EQ-5D components by time point, age group and country - Brazil (Total Vaccinated Cohort)

			50-59YOA N = 298	60-69YOA N = 180	70-79YOA N = 600	80-89YOA N = 174	≥90YOA N = 5	Total N = 1257
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	297	179	597	174	5	1252
		Mean	84.24	77.00	72.96	64.35	45.00	74.90
		SD	18.643	22.498	23.450	25.570	33.541	23.505
	SF36 RP	N	298	179	599	174	5	1255
		Mean	90.06	81.77	78.88	77.73	66.25	81.74
		SD	18.285	21.831	25.493	26.858	39.922	24.185
	SF36 BP	N	297	179	599	173	5	1253
		Mean	74.29	70.64	67.71	66.95	64.80	69.57
		SD	24.687	27.055	26.110	26.103	32.980	26.057
	SF36 GH	N	298	179	599	174	5	1255
		Mean	79.86	76.90	74.42	75.63	78.60	76.25
		SD	18.608	18.175	19.147	19.244	14.843	18.983
	SF36 VT	N	297	178	596	174	5	1250
		Mean	75.52	72.43	72.19	68.93	63.75	72.53
		SD	19.989	18.930	21.023	22.733	26.295	20.835
	SF36 SF	N	298	179	599	174	5	1255
		Mean	88.46	83.24	83.35	82.18	70.00	84.33
		SD	18.367	22.215	22.239	22.420	18.957	21.505
	SF36 RE	N	297	179	596	173	5	1250
		Mean	89.62	83.89	80.92	81.07	91.67	83.48
		SD	17.948	22.686	24.095	25.099	18.634	22.963
	SF36 MH	N	297	179	596	174	5	1251
		Mean	80.44	79.42	78.68	78.25	75.00	79.13
		SD	18.161	17.621	19.771	20.536	16.583	19.192
	EQ5D Utility	N	294	179	589	172	5	1239
		Mean	0.8897	0.8626	0.8449	0.8368	0.7178	0.8565
		SD	0.13689	0.14243	0.14323	0.14952	0.12691	0.14387
	EQ5D VAS	N	297	179	594	174	5	1249
		Mean	85.67	82.77	82.02	81.69	74.00	82.92
		SD	12.645	15.866	15.926	17.758	20.736	15.561
Month 14	SF36 PF	N	282	168	545	149	5	1149
		Mean	81.08	74.93	70.57	62.14	50.00	72.60
		SD	21.616	21.993	23.254	26.824	36.572	23.984
	SF36 RP	N	282	168	544	149	5	1148
		Mean	84.93	80.65	76.62	74.86	72.50	79.01
		SD	22.978	24.039	27.263	29.190	28.504	26.311
	SF36 BP	N	282	168	545	150	5	1150
		Mean	70.13	70.32	66.59	67.04	84.60	68.14
		SD	25.971	25.789	25.882	27.048	22.356	26.068
	SF36 GH	N	282	168	546	150	5	1151
		Mean	78.43	75.31	71.77	72.62	88.00	74.10
		SD	18.393	16.100	19.816	19.590	12.450	19.110
	SF36 VT	N	282	168	545	150	5	1150
		Mean	72.01	73.03	72.06	67.85	86.25	71.70
		SD	22.055	20.849	21.963	21.000	10.270	21.709
	SF36 SF	N	282	168	545	150	5	1150
		Mean	84.97	86.31	81.77	81.58	87.50	83.22
		SD	22.685	20.621	24.391	23.783	17.678	23.396

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			50-59YOA N = 298	60-69YOA N = 180	70-79YOA N = 600	80-89YOA N = 174	≥90YOA N = 5	Total N = 1257
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	282	168	545	150	5	1150
		Mean	88.71	85.71	82.19	80.11	91.67	84.07
		SD	19.689	19.626	24.402	27.236	18.634	23.233
	SF36 MH	N	282	168	545	150	5	1150
		Mean	78.65	79.46	77.96	76.88	85.00	78.24
		SD	20.450	18.499	21.074	19.546	8.660	20.318
	EQ5D Utility	N	280	169	543	149	5	1146
		Mean	0.8632	0.8542	0.8510	0.8380	0.7772	0.8524
		SD	0.14376	0.14799	0.14097	0.16438	0.23522	0.14637
	EQ5D VAS	N	281	169	542	148	5	1145
		Mean	83.90	81.44	80.84	79.77	88.00	81.57
		SD	12.968	16.198	17.033	18.945	13.038	16.303
Month 26	SF36 PF	N	279	165	531	138	5	1118
		Mean	83.01	75.72	70.93	60.14	63.00	73.28
		SD	19.227	23.836	23.033	28.991	39.937	24.185
	SF36 RP	N	279	165	531	137	5	1117
		Mean	85.19	80.72	81.54	77.33	90.00	81.85
		SD	24.104	26.231	24.481	29.481	15.687	25.360
	SF36 BP	N	279	165	530	137	5	1116
		Mean	71.00	70.36	68.78	69.27	82.80	69.69
		SD	27.237	27.282	26.178	27.348	25.830	26.737
	SF36 GH	N	279	165	531	138	5	1118
		Mean	78.58	78.01	72.41	73.33	88.60	74.96
		SD	19.528	17.338	19.986	18.938	15.258	19.553
	SF36 VT	N	279	165	531	137	5	1117
		Mean	73.54	73.98	70.76	70.80	66.25	71.92
		SD	21.184	21.209	21.857	23.595	12.960	21.804
	SF36 SF	N	279	165	531	137	5	1117
		Mean	86.51	85.30	86.46	82.30	82.50	85.78
		SD	23.473	23.261	21.544	25.030	16.771	22.726
	SF36 RE	N	279	165	530	137	5	1116
		Mean	87.90	87.12	84.72	83.64	93.33	85.78
		SD	20.638	19.918	21.162	25.171	10.865	21.389
	SF36 MH	N	279	165	531	137	5	1117
		Mean	78.66	82.27	79.07	79.60	94.00	79.57
		SD	19.785	19.266	20.080	20.838	6.519	19.974
	EQ5D Utility	N	278	164	530	138	5	1115
		Mean	0.8737	0.8557	0.8453	0.8438	0.7896	0.8535
		SD	0.14316	0.15006	0.14907	0.15372	0.21583	0.14893
	EQ5D VAS	N	278	165	531	138	5	1117
		Mean	84.40	82.57	80.50	81.38	97.00	81.96
		SD	12.248	17.164	16.344	18.575	4.472	15.919
Month 38	SF36 PF	N	277	159	524	130	4	1094
		Mean	81.77	75.10	67.45	60.19	35.00	71.21
		SD	20.636	22.519	25.040	29.090	38.079	25.322
	SF36 RP	N	277	159	525	130	4	1095
		Mean	85.53	81.01	77.29	78.41	87.50	80.08
		SD	23.826	25.323	26.918	28.157	25.000	26.268
	SF36 BP	N	277	159	525	130	4	1095
		Mean	70.84	70.55	66.99	69.09	79.00	68.77
		SD	26.910	25.409	26.634	28.847	19.967	26.803

			50-59YOA N = 298	60-69YOA N = 180	70-79YOA N = 600	80-89YOA N = 174	≥90YOA N = 5	Total N = 1257
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	277	159	525	130	4	1095
		Mean	76.73	76.82	71.03	69.84	74.25	73.18
		SD	20.750	17.954	19.566	22.159	13.500	20.140
	SF36 VT	N	277	159	525	130	4	1095
		Mean	72.07	70.05	70.62	68.22	68.75	70.61
		SD	21.739	19.853	20.053	21.469	19.764	20.626
	SF36 SF	N	277	159	525	130	4	1095
		Mean	86.64	84.28	82.69	81.92	78.13	83.81
		SD	20.213	21.105	22.832	23.453	21.348	22.055
	SF36 RE	N	277	159	525	130	4	1095
		Mean	88.12	85.48	82.13	82.95	93.75	84.27
		SD	21.161	21.011	23.775	23.952	12.500	22.853
	SF36 MH	N	277	159	525	130	4	1095
		Mean	78.64	79.35	77.59	76.31	77.50	77.96
		SD	20.141	19.119	20.286	20.189	16.583	20.046
	EQ5D Utility	N	277	159	524	130	4	1094
		Mean	0.8642	0.8499	0.8300	0.8289	0.7305	0.8410
		SD	0.14883	0.16270	0.16093	0.16939	0.28374	0.16028
	EQ5D VAS	N	277	159	524	130	4	1094
		Mean	83.69	81.97	80.48	79.86	74.25	81.41
		SD	15.717	15.384	15.942	19.125	14.104	16.253

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.3 SF-36 and EQ-5D components by time point, age group and country - Canada (Total Vaccinated Cohort)

			50-59YOA N = 231	60-69YOA N = 146	70-79YOA N = 780	80-89YOA N = 221	≥90YOA N = 14	Total N = 1392
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	225	146	768	212	14	1365
		Mean	82.48	85.27	76.07	64.74	50.56	76.09
		SD	21.348	19.434	22.148	23.777	32.305	23.037
	SF36 RP	N	228	146	776	221	14	1385
		Mean	85.77	88.78	79.42	74.66	76.34	80.66
		SD	23.450	17.119	23.575	24.042	28.817	23.449
	SF36 BP	N	225	145	769	212	14	1365
		Mean	74.27	79.56	75.07	72.00	90.71	75.10
		SD	23.802	20.079	22.863	24.629	16.597	23.078
	SF36 GH	N	228	146	777	221	14	1386
		Mean	78.02	80.83	78.89	76.29	77.29	78.52
		SD	17.082	15.055	16.043	16.814	22.224	16.334
	SF36 VT	N	228	145	777	220	14	1384
		Mean	69.76	74.57	72.51	68.55	76.34	71.69
		SD	18.814	15.497	16.334	16.553	17.191	16.811
	SF36 SF	N	228	145	777	221	14	1385
		Mean	89.47	94.57	91.43	89.65	91.96	91.16
		SD	19.070	13.078	16.200	17.424	20.573	16.701
	SF36 RE	N	228	146	776	220	14	1384
		Mean	90.46	93.04	88.23	84.02	92.86	88.48
		SD	19.018	14.714	19.340	21.900	10.770	19.363
	SF36 MH	N	228	145	777	220	14	1384
		Mean	81.30	85.90	83.61	82.60	89.64	83.37
		SD	15.508	12.289	14.424	14.123	15.375	14.410
	EQ5D Utility	N	228	146	772	219	14	1379
		Mean	0.8988	0.9174	0.8905	0.8581	0.8687	0.8894
		SD	0.12215	0.11215	0.11832	0.12766	0.18359	0.12153
	EQ5D VAS	N	229	146	774	220	14	1383
		Mean	84.52	85.92	84.08	80.23	85.71	83.75
		SD	12.753	12.339	12.020	13.857	13.425	12.586
Month 14	SF36 PF	N	227	143	756	204	11	1341
		Mean	83.46	84.00	72.70	59.90	42.22	73.53
		SD	21.307	21.375	24.935	27.113	26.010	25.628
	SF36 RP	N	227	143	756	204	11	1341
		Mean	85.13	88.81	75.61	66.70	57.39	77.13
		SD	24.424	19.126	25.812	25.978	29.291	25.882
	SF36 BP	N	226	143	756	203	11	1339
		Mean	74.12	74.74	72.26	70.99	73.64	72.65
		SD	25.627	21.775	24.370	24.400	26.504	24.338
	SF36 GH	N	227	143	756	204	11	1341
		Mean	76.37	78.48	75.49	70.59	66.64	75.14
		SD	20.286	17.613	17.881	16.342	16.901	18.174
	SF36 VT	N	226	143	755	203	11	1338
		Mean	68.09	73.16	68.75	64.77	56.25	68.40
		SD	21.203	16.944	18.898	17.539	19.162	19.040
	SF36 SF	N	226	143	756	203	11	1339
		Mean	89.27	91.78	87.81	84.61	54.55	87.72
		SD	20.741	16.053	19.895	19.511	28.653	19.983

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			50-59YOA N = 231	60-69YOA N = 146	70-79YOA N = 780	80-89YOA N = 221	≥90YOA N = 14	Total N = 1392
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	227	143	756	204	11	1341
		Mean	90.93	95.16	84.65	77.37	62.88	85.55
		SD	18.898	12.604	22.704	25.598	28.471	22.416
	SF36 MH	N	226	143	755	203	11	1338
		Mean	80.44	85.03	81.97	79.69	66.36	81.57
		SD	17.134	13.447	15.066	16.387	22.704	15.655
	EQ5D Utility	N	226	143	751	204	11	1335
		Mean	0.8767	0.8905	0.8656	0.8334	0.7984	0.8647
		SD	0.16884	0.13473	0.13866	0.13582	0.13749	0.14416
	EQ5D VAS	N	225	143	756	204	11	1339
		Mean	82.91	84.87	81.77	77.49	75.36	81.59
		SD	14.427	12.023	13.392	14.660	8.477	13.743
Month 26	SF36 PF	N	224	143	726	185	8	1286
		Mean	81.76	83.14	72.51	57.50	44.38	72.97
		SD	22.628	21.077	24.447	27.035	20.255	25.430
	SF36 RP	N	224	143	732	185	8	1292
		Mean	83.40	87.15	74.94	66.32	47.66	76.35
		SD	26.286	19.311	24.724	27.890	24.535	25.745
	SF36 BP	N	224	143	726	185	8	1286
		Mean	72.63	74.94	71.57	68.12	68.63	71.62
		SD	25.922	21.787	23.488	24.525	26.907	23.950
	SF36 GH	N	224	143	732	185	8	1292
		Mean	75.67	77.62	75.60	69.36	62.38	74.86
		SD	19.773	18.672	17.566	19.503	20.729	18.540
	SF36 VT	N	224	143	732	185	8	1292
		Mean	68.58	71.85	67.77	63.40	56.25	67.67
		SD	19.559	16.417	18.584	21.013	19.480	19.021
	SF36 SF	N	224	143	732	185	8	1292
		Mean	88.67	92.48	88.08	82.77	75.00	87.83
		SD	21.193	14.394	19.020	23.413	23.146	19.836
	SF36 RE	N	224	143	731	184	8	1290
		Mean	90.44	92.72	84.37	76.31	65.63	85.08
		SD	19.810	14.564	22.052	27.962	27.616	22.514
	SF36 MH	N	224	143	732	185	8	1292
		Mean	82.08	84.51	81.86	79.25	72.50	81.76
		SD	15.461	13.166	15.296	17.012	20.874	15.452
	EQ5D Utility	N	224	142	726	184	7	1283
		Mean	0.8763	0.8926	0.8664	0.8251	0.8261	0.8649
		SD	0.14534	0.10680	0.12369	0.15954	0.14061	0.13286
	EQ5D VAS	N	221	143	732	183	8	1287
		Mean	82.20	82.94	81.38	77.19	70.63	81.03
		SD	14.551	14.446	13.638	16.280	9.797	14.370
Month 38	SF36 PF	N	219	140	716	170	6	1251
		Mean	82.55	81.68	69.98	56.47	47.50	71.54
		SD	19.964	21.621	25.296	25.881	22.749	25.455
	SF36 RP	N	219	141	716	170	6	1252
		Mean	84.37	84.49	72.93	64.08	75.00	75.04
		SD	22.321	21.748	26.651	27.095	34.460	26.340
	SF36 BP	N	219	141	715	170	6	1251
		Mean	71.74	73.63	69.08	67.79	78.83	69.93
		SD	24.886	22.549	24.588	24.885	25.538	24.498

			50-59YOA N = 231	60-69YOA N = 146	70-79YOA N = 780	80-89YOA N = 221	≥90YOA N = 14	Total N = 1392
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	219	141	716	170	6	1252
		Mean	76.11	77.02	73.69	69.37	53.33	73.81
		SD	19.079	17.254	18.815	17.421	23.972	18.686
	SF36 VT	N	219	141	715	170	6	1251
		Mean	67.55	71.56	66.88	60.78	53.13	66.63
		SD	20.123	16.264	18.986	18.737	17.116	19.059
	SF36 SF	N	219	141	715	170	6	1251
		Mean	86.70	91.13	85.52	81.32	64.58	85.69
		SD	21.201	15.493	20.927	22.519	39.065	20.937
	SF36 RE	N	219	141	716	170	6	1252
		Mean	90.22	91.19	83.26	78.68	80.56	84.74
		SD	18.595	16.480	23.330	23.709	31.914	22.316
	SF36 MH	N	219	141	715	170	6	1251
		Mean	79.06	83.65	80.86	78.60	74.17	80.52
		SD	18.057	13.335	16.514	17.303	23.752	16.659
	EQ5D Utility	N	218	140	714	169	6	1247
		Mean	0.8730	0.8676	0.8493	0.8200	0.8365	0.8515
		SD	0.13173	0.13365	0.13863	0.14644	0.21277	0.13904
	EQ5D VAS	N	219	141	715	170	6	1251
		Mean	82.22	83.87	80.15	75.83	56.67	80.23
		SD	12.695	12.615	15.315	16.445	19.916	15.018

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.4 SF-36 and EQ-5D components by time point, age group and country - Czechia (Total Vaccinated Cohort)

			50-59YOA N = 485	60-69YOA N = 309	70-79YOA N = 388	80-89YOA N = 44	Total N = 1226
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	485	309	388	44	1226
		Mean	88.35	85.74	77.59	70.00	83.63
		SD	15.513	13.263	17.423	22.283	16.758
	SF36 RP	N	485	309	388	44	1226
		Mean	85.30	83.96	81.20	81.39	83.52
		SD	19.515	18.770	21.949	24.206	20.371
	SF36 BP	N	485	309	388	44	1226
		Mean	84.76	83.59	73.69	78.20	80.72
		SD	21.928	20.977	24.420	28.465	23.278
	SF36 GH	N	485	309	388	44	1226
		Mean	73.18	69.13	64.46	57.89	68.85
		SD	17.888	16.861	19.104	20.030	18.579
	SF36 VT	N	485	309	388	44	1226
		Mean	70.99	71.82	68.64	63.78	70.20
		SD	18.349	16.632	17.264	18.412	17.658
	SF36 SF	N	485	309	388	44	1226
		Mean	89.87	88.96	90.43	88.64	89.77
		SD	18.346	17.444	16.759	20.141	17.686
	SF36 RE	N	485	309	388	44	1226
		Mean	87.92	86.89	86.83	88.83	87.35
		SD	18.221	18.656	19.663	20.169	18.853
	SF36 MH	N	485	309	388	44	1226
		Mean	78.66	79.09	78.71	80.57	78.85
		SD	15.947	15.924	15.828	13.649	15.813
	EQ5D Utility	N	485	309	388	44	1226
		Mean	0.8979	0.8735	0.8455	0.8206	0.8724
		SD	0.11894	0.12507	0.13877	0.16406	0.13090
	EQ5D VAS	N	485	309	388	44	1226
		Mean	85.87	84.75	80.86	74.73	83.60
		SD	13.186	12.407	13.788	16.900	13.604
Month 14	SF36 PF	N	480	306	380	44	1210
		Mean	87.11	83.51	73.53	62.39	81.04
		SD	17.701	16.585	21.606	24.196	20.182
	SF36 RP	N	480	306	380	44	1210
		Mean	78.92	72.53	64.10	56.25	71.82
		SD	21.711	20.785	23.381	22.230	23.074
	SF36 BP	N	480	306	380	44	1210
		Mean	81.49	77.55	69.93	63.98	76.22
		SD	24.186	22.604	26.567	27.531	25.263
	SF36 GH	N	480	306	380	44	1210
		Mean	73.16	68.29	60.78	52.20	67.28
		SD	19.349	17.817	19.450	17.209	19.827
	SF36 VT	N	480	306	380	44	1210
		Mean	67.19	67.93	61.86	56.82	65.33
		SD	18.887	16.489	17.768	17.771	18.155
	SF36 SF	N	480	306	380	44	1210
		Mean	86.98	86.07	80.53	71.88	84.17
		SD	20.854	19.325	23.077	25.450	21.684

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			50-59YOA N = 485	60-69YOA N = 309	70-79YOA N = 388	80-89YOA N = 44	Total N = 1226
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 RE	N	480	306	380	44	1210
		Mean	82.38	79.11	73.44	67.61	78.21
		SD	20.386	19.941	21.530	22.173	21.121
	SF36 MH	N	480	306	380	44	1210
		Mean	75.30	74.90	72.41	70.91	74.13
		SD	17.352	16.401	17.257	14.796	17.039
	EQ5D Utility	N	480	306	380	44	1210
		Mean	0.8594	0.8310	0.7777	0.7163	0.8214
		SD	0.16129	0.15264	0.15234	0.14140	0.16054
	EQ5D VAS	N	480	306	380	44	1210
		Mean	86.23	85.27	80.20	73.00	83.61
		SD	15.369	13.345	14.958	16.081	15.134
Month 26	SF36 PF	N	475	303	379	42	1199
		Mean	84.94	81.02	69.05	58.81	78.01
		SD	19.231	17.556	24.825	25.467	22.368
	SF36 RP	N	475	303	379	42	1199
		Mean	74.47	70.73	59.83	53.87	68.18
		SD	21.014	20.081	22.660	24.730	22.493
	SF36 BP	N	475	303	379	42	1199
		Mean	77.97	74.93	65.65	65.10	72.86
		SD	23.882	24.076	26.597	27.003	25.494
	SF36 GH	N	475	303	379	42	1199
		Mean	69.39	65.68	57.74	49.76	64.08
		SD	20.527	17.503	19.813	19.735	20.318
	SF36 VT	N	475	303	379	42	1199
		Mean	64.86	65.08	57.90	54.61	62.35
		SD	18.915	16.573	17.406	19.427	18.222
	SF36 SF	N	475	303	379	42	1199
		Mean	84.61	84.28	77.11	71.13	81.68
		SD	21.655	20.318	23.980	24.768	22.531
	SF36 RE	N	475	303	379	42	1199
		Mean	79.91	78.30	69.99	67.46	75.93
		SD	20.665	20.051	23.339	26.913	22.099
	SF36 MH	N	475	303	379	42	1199
		Mean	73.00	74.17	70.78	69.52	72.47
		SD	17.869	15.941	16.801	13.740	16.970
	EQ5D Utility	N	475	303	379	42	1199
		Mean	0.8417	0.8122	0.7594	0.7034	0.8034
		SD	0.16040	0.14590	0.15809	0.13265	0.16000
	EQ5D VAS	N	475	303	379	42	1199
		Mean	84.15	82.54	77.45	73.24	81.24
		SD	15.293	13.864	16.067	14.052	15.485
Month 38	SF36 PF	N	473	300	366	38	1177
		Mean	84.26	79.98	68.67	58.03	77.48
		SD	19.970	19.108	24.354	27.743	22.752
	SF36 RP	N	473	300	366	38	1177
		Mean	74.37	68.77	59.02	53.78	67.50
		SD	21.259	20.264	22.188	26.854	22.564
	SF36 BP	N	473	300	366	38	1177
		Mean	77.56	72.30	65.48	65.42	72.07
		SD	25.309	24.192	26.223	27.651	25.893

			50-59YOA N = 485	60-69YOA N = 309	70-79YOA N = 388	80-89YOA N = 44	Total N = 1226
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 GH	N	473	300	366	38	1177
		Mean	70.29	65.03	57.09	56.21	64.39
		SD	20.265	18.260	18.625	19.540	20.053
	SF36 VT	N	473	300	366	38	1177
		Mean	66.13	65.29	59.31	60.20	63.60
		SD	18.014	16.768	16.871	20.623	17.688
	SF36 SF	N	473	300	366	38	1177
		Mean	85.49	83.54	77.90	69.74	82.13
		SD	21.511	20.433	23.070	29.008	22.341
	SF36 RE	N	473	300	366	38	1177
		Mean	79.60	75.53	68.40	69.96	74.77
		SD	20.956	21.894	22.311	26.462	22.306
	SF36 MH	N	473	300	366	38	1177
		Mean	74.10	74.03	69.97	73.42	72.78
		SD	17.167	16.648	16.655	17.519	16.972
	EQ5D Utility	N	473	300	366	38	1177
		Mean	0.8502	0.8079	0.7639	0.7088	0.8080
		SD	0.15832	0.15624	0.16840	0.15805	0.16581
	EQ5D VAS	N	473	300	366	38	1177
		Mean	84.99	82.32	78.42	72.95	81.88
		SD	14.260	14.550	15.864	19.374	15.349

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.5 SF-36 and EQ-5D components by time point, age group and country - Estonia (Total Vaccinated Cohort)

			50-59YOA N = 519	60-69YOA N = 324	70-79YOA N = 962	80-89YOA N = 314	≥90YOA N = 6	Total N = 2125
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	519	324	962	314	6	2125
		Mean	86.92	84.69	82.40	78.70	68.33	83.27
		SD	17.975	18.267	17.699	17.507	24.221	18.040
	SF36 RP	N	519	324	962	314	6	2125
		Mean	79.96	80.69	77.81	69.23	81.25	77.52
		SD	27.069	25.665	26.040	27.565	20.917	26.681
	SF36 BP	N	519	324	962	314	6	2125
		Mean	72.72	75.61	74.86	73.54	91.00	74.30
		SD	25.157	24.327	24.956	23.727	15.582	24.729
	SF36 GH	N	519	324	962	314	6	2125
		Mean	61.35	62.68	57.15	53.55	59.67	58.49
		SD	20.132	17.971	18.706	17.883	13.003	19.050
	SF36 VT	N	519	324	962	314	6	2125
		Mean	73.98	75.08	75.58	72.83	81.25	74.72
		SD	17.637	17.058	16.888	16.408	13.693	17.041
	SF36 SF	N	519	324	962	314	6	2125
		Mean	91.67	91.63	92.14	91.00	91.67	91.78
		SD	15.702	15.671	15.826	16.008	20.412	15.802
	SF36 RE	N	519	324	962	314	6	2125
		Mean	90.41	89.71	92.59	93.13	87.50	91.69
		SD	16.708	18.583	15.104	15.186	20.917	16.141
	SF36 MH	N	519	324	962	314	6	2125
		Mean	78.49	79.70	80.78	80.48	90.42	80.04
		SD	15.437	16.893	14.675	15.065	6.003	15.286
	EQ5D Utility	N	517	322	962	314	5	2120
		Mean	0.8386	0.8447	0.8431	0.8226	0.8584	0.8393
		SD	0.15103	0.14059	0.13194	0.13260	0.11295	0.13827
	EQ5D VAS	N	519	320	962	314	6	2121
		Mean	76.46	74.24	70.07	65.21	80.83	71.57
		SD	15.445	15.769	16.913	17.485	11.143	16.882
Month 14	SF36 PF	N	500	314	945	297	3	2059
		Mean	83.12	80.73	73.17	67.93	68.33	75.97
		SD	21.201	20.793	23.926	24.273	25.658	23.487
	SF36 RP	N	500	314	945	297	3	2059
		Mean	83.18	81.38	75.13	70.71	77.08	77.40
		SD	23.765	23.638	26.333	28.326	20.091	25.983
	SF36 BP	N	500	314	945	297	3	2059
		Mean	73.36	75.51	70.46	69.56	82.00	71.82
		SD	25.410	24.542	25.018	24.845	19.079	25.076
	SF36 GH	N	500	314	945	297	3	2059
		Mean	62.08	62.80	54.85	50.36	60.00	57.17
		SD	19.164	17.366	17.955	17.878	13.229	18.677
	SF36 VT	N	500	314	945	297	3	2059
		Mean	73.41	73.15	70.09	66.96	66.67	70.91
		SD	17.613	18.524	18.604	18.433	20.091	18.447
	SF36 SF	N	500	314	945	297	3	2059
		Mean	91.53	92.40	90.34	90.82	79.17	91.00
		SD	16.497	16.000	17.194	16.536	19.094	16.763

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			50-59YOA N = 519	60-69YOA N = 324	70-79YOA N = 962	80-89YOA N = 314	≥90YOA N = 6	Total N = 2125
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	500	314	945	297	3	2059
		Mean	87.67	88.30	84.66	86.22	80.56	86.16
		SD	19.272	18.650	22.556	22.497	26.788	21.264
	SF36 MH	N	500	314	945	297	3	2059
		Mean	79.37	80.37	78.66	79.26	73.33	79.17
		SD	15.971	17.432	16.866	15.611	25.658	16.572
	EQ5D Utility	N	498	314	944	297	3	2056
		Mean	0.8127	0.8046	0.7666	0.7415	0.5513	0.7796
		SD	0.16810	0.16669	0.15783	0.16274	0.24541	0.16461
	EQ5D VAS	N	499	314	945	297	3	2058
		Mean	78.05	76.47	68.90	64.34	66.67	71.61
		SD	15.219	15.741	17.712	18.324	25.166	17.646
Month 26	SF36 PF	N	499	312	929	289	2	2031
		Mean	75.27	70.53	62.38	56.57	40.00	65.95
		SD	24.567	24.419	25.540	26.284	21.213	26.066
	SF36 RP	N	498	313	928	289	2	2030
		Mean	75.68	72.20	64.28	59.21	34.38	67.55
		SD	26.147	25.553	28.063	28.403	30.936	27.894
	SF36 BP	N	499	312	928	289	2	2030
		Mean	68.28	70.05	64.78	62.93	52.00	66.18
		SD	26.459	25.358	24.538	24.219	0.000	25.194
	SF36 GH	N	499	313	929	289	2	2032
		Mean	57.99	56.80	49.46	45.80	35.00	52.15
		SD	19.344	18.078	17.928	16.387	7.071	18.654
	SF36 VT	N	499	312	929	289	2	2031
		Mean	67.82	67.53	62.98	61.56	50.00	64.66
		SD	18.449	18.175	19.858	18.676	8.839	19.248
	SF36 SF	N	499	313	929	289	2	2032
		Mean	85.22	85.02	83.64	84.13	87.50	84.31
		SD	21.036	20.286	21.543	21.637	17.678	21.233
	SF36 RE	N	498	313	928	289	2	2030
		Mean	79.97	76.30	72.11	70.70	66.67	74.48
		SD	23.970	24.448	26.647	28.269	47.140	26.156
	SF36 MH	N	499	312	929	289	2	2031
		Mean	75.05	75.77	74.43	75.48	75.00	74.94
		SD	17.658	18.085	17.741	16.006	21.213	17.531
	EQ5D Utility	N	497	311	927	288	2	2025
		Mean	0.7619	0.7403	0.6999	0.6737	0.7030	0.7176
		SD	0.17964	0.16960	0.17176	0.17654	0.14665	0.17669
	EQ5D VAS	N	499	313	927	289	2	2030
		Mean	73.55	70.11	63.51	59.26	60.00	66.39
		SD	18.744	16.880	18.710	18.496	14.142	19.086
Month 38	SF36 PF	N	493	309	913	277	2	1994
		Mean	72.81	68.48	54.74	48.06	15.00	60.37
		SD	24.875	23.857	24.612	23.989	21.213	26.153
	SF36 RP	N	493	309	912	277	2	1993
		Mean	73.64	67.64	57.13	51.96	40.63	62.11
		SD	25.667	26.056	26.763	23.791	22.097	27.161
	SF36 BP	N	493	309	913	277	2	1994
		Mean	65.79	64.03	56.64	52.27	70.50	59.45
		SD	25.030	22.565	22.090	21.311	41.719	23.335

			50-59YOA N = 519	60-69YOA N = 324	70-79YOA N = 962	80-89YOA N = 314	≥90YOA N = 6	Total N = 2125
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	493	309	913	277	2	1994
		Mean	55.90	54.44	44.88	40.83	55.00	48.53
		SD	18.682	17.851	15.692	15.082	0.000	17.687
	SF36 VT	N	493	309	913	277	2	1994
		Mean	66.47	63.41	60.43	56.23	46.88	61.79
		SD	18.755	19.020	18.527	17.626	4.419	18.816
	SF36 SF	N	493	309	912	277	2	1993
		Mean	84.18	82.40	80.77	77.89	62.50	81.45
		SD	21.102	21.960	20.668	22.234	17.678	21.281
	SF36 RE	N	493	309	912	277	2	1993
		Mean	78.72	72.06	66.83	63.93	87.50	70.20
		SD	23.486	25.092	26.137	27.498	17.678	26.084
	SF36 MH	N	493	309	913	277	2	1994
		Mean	74.48	72.25	72.97	71.91	72.50	73.08
		SD	17.755	18.946	16.801	15.538	3.536	17.225
	EQ5D Utility	N	492	309	911	277	2	1991
		Mean	0.7351	0.7068	0.6568	0.6288	0.6516	0.6800
		SD	0.17915	0.16406	0.15655	0.14858	0.07396	0.16682
	EQ5D VAS	N	493	309	911	277	2	1992
		Mean	73.49	69.74	61.49	55.49	50.00	64.89
		SD	18.022	16.173	17.198	17.014	0.000	18.325

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.6 SF-36 and EQ-5D components by time point, age group and country - Finland (Total Vaccinated Cohort)

			50-59YOA N = 638	60-69YOA N = 359	70-79YOA N = 1743	80-89YOA N = 385	Total N = 3125
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	635	356	1719	376	3086
		Mean	91.43	87.18	83.84	74.60	84.66
		SD	13.674	16.060	16.576	22.168	17.428
	SF36 RP	N	637	357	1720	374	3088
		Mean	93.44	90.56	85.46	74.36	86.35
		SD	15.866	16.606	20.583	23.576	20.421
	SF36 BP	N	636	355	1722	373	3086
		Mean	79.38	79.27	78.60	74.24	78.31
		SD	19.843	20.112	19.667	21.382	20.019
	SF36 GH	N	638	357	1735	383	3113
		Mean	77.56	75.57	71.45	64.27	72.29
		SD	16.526	16.453	16.115	17.173	16.823
	SF36 VT	N	637	353	1719	372	3081
		Mean	73.88	77.33	74.59	69.82	74.18
		SD	15.372	13.934	16.286	18.117	16.187
	SF36 SF	N	638	357	1731	377	3103
		Mean	93.97	95.13	94.45	91.68	94.09
		SD	13.521	12.410	12.079	16.230	13.016
	SF36 RE	N	637	356	1716	373	3082
		Mean	95.35	94.99	89.22	80.62	90.11
		SD	11.858	11.060	18.070	22.422	17.475
	SF36 MH	N	637	353	1718	371	3079
		Mean	85.98	87.71	86.83	85.08	86.54
		SD	11.760	11.560	12.639	14.193	12.558
	EQ5D Utility	N	625	347	1665	356	2993
		Mean	0.8991	0.8940	0.8736	0.8347	0.8767
		SD	0.15450	0.15163	0.15775	0.17124	0.15909
	EQ5D VAS	N	630	346	1649	352	2977
		Mean	85.59	85.68	83.28	79.28	83.57
		SD	12.081	9.986	11.440	13.059	11.773
Month 14	SF36 PF	N	611	346	1656	349	2962
		Mean	89.31	84.83	80.79	68.43	81.56
		SD	15.875	18.232	19.416	23.811	20.057
	SF36 RP	N	613	343	1661	347	2964
		Mean	90.25	86.95	82.18	69.24	82.89
		SD	19.129	19.559	22.907	27.243	23.143
	SF36 BP	N	614	345	1658	349	2966
		Mean	75.24	76.17	73.96	67.79	73.76
		SD	23.427	22.148	21.450	23.404	22.297
	SF36 GH	N	615	346	1668	350	2979
		Mean	75.22	73.32	67.99	61.58	69.35
		SD	17.925	17.677	17.229	18.267	18.022
	SF36 VT	N	614	343	1654	348	2959
		Mean	71.02	75.10	71.33	64.47	70.90
		SD	17.312	17.331	18.584	20.590	18.617
	SF36 SF	N	615	346	1665	350	2976
		Mean	92.38	93.21	92.24	88.82	91.98
		SD	16.333	15.636	15.558	19.726	16.306

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			50-59YOA N = 638	60-69YOA N = 359	70-79YOA N = 1743	80-89YOA N = 385	Total N = 3125
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 RE	N	613	342	1661	348	2964
		Mean	93.11	92.82	87.25	77.07	87.91
		SD	15.560	14.396	19.889	26.015	19.929
	SF36 MH	N	614	343	1654	349	2960
		Mean	85.25	86.58	85.79	83.42	85.49
		SD	12.742	12.538	13.473	15.727	13.528
	EQ5D Utility	N	601	339	1614	339	2893
		Mean	0.8722	0.8576	0.8395	0.7805	0.8415
		SD	0.16695	0.17101	0.16738	0.17648	0.17068
	EQ5D VAS	N	607	334	1636	341	2918
		Mean	83.25	83.03	81.13	75.65	81.15
		SD	13.460	13.363	13.109	14.490	13.553
Month 26	SF36 PF	N	608	336	1619	327	2890
		Mean	89.70	85.17	79.24	66.43	80.68
		SD	14.855	17.843	20.332	24.245	20.609
	SF36 RP	N	607	336	1622	326	2891
		Mean	90.29	87.70	79.62	66.26	81.29
		SD	19.233	20.784	24.790	28.016	24.688
	SF36 BP	N	608	334	1614	324	2880
		Mean	77.25	77.52	72.96	66.80	73.70
		SD	20.830	22.192	22.135	24.050	22.313
	SF36 GH	N	608	337	1628	330	2903
		Mean	74.28	72.23	66.93	59.58	68.25
		SD	18.467	18.313	17.526	18.565	18.451
	SF36 VT	N	607	336	1618	326	2887
		Mean	72.23	75.07	70.27	61.75	70.28
		SD	17.540	17.602	18.482	20.739	18.764
	SF36 SF	N	608	337	1626	329	2900
		Mean	93.15	92.62	90.92	86.93	91.13
		SD	15.022	16.669	16.771	20.315	16.940
	SF36 RE	N	607	336	1621	324	2888
		Mean	93.19	91.72	85.84	74.31	86.78
		SD	14.743	16.704	21.211	25.546	20.806
	SF36 MH	N	607	336	1617	327	2887
		Mean	85.68	86.76	84.80	82.03	84.90
		SD	12.941	13.313	14.353	16.521	14.261
	EQ5D Utility	N	593	333	1586	316	2828
		Mean	0.8714	0.8632	0.8336	0.7593	0.8367
		SD	0.16674	0.16519	0.17052	0.17710	0.17273
	EQ5D VAS	N	602	331	1593	320	2846
		Mean	84.24	83.67	80.57	73.32	80.89
		SD	13.145	11.940	13.012	15.355	13.565
Month 38	SF36 PF	N	602	335	1597	310	2844
		Mean	88.18	83.38	77.88	63.52	79.14
		SD	16.676	18.779	21.430	25.928	21.864
	SF36 RP	N	605	335	1601	309	2850
		Mean	88.36	85.50	78.81	62.55	79.86
		SD	20.411	22.412	24.139	29.253	24.883
	SF36 BP	N	606	335	1606	312	2859
		Mean	74.82	74.31	72.74	64.41	72.46
		SD	21.872	22.203	22.257	24.729	22.635

			50-59YOA N = 638	60-69YOA N = 359	70-79YOA N = 1743	80-89YOA N = 385	Total N = 3125
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 GH	N	606	337	1609	312	2864
		Mean	72.96	71.39	65.58	57.00	66.89
		SD	18.506	19.088	18.139	18.892	18.987
	SF36 VT	N	606	335	1603	310	2854
		Mean	71.64	73.27	69.43	59.81	69.30
		SD	17.897	18.036	18.927	21.410	19.226
	SF36 SF	N	606	337	1609	312	2864
		Mean	93.44	92.40	90.40	84.66	90.65
		SD	14.633	16.568	16.938	22.334	17.284
	SF36 RE	N	605	334	1600	309	2848
		Mean	93.75	90.23	85.00	70.52	85.90
		SD	12.891	17.493	21.203	27.972	21.204
	SF36 MH	N	606	335	1603	310	2854
		Mean	85.87	86.24	84.52	80.25	84.54
		SD	12.776	13.749	14.297	18.094	14.481
	EQ5D Utility	N	598	327	1566	303	2794
		Mean	0.8626	0.8501	0.8217	0.7400	0.8249
		SD	0.16706	0.17070	0.17234	0.18877	0.17615
	EQ5D VAS	N	601	332	1572	302	2807
		Mean	83.80	82.58	79.99	71.69	80.22
		SD	12.921	13.403	13.109	15.542	13.795

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.7 SF-36 and EQ-5D components by time point, age group and country - France (Total Vaccinated Cohort)

			50-59YOA N = 267	60-69YOA N = 202	70-79YOA N = 476	80-89YOA N = 184	≥90YOA N = 7	Total N = 1136
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	266	196	473	179	6	1120
		Mean	81.58	82.95	72.93	64.85	65.56	75.41
		SD	23.968	20.987	25.035	24.127	14.895	24.712
	SF36 RP	N	266	196	473	180	6	1121
		Mean	80.04	81.27	71.23	61.10	81.25	73.50
		SD	23.563	21.420	24.357	25.692	20.540	24.831
	SF36 BP	N	265	195	471	180	6	1117
		Mean	71.12	73.21	65.11	61.04	63.00	67.29
		SD	25.564	22.543	22.912	23.549	23.350	23.946
	SF36 GH	N	266	196	473	180	6	1121
		Mean	66.30	67.01	64.97	59.39	63.33	64.74
		SD	16.955	16.337	15.822	16.256	8.981	16.392
	SF36 VT	N	265	193	466	179	6	1109
		Mean	61.89	66.23	60.00	55.41	46.88	60.73
		SD	19.151	18.544	16.760	18.133	15.181	18.170
	SF36 SF	N	265	195	471	180	6	1117
		Mean	80.90	85.38	80.68	74.93	77.08	80.61
		SD	20.872	19.609	19.025	20.870	26.712	20.116
	SF36 RE	N	266	196	472	180	6	1120
		Mean	81.45	82.95	74.13	66.53	83.33	76.24
		SD	22.422	21.866	23.853	25.170	26.352	24.041
	SF36 MH	N	265	193	467	179	6	1110
		Mean	66.93	73.35	68.21	63.32	60.83	67.97
		SD	19.513	18.082	17.118	17.401	28.882	18.216
	EQ5D Utility	N	257	191	459	173	6	1086
		Mean	0.8600	0.8878	0.8117	0.7510	0.7618	0.8266
		SD	0.16855	0.14985	0.20899	0.24313	0.18593	0.20137
	EQ5D VAS	N	253	190	464	175	6	1088
		Mean	77.62	78.37	73.46	68.14	67.00	74.39
		SD	16.448	15.217	15.248	15.239	14.505	15.885
Month 14	SF36 PF	N	260	195	454	173	7	1089
		Mean	83.95	82.01	73.01	60.70	57.86	75.18
		SD	20.015	20.483	24.474	26.763	15.236	24.455
	SF36 RP	N	259	194	455	172	7	1087
		Mean	80.23	77.21	67.11	59.92	75.00	70.95
		SD	22.825	22.650	23.812	23.578	28.641	24.437
	SF36 BP	N	260	194	454	174	7	1089
		Mean	69.27	70.08	62.06	59.37	54.14	64.73
		SD	24.174	23.801	22.572	22.063	9.940	23.409
	SF36 GH	N	260	195	455	174	7	1091
		Mean	65.50	66.41	62.16	56.58	58.39	62.80
		SD	17.568	17.449	15.636	15.902	9.228	16.748
	SF36 VT	N	260	194	452	171	7	1084
		Mean	61.22	64.45	57.59	52.08	39.29	58.70
		SD	19.189	17.796	17.507	16.522	18.298	18.280
	SF36 SF	N	260	194	455	174	7	1090
		Mean	78.99	80.35	76.24	69.32	80.36	76.55
		SD	21.165	20.149	20.225	20.096	21.478	20.693

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			50-59YOA N = 267	60-69YOA N = 202	70-79YOA N = 476	80-89YOA N = 184	≥90YOA N = 7	Total N = 1136
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	259	194	454	171	7	1085
		Mean	79.70	78.09	71.38	63.65	76.19	73.38
		SD	24.043	22.883	22.619	24.334	25.198	23.899
	SF36 MH	N	260	194	451	171	7	1083
		Mean	67.58	69.96	66.53	62.83	59.82	66.77
		SD	18.831	17.943	17.619	18.441	21.752	18.228
	EQ5D Utility	N	251	192	439	172	6	1060
		Mean	0.8687	0.8725	0.7972	0.7110	0.8248	0.8139
		SD	0.18834	0.18568	0.23290	0.27856	0.14250	0.22983
	EQ5D VAS	N	252	188	439	169	7	1055
		Mean	77.22	77.51	71.60	67.67	62.43	73.30
		SD	15.355	14.167	15.456	15.448	12.012	15.614
Month 26	SF36 PF	N	243	181	421	157	7	1009
		Mean	84.19	80.56	72.36	58.24	55.00	74.36
		SD	19.645	22.832	24.249	25.631	18.257	24.684
	SF36 RP	N	243	183	421	158	7	1012
		Mean	77.87	75.43	64.89	54.10	65.18	68.23
		SD	23.848	22.484	23.835	24.184	24.436	25.003
	SF36 BP	N	243	180	420	155	7	1005
		Mean	69.09	66.41	60.62	54.70	56.14	62.76
		SD	24.921	24.493	21.965	24.261	12.294	23.949
	SF36 GH	N	243	184	422	158	7	1014
		Mean	64.28	64.64	61.02	54.85	55.71	61.46
		SD	19.036	17.892	16.279	15.724	13.048	17.457
	SF36 VT	N	241	180	421	157	7	1006
		Mean	59.36	62.81	56.37	50.11	41.07	57.15
		SD	20.112	20.462	16.803	19.195	18.349	19.107
	SF36 SF	N	243	181	421	157	7	1009
		Mean	77.47	77.14	75.33	66.96	75.00	74.86
		SD	22.159	22.393	20.798	21.184	27.951	21.775
	SF36 RE	N	243	183	421	158	7	1012
		Mean	80.32	76.14	68.66	58.33	79.76	71.27
		SD	22.589	23.306	23.568	23.832	23.500	24.405
	SF36 MH	N	241	180	421	157	7	1006
		Mean	66.50	67.02	66.23	59.88	55.71	65.37
		SD	19.361	21.280	16.970	17.778	20.702	18.671
	EQ5D Utility	N	239	177	410	153	7	986
		Mean	0.8768	0.8623	0.7970	0.6792	0.7479	0.8094
		SD	0.17987	0.19359	0.24381	0.28376	0.14333	0.23680
	EQ5D VAS	N	233	178	407	151	6	975
		Mean	77.98	76.43	71.35	65.99	60.83	72.97
		SD	15.904	15.063	15.275	15.979	6.524	16.001
Month 38	SF36 PF	N	245	180	412	153	6	996
		Mean	83.13	82.66	71.53	57.23	43.33	74.03
		SD	19.965	20.830	24.095	27.176	21.134	24.824
	SF36 RP	N	245	180	412	152	6	995
		Mean	77.30	75.49	64.55	53.84	57.29	67.99
		SD	24.694	23.155	23.047	24.883	21.439	25.099
	SF36 BP	N	245	180	412	152	6	995
		Mean	68.02	66.99	58.93	55.36	48.17	62.02
		SD	24.642	22.816	20.586	23.431	12.287	22.966

			50-59YOA N = 267	60-69YOA N = 202	70-79YOA N = 476	80-89YOA N = 184	≥90YOA N = 7	Total N = 1136
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	245	180	413	153	6	997
		Mean	63.25	64.78	59.78	53.93	54.33	60.60
		SD	18.119	17.093	15.725	16.581	11.396	17.031
	SF36 VT	N	245	180	409	153	6	993
		Mean	59.13	62.43	55.82	49.92	42.36	56.85
		SD	19.581	18.616	16.793	19.304	20.819	18.659
	SF36 SF	N	245	180	413	153	6	997
		Mean	76.58	76.25	72.67	68.63	77.08	73.68
		SD	22.507	22.505	20.150	23.347	22.936	21.831
	SF36 RE	N	245	180	412	153	6	996
		Mean	78.50	77.45	68.85	58.99	73.61	71.29
		SD	23.975	22.296	23.106	23.522	26.043	24.172
	SF36 MH	N	245	180	409	153	6	993
		Mean	65.69	68.02	65.98	61.14	59.17	65.49
		SD	18.735	19.371	16.748	19.112	17.440	18.203
	EQ5D Utility	N	240	178	402	151	6	977
		Mean	0.8467	0.8637	0.7937	0.6576	0.7323	0.7981
		SD	0.21904	0.20468	0.23203	0.29663	0.20956	0.24427
	EQ5D VAS	N	241	178	404	149	5	977
		Mean	77.92	78.05	71.15	67.34	59.60	73.44
		SD	15.714	13.548	14.802	14.097	13.390	15.264

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.8 SF-36 and EQ-5D components by time point, age group and country - Germany (Total Vaccinated Cohort)

			50-59YOA N = 283	60-69YOA N = 171	70-79YOA N = 1104	80-89YOA N = 353	≥90YOA N = 16	Total N = 1927
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	281	171	1099	349	15	1915
		Mean	84.39	81.17	74.82	61.80	57.81	74.28
		SD	21.074	21.097	23.884	26.967	24.426	24.865
	SF36 RP	N	283	170	1101	350	15	1919
		Mean	79.88	78.53	72.37	63.74	60.28	72.36
		SD	25.446	24.200	25.557	27.354	33.347	26.307
	SF36 BP	N	283	171	1101	350	15	1920
		Mean	74.72	74.67	72.65	65.20	77.33	71.81
		SD	29.033	26.769	26.736	28.152	27.562	27.520
	SF36 GH	N	283	171	1101	351	15	1921
		Mean	71.04	72.54	67.89	62.62	66.27	67.79
		SD	19.319	17.586	16.735	19.279	16.011	17.909
	SF36 VT	N	283	171	1098	351	15	1918
		Mean	67.17	70.98	67.04	59.88	61.67	66.06
		SD	20.051	18.211	17.646	20.396	16.682	18.835
	SF36 SF	N	283	171	1101	350	15	1920
		Mean	86.35	90.57	87.90	84.93	85.83	87.35
		SD	22.301	16.147	18.738	19.862	22.093	19.367
	SF36 RE	N	283	170	1100	350	15	1918
		Mean	84.69	87.30	80.83	75.05	65.56	80.80
		SD	24.354	22.080	24.329	26.600	39.323	24.970
	SF36 MH	N	283	171	1098	351	15	1918
		Mean	75.72	79.40	76.71	74.44	78.00	76.40
		SD	19.336	16.644	17.299	18.618	12.928	17.804
	EQ5D Utility	N	282	171	1096	346	15	1910
		Mean	0.9167	0.9093	0.8980	0.8234	0.8301	0.8877
		SD	0.15062	0.15620	0.15256	0.20768	0.18250	0.16705
	EQ5D VAS	N	281	170	1091	348	15	1905
		Mean	81.95	80.47	77.24	71.49	69.33	77.11
		SD	16.699	16.980	16.324	19.291	17.831	17.322
Month 14	SF36 PF	N	272	156	1028	322	14	1792
		Mean	83.33	77.56	71.59	53.82	52.98	70.55
		SD	20.840	22.125	24.999	28.249	26.716	26.402
	SF36 RP	N	273	157	1049	324	14	1817
		Mean	79.62	75.92	70.83	59.90	56.25	70.53
		SD	24.602	26.067	26.317	28.378	30.024	27.114
	SF36 BP	N	272	157	1048	324	14	1815
		Mean	72.68	71.80	69.24	60.22	73.43	68.40
		SD	28.408	27.466	27.602	27.752	31.561	28.031
	SF36 GH	N	273	157	1050	324	14	1818
		Mean	69.46	69.55	66.60	59.17	53.43	65.86
		SD	20.365	19.418	17.292	18.114	16.008	18.435
	SF36 VT	N	271	157	1048	324	14	1814
		Mean	65.38	69.71	65.13	57.09	57.59	64.07
		SD	20.311	18.128	19.222	19.396	14.745	19.605
	SF36 SF	N	273	157	1049	324	14	1817
		Mean	87.32	88.93	87.50	81.60	74.11	86.44
		SD	21.167	21.039	20.293	22.351	22.179	21.019

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			50-59YOA N = 283	60-69YOA N = 171	70-79YOA N = 1104	80-89YOA N = 353	≥90YOA N = 16	Total N = 1927
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	273	157	1049	323	14	1816
		Mean	83.39	85.83	78.95	71.80	71.43	78.88
		SD	22.313	21.834	25.996	28.921	27.095	26.001
	SF36 MH	N	271	157	1048	324	14	1814
		Mean	74.90	79.81	75.92	71.44	75.00	75.30
		SD	19.077	16.888	17.854	18.881	13.728	18.230
	EQ5D Utility	N	268	157	1034	320	14	1793
		Mean	0.8914	0.8964	0.8719	0.8034	0.8270	0.8644
		SD	0.18593	0.15175	0.17447	0.22114	0.23885	0.18635
	EQ5D VAS	N	269	157	1044	319	14	1803
		Mean	80.04	77.95	74.32	66.74	67.29	74.09
		SD	16.756	16.879	18.044	19.390	11.841	18.406
Month 26	SF36 PF	N	272	159	1032	293	13	1769
		Mean	82.27	75.94	68.91	54.15	50.51	69.01
		SD	21.093	24.187	25.742	27.869	23.048	26.633
	SF36 RP	N	272	159	1034	293	13	1771
		Mean	77.02	74.71	67.87	57.21	46.63	67.97
		SD	25.692	25.090	27.557	28.786	26.469	27.948
	SF36 BP	N	272	160	1034	292	13	1771
		Mean	71.64	74.69	66.06	59.92	76.92	66.77
		SD	29.857	24.966	28.346	28.183	27.960	28.555
	SF36 GH	N	273	160	1034	293	13	1773
		Mean	68.10	69.98	64.48	59.67	52.77	64.65
		SD	20.012	18.703	18.022	18.267	18.331	18.682
	SF36 VT	N	273	159	1033	292	13	1770
		Mean	63.58	69.71	63.06	56.04	51.44	62.50
		SD	20.932	20.212	19.299	19.178	15.761	19.903
	SF36 SF	N	273	160	1034	293	13	1773
		Mean	83.79	89.22	85.40	82.25	67.31	84.84
		SD	22.368	18.035	20.219	23.515	35.553	21.200
	SF36 RE	N	272	160	1034	293	13	1772
		Mean	81.10	84.61	78.09	69.85	77.56	77.77
		SD	24.910	22.023	25.807	29.773	27.298	26.354
	SF36 MH	N	273	159	1032	292	13	1769
		Mean	73.85	81.11	74.45	71.70	73.08	74.49
		SD	20.852	15.721	18.291	18.228	11.821	18.575
	EQ5D Utility	N	273	160	1024	289	13	1759
		Mean	0.8976	0.9154	0.8570	0.7836	0.7923	0.8561
		SD	0.16552	0.13028	0.19071	0.22533	0.28707	0.19313
	EQ5D VAS	N	272	160	1028	291	13	1764
		Mean	77.39	76.79	72.82	64.92	57.69	72.47
		SD	18.273	17.805	18.336	19.390	23.368	18.917
Month 38	SF36 PF	N	269	155	1005	264	11	1704
		Mean	79.64	73.97	66.84	48.51	45.35	66.53
		SD	23.581	23.130	26.701	28.269	23.208	27.718
	SF36 RP	N	269	155	1003	264	11	1702
		Mean	77.04	69.35	64.98	51.81	46.59	65.12
		SD	25.079	25.757	27.497	28.358	26.570	28.052
	SF36 BP	N	269	155	1004	263	11	1702
		Mean	69.90	68.71	64.87	56.66	72.18	64.79
		SD	27.841	28.625	27.969	28.931	31.767	28.435

			50-59YOA N = 283	60-69YOA N = 171	70-79YOA N = 1104	80-89YOA N = 353	≥90YOA N = 16	Total N = 1927
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	269	155	1005	264	11	1704
		Mean	69.05	64.33	62.73	56.98	52.45	62.92
		SD	19.372	19.050	18.865	18.441	17.300	19.191
	SF36 VT	N	269	155	1002	264	11	1701
		Mean	63.45	63.91	61.40	52.26	48.86	60.45
		SD	18.768	19.956	19.472	21.351	16.493	20.033
	SF36 SF	N	269	155	1005	264	11	1704
		Mean	83.55	87.02	83.08	77.60	67.05	82.56
		SD	21.463	19.681	22.709	27.005	29.194	23.166
	SF36 RE	N	269	154	1002	264	11	1700
		Mean	81.88	80.25	75.37	67.23	74.24	75.57
		SD	23.376	24.606	26.739	30.343	29.687	26.996
	SF36 MH	N	269	155	1002	264	11	1701
		Mean	73.96	75.72	72.95	69.34	72.61	72.80
		SD	18.971	17.931	18.535	19.245	16.245	18.705
	EQ5D Utility	N	267	154	997	263	11	1692
		Mean	0.8801	0.8668	0.8389	0.7494	0.7527	0.8335
		SD	0.18196	0.17438	0.20617	0.24259	0.25085	0.20997
	EQ5D VAS	N	269	153	1000	264	11	1697
		Mean	77.46	74.04	71.02	62.08	51.55	70.79
		SD	17.152	17.395	18.673	19.378	24.043	19.049

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.9 SF-36 and EQ-5D components by time point, age group and country - Hong Kong (Total Vaccinated Cohort)

			50-59YOA N = 247	60-69YOA N = 154	70-79YOA N = 208	80-89YOA N = 39	≥90YOA N = 2	Total N = 650
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	247	154	207	38	2	648
		Mean	87.67	86.59	77.93	69.08	87.50	83.21
		SD	13.628	16.227	20.087	24.213	10.607	18.057
	SF36 RP	N	247	154	207	38	2	648
		Mean	83.25	84.42	75.54	71.55	71.88	80.34
		SD	18.993	18.569	23.861	26.782	39.775	21.511
	SF36 BP	N	247	154	207	38	2	648
		Mean	73.76	73.10	66.77	65.45	100.00	70.96
		SD	23.023	22.572	25.227	25.057	0.000	23.972
	SF36 GH	N	247	154	207	38	2	648
		Mean	66.88	67.18	61.80	60.45	77.00	64.98
		SD	17.500	17.052	19.485	19.264	0.000	18.295
	SF36 VT	N	247	154	206	38	2	647
		Mean	68.60	71.27	64.38	62.50	75.00	67.55
		SD	16.284	17.261	19.381	24.009	0.000	18.230
	SF36 SF	N	247	154	207	38	2	648
		Mean	87.45	88.64	82.73	79.93	93.75	85.80
		SD	16.698	15.874	19.646	24.235	8.839	18.176
	SF36 RE	N	247	154	207	38	2	648
		Mean	83.97	84.04	80.48	72.37	75.00	82.16
		SD	18.201	16.936	20.152	24.820	35.355	19.210
	SF36 MH	N	247	154	206	38	2	647
		Mean	75.69	76.04	75.36	70.39	97.50	75.43
		SD	15.306	16.644	17.446	23.173	3.536	16.891
	EQ5D Utility	N	247	154	207	38	2	648
		Mean	0.9061	0.8865	0.8394	0.8014	1.0000	0.8743
		SD	0.12786	0.12919	0.14346	0.18047	0.00000	0.14053
	EQ5D VAS	N	247	154	207	38	2	648
		Mean	84.62	84.19	79.11	77.76	74.50	82.32
		SD	10.943	12.068	13.212	15.143	7.778	12.502
Month 14	SF36 PF	N	241	150	195	35	1	622
		Mean	84.77	82.70	73.33	62.14	45.00	79.35
		SD	16.376	18.875	21.479	24.323	0.000	20.242
	SF36 RP	N	241	150	195	35	1	622
		Mean	78.42	77.92	70.00	69.11	62.50	75.11
		SD	22.345	22.138	25.101	28.599	0.000	23.850
	SF36 BP	N	241	150	195	35	1	622
		Mean	69.46	69.07	66.86	59.83	52.00	67.98
		SD	23.267	25.076	24.747	25.559	0.000	24.349
	SF36 GH	N	241	150	195	35	1	622
		Mean	63.99	65.44	59.11	53.49	72.00	62.23
		SD	19.006	18.229	20.009	19.394	0.000	19.396
	SF36 VT	N	241	150	195	35	1	622
		Mean	64.83	66.33	63.08	58.57	50.00	64.27
		SD	18.525	17.983	19.396	24.958	0.000	19.121
	SF36 SF	N	241	150	195	35	1	622
		Mean	83.61	84.67	79.36	72.14	50.00	81.83
		SD	19.857	19.599	22.387	26.095	0.000	21.223

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			50-59YOA N = 247	60-69YOA N = 154	70-79YOA N = 208	80-89YOA N = 39	≥90YOA N = 2	Total N = 650
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	241	150	195	35	1	622
		Mean	80.98	80.50	73.21	73.57	66.67	77.99
		SD	20.276	21.607	24.118	27.153	0.000	22.505
	SF36 MH	N	241	150	195	35	1	622
		Mean	74.56	73.40	73.97	69.43	65.00	73.79
		SD	17.209	16.120	17.826	22.484	0.000	17.471
	EQ5D Utility	N	239	150	195	35	1	620
		Mean	0.8648	0.8496	0.8158	0.7558	1.0000	0.8398
		SD	0.14758	0.14703	0.15819	0.17967	0.00000	0.15518
	EQ5D VAS	N	241	150	195	35	1	622
		Mean	81.19	83.89	79.92	76.06	70.00	81.14
		SD	13.248	12.146	12.927	16.345	0.000	13.191
Month 26	SF36 PF	N	239	149	186	30	0	604
		Mean	85.29	80.47	70.50	62.67	-	78.42
		SD	15.769	21.540	23.985	25.722	-	21.721
	SF36 RP	N	239	149	186	30	0	604
		Mean	80.91	75.29	70.55	66.67	-	75.63
		SD	21.130	24.567	25.945	25.656	-	24.198
	SF36 BP	N	239	149	186	30	0	604
		Mean	71.64	69.42	64.06	64.97	-	68.43
		SD	23.317	23.487	23.950	23.394	-	23.730
	SF36 GH	N	239	149	186	30	0	604
		Mean	63.43	63.45	57.71	54.50	-	61.23
		SD	19.507	18.248	21.907	19.456	-	20.163
	SF36 VT	N	239	149	186	30	0	604
		Mean	64.36	65.56	61.63	58.33	-	63.51
		SD	20.207	18.303	19.756	22.345	-	19.771
	SF36 SF	N	239	149	186	30	0	604
		Mean	84.68	81.96	75.54	80.00	-	80.96
		SD	19.341	21.375	24.791	19.028	-	21.922
	SF36 RE	N	239	149	186	30	0	604
		Mean	81.97	79.19	71.68	74.44	-	77.75
		SD	19.984	21.912	25.590	27.240	-	23.055
	SF36 MH	N	239	149	186	30	0	604
		Mean	73.95	74.60	71.60	69.17	-	73.15
		SD	16.416	15.569	17.224	16.246	-	16.489
	EQ5D Utility	N	237	148	186	30	0	601
		Mean	0.8817	0.8559	0.8016	0.7969	-	0.8463
		SD	0.14774	0.15726	0.16066	0.15003	-	0.15796
	EQ5D VAS	N	239	149	186	30	0	604
		Mean	80.46	82.11	77.90	71.83	-	79.65
		SD	14.530	11.798	13.988	19.131	-	14.173
Month 38	SF36 PF	N	238	144	186	27	0	595
		Mean	85.57	79.20	68.78	58.33	-	77.54
		SD	15.583	21.796	25.913	27.735	-	22.833
	SF36 RP	N	238	144	186	27	0	595
		Mean	80.00	74.26	66.77	62.27	-	73.67
		SD	20.347	23.508	28.140	27.653	-	24.805
	SF36 BP	N	238	144	186	27	0	595
		Mean	71.07	65.80	63.87	66.52	-	67.34
		SD	22.893	23.515	26.549	25.162	-	24.483

			50-59YOA N = 247	60-69YOA N = 154	70-79YOA N = 208	80-89YOA N = 39	≥90YOA N = 2	Total N = 650
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	238	144	186	27	0	595
		Mean	64.77	62.93	56.99	53.78	-	61.39
		SD	19.118	19.019	20.325	18.048	-	19.740
	SF36 VT	N	238	144	186	27	0	595
		Mean	66.62	66.49	59.58	59.26	-	64.05
		SD	19.074	18.205	23.396	22.692	-	20.721
	SF36 SF	N	238	144	186	27	0	595
		Mean	85.66	83.07	75.81	78.24	-	81.62
		SD	18.044	20.878	25.389	22.088	-	21.797
	SF36 RE	N	238	144	186	27	0	595
		Mean	81.97	78.99	68.15	68.52	-	76.32
		SD	21.122	21.992	27.490	24.387	-	24.373
	SF36 MH	N	238	144	186	27	0	595
		Mean	74.45	75.87	68.76	70.19	-	72.82
		SD	16.780	15.648	18.301	19.038	-	17.329
	EQ5D Utility	N	238	144	186	27	0	595
		Mean	0.8757	0.8480	0.7956	0.7738	-	0.8393
		SD	0.13771	0.15032	0.16724	0.16356	-	0.15566
	EQ5D VAS	N	238	144	186	27	0	595
		Mean	82.53	83.78	76.82	72.93	-	80.61
		SD	11.741	11.392	15.598	17.705	-	13.669

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.10 SF-36 and EQ-5D components by time point, age group and country - Italy (Total Vaccinated Cohort)

			50-59YOA N = 114	60-69YOA N = 79	70-79YOA N = 77	80-89YOA N = 9	Total N = 279
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	114	79	76	9	278
		Mean	88.40	90.51	81.80	67.78	86.53
		SD	21.227	12.850	21.359	20.327	19.730
	SF36 RP	N	114	79	75	9	277
		Mean	87.01	81.96	77.42	64.58	82.24
		SD	21.412	21.206	24.658	30.136	23.022
	SF36 BP	N	114	79	76	9	278
		Mean	81.23	77.68	72.63	72.89	77.60
		SD	21.474	23.626	22.334	24.982	22.612
	SF36 GH	N	114	79	76	9	278
		Mean	72.12	69.85	64.17	57.56	68.83
		SD	16.483	16.320	16.906	17.436	16.936
	SF36 VT	N	114	79	76	9	278
		Mean	71.45	69.86	65.43	61.11	69.02
		SD	14.295	16.529	18.112	21.144	16.438
	SF36 SF	N	114	79	76	9	278
		Mean	84.43	83.23	82.57	76.39	83.32
		SD	18.031	17.321	19.048	18.162	18.086
	SF36 RE	N	114	79	75	9	277
		Mean	87.43	79.96	77.67	62.04	81.83
		SD	20.147	24.406	24.780	28.294	23.533
	SF36 MH	N	114	79	76	9	278
		Mean	77.37	73.42	72.83	56.67	74.33
		SD	13.877	19.091	16.620	23.452	16.931
	EQ5D Utility	N	113	78	76	9	276
		Mean	0.8674	0.8272	0.7669	0.6696	0.8219
		SD	0.12975	0.13137	0.16052	0.17684	0.14860
	EQ5D VAS	N	114	77	75	9	275
		Mean	83.32	79.69	75.76	69.78	79.80
		SD	11.923	13.510	13.074	16.285	13.270
Month 14	SF36 PF	N	105	75	77	7	264
		Mean	92.19	86.93	82.40	72.14	87.31
		SD	12.593	15.680	16.674	23.954	15.749
	SF36 RP	N	105	75	77	7	264
		Mean	86.85	80.83	73.78	68.75	80.85
		SD	18.908	21.634	22.987	36.622	22.119
	SF36 BP	N	105	75	76	7	263
		Mean	83.30	75.51	66.33	86.29	76.25
		SD	22.574	25.339	19.550	17.105	23.474
	SF36 GH	N	105	75	77	7	264
		Mean	71.60	66.84	63.11	58.86	67.43
		SD	15.926	15.419	15.641	7.244	15.923
	SF36 VT	N	105	75	77	7	264
		Mean	68.81	67.17	64.69	65.18	67.05
		SD	15.828	18.526	14.684	15.248	16.316
	SF36 SF	N	105	75	77	7	264
		Mean	84.64	84.00	78.73	87.50	82.81
		SD	18.366	17.744	19.875	10.206	18.593

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			50-59YOA N = 114	60-69YOA N = 79	70-79YOA N = 77	80-89YOA N = 9	Total N = 279
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 RE	N	105	75	77	7	264
		Mean	87.22	82.33	78.90	76.19	83.11
		SD	17.375	18.682	21.012	22.786	19.246
	SF36 MH	N	105	75	77	7	264
		Mean	75.19	72.87	72.86	64.29	73.56
		SD	14.226	17.246	15.205	21.876	15.655
	EQ5D Utility	N	104	74	76	7	261
		Mean	0.8969	0.8236	0.7744	0.8190	0.8383
		SD	0.12218	0.13386	0.13723	0.11482	0.13899
	EQ5D VAS	N	102	75	76	7	260
		Mean	83.26	77.91	76.89	78.14	79.72
		SD	10.709	15.480	12.829	6.256	13.041
Month 26	SF36 PF	N	102	71	72	6	251
		Mean	91.60	85.48	81.13	63.33	86.19
		SD	15.058	17.561	20.907	21.370	18.527
	SF36 RP	N	102	71	72	6	251
		Mean	87.07	75.70	73.61	45.83	79.01
		SD	16.878	25.954	24.017	33.463	23.544
	SF36 BP	N	102	71	72	6	251
		Mean	79.84	71.85	70.49	65.00	74.54
		SD	21.982	26.116	24.009	24.315	24.129
	SF36 GH	N	102	71	72	6	251
		Mean	69.58	67.52	60.01	54.33	65.89
		SD	15.961	15.167	17.254	11.911	16.558
	SF36 VT	N	102	71	72	6	251
		Mean	69.73	67.05	62.85	55.21	66.65
		SD	13.871	17.864	17.736	11.468	16.440
	SF36 SF	N	102	71	72	6	251
		Mean	84.44	78.70	77.43	68.75	80.43
		SD	16.728	22.300	20.730	23.385	19.963
	SF36 RE	N	102	71	72	6	251
		Mean	88.89	78.64	79.86	51.39	82.50
		SD	15.439	20.351	24.134	36.673	21.230
	SF36 MH	N	102	71	72	6	251
		Mean	76.47	72.06	69.03	61.67	72.73
		SD	12.947	17.630	18.321	28.048	16.689
	EQ5D Utility	N	102	71	71	6	250
		Mean	0.8957	0.8165	0.7884	0.7763	0.8398
		SD	0.11520	0.13938	0.15595	0.11714	0.14228
	EQ5D VAS	N	102	71	72	6	251
		Mean	82.71	77.83	74.99	71.33	78.84
		SD	10.663	13.618	12.878	14.720	12.701
Month 38	SF36 PF	N	100	68	69	6	243
		Mean	89.40	86.25	77.46	73.33	84.73
		SD	14.058	14.413	22.616	28.048	18.063
	SF36 RP	N	100	68	69	6	243
		Mean	84.13	81.25	65.76	54.17	77.37
		SD	19.532	20.545	25.424	32.516	23.479
	SF36 BP	N	100	68	68	6	242
		Mean	79.22	73.91	64.59	54.67	73.01
		SD	23.287	23.000	22.066	34.961	23.983

			50-59YOA N = 114	60-69YOA N = 79	70-79YOA N = 77	80-89YOA N = 9	Total N = 279
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 GH	N	100	68	69	6	243
		Mean	67.59	65.60	56.49	53.00	63.52
		SD	16.872	16.600	17.119	18.719	17.528
	SF36 VT	N	99	68	67	6	240
		Mean	67.17	66.27	57.21	46.88	63.63
		SD	15.370	18.645	19.812	25.233	18.488
	SF36 SF	N	100	68	68	6	242
		Mean	82.00	81.80	72.61	62.50	78.82
		SD	18.661	18.881	22.262	26.220	20.455
	SF36 RE	N	100	68	68	6	242
		Mean	85.17	81.74	71.32	54.17	79.55
		SD	20.016	20.425	25.078	29.226	22.863
	SF36 MH	N	99	68	67	6	240
		Mean	74.55	70.96	66.47	53.33	70.74
		SD	14.017	19.817	17.119	26.957	17.479
	EQ5D Utility	N	99	68	69	6	242
		Mean	0.8662	0.8239	0.7519	0.6869	0.8173
		SD	0.12892	0.15479	0.17280	0.24908	0.16055
	EQ5D VAS	N	98	68	69	6	241
		Mean	80.58	77.21	72.94	70.50	77.19
		SD	11.650	17.158	14.792	14.734	14.648

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.11 SF-36 and EQ-5D components by time point, age group and country - Japan (Total Vaccinated Cohort)

			50-59YOA N = 212	60-69YOA N = 109	70-79YOA N = 347	80-89YOA N = 104	Total N = 772
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	212	109	347	103	771
		Mean	93.73	93.17	87.58	78.77	88.88
		SD	8.614	7.536	12.299	18.801	12.908
	SF36 RP	N	212	109	347	103	771
		Mean	95.37	95.53	89.57	88.17	91.82
		SD	12.446	11.665	17.915	19.529	16.302
	SF36 BP	N	212	109	347	103	771
		Mean	83.83	82.26	81.94	81.41	82.43
		SD	20.206	19.149	19.021	19.726	19.448
	SF36 GH	N	212	109	347	103	771
		Mean	71.73	69.79	70.30	70.85	70.69
		SD	15.155	14.752	16.081	16.986	15.760
	SF36 VT	N	212	109	347	103	771
		Mean	72.23	74.43	74.89	71.36	73.62
		SD	16.135	16.105	17.433	17.990	17.006
	SF36 SF	N	212	109	347	103	771
		Mean	93.51	94.61	91.50	91.99	92.56
		SD	13.631	11.707	16.093	14.629	14.706
	SF36 RE	N	212	109	347	103	771
		Mean	94.93	94.19	91.26	90.86	92.63
		SD	12.602	13.490	17.013	17.601	15.595
	SF36 MH	N	212	109	347	103	771
		Mean	81.06	81.56	81.20	81.26	81.22
		SD	15.104	14.055	15.519	16.160	15.266
	EQ5D Utility	N	212	109	346	103	770
		Mean	0.9343	0.9424	0.9049	0.8717	0.9139
		SD	0.13714	0.10409	0.12470	0.15151	0.13118
	EQ5D VAS	N	212	109	347	103	771
		Mean	81.50	80.73	80.49	77.72	80.43
		SD	12.837	12.391	11.766	14.410	12.559
Month 14	SF36 PF	N	205	108	331	94	738
		Mean	94.20	92.82	88.54	80.32	89.69
		SD	8.148	7.772	12.086	16.813	12.128
	SF36 RP	N	205	108	331	94	738
		Mean	95.40	89.81	91.43	85.04	91.48
		SD	12.406	18.732	17.248	22.248	17.297
	SF36 BP	N	205	108	331	94	738
		Mean	83.67	80.58	79.83	73.36	80.18
		SD	19.323	23.934	21.427	23.912	21.763
	SF36 GH	N	205	108	331	94	738
		Mean	70.43	69.69	72.61	72.10	71.51
		SD	16.551	15.534	16.722	17.724	16.647
	SF36 VT	N	205	108	331	94	738
		Mean	71.95	71.53	75.94	72.27	73.72
		SD	18.551	19.132	18.200	18.389	18.533
	SF36 SF	N	205	108	331	94	738
		Mean	93.84	90.97	92.48	92.55	92.65
		SD	14.572	18.233	16.069	13.757	15.728

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			50-59YOA N = 212	60-69YOA N = 109	70-79YOA N = 347	80-89YOA N = 104	Total N = 772
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 RE	N	205	108	331	94	738
		Mean	96.02	91.74	92.15	88.56	92.71
		SD	10.776	16.292	16.501	19.049	15.618
	SF36 MH	N	205	108	331	94	738
		Mean	81.44	79.86	82.99	81.76	81.94
		SD	15.033	16.341	16.746	17.730	16.363
	EQ5D Utility	N	204	108	331	94	737
		Mean	0.9296	0.9288	0.8943	0.8316	0.9011
		SD	0.12019	0.11429	0.13884	0.17689	0.13948
	EQ5D VAS	N	205	108	331	94	738
		Mean	81.63	78.53	82.53	81.22	81.53
		SD	13.969	14.739	11.592	12.438	12.924
Month 26	SF36 PF	N	201	107	322	93	723
		Mean	93.71	91.12	86.75	75.97	87.94
		SD	9.517	12.688	12.887	22.107	14.652
	SF36 RP	N	201	107	322	93	723
		Mean	95.52	92.11	90.10	78.36	90.40
		SD	11.205	18.178	17.822	28.560	18.839
	SF36 BP	N	201	107	322	93	723
		Mean	84.12	81.83	78.67	74.58	80.13
		SD	19.276	20.051	20.746	24.051	20.899
	SF36 GH	N	201	107	322	93	723
		Mean	70.20	68.56	70.49	70.17	70.08
		SD	16.506	16.016	16.962	19.679	17.053
	SF36 VT	N	201	107	322	93	723
		Mean	70.90	72.31	74.88	70.77	72.86
		SD	18.474	18.072	17.511	20.003	18.257
	SF36 SF	N	201	107	322	93	723
		Mean	93.84	92.29	91.11	88.84	91.75
		SD	13.470	15.797	16.862	18.473	16.104
	SF36 RE	N	201	107	322	93	723
		Mean	95.23	93.46	92.24	87.37	92.62
		SD	12.572	17.323	15.345	20.837	15.921
	SF36 MH	N	201	107	322	93	723
		Mean	81.07	81.78	83.07	82.46	82.25
		SD	15.976	16.067	15.629	15.486	15.763
	EQ5D Utility	N	201	106	322	92	721
		Mean	0.9260	0.9185	0.8779	0.8201	0.8899
		SD	0.12076	0.12255	0.13408	0.15797	0.13631
	EQ5D VAS	N	201	107	322	93	723
		Mean	82.39	80.50	82.45	79.51	81.76
		SD	15.092	12.577	12.723	14.069	13.591
Month 38	SF36 PF	N	199	104	317	82	702
		Mean	93.54	91.63	85.88	75.12	87.65
		SD	11.421	11.894	16.941	20.291	16.327
	SF36 RP	N	199	104	317	82	702
		Mean	93.69	92.43	88.35	82.24	89.75
		SD	15.514	16.925	20.023	24.581	19.328
	SF36 BP	N	199	104	317	82	702
		Mean	82.64	80.62	80.37	74.66	80.38
		SD	20.030	21.311	21.298	24.177	21.386

			50-59YOA N = 212	60-69YOA N = 109	70-79YOA N = 347	80-89YOA N = 104	Total N = 772
Timepoint	Component	Parameters	Value	Value	Value	Value	Value
	SF36 GH	N	199	104	317	82	702
		Mean	70.50	70.03	69.08	69.93	69.72
		SD	17.390	17.140	18.121	18.548	17.798
	SF36 VT	N	199	104	317	82	702
		Mean	69.63	74.16	73.64	66.69	71.77
		SD	19.341	18.882	19.814	20.437	19.749
	SF36 SF	N	199	104	317	82	702
		Mean	94.10	93.63	90.62	88.57	91.81
		SD	12.550	13.379	18.754	20.431	16.776
	SF36 RE	N	199	104	317	82	702
		Mean	94.81	93.83	89.80	86.59	91.44
		SD	14.173	14.825	19.244	21.507	17.817
	SF36 MH	N	199	104	317	82	702
		Mean	81.43	82.12	81.77	81.46	81.69
		SD	15.402	16.350	16.877	18.400	16.549
	EQ5D Utility	N	199	104	317	82	702
		Mean	0.9328	0.9193	0.8786	0.8324	0.8946
		SD	0.11798	0.13392	0.15110	0.16395	0.14504
	EQ5D VAS	N	199	104	317	82	702
		Mean	82.48	79.84	80.59	77.50	80.65
		SD	12.638	12.338	13.565	14.742	13.332

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.12 SF-36 and EQ-5D components by time point, age group and country - Republic of Korea (Total Vaccinated Cohort)

			50-59YOA N = 247	60-69YOA N = 154	70-79YOA N = 524	80-89YOA N = 139	≥90YOA N = 3	Total N = 1067
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	247	154	524	138	3	1066
		Mean	82.76	74.22	64.82	45.14	60.00	67.77
		SD	18.130	21.517	25.967	31.034	27.839	26.978
	SF36 RP	N	247	154	524	138	3	1066
		Mean	86.82	82.43	75.36	63.09	70.83	77.43
		SD	20.927	23.426	28.575	35.217	50.518	28.253
	SF36 BP	N	247	154	524	138	3	1066
		Mean	83.55	81.13	75.69	66.72	100.00	77.21
		SD	18.897	19.990	23.496	25.223	0.000	22.831
	SF36 GH	N	247	154	524	138	3	1066
		Mean	66.06	66.38	62.83	57.91	83.67	63.51
		SD	15.996	15.497	18.531	19.436	14.434	17.871
	SF36 VT	N	247	154	524	138	3	1066
		Mean	68.74	68.91	60.83	49.77	64.58	62.41
		SD	18.846	16.818	22.677	21.853	34.422	21.822
	SF36 SF	N	247	154	524	138	3	1066
		Mean	90.84	90.26	89.15	82.79	100.00	88.91
		SD	15.787	15.930	18.615	20.386	0.000	18.000
	SF36 RE	N	247	154	524	138	3	1066
		Mean	88.53	86.26	81.62	74.03	77.78	82.90
		SD	21.173	22.618	25.930	30.274	38.490	25.455
	SF36 MH	N	247	154	524	138	3	1066
		Mean	77.72	79.22	77.24	73.33	83.33	77.15
		SD	16.595	15.330	18.727	18.594	10.408	17.804
	EQ5D Utility	N	247	154	521	138	3	1063
		Mean	0.8907	0.8696	0.8057	0.7370	1.0000	0.8263
		SD	0.14188	0.14378	0.17132	0.16605	0.00000	0.16773
	EQ5D VAS	N	246	154	523	138	3	1064
		Mean	82.36	80.81	79.62	74.98	77.00	79.81
		SD	10.826	12.550	14.327	16.219	5.196	13.754
Month 14	SF36 PF	N	232	141	452	112	3	940
		Mean	80.26	72.78	64.96	50.01	55.00	68.09
		SD	19.523	21.539	25.215	26.438	18.028	25.214
	SF36 RP	N	232	141	452	112	3	940
		Mean	85.02	83.20	77.36	71.32	89.58	79.45
		SD	21.750	22.425	28.428	34.433	13.010	27.205
	SF36 BP	N	232	141	452	112	3	940
		Mean	80.41	78.19	74.75	69.64	94.67	76.12
		SD	22.342	22.457	23.827	24.543	9.238	23.543
	SF36 GH	N	232	141	452	112	3	940
		Mean	63.72	63.48	58.23	56.06	78.67	60.18
		SD	16.556	15.655	18.621	16.946	2.887	17.724
	SF36 VT	N	232	141	452	112	3	940
		Mean	62.85	64.57	56.28	47.49	56.25	58.10
		SD	21.010	20.070	22.372	21.048	16.536	22.111
	SF36 SF	N	232	141	452	112	3	940
		Mean	89.06	90.78	87.06	87.83	100.00	88.24
		SD	17.239	15.063	21.103	19.815	0.000	19.223

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			50-59YOA N = 247	60-69YOA N = 154	70-79YOA N = 524	80-89YOA N = 139	≥90YOA N = 3	Total N = 1067
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	232	141	452	112	3	940
		Mean	86.03	84.10	80.68	80.73	88.89	82.54
		SD	22.385	22.711	26.620	27.401	12.729	25.203
	SF36 MH	N	232	141	452	112	3	940
		Mean	74.68	74.79	72.23	73.88	71.67	73.41
		SD	17.277	18.253	20.759	21.337	2.887	19.630
	EQ5D Utility	N	232	141	451	112	3	939
		Mean	0.8724	0.8470	0.7741	0.7380	0.7807	0.8050
		SD	0.15082	0.15614	0.17818	0.17062	0.19122	0.17430
	EQ5D VAS	N	232	141	452	112	3	940
		Mean	81.54	79.01	75.45	71.06	70.00	76.95
		SD	13.448	14.365	15.619	16.760	17.321	15.411
Month 26	SF36 PF	N	227	138	434	105	1	905
		Mean	80.29	72.19	64.72	51.29	80.00	68.22
		SD	19.610	21.570	28.318	31.631	0.000	27.279
	SF36 RP	N	227	138	434	105	1	905
		Mean	84.14	81.20	75.36	64.40	50.00	77.15
		SD	24.681	23.969	29.480	36.793	0.000	29.110
	SF36 BP	N	228	138	434	105	1	906
		Mean	81.46	79.21	74.19	67.67	100.00	76.05
		SD	21.303	19.719	23.068	25.303	0.000	22.808
	SF36 GH	N	228	138	434	105	1	906
		Mean	63.62	63.97	57.53	53.54	62.00	59.59
		SD	16.781	16.049	17.607	18.178	0.000	17.585
	SF36 VT	N	228	137	434	105	1	905
		Mean	67.19	62.21	51.86	42.80	12.50	56.19
		SD	18.666	19.593	20.213	16.576	0.000	20.988
	SF36 SF	N	228	138	434	105	1	906
		Mean	89.53	88.04	87.67	85.83	100.00	88.00
		SD	17.023	17.078	19.446	22.936	0.000	18.962
	SF36 RE	N	228	138	434	105	1	906
		Mean	86.00	84.90	82.12	81.27	100.00	83.44
		SD	21.703	23.038	25.898	25.601	0.000	24.461
	SF36 MH	N	228	137	434	105	1	905
		Mean	77.83	75.21	71.14	69.90	80.00	73.31
		SD	16.108	17.202	18.731	18.938	0.000	18.120
	EQ5D Utility	N	227	137	434	105	1	904
		Mean	0.8779	0.8422	0.7867	0.7328	1.0000	0.8120
		SD	0.14163	0.15506	0.16576	0.17165	0.00000	0.16588
	EQ5D VAS	N	227	137	434	105	1	904
		Mean	81.21	80.54	74.37	70.23	60.00	76.53
		SD	11.491	13.174	15.304	14.774	0.000	14.551
Month 38	SF36 PF	N	225	131	412	93	1	862
		Mean	79.08	72.89	66.27	49.13	65.00	68.77
		SD	19.403	19.593	24.764	25.845	0.000	24.394
	SF36 RP	N	226	131	412	93	1	863
		Mean	83.96	79.20	76.03	63.64	50.00	77.22
		SD	22.843	23.912	30.461	34.834	0.000	28.780
	SF36 BP	N	226	131	412	93	1	863
		Mean	78.59	76.72	75.97	68.69	41.00	75.94
		SD	21.370	20.994	23.864	25.710	0.000	23.169

			50-59YOA N = 247	60-69YOA N = 154	70-79YOA N = 524	80-89YOA N = 139	≥90YOA N = 3	Total N = 1067
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	226	131	412	93	1	863
		Mean	62.69	62.14	60.52	56.63	52.00	60.91
		SD	16.428	17.259	19.444	21.656	0.000	18.678
	SF36 VT	N	225	131	412	93	1	862
		Mean	65.14	61.83	58.47	51.75	56.25	59.99
		SD	19.204	19.677	22.492	20.049	0.000	21.325
	SF36 SF	N	226	131	412	93	1	863
		Mean	89.60	89.12	86.83	82.12	62.50	87.37
		SD	16.989	16.437	21.366	25.230	0.000	20.181
	SF36 RE	N	226	131	412	93	1	863
		Mean	86.10	83.97	82.30	77.33	58.33	82.99
		SD	19.580	22.871	26.724	29.007	0.000	24.826
	SF36 MH	N	225	131	412	93	1	862
		Mean	74.79	74.23	72.03	71.21	55.00	72.97
		SD	18.224	17.164	18.189	19.794	0.000	18.246
	EQ5D Utility	N	224	130	412	93	1	860
		Mean	0.8602	0.8535	0.7956	0.7319	0.5320	0.8140
		SD	0.14574	0.15831	0.19327	0.21236	0.00000	0.18373
	EQ5D VAS	N	224	130	410	93	1	858
		Mean	80.09	78.44	74.52	68.95	80.00	75.97
		SD	12.655	12.055	14.747	16.382	0.000	14.418

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.13 SF-36 and EQ-5D components by time point, age group and country - Mexico (Total Vaccinated Cohort)

			50-59YOA N = 357	60-69YOA N = 168	70-79YOA N = 342	80-89YOA N = 61	≥90YOA N = 3	Total N = 931
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	356	167	341	61	3	928
		Mean	85.66	75.77	70.27	54.98	38.33	76.06
		SD	19.160	23.621	25.670	26.164	33.292	24.708
	SF36 RP	N	356	167	341	61	3	928
		Mean	82.23	72.16	71.00	65.88	29.17	75.05
		SD	23.388	25.967	25.922	26.035	26.021	25.724
	SF36 BP	N	356	167	342	61	3	929
		Mean	75.45	71.46	71.34	71.95	87.33	73.03
		SD	24.650	23.189	23.856	26.339	21.939	24.251
	SF36 GH	N	356	167	342	61	3	929
		Mean	68.90	63.20	62.02	61.30	70.00	64.84
		SD	21.185	21.233	22.139	20.042	26.458	21.693
	SF36 VT	N	356	167	342	61	3	929
		Mean	72.71	66.48	65.75	67.11	60.42	68.62
		SD	19.585	17.602	20.746	19.193	3.608	19.869
	SF36 SF	N	356	167	342	61	3	929
		Mean	84.76	81.51	80.15	78.28	62.50	81.98
		SD	20.501	19.685	21.437	22.696	0.000	20.943
	SF36 RE	N	356	167	341	61	3	928
		Mean	80.85	76.05	74.90	74.32	25.00	77.19
		SD	23.564	22.761	24.211	23.437	25.000	23.958
	SF36 MH	N	356	167	342	61	3	929
		Mean	74.09	70.87	70.50	74.84	53.33	72.17
		SD	20.184	19.122	19.818	16.481	10.408	19.691
	EQ5D Utility	N	355	166	341	61	3	926
		Mean	0.9086	0.8802	0.8751	0.8396	0.7957	0.8863
		SD	0.12122	0.11698	0.14446	0.15200	0.19200	0.13315
	EQ5D VAS	N	355	165	340	61	3	924
		Mean	84.65	82.39	82.54	86.30	83.33	83.57
		SD	12.698	12.559	14.680	10.531	5.774	13.337
Month 14	SF36 PF	N	318	150	296	51	3	818
		Mean	83.69	76.91	65.64	50.35	55.00	73.73
		SD	19.471	23.364	27.300	27.988	15.000	25.765
	SF36 RP	N	318	150	297	51	3	819
		Mean	80.90	78.04	71.53	69.85	91.67	76.33
		SD	24.247	27.188	31.876	32.130	14.434	28.535
	SF36 BP	N	318	150	297	51	3	819
		Mean	72.89	72.57	68.87	71.43	87.00	71.34
		SD	27.107	26.326	28.121	25.655	22.517	27.257
	SF36 GH	N	318	150	297	51	3	819
		Mean	67.10	66.03	60.42	56.41	69.67	63.83
		SD	24.172	23.099	25.278	25.299	24.420	24.663
	SF36 VT	N	318	150	297	51	3	819
		Mean	69.67	70.42	63.40	63.11	70.83	67.13
		SD	22.226	23.020	25.079	21.369	26.021	23.573
	SF36 SF	N	318	150	297	51	3	819
		Mean	85.06	87.83	82.15	79.17	95.83	84.19
		SD	23.007	18.486	24.017	27.801	7.217	23.017

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			50-59YOA N = 357	60-69YOA N = 168	70-79YOA N = 342	80-89YOA N = 61	≥90YOA N = 3	Total N = 931
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	318	150	297	51	3	819
		Mean	85.44	82.86	77.53	81.54	86.11	81.86
		SD	22.309	24.337	29.553	23.648	24.056	25.777
	SF36 MH	N	318	150	297	51	3	819
		Mean	73.75	75.50	71.47	73.73	78.33	73.26
		SD	22.907	21.180	23.699	22.019	16.073	22.822
	EQ5D Utility	N	317	150	297	51	3	818
		Mean	0.8956	0.8935	0.8462	0.8365	0.8097	0.8733
		SD	0.13564	0.13012	0.16503	0.15529	0.19050	0.14923
	EQ5D VAS	N	316	149	293	51	3	812
		Mean	83.57	84.48	82.11	81.65	90.00	83.11
		SD	13.208	12.097	15.259	15.470	10.000	13.943
Month 26	SF36 PF	N	312	141	282	47	3	785
		Mean	79.62	71.92	60.61	45.53	35.00	69.20
		SD	22.350	24.783	28.811	29.474	30.414	27.709
	SF36 RP	N	312	141	282	47	3	785
		Mean	79.69	77.04	74.34	67.82	81.25	76.59
		SD	24.774	25.840	30.538	35.499	27.243	27.985
	SF36 BP	N	312	141	282	47	3	785
		Mean	72.11	74.87	66.97	69.68	77.67	70.63
		SD	25.427	25.590	27.609	25.783	20.108	26.378
	SF36 GH	N	312	141	282	47	3	785
		Mean	64.65	62.09	57.99	56.43	68.67	61.32
		SD	24.418	24.382	23.888	22.919	20.207	24.274
	SF36 VT	N	312	141	282	47	3	785
		Mean	67.33	67.11	63.75	62.10	77.08	65.73
		SD	23.334	24.211	25.102	25.816	20.091	24.304
	SF36 SF	N	312	141	282	47	3	785
		Mean	82.73	85.82	82.76	83.24	83.33	83.33
		SD	21.911	20.443	24.915	23.498	28.868	22.879
	SF36 RE	N	312	141	282	47	3	785
		Mean	80.29	83.63	79.82	79.08	100.00	80.72
		SD	24.050	23.913	28.248	28.333	0.000	25.848
	SF36 MH	N	312	141	282	47	3	785
		Mean	71.55	77.36	73.23	73.09	75.00	73.30
		SD	23.121	21.867	22.516	24.903	21.794	22.825
	EQ5D Utility	N	311	141	282	46	3	783
		Mean	0.8690	0.8791	0.8512	0.8188	0.8783	0.8615
		SD	0.15963	0.13365	0.16556	0.20231	0.11151	0.16050
	EQ5D VAS	N	309	140	274	47	3	773
		Mean	83.44	81.61	80.56	80.40	96.33	81.96
		SD	14.263	14.776	17.782	21.150	5.508	16.173
Month 38	SF36 PF	N	305	136	263	42	3	749
		Mean	76.80	66.58	55.59	39.64	35.00	65.25
		SD	23.151	25.760	30.505	26.397	35.000	28.863
	SF36 RP	N	305	136	263	42	3	749
		Mean	74.77	68.57	68.13	63.54	66.67	70.65
		SD	26.088	28.987	32.944	34.919	57.735	29.950
	SF36 BP	N	305	136	263	42	3	749
		Mean	69.52	68.05	64.70	64.00	87.00	67.32
		SD	25.147	25.255	27.435	28.237	22.517	26.220

			50-59YOA N = 357	60-69YOA N = 168	70-79YOA N = 342	80-89YOA N = 61	≥90YOA N = 3	Total N = 931
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	305	136	263	42	3	749
		Mean	62.97	59.32	58.13	52.45	57.33	59.99
		SD	23.495	22.911	24.288	25.191	33.561	23.909
	SF36 VT	N	305	136	263	42	3	749
		Mean	65.55	64.66	63.20	54.61	60.42	63.93
		SD	22.590	23.016	23.599	23.792	34.422	23.206
	SF36 SF	N	305	136	263	42	3	749
		Mean	78.36	80.15	78.47	68.15	66.67	78.10
		SD	24.835	24.460	24.283	35.592	38.188	25.405
	SF36 RE	N	305	136	263	42	3	749
		Mean	76.17	72.92	71.93	68.45	55.56	73.58
		SD	25.796	26.600	31.015	31.480	50.918	28.335
	SF36 MH	N	305	136	263	42	3	749
		Mean	71.21	71.80	71.38	67.26	78.33	71.19
		SD	21.796	21.719	22.223	21.589	18.930	21.882
	EQ5D Utility	N	305	136	261	42	3	747
		Mean	0.8646	0.8598	0.8250	0.8035	0.8673	0.8465
		SD	0.14730	0.13176	0.18229	0.18881	0.11780	0.16123
	EQ5D VAS	N	303	136	262	41	3	745
		Mean	82.06	80.90	78.34	80.85	87.00	80.49
		SD	15.014	16.524	19.086	20.026	22.517	17.163

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.14 SF-36 and EQ-5D components by time point, age group and country - Spain (Total Vaccinated Cohort)

			50-59YOA N = 495	60-69YOA N = 310	70-79YOA N = 904	80-89YOA N = 272	≥90YOA N = 9	Total N = 1990
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	494	310	901	272	9	1986
		Mean	88.03	87.96	75.21	67.66	57.36	79.28
		SD	15.910	15.728	22.277	23.924	26.784	21.596
	SF36 RP	N	494	310	901	272	9	1986
		Mean	91.08	92.66	85.16	84.70	88.89	87.75
		SD	18.135	15.630	23.459	23.266	17.891	21.338
	SF36 BP	N	495	310	901	272	9	1987
		Mean	78.94	83.87	73.22	71.65	63.22	76.05
		SD	23.216	20.269	25.873	25.758	23.290	24.753
	SF36 GH	N	495	310	901	272	9	1987
		Mean	74.35	74.44	65.38	63.53	56.89	68.73
		SD	17.249	17.226	18.447	16.499	18.831	18.313
	SF36 VT	N	495	310	901	272	9	1987
		Mean	75.17	81.61	71.52	71.65	67.36	74.00
		SD	19.532	17.367	21.730	21.513	16.764	20.813
	SF36 SF	N	495	310	901	272	9	1987
		Mean	91.94	94.92	89.98	89.43	93.06	91.18
		SD	16.923	13.432	18.226	17.473	12.672	17.192
	SF36 RE	N	494	310	901	272	9	1986
		Mean	92.49	94.87	89.96	89.80	92.59	91.34
		SD	16.360	13.799	19.648	18.512	19.295	17.970
	SF36 MH	N	495	310	901	272	9	1987
		Mean	80.70	85.74	78.61	78.64	81.11	80.26
		SD	18.689	16.379	20.833	17.910	16.915	19.405
	EQ5D Utility	N	494	310	893	271	9	1977
		Mean	0.9267	0.9417	0.8605	0.8118	0.7744	0.8827
		SD	0.14601	0.16096	0.20599	0.24516	0.20772	0.19725
	EQ5D VAS	N	495	310	900	272	9	1986
		Mean	83.35	85.79	76.77	74.69	57.33	79.44
		SD	14.008	13.553	17.471	17.887	24.192	16.744
Month 14	SF36 PF	N	484	291	821	247	7	1850
		Mean	84.69	83.28	72.07	60.22	55.00	75.49
		SD	18.736	18.284	24.099	28.272	28.431	24.090
	SF36 RP	N	484	291	821	247	7	1850
		Mean	87.05	90.53	83.91	78.80	91.07	85.12
		SD	22.154	18.881	23.415	27.800	20.996	23.307
	SF36 BP	N	484	291	820	247	7	1849
		Mean	72.81	77.23	69.70	67.21	76.57	71.39
		SD	25.210	25.562	27.387	27.459	24.521	26.702
	SF36 GH	N	484	291	821	247	7	1850
		Mean	72.32	71.90	63.98	61.65	51.29	67.05
		SD	18.552	18.350	19.409	19.407	17.279	19.516
	SF36 VT	N	484	291	819	247	7	1848
		Mean	69.99	74.23	66.97	63.54	61.61	68.42
		SD	21.551	21.190	23.650	24.298	30.283	23.055
	SF36 SF	N	484	291	821	247	7	1850
		Mean	87.76	91.15	88.05	85.32	96.43	88.13
		SD	21.477	19.087	21.387	22.787	9.449	21.275

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			50-59YOA N = 495	60-69YOA N = 310	70-79YOA N = 904	80-89YOA N = 272	≥90YOA N = 9	Total N = 1990
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	484	291	821	247	7	1850
		Mean	90.82	92.04	89.11	86.88	80.95	89.69
		SD	19.012	18.534	20.889	21.870	33.923	20.295
	SF36 MH	N	484	291	818	247	7	1847
		Mean	78.08	79.69	74.95	72.69	76.43	76.22
		SD	18.547	18.609	22.024	21.709	20.354	20.698
	EQ5D Utility	N	482	291	812	246	7	1838
		Mean	0.8850	0.9111	0.8137	0.7364	0.7401	0.8372
		SD	0.16288	0.14764	0.25453	0.28848	0.37489	0.23163
	EQ5D VAS	N	483	291	819	246	7	1846
		Mean	79.16	80.78	73.28	69.33	60.00	75.42
		SD	14.986	14.454	17.894	18.950	20.817	17.281
Month 26	SF36 PF	N	477	290	792	231	5	1795
		Mean	83.60	81.55	70.66	58.07	48.00	74.18
		SD	19.501	20.060	24.240	27.752	30.125	24.468
	SF36 RP	N	477	290	791	231	5	1794
		Mean	85.73	86.40	78.59	75.49	70.00	81.33
		SD	22.848	23.420	27.094	29.702	44.721	26.181
	SF36 BP	N	477	290	792	231	5	1795
		Mean	71.02	75.60	67.65	66.04	72.40	69.64
		SD	25.962	25.884	27.681	27.523	43.690	27.123
	SF36 GH	N	477	290	792	231	5	1795
		Mean	71.28	71.46	63.11	58.61	46.20	66.01
		SD	18.285	18.847	18.854	19.205	22.163	19.368
	SF36 VT	N	477	289	792	230	5	1793
		Mean	69.64	72.39	66.07	58.21	46.25	66.97
		SD	21.810	21.804	23.459	24.488	31.125	23.292
	SF36 SF	N	477	290	792	231	5	1795
		Mean	87.76	89.53	87.37	84.58	75.00	87.43
		SD	21.034	20.209	21.435	24.414	43.301	21.646
	SF36 RE	N	477	290	791	231	5	1794
		Mean	90.64	88.94	88.21	84.27	75.00	88.43
		SD	20.575	20.820	21.165	24.494	43.301	21.561
	SF36 MH	N	477	289	792	230	5	1793
		Mean	77.56	78.63	75.11	70.22	54.00	75.64
		SD	19.890	19.885	21.174	20.576	34.533	20.759
	EQ5D Utility	N	476	288	788	227	5	1784
		Mean	0.8675	0.8764	0.8127	0.7279	0.6872	0.8265
		SD	0.20765	0.19700	0.25043	0.29050	0.40900	0.24231
	EQ5D VAS	N	475	290	792	230	5	1792
		Mean	79.06	79.97	73.67	70.78	62.00	75.71
		SD	14.496	15.271	17.427	18.588	26.833	16.869
Month 38	SF36 PF	N	471	285	774	209	5	1744
		Mean	82.87	82.10	68.03	53.82	52.00	72.59
		SD	20.166	19.288	25.632	28.934	30.943	25.686
	SF36 RP	N	471	284	774	209	5	1743
		Mean	85.16	86.13	78.41	75.90	73.75	81.18
		SD	22.763	23.396	27.118	29.205	43.391	26.008
	SF36 BP	N	471	284	774	209	5	1743
		Mean	70.81	74.93	68.14	65.12	74.00	69.62
		SD	26.018	26.366	26.962	28.643	36.387	26.974

			50-59YOA N = 495	60-69YOA N = 310	70-79YOA N = 904	80-89YOA N = 272	≥90YOA N = 9	Total N = 1990
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	471	285	775	209	5	1745
		Mean	70.12	71.14	61.25	57.76	56.40	64.83
		SD	18.136	19.449	19.201	19.064	22.412	19.604
	SF36 VT	N	470	285	774	209	5	1743
		Mean	68.59	71.70	63.43	57.72	46.25	65.44
		SD	21.519	22.357	23.597	22.374	24.447	23.097
	SF36 SF	N	470	285	775	209	5	1744
		Mean	86.86	89.56	87.19	84.69	77.50	87.16
		SD	21.741	19.246	21.793	24.151	43.661	21.780
	SF36 RE	N	471	284	774	208	5	1742
		Mean	89.74	89.94	88.46	88.26	70.00	88.97
		SD	20.076	19.292	21.005	18.446	41.500	20.277
	SF36 MH	N	470	285	774	208	5	1742
		Mean	76.55	79.54	73.38	72.73	65.00	75.14
		SD	18.913	19.979	21.692	20.562	36.228	20.731
	EQ5D Utility	N	468	283	773	207	5	1736
		Mean	0.8691	0.8902	0.7981	0.7297	0.6114	0.8236
		SD	0.19607	0.19494	0.26120	0.28112	0.53574	0.24430
	EQ5D VAS	N	470	285	774	209	5	1743
		Mean	78.29	80.70	72.84	67.98	58.80	74.97
		SD	16.146	16.277	17.293	18.412	27.335	17.471

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.15 SF-36 and EQ-5D components by time point, age group and country - Sweden (Total Vaccinated Cohort)

			50-59YOA N = 426	60-69YOA N = 255	70-79YOA N = 813	80-89YOA N = 262	≥90YOA N = 5	Total N = 1761
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	425	254	806	259	4	1748
		Mean	91.69	89.07	82.31	72.95	48.19	84.11
		SD	15.186	13.516	18.792	20.851	25.533	18.733
	SF36 RP	N	425	254	805	258	5	1747
		Mean	94.20	93.60	87.93	78.44	72.50	88.84
		SD	15.281	14.900	19.632	23.427	28.504	19.401
	SF36 BP	N	425	254	803	260	4	1746
		Mean	80.92	81.54	78.73	74.95	61.75	79.07
		SD	22.035	21.235	22.566	24.467	31.245	22.648
	SF36 GH	N	425	254	808	261	5	1753
		Mean	84.28	85.65	78.96	73.49	63.20	80.36
		SD	17.252	14.619	16.539	17.378	28.288	17.091
	SF36 VT	N	425	254	801	260	5	1745
		Mean	75.19	80.37	77.26	70.45	60.42	76.15
		SD	17.591	17.380	17.678	18.802	24.251	18.033
	SF36 SF	N	425	254	803	260	5	1747
		Mean	94.65	95.42	93.90	90.53	85.00	93.78
		SD	14.341	13.588	13.948	16.870	20.540	14.547
	SF36 RE	N	425	254	805	257	5	1746
		Mean	96.20	96.00	92.29	84.52	76.67	92.59
		SD	12.178	12.589	15.450	21.993	21.570	16.008
	SF36 MH	N	425	254	801	260	5	1745
		Mean	88.62	89.47	86.79	82.89	76.00	87.01
		SD	10.734	12.392	14.514	14.205	13.874	13.481
	EQ5D Utility	N	422	254	797	256	4	1733
		Mean	0.8714	0.8708	0.8495	0.8165	0.7029	0.8527
		SD	0.13095	0.14504	0.12972	0.13152	0.21312	0.13410
	EQ5D VAS	N	422	253	793	254	4	1726
		Mean	86.80	87.71	84.60	80.97	78.75	85.05
		SD	12.012	11.779	12.352	14.067	13.745	12.622
Month 14	SF36 PF	N	415	250	774	241	3	1683
		Mean	89.86	86.48	79.47	68.79	41.67	81.48
		SD	16.361	16.244	20.144	22.440	24.664	20.319
	SF36 RP	N	414	250	774	241	3	1682
		Mean	90.53	89.95	84.71	74.38	64.58	85.40
		SD	20.602	19.084	22.425	25.348	20.091	22.576
	SF36 BP	N	413	250	771	238	3	1675
		Mean	78.11	77.30	75.85	71.04	53.67	75.90
		SD	24.278	23.846	24.165	26.726	41.477	24.641
	SF36 GH	N	415	250	775	241	3	1684
		Mean	80.96	79.84	74.49	68.66	50.67	76.00
		SD	18.478	17.122	18.773	17.882	14.012	18.800
	SF36 VT	N	414	250	772	239	3	1678
		Mean	72.45	77.18	74.06	66.49	52.08	73.01
		SD	19.644	20.384	20.358	21.003	13.010	20.496
	SF36 SF	N	414	250	772	239	3	1678
		Mean	92.81	93.30	91.42	88.49	79.17	91.60
		SD	16.836	16.199	17.529	18.855	19.094	17.418

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			50-59YOA N = 426	60-69YOA N = 255	70-79YOA N = 813	80-89YOA N = 262	≥90YOA N = 5	Total N = 1761
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	414	250	774	241	3	1682
		Mean	95.55	94.07	90.18	82.66	66.67	90.96
		SD	14.387	14.552	18.583	22.712	28.868	18.262
	SF36 MH	N	414	250	772	239	3	1678
		Mean	88.08	87.35	85.79	83.01	78.33	86.18
		SD	12.208	14.199	15.938	15.510	12.583	14.848
	EQ5D Utility	N	415	248	764	237	3	1667
		Mean	0.8714	0.8579	0.8319	0.7855	0.6388	0.8387
		SD	0.13762	0.13288	0.14028	0.14915	0.22397	0.14270
	EQ5D VAS	N	414	247	768	239	3	1671
		Mean	85.36	84.83	81.74	76.54	60.00	82.31
		SD	13.923	14.838	14.732	14.244	20.000	14.782
Month 26	SF36 PF	N	411	249	764	228	3	1655
		Mean	89.89	87.26	77.54	67.72	53.33	80.67
		SD	16.484	14.675	21.392	23.073	2.887	20.988
	SF36 RP	N	411	249	765	228	3	1656
		Mean	89.73	92.16	83.04	72.97	45.83	84.62
		SD	21.506	16.165	23.500	26.341	7.217	23.270
	SF36 BP	N	410	248	765	227	3	1653
		Mean	77.95	77.63	73.77	71.52	34.67	75.01
		SD	24.905	21.780	24.289	25.470	10.970	24.387
	SF36 GH	N	411	249	767	229	3	1659
		Mean	81.13	80.34	74.09	68.14	46.67	75.90
		SD	19.168	16.154	19.337	18.785	10.408	19.298
	SF36 VT	N	410	248	764	227	3	1652
		Mean	72.57	77.57	71.66	64.76	47.92	71.78
		SD	20.986	17.570	21.317	20.987	9.547	20.945
	SF36 SF	N	410	248	765	227	3	1653
		Mean	91.49	93.85	90.20	86.78	79.17	90.58
		SD	18.138	14.316	18.904	19.327	7.217	18.238
	SF36 RE	N	411	249	764	228	3	1655
		Mean	94.97	95.05	88.80	80.68	50.00	90.08
		SD	15.346	12.962	19.366	23.152	25.000	18.878
	SF36 MH	N	410	248	764	227	3	1652
		Mean	87.03	88.27	84.41	81.64	63.33	85.22
		SD	13.319	13.041	16.875	15.887	12.583	15.521
	EQ5D Utility	N	411	248	756	226	3	1644
		Mean	0.8727	0.8507	0.8292	0.7869	0.6155	0.8371
		SD	0.13908	0.12999	0.14108	0.15138	0.22374	0.14325
	EQ5D VAS	N	409	248	753	228	3	1641
		Mean	84.18	86.55	81.26	77.44	46.67	82.19
		SD	15.621	10.452	15.219	14.565	15.275	14.924
Month 38	SF36 PF	N	412	246	751	217	2	1628
		Mean	89.06	85.03	76.89	62.23	42.50	79.20
		SD	16.555	16.571	21.709	24.193	31.820	21.873
	SF36 RP	N	412	246	750	216	2	1626
		Mean	88.56	88.52	81.33	65.31	56.25	82.09
		SD	24.326	19.465	24.150	28.787	61.872	25.357
	SF36 BP	N	412	246	750	216	2	1626
		Mean	77.87	75.89	74.01	67.05	100.00	74.38
		SD	25.367	23.214	24.434	24.744	0.000	24.731

			50-59YOA N = 426	60-69YOA N = 255	70-79YOA N = 813	80-89YOA N = 262	≥90YOA N = 5	Total N = 1761
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	412	246	753	217	2	1630
		Mean	79.34	79.45	72.48	64.44	68.50	74.19
		SD	19.943	16.067	19.435	18.964	12.021	19.653
	SF36 VT	N	412	246	751	216	2	1627
		Mean	72.46	76.68	71.08	59.92	50.00	70.77
		SD	20.421	18.010	21.641	22.687	26.517	21.471
	SF36 SF	N	412	246	751	216	2	1627
		Mean	92.29	93.19	90.45	82.58	68.75	90.26
		SD	17.693	15.173	18.310	22.483	26.517	18.614
	SF36 RE	N	412	246	750	216	2	1626
		Mean	94.03	93.70	88.19	75.89	58.33	88.83
		SD	16.151	13.692	20.427	26.060	58.926	20.313
	SF36 MH	N	412	246	751	216	2	1627
		Mean	86.03	88.03	84.42	80.15	85.00	84.81
		SD	14.265	13.088	16.988	16.859	21.213	15.910
	EQ5D Utility	N	411	245	746	215	2	1619
		Mean	0.8464	0.8372	0.8173	0.7535	0.7115	0.8191
		SD	0.15229	0.13248	0.14386	0.15319	0.37498	0.14856
	EQ5D VAS	N	412	245	743	216	2	1618
		Mean	84.02	86.00	80.27	72.95	70.50	81.11
		SD	16.187	11.481	15.655	17.601	27.577	15.993

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.16 SF-36 and EQ-5D components by time point, age group and country - Taiwan (Total Vaccinated Cohort)

			50-59YOA N = 618	60-69YOA N = 387	70-79YOA N = 1033	80-89YOA N = 345	≥90YOA N = 5	Total N = 2388
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	618	387	1027	345	5	2382
		Mean	90.65	84.95	80.81	74.54	52.00	83.07
		SD	16.255	19.695	20.522	23.164	31.345	20.550
	SF36 RP	N	618	387	1027	345	5	2382
		Mean	89.03	84.67	82.34	78.73	60.00	83.88
		SD	17.810	19.491	23.044	25.215	42.066	21.920
	SF36 BP	N	618	387	1026	345	5	2381
		Mean	86.59	83.99	81.93	81.12	87.20	83.37
		SD	16.643	19.338	20.196	21.102	12.458	19.421
	SF36 GH	N	618	387	1027	345	5	2382
		Mean	74.45	71.01	68.09	67.64	65.80	70.15
		SD	17.286	18.821	19.300	19.039	26.574	18.885
	SF36 VT	N	618	386	1026	345	5	2380
		Mean	73.89	72.34	72.12	70.10	58.75	72.29
		SD	16.804	17.705	18.814	20.289	33.541	18.430
	SF36 SF	N	618	387	1026	345	5	2381
		Mean	91.69	89.63	90.38	88.99	100.00	90.41
		SD	12.446	14.822	15.160	15.807	0.000	14.557
	SF36 RE	N	618	387	1027	345	5	2382
		Mean	89.67	86.99	86.01	82.37	71.67	86.56
		SD	16.005	17.892	20.568	22.164	34.157	19.473
	SF36 MH	N	618	386	1026	345	5	2380
		Mean	76.86	77.15	78.67	79.53	71.00	78.06
		SD	15.471	16.171	17.138	17.044	27.704	16.593
	EQ5D Utility	N	618	386	1024	344	5	2377
		Mean	0.9457	0.9211	0.9074	0.8849	0.7204	0.9159
		SD	0.10282	0.12081	0.13532	0.14888	0.19962	0.12941
	EQ5D VAS	N	618	387	1025	345	5	2380
		Mean	86.47	85.06	81.56	80.14	79.00	83.20
		SD	9.877	11.729	12.445	11.982	15.166	11.888
Month 14	SF36 PF	N	602	376	959	305	4	2246
		Mean	90.66	86.77	80.97	72.89	45.00	83.38
		SD	14.652	15.176	18.551	22.527	35.824	18.693
	SF36 RP	N	602	376	959	305	4	2246
		Mean	88.04	84.67	81.46	75.84	56.25	82.95
		SD	18.131	20.071	23.524	25.422	51.539	22.339
	SF36 BP	N	602	376	959	305	4	2246
		Mean	84.92	81.47	80.09	79.89	73.25	81.58
		SD	17.918	19.448	21.204	21.381	31.106	20.215
	SF36 GH	N	602	376	959	305	4	2246
		Mean	74.12	70.07	66.39	66.75	54.75	69.11
		SD	18.342	18.856	19.237	18.244	37.518	19.118
	SF36 VT	N	602	376	959	305	4	2246
		Mean	72.10	71.26	69.20	67.42	45.31	70.03
		SD	17.229	17.394	20.468	20.489	38.654	19.270
	SF36 SF	N	602	376	959	305	4	2246
		Mean	91.74	90.79	89.47	85.66	68.75	89.74
		SD	12.499	14.846	16.069	18.728	23.936	15.538

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			50-59YOA N = 618	60-69YOA N = 387	70-79YOA N = 1033	80-89YOA N = 345	≥90YOA N = 5	Total N = 2388
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	602	376	959	305	4	2246
		Mean	89.13	85.64	83.56	80.93	50.00	84.98
		SD	16.595	19.270	20.211	21.864	45.644	19.686
	SF36 MH	N	602	376	959	305	4	2246
		Mean	76.60	76.84	77.40	80.13	53.75	77.42
		SD	15.626	15.891	17.243	16.701	33.260	16.610
	EQ5D Utility	N	602	375	956	304	4	2241
		Mean	0.9551	0.9223	0.8943	0.8672	0.7230	0.9114
		SD	0.09772	0.12687	0.14419	0.14998	0.34738	0.13530
	EQ5D VAS	N	602	376	958	305	4	2245
		Mean	85.78	84.37	80.29	78.92	78.50	82.25
		SD	11.438	12.017	12.549	12.524	20.551	12.466
Month 26	SF36 PF	N	593	371	935	285	4	2188
		Mean	90.86	85.83	79.06	69.50	35.00	82.08
		SD	12.844	16.537	20.009	25.136	34.881	19.937
	SF36 RP	N	593	371	935	285	4	2188
		Mean	88.68	84.84	79.49	74.25	68.75	82.18
		SD	16.862	20.371	24.653	28.366	47.324	23.207
	SF36 BP	N	593	370	935	285	4	2187
		Mean	84.86	81.24	79.22	77.49	67.00	80.84
		SD	18.187	19.305	21.529	23.113	38.419	20.720
	SF36 GH	N	593	371	935	285	4	2188
		Mean	73.74	70.55	65.63	64.91	61.00	68.56
		SD	18.367	19.799	20.532	21.454	27.471	20.296
	SF36 VT	N	593	370	935	285	4	2187
		Mean	73.57	72.25	68.62	64.76	53.13	70.04
		SD	17.298	17.343	19.653	20.801	31.250	19.068
	SF36 SF	N	593	370	935	285	4	2187
		Mean	91.53	91.42	89.17	85.88	56.25	89.70
		SD	13.411	13.330	16.094	20.235	42.696	15.829
	SF36 RE	N	593	371	935	285	4	2188
		Mean	88.43	87.17	83.32	79.77	60.42	84.86
		SD	17.086	18.422	21.045	24.555	42.696	20.402
	SF36 MH	N	593	370	935	285	4	2187
		Mean	77.02	78.31	76.40	77.49	57.50	77.00
		SD	16.464	16.123	17.658	18.254	29.011	17.208
	EQ5D Utility	N	592	370	932	281	4	2179
		Mean	0.9512	0.9167	0.8851	0.8358	0.7463	0.9018
		SD	0.10311	0.12671	0.14753	0.16964	0.34052	0.14211
	EQ5D VAS	N	593	371	934	285	4	2187
		Mean	86.92	84.97	81.11	77.62	76.25	82.88
		SD	10.259	10.894	12.538	14.610	17.970	12.412
Month 38	SF36 PF	N	586	362	894	260	2	2104
		Mean	90.46	84.95	76.56	66.50	65.00	80.62
		SD	13.499	17.031	21.774	27.058	42.426	21.330
	SF36 RP	N	586	362	895	260	2	2105
		Mean	84.65	81.23	75.88	68.95	87.50	78.40
		SD	20.998	23.080	25.805	30.105	17.678	25.194
	SF36 BP	N	586	362	895	260	2	2105
		Mean	83.05	81.26	77.01	77.98	92.00	79.55
		SD	19.413	19.824	22.441	23.098	11.314	21.425

			50-59YOA N = 618	60-69YOA N = 387	70-79YOA N = 1033	80-89YOA N = 345	≥90YOA N = 5	Total N = 2388
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	586	362	896	260	2	2106
		Mean	73.13	68.34	64.01	62.52	79.50	67.12
		SD	18.953	19.418	20.183	20.033	10.607	20.107
	SF36 VT	N	586	362	894	260	2	2104
		Mean	72.59	70.25	67.16	61.92	81.25	68.57
		SD	18.204	17.203	20.067	20.739	8.839	19.453
	SF36 SF	N	586	362	895	260	2	2105
		Mean	90.27	89.50	85.88	80.72	100.00	87.10
		SD	14.701	14.662	18.304	22.625	0.000	17.663
	SF36 RE	N	586	362	895	260	2	2105
		Mean	86.11	83.31	79.04	74.90	100.00	81.25
		SD	19.109	20.901	23.171	25.000	0.000	22.276
	SF36 MH	N	586	362	894	260	2	2104
		Mean	77.02	76.16	75.80	75.75	85.00	76.20
		SD	16.363	16.069	18.095	18.167	14.142	17.290
	EQ5D Utility	N	582	361	892	258	2	2095
		Mean	0.9423	0.9161	0.8719	0.8202	0.8865	0.8927
		SD	0.11183	0.13031	0.15436	0.19017	0.16051	0.15029
	EQ5D VAS	N	586	359	893	260	2	2100
		Mean	85.80	84.20	79.43	76.13	75.00	81.61
		SD	10.340	11.143	13.227	13.859	7.071	12.684

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.17 SF-36 and EQ-5D components by time point, age group and country - United Kingdom (Total Vaccinated Cohort)

			50-59YOA N = 269	60-69YOA N = 153	70-79YOA N = 725	80-89YOA N = 161	≥90YOA N = 1	Total N = 1309
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	263	152	717	160	1	1293
		Mean	77.83	74.13	72.03	58.00	65.00	71.71
		SD	28.756	28.200	25.973	28.635	0.000	27.696
	SF36 RP	N	263	152	718	160	1	1294
		Mean	82.91	79.63	80.67	68.32	75.00	79.47
		SD	27.438	26.378	24.273	28.979	0.000	26.123
	SF36 BP	N	264	153	723	160	1	1301
		Mean	72.22	73.24	74.06	69.50	84.00	73.04
		SD	28.122	28.103	24.849	26.123	0.000	26.098
	SF36 GH	N	264	153	724	161	1	1303
		Mean	67.56	69.82	73.16	71.37	92.00	71.43
		SD	23.433	21.731	17.993	16.999	0.000	19.664
	SF36 VT	N	264	153	722	161	1	1301
		Mean	63.57	64.95	66.60	59.64	68.75	64.93
		SD	22.744	20.230	19.369	19.822	0.000	20.355
	SF36 SF	N	264	153	724	161	1	1303
		Mean	84.80	86.19	89.71	87.34	100.00	88.02
		SD	26.124	24.550	19.709	19.314	0.000	21.772
	SF36 RE	N	263	151	718	160	1	1293
		Mean	86.66	84.69	89.52	84.95	100.00	87.82
		SD	26.348	25.150	19.764	25.330	0.000	22.674
	SF36 MH	N	264	153	722	161	1	1301
		Mean	76.47	80.61	82.02	79.84	80.00	80.46
		SD	20.925	17.577	15.960	15.708	0.000	17.348
	EQ5D Utility	N	262	151	716	161	1	1291
		Mean	0.7871	0.7941	0.8232	0.7792	0.8140	0.8069
		SD	0.28591	0.27426	0.19503	0.20980	0.00000	0.22841
	EQ5D VAS	N	262	151	721	161	1	1296
		Mean	77.94	78.80	80.69	76.36	80.00	79.37
		SD	17.831	17.726	14.890	16.806	0.000	16.162
Month 14	SF36 PF	N	249	148	681	149	1	1228
		Mean	76.39	70.78	67.90	58.08	70.00	68.78
		SD	30.126	30.934	27.066	30.332	0.000	29.011
	SF36 RP	N	249	148	683	148	1	1229
		Mean	79.49	75.32	73.40	63.01	50.00	73.59
		SD	31.246	33.586	28.469	31.731	0.000	30.401
	SF36 BP	N	250	148	685	149	1	1233
		Mean	67.30	69.61	69.70	67.00	74.00	68.88
		SD	29.904	27.873	25.974	28.282	0.000	27.303
	SF36 GH	N	251	149	688	149	1	1238
		Mean	66.15	65.60	68.83	65.86	82.00	67.55
		SD	24.412	23.553	20.029	19.245	0.000	21.359
	SF36 VT	N	250	148	686	149	1	1234
		Mean	59.76	61.78	62.33	55.66	62.50	60.94
		SD	23.420	22.003	20.723	24.013	0.000	21.934
	SF36 SF	N	250	148	686	149	1	1234
		Mean	81.50	82.94	87.43	83.22	87.50	85.18
		SD	28.123	26.573	21.003	26.587	0.000	24.093

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			50-59YOA N = 269	60-69YOA N = 153	70-79YOA N = 725	80-89YOA N = 161	≥90YOA N = 1	Total N = 1309
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	248	148	682	148	1	1227
		Mean	83.94	84.23	86.28	83.56	100.00	85.24
		SD	29.239	28.056	23.527	26.153	0.000	25.645
	SF36 MH	N	250	147	686	149	1	1233
		Mean	74.02	78.17	80.95	81.06	95.00	79.24
		SD	21.616	19.629	16.597	17.043	0.000	18.331
	EQ5D Utility	N	248	148	682	146	1	1225
		Mean	0.7456	0.7578	0.7925	0.7555	0.6910	0.7743
		SD	0.34070	0.29552	0.21716	0.24505	0.00000	0.26018
	EQ5D VAS	N	246	145	687	148	1	1227
		Mean	76.02	75.67	79.30	73.16	70.00	77.47
		SD	20.148	19.695	16.110	19.475	0.000	17.954
Month 26	SF36 PF	N	252	141	651	134	1	1179
		Mean	72.48	72.38	67.28	55.88	45.00	67.69
		SD	32.256	30.163	26.752	28.081	0.000	28.942
	SF36 RP	N	251	141	652	134	1	1179
		Mean	75.52	76.60	73.00	61.24	25.00	72.59
		SD	33.324	29.697	27.506	30.056	0.000	29.682
	SF36 BP	N	251	145	656	135	1	1188
		Mean	66.04	67.10	68.79	67.19	52.00	67.81
		SD	29.957	29.057	26.087	27.418	0.000	27.447
	SF36 GH	N	252	145	656	135	1	1189
		Mean	63.99	65.00	69.24	68.39	87.00	67.53
		SD	26.193	23.365	19.122	18.554	0.000	21.378
	SF36 VT	N	252	145	656	135	1	1189
		Mean	56.47	62.56	61.75	55.20	62.50	59.99
		SD	26.468	23.023	20.844	20.990	0.000	22.567
	SF36 SF	N	252	145	656	135	1	1189
		Mean	78.72	82.24	84.55	83.61	75.00	82.92
		SD	31.170	27.070	23.789	24.120	0.000	26.021
	SF36 RE	N	251	141	651	134	1	1178
		Mean	80.83	83.33	84.72	79.73	100.00	83.17
		SD	31.748	27.204	24.324	26.871	0.000	26.731
	SF36 MH	N	252	145	656	135	1	1189
		Mean	73.33	78.42	79.55	80.15	100.00	78.18
		SD	24.474	17.927	17.832	15.516	0.000	19.361
	EQ5D Utility	N	251	141	651	135	1	1179
		Mean	0.7039	0.7491	0.7786	0.7296	0.6910	0.7535
		SD	0.37199	0.27838	0.22957	0.23649	0.00000	0.27379
	EQ5D VAS	N	250	144	650	135	1	1180
		Mean	73.41	75.92	78.57	73.59	70.00	76.58
		SD	21.030	19.867	16.066	18.257	0.000	18.074
Month 38	SF36 PF	N	243	146	646	126	1	1162
		Mean	74.54	69.59	66.01	51.43	40.00	66.64
		SD	29.985	30.659	26.582	29.175	0.000	28.795
	SF36 RP	N	243	146	646	126	1	1162
		Mean	77.34	74.61	71.07	58.78	31.25	71.46
		SD	30.605	31.377	28.142	30.075	0.000	29.715
	SF36 BP	N	244	146	644	127	1	1162
		Mean	66.96	66.73	68.17	68.35	52.00	67.74
		SD	30.227	28.826	25.919	28.080	0.000	27.445

			50-59YOA N = 269	60-69YOA N = 153	70-79YOA N = 725	80-89YOA N = 161	≥90YOA N = 1	Total N = 1309
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	244	146	648	127	1	1166
		Mean	64.78	64.89	68.73	68.24	92.00	67.39
		SD	23.886	23.291	18.974	18.451	0.000	20.666
	SF36 VT	N	244	146	647	127	1	1165
		Mean	57.87	60.73	60.94	55.53	12.50	59.64
		SD	23.962	19.926	20.568	22.342	0.000	21.532
	SF36 SF	N	244	146	647	127	1	1165
		Mean	79.20	83.99	84.25	81.89	100.00	82.92
		SD	29.577	25.118	22.710	25.623	0.000	24.958
	SF36 RE	N	243	146	646	126	1	1162
		Mean	81.94	84.13	84.06	81.81	75.00	83.37
		SD	28.645	26.933	24.531	25.656	0.000	25.844
	SF36 MH	N	244	146	647	127	1	1165
		Mean	73.67	77.93	80.10	81.22	85.00	78.61
		SD	22.808	17.902	16.840	15.920	0.000	18.453
	EQ5D Utility	N	243	146	646	126	1	1162
		Mean	0.7278	0.7421	0.7801	0.7118	0.6910	0.7569
		SD	0.33263	0.30180	0.21599	0.25048	0.00000	0.26046
	EQ5D VAS	N	243	146	646	127	1	1163
		Mean	75.30	76.34	78.60	72.80	60.00	76.98
		SD	20.260	18.510	15.983	18.171	0.000	17.609

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.2.4.18 SF-36 and EQ-5D components by time point, age group and country - United States (Total Vaccinated Cohort)

			50-59YOA N = 727	60-69YOA N = 456	70-79YOA N = 1559	80-89YOA N = 396	≥90YOA N = 8	Total N = 3146
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
Month 0	SF36 PF	N	720	452	1544	390	8	3114
		Mean	84.32	80.07	74.81	64.79	48.13	76.45
		SD	20.965	22.154	23.311	24.990	28.528	23.632
	SF36 RP	N	726	454	1552	392	8	3132
		Mean	87.99	86.07	80.04	70.97	63.28	81.58
		SD	20.806	21.627	23.618	24.621	33.146	23.473
	SF36 BP	N	720	454	1546	390	8	3118
		Mean	78.39	76.20	74.48	71.25	61.88	75.20
		SD	20.897	20.507	21.329	22.871	20.124	21.417
	SF36 GH	N	726	456	1555	394	8	3139
		Mean	78.46	79.04	78.43	74.95	67.38	78.06
		SD	17.519	16.329	16.056	15.806	21.340	16.471
	SF36 VT	N	726	456	1555	393	8	3138
		Mean	71.09	71.82	70.20	65.28	56.25	69.99
		SD	17.716	17.699	17.396	16.982	14.940	17.564
	SF36 SF	N	720	454	1547	391	8	3120
		Mean	92.14	93.31	92.67	90.22	73.44	92.28
		SD	16.389	16.307	15.669	16.439	30.936	16.120
	SF36 RE	N	726	454	1552	393	8	3133
		Mean	92.77	91.74	90.46	85.01	66.67	90.44
		SD	16.008	18.834	18.378	21.359	38.832	18.574
	SF36 MH	N	726	456	1555	393	8	3138
		Mean	83.43	84.25	85.71	83.95	78.75	84.73
		SD	13.948	14.167	13.087	13.621	15.526	13.554
	EQ5D Utility	N	721	452	1540	391	8	3112
		Mean	0.9016	0.8896	0.8831	0.8537	0.7604	0.8843
		SD	0.12814	0.12444	0.11883	0.13280	0.25768	0.12499
	EQ5D VAS	N	724	453	1552	391	8	3128
		Mean	85.75	86.76	85.28	82.41	75.75	85.22
		SD	12.622	12.293	12.264	13.237	19.645	12.555
Month 14	SF36 PF	N	640	420	1413	333	6	2812
		Mean	82.53	78.44	72.91	63.07	45.83	74.70
		SD	23.452	23.867	25.139	24.901	29.735	25.252
	SF36 RP	N	641	422	1421	335	6	2825
		Mean	86.49	83.81	76.36	66.71	53.13	78.58
		SD	23.095	23.090	26.509	27.815	37.239	26.202
	SF36 BP	N	637	419	1411	331	6	2804
		Mean	75.56	74.62	72.18	70.02	55.33	73.02
		SD	23.815	22.638	23.556	23.214	18.435	23.499
	SF36 GH	N	641	422	1423	337	6	2829
		Mean	74.74	76.50	76.33	71.96	60.00	75.44
		SD	20.084	18.138	16.668	16.659	25.652	17.797
	SF36 VT	N	638	421	1417	335	6	2817
		Mean	67.44	68.78	67.58	62.79	54.17	67.13
		SD	19.742	18.631	19.013	17.099	20.412	18.980
	SF36 SF	N	640	420	1414	333	6	2813
		Mean	89.79	92.05	90.16	87.42	70.83	89.99
		SD	19.765	18.004	18.283	19.621	28.137	18.818

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Report Final

			50-59YOA N = 727	60-69YOA N = 456	70-79YOA N = 1559	80-89YOA N = 396	≥90YOA N = 8	Total N = 3146
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 RE	N	641	422	1421	335	6	2825
		Mean	90.56	92.04	87.44	81.19	70.83	88.06
		SD	19.884	17.451	21.750	25.000	36.799	21.433
	SF36 MH	N	638	421	1417	335	6	2817
		Mean	81.93	84.44	84.36	82.88	65.83	83.61
		SD	15.793	13.411	14.511	14.729	15.943	14.733
	EQ5D Utility	N	634	420	1401	334	6	2795
		Mean	0.8921	0.8730	0.8737	0.8514	0.6965	0.8747
		SD	0.15063	0.13799	0.13597	0.12901	0.29202	0.14000
	EQ5D VAS	N	634	418	1407	334	6	2799
		Mean	83.96	85.52	84.65	80.28	67.00	84.06
		SD	14.964	13.358	13.375	14.960	22.768	14.054
Month 26	SF36 PF	N	604	412	1356	294	3	2669
		Mean	82.20	77.53	72.16	60.39	36.67	73.93
		SD	23.171	24.692	25.253	24.575	32.146	25.438
	SF36 RP	N	610	414	1360	295	3	2682
		Mean	85.45	83.07	75.68	66.65	31.25	78.00
		SD	23.904	23.939	26.361	26.271	27.243	26.125
	SF36 BP	N	596	405	1352	294	3	2650
		Mean	75.11	74.03	72.37	70.47	55.67	73.01
		SD	24.845	22.745	23.420	22.459	26.690	23.580
	SF36 GH	N	611	414	1361	296	3	2685
		Mean	75.53	76.31	75.21	70.56	51.33	74.92
		SD	19.956	18.317	17.632	15.734	26.006	18.181
	SF36 VT	N	601	408	1354	292	3	2658
		Mean	67.94	68.38	67.13	62.37	41.67	66.95
		SD	19.540	19.388	19.563	17.555	32.073	19.411
	SF36 SF	N	606	412	1358	295	3	2674
		Mean	89.71	91.93	90.10	87.37	50.00	89.94
		SD	20.719	17.442	18.435	19.629	25.000	19.038
	SF36 RE	N	610	414	1359	295	3	2681
		Mean	91.15	92.19	86.80	80.23	30.56	87.83
		SD	18.377	17.582	21.995	24.499	26.788	21.258
	SF36 MH	N	601	408	1354	292	3	2658
		Mean	82.17	84.48	83.84	83.24	66.67	83.48
		SD	15.605	14.768	15.200	13.978	15.275	15.118
	EQ5D Utility	N	603	406	1340	292	3	2644
		Mean	0.8825	0.8804	0.8691	0.8572	0.5627	0.8722
		SD	0.16206	0.12262	0.13363	0.12454	0.37100	0.13899
	EQ5D VAS	N	602	408	1350	296	3	2659
		Mean	83.55	85.00	84.04	80.36	48.00	83.63
		SD	15.898	13.926	13.417	14.599	34.598	14.344
Month 38	SF36 PF	N	585	397	1275	259	2	2518
		Mean	80.66	75.55	69.27	57.30	50.00	71.66
		SD	25.266	24.669	25.821	25.467	7.071	26.334
	SF36 RP	N	586	398	1278	262	2	2526
		Mean	84.03	79.74	73.83	62.74	65.63	75.97
		SD	25.264	26.306	26.408	26.054	4.419	26.785
	SF36 BP	N	585	397	1273	261	2	2518
		Mean	73.38	72.03	70.78	68.07	87.00	71.31
		SD	24.658	23.350	23.452	22.734	18.385	23.682

			50-59YOA N = 727	60-69YOA N = 456	70-79YOA N = 1559	80-89YOA N = 396	≥90YOA N = 8	Total N = 3146
Timepoint	Component	Parameters	Value	Value	Value	Value	Value	Value
	SF36 GH	N	586	399	1280	263	2	2530
		Mean	73.45	74.57	73.33	70.35	59.50	73.23
		SD	20.741	18.722	17.803	17.918	17.678	18.699
	SF36 VT	N	585	398	1279	262	2	2526
		Mean	66.74	67.21	65.68	61.76	40.63	65.74
		SD	20.217	20.104	19.144	17.860	22.097	19.480
	SF36 SF	N	585	399	1278	262	2	2526
		Mean	88.70	90.57	89.02	85.26	68.75	88.78
		SD	20.887	19.514	19.115	20.625	8.839	19.795
	SF36 RE	N	586	398	1278	262	2	2526
		Mean	90.10	90.98	86.33	80.06	70.83	87.28
		SD	20.653	18.817	22.528	25.135	5.893	22.058
	SF36 MH	N	585	398	1279	262	2	2526
		Mean	81.87	83.77	83.49	83.97	70.00	83.20
		SD	15.735	15.395	15.101	13.491	14.142	15.151
	EQ5D Utility	N	582	395	1269	259	2	2507
		Mean	0.8700	0.8608	0.8569	0.8297	0.6955	0.8576
		SD	0.16842	0.14882	0.14201	0.12960	0.13930	0.14879
	EQ5D VAS	N	582	395	1273	262	2	2514
		Mean	83.07	83.92	82.99	79.28	58.50	82.75
		SD	15.013	14.671	14.572	14.980	12.021	14.788

50-59YOA = 50-59 years old subjects

60-69YOA = 60-69 years old subjects

70-79YOA = 70-79 years old subjects

80-89YOA = 80-89 years old subjects

≥90YOA = ≥90 years old subjects

N in the column header is the total number of subjects in the age group. N = number of subjects with a non missing value at each timepoint

SD=Standard Deviation

PF=Physical Functioning, RP=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health. VAS=Visual Analogue Scale

Table 14.3.1.1 Number and percentage of subjects who received study vaccine doses by frailty status (Total Vaccinated Cohort)

	Non-Frail				Pre-Frail				Frail				Unknown				Total			
	HZ/su		Placebo		HZ/su		Placebo		HZ/su		Placebo		HZ/su		Placebo		HZ/su		Placebo	
	N = 5784		N = 5734		N = 6071		N = 6219		N = 1573		N = 1464		N = 59		N = 72		N = 13487		N = 13489	
Total number of doses received	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
1	221	3.8	165	2.9	321	5.3	234	3.8	122	7.8	112	7.7	5	8.5	9	12.5	669	5.0	520	3.9
2	5563	96.2	5569	97.1	5750	94.7	5985	96.2	1451	92.2	1352	92.3	54	91.5	63	87.5	12818	95.0	12969	96.1
Any	5784	100	5734	100	6071	100	6219	100	1573	100	1464	100	59	100	72	100	13487	100	13489	100

Non-Frail = Subjects with frailty index score ≤ 0.08 Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25 Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of subjects in each group or in total included in the considered cohort

n/% = number/percentage of subjects receiving the specified total number of doses

Any = number and percentage of subjects receiving at least one dose

Table 14.3.1.2 Incidence and nature of symptoms (solicited only) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom					General symptoms					Local symptoms				
						95% CI					95% CI					95% CI	
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Non-Frail	HZ/su	2004	1647	82.2	80.4	83.8	2001	1068	53.4	51.2	55.6	2000	1569	78.5	76.6	80.2
		Placebo	2032	503	24.8	22.9	26.7	2032	420	20.7	18.9	22.5	2031	168	8.3	7.1	9.6
	Pre-Frail	HZ/su	1971	1497	76.0	74.0	77.8	1963	965	49.2	46.9	51.4	1970	1393	70.7	68.6	72.7
		Placebo	1962	502	25.6	23.7	27.6	1960	429	21.9	20.1	23.8	1962	158	8.1	6.9	9.3
	Frail	HZ/su	483	316	65.4	61.0	69.7	480	186	38.8	34.4	43.3	483	292	60.5	55.9	64.8
		Placebo	462	134	29.0	24.9	33.4	461	123	26.7	22.7	31.0	461	33	7.2	5.0	9.9
	Unknown	HZ/su	21	16	76.2	52.8	91.8	20	11	55.0	31.5	76.9	21	15	71.4	47.8	88.7
		Placebo	18	6	33.3	13.3	59.0	18	5	27.8	9.7	53.5	17	2	11.8	1.5	36.4
Dose 2	Non-Frail	HZ/su	1943	1558	80.2	78.3	81.9	1942	1098	56.5	54.3	58.8	1941	1457	75.1	73.1	77.0
		Placebo	1988	367	18.5	16.8	20.2	1988	304	15.3	13.7	17.0	1988	111	5.6	4.6	6.7
	Pre-Frail	HZ/su	1911	1373	71.8	69.8	73.9	1906	933	49.0	46.7	51.2	1909	1259	66.0	63.8	68.1
		Placebo	1899	364	19.2	17.4	21.0	1895	315	16.6	15.0	18.4	1899	115	6.1	5.0	7.2
	Frail	HZ/su	456	294	64.5	59.9	68.9	456	190	41.7	37.1	46.3	455	268	58.9	54.2	63.5
		Placebo	444	98	22.1	18.3	26.2	443	85	19.2	15.6	23.2	442	35	7.9	5.6	10.8
	Unknown	HZ/su	18	12	66.7	41.0	86.7	18	5	27.8	9.7	53.5	18	11	61.1	35.7	82.7
		Placebo	15	3	20.0	4.3	48.1	15	3	20.0	4.3	48.1	15	0	0.0	0.0	21.8
Overall/dose	Non-Frail	HZ/su	3947	3205	81.2	79.9	82.4	3943	2166	54.9	53.4	56.5	3941	3026	76.8	75.4	78.1
		Placebo	4020	870	21.6	20.4	22.9	4020	724	18.0	16.8	19.2	4019	279	6.9	6.2	7.8
	Pre-Frail	HZ/su	3882	2870	73.9	72.5	75.3	3869	1898	49.1	47.5	50.6	3879	2652	68.4	66.9	69.8
		Placebo	3861	866	22.4	21.1	23.8	3855	744	19.3	18.1	20.6	3861	273	7.1	6.3	7.9
	Frail	HZ/su	939	610	65.0	61.8	68.0	936	376	40.2	37.0	43.4	938	560	59.7	56.5	62.9
		Placebo	906	232	25.6	22.8	28.6	904	208	23.0	20.3	25.9	903	68	7.5	5.9	9.4
	Unknown	HZ/su	39	28	71.8	55.1	85.0	38	16	42.1	26.3	59.2	39	26	66.7	49.8	80.9
		Placebo	33	9	27.3	13.3	45.5	33	8	24.2	11.1	42.3	32	2	6.3	0.8	20.8
Overall/subject	Non-Frail	HZ/su	2008	1752	87.3	85.7	88.7	2007	1369	68.2	66.1	70.2	2007	1699	84.7	83.0	86.2
		Placebo	2034	654	32.2	30.1	34.2	2034	558	27.4	25.5	29.4	2034	227	11.2	9.8	12.6
	Pre-Frail	HZ/su	1977	1649	83.4	81.7	85.0	1971	1242	63.0	60.8	65.1	1977	1559	78.9	77.0	80.6
		Placebo	1964	662	33.7	31.6	35.8	1964	575	29.3	27.3	31.3	1964	227	11.6	10.2	13.1
	Frail	HZ/su	490	360	73.5	69.3	77.3	488	248	50.8	46.3	55.3	489	335	68.5	64.2	72.6
		Placebo	468	169	36.1	31.8	40.6	468	154	32.9	28.7	37.4	468	51	10.9	8.2	14.1
	Unknown	HZ/su	21	18	85.7	63.7	97.0	21	11	52.4	29.8	74.3	21	17	81.0	58.1	94.6
		Placebo	18	7	38.9	17.3	64.3	18	6	33.3	13.3	59.0	17	2	11.8	1.5	36.4

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 14.3.1.3 Incidence and nature of grade 3 symptoms (solicited only) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom					General symptoms					Local symptoms				
			95% CI					95% CI					95% CI				
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Non-Frail	HZ/su	2004	180	9.0	7.8	10.3	2001	104	5.2	4.3	6.3	2000	110	5.5	4.5	6.6
		Placebo	2032	23	1.1	0.7	1.7	2032	22	1.1	0.7	1.6	2031	3	0.1	0.0	0.4
	Pre-Frail	HZ/su	1971	163	8.3	7.1	9.6	1963	99	5.0	4.1	6.1	1970	99	5.0	4.1	6.1
		Placebo	1962	27	1.4	0.9	2.0	1960	26	1.3	0.9	1.9	1962	2	0.1	0.0	0.4
	Frail	HZ/su	483	45	9.3	6.9	12.3	480	27	5.6	3.7	8.1	483	26	5.4	3.5	7.8
		Placebo	462	14	3.0	1.7	5.0	461	14	3.0	1.7	5.0	461	1	0.2	0.0	1.2
Dose 2	Non-Frail	HZ/su	1943	237	12.2	10.8	13.7	1942	172	8.9	7.6	10.2	1941	118	6.1	5.1	7.2
		Placebo	1988	18	0.9	0.5	1.4	1988	18	0.9	0.5	1.4	1988	1	0.1	0.0	0.3
	Pre-Frail	HZ/su	1911	168	8.8	7.6	10.2	1906	112	5.9	4.9	7.0	1909	100	5.2	4.3	6.3
		Placebo	1899	23	1.2	0.8	1.8	1895	20	1.1	0.6	1.6	1899	4	0.2	0.1	0.5
	Frail	HZ/su	456	49	10.7	8.1	14.0	456	31	6.8	4.7	9.5	455	33	7.3	5.0	10.0
		Placebo	444	14	3.2	1.7	5.2	443	12	2.7	1.4	4.7	442	4	0.9	0.2	2.3
Overall/dose	Non-Frail	HZ/su	3947	417	10.6	9.6	11.6	3943	276	7.0	6.2	7.8	3941	228	5.8	5.1	6.6
		Placebo	4020	41	1.0	0.7	1.4	4020	40	1.0	0.7	1.4	4019	4	0.1	0.0	0.3
	Pre-Frail	HZ/su	3882	331	8.5	7.7	9.4	3869	211	5.5	4.8	6.2	3879	199	5.1	4.5	5.9
		Placebo	3861	50	1.3	1.0	1.7	3855	46	1.2	0.9	1.6	3861	6	0.2	0.1	0.3
	Frail	HZ/su	939	94	10.0	8.2	12.1	936	58	6.2	4.7	7.9	938	59	6.3	4.8	8.0
		Placebo	906	28	3.1	2.1	4.4	904	26	2.9	1.9	4.2	903	5	0.6	0.2	1.3
Overall/subject	Non-Frail	HZ/su	39	1	2.6	0.1	13.5	38	0	0.0	0.0	9.3	39	1	2.6	0.1	13.5
		Placebo	33	0	0.0	0.0	10.6	33	0	0.0	0.0	10.6	32	0	0.0	0.0	10.9
	Pre-Frail	HZ/su	2008	349	17.4	15.7	19.1	2007	240	12.0	10.6	13.5	2007	190	9.5	8.2	10.8
		Placebo	2034	37	1.8	1.3	2.5	2034	36	1.8	1.2	2.4	2034	4	0.2	0.1	0.5
	Frail	HZ/su	1977	279	14.1	12.6	15.7	1971	185	9.4	8.1	10.8	1977	172	8.7	7.5	10.0
		Placebo	1964	44	2.2	1.6	3.0	1964	40	2.0	1.5	2.8	1964	6	0.3	0.1	0.7
Overall/subject	Non-Frail	HZ/su	490	75	15.3	12.2	18.8	488	50	10.2	7.7	13.3	489	50	10.2	7.7	13.3
		Placebo	468	24	5.1	3.3	7.5	468	22	4.7	3.0	7.0	468	5	1.1	0.3	2.5
	Frail	HZ/su	21	1	4.8	0.1	23.8	21	0	0.0	0.0	16.1	21	1	4.8	0.1	23.8
		Placebo	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	17	0	0.0	0.0	19.5
	Pre-Frail	HZ/su	1977	279	14.1	12.6	15.7	1971	185	9.4	8.1	10.8	1977	172	8.7	7.5	10.0
		Placebo	1964	44	2.2	1.6	3.0	1964	40	2.0	1.5	2.8	1964	6	0.3	0.1	0.7

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 14.3.1.4 Incidence and nature of related symptoms (solicited only) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom					General symptoms					Local symptoms				
						95% CI					95% CI					95% CI	
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Non-Frail	HZ/su	2004	1634	81.5	79.8	83.2	2001	930	46.5	44.3	48.7	2000	1569	78.5	76.6	80.2
		Placebo	2032	400	19.7	18.0	21.5	2032	291	14.3	12.8	15.9	2031	168	8.3	7.1	9.6
	Pre-Frail	HZ/su	1971	1463	74.2	72.2	76.1	1963	796	40.6	38.4	42.8	1970	1393	70.7	68.6	72.7
		Placebo	1962	376	19.2	17.4	21.0	1960	282	14.4	12.9	16.0	1962	158	8.1	6.9	9.3
	Frail	HZ/su	483	308	63.8	59.3	68.1	480	144	30.0	25.9	34.3	483	292	60.5	55.9	64.8
		Placebo	462	90	19.5	16.0	23.4	461	74	16.1	12.8	19.7	461	33	7.2	5.0	9.9
	Unknown	HZ/su	21	16	76.2	52.8	91.8	20	8	40.0	19.1	63.9	21	15	71.4	47.8	88.7
		Placebo	18	6	33.3	13.3	59.0	18	5	27.8	9.7	53.5	17	2	11.8	1.5	36.4
Dose 2	Non-Frail	HZ/su	1943	1540	79.3	77.4	81.0	1942	980	50.5	48.2	52.7	1941	1457	75.1	73.1	77.0
		Placebo	1988	286	14.4	12.9	16.0	1988	217	10.9	9.6	12.4	1988	111	5.6	4.6	6.7
	Pre-Frail	HZ/su	1911	1347	70.5	68.4	72.5	1906	801	42.0	39.8	44.3	1909	1259	66.0	63.8	68.1
		Placebo	1899	279	14.7	13.1	16.4	1895	217	11.5	10.1	13.0	1899	115	6.1	5.0	7.2
	Frail	HZ/su	456	287	62.9	58.3	67.4	456	163	35.7	31.3	40.3	455	268	58.9	54.2	63.5
		Placebo	444	66	14.9	11.7	18.5	443	46	10.4	7.7	13.6	442	35	7.9	5.6	10.8
	Unknown	HZ/su	18	12	66.7	41.0	86.7	18	4	22.2	6.4	47.6	18	11	61.1	35.7	82.7
		Placebo	15	1	6.7	0.2	31.9	15	1	6.7	0.2	31.9	15	0	0.0	0.0	21.8
Overall/dose	Non-Frail	HZ/su	3947	3174	80.4	79.1	81.6	3943	1910	48.4	46.9	50.0	3941	3026	76.8	75.4	78.1
		Placebo	4020	686	17.1	15.9	18.3	4020	508	12.6	11.6	13.7	4019	279	6.9	6.2	7.8
	Pre-Frail	HZ/su	3882	2810	72.4	70.9	73.8	3869	1597	41.3	39.7	42.8	3879	2652	68.4	66.9	69.8
		Placebo	3861	655	17.0	15.8	18.2	3855	499	12.9	11.9	14.0	3861	273	7.1	6.3	7.9
	Frail	HZ/su	939	595	63.4	60.2	66.5	936	307	32.8	29.8	35.9	938	560	59.7	56.5	62.9
		Placebo	906	156	17.2	14.8	19.8	904	120	13.3	11.1	15.7	903	68	7.5	5.9	9.4
	Unknown	HZ/su	39	28	71.8	55.1	85.0	38	12	31.6	17.5	48.7	39	26	66.7	49.8	80.9
		Placebo	33	7	21.2	9.0	38.9	33	6	18.2	7.0	35.5	32	2	6.3	0.8	20.8
Overall/subject	Non-Frail	HZ/su	2008	1740	86.7	85.1	88.1	2007	1235	61.5	59.4	63.7	2007	1699	84.7	83.0	86.2
		Placebo	2034	529	26.0	24.1	28.0	2034	409	20.1	18.4	21.9	2034	227	11.2	9.8	12.6
	Pre-Frail	HZ/su	1977	1621	82.0	80.2	83.7	1971	1079	54.7	52.5	57.0	1977	1559	78.9	77.0	80.6
		Placebo	1964	519	26.4	24.5	28.4	1964	403	20.5	18.8	22.4	1964	227	11.6	10.2	13.1
	Frail	HZ/su	490	352	71.8	67.6	75.8	488	211	43.2	38.8	47.8	489	335	68.5	64.2	72.6
		Placebo	468	115	24.6	20.7	28.7	468	93	19.9	16.3	23.8	468	51	10.9	8.2	14.1
	Unknown	HZ/su	21	18	85.7	63.7	97.0	21	8	38.1	18.1	61.6	21	17	81.0	58.1	94.6
		Placebo	18	7	38.9	17.3	64.3	18	6	33.3	13.3	59.0	17	2	11.8	1.5	36.4

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 14.3.1.5 Incidence and nature of grade 3 related symptoms (solicited only) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom					General symptoms					Local symptoms				
			95% CI					95% CI					95% CI				
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Non-Frail	HZ/su	2004	170	8.5	7.3	9.8	2001	90	4.5	3.6	5.5	2000	110	5.5	4.5	6.6
		Placebo	2032	16	0.8	0.5	1.3	2032	14	0.7	0.4	1.2	2031	3	0.1	0.0	0.4
	Pre-Frail	HZ/su	1971	150	7.6	6.5	8.9	1963	81	4.1	3.3	5.1	1970	99	5.0	4.1	6.1
		Placebo	1962	17	0.9	0.5	1.4	1960	16	0.8	0.5	1.3	1962	2	0.1	0.0	0.4
	Frail	HZ/su	483	38	7.9	5.6	10.6	480	20	4.2	2.6	6.4	483	26	5.4	3.5	7.8
		Placebo	462	7	1.5	0.6	3.1	461	7	1.5	0.6	3.1	461	1	0.2	0.0	1.2
	Unknown	HZ/su	21	1	4.8	0.1	23.8	20	0	0.0	0.0	16.8	21	1	4.8	0.1	23.8
		Placebo	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	17	0	0.0	0.0	19.5
Dose 2	Non-Frail	HZ/su	1943	228	11.7	10.3	13.2	1942	159	8.2	7.0	9.5	1941	118	6.1	5.1	7.2
		Placebo	1988	11	0.6	0.3	1.0	1988	11	0.6	0.3	1.0	1988	1	0.1	0.0	0.3
	Pre-Frail	HZ/su	1911	160	8.4	7.2	9.7	1906	100	5.2	4.3	6.3	1909	100	5.2	4.3	6.3
		Placebo	1899	13	0.7	0.4	1.2	1895	10	0.5	0.3	1.0	1899	4	0.2	0.1	0.5
	Frail	HZ/su	456	47	10.3	7.7	13.5	456	29	6.4	4.3	9.0	455	33	7.3	5.0	10.0
		Placebo	444	10	2.3	1.1	4.1	443	7	1.6	0.6	3.2	442	4	0.9	0.2	2.3
	Unknown	HZ/su	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5
		Placebo	15	0	0.0	0.0	21.8	15	0	0.0	0.0	21.8	15	0	0.0	0.0	21.8
Overall/dose	Non-Frail	HZ/su	3947	398	10.1	9.2	11.1	3943	249	6.3	5.6	7.1	3941	228	5.8	5.1	6.6
		Placebo	4020	27	0.7	0.4	1.0	4020	25	0.6	0.4	0.9	4019	4	0.1	0.0	0.3
	Pre-Frail	HZ/su	3882	310	8.0	7.2	8.9	3869	181	4.7	4.0	5.4	3879	199	5.1	4.5	5.9
		Placebo	3861	30	0.8	0.5	1.1	3855	26	0.7	0.4	1.0	3861	6	0.2	0.1	0.3
	Frail	HZ/su	939	85	9.1	7.3	11.1	936	49	5.2	3.9	6.9	938	59	6.3	4.8	8.0
		Placebo	906	17	1.9	1.1	3.0	904	14	1.5	0.8	2.6	903	5	0.6	0.2	1.3
	Unknown	HZ/su	39	1	2.6	0.1	13.5	38	0	0.0	0.0	9.3	39	1	2.6	0.1	13.5
		Placebo	33	0	0.0	0.0	10.6	33	0	0.0	0.0	10.6	32	0	0.0	0.0	10.9
Overall/subject	Non-Frail	HZ/su	2008	335	16.7	15.1	18.4	2007	219	10.9	9.6	12.4	2007	190	9.5	8.2	10.8
		Placebo	2034	25	1.2	0.8	1.8	2034	23	1.1	0.7	1.7	2034	4	0.2	0.1	0.5
	Pre-Frail	HZ/su	1977	263	13.3	11.8	14.9	1971	162	8.2	7.0	9.5	1977	172	8.7	7.5	10.0
		Placebo	1964	28	1.4	0.9	2.1	1964	24	1.2	0.8	1.8	1964	6	0.3	0.1	0.7
	Frail	HZ/su	490	69	14.1	11.1	17.5	488	43	8.8	6.5	11.7	489	50	10.2	7.7	13.3
		Placebo	468	16	3.4	2.0	5.5	468	13	2.8	1.5	4.7	468	5	1.1	0.3	2.5
	Unknown	HZ/su	21	1	4.8	0.1	23.8	21	0	0.0	0.0	16.1	21	1	4.8	0.1	23.8
		Placebo	18	0	0.0	0.0	18.5	18	0	0.0	0.0	18.5	17	0	0.0	0.0	19.5

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 14.3.1.6 Incidence and nature of symptoms (solicited and unsolicited) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom					General symptoms					Local symptoms				
						95% CI					95% CI					95% CI	
	Sub-group	Group	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1	Non-Frail	HZ/su	2032	1657	81.5	79.8	83.2	2032	1096	53.9	51.7	56.1	2032	1571	77.3	75.4	79.1
		Placebo	2066	556	26.9	25.0	28.9	2066	477	23.1	21.3	25.0	2066	173	8.4	7.2	9.7
	Pre-Frail	HZ/su	2013	1513	75.2	73.2	77.0	2013	1008	50.1	47.9	52.3	2013	1395	69.3	67.2	71.3
		Placebo	1999	570	28.5	26.5	30.5	1999	498	24.9	23.0	26.9	1999	162	8.1	6.9	9.4
	Frail	HZ/su	503	319	63.4	59.0	67.6	503	196	39.0	34.7	43.4	503	294	58.4	54.0	62.8
		Placebo	484	146	30.2	26.1	34.5	484	136	28.1	24.1	32.3	484	36	7.4	5.3	10.1
	Unknown	HZ/su	22	16	72.7	49.8	89.3	22	11	50.0	28.2	71.8	22	15	68.2	45.1	86.1
		Placebo	22	7	31.8	13.9	54.9	22	6	27.3	10.7	50.2	22	2	9.1	1.1	29.2
Dose 2	Non-Frail	HZ/su	1954	1567	80.2	78.4	81.9	1954	1124	57.5	55.3	59.7	1954	1459	74.7	72.7	76.6
		Placebo	2001	407	20.3	18.6	22.2	2001	344	17.2	15.6	18.9	2001	115	5.7	4.8	6.9
	Pre-Frail	HZ/su	1929	1395	72.3	70.3	74.3	1929	969	50.2	48.0	52.5	1929	1263	65.5	63.3	67.6
		Placebo	1919	437	22.8	20.9	24.7	1919	389	20.3	18.5	22.1	1919	118	6.1	5.1	7.3
	Frail	HZ/su	465	300	64.5	60.0	68.9	465	202	43.4	38.9	48.1	465	269	57.8	53.2	62.4
		Placebo	449	110	24.5	20.6	28.7	449	98	21.8	18.1	25.9	449	36	8.0	5.7	10.9
	Unknown	HZ/su	20	12	60.0	36.1	80.9	20	6	30.0	11.9	54.3	20	11	55.0	31.5	76.9
		Placebo	17	3	17.6	3.8	43.4	17	3	17.6	3.8	43.4	17	0	0.0	0.0	19.5
Overall/dose	Non-Frail	HZ/su	3986	3224	80.9	79.6	82.1	3986	2220	55.7	54.1	57.2	3986	3030	76.0	74.7	77.3
		Placebo	4067	963	23.7	22.4	25.0	4067	821	20.2	19.0	21.5	4067	288	7.1	6.3	7.9
	Pre-Frail	HZ/su	3942	2908	73.8	72.4	75.1	3942	1977	50.2	48.6	51.7	3942	2658	67.4	65.9	68.9
		Placebo	3918	1007	25.7	24.3	27.1	3918	887	22.6	21.3	24.0	3918	280	7.1	6.4	8.0
	Frail	HZ/su	968	619	63.9	60.8	67.0	968	398	41.1	38.0	44.3	968	563	58.2	55.0	61.3
		Placebo	933	256	27.4	24.6	30.4	933	234	25.1	22.3	28.0	933	72	7.7	6.1	9.6
	Unknown	HZ/su	42	28	66.7	50.5	80.4	42	17	40.5	25.6	56.7	42	26	61.9	45.6	76.4
		Placebo	39	10	25.6	13.0	42.1	39	9	23.1	11.1	39.3	39	2	5.1	0.6	17.3
Overall/subject	Non-Frail	HZ/su	2032	1761	86.7	85.1	88.1	2032	1405	69.1	67.1	71.1	2032	1702	83.8	82.1	85.3
		Placebo	2066	722	34.9	32.9	37.0	2066	629	30.4	28.5	32.5	2066	234	11.3	10.0	12.8
	Pre-Frail	HZ/su	2013	1670	83.0	81.2	84.6	2013	1297	64.4	62.3	66.5	2013	1561	77.5	75.7	79.4
		Placebo	1999	767	38.4	36.2	40.5	1999	684	34.2	32.1	36.3	1999	232	11.6	10.2	13.1
	Frail	HZ/su	503	365	72.6	68.4	76.4	503	264	52.5	48.0	56.9	503	338	67.2	62.9	71.3
		Placebo	484	188	38.8	34.5	43.3	484	173	35.7	31.5	40.2	484	55	11.4	8.7	14.5
	Unknown	HZ/su	22	18	81.8	59.7	94.8	22	12	54.5	32.2	75.6	22	17	77.3	54.6	92.2
		Placebo	22	8	36.4	17.2	59.3	22	7	31.8	13.9	54.9	22	2	9.1	1.1	29.2

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of administered doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

Table 14.3.1.7 Incidence and nature of grade 3 symptoms (solicited and unsolicited) reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

			Any symptom						General symptoms						Local symptoms					
						95% CI						95% CI						95% CI		
	Sub-group	Group	N	n	%	LL	UL		N	n	%	LL	UL		N	n	%	LL	UL	
Dose 1	Non-Frail	HZ/su	2032	191	9.4	8.2	10.8	2032	115	5.7	4.7	6.8	2032	111	5.5	4.5	6.5			
		Placebo	2066	29	1.4	0.9	2.0	2066	28	1.4	0.9	2.0	2066	3	0.1	0.0	0.4			
	Pre-Frail	HZ/su	2013	174	8.6	7.5	10.0	2013	113	5.6	4.6	6.7	2013	99	4.9	4.0	6.0			
		Placebo	1999	34	1.7	1.2	2.4	1999	32	1.6	1.1	2.3	1999	3	0.2	0.0	0.4			
	Frail	HZ/su	503	47	9.3	6.9	12.2	503	29	5.8	3.9	8.2	503	26	5.2	3.4	7.5			
		Placebo	484	18	3.7	2.2	5.8	484	18	3.7	2.2	5.8	484	1	0.2	0.0	1.1			
	Unknown	HZ/su	22	1	4.5	0.1	22.8	22	0	0.0	0.0	15.4	22	1	4.5	0.1	22.8			
		Placebo	22	0	0.0	0.0	15.4	22	0	0.0	0.0	15.4	22	0	0.0	0.0	15.4			
Dose 2	Non-Frail	HZ/su	1954	248	12.7	11.2	14.2	1954	184	9.4	8.2	10.8	1954	118	6.0	5.0	7.2			
		Placebo	2001	21	1.0	0.7	1.6	2001	21	1.0	0.7	1.6	2001	1	0.0	0.0	0.3			
	Pre-Frail	HZ/su	1929	176	9.1	7.9	10.5	1929	120	6.2	5.2	7.4	1929	100	5.2	4.2	6.3			
		Placebo	1919	29	1.5	1.0	2.2	1919	26	1.4	0.9	2.0	1919	4	0.2	0.1	0.5			
	Frail	HZ/su	465	51	11.0	8.3	14.2	465	33	7.1	4.9	9.8	465	33	7.1	4.9	9.8			
		Placebo	449	18	4.0	2.4	6.3	449	16	3.6	2.1	5.7	449	4	0.9	0.2	2.3			
	Unknown	HZ/su	20	0	0.0	0.0	16.8	20	0	0.0	0.0	16.8	20	0	0.0	0.0	16.8			
		Placebo	17	0	0.0	0.0	19.5	17	0	0.0	0.0	19.5	17	0	0.0	0.0	19.5			
Overall/dose	Non-Frail	HZ/su	3986	439	11.0	10.1	12.0	3986	299	7.5	6.7	8.4	3986	229	5.7	5.0	6.5			
		Placebo	4067	50	1.2	0.9	1.6	4067	49	1.2	0.9	1.6	4067	4	0.1	0.0	0.3			
	Pre-Frail	HZ/su	3942	350	8.9	8.0	9.8	3942	233	5.9	5.2	6.7	3942	199	5.0	4.4	5.8			
		Placebo	3918	63	1.6	1.2	2.1	3918	58	1.5	1.1	1.9	3918	7	0.2	0.1	0.4			
	Frail	HZ/su	968	98	10.1	8.3	12.2	968	62	6.4	4.9	8.1	968	59	6.1	4.7	7.8			
		Placebo	933	36	3.9	2.7	5.3	933	34	3.6	2.5	5.1	933	5	0.5	0.2	1.2			
	Unknown	HZ/su	42	1	2.4	0.1	12.6	42	0	0.0	0.0	8.4	42	1	2.4	0.1	12.6			
		Placebo	39	0	0.0	0.0	9.0	39	0	0.0	0.0	9.0	39	0	0.0	0.0	9.0			
Overall/subject	Non-Frail	HZ/su	2032	367	18.1	16.4	19.8	2032	259	12.7	11.3	14.3	2032	191	9.4	8.2	10.8			
		Placebo	2066	46	2.2	1.6	3.0	2066	45	2.2	1.6	2.9	2066	4	0.2	0.1	0.5			
	Pre-Frail	HZ/su	2013	294	14.6	13.1	16.2	2013	202	10.0	8.8	11.4	2013	172	8.5	7.4	9.9			
		Placebo	1999	57	2.9	2.2	3.7	1999	52	2.6	1.9	3.4	1999	7	0.4	0.1	0.7			
	Frail	HZ/su	503	79	15.7	12.6	19.2	503	54	10.7	8.2	13.8	503	50	9.9	7.5	12.9			
		Placebo	484	31	6.4	4.4	9.0	484	29	6.0	4.0	8.5	484	5	1.0	0.3	2.4			
	Unknown	HZ/su	22	1	4.5	0.1	22.8	22	0	0.0	0.0	15.4	22	1	4.5	0.1	22.8			
		Placebo	22	0	0.0	0.0	15.4	22	0	0.0	0.0	15.4	22	0	0.0	0.0	15.4			

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects presenting at least one type of symptom

For overall/dose:

N = number of administered doses

n/% = number/percentage of doses followed by at least one type of symptom

95% CI = exact 95% confidence interval, LL = Lower Limit, UL = Upper Limit

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Table 14.3.1.8 Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
Symptom	Type	N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI						
					LL	UL				LL	UL				LL	UL				LL	UL				LL	UL				LL	UL				LL	UL	LL	UL			
Dose 1																																									
Pain	All	2000	1515	75.8	73.8	77.6	2031	154	7.6	6.5	8.8	1970	1315	66.8	64.6	68.8	1962	143	7.3	6.2	8.5	483	276	57.1	52.6	61.6	461	32	6.9	4.8	9.7	21	15	71.4	47.8	88.7	17	1	5.9	0.1	28.7
	Grade 1	2000	1034	51.7	49.5	53.9	2031	133	6.5	5.5	7.7	1970	913	46.3	44.1	48.6	1962	128	6.5	5.5	7.7	483	164	34.0	29.7	38.4	461	29	6.3	4.3	8.9	21	13	61.9	38.4	81.9	17	1	5.9	0.1	28.7
	Grade 2	2000	420	21.0	19.2	22.9	2031	18	0.9	0.5	1.4	1970	335	17.0	15.4	18.7	1962	12	0.6	0.3	1.1	483	92	19.0	15.6	22.8	461	2	0.4	0.1	1.6	21	1	4.8	0.1	23.8	17	0	0.0	0.0	19.5
	Grade 3	2000	60	3.0	2.3	3.8	2031	3	0.1	0.0	0.4	1970	65	3.3	2.6	4.2	1962	2	0.1	0.0	0.4	483	20	4.1	2.5	6.3	461	1	0.2	0.0	1.2	21	1	4.8	0.1	23.8	17	0	0.0	0.0	19.5
Redness (mm)	All	2000	599	30.0	27.9	32.0	2031	18	0.9	0.5	1.4	1970	526	26.7	24.8	28.7	1962	19	1.0	0.6	1.5	483	119	24.6	20.9	28.7	461	1	0.2	0.0	1.2	21	6	28.6	11.3	52.2	17	0	0.0	0.0	19.5
	≥20 and ≤50	2000	284	14.2	12.7	15.8	2031	17	0.8	0.5	1.3	1970	253	12.8	11.4	14.4	1962	15	0.8	0.4	1.3	483	56	11.6	8.9	14.8	461	1	0.2	0.0	1.2	21	2	9.5	1.2	30.4	17	0	0.0	0.0	19.5
	>50 and ≤100	2000	266	13.3	11.8	14.9	2031	1	0.0	0.0	0.3	1970	239	12.1	10.7	13.7	1962	3	0.2	0.0	0.4	483	54	11.2	8.5	14.3	461	0	0.0	0.0	0.8	21	4	19.0	5.4	41.9	17	0	0.0	0.0	19.5
	>100	2000	49	2.5	1.8	3.2	2031	0	0.0	0.0	0.2	1970	30	1.5	1.0	2.2	1962	0	0.0	0.0	0.2	483	6	1.2	0.5	2.7	461	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5
Swelling (mm)	All	2000	383	19.2	17.4	20.9	2031	12	0.6	0.3	1.0	1970	340	17.3	15.6	19.0	1962	15	0.8	0.4	1.3	483	79	16.4	13.2	20.0	461	2	0.4	0.1	1.6	21	5	23.8	8.2	47.2	17	1	5.9	0.1	28.7
	≥20 and ≤50	2000	208	10.4	9.1	11.8	2031	11	0.5	0.3	1.0	1970	183	9.3	8.0	10.7	1962	12	0.6	0.3	1.1	483	40	8.3	6.0	11.1	461	2	0.4	0.1	1.6	21	2	9.5	1.2	30.4	17	1	5.9	0.1	28.7
	>50 and ≤100	2000	161	8.1	6.9	9.3	2031	1	0.0	0.0	0.3	1970	136	6.9	5.8	8.1	1962	1	0.1	0.0	0.3	483	36	7.5	5.3	10.2	461	0	0.0	0.0	0.8	21	3	14.3	3.0	36.3	17	0	0.0	0.0	19.5
	>100	2000	13	0.7	0.3	1.1	2031	0	0.0	0.0	0.2	1970	12	0.6	0.3	1.1	1962	0	0.0	0.0	0.2	483	0	0.0	0.0	0.8	461	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5
Dose 2																																									
Pain	All	1941	1382	71.2	69.1	73.2	1988	106	5.3	4.4	6.4	1909	1187	62.2	60.0	64.4	1899	110	5.8	4.8	6.9	455	256	56.3	51.6	60.9	442	35	7.9	5.6	10.8	18	11	61.1	35.7	82.7	15	0	0.0	0.0	21.8
	Grade 1	1941	936	48.2	46.0	50.5	1988	96	4.8	3.9	5.9	1909	776	40.6	38.4	42.9	1899	93	4.9	4.0	6.0	455	150	33.0	28.7	37.5	442	28	6.3	4.3	9.0	18	10	55.6	30.8	78.5	15	0	0.0	0.0	21.8
	Grade 2	1941	365	18.8	17.1	20.6	1988	9	0.5	0.2	0.9	1909	331	17.3	15.7	19.1	1899	13	0.7	0.4	1.2	455	81	17.8	14.4	21.6	442	3	0.7	0.1	2.0	18	1	5.6	0.1	27.3	15	0	0.0	0.0	21.8
	Grade 3	1941	80	4.1	3.3	5.1	1988	1	0.1	0.0	0.3	1909	78	4.1	3.2	5.1	1899	4	0.2	0.1	0.5	455	25	5.5	3.6	8.0	442	4	0.9	0.2	2.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Redness (mm)	All	1941	583	30.0	28.0	32.1	1988	8	0.4	0.2	0.8	1909	499	26.1	24.2	28.2	1899	12	0.6	0.3	1.1	455	104	22.9	19.1	27.0	442	1	0.2	0.0	1.3	18	6	33.3	13.3	59.0	15	0	0.0	0.0	21.8
	≥20 and ≤50	1941	272	14.0	12.5	15.6	1988	6	0.3	0.1	0.7	1909	225	11.8	10.4	13.3	1899	11	0.6	0.3	1.0	455	54	11.9	9.0	15.2	442	1	0.2	0.0	1.3	18	5	27.8	9.7	53.5	15	0	0.0	0.0	21.8
	>50 and ≤100	1941	271	14.0	12.4	15.6	1988	1	0.1	0.0	0.3	1909	247	12.9	11.5	14.5	1899	1	0.1	0.0	0.3	455	41	9.0	6.5	12.0	442	0	0.0	0.0	0.8	18	1	5.6	0.1	27.3	15	0	0.0	0.0	21.8
	>100	1941	37	1.9	1.3	2.6	1988	0	0.0	0.0	0.2	1909	22	1.2	0.7	1.7	1899	0	0.0	0.0	0.2	455	8	1.8	0.8	3.4	442	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Swelling (mm)	All	1941	364	18.8	17.0	20.6	1988	6	0.3	0.1	0.7	1909	336	17.6	15.9	19.4	1899	9	0.5	0.2	0.9	455	63	13.8	10.8	17.4	442	1	0.2	0.0	1.3	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	≥20 and ≤50	1941	208	10.7	9.4	12.2	1988	5	0.3	0.1	0.6	1909	200	10.5	9.1	11.9	1899	9	0.5	0.2	0.9	455	38	8.4	6.0	11.3	442	1	0.2	0.0	1.3	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	>50 and ≤100	1941	140	7.2	6.1	8.5	1988	1	0.1	0.0	0.3	1909	120	6.3	5.2	7.5	1899	0	0.0	0.0	0.2	455	22	4.8	3.1	7.2	442	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	>100	1941	13	0.7	0.4	1.1	1988	0	0.0	0.0	0.2	1909	9	0.5	0.2	0.9	1899	0	0.0	0.0	0.2	455	2	0.4	0.1	1.6	442	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Overall/dose																																									
Pain	All	3941	2897	73.5	72.1	74.9	4019	260	6.5	5.7	7.3	3879	2502	64.5	63.0	66.0	3861	253	6.6	5.8	7.4	938	532	56.7	53.5	59.9	903	67	7.4	5.8	9.3	39	26	66.7	49.8	80.9	32	1	3.1	0.1	16.2
	Grade 1	3941	1970	50.0	48.4	51.6	4019	229	5.7	5.0	6.5	3879	1689	43.5	42.0	45.1	3861	221	5.7	5.0	6.5	938	314	33.5	30.5	36.6	903	57	6.3	4.8	8.1	39	23	59.0	42.1	74.4	32	1	3.1	0.1	16.2
	Grade 2	3941	785	19.9	18.7	21.2	4019	27	0.7	0.4	1.0	3879	666	17.2	16.0	18.4	3861	25	0.6	0.4	1.0	938	173	18.4	16.0	21.1	903	5	0.6	0.2	1.3	39	2	5.1	0.6	17.3	32	0	0.0	0.0	10.9
	Grade 3	3941	140	3.6	3.0	4.2	4019	4	0.1	0.0	0.3	3879	143	3.7	3.1	4.3	3861	6	0.2	0.1	0.3	938	45	4.8	3.5	6.4	903	5	0.6	0.2	1.3	39	1	2.6	0.1	13.5	32	0	0.0	0.0	10.9
Redness (mm)	All	3941	1182	30.0	28.6	31.5	4019	26	0.6	0.4	0.9	3879	1025	26.4	25.0	27.8	3861	31	0.8	0.5	1.1	938	223	23.8	21.1	26.6	903	2	0.2	0.0	0.8	39	12	30.8	17.0	47.6	32	0	0.0	0.0	10.9
	≥20 and ≤50	3941	556	14.1	13.0	15.2	4019	23	0.6	0.4	0.9	3879	478	12.3	11.3	13.4	3861	26	0.7	0.4	1.0	938	110	11.7	9.7	14.0	903	2	0.2	0.0	0.8	39	7	17.9	7.5	33.5	32	0	0.0	0.0	10.9
	>50 and ≤100	3941	537	13.6	12.6	14.7	4019	2	0.0	0.0	0.2	3879	486	12.5	11.5	13.6	3861	4	0.1	0.0	0.3	938	95	10.1	8.3	12.2	903	0	0.0	0.0	0.4	39	5	12.8	4.3	27.4	32	0	0.0	0.0	10.9
	>100	3941	86	2.2	1.7	2.7	4019	0	0.0	0.0	0.1	3879	52	1.3	1.0	1.8	3861	0	0.0	0.0	0.1	938	14	1.5	0.8	2.5	903	0	0.0	0.0	0.4	39	0	0.0	0.0	9.0	32	0	0.0	0.0	10.9

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		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Swelling (mm)	All	3941	747	19.0	17.7	20.2	4019	18	0.4	0.3	0.7	3879	676	17.4	16.2	18.7	3861	24	0.6	0.4	0.9	938	142	15.1	12.9	17.6	903	3	0.3	0.1	1.0	39	7	17.9	7.5	33.5	32	1	3.1	0.1	16.2
	≥20 and ≤50	3941	416	10.6	9.6	11.6	4019	16	0.4	0.2	0.6	3879	383	9.9	9.0	10.9	3861	21	0.5	0.3	0.8	938	78	8.3	6.6	10.3	903	3	0.3	0.1	1.0	39	4	10.3	2.9	24.2	32	1	3.1	0.1	16.2
	>50 and ≤100	3941	301	7.6	6.8	8.5	4019	2	0.0	0.0	0.2	3879	256	6.6	5.8	7.4	3861	1	0.0	0.0	0.1	938	58	6.2	4.7	7.9	903	0	0.0	0.0	0.4	39	3	7.7	1.6	20.9	32	0	0.0	0.0	10.9
	>100	3941	26	0.7	0.4	1.0	4019	0	0.0	0.0	0.1	3879	21	0.5	0.3	0.8	3861	0	0.0	0.0	0.1	938	2	0.2	0.0	0.8	903	0	0.0	0.0	0.4	39	0	0.0	0.0	9.0	32	0	0.0	0.0	10.9
Overall/subject																																									
Pain	All	2007	1655	82.5	80.7	84.1	2034	209	10.3	9.0	11.7	1977	1494	75.6	73.6	77.4	1964	211	10.7	9.4	12.2	489	322	65.8	61.5	70.0	468	51	10.9	8.2	14.1	21	17	81.0	58.1	94.6	17	1	5.9	0.1	28.7
	Grade 1	2007	960	47.8	45.6	50.0	2034	180	8.8	7.7	10.2	1977	882	44.6	42.4	46.8	1964	184	9.4	8.1	10.7	489	155	31.7	27.6	36.0	468	43	9.2	6.7	12.2	21	14	66.7	43.0	85.4	17	1	5.9	0.1	28.7
	Grade 2	2007	579	28.8	26.9	30.9	2034	25	1.2	0.8	1.8	1977	483	24.4	22.6	26.4	1964	20	1.0	0.6	1.6	489	129	26.4	22.5	30.5	468	3	0.6	0.1	1.9	21	2	9.5	1.2	30.4	17	0	0.0	0.0	19.5
	Grade 3	2007	115	5.7	4.8	6.8	2034	4	0.2	0.1	0.5	1977	125	6.3	5.3	7.5	1964	6	0.3	0.1	0.7	489	38	7.8	5.6	10.5	468	5	1.1	0.3	2.5	21	1	4.8	0.1	23.8	17	0	0.0	0.0	19.5
Redness (mm)	All	2007	805	40.1	38.0	42.3	2034	25	1.2	0.8	1.8	1977	734	37.1	35.0	39.3	1964	28	1.4	0.9	2.1	489	160	32.7	28.6	37.1	468	2	0.4	0.1	1.5	21	11	52.4	29.8	74.3	17	0	0.0	0.0	19.5
	≥20 and ≤50	2007	336	16.7	15.1	18.4	2034	22	1.1	0.7	1.6	1977	318	16.1	14.5	17.8	1964	23	1.2	0.7	1.8	489	74	15.1	12.1	18.6	468	2	0.4	0.1	1.5	21	6	28.6	11.3	52.2	17	0	0.0	0.0	19.5
	>50 and ≤100	2007	393	19.6	17.9	21.4	2034	2	0.1	0.0	0.4	1977	363	18.4	16.7	20.1	1964	4	0.2	0.1	0.5	489	70	14.3	11.3	17.7	468	0	0.0	0.0	0.8	21	5	23.8	8.2	47.2	17	0	0.0	0.0	19.5
	>100	2007	75	3.7	3.0	4.7	2034	0	0.0	0.0	0.2	1977	46	2.3	1.7	3.1	1964	0	0.0	0.0	0.2	489	12	2.5	1.3	4.2	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5
Swelling (mm)	All	2007	545	27.2	25.2	29.2	2034	18	0.9	0.5	1.4	1977	497	25.1	23.2	27.1	1964	22	1.1	0.7	1.7	489	107	21.9	18.3	25.8	468	3	0.6	0.1	1.9	21	6	28.6	11.3	52.2	17	1	5.9	0.1	28.7
	≥20 and ≤50	2007	285	14.2	12.7	15.8	2034	16	0.8	0.5	1.3	1977	263	13.3	11.8	14.9	1964	19	1.0	0.6	1.5	489	51	10.4	7.9	13.5	468	3	0.6	0.1	1.9	21	3	14.3	3.0	36.3	17	1	5.9	0.1	28.7
	>50 and ≤100	2007	233	11.6	10.2	13.1	2034	2	0.1	0.0	0.4	1977	204	10.3	9.0	11.7	1964	1	0.1	0.0	0.3	489	50	10.2	7.7	13.3	468	0	0.0	0.0	0.8	21	3	14.3	3.0	36.3	17	0	0.0	0.0	19.5
	>100	2007	24	1.2	0.8	1.8	2034	0	0.0	0.0	0.2	1977	19	1.0	0.6	1.5	1964	0	0.0	0.0	0.2	489	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	17	0	0.0	0.0	19.5

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

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Table 14.3.1.9 Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall by frailty status (Total Vaccinated Cohort - Diary Card Subset)

		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Dose 1																																									
Fatigue	All	2001	650	32.5	30.4	34.6	2032	219	10.8	9.5	12.2	1963	592	30.2	28.1	32.2	1960	237	12.1	10.7	13.6	480	114	23.8	20.0	27.8	461	77	16.7	13.4	20.4	20	4	20.0	5.7	43.7	18	4	22.2	6.4	47.6
	Grade 1	2001	449	22.4	20.6	24.3	2032	173	8.5	7.3	9.8	1963	399	20.3	18.6	22.2	1960	179	9.1	7.9	10.5	480	68	14.2	11.2	17.6	461	46	10.0	7.4	13.1	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Grade 2	2001	158	7.9	6.8	9.2	2032	37	1.8	1.3	2.5	1963	147	7.5	6.4	8.7	1960	45	2.3	1.7	3.1	480	32	6.7	4.6	9.3	461	26	5.6	3.7	8.2	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Grade 3	2001	43	2.1	1.6	2.9	2032	9	0.4	0.2	0.8	1963	46	2.3	1.7	3.1	1960	12	0.6	0.3	1.1	480	14	2.9	1.6	4.8	461	5	1.1	0.4	2.5	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	565	28.2	26.3	30.3	2032	160	7.9	6.7	9.1	1963	482	24.6	22.7	26.5	1960	147	7.5	6.4	8.8	480	88	18.3	15.0	22.1	461	40	8.7	6.3	11.6	20	4	20.0	5.7	43.7	18	4	22.2	6.4	47.6
	Grade 1	2001	390	19.5	17.8	21.3	2032	124	6.1	5.1	7.2	1963	321	16.4	14.7	18.1	1960	115	5.9	4.9	7.0	480	53	11.0	8.4	14.2	461	23	5.0	3.2	7.4	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Related																																								
	Grade 2	2001	138	6.9	5.8	8.1	2032	29	1.4	1.0	2.0	1963	127	6.5	5.4	7.6	1960	24	1.2	0.8	1.8	480	24	5.0	3.2	7.3	461	14	3.0	1.7	5.0	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Related																																								
	Grade 3	2001	37	1.8	1.3	2.5	2032	7	0.3	0.1	0.7	1963	34	1.7	1.2	2.4	1960	8	0.4	0.2	0.8	480	11	2.3	1.1	4.1	461	3	0.7	0.1	1.9	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related																																								
Gastrointestinal symptoms	All	2001	219	10.9	9.6	12.4	2032	100	4.9	4.0	6.0	1963	188	9.6	8.3	11.0	1960	117	6.0	5.0	7.1	480	38	7.9	5.7	10.7	461	39	8.5	6.1	11.4	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Grade 1	2001	162	8.1	6.9	9.4	2032	78	3.8	3.0	4.8	1963	146	7.4	6.3	8.7	1960	84	4.3	3.4	5.3	480	23	4.8	3.1	7.1	461	25	5.4	3.5	7.9	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3
	Grade 2	2001	44	2.2	1.6	2.9	2032	18	0.9	0.5	1.4	1963	28	1.4	0.9	2.1	1960	25	1.3	0.8	1.9	480	10	2.1	1.0	3.8	461	13	2.8	1.5	4.8	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3
	Grade 3	2001	13	0.6	0.3	1.1	2032	4	0.2	0.1	0.5	1963	14	0.7	0.4	1.2	1960	7	0.4	0.1	0.7	480	4	0.8	0.2	2.1	461	1	0.2	0.0	1.2	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	166	8.3	7.1	9.6	2032	54	2.7	2.0	3.5	1963	114	5.8	4.8	6.9	1960	62	3.2	2.4	4.0	480	21	4.4	2.7	6.6	461	18	3.9	2.3	6.1	20	0	0.0	0.0	16.8	18	2	11.1	1.4	34.7
	Grade 1	2001	121	6.0	5.0	7.2	2032	39	1.9	1.4	2.6	1963	87	4.4	3.6	5.4	1960	48	2.4	1.8	3.2	480	15	3.1	1.8	5.1	461	11	2.4	1.2	4.2	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3
	Related																																								
	Grade 2	2001	37	1.8	1.3	2.5	2032	13	0.6	0.3	1.1	1963	18	0.9	0.5	1.4	1960	12	0.6	0.3	1.1	480	4	0.8	0.2	2.1	461	7	1.5	0.6	3.1	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3
	Related																																								
	Grade 3	2001	8	0.4	0.2	0.8	2032	2	0.1	0.0	0.4	1963	9	0.5	0.2	0.9	1960	2	0.1	0.0	0.4	480	2	0.4	0.1	1.5	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related																																								

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		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI									
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL					
Headache	All	2001	538	26.9	25.0	28.9	2032	215	10.6	9.3	12.0	1963	435	22.2	20.3	24.1	1960	214	10.9	9.6	12.4	480	96	20.0	16.5	23.9	461	70	15.2	12.0	18.8	20	5	25.0	8.7	49.1	18	2	11.1	1.4	34.7					
	Grade 1	2001	389	19.4	17.7	21.2	2032	172	8.5	7.3	9.8	1963	327	16.7	15.0	18.4	1960	170	8.7	7.5	10.0	480	66	13.8	10.8	17.2	461	50	10.8	8.2	14.0	20	4	20.0	5.7	43.7	18	1	5.6	0.1	27.3					
	Grade 2	2001	116	5.8	4.8	6.9	2032	38	1.9	1.3	2.6	1963	85	4.3	3.5	5.3	1960	35	1.8	1.2	2.5	480	24	5.0	3.2	7.3	461	13	2.8	1.5	4.8	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3					
	Grade 3	2001	33	1.6	1.1	2.3	2032	5	0.2	0.1	0.6	1963	23	1.2	0.7	1.8	1960	8	0.4	0.2	0.8	480	6	1.3	0.5	2.7	461	7	1.5	0.6	3.1	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5					
	Related	2001	451	22.5	20.7	24.4	2032	151	7.4	6.3	8.7	1963	347	17.7	16.0	19.4	1960	132	6.7	5.7	7.9	480	73	15.2	12.1	18.7	461	47	10.2	7.6	13.3	20	5	25.0	8.7	49.1	18	2	11.1	1.4	34.7					
	Grade 1	2001	324	16.2	14.6	17.9	2032	125	6.2	5.1	7.3	1963	260	13.2	11.8	14.8	1960	107	5.5	4.5	6.6	480	51	10.6	8.0	13.7	461	37	8.0	5.7	10.9	20	4	20.0	5.7	43.7	18	1	5.6	0.1	27.3					
	Related																																													
	Grade 2	2001	98	4.9	4.0	5.9	2032	22	1.1	0.7	1.6	1963	69	3.5	2.7	4.4	1960	21	1.1	0.7	1.6	480	17	3.5	2.1	5.6	461	6	1.3	0.5	2.8	20	1	5.0	0.1	24.9	18	1	5.6	0.1	27.3					
	Grade 3	2001	29	1.4	1.0	2.1	2032	4	0.2	0.1	0.5	1963	18	0.9	0.5	1.4	1960	4	0.2	0.1	0.5	480	5	1.0	0.3	2.4	461	4	0.9	0.2	2.2	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5					
Myalgia	All	2001	682	34.1	32.0	36.2	2032	149	7.3	6.2	8.6	1963	591	30.1	28.1	32.2	1960	152	7.8	6.6	9.0	480	113	23.5	19.8	27.6	461	57	12.4	9.5	15.7	20	4	20.0	5.7	43.7	18	2	11.1	1.4	34.7					
	Grade 1	2001	471	23.5	21.7	25.5	2032	127	6.3	5.2	7.4	1963	422	21.5	19.7	23.4	1960	113	5.8	4.8	6.9	480	66	13.8	10.8	17.2	461	37	8.0	5.7	10.9	20	4	20.0	5.7	43.7	18	1	5.6	0.1	27.3					
	Grade 2	2001	171	8.5	7.4	9.9	2032	17	0.8	0.5	1.3	1963	123	6.3	5.2	7.4	1960	31	1.6	1.1	2.2	480	34	7.1	5.0	9.8	461	11	2.4	1.2	4.2	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3					
	Grade 3	2001	40	2.0	1.4	2.7	2032	5	0.2	0.1	0.6	1963	46	2.3	1.7	3.1	1960	7	0.4	0.1	0.7	480	13	2.7	1.4	4.6	461	9	2.0	0.9	3.7	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5					
	Related	2001	604	30.2	28.2	32.2	2032	106	5.2	4.3	6.3	1963	503	25.6	23.7	27.6	1960	105	5.4	4.4	6.4	480	90	18.8	15.4	22.5	461	34	7.4	5.2	10.2	20	3	15.0	3.2	37.9	18	2	11.1	1.4	34.7					
	Grade 1	2001	411	20.5	18.8	22.4	2032	90	4.4	3.6	5.4	1963	359	18.3	16.6	20.1	1960	81	4.1	3.3	5.1	480	50	10.4	7.8	13.5	461	26	5.6	3.7	8.2	20	3	15.0	3.2	37.9	18	1	5.6	0.1	27.3					
	Related																																													
	Grade 2	2001	156	7.8	6.7	9.1	2032	12	0.6	0.3	1.0	1963	108	5.5	4.5	6.6	1960	19	1.0	0.6	1.5	480	29	6.0	4.1	8.6	461	3	0.7	0.1	1.9	20	0	0.0	0.0	16.8	18	1	5.6	0.1	27.3					
	Grade 3	2001	37	1.8	1.3	2.5	2032	4	0.2	0.1	0.5	1963	36	1.8	1.3	2.5	1960	5	0.3	0.1	0.6	480	11	2.3	1.1	4.1	461	5	1.1	0.4	2.5	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5					
Shivering	All	2001	317	15.8	14.3	17.5	2032	69	3.4	2.7	4.3	1963	240	12.2	10.8	13.8	1960	75	3.8	3.0	4.8	480	40	8.3	6.0	11.2	461	23	5.0	3.2	7.4	20	3	15.0	3.2	37.9	18	2	11.1	1.4	34.7					
	Grade 1	2001	196	9.8	8.5	11.2	2032	58	2.9	2.2	3.7	1963	158	8.0	6.9	9.3	1960	63	3.2	2.5	4.1	480	29	6.0	4.1	8.6	461	20	4.3	2.7	6.6	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7					
	Grade 2	2001	83	4.1	3.3	5.1	2032	10	0.5	0.2	0.9	1963	60	3.1	2.3	3.9	1960	8	0.4	0.2	0.8	480	5	1.0	0.3	2.4	461	3	0.7	0.1	1.9	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5					
	Grade 3	2001	38	1.9	1.3	2.6	2032	1	0.0	0.0	0.3	1963	22	1.1	0.7	1.7	1960	3	0.2	0.0	0.4	480	6	1.3	0.5	2.7	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5					
	Related	2001	279	13.9	12.5	15.5	2032	43	2.1	1.5	2.8	1963	206	10.5	9.2	11.9	1960	50	2.6	1.9	3.3	480	31	6.5	4.4	9.0	461	11	2.4	1.2	4.2	20	3	15.0	3.2	37.9	18	2	11.1	1.4	34.7					

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					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI						
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL					
	Grade 1 Related	2001	168	8.4	7.2	9.7	2032	39	1.9	1.4	2.6	1963	137	7.0	5.9	8.2	1960	42	2.1	1.5	2.9	480	23	4.8	3.1	7.1	461	10	2.2	1.0	4.0	20	2	10.0	1.2	31.7	18	2	11.1	1.4	34.7
	Grade 2 Related	2001	75	3.7	3.0	4.7	2032	4	0.2	0.1	0.5	1963	52	2.6	2.0	3.5	1960	5	0.3	0.1	0.6	480	3	0.6	0.1	1.8	461	1	0.2	0.0	1.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	Grade 3 Related	2001	36	1.8	1.3	2.5	2032	0	0.0	0.0	0.2	1963	17	0.9	0.5	1.4	1960	3	0.2	0.0	0.4	480	5	1.0	0.3	2.4	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
Temperature/(*) (°C)	All	2001	242	12.1	10.7	13.6	2032	24	1.2	0.8	1.8	1963	210	10.7	9.4	12.1	1960	31	1.6	1.1	2.2	480	33	6.9	4.8	9.5	461	10	2.2	1.0	4.0	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	≥37.5 and ≤38	2001	190	9.5	8.2	10.9	2032	18	0.9	0.5	1.4	1963	154	7.8	6.7	9.1	1960	23	1.2	0.7	1.8	480	26	5.4	3.6	7.8	461	9	2.0	0.9	3.7	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	>38 and ≤39	2001	50	2.5	1.9	3.3	2032	3	0.1	0.0	0.4	1963	48	2.4	1.8	3.2	1960	4	0.2	0.1	0.5	480	4	0.8	0.2	2.1	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	>39.0	2001	2	0.1	0.0	0.4	2032	1	0.0	0.0	0.3	1963	3	0.2	0.0	0.4	1960	2	0.1	0.0	0.4	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	Related	2001	213	10.6	9.3	12.1	2032	17	0.8	0.5	1.3	1963	176	9.0	7.7	10.3	1960	16	0.8	0.5	1.3	480	24	5.0	3.2	7.3	461	4	0.9	0.2	2.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	≥37.5 and ≤38 Related	2001	165	8.2	7.1	9.5	2032	15	0.7	0.4	1.2	1963	133	6.8	5.7	8.0	1960	14	0.7	0.4	1.2	480	19	4.0	2.4	6.1	461	4	0.9	0.2	2.2	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5
	>38 and ≤39 Related	2001	47	2.3	1.7	3.1	2032	2	0.1	0.0	0.4	1963	40	2.0	1.5	2.8	1960	2	0.1	0.0	0.4	480	3	0.6	0.1	1.8	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
	>39.0 Related	2001	1	0.0	0.0	0.3	2032	0	0.0	0.0	0.2	1963	3	0.2	0.0	0.4	1960	0	0.0	0.0	0.2	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5
Dose 2																																									
Fatigue	All	1942	711	36.6	34.5	38.8	1988	147	7.4	6.3	8.6	1906	597	31.3	29.2	33.5	1895	192	10.1	8.8	11.6	456	120	26.3	22.3	30.6	443	46	10.4	7.7	13.6	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 1	1942	408	21.0	19.2	22.9	1988	127	6.4	5.4	7.6	1906	360	18.9	17.2	20.7	1895	147	7.8	6.6	9.1	456	68	14.9	11.8	18.5	443	26	5.9	3.9	8.5	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 2	1942	224	11.5	10.1	13.0	1988	14	0.7	0.4	1.2	1906	183	9.6	8.3	11.0	1895	39	2.1	1.5	2.8	456	39	8.6	6.2	11.5	443	17	3.8	2.3	6.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	79	4.1	3.2	5.0	1988	6	0.3	0.1	0.7	1906	54	2.8	2.1	3.7	1895	5	0.3	0.1	0.6	456	13	2.9	1.5	4.8	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	635	32.7	30.6	34.8	1988	120	6.0	5.0	7.2	1906	510	26.8	24.8	28.8	1895	141	7.4	6.3	8.7	456	104	22.8	19.0	26.9	443	27	6.1	4.1	8.7	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8
	Grade 1 Related	1942	362	18.6	16.9	20.4	1988	103	5.2	4.2	6.2	1906	302	15.8	14.2	17.6	1895	109	5.8	4.7	6.9	456	59	12.9	10.0	16.4	443	14	3.2	1.7	5.2	18	2	11.1	1.4	34.7	15	0	0.0	0.0	21.8

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				95 % CI				95 % CI						95 % CI				95 % CI						95 % CI				95 % CI				95 % CI				95 % CI				95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	Grade 2	1942	199	10.2	8.9	11.7	1988	12	0.6	0.3	1.1	1906	161	8.4	7.2	9.8	1895	27	1.4	0.9	2.1	456	33	7.2	5.0	10.0	443	10	2.3	1.1	4.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
	Grade 3	1942	74	3.8	3.0	4.8	1988	5	0.3	0.1	0.6	1906	47	2.5	1.8	3.3	1895	5	0.3	0.1	0.6	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
Gastrointestinal symptoms	All	1942	237	12.2	10.8	13.7	1988	75	3.8	3.0	4.7	1906	201	10.5	9.2	12.0	1895	79	4.2	3.3	5.2	456	44	9.6	7.1	12.7	443	29	6.5	4.4	9.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 1	1942	179	9.2	8.0	10.6	1988	50	2.5	1.9	3.3	1906	139	7.3	6.2	8.6	1895	62	3.3	2.5	4.2	456	27	5.9	3.9	8.5	443	14	3.2	1.7	5.2	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 2	1942	44	2.3	1.7	3.0	1988	17	0.9	0.5	1.4	1906	45	2.4	1.7	3.1	1895	15	0.8	0.4	1.3	456	15	3.3	1.9	5.4	443	10	2.3	1.1	4.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	13	0.7	0.4	1.1	1988	8	0.4	0.2	0.8	1906	17	0.9	0.5	1.4	1895	1	0.1	0.0	0.3	456	2	0.4	0.1	1.6	443	5	1.1	0.4	2.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	200	10.3	9.0	11.7	1988	40	2.0	1.4	2.7	1906	150	7.9	6.7	9.2	1895	41	2.2	1.6	2.9	456	34	7.5	5.2	10.3	443	13	2.9	1.6	5.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 1	1942	149	7.7	6.5	8.9	1988	26	1.3	0.9	1.9	1906	104	5.5	4.5	6.6	1895	33	1.7	1.2	2.4	456	20	4.4	2.7	6.7	443	8	1.8	0.8	3.5	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
	Grade 2	1942	39	2.0	1.4	2.7	1988	10	0.5	0.2	0.9	1906	34	1.8	1.2	2.5	1895	8	0.4	0.2	0.8	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
	Grade 3	1942	12	0.6	0.3	1.1	1988	4	0.2	0.1	0.5	1906	12	0.6	0.3	1.1	1895	0	0.0	0.0	0.2	456	2	0.4	0.1	1.6	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
Headache	All	1942	627	32.3	30.2	34.4	1988	131	6.6	5.5	7.8	1906	463	24.3	22.4	26.3	1895	160	8.4	7.2	9.8	456	104	22.8	19.0	26.9	443	43	9.7	7.1	12.9	18	3	16.7	3.6	41.4	15	1	6.7	0.2	31.9
	Grade 1	1942	395	20.3	18.6	22.2	1988	99	5.0	4.1	6.0	1906	309	16.2	14.6	17.9	1895	124	6.5	5.5	7.8	456	55	12.1	9.2	15.4	443	22	5.0	3.1	7.4	18	3	16.7	3.6	41.4	15	1	6.7	0.2	31.9
	Grade 2	1942	184	9.5	8.2	10.9	1988	29	1.5	1.0	2.1	1906	117	6.1	5.1	7.3	1895	29	1.5	1.0	2.2	456	36	7.9	5.6	10.8	443	16	3.6	2.1	5.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	48	2.5	1.8	3.3	1988	3	0.2	0.0	0.4	1906	37	1.9	1.4	2.7	1895	6	0.3	0.1	0.7	456	12	2.6	1.4	4.6	443	4	0.9	0.2	2.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	562	28.9	26.9	31.0	1988	91	4.6	3.7	5.6	1906	413	21.7	19.8	23.6	1895	103	5.4	4.5	6.6	456	90	19.7	16.2	23.7	443	24	5.4	3.5	8.0	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Grade 1	1942	345	17.8	16.1	19.5	1988	69	3.5	2.7	4.4	1906	271	14.2	12.7	15.9	1895	84	4.4	3.6	5.5	456	47	10.3	7.7	13.5	443	12	2.7	1.4	4.7	18	2	11.1	1.4	34.7	15	1	6.7	0.2	31.9
	Related																																								
	Grade 2	1942	171	8.8	7.6	10.2	1988	20	1.0	0.6	1.5	1906	109	5.7	4.7	6.9	1895	18	0.9	0.6	1.5	456	31	6.8	4.7	9.5	443	8	1.8	0.8	3.5	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
	Grade 3	1942	46	2.4	1.7	3.1	1988	2	0.1	0.0	0.4	1906	33	1.7	1.2	2.4	1895	1	0.1	0.0	0.3	456	12	2.6	1.4	4.6	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
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		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Myalgia	All	1942	713	36.7	34.6	38.9	1988	109	5.5	4.5	6.6	1906	587	30.8	28.7	32.9	1895	117	6.2	5.1	7.4	456	119	26.1	22.1	30.4	443	38	8.6	6.1	11.6	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 1	1942	419	21.6	19.8	23.5	1988	91	4.6	3.7	5.6	1906	342	17.9	16.2	19.7	1895	90	4.7	3.8	5.8	456	59	12.9	10.0	16.4	443	19	4.3	2.6	6.6	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 2	1942	220	11.3	10.0	12.8	1988	15	0.8	0.4	1.2	1906	192	10.1	8.8	11.5	1895	24	1.3	0.8	1.9	456	42	9.2	6.7	12.2	443	14	3.2	1.7	5.2	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	74	3.8	3.0	4.8	1988	3	0.2	0.0	0.4	1906	53	2.8	2.1	3.6	1895	2	0.1	0.0	0.4	456	18	3.9	2.4	6.2	443	5	1.1	0.4	2.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	639	32.9	30.8	35.0	1988	82	4.1	3.3	5.1	1906	521	27.3	25.3	29.4	1895	91	4.8	3.9	5.9	456	106	23.2	19.4	27.4	443	21	4.7	3.0	7.2	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 1 Related	1942	374	19.3	17.5	21.1	1988	69	3.5	2.7	4.4	1906	300	15.7	14.1	17.5	1895	70	3.7	2.9	4.6	456	53	11.6	8.8	14.9	443	10	2.3	1.1	4.1	18	3	16.7	3.6	41.4	15	0	0.0	0.0	21.8
	Grade 2 Related	1942	197	10.1	8.8	11.6	1988	11	0.6	0.3	1.0	1906	172	9.0	7.8	10.4	1895	18	0.9	0.6	1.5	456	36	7.9	5.6	10.8	443	10	2.3	1.1	4.1	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	68	3.5	2.7	4.4	1988	2	0.1	0.0	0.4	1906	49	2.6	1.9	3.4	1895	2	0.1	0.0	0.4	456	17	3.7	2.2	5.9	443	1	0.2	0.0	1.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	500	25.7	23.8	27.8	1988	58	2.9	2.2	3.8	1906	338	17.7	16.0	19.5	1895	47	2.5	1.8	3.3	456	64	14.0	11.0	17.6	443	24	5.4	3.5	8.0	18	0	0.0	0.0	18.5	15	2	13.3	1.7	40.5
Shivering	Grade 1	1942	279	14.4	12.8	16.0	1988	48	2.4	1.8	3.2	1906	198	10.4	9.1	11.8	1895	37	2.0	1.4	2.7	456	32	7.0	4.8	9.8	443	16	3.6	2.1	5.8	18	0	0.0	0.0	18.5	15	2	13.3	1.7	40.5
	Grade 2	1942	146	7.5	6.4	8.8	1988	7	0.4	0.1	0.7	1906	99	5.2	4.2	6.3	1895	5	0.3	0.1	0.6	456	19	4.2	2.5	6.4	443	6	1.4	0.5	2.9	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3	1942	74	3.8	3.0	4.8	1988	3	0.2	0.0	0.4	1906	41	2.2	1.5	2.9	1895	4	0.2	0.1	0.5	456	13	2.9	1.5	4.8	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	453	23.3	21.5	25.3	1988	44	2.2	1.6	3.0	1906	289	15.2	13.6	16.9	1895	32	1.7	1.2	2.4	456	58	12.7	9.8	16.1	443	14	3.2	1.7	5.2	18	0	0.0	0.0	18.5	15	1	6.7	0.2	31.9
	Grade 1 Related	1942	249	12.8	11.4	14.4	1988	38	1.9	1.4	2.6	1906	166	8.7	7.5	10.1	1895	24	1.3	0.8	1.9	456	30	6.6	4.5	9.3	443	9	2.0	0.9	3.8	18	0	0.0	0.0	18.5	15	1	6.7	0.2	31.9
	Grade 2 Related	1942	136	7.0	5.9	8.2	1988	4	0.2	0.1	0.5	1906	84	4.4	3.5	5.4	1895	5	0.3	0.1	0.6	456	15	3.3	1.9	5.4	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Grade 3 Related	1942	68	3.5	2.7	4.4	1988	2	0.1	0.0	0.4	1906	39	2.0	1.5	2.8	1895	2	0.1	0.0	0.4	456	13	2.9	1.5	4.8	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	335	17.3	15.6	19.0	1988	31	1.6	1.1	2.2	1906	230	12.1	10.6	13.6	1895	25	1.3	0.9	1.9	456	48	10.5	7.9	13.7	443	11	2.5	1.2	4.4	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	≥37.5 and ≤38	1942	234	12.0	10.6	13.6	1988	22	1.1	0.7	1.7	1906	160	8.4	7.2	9.7	1895	19	1.0	0.6	1.6	456	32	7.0	4.8	9.8	443	9	2.0	0.9	3.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
Temperature/(*) (°C)	>38 and ≤39	1942	96	4.9	4.0	6.0	1988	5	0.3	0.1	0.6	1906	64	3.4	2.6	4.3	1895	4	0.2	0.1	0.5	456	14	3.1	1.7	5.1	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8

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		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	>39.0	1942	4	0.2	0.1	0.5	1988	4	0.2	0.1	0.5	1906	2	0.1	0.0	0.4	1895	2	0.1	0.0	0.4	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related	1942	306	15.8	14.2	17.5	1988	18	0.9	0.5	1.4	1906	200	10.5	9.2	12.0	1895	13	0.7	0.4	1.2	456	43	9.4	6.9	12.5	443	4	0.9	0.2	2.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	≥37.5 and ≤38	1942	214	11.0	9.7	12.5	1988	13	0.7	0.3	1.1	1906	139	7.3	6.2	8.6	1895	11	0.6	0.3	1.0	456	29	6.4	4.3	9.0	443	3	0.7	0.1	2.0	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
	>38 and ≤39	1942	88	4.5	3.6	5.6	1988	3	0.2	0.0	0.4	1906	58	3.0	2.3	3.9	1895	2	0.1	0.0	0.4	456	13	2.9	1.5	4.8	443	1	0.2	0.0	1.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
	>39.0	1942	4	0.2	0.1	0.5	1988	2	0.1	0.0	0.4	1906	2	0.1	0.0	0.4	1895	0	0.0	0.0	0.2	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8
	Related																																								
Overall/dose																																									
Fatigue	All	3943	1361	34.5	33.0	36.0	4020	366	9.1	8.2	10.0	3869	1189	30.7	29.3	32.2	3855	429	11.1	10.2	12.2	936	234	25.0	22.3	27.9	904	123	13.6	11.4	16.0	38	6	15.8	6.0	31.3	33	5	15.2	5.1	31.9
	Grade 1	3943	857	21.7	20.5	23.1	4020	300	7.5	6.7	8.3	3869	759	19.6	18.4	20.9	3855	326	8.5	7.6	9.4	936	136	14.5	12.3	17.0	904	72	8.0	6.3	9.9	38	4	10.5	2.9	24.8	33	3	9.1	1.9	24.3
	Grade 2	3943	382	9.7	8.8	10.7	4020	51	1.3	0.9	1.7	3869	330	8.5	7.7	9.5	3855	84	2.2	1.7	2.7	936	71	7.6	6.0	9.5	904	43	4.8	3.5	6.4	38	2	5.3	0.6	17.7	33	2	6.1	0.7	20.2
	Grade 3	3943	122	3.1	2.6	3.7	4020	15	0.4	0.2	0.6	3869	100	2.6	2.1	3.1	3855	17	0.4	0.3	0.7	936	27	2.9	1.9	4.2	904	8	0.9	0.4	1.7	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	1200	30.4	29.0	31.9	4020	280	7.0	6.2	7.8	3869	992	25.6	24.3	27.0	3855	288	7.5	6.7	8.3	936	192	20.5	18.0	23.2	904	67	7.4	5.8	9.3	38	6	15.8	6.0	31.3	33	4	12.1	3.4	28.2
	Grade 1	3943	752	19.1	17.9	20.3	4020	227	5.6	5.0	6.4	3869	623	16.1	15.0	17.3	3855	224	5.8	5.1	6.6	936	112	12.0	10.0	14.2	904	37	4.1	2.9	5.6	38	4	10.5	2.9	24.8	33	2	6.1	0.7	20.2
	Related																																								
	Grade 2	3943	337	8.5	7.7	9.5	4020	41	1.0	0.7	1.4	3869	288	7.4	6.6	8.3	3855	51	1.3	1.0	1.7	936	57	6.1	4.6	7.8	904	24	2.7	1.7	3.9	38	2	5.3	0.6	17.7	33	2	6.1	0.7	20.2
	Related																																								
	Grade 3	3943	111	2.8	2.3	3.4	4020	12	0.3	0.2	0.5	3869	81	2.1	1.7	2.6	3855	13	0.3	0.2	0.6	936	23	2.5	1.6	3.7	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related																																								
Gastrointestinal symptoms	All	3943	456	11.6	10.6	12.6	4020	175	4.4	3.7	5.0	3869	389	10.1	9.1	11.0	3855	196	5.1	4.4	5.8	936	82	8.8	7.0	10.8	904	68	7.5	5.9	9.4	38	2	5.3	0.6	17.7	33	2	6.1	0.7	20.2
	Grade 1	3943	341	8.6	7.8	9.6	4020	128	3.2	2.7	3.8	3869	285	7.4	6.6	8.2	3855	146	3.8	3.2	4.4	936	50	5.3	4.0	7.0	904	39	4.3	3.1	5.9	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 2	3943	88	2.2	1.8	2.7	4020	35	0.9	0.6	1.2	3869	73	1.9	1.5	2.4	3855	40	1.0	0.7	1.4	936	25	2.7	1.7	3.9	904	23	2.5	1.6	3.8	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 3	3943	26	0.7	0.4	1.0	4020	12	0.3	0.2	0.5	3869	31	0.8	0.5	1.1	3855	8	0.2	0.1	0.4	936	6	0.6	0.2	1.4	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	366	9.3	8.4	10.2	4020	94	2.3	1.9	2.9	3869	264	6.8	6.0	7.7	3855	103	2.7	2.2	3.2	936	55	5.9	4.5	7.6	904	31	3.4	2.3	4.8	38	0	0.0	0.0	9.3	33	2	6.1	0.7	20.2
	Grade 1	3943	270	6.8	6.1	7.7	4020	65	1.6	1.3	2.1	3869	191	4.9	4.3	5.7	3855	81	2.1	1.7	2.6	936	35	3.7	2.6	5.2	904	19	2.1	1.3	3.3	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
	Related																																								

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		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL					
	Grade 2 Related	3943	76	1.9	1.5	2.4	4020	23	0.6	0.4	0.9	3869	52	1.3	1.0	1.8	3855	20	0.5	0.3	0.8	936	16	1.7	1.0	2.8	904	10	1.1	0.5	2.0	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
	Grade 3 Related	3943	20	0.5	0.3	0.8	4020	6	0.1	0.1	0.3	3869	21	0.5	0.3	0.8	3855	2	0.1	0.0	0.2	936	4	0.4	0.1	1.1	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Headache	All	3943	1165	29.5	28.1	31.0	4020	346	8.6	7.8	9.5	3869	898	23.2	21.9	24.6	3855	374	9.7	8.8	10.7	936	200	21.4	18.8	24.1	904	113	12.5	10.4	14.8	38	8	21.1	9.6	37.3	33	3	9.1	1.9	24.3
	Grade 1	3943	784	19.9	18.6	21.2	4020	271	6.7	6.0	7.6	3869	636	16.4	15.3	17.6	3855	294	7.6	6.8	8.5	936	121	12.9	10.8	15.2	904	72	8.0	6.3	9.9	38	7	18.4	7.7	34.3	33	2	6.1	0.7	20.2
	Grade 2	3943	300	7.6	6.8	8.5	4020	67	1.7	1.3	2.1	3869	202	5.2	4.5	6.0	3855	64	1.7	1.3	2.1	936	60	6.4	4.9	8.2	904	29	3.2	2.2	4.6	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 3	3943	81	2.1	1.6	2.5	4020	8	0.2	0.1	0.4	3869	60	1.6	1.2	2.0	3855	14	0.4	0.2	0.6	936	18	1.9	1.1	3.0	904	11	1.2	0.6	2.2	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	1013	25.7	24.3	27.1	4020	242	6.0	5.3	6.8	3869	760	19.6	18.4	20.9	3855	235	6.1	5.4	6.9	936	163	17.4	15.0	20.0	904	71	7.9	6.2	9.8	38	7	18.4	7.7	34.3	33	3	9.1	1.9	24.3
	Grade 1 Related	3943	669	17.0	15.8	18.2	4020	194	4.8	4.2	5.5	3869	531	13.7	12.7	14.8	3855	191	5.0	4.3	5.7	936	98	10.5	8.6	12.6	904	49	5.4	4.0	7.1	38	6	15.8	6.0	31.3	33	2	6.1	0.7	20.2
	Grade 2 Related	3943	269	6.8	6.1	7.7	4020	42	1.0	0.8	1.4	3869	178	4.6	4.0	5.3	3855	39	1.0	0.7	1.4	936	48	5.1	3.8	6.7	904	14	1.5	0.8	2.6	38	1	2.6	0.1	13.8	33	1	3.0	0.1	15.8
	Grade 3 Related	3943	75	1.9	1.5	2.4	4020	6	0.1	0.1	0.3	3869	51	1.3	1.0	1.7	3855	5	0.1	0.0	0.3	936	17	1.8	1.1	2.9	904	7	0.8	0.3	1.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Myalgia	All	3943	1395	35.4	33.9	36.9	4020	258	6.4	5.7	7.2	3869	1178	30.4	29.0	31.9	3855	269	7.0	6.2	7.8	936	232	24.8	22.0	27.7	904	95	10.5	8.6	12.7	38	7	18.4	7.7	34.3	33	2	6.1	0.7
Grade 1		3943	890	22.6	21.3	23.9	4020	218	5.4	4.7	6.2	3869	764	19.7	18.5	21.0	3855	203	5.3	4.6	6.0	936	125	13.4	11.2	15.7	904	56	6.2	4.7	8.0	38	7	18.4	7.7	34.3	33	1	3.0	0.1	15.8
Grade 2		3943	391	9.9	9.0	10.9	4020	32	0.8	0.5	1.1	3869	315	8.1	7.3	9.0	3855	55	1.4	1.1	1.9	936	76	8.1	6.5	10.1	904	25	2.8	1.8	4.1	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
Grade 3		3943	114	2.9	2.4	3.5	4020	8	0.2	0.1	0.4	3869	99	2.6	2.1	3.1	3855	9	0.2	0.1	0.4	936	31	3.3	2.3	4.7	904	14	1.5	0.8	2.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Related		3943	1243	31.5	30.1	33.0	4020	188	4.7	4.0	5.4	3869	1024	26.5	25.1	27.9	3855	196	5.1	4.4	5.8	936	196	20.9	18.4	23.7	904	55	6.1	4.6	7.8	38	6	15.8	6.0	31.3	33	2	6.1	0.7	20.2
Grade 1 Related		3943	785	19.9	18.7	21.2	4020	159	4.0	3.4	4.6	3869	659	17.0	15.9	18.3	3855	151	3.9	3.3	4.6	936	103	11.0	9.1	13.2	904	36	4.0	2.8	5.5	38	6	15.8	6.0	31.3	33	1	3.0	0.1	15.8
Grade 2 Related		3943	353	9.0	8.1	9.9	4020	23	0.6	0.4	0.9	3869	280	7.2	6.4	8.1	3855	37	1.0	0.7	1.3	936	65	6.9	5.4	8.8	904	13	1.4	0.8	2.4	38	0	0.0	0.0	9.3	33	1	3.0	0.1	15.8
Grade 3 Related		3943	105	2.7	2.2	3.2	4020	6	0.1	0.1	0.3	3869	85	2.2	1.8	2.7	3855	7	0.2	0.1	0.4	936	28	3.0	2.0	4.3	904	6	0.7	0.2	1.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6

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		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
Shivering	All	3943	817	20.7	19.5	22.0	4020	127	3.2	2.6	3.7	3869	578	14.9	13.8	16.1	3855	122	3.2	2.6	3.8	936	104	11.1	9.2	13.3	904	47	5.2	3.8	6.9	38	3	7.9	1.7	21.4	33	4	12.1	3.4	28.2
	Grade 1	3943	475	12.0	11.0	13.1	4020	106	2.6	2.2	3.2	3869	356	9.2	8.3	10.2	3855	100	2.6	2.1	3.1	936	61	6.5	5.0	8.3	904	36	4.0	2.8	5.5	38	2	5.3	0.6	17.7	33	4	12.1	3.4	28.2
	Grade 2	3943	229	5.8	5.1	6.6	4020	17	0.4	0.2	0.7	3869	159	4.1	3.5	4.8	3855	13	0.3	0.2	0.6	936	24	2.6	1.6	3.8	904	9	1.0	0.5	1.9	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	Grade 3	3943	112	2.8	2.3	3.4	4020	4	0.1	0.0	0.3	3869	63	1.6	1.3	2.1	3855	7	0.2	0.1	0.4	936	19	2.0	1.2	3.2	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	732	18.6	17.4	19.8	4020	87	2.2	1.7	2.7	3869	495	12.8	11.8	13.9	3855	82	2.1	1.7	2.6	936	89	9.5	7.7	11.6	904	25	2.8	1.8	4.1	38	3	7.9	1.7	21.4	33	3	9.1	1.9	24.3
	Grade 1 Related	3943	417	10.6	9.6	11.6	4020	77	1.9	1.5	2.4	3869	303	7.8	7.0	8.7	3855	66	1.7	1.3	2.2	936	53	5.7	4.3	7.3	904	19	2.1	1.3	3.3	38	2	5.3	0.6	17.7	33	3	9.1	1.9	24.3
	Grade 2 Related	3943	211	5.4	4.7	6.1	4020	8	0.2	0.1	0.4	3869	136	3.5	3.0	4.1	3855	10	0.3	0.1	0.5	936	18	1.9	1.1	3.0	904	4	0.4	0.1	1.1	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	Grade 3 Related	3943	104	2.6	2.2	3.2	4020	2	0.0	0.0	0.2	3869	56	1.4	1.1	1.9	3855	5	0.1	0.0	0.3	936	18	1.9	1.1	3.0	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
Temperature/(*) (°C)	All	3943	577	14.6	13.5	15.8	4020	55	1.4	1.0	1.8	3869	440	11.4	10.4	12.4	3855	56	1.5	1.1	1.9	936	81	8.7	6.9	10.6	904	21	2.3	1.4	3.5	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	≥37.5 and ≤38	3943	424	10.8	9.8	11.8	4020	40	1.0	0.7	1.4	3869	314	8.1	7.3	9.0	3855	42	1.1	0.8	1.5	936	58	6.2	4.7	7.9	904	18	2.0	1.2	3.1	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	>38 and ≤39	3943	146	3.7	3.1	4.3	4020	8	0.2	0.1	0.4	3869	112	2.9	2.4	3.5	3855	8	0.2	0.1	0.4	936	18	1.9	1.1	3.0	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	>39.0	3943	6	0.2	0.1	0.3	4020	5	0.1	0.0	0.3	3869	5	0.1	0.0	0.3	3855	4	0.1	0.0	0.3	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	Related	3943	519	13.2	12.1	14.3	4020	35	0.9	0.6	1.2	3869	376	9.7	8.8	10.7	3855	29	0.8	0.5	1.1	936	67	7.2	5.6	9.0	904	8	0.9	0.4	1.7	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	≥37.5 and ≤38 Related	3943	379	9.6	8.7	10.6	4020	28	0.7	0.5	1.0	3869	272	7.0	6.2	7.9	3855	25	0.6	0.4	1.0	936	48	5.1	3.8	6.7	904	7	0.8	0.3	1.6	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6
	>38 and ≤39 Related	3943	135	3.4	2.9	4.0	4020	5	0.1	0.0	0.3	3869	98	2.5	2.1	3.1	3855	4	0.1	0.0	0.3	936	16	1.7	1.0	2.8	904	1	0.1	0.0	0.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6
	>39.0 Related	3943	5	0.1	0.0	0.3	4020	2	0.0	0.0	0.2	3869	5	0.1	0.0	0.3	3855	0	0.0	0.0	0.1	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6

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		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI							
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL						
Overall/subject																																										
Fatigue	All	2007	951	47.4	45.2	49.6	2034	301	14.8	13.3	16.4	1971	848	43.0	40.8	45.2	1964	339	17.3	15.6	19.0	488	164	33.6	29.4	38.0	468	96	20.5	16.9	24.5	21	5	23.8	8.2	47.2	18	4	22.2	6.4	47.6	
	Grade 1	2007	537	26.8	24.8	28.8	2034	237	11.7	10.3	13.1	1971	500	25.4	23.5	27.3	1964	244	12.4	11.0	14.0	488	89	18.2	14.9	22.0	468	53	11.3	8.6	14.6	21	3	14.3	3.0	36.3	18	2	11.1	1.4	34.7	
	Grade 2	2007	300	14.9	13.4	16.6	2034	49	2.4	1.8	3.2	1971	255	12.9	11.5	14.5	1964	76	3.9	3.1	4.8	488	53	10.9	8.2	14.0	468	35	7.5	5.3	10.2	21	2	9.5	1.2	30.4	18	2	11.1	1.4	34.7	
	Grade 3	2007	114	5.7	4.7	6.8	2034	15	0.7	0.4	1.2	1971	93	4.7	3.8	5.7	1964	17	0.9	0.5	1.4	488	22	4.5	2.8	6.7	468	8	1.7	0.7	3.3	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5	
	Related	2007	848	42.3	40.1	44.4	2034	233	11.5	10.1	12.9	1971	715	36.3	34.1	38.4	1964	231	11.8	10.4	13.3	488	139	28.5	24.5	32.7	468	54	11.5	8.8	14.8	21	5	23.8	8.2	47.2	18	4	22.2	6.4	47.6	
	Grade 1 Related	2007	476	23.7	21.9	25.6	2034	181	8.9	7.7	10.2	1971	415	21.1	19.3	22.9	1964	170	8.7	7.4	10.0	488	75	15.4	12.3	18.9	468	30	6.4	4.4	9.0	21	3	14.3	3.0	36.3	18	2	11.1	1.4	34.7	
	Grade 2 Related	2007	269	13.4	11.9	15.0	2034	40	2.0	1.4	2.7	1971	223	11.3	9.9	12.8	1964	48	2.4	1.8	3.2	488	45	9.2	6.8	12.1	468	18	3.8	2.3	6.0	21	2	9.5	1.2	30.4	18	2	11.1	1.4	34.7	
	Grade 3 Related	2007	103	5.1	4.2	6.2	2034	12	0.6	0.3	1.0	1971	77	3.9	3.1	4.9	1964	13	0.7	0.4	1.1	488	19	3.9	2.4	6.0	468	6	1.3	0.5	2.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5	
Gastrointestinal symptoms	All	2007	369	18.4	16.7	20.2	2034	157	7.7	6.6	9.0	1971	325	16.5	14.9	18.2	1964	166	8.5	7.3	9.8	488	65	13.3	10.4	16.7	468	56	12.0	9.2	15.3	21	2	9.5	1.2	30.4	18	2	11.1	1.4	34.7	
	Grade 1	2007	265	13.2	11.8	14.8	2034	111	5.5	4.5	6.5	1971	233	11.8	10.4	13.3	1964	122	6.2	5.2	7.4	488	39	8.0	5.7	10.8	468	32	6.8	4.7	9.5	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3	
	Grade 2	2007	77	3.8	3.0	4.8	2034	35	1.7	1.2	2.4	1971	64	3.2	2.5	4.1	1964	35	1.8	1.2	2.5	488	20	4.1	2.5	6.3	468	19	4.1	2.5	6.3	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3	
	Grade 3	2007	26	1.3	0.8	1.9	2034	11	0.5	0.3	1.0	1971	28	1.4	0.9	2.0	1964	8	0.4	0.2	0.8	488	6	1.2	0.5	2.7	468	5	1.1	0.3	2.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5	
	Related	2007	298	14.8	13.3	16.5	2034	88	4.3	3.5	5.3	1971	229	11.6	10.2	13.1	1964	86	4.4	3.5	5.4	488	44	9.0	6.6	11.9	468	26	5.6	3.7	8.0	21	0	0.0	0.0	16.1	18	2	11.1	1.4	34.7	
	Grade 1 Related	2007	213	10.6	9.3	12.0	2034	59	2.9	2.2	3.7	1971	164	8.3	7.1	9.6	1964	66	3.4	2.6	4.3	488	27	5.5	3.7	7.9	468	15	3.2	1.8	5.2	21	0	0.0	0.0	16.1	18	1	5.6	0.1	27.3	
	Grade 2 Related	2007	65	3.2	2.5	4.1	2034	23	1.1	0.7	1.7	1971	45	2.3	1.7	3.0	1964	18	0.9	0.5	1.4	488	13	2.7	1.4	4.5	468	9	1.9	0.9	3.6	21	0	0.0	0.0	16.1	18	1	5.6	0.1	27.3	
	Grade 3 Related	2007	20	1.0	0.6	1.5	2034	6	0.3	0.1	0.6	1971	20	1.0	0.6	1.6	1964	2	0.1	0.0	0.4	488	4	0.8	0.2	2.1	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5	
Headache	All	2007	838	41.8	39.6	43.9	2034	287	14.1	12.6	15.7	1971	676	34.3	32.2	36.4	1964	311	15.8	14.2	17.5	488	147	30.1	26.1	34.4	468	89	19.0	15.6	22.9	21	6	28.6	11.3	52.2	18	3	16.7	3.6	41.4	
	Grade 1	2007	514	25.6	23.7	27.6	2034	221	10.9	9.5	12.3	1971	448	22.7	20.9	24.6	1964	239	12.2	10.8	13.7	488	84	17.2	14.0	20.9	468	50	10.7	8.0	13.8	21	5	23.8	8.2	47.2	18	2	11.1	1.4	34.7	
	Grade 2	2007	250	12.5	11.0	14.0	2034	58	2.9	2.2	3.7	1971	175	8.9	7.7	10.2	1964	58	3.0	2.2	3.8	488	45	9.2	6.8	12.1	468	29	6.2	4.2	8.8	21	1	4.8	0.1	23.8	18	1	5.6	0.1	27.3	

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		95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI				
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL					
	Grade 3	2007	74	3.7	2.9	4.6	2034	8	0.4	0.2	0.8	1971	53	2.7	2.0	3.5	1964	12	0.6	0.3	1.1	488	17	3.5	2.0	5.5	468	10	2.1	1.0	3.9	210	0.0	0.0	16.1	18.0	0.0	0.0	18.5		
	Related	2007	735	36.6	34.5	38.8	2034	202	9.9	8.7	11.3	1971	582	29.5	27.5	31.6	1964	198	10.1	8.8	11.5	488	122	25.0	21.2	29.1	468	59	12.6	9.7	16.0	215	23.8	8.2	47.2	18.3	16.7	3.6	41.4		
	Grade 1	2007	441	22.0	20.2	23.8	2034	159	7.8	6.7	9.1	1971	380	19.3	17.6	21.1	1964	156	7.9	6.8	9.2	488	68	13.9	11.0	17.3	468	39	8.3	6.0	11.2	214	19.0	5.4	41.9	18.2	11.1	1.4	34.7		
	Related																																								
	Grade 2	2007	225	11.2	9.9	12.7	2034	37	1.8	1.3	2.5	1971	155	7.9	6.7	9.1	1964	37	1.9	1.3	2.6	488	38	7.8	5.6	10.5	468	14	3.0	1.6	5.0	211	4.8	0.1	23.8	18.1	5.6	0.1	27.3		
	Related																																								
	Grade 3	2007	69	3.4	2.7	4.3	2034	6	0.3	0.1	0.6	1971	47	2.4	1.8	3.2	1964	5	0.3	0.1	0.6	488	16	3.3	1.9	5.3	468	6	1.3	0.5	2.8	210	0.0	0.0	16.1	18.0	0.0	0.0	18.5		
	Related																																								
Myalgia	All	2007	952	47.4	45.2	49.6	2034	209	10.3	9.0	11.7	1971	828	42.0	39.8	44.2	1964	225	11.5	10.1	12.9	488	173	35.5	31.2	39.9	468	75	16.0	12.8	19.7	215	23.8	8.2	47.2	18.2	11.1	1.4	34.7		
	Grade 1	2007	551	27.5	25.5	29.5	2034	170	8.4	7.2	9.6	1971	487	24.7	22.8	26.7	1964	166	8.5	7.3	9.8	488	81	16.6	13.4	20.2	468	43	9.2	6.7	12.2	215	23.8	8.2	47.2	18.1	5.6	0.1	27.3		
	Grade 2	2007	301	15.0	13.5	16.6	2034	31	1.5	1.0	2.2	1971	252	12.8	11.3	14.3	1964	50	2.5	1.9	3.3	488	64	13.1	10.2	16.4	468	20	4.3	2.6	6.5	210	0.0	0.0	16.1	18.1	5.6	0.1	27.3		
	Grade 3	2007	100	5.0	4.1	6.0	2034	8	0.4	0.2	0.8	1971	89	4.5	3.6	5.5	1964	8	0.4	0.2	0.8	488	28	5.7	3.8	8.2	468	12	2.6	1.3	4.4	210	0.0	0.0	16.1	18.0	0.0	0.0	18.5		
	Related	2007	864	43.0	40.9	45.2	2034	153	7.5	6.4	8.8	1971	730	37.0	34.9	39.2	1964	172	8.8	7.5	10.1	488	148	30.3	26.3	34.6	468	47	10.0	7.5	13.1	214	19.0	5.4	41.9	18.2	11.1	1.4	34.7		
	Grade 1	2007	495	24.7	22.8	26.6	2034	125	6.1	5.1	7.3	1971	428	21.7	19.9	23.6	1964	132	6.7	5.7	7.9	488	68	13.9	11.0	17.3	468	30	6.4	4.4	9.0	214	19.0	5.4	41.9	18.1	5.6	0.1	27.3		
	Related																																								
	Grade 2	2007	276	13.8	12.3	15.3	2034	22	1.1	0.7	1.6	1971	225	11.4	10.0	12.9	1964	34	1.7	1.2	2.4	488	55	11.3	8.6	14.4	468	11	2.4	1.2	4.2	210	0.0	0.0	16.1	18.1	5.6	0.1	27.3		
	Related																																								
	Grade 3	2007	93	4.6	3.8	5.6	2034	6	0.3	0.1	0.6	1971	77	3.9	3.1	4.9	1964	6	0.3	0.1	0.7	488	25	5.1	3.3	7.5	468	6	1.3	0.5	2.8	210	0.0	0.0	16.1	18.0	0.0	0.0	18.5		
	Related																																								
Shivering	All	2007	623	31.0	29.0	33.1	2034	111	5.5	4.5	6.5	1971	459	23.3	21.4	25.2	1964	107	5.4	4.5	6.5	488	86	17.6	14.3	21.3	468	41	8.8	6.4	11.7	213	14.3	3.0	36.3	18.3	16.7	3.6	41.4		
	Grade 1	2007	336	16.7	15.1	18.4	2034	91	4.5	3.6	5.5	1971	264	13.4	11.9	15.0	1964	87	4.4	3.6	5.4	488	48	9.8	7.3	12.8	468	31	6.6	4.5	9.3	212	9.5	1.2	30.4	18.3	16.7	3.6	41.4		
	Grade 2	2007	183	9.1	7.9	10.5	2034	16	0.8	0.5	1.3	1971	138	7.0	5.9	8.2	1964	12	0.6	0.3	1.1	488	20	4.1	2.5	6.3	468	8	1.7	0.7	3.3	211	4.8	0.1	23.8	18.0	0.0	0.0	18.5		
	Grade 3	2007	103	5.1	4.2	6.2	2034	4	0.2	0.1	0.5	1971	57	2.9	2.2	3.7	1964	6	0.3	0.1	0.7	488	18	3.7	2.2	5.8	468	2	0.4	0.1	1.5	210	0.0	0.0	16.1	18.0	0.0	0.0	18.5		
	Related	2007	559	27.9	25.9	29.9	2034	80	3.9	3.1	4.9	1971	398	20.2	18.4	22.0	1964	74	3.8	3.0	4.7	488	74	15.2	12.1	18.7	468	22	4.7	3.0	7.0	213	14.3	3.0	36.3	18.3	16.7	3.6	41.4		
	Grade 1	2007	292	14.5	13.0	16.2	2034	70	3.4	2.7	4.3	1971	229	11.6	10.2	13.1	1964	58	3.0	2.2	3.8	488	41	8.4	6.1	11.2	468	17	3.6	2.1	5.8	212	9.5	1.2	30.4	18.3	16.7	3.6	41.4		
	Related																																								

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		Non-Frail										Pre-Frail										Frail										Unknown									
		HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo					HZ/su					Placebo				
					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI					95 % CI	
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL
	Grade 2	2007	171	8.5	7.3	9.8	2034	8	0.4	0.2	0.8	1971	118	6.0	5.0	7.1	1964	10	0.5	0.2	0.9	488	16	3.3	1.9	5.3	468	3	0.6	0.1	1.9	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5
	Related																																								
	Grade 3	2007	96	4.8	3.9	5.8	2034	2	0.1	0.0	0.4	1971	51	2.6	1.9	3.4	1964	5	0.3	0.1	0.6	488	17	3.5	2.0	5.5	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related																																								
Temperature/(*) (°C)	All	2007	465	23.2	21.3	25.1	2034	52	2.6	1.9	3.3	1971	368	18.7	17.0	20.5	1964	55	2.8	2.1	3.6	488	70	14.3	11.4	17.8	468	19	4.1	2.5	6.3	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5
	≥37.5 and ≤38	2007	328	16.3	14.8	18.0	2034	38	1.9	1.3	2.6	1971	253	12.8	11.4	14.4	1964	42	2.1	1.5	2.9	488	49	10.0	7.5	13.1	468	16	3.4	2.0	5.5	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5
	>38 and ≤39	2007	130	6.5	5.4	7.6	2034	8	0.4	0.2	0.8	1971	104	5.3	4.3	6.4	1964	8	0.4	0.2	0.8	488	16	3.3	1.9	5.3	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	>39.0	2007	6	0.3	0.1	0.6	2034	4	0.2	0.1	0.5	1971	5	0.3	0.1	0.6	1964	3	0.2	0.0	0.4	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related	2007	419	20.9	19.1	22.7	2034	35	1.7	1.2	2.4	1971	316	16.0	14.4	17.7	1964	29	1.5	1.0	2.1	488	57	11.7	9.0	14.9	468	8	1.7	0.7	3.3	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5
	≥37.5 and ≤38	2007	293	14.6	13.1	16.2	2034	28	1.4	0.9	2.0	1971	219	11.1	9.8	12.6	1964	25	1.3	0.8	1.9	488	40	8.2	5.9	11.0	468	7	1.5	0.6	3.1	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5
	Related																																								
	>38 and ≤39	2007	121	6.0	5.0	7.2	2034	5	0.2	0.1	0.6	1971	91	4.6	3.7	5.6	1964	4	0.2	0.1	0.5	488	14	2.9	1.6	4.8	468	1	0.2	0.0	1.2	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related																																								
	>39.0	2007	5	0.2	0.1	0.6	2034	2	0.1	0.0	0.4	1971	5	0.3	0.1	0.6	1964	0	0.0	0.0	0.2	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5
	Related																																								

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

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All = all subjects who have experienced the symptom

*Temperature is measured by oral, axillary, rectal or tympanic routes

Fever is defined as temperature $\geq 37.5^{\circ}\text{C}$ for oral, axillary or tympanic route, or $\geq 38.0^{\circ}\text{C}$ for rectal route

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Table 14.3.1.10 Summary of temperature value by half degree increment reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (no conversion) by frailty status (Total Vaccinated Cohort - Diary Card Subset)

		Non-Frail												Pre-Frail												Frail												Unknown											
		HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo					
		95 % CI						95 % CI						95 % CI						95 % CI						95 % CI						95 % CI						95 % CI						95 % CI					
Symptom	Type	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL	N	n	%	LL	UL								
Dose 1																																																	
Temperature/(*) (°C)	All	2001	242	12.1	10.7	13.6	2032	24	1.2	0.8	1.8	1963	210	10.7	9.4	12.1	1960	31	1.6	1.1	2.2	480	33	6.9	4.8	9.5	461	10	2.2	1.0	4.0	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5								
	≥37.5	2001	242	12.1	10.7	13.6	2032	22	1.1	0.7	1.6	1963	205	10.4	9.1	11.9	1960	29	1.5	1.0	2.1	480	31	6.5	4.4	9.0	461	9	2.0	0.9	3.7	20	1	5.0	0.1	24.9	18	0	0.0	0.0	18.5								
	>38.0	2001	52	2.6	1.9	3.4	2032	4	0.2	0.1	0.5	1963	52	2.6	2.0	3.5	1960	6	0.3	0.1	0.7	480	5	1.0	0.3	2.4	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5								
	>38.5	2001	13	0.6	0.3	1.1	2032	1	0.0	0.0	0.3	1963	14	0.7	0.4	1.2	1960	4	0.2	0.1	0.5	480	3	0.6	0.1	1.8	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5								
	>39.0	2001	2	0.1	0.0	0.4	2032	1	0.0	0.0	0.3	1963	3	0.2	0.0	0.4	1960	2	0.1	0.0	0.4	480	1	0.2	0.0	1.2	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5								
	>39.5	2001	1	0.0	0.0	0.3	2032	1	0.0	0.0	0.3	1963	0	0.0	0.0	0.2	1960	1	0.1	0.0	0.3	480	0	0.0	0.0	0.8	461	0	0.0	0.0	0.8	20	0	0.0	0.0	16.8	18	0	0.0	0.0	18.5								
Dose 2																																																	
Temperature/(*) (°C)	All	1942	335	17.3	15.6	19.0	1988	31	1.6	1.1	2.2	1906	230	12.1	10.6	13.6	1895	25	1.3	0.9	1.9	456	48	10.5	7.9	13.7	443	11	2.5	1.2	4.4	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8								
	≥37.5	1942	334	17.2	15.5	19.0	1988	31	1.6	1.1	2.2	1906	226	11.9	10.4	13.4	1895	25	1.3	0.9	1.9	456	47	10.3	7.7	13.5	443	11	2.5	1.2	4.4	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8								
	>38.0	1942	101	5.2	4.3	6.3	1988	9	0.5	0.2	0.9	1906	67	3.5	2.7	4.4	1895	6	0.3	0.1	0.7	456	15	3.3	1.9	5.4	443	2	0.5	0.1	1.6	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8								
	>38.5	1942	31	1.6	1.1	2.3	1988	7	0.4	0.1	0.7	1906	16	0.8	0.5	1.4	1895	4	0.2	0.1	0.5	456	5	1.1	0.4	2.5	443	1	0.2	0.0	1.3	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8								
	>39.0	1942	4	0.2	0.1	0.5	1988	4	0.2	0.1	0.5	1906	2	0.1	0.0	0.4	1895	2	0.1	0.0	0.4	456	1	0.2	0.0	1.2	443	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8								
	>39.5	1942	0	0.0	0.0	0.2	1988	3	0.2	0.0	0.4	1906	1	0.1	0.0	0.3	1895	2	0.1	0.0	0.4	456	0	0.0	0.0	0.8	443	0	0.0	0.0	0.8	18	0	0.0	0.0	18.5	15	0	0.0	0.0	21.8								
Overall/dose																																																	
Temperature/(*) (°C)	All	3943	577	14.6	13.5	15.8	4020	55	1.4	1.0	1.8	3869	440	11.4	10.4	12.4	3855	56	1.5	1.1	1.9	936	81	8.7	6.9	10.6	904	21	2.3	1.4	3.5	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6								
	≥37.5	3943	576	14.6	13.5	15.7	4020	53	1.3	1.0	1.7	3869	431	11.1	10.2	12.2	3855	54	1.4	1.1	1.8	936	78	8.3	6.6	10.3	904	20	2.2	1.4	3.4	38	1	2.6	0.1	13.8	33	0	0.0	0.0	10.6								
	>38.0	3943	153	3.9	3.3	4.5	4020	13	0.3	0.2	0.6	3869	119	3.1	2.6	3.7	3855	12	0.3	0.2	0.5	936	20	2.1	1.3	3.3	904	2	0.2	0.0	0.8	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6								
	>38.5	3943	44	1.1	0.8	1.5	4020	8	0.2	0.1	0.4	3869	30	0.8	0.5	1.1	3855	8	0.2	0.1	0.4	936	8	0.9	0.4	1.7	904	1	0.1	0.0	0.6	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6								
	>39.0	3943	6	0.2	0.1	0.3	4020	5	0.1	0.0	0.3	3869	5	0.1	0.0	0.3	3855	4	0.1	0.0	0.3	936	2	0.2	0.0	0.8	904	0	0.0	0.0	0.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6								
	>39.5	3943	1	0.0	0.0	0.1	4020	4	0.1	0.0	0.3	3869	1	0.0	0.0	0.1	3855	3	0.1	0.0	0.2	936	0	0.0	0.0	0.4	904	0	0.0	0.0	0.4	38	0	0.0	0.0	9.3	33	0	0.0	0.0	10.6								
Overall/subject																																																	
Temperature/(*) (°C)	All	2007	465	23.2	21.3	25.1	2034	52	2.6	1.9	3.3	1971	368	18.7	17.0	20.5	1964	55	2.8	2.1	3.6	488	70	14.3	11.4	17.8	468	19	4.1	2.5	6.3	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5								
	≥37.5	2007	464	23.1	21.3	25.0	2034	50	2.5	1.8	3.2	1971	362	18.4	16.7	20.1	1964	53	2.7	2.0	3.5	488	67	13.7	10.8	17.1	468	18	3.8	2.3	6.0	21	1	4.8	0.1	23.8	18	0	0.0	0.0	18.5								
	>38.0	2007	137	6.8	5.8	8.0	2034	12	0.6	0.3	1.0	1971	111	5.6	4.7	6.7	1964	11	0.6	0.3	1.0	488	18	3.7	2.2	5.8	468	2	0.4	0.1	1.5	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5								
	>38.5	2007	42	2.1	1.5	2.8	2034	7	0.3	0.1	0.7	1971	30	1.5	1.0	2.2	1964	7	0.4	0.1	0.7	488	8	1.6	0.7	3.2	468	1	0.2	0.0	1.2	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5								
	>39.0	2007	6	0.3	0.1	0.6	2034	4	0.2	0.1	0.5	1971	5	0.3	0.1	0.6	1964	3	0.2	0.0	0.4	488	2	0.4	0.0	1.5	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5								
	>39.5	2007	1	0.0	0.0	0.3	2034	3	0.1	0.0	0.4	1971	1	0.1	0.0	0.3	1964	2	0.1	0.0	0.4	488	0	0.0	0.0	0.8	468	0	0.0	0.0	0.8	21	0	0.0	0.0	16.1	18	0	0.0	0.0	18.5								

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

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For each dose and overall/subject:

N = number of subjects with at least one documented dose

n/% = number/percentage of subjects reporting the symptom at least once when the intensity is maximum

For Overall/dose:

N = number of documented doses

n/% = number/percentage of doses followed by at least one type of symptom

95%CI = Exact 95% confidence interval; LL = lower limit, UL = upper limit

*Temperature is measured by oral, axillary, rectal or tympanic routes

Table 14.3.1.11 Number of days with local symptoms during the solicited post-vaccination period by frailty status (Total Vaccinated Cohort - Diary Card Subset)

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
Pain	Dose 1	Non-Frail	HZ/su	2032	1515	3.0	1.0	2.0	3.0	4.0	7.0
			Placebo	2066	154	2.1	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	2013	1315	3.1	1.0	2.0	3.0	4.0	7.0
			Placebo	1999	143	2.0	1.0	1.0	1.0	2.0	7.0
		Frail	HZ/su	503	276	3.3	1.0	2.0	3.0	4.0	7.0
			Placebo	484	32	2.0	1.0	1.0	1.5	2.5	7.0
		Unknown	HZ/su	22	15	2.5	1.0	1.0	2.0	4.0	6.0
			Placebo	22	1	2.0	2.0	2.0	2.0	2.0	2.0
	Dose 2	Non-Frail	HZ/su	1954	1382	2.8	1.0	2.0	3.0	4.0	7.0
			Placebo	2001	106	2.0	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	1929	1187	2.9	1.0	2.0	3.0	4.0	7.0
			Placebo	1919	110	2.3	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	465	256	3.0	1.0	2.0	3.0	4.0	7.0
			Placebo	449	35	2.8	1.0	1.0	2.0	4.0	7.0
		Unknown	HZ/su	20	11	2.7	1.0	2.0	3.0	4.0	4.0
	Overall/dose	Non-Frail	HZ/su	3986	2897	2.9	1.0	2.0	3.0	4.0	7.0
			Placebo	4067	260	2.1	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	3942	2502	3.0	1.0	2.0	3.0	4.0	7.0
			Placebo	3918	253	2.1	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	968	532	3.2	1.0	2.0	3.0	4.0	7.0
			Placebo	933	67	2.4	1.0	1.0	2.0	3.0	7.0
		Unknown	HZ/su	42	26	2.6	1.0	1.0	2.5	4.0	6.0
			Placebo	39	1	2.0	2.0	2.0	2.0	2.0	2.0
Redness	Dose 1	Non-Frail	HZ/su	2032	599	3.5	1.0	2.0	3.0	5.0	7.0
			Placebo	2066	18	3.4	1.0	2.0	2.5	5.0	7.0
		Pre-Frail	HZ/su	2013	526	3.5	1.0	2.0	3.0	5.0	7.0
			Placebo	1999	19	3.2	1.0	1.0	3.0	4.0	7.0
		Frail	HZ/su	503	119	3.4	1.0	2.0	3.0	5.0	7.0
			Placebo	484	1	3.0	3.0	3.0	3.0	3.0	3.0
		Unknown	HZ/su	22	6	3.8	2.0	3.0	4.0	5.0	5.0
	Dose 2	Non-Frail	HZ/su	1954	583	3.1	1.0	2.0	3.0	4.0	7.0
			Placebo	2001	8	3.0	1.0	1.0	2.5	4.5	7.0
		Pre-Frail	HZ/su	1929	499	3.4	1.0	2.0	3.0	4.0	7.0
			Placebo	1919	12	2.9	1.0	1.0	1.5	5.0	7.0
		Frail	HZ/su	465	104	3.4	1.0	2.0	3.0	4.0	7.0
			Placebo	449	1	6.0	6.0	6.0	6.0	6.0	6.0
		Unknown	HZ/su	20	6	3.0	2.0	2.0	2.0	5.0	5.0
	Overall/dose	Non-Frail	HZ/su	3986	1182	3.3	1.0	2.0	3.0	4.0	7.0
			Placebo	4067	26	3.3	1.0	1.0	2.5	5.0	7.0
		Pre-Frail	HZ/su	3942	1025	3.4	1.0	2.0	3.0	5.0	7.0
			Placebo	3918	31	3.1	1.0	1.0	3.0	4.0	7.0
		Frail	HZ/su	968	223	3.4	1.0	2.0	3.0	5.0	7.0
			Placebo	933	2	4.5	3.0	3.0	4.5	6.0	6.0
		Unknown	HZ/su	42	12	3.4	2.0	2.0	3.5	5.0	5.0
Swelling	Dose 1	Non-Frail	HZ/su	2032	383	3.2	1.0	2.0	3.0	4.0	7.0
			Placebo	2066	12	2.9	1.0	1.0	2.0	4.0	7.0
		Pre-Frail	HZ/su	2013	340	3.4	1.0	2.0	3.0	5.0	7.0
			Placebo	1999	15	2.2	1.0	1.0	1.0	3.0	7.0
		Frail	HZ/su	503	79	3.2	1.0	2.0	3.0	4.0	7.0
			Placebo	484	2	4.0	1.0	1.0	4.0	7.0	7.0
		Unknown	HZ/su	22	5	3.2	1.0	3.0	3.0	3.0	6.0

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max	
	Dose 2	Non-Frail	Placebo	22	1	2.0	2.0	2.0	2.0	2.0	2.0	
			HZ/su	1954	364	3.0	1.0	2.0	3.0	4.0	7.0	
			Placebo	2001	6	1.8	1.0	1.0	1.5	3.0	3.0	
			HZ/su	1929	336	3.2	1.0	2.0	3.0	4.0	7.0	
		Pre-Frail	Placebo	1919	9	2.6	1.0	1.0	2.0	3.0	7.0	
			HZ/su	465	63	3.4	1.0	3.0	3.0	4.0	7.0	
		Frail	Placebo	449	1	3.0	3.0	3.0	3.0	3.0	3.0	
			HZ/su	20	2	2.0	1.0	1.0	2.0	3.0	3.0	
		Unknown	HZ/su	20	2	2.0	1.0	1.0	2.0	3.0	3.0	
			Placebo	449	1	3.0	3.0	3.0	3.0	3.0	3.0	
		Overall/dose	Non-Frail	HZ/su	3986	747	3.1	1.0	2.0	3.0	4.0	7.0
				Placebo	4067	18	2.6	1.0	1.0	2.0	4.0	7.0
	Pre-Frail		HZ/su	3942	676	3.3	1.0	2.0	3.0	4.5	7.0	
			Placebo	3918	24	2.3	1.0	1.0	2.0	3.0	7.0	
	Frail		HZ/su	968	142	3.3	1.0	2.0	3.0	4.0	7.0	
			Placebo	933	3	3.7	1.0	1.0	3.0	7.0	7.0	
Unknown	HZ/su		42	7	2.9	1.0	1.0	3.0	3.0	6.0		
	Placebo		39	1	2.0	2.0	2.0	2.0	2.0	2.0		

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of administered doses

n = number of doses with the symptom

Q1 = 25th percentile

Q3 = 75th percentile

Table 14.3.1.12 Number of days with grade 3 local symptoms during the solicited post-vaccination period by frailty status (Total Vaccinated Cohort - Diary Card Subset)

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
Pain	Dose 1	Non-Frail	HZ/su	2032	60	1.5	1.0	1.0	1.0	2.0	4.0
			Placebo	2066	3	1.3	1.0	1.0	1.0	2.0	2.0
		Pre-Frail	HZ/su	2013	65	1.7	1.0	1.0	1.0	2.0	7.0
			Placebo	1999	2	1.0	1.0	1.0	1.0	1.0	1.0
		Frail	HZ/su	503	20	2.0	1.0	1.0	1.0	2.0	7.0
			Placebo	484	1	7.0	7.0	7.0	7.0	7.0	7.0
		Unknown	HZ/su	22	1	1.0	1.0	1.0	1.0	1.0	1.0
	Dose 2	Non-Frail	HZ/su	1954	80	1.7	1.0	1.0	1.0	2.0	7.0
			Placebo	2001	1	2.0	2.0	2.0	2.0	2.0	2.0
		Pre-Frail	HZ/su	1929	78	1.6	1.0	1.0	1.0	2.0	5.0
			Placebo	1919	4	2.8	1.0	1.0	1.5	4.5	7.0
		Frail	HZ/su	465	25	1.6	1.0	1.0	1.0	2.0	4.0
			Placebo	449	4	2.8	1.0	1.5	2.5	4.0	5.0
	Overall/dose	Non-Frail	HZ/su	3986	140	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	4067	4	1.5	1.0	1.0	1.5	2.0	2.0
		Pre-Frail	HZ/su	3942	143	1.7	1.0	1.0	1.0	2.0	7.0
			Placebo	3918	6	2.2	1.0	1.0	1.0	2.0	7.0
		Frail	HZ/su	968	45	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	933	5	3.6	1.0	2.0	3.0	5.0	7.0
		Unknown	HZ/su	42	1	1.0	1.0	1.0	1.0	1.0	1.0
Redness	Dose 1	Non-Frail	HZ/su	2032	49	2.2	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	2013	30	2.2	1.0	1.0	2.0	3.0	6.0
		Frail	HZ/su	503	6	1.7	1.0	1.0	1.0	2.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	37	1.8	1.0	1.0	1.0	2.0	5.0
		Pre-Frail	HZ/su	1929	22	2.3	1.0	1.0	2.0	3.0	5.0
		Frail	HZ/su	465	8	1.6	1.0	1.0	1.0	2.5	3.0
	Overall/dose	Non-Frail	HZ/su	3986	86	2.0	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	3942	52	2.3	1.0	1.0	2.0	3.0	6.0
		Frail	HZ/su	968	14	1.6	1.0	1.0	1.0	2.0	4.0
Swelling	Dose 1	Non-Frail	HZ/su	2032	13	1.9	1.0	1.0	1.0	3.0	4.0
		Pre-Frail	HZ/su	2013	12	1.5	1.0	1.0	1.5	2.0	2.0
	Dose 2	Non-Frail	HZ/su	1954	13	1.5	1.0	1.0	1.0	2.0	3.0
		Pre-Frail	HZ/su	1929	9	1.4	1.0	1.0	1.0	1.0	3.0
		Frail	HZ/su	465	2	1.0	1.0	1.0	1.0	1.0	1.0
	Overall/dose	Non-Frail	HZ/su	3986	26	1.7	1.0	1.0	1.0	2.0	4.0
		Pre-Frail	HZ/su	3942	21	1.5	1.0	1.0	1.0	2.0	3.0
		Frail	HZ/su	968	2	1.0	1.0	1.0	1.0	1.0	1.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of administered doses

n = number of doses with the symptom

Q1 = 25th percentile

Q3 = 75th percentile

Table 14.3.1.13 Number of days with local symptoms by frailty status (Total Vaccinated Cohort - Diary Card Subset)

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
Pain	Dose 1	Non-Frail	HZ/su	2032	1515	3.1	1.0	2.0	3.0	4.0	28.0
			Placebo	2066	154	2.3	1.0	1.0	1.0	3.0	21.0
		Pre-Frail	HZ/su	2013	1315	3.2	1.0	2.0	3.0	4.0	22.0
			Placebo	1999	143	2.4	1.0	1.0	1.0	2.0	47.0
		Frail	HZ/su	503	276	3.6	1.0	2.0	3.0	4.0	41.0
			Placebo	484	32	2.0	1.0	1.0	1.5	2.5	8.0
		Unknown	HZ/su	22	15	2.5	1.0	1.0	2.0	4.0	6.0
			Placebo	22	1	2.0	2.0	2.0	2.0	2.0	2.0
	Dose 2	Non-Frail	HZ/su	1954	1382	2.8	1.0	2.0	3.0	4.0	13.0
			Placebo	2001	106	2.2	1.0	1.0	1.0	3.0	19.0
		Pre-Frail	HZ/su	1929	1187	3.0	1.0	2.0	3.0	4.0	31.0
			Placebo	1919	110	2.4	1.0	1.0	2.0	3.0	12.0
		Frail	HZ/su	465	256	3.0	1.0	2.0	3.0	4.0	17.0
			Placebo	449	35	2.9	1.0	1.0	2.0	4.0	13.0
		Unknown	HZ/su	20	11	2.7	1.0	2.0	3.0	4.0	4.0
	Overall/dose	Non-Frail	HZ/su	3986	2897	2.9	1.0	2.0	3.0	4.0	28.0
			Placebo	4067	260	2.2	1.0	1.0	1.0	3.0	21.0
		Pre-Frail	HZ/su	3942	2502	3.1	1.0	2.0	3.0	4.0	31.0
			Placebo	3918	253	2.4	1.0	1.0	2.0	3.0	47.0
		Frail	HZ/su	968	532	3.3	1.0	2.0	3.0	4.0	41.0
			Placebo	933	67	2.5	1.0	1.0	2.0	3.0	13.0
		Unknown	HZ/su	42	26	2.6	1.0	1.0	2.5	4.0	6.0
			Placebo	39	1	2.0	2.0	2.0	2.0	2.0	2.0
Redness	Dose 1	Non-Frail	HZ/su	2032	599	4.1	1.0	2.0	3.0	5.0	33.0
			Placebo	2066	18	4.0	1.0	2.0	2.5	5.0	15.0
		Pre-Frail	HZ/su	2013	526	4.3	1.0	2.0	3.0	5.0	41.0
			Placebo	1999	19	3.8	1.0	2.0	3.0	5.0	9.0
		Frail	HZ/su	503	119	3.9	1.0	2.0	3.0	5.0	26.0
			Placebo	484	1	3.0	3.0	3.0	3.0	3.0	3.0
		Unknown	HZ/su	22	6	3.8	2.0	3.0	4.0	5.0	5.0
	Dose 2	Non-Frail	HZ/su	1954	583	3.4	1.0	2.0	3.0	4.0	24.0
			Placebo	2001	8	3.0	1.0	1.0	2.5	4.5	7.0
		Pre-Frail	HZ/su	1929	499	3.7	1.0	2.0	3.0	4.0	44.0
			Placebo	1919	12	3.3	1.0	1.0	1.5	5.0	11.0
		Frail	HZ/su	465	104	3.5	1.0	2.0	3.0	5.0	10.0
			Placebo	449	1	6.0	6.0	6.0	6.0	6.0	6.0
		Unknown	HZ/su	20	6	3.3	2.0	2.0	2.0	5.0	7.0
	Overall/dose	Non-Frail	HZ/su	3986	1182	3.7	1.0	2.0	3.0	5.0	33.0
			Placebo	4067	26	3.7	1.0	1.0	2.5	5.0	15.0
		Pre-Frail	HZ/su	3942	1025	4.0	1.0	2.0	3.0	5.0	44.0
			Placebo	3918	31	3.6	1.0	1.0	3.0	5.0	11.0
		Frail	HZ/su	968	223	3.7	1.0	2.0	3.0	5.0	26.0
			Placebo	933	2	4.5	3.0	3.0	4.5	6.0	6.0
		Unknown	HZ/su	42	12	3.6	2.0	2.0	3.5	5.0	7.0
Swelling	Dose 1	Non-Frail	HZ/su	2032	383	3.5	1.0	2.0	3.0	4.0	15.0
			Placebo	2066	12	3.8	1.0	1.0	2.0	4.0	15.0
		Pre-Frail	HZ/su	2013	340	3.6	1.0	2.0	3.0	5.0	15.0
			Placebo	1999	15	2.2	1.0	1.0	1.0	3.0	7.0
		Frail	HZ/su	503	79	3.4	1.0	2.0	3.0	4.0	12.0
			Placebo	484	2	4.0	1.0	1.0	4.0	7.0	7.0
		Unknown	HZ/su	22	5	3.2	1.0	3.0	3.0	3.0	6.0
			Placebo	22	1	2.0	2.0	2.0	2.0	2.0	2.0

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
	Dose 2	Non-Frail	HZ/su	1954	364	3.1	1.0	2.0	3.0	4.0	16.0
			Placebo	2001	6	1.8	1.0	1.0	1.5	3.0	3.0
		Pre-Frail	HZ/su	1929	336	3.5	1.0	2.0	3.0	4.0	31.0
			Placebo	1919	9	2.6	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	465	63	3.6	1.0	3.0	3.0	4.0	13.0
			Placebo	449	1	3.0	3.0	3.0	3.0	3.0	3.0
		Unknown	HZ/su	20	2	2.0	1.0	1.0	2.0	3.0	3.0
	Overall/dose	Non-Frail	HZ/su	3986	747	3.3	1.0	2.0	3.0	4.0	16.0
			Placebo	4067	18	3.2	1.0	1.0	2.0	4.0	15.0
		Pre-Frail	HZ/su	3942	676	3.5	1.0	2.0	3.0	5.0	31.0
			Placebo	3918	24	2.3	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	968	142	3.5	1.0	2.0	3.0	4.0	13.0
			Placebo	933	3	3.7	1.0	1.0	3.0	7.0	7.0
		Unknown	HZ/su	42	7	2.9	1.0	1.0	3.0	3.0	6.0
			Placebo	39	1	2.0	2.0	2.0	2.0	2.0	2.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of administered doses

n = number of doses with the symptom (during the solicited post-vaccination period and beyond)

Q1 = 25th percentile

Q3 = 75th percentile

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Table 14.3.1.14 Solicited local symptoms ongoing beyond the 7-day (Days 0-6) post-vaccination period by frailty status (Total Vaccinated Cohort - Diary Card Subset)

		Non-Frail												Pre-Frail												Frail												Unknown											
		HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo					
					Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)								
Symptoms	Type	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3						
Dose 1																																																	
Pain	Any	200	151	22	2	3	6	203	154	6	1	3.5	5	197	131	2	2	3.5	8	196	143	5	1	6	1	48	27	6	2	3.5	34	46	32	1	1	1	1	2	15	0	-	-	-	1	1	0	-	-	-
	Grade 3	200	60	6	2	4.5	7	203	3	1	1	1	1	197	65	7	1	8	11	196	2	0	-	-	-	48	3	20	1	34	34	34	46	1	1	1	1	1	2	1	0	-	-	-	1	0	0	-	-
Redness	Any	200	599	78	2	3	5	203	18	2	3	5.5	8	197	526	6	3	4	7	196	19	4	2	3	3	48	11	9	3	4	7	46	1	0	-	-	-	2	6	0	-	-	-	1	0	0	-	-	-
	Grade 3	200	49	20	2	3	4.5	203	0	0	-	-	-	197	30	8	3	4.5	15.5	196	0	0	-	-	-	48	6	1	8	8	8	46	0	0	-	-	-	2	0	0	-	-	-	1	0	0	-	-	-
Swelling	Any	200	383	28	2	3	5	203	12	2	3	5.5	8	197	340	1	2	3	4	196	15	0	-	-	-	48	79	3	2	4	5	46	2	0	-	-	-	2	5	0	-	-	-	1	1	0	-	-	-
	Grade 3	200	13	5	2	3	4	203	0	0	-	-	-	197	12	0	-	-	-	196	0	0	-	-	-	48	0	0	-	-	-	46	0	0	-	-	-	2	0	0	-	-	-	1	0	0	-	-	-
Dose 2																																																	
Pain	Any	194	138	10	1	3	5	198	10	2	1	4	1	190	118	1	2	4.5	8	189	11	4	2	2	5	45	25	3	5	8	11	44	35	2	6	6	6	1	11	0	-	-	-	1	0	0	-	-	-
	Grade 3	194	80	5	1	2	4.5	198	1	0	-	-	-	190	78	5	4	4	9	189	4	1	2	2	2	45	25	2	5	8	11	44	4	2	6	6	6	1	0	0	-	-	-	1	0	0	-	-	-
Redness	Any	194	583	25	3	4	7	198	8	0	-	-	-	190	499	2	2	4	10	189	12	1	4	4	4	45	10	5	2	4	4	44	1	0	-	-	-	1	6	1	2	2	2	1	0	0	-	-	-
	Grade 3	194	37	2	3	3.5	4	198	0	0	-	-	-	190	22	5	1	3	15	189	0	0	-	-	-	45	8	1	2	2	2	44	0	0	-	-	-	1	0	0	-	-	-	1	0	0	-	-	-
Swelling	Any	194	364	13	3	3	4	198	6	0	-	-	-	190	336	1	3	7	10	189	9	0	-	-	-	45	63	2	6	7	8	44	1	0	-	-	-	1	2	0	-	-	-	1	0	0	-	-	-
	Grade 3	194	13	2	1	2	3	198	0	0	-	-	-	190	9	1	3	3	3	189	0	0	-	-	-	45	2	0	-	-	-	44	0	0	-	-	-	1	0	0	-	-	-	1	0	0	-	-	-
Overall/dose																																																	
Pain	Any	394	289	32	2	3	6	401	26	8	1	4	1	387	250	4	2	4	8	386	25	9	1	3.5	9	93	53	9	2	4.5	22	90	67	3	1	3.5	6	3	26	0	-	-	-	3	1	0	-	-	-
	Grade 3	394	140	11	2	3	6	401	4	1	1	1	1	387	143	1	2	6	9.5	386	6	1	2	2	2	93	45	3	5	11	34	90	5	3	1	3.5	6	3	1	0	-	-	-	3	0	0	-	-	-
Redness	Any	394	118	10	2	3	6	401	26	2	3	5.5	8	387	102	8	2	4	8	386	31	5	3	3	3	93	22	1	2	4	6	90	2	0	-	-	-	3	12	1	2	2	2	3	0	0	-	-	-
	Grade 3	394	86	22	2	3	4	401	0	0	-	-	-	387	52	1	3	3	15	386	0	0	-	-	-	93	14	2	2	5	8	90	0	0	-	-	-	3	0	0	-	-	-	3	0	0	-	-	-

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		Non-Frail												Pre-Frail												Frail												Unknown											
		HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo					
		Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)											
Symptoms	Type	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3						
Swelling	Any	3941	747	41	2	3	4	4019	18	2	3	5.5	8	3879	676	3	2	3	8	3861	24	0	-	-	-	938	14	5	4	5	6	903	3	0	-	-	-	39	7	0	-	-	-	3	1	0	-	-	-
	Grade 3	3941	26	7	1	3	4	4019	0	0	-	-	-	3879	21	1	3	3	3	3861	0	0	-	-	-	938	2	0	-	-	-	903	0	0	-	-	-	39	0	0	-	-	-	3	0	0	-	-	-

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of documented doses

Ns = total number of reports for a given symptom

n = number of symptoms that were ongoing after the follow-up period

Time to resolution : number of days beyond the end of the follow-up period

Q1 = 25th percentile

Q3 = 75th percentile

Table 14.3.1.15 Number of days with general symptoms during the solicited post-vaccination period by frailty status (Total Vaccinated Cohort - Diary Card Subset)

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
Fatigue	Dose 1	Non-Frail	HZ/su	2032	650	2.3	1.0	1.0	2.0	3.0	7.0
			Placebo	2066	219	2.6	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	2013	592	2.6	1.0	1.0	2.0	3.0	7.0
			Placebo	1999	237	2.8	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	503	114	3.8	1.0	2.0	3.0	6.0	7.0
			Placebo	484	77	3.6	1.0	2.0	3.0	6.0	7.0
		Unknown	HZ/su	22	4	1.3	1.0	1.0	1.0	1.5	2.0
			Placebo	22	4	5.0	1.0	3.5	6.0	6.5	7.0
	Dose 2	Non-Frail	HZ/su	1954	711	2.2	1.0	1.0	2.0	3.0	7.0
			Placebo	2001	147	2.4	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	1929	597	2.6	1.0	1.0	2.0	3.0	7.0
			Placebo	1919	192	3.0	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	465	120	3.4	1.0	1.0	3.0	5.5	7.0
			Placebo	449	46	3.8	1.0	2.0	3.0	6.0	7.0
		Unknown	HZ/su	20	2	1.5	1.0	1.0	1.5	2.0	2.0
			Placebo	17	1	7.0	7.0	7.0	7.0	7.0	7.0
	Overall/dose	Non-Frail	HZ/su	3986	1361	2.3	1.0	1.0	2.0	3.0	7.0
			Placebo	4067	366	2.5	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	3942	1189	2.6	1.0	1.0	2.0	3.0	7.0
			Placebo	3918	429	2.9	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	968	234	3.6	1.0	2.0	3.0	6.0	7.0
			Placebo	933	123	3.6	1.0	2.0	3.0	6.0	7.0
		Unknown	HZ/su	42	6	1.3	1.0	1.0	1.0	2.0	2.0
			Placebo	39	5	5.4	1.0	6.0	6.0	7.0	7.0
Gastrointestinal symptoms	Dose 1	Non-Frail	HZ/su	2032	219	2.2	1.0	1.0	1.0	3.0	7.0
			Placebo	2066	100	2.4	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	2013	188	2.2	1.0	1.0	2.0	3.0	7.0
			Placebo	1999	117	2.6	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	503	38	2.4	1.0	1.0	2.0	3.0	7.0
			Placebo	484	39	2.7	1.0	1.0	2.0	3.0	7.0
		Unknown	HZ/su	22	2	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	22	2	4.0	4.0	4.0	4.0	4.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	237	1.9	1.0	1.0	1.0	2.0	7.0
			Placebo	2001	75	2.2	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	1929	201	2.4	1.0	1.0	2.0	3.0	7.0
			Placebo	1919	79	2.8	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	465	44	2.6	1.0	1.0	2.0	3.5	7.0
			Placebo	449	29	2.7	1.0	1.0	1.0	4.0	7.0
	Overall/dose	Non-Frail	HZ/su	3986	456	2.1	1.0	1.0	1.0	3.0	7.0
			Placebo	4067	175	2.3	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	3942	389	2.3	1.0	1.0	2.0	3.0	7.0
			Placebo	3918	196	2.7	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	968	82	2.5	1.0	1.0	2.0	3.0	7.0
			Placebo	933	68	2.7	1.0	1.0	2.0	3.5	7.0
		Unknown	HZ/su	42	2	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	39	2	4.0	4.0	4.0	4.0	4.0	4.0
Headache	Dose 1	Non-Frail	HZ/su	2032	538	2.0	1.0	1.0	2.0	2.0	7.0
			Placebo	2066	215	1.9	1.0	1.0	1.0	2.0	7.0
		Pre-Frail	HZ/su	2013	435	2.2	1.0	1.0	2.0	3.0	7.0
			Placebo	1999	214	2.4	1.0	1.0	2.0	3.0	7.0

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Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
		Frail	HZ/su	503	96	2.7	1.0	1.0	2.0	4.0	7.0
			Placebo	484	70	2.7	1.0	1.0	2.0	4.0	7.0
		Unknown	HZ/su	22	5	1.2	1.0	1.0	1.0	1.0	2.0
			Placebo	22	2	2.5	1.0	1.0	2.5	4.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	627	2.0	1.0	1.0	2.0	2.0	7.0
			Placebo	2001	131	2.1	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	1929	463	2.3	1.0	1.0	2.0	3.0	7.0
			Placebo	1919	160	2.4	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	465	104	2.6	1.0	1.0	2.0	3.0	7.0
			Placebo	449	43	3.3	1.0	2.0	3.0	4.0	7.0
		Unknown	HZ/su	20	3	1.7	1.0	1.0	1.0	3.0	3.0
			Placebo	17	1	1.0	1.0	1.0	1.0	1.0	1.0
	Overall/dose	Non-Frail	HZ/su	3986	1165	2.0	1.0	1.0	2.0	2.0	7.0
			Placebo	4067	346	2.0	1.0	1.0	1.0	2.0	7.0
		Pre-Frail	HZ/su	3942	898	2.2	1.0	1.0	2.0	3.0	7.0
			Placebo	3918	374	2.4	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	968	200	2.7	1.0	1.0	2.0	4.0	7.0
			Placebo	933	113	2.9	1.0	1.0	2.0	4.0	7.0
		Unknown	HZ/su	42	8	1.4	1.0	1.0	1.0	1.5	3.0
			Placebo	39	3	2.0	1.0	1.0	1.0	4.0	4.0
Myalgia	Dose 1	Non-Frail	HZ/su	2032	682	2.4	1.0	1.0	2.0	3.0	7.0
			Placebo	2066	149	2.6	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	2013	591	2.7	1.0	1.0	2.0	4.0	7.0
			Placebo	1999	152	3.0	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	503	113	3.4	1.0	2.0	3.0	5.0	7.0
			Placebo	484	57	3.5	1.0	2.0	3.0	6.0	7.0
		Unknown	HZ/su	22	4	2.8	1.0	1.0	2.5	4.5	5.0
			Placebo	22	2	4.5	4.0	4.0	4.5	5.0	5.0
	Dose 2	Non-Frail	HZ/su	1954	713	2.3	1.0	1.0	2.0	3.0	7.0
			Placebo	2001	109	3.0	1.0	2.0	2.0	4.0	7.0
		Pre-Frail	HZ/su	1929	587	2.7	1.0	1.0	2.0	3.0	7.0
			Placebo	1919	117	3.0	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	465	119	3.0	1.0	2.0	3.0	4.0	7.0
			Placebo	449	38	3.9	1.0	2.0	4.0	6.0	7.0
		Unknown	HZ/su	20	3	2.3	1.0	1.0	3.0	3.0	3.0
	Overall/dose	Non-Frail	HZ/su	3986	1395	2.4	1.0	1.0	2.0	3.0	7.0
			Placebo	4067	258	2.8	1.0	1.0	2.0	4.0	7.0
		Pre-Frail	HZ/su	3942	1178	2.7	1.0	1.0	2.0	4.0	7.0
			Placebo	3918	269	3.0	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	968	232	3.2	1.0	2.0	3.0	4.0	7.0
			Placebo	933	95	3.7	1.0	2.0	3.0	6.0	7.0
		Unknown	HZ/su	42	7	2.6	1.0	1.0	3.0	4.0	5.0
			Placebo	39	2	4.5	4.0	4.0	4.5	5.0	5.0
Shivering	Dose 1	Non-Frail	HZ/su	2032	317	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	2066	69	2.0	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	2013	240	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	1999	75	2.1	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	503	40	2.5	1.0	1.0	2.0	3.5	7.0
			Placebo	484	23	3.1	1.0	1.0	2.0	4.0	7.0
		Unknown	HZ/su	22	3	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	22	2	2.5	1.0	1.0	2.5	4.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	500	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	2001	58	2.3	1.0	1.0	1.5	3.0	7.0
		Pre-Frail	HZ/su	1929	338	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	1919	47	2.3	1.0	1.0	2.0	3.0	7.0

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
		Frail	HZ/su	465	64	2.1	1.0	1.0	2.0	3.0	7.0
			Placebo	449	24	3.0	1.0	1.0	2.0	5.0	7.0
		Unknown	Placebo	17	2	2.0	1.0	1.0	2.0	3.0	3.0
	Overall/dose	Non-Frail	HZ/su	3986	817	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	4067	127	2.1	1.0	1.0	2.0	3.0	7.0
		Pre-Frail	HZ/su	3942	578	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	3918	122	2.2	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	968	104	2.3	1.0	1.0	2.0	3.0	7.0
			Placebo	933	47	3.1	1.0	1.0	2.0	5.0	7.0
		Unknown	HZ/su	42	3	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	39	4	2.3	1.0	1.0	2.0	3.5	4.0
Temperature	Dose 1	Non-Frail	HZ/su	2032	242	1.5	1.0	1.0	1.0	1.0	7.0
			Placebo	2066	24	2.1	1.0	1.0	1.0	3.0	6.0
		Pre-Frail	HZ/su	2013	210	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	1999	31	1.6	1.0	1.0	1.0	2.0	6.0
		Frail	HZ/su	503	33	2.1	1.0	1.0	1.0	2.0	7.0
			Placebo	484	10	1.6	1.0	1.0	1.0	2.0	4.0
		Unknown	HZ/su	22	1	1.0	1.0	1.0	1.0	1.0	1.0
	Dose 2	Non-Frail	HZ/su	1954	335	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	2001	31	2.3	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	1929	230	1.9	1.0	1.0	1.0	2.0	7.0
			Placebo	1919	25	2.2	1.0	1.0	2.0	2.0	7.0
		Frail	HZ/su	465	48	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	449	11	2.8	1.0	1.0	2.0	5.0	7.0
	Overall/dose	Non-Frail	HZ/su	3986	577	1.5	1.0	1.0	1.0	2.0	7.0
			Placebo	4067	55	2.2	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	3942	440	1.7	1.0	1.0	1.0	2.0	7.0
			Placebo	3918	56	1.9	1.0	1.0	1.0	2.0	7.0
		Frail	HZ/su	968	81	1.9	1.0	1.0	1.0	2.0	7.0
			Placebo	933	21	2.2	1.0	1.0	1.0	3.0	7.0
		Unknown	HZ/su	42	1	1.0	1.0	1.0	1.0	1.0	1.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of administered doses

n = number of doses with the symptom

Q1 = 25th percentile

Q3 = 75th percentile

*Temperature is measured by oral, axillary, rectal or tympanic routes

Table 14.3.1.16 Number of days with grade 3 general symptoms during the solicited post-vaccination period by frailty status (Total Vaccinated Cohort - Diary Card Subset)

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
Fatigue	Dose 1	Non-Frail	HZ/su	2032	43	1.5	1.0	1.0	1.0	2.0	5.0
			Placebo	2066	9	1.6	1.0	1.0	1.0	2.0	3.0
		Pre-Frail	HZ/su	2013	46	1.6	1.0	1.0	1.0	2.0	6.0
			Placebo	1999	12	2.7	1.0	1.0	2.0	4.0	7.0
		Frail	HZ/su	503	14	2.4	1.0	1.0	2.0	3.0	7.0
			Placebo	484	5	2.6	1.0	1.0	2.0	2.0	7.0
	Dose 2	Non-Frail	HZ/su	1954	79	1.4	1.0	1.0	1.0	2.0	3.0
			Placebo	2001	6	1.7	1.0	1.0	1.0	3.0	3.0
		Pre-Frail	HZ/su	1929	54	1.5	1.0	1.0	1.0	2.0	7.0
			Placebo	1919	5	2.8	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	465	13	1.5	1.0	1.0	1.0	2.0	3.0
			Placebo	449	3	3.3	2.0	2.0	3.0	5.0	5.0
	Overall/dose	Non-Frail	HZ/su	3986	122	1.4	1.0	1.0	1.0	2.0	5.0
			Placebo	4067	15	1.6	1.0	1.0	1.0	2.0	3.0
		Pre-Frail	HZ/su	3942	100	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	3918	17	2.7	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	968	27	1.9	1.0	1.0	1.0	3.0	7.0
			Placebo	933	8	2.9	1.0	1.5	2.0	4.0	7.0
Gastrointestinal symptoms	Dose 1	Non-Frail	HZ/su	2032	13	1.7	1.0	1.0	1.0	2.0	4.0
			Placebo	2066	4	1.3	1.0	1.0	1.0	1.5	2.0
		Pre-Frail	HZ/su	2013	14	1.5	1.0	1.0	1.0	2.0	3.0
			Placebo	1999	7	1.3	1.0	1.0	1.0	2.0	2.0
		Frail	HZ/su	503	4	1.3	1.0	1.0	1.0	1.5	2.0
			Placebo	484	1	2.0	2.0	2.0	2.0	2.0	2.0
	Dose 2	Non-Frail	HZ/su	1954	13	1.5	1.0	1.0	1.0	1.0	5.0
			Placebo	2001	8	1.1	1.0	1.0	1.0	1.0	2.0
		Pre-Frail	HZ/su	1929	17	1.5	1.0	1.0	1.0	2.0	3.0
			Placebo	1919	1	1.0	1.0	1.0	1.0	1.0	1.0
		Frail	HZ/su	465	2	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	449	5	1.6	1.0	1.0	1.0	2.0	3.0
	Overall/dose	Non-Frail	HZ/su	3986	26	1.6	1.0	1.0	1.0	2.0	5.0
			Placebo	4067	12	1.2	1.0	1.0	1.0	1.0	2.0
		Pre-Frail	HZ/su	3942	31	1.5	1.0	1.0	1.0	2.0	3.0
			Placebo	3918	8	1.3	1.0	1.0	1.0	1.5	2.0
		Frail	HZ/su	968	6	1.2	1.0	1.0	1.0	1.0	2.0
			Placebo	933	6	1.7	1.0	1.0	1.5	2.0	3.0
Headache	Dose 1	Non-Frail	HZ/su	2032	33	1.4	1.0	1.0	1.0	1.0	5.0
			Placebo	2066	5	1.4	1.0	1.0	1.0	2.0	2.0
		Pre-Frail	HZ/su	2013	23	1.3	1.0	1.0	1.0	2.0	3.0
			Placebo	1999	8	2.5	1.0	1.0	2.0	3.0	7.0
		Frail	HZ/su	503	6	2.8	1.0	1.0	2.0	4.0	7.0
			Placebo	484	7	2.1	1.0	1.0	1.0	2.0	7.0
	Dose 2	Non-Frail	HZ/su	1954	48	1.5	1.0	1.0	1.0	2.0	7.0
			Placebo	2001	3	2.0	1.0	1.0	2.0	3.0	3.0
		Pre-Frail	HZ/su	1929	37	1.9	1.0	1.0	2.0	2.0	7.0
			Placebo	1919	6	1.2	1.0	1.0	1.0	1.0	2.0
		Frail	HZ/su	465	12	1.3	1.0	1.0	1.0	1.5	3.0
			Placebo	449	4	1.8	1.0	1.0	1.5	2.5	3.0
	Overall/dose	Non-Frail	HZ/su	3986	81	1.4	1.0	1.0	1.0	2.0	7.0
			Placebo	4067	8	1.6	1.0	1.0	1.5	2.0	3.0

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max		
		Pre-Frail	HZ/su	3942	60	1.7	1.0	1.0	1.0	2.0	7.0		
			Placebo	3918	14	1.9	1.0	1.0	1.0	2.0	7.0		
		Frail	HZ/su	968	18	1.8	1.0	1.0	1.0	2.0	7.0		
			Placebo	933	11	2.0	1.0	1.0	1.0	2.0	7.0		
Myalgia	Dose 1	Non-Frail	HZ/su	2032	40	1.6	1.0	1.0	1.0	2.0	6.0		
			Placebo	2066	5	1.8	1.0	1.0	1.0	3.0	3.0		
		Pre-Frail	HZ/su	2013	46	1.7	1.0	1.0	1.0	2.0	4.0		
			Placebo	1999	7	2.0	1.0	1.0	2.0	3.0	3.0		
		Frail	HZ/su	503	13	2.2	1.0	1.0	2.0	3.0	7.0		
			Placebo	484	9	3.6	1.0	1.0	3.0	6.0	7.0		
		Dose 2	Non-Frail	HZ/su	1954	74	1.6	1.0	1.0	1.0	2.0	7.0	
				Placebo	2001	3	2.3	2.0	2.0	2.0	3.0	3.0	
			Pre-Frail	HZ/su	1929	53	1.6	1.0	1.0	1.0	2.0	4.0	
				Placebo	1919	2	1.0	1.0	1.0	1.0	1.0	1.0	
	Frail		HZ/su	465	18	1.2	1.0	1.0	1.0	1.0	3.0		
			Placebo	449	5	3.0	1.0	1.0	3.0	3.0	7.0		
	Overall/dose	Non-Frail	HZ/su	3986	114	1.6	1.0	1.0	1.0	2.0	7.0		
			Placebo	4067	8	2.0	1.0	1.0	2.0	3.0	3.0		
		Pre-Frail	HZ/su	3942	99	1.6	1.0	1.0	1.0	2.0	4.0		
			Placebo	3918	9	1.8	1.0	1.0	1.0	3.0	3.0		
		Frail	HZ/su	968	31	1.6	1.0	1.0	1.0	2.0	7.0		
			Placebo	933	14	3.4	1.0	1.0	3.0	6.0	7.0		
		Shivering	Dose 1	Non-Frail	HZ/su	2032	38	1.3	1.0	1.0	1.0	1.0	6.0
					Placebo	2066	1	1.0	1.0	1.0	1.0	1.0	1.0
	Pre-Frail			HZ/su	2013	22	1.5	1.0	1.0	1.0	2.0	3.0	
				Placebo	1999	3	1.3	1.0	1.0	1.0	2.0	2.0	
Frail	HZ/su			503	6	2.7	1.0	1.0	1.5	4.0	7.0		
Dose 2	Non-Frail		HZ/su	1954	74	1.3	1.0	1.0	1.0	1.0	4.0		
			Placebo	2001	3	2.0	1.0	1.0	2.0	3.0	3.0		
	Pre-Frail		HZ/su	1929	41	1.5	1.0	1.0	1.0	2.0	5.0		
			Placebo	1919	4	1.3	1.0	1.0	1.0	1.5	2.0		
	Frail		HZ/su	465	13	1.0	1.0	1.0	1.0	1.0	1.0		
			Placebo	449	2	2.0	1.0	1.0	2.0	3.0	3.0		
Overall/dose	Non-Frail	HZ/su	3986	112	1.3	1.0	1.0	1.0	1.0	6.0			
		Placebo	4067	4	1.8	1.0	1.0	1.5	2.5	3.0			
	Pre-Frail	HZ/su	3942	63	1.5	1.0	1.0	1.0	2.0	5.0			
		Placebo	3918	7	1.3	1.0	1.0	1.0	2.0	2.0			
	Frail	HZ/su	968	19	1.5	1.0	1.0	1.0	1.0	7.0			
		Placebo	933	2	2.0	1.0	1.0	2.0	3.0	3.0			
Temperature	Dose 1	Non-Frail	HZ/su	2032	2	1.0	1.0	1.0	1.0	1.0	1.0		
			Placebo	2066	1	1.0	1.0	1.0	1.0	1.0	1.0		
		Pre-Frail	HZ/su	2013	3	1.0	1.0	1.0	1.0	1.0	1.0		
			Placebo	1999	2	2.5	1.0	1.0	2.5	4.0	4.0		
		Frail	HZ/su	503	1	1.0	1.0	1.0	1.0	1.0	1.0		
		Dose 2	Non-Frail	HZ/su	1954	4	1.0	1.0	1.0	1.0	1.0	1.0	
				Placebo	2001	4	1.0	1.0	1.0	1.0	1.0	1.0	
	Pre-Frail		HZ/su	1929	2	1.0	1.0	1.0	1.0	1.0	1.0		
			Placebo	1919	2	1.0	1.0	1.0	1.0	1.0	1.0		
	Frail	HZ/su	465	1	1.0	1.0	1.0	1.0	1.0	1.0			
		Overall/dose	Non-Frail	HZ/su	3986	6	1.0	1.0	1.0	1.0	1.0	1.0	
				Placebo	4067	5	1.0	1.0	1.0	1.0	1.0	1.0	
	Pre-Frail		HZ/su	3942	5	1.0	1.0	1.0	1.0	1.0	1.0		
			Placebo	3918	4	1.8	1.0	1.0	1.0	2.5	4.0		
Frail	HZ/su		968	2	1.0	1.0	1.0	1.0	1.0	1.0			

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of administered doses

n = number of doses with the symptom

Q1 = 25th percentile

Q3 = 75th percentile

*Temperature is measured by oral, axillary, rectal or tympanic routes

Table 14.3.1.17 Number of days with general symptoms by frailty status (Total Vaccinated Cohort - Diary Card Subset)

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
Fatigue	Dose 1	Non-Frail	HZ/su	2032	650	2.4	1.0	1.0	2.0	3.0	32.0
			Placebo	2066	219	3.2	1.0	1.0	2.0	4.0	62.0
		Pre-Frail	HZ/su	2013	592	3.4	1.0	1.0	2.0	3.0	123.0
			Placebo	1999	237	3.4	1.0	1.0	2.0	4.0	50.0
		Frail	HZ/su	503	114	5.0	1.0	2.0	3.5	6.0	70.0
			Placebo	484	77	7.4	1.0	2.0	3.0	6.0	88.0
		Unknown	HZ/su	22	4	1.3	1.0	1.0	1.5	2.0	
			Placebo	22	4	8.8	1.0	3.5	6.0	14.0	22.0
	Dose 2	Non-Frail	HZ/su	1954	711	2.3	1.0	1.0	2.0	3.0	25.0
			Placebo	2001	147	2.8	1.0	1.0	2.0	3.0	45.0
		Pre-Frail	HZ/su	1929	597	3.2	1.0	1.0	2.0	3.0	66.0
			Placebo	1919	192	4.0	1.0	1.0	2.0	4.5	35.0
		Frail	HZ/su	465	120	5.4	1.0	1.0	3.0	6.0	95.0
			Placebo	449	46	4.3	1.0	2.0	3.0	6.0	15.0
		Unknown	HZ/su	20	2	1.5	1.0	1.0	1.5	2.0	2.0
			Placebo	17	1	30.0	30.0	30.0	30.0	30.0	30.0
	Overall/dose	Non-Frail	HZ/su	3986	1361	2.4	1.0	1.0	2.0	3.0	32.0
			Placebo	4067	366	3.0	1.0	1.0	2.0	3.0	62.0
		Pre-Frail	HZ/su	3942	1189	3.3	1.0	1.0	2.0	3.0	123.0
			Placebo	3918	429	3.7	1.0	1.0	2.0	4.0	50.0
		Frail	HZ/su	968	234	5.2	1.0	2.0	3.0	6.0	95.0
			Placebo	933	123	6.2	1.0	2.0	3.0	6.0	88.0
		Unknown	HZ/su	42	6	1.3	1.0	1.0	1.0	2.0	2.0
			Placebo	39	5	13.0	1.0	6.0	6.0	22.0	30.0
Gastrointestinal symptoms	Dose 1	Non-Frail	HZ/su	2032	219	2.3	1.0	1.0	1.0	3.0	18.0
			Placebo	2066	100	7.0	1.0	1.0	2.0	3.0	390.0
		Pre-Frail	HZ/su	2013	188	2.4	1.0	1.0	2.0	3.0	26.0
			Placebo	1999	117	3.3	1.0	1.0	2.0	4.0	66.0
		Frail	HZ/su	503	38	2.4	1.0	1.0	2.0	3.0	7.0
			Placebo	484	39	4.1	1.0	1.0	2.0	4.0	51.0
		Unknown	HZ/su	22	2	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	22	2	4.0	4.0	4.0	4.0	4.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	237	2.6	1.0	1.0	1.0	2.0	140.0
			Placebo	2001	75	2.9	1.0	1.0	2.0	3.0	44.0
		Pre-Frail	HZ/su	1929	201	3.5	1.0	1.0	2.0	3.0	66.0
			Placebo	1919	79	3.3	1.0	1.0	2.0	4.0	32.0
		Frail	HZ/su	465	44	2.8	1.0	1.0	2.0	4.0	10.0
			Placebo	449	29	2.9	1.0	1.0	2.0	4.0	7.0
	Overall/dose	Non-Frail	HZ/su	3986	456	2.5	1.0	1.0	1.0	3.0	140.0
			Placebo	4067	175	5.3	1.0	1.0	2.0	3.0	390.0
		Pre-Frail	HZ/su	3942	389	3.0	1.0	1.0	2.0	3.0	66.0
			Placebo	3918	196	3.3	1.0	1.0	2.0	4.0	66.0
		Frail	HZ/su	968	82	2.6	1.0	1.0	2.0	4.0	10.0
			Placebo	933	68	3.6	1.0	1.0	2.0	4.0	51.0
		Unknown	HZ/su	42	2	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	39	2	4.0	4.0	4.0	4.0	4.0	4.0
Headache	Dose 1	Non-Frail	HZ/su	2032	538	2.3	1.0	1.0	2.0	2.0	46.0
			Placebo	2066	215	2.3	1.0	1.0	1.0	2.0	62.0
		Pre-Frail	HZ/su	2013	435	2.8	1.0	1.0	2.0	3.0	121.0
			Placebo	1999	214	2.9	1.0	1.0	2.0	3.0	66.0
		Frail	HZ/su	503	96	3.7	1.0	1.0	2.0	4.0	43.0
			Placebo	484	70	3.6	1.0	1.0	2.0	5.0	55.0

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204878 (ZOSTER-064)

Report Final

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
		Unknown	HZ/su	22	5	1.2	1.0	1.0	1.0	1.0	2.0
			Placebo	22	2	2.5	1.0	1.0	2.5	4.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	627	2.0	1.0	1.0	2.0	2.0	11.0
			Placebo	2001	131	2.1	1.0	1.0	2.0	3.0	10.0
		Pre-Frail	HZ/su	1929	463	2.7	1.0	1.0	2.0	3.0	70.0
			Placebo	1919	160	3.1	1.0	1.0	2.0	3.0	32.0
		Frail	HZ/su	465	104	2.8	1.0	1.0	2.0	3.0	12.0
			Placebo	449	43	3.7	1.0	2.0	3.0	4.0	16.0
		Unknown	HZ/su	20	3	1.7	1.0	1.0	1.0	3.0	3.0
			Placebo	17	1	1.0	1.0	1.0	1.0	1.0	1.0
	Overall/dose	Non-Frail	HZ/su	3986	1165	2.1	1.0	1.0	2.0	2.0	46.0
			Placebo	4067	346	2.2	1.0	1.0	1.0	2.0	62.0
		Pre-Frail	HZ/su	3942	898	2.7	1.0	1.0	2.0	3.0	121.0
			Placebo	3918	374	3.0	1.0	1.0	2.0	3.0	66.0
		Frail	HZ/su	968	200	3.2	1.0	1.0	2.0	4.0	43.0
			Placebo	933	113	3.7	1.0	1.0	2.0	5.0	55.0
		Unknown	HZ/su	42	8	1.4	1.0	1.0	1.0	1.5	3.0
			Placebo	39	3	2.0	1.0	1.0	1.0	4.0	4.0
Myalgia	Dose 1	Non-Frail	HZ/su	2032	682	2.5	1.0	1.0	2.0	3.0	11.0
			Placebo	2066	149	3.3	1.0	1.0	2.0	3.0	57.0
		Pre-Frail	HZ/su	2013	591	2.9	1.0	2.0	2.0	4.0	32.0
			Placebo	1999	152	4.0	1.0	1.0	2.0	5.0	46.0
		Frail	HZ/su	503	113	3.9	1.0	2.0	3.0	5.0	50.0
			Placebo	484	57	4.8	1.0	2.0	3.0	6.0	54.0
		Unknown	HZ/su	22	4	2.8	1.0	1.0	2.5	4.5	5.0
			Placebo	22	2	4.5	4.0	4.0	4.5	5.0	5.0
	Dose 2	Non-Frail	HZ/su	1954	713	2.5	1.0	1.0	2.0	3.0	32.0
			Placebo	2001	109	3.8	1.0	2.0	2.0	5.0	47.0
		Pre-Frail	HZ/su	1929	587	3.0	1.0	1.0	2.0	4.0	36.0
			Placebo	1919	117	4.7	1.0	1.0	2.0	4.0	48.0
		Frail	HZ/su	465	119	3.4	1.0	2.0	3.0	4.0	37.0
			Placebo	449	38	3.9	1.0	2.0	4.0	6.0	8.0
		Unknown	HZ/su	20	3	2.3	1.0	1.0	3.0	3.0	3.0
			Placebo	39	2	4.5	4.0	4.0	4.5	5.0	5.0
	Overall/dose	Non-Frail	HZ/su	3986	1395	2.5	1.0	1.0	2.0	3.0	32.0
			Placebo	4067	258	3.5	1.0	1.0	2.0	4.0	57.0
		Pre-Frail	HZ/su	3942	1178	2.9	1.0	1.0	2.0	4.0	36.0
			Placebo	3918	269	4.3	1.0	1.0	2.0	4.0	48.0
		Frail	HZ/su	968	232	3.6	1.0	2.0	3.0	4.0	50.0
			Placebo	933	95	4.4	1.0	2.0	3.0	6.0	54.0
		Unknown	HZ/su	42	7	2.6	1.0	1.0	3.0	4.0	5.0
			Placebo	39	2	4.5	4.0	4.0	4.5	5.0	5.0
Shivering	Dose 1	Non-Frail	HZ/su	2032	317	1.8	1.0	1.0	1.0	2.0	47.0
			Placebo	2066	69	2.3	1.0	1.0	2.0	3.0	18.0
		Pre-Frail	HZ/su	2013	240	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	1999	75	2.1	1.0	1.0	2.0	3.0	8.0
		Frail	HZ/su	503	40	2.8	1.0	1.0	2.0	3.5	15.0
			Placebo	484	23	5.5	1.0	1.0	2.0	4.0	60.0
		Unknown	HZ/su	22	3	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	22	2	2.5	1.0	1.0	2.5	4.0	4.0
	Dose 2	Non-Frail	HZ/su	1954	500	1.6	1.0	1.0	1.0	2.0	41.0
			Placebo	2001	58	2.5	1.0	1.0	1.5	3.0	12.0
		Pre-Frail	HZ/su	1929	338	2.0	1.0	1.0	1.0	2.0	41.0
			Placebo	1919	47	2.5	1.0	1.0	2.0	3.0	15.0
		Frail	HZ/su	465	64	2.1	1.0	1.0	2.0	3.0	7.0
			Placebo	449	24	3.0	1.0	1.0	2.0	5.5	7.0

Solicited symptom	Dose	Sub-group	Group	N	n	Mean	Min	Q1	Median	Q3	Max
	Overall/dose	Unknown	Placebo	17	2	2.0	1.0	1.0	2.0	3.0	3.0
		Non-Frail	HZ/su	3986	817	1.7	1.0	1.0	1.0	2.0	47.0
			Placebo	4067	127	2.4	1.0	1.0	2.0	3.0	18.0
		Pre-Frail	HZ/su	3942	578	1.9	1.0	1.0	1.0	2.0	41.0
			Placebo	3918	122	2.3	1.0	1.0	2.0	3.0	15.0
		Frail	HZ/su	968	104	2.4	1.0	1.0	2.0	3.0	15.0
			Placebo	933	47	4.3	1.0	1.0	2.0	5.0	60.0
		Unknown	HZ/su	42	3	1.0	1.0	1.0	1.0	1.0	1.0
			Placebo	39	4	2.3	1.0	1.0	2.0	3.5	4.0
Temperature*	Dose 1	Non-Frail	HZ/su	2032	242	1.7	1.0	1.0	1.0	1.0	50.0
			Placebo	2066	24	2.2	1.0	1.0	1.0	3.0	7.0
		Pre-Frail	HZ/su	2013	210	1.6	1.0	1.0	1.0	2.0	7.0
			Placebo	1999	31	1.7	1.0	1.0	1.0	2.0	6.0
		Frail	HZ/su	503	33	2.1	1.0	1.0	1.0	2.0	7.0
			Placebo	484	10	1.6	1.0	1.0	1.0	2.0	4.0
		Unknown	HZ/su	22	1	1.0	1.0	1.0	1.0	1.0	1.0
	Dose 2	Non-Frail	HZ/su	1954	335	1.6	1.0	1.0	1.0	2.0	8.0
			Placebo	2001	31	3.4	1.0	1.0	1.0	3.0	38.0
		Pre-Frail	HZ/su	1929	230	2.0	1.0	1.0	1.0	2.0	30.0
			Placebo	1919	25	2.7	1.0	1.0	2.0	3.0	12.0
		Frail	HZ/su	465	48	1.8	1.0	1.0	1.0	2.0	7.0
			Placebo	449	11	2.9	1.0	1.0	2.0	5.0	7.0
	Overall/dose	Non-Frail	HZ/su	3986	577	1.6	1.0	1.0	1.0	2.0	50.0
			Placebo	4067	55	2.9	1.0	1.0	1.0	3.0	38.0
		Pre-Frail	HZ/su	3942	440	1.8	1.0	1.0	1.0	2.0	30.0
			Placebo	3918	56	2.1	1.0	1.0	1.5	2.0	12.0
		Frail	HZ/su	968	81	1.9	1.0	1.0	1.0	2.0	7.0
			Placebo	933	21	2.3	1.0	1.0	1.0	3.0	7.0
		Unknown	HZ/su	42	1	1.0	1.0	1.0	1.0	1.0	1.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of administered doses

n = number of doses with the symptom (during the solicited post-vaccination period and beyond)

Q1 = 25th percentile

Q3 = 75th percentile

*Temperature is measured by oral, axillary, rectal or tympanic routes

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**Table 14.3.1.18 Solicited general symptoms ongoing beyond the 7-day (Days 0-6) post-vaccination period by frailty status
(Total Vaccinated Cohort - Diary Card Subset)**

		Non-Frail												Pre-Frail												Frail												Unknown											
		HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo					
					Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)								
Symptoms	Type	N	Ns	n	q	media	q	N	Ns	n	q	media	q	N	Ns	n	q	media	q	N	Ns	n	q	media	q	N	Ns	n	q	media	q	N	Ns	n	q	media	q	N	Ns	n	q	media	q						
Dose 1																																																	
Fatigue	Any	2001	650	15	23	4	2032	219	13	23	9	1963	592	24	7.5	40	1960	237	21	2.5	7.5	480	114	14	4	4	9	461	77	15	36	36	20	40	-	-	-	18	42	15	15	15							
	Grade 3	2001	43	32	34	4	2032	91	88	8	1963	46	41	1.5	6.5	1960	127	71	3	7	480	145	34	4	4	34	461	52	318.5	34	20	00	-	-	-	18	00	-	-	-									
Gastrointestinal symptoms	Any	2001	219	92	34	4	2032	109	25	28	1963	188	81	4	12	1960	117	11	2	6	480	381	22	2	2	2	461	39	53	5	48	20	20	-	-	-	18	20	-	-	-								
	Grade 3	2001	13	42	3.5	8	2032	40	-	-	-	1963	14	0	-	-	1960	71	66	6	6	480	40	-	-	-	461	10	-	-	-	20	00	-	-	-	18	00	-	-	-								
Headache	Any	2001	538	165	14	65	2032	215	81	2.5	4.5	1963	435	13	7	25	1960	214	14	7	7	480	967	27	7	34	461	70	13	3	25	00	-	-	-	18	20	-	-	-									
	Grade 3	2001	33	23	3.5	4	2032	50	-	-	-	1963	23	17	7	7	1960	83	77.5	8	8	480	62	47	10	461	72	124.5	48	20	00	-	-	-	18	00	-	-	-										
Myalgia	Any	2001	682	83	44	4	2032	149	35	4	16	1963	591	12	4	7.5	1960	152	11	3	6	480	113	71	4	8	461	57	11	3	5	24	00	-	-	-	18	20	-	-	-								
	Grade 3	2001	40	33	34	4	2032	50	-	-	-	1963	46	55	5	5	1960	73	113	38	38	480	132	423.5	43	461	95	12	25.5	25	20	00	-	-	-	18	00	-	-	-									
Shivering	Any	2001	317	42	3.5	24	2032	69	61	24	1963	240	12	22	2	1960	75	41	1	1.5	480	402	46	8	8	461	23	21	27.5	54	23	00	-	-	-	18	20	-	-	-									
	Grade 3	2001	38	11	11	1	2032	10	-	-	-	1963	22	0	-	-	1960	30	-	-	-	480	61	44	4	4	461	00	-	-	-	20	00	-	-	-	18	00	-	-	-								
Temperature	Any	2001	242	31	349	2032	24	21	1.5	2	1963	210	0	-	-	-	1960	31	11	1	1	480	331	-	-	-	461	10	0	-	-	21	00	-	-	-	18	00	-	-	-								
	Grade 3	2001	2	0	-	-	-	2032	10	-	-	-	1963	3	0	-	-	1960	20	-	-	-	480	10	-	-	-	461	00	-	-	-	20	00	-	-	-	18	00	-	-	-							
Dose 2																																																	
Fatigue	Any	1942	711	14	35	7	1988	147	72	2.5	4	1906	597	23	5	20	1895	192	28	17	456	120	14	17	32	443	46	10	46	7.5	18	20	00	-	-	-	15	11	12	23	23								
	Grade 3	1942	79	26	6.5	7	1988	61	44	4	1906	54	73	6	6	1895	52	-	-	-	456	132	44	4	4	443	31	88	8	10	00	00	-	-	-	15	00	-	-	-									

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		Non-Frail												Pre-Frail												Frail												Unknown											
		HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo					
					Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)								
Symptoms	Type	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3	N	Ns	n	q1	median	q3						
Gastrointestinal symptoms	Any	1942	237	7	1	2	5	1988	75	6	3	4	8	1906	2016	1	3	5	25	1895	79	7	2	3.5	8	456	44	3	1	4	5	443	29	3	5	5	5	18	0	0	-	-	-	15	0	0	-	-	-
	Grade 3	1942	13	0	-	-	-	1988	8	1	1	1	1	1906	17	4	4	5	32.5	1895	1	0	-	-	-	456	2	0	-	-	-	443	5	1	-	-	-	18	0	0	-	-	-	15	0	0	-	-	-
Headache	Any	1942	627	6	2	2.5	5	1988	13	4	1	1	4	1906	463	1	1	4.5	14	1895	16	1	2	3	8	456	10	7	2	2.5	4	443	43	6	3	3.5	6.5	13	0	-	-	-	15	1	0	-	-	-	
	Grade 3	1942	48	0	-	-	-	1988	3	1	4	4	4	1906	37	6	3	11	34	1895	6	1	1	1	1	456	12	0	-	-	-	443	4	0	-	-	-	18	0	0	-	-	-	15	0	0	-	-	-
Myalgia	Any	1942	713	1	2	5	7	1988	10	1	1	3	6	1906	587	2	2	4	13	1895	11	1	3	7.5	24	456	11	3	10	21	32	443	38	6	2	2	2	13	0	-	-	-	15	0	0	-	-	-	
	Grade 3	1942	74	5	4	6.5	19	1988	3	1	4	4	4	1906	53	5	2	3	4	1895	2	0	-	-	-	456	18	0	-	-	-	443	5	3	2	2	2	18	0	0	-	-	-	15	0	0	-	-	-
Shivering	Any	1942	500	3	2	18	34	1988	58	2	4	4.5	5	1906	338	6	4	14	29	1895	47	3	2	5	8	456	64	1	2	2	2	443	24	2	1	1	1	18	0	0	-	-	-	15	2	0	-	-	-
	Grade 3	1942	74	0	-	-	-	1988	3	1	4	4	4	1906	41	2	4	19	34	1895	4	1	2	2	2	456	13	0	-	-	-	443	2	1	1	1	1	18	0	0	-	-	-	15	0	0	-	-	-
Temperature	Any	1942	335	3	1	2	2	1988	31	2	4	17.5	31	1906	230	4	1	5	18	1895	25	2	3	5.5	8	456	48	1	-	-	-	443	11	1	1	1	1	18	0	0	-	-	-	15	0	0	-	-	-
	Grade 3	1942	4	0	-	-	-	1988	4	0	-	-	-	1906	2	0	-	-	-	1895	2	0	-	-	-	456	1	0	-	-	-	443	0	0	-	-	-	18	0	0	-	-	-	15	0	0	-	-	-
Overall/dose																																																	
Fatigue	Any	3943	136	2	2	3	6	4020	36	2	2	3	9	3869	118	5	2	5.5	27	3855	42	4	1	6	12	93	23	2	4	6	30	90	12	2	3	6	34	3	6	0	-	-	-	33	5	3	1	19	2
	Grade 3	3943	122	5	3	4	6	4020	15	2	4	6	8	3869	100	1	1	2	6	3855	17	9	1	3	7	93	27	7	4	4	4	90	8	3	3	8	34	3	0	0	-	-	-	33	0	0	-	-	-
Gastrointestinal symptoms	Any	3943	456	1	1	2.5	4	4020	17	1	3	4	8	3869	389	2	3	4.5	19	3855	19	1	1	2	7	93	82	4	1	3	4	90	68	8	4	5	26	3	2	0	-	-	-	33	2	0	-	-	-
	Grade 3	3943	26	4	2	3.5	8	4020	12	1	1	1	1	3869	31	4	4	5	32.5	3855	8	1	6	6	6	93	6	0	-	-	-	90	6	1	-	-	-	38	0	0	-	-	-	33	0	0	-	-	-
Headache	Any	3943	116	2	2	3.5	6	4020	34	1	1	2	4	3869	898	3	2	5	16	3855	37	3	1	3.5	8	93	20	1	2	3.5	8	90	11	1	1	3	4	3	8	0	-	-	-	33	3	0	-	-	-
	Grade 3	3943	81	2	3	3.5	4	4020	8	1	4	4	4	3869	60	7	3	7	34	3855	14	4	1	7	8	93	18	2	4	7	10	90	11	2	1	24.5	48	3	0	0	-	-	-	33	0	0	-	-	-
Myalgia	Any	3943	139	2	3	4	6	4020	25	2	2	4	11	3869	117	4	2	4	9	3855	26	3	1	4	19	93	23	1	1	8	32	90	95	1	1	2.5	5	3	7	0	-	-	-	33	2	0	-	-	-
	Grade 3	3943	114	8	3	4	7	4020	8	1	4	4	4	3869	99	1	2	4	5	3855	9	3	1	13	38	93	31	2	4	23.5	43	90	14	8	1	2	3	3	0	0	-	-	-	33	0	0	-	-	-

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		Non-Frail												Pre-Frail												Frail												Unknown											
		HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo						HZ/su						Placebo					
					Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)						Time to resolution (days)								
Symptoms	Type	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3	N	Ns	n	q1	media	q3						
Shivering	Any	3943	817	7	2	3.5	34	4020	127	8	1.5	3	4.5	3869	578	7	2	4	29	3855	122	7	1	1.5	2	936	104	3	2	4	8	904	47	4	1	1	54	38	30	-	-	33	40	-	-				
	Grade 3	3943	112	1	1	1	1	4020	4	1	4	4	4	3869	63	2	4	19	34	3855	7	1	2	2	2	936	19	1	4	4	4	904	2	1	1	1	1	38	30	0	-	-	33	0	0	-	-		
Temperature	Any	3943	577	6	1	2	3	4020	55	4	1.5	3	17.5	3869	440	4	1.5	5	18	3855	56	3	1	3	8	936	81	2	-	-	-	904	21	1	1	1	1	38	30	0	-	-	33	0	0	-	-		
	Grade 3	3943	6	0	-	-	-	4020	5	0	-	-	-	3869	5	0	-	-	-	3855	4	0	-	-	-	936	2	0	-	-	-	904	0	0	-	-	-	38	30	0	-	-	33	0	0	-	-		

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

N = number of documented doses

Ns = total number of reports for a given symptom

n = number of symptoms that were ongoing after the follow-up period

Time to resolution : number of days beyond the end of the follow-up period

Q1 = 25th percentile

Q3 = 75th percentile

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Table 14.3.1.19 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Non-Frail								Pre-Frail								Frail								Unknown							
	HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
	95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom	2984	51.6	50.3	52.9	1696	29.6	28.4	30.8	3019	49.7	48.5	51.0	2034	32.7	31.5	33.9	754	47.9	45.4	50.4	520	35.5	33.1	38.0	23	39.0	26.5	52.6	22	30.6	20.2	42.5
Blood and lymphatic system disorders (10005329)	22	0.4	0.2	0.6	5	0.1	0.0	0.2	13	0.2	0.1	0.4	10	0.2	0.1	0.3	5	0.3	0.1	0.7	12	0.8	0.4	1.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	24	0.4	0.3	0.6	29	0.5	0.3	0.7	49	0.8	0.6	1.1	52	0.8	0.6	1.1	26	1.7	1.1	2.4	30	2.0	1.4	2.9	2	3.4	0.4	11.7	1	1.4	0.0	7.5
Congenital, familial and genetic disorders (10010331)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	36	0.6	0.4	0.9	26	0.5	0.3	0.7	43	0.7	0.5	1.0	42	0.7	0.5	0.9	14	0.9	0.5	1.5	13	0.9	0.5	1.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Endocrine disorders (10014698)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	9	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	42	0.7	0.5	1.0	46	0.8	0.6	1.1	60	1.0	0.8	1.3	66	1.1	0.8	1.3	22	1.4	0.9	2.1	15	1.0	0.6	1.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Gastrointestinal disorders (10017947)	318	5.5	4.9	6.1	218	3.8	3.3	4.3	310	5.1	4.6	5.7	275	4.4	3.9	5.0	91	5.8	4.7	7.1	79	5.4	4.3	6.7	4	6.8	1.9	16.5	2	2.8	0.3	9.7
General disorders and administration site conditions (10018065)	2118	36.6	35.4	37.9	298	5.2	4.6	5.8	1882	31.0	29.8	32.2	362	5.8	5.3	6.4	439	27.9	25.7	30.2	84	5.7	4.6	7.1	14	23.7	13.6	36.6	7	9.7	4.0	19.0
Hepatobiliary disorders (10019805)	7	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	16	0.3	0.1	0.4	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	12	0.2	0.1	0.4	14	0.2	0.1	0.4	14	0.2	0.1	0.4	15	0.2	0.1	0.4	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	642	11.1	10.3	11.9	653	11.4	10.6	12.2	685	11.3	10.5	12.1	686	11.0	10.3	11.8	183	11.6	10.1	13.3	171	11.7	10.1	13.4	4	6.8	1.9	16.5	6	8.3	3.1	17.3
Injury, poisoning and procedural complications (10022117)	76	1.3	1.0	1.6	98	1.7	1.4	2.1	112	1.8	1.5	2.2	126	2.0	1.7	2.4	41	2.6	1.9	3.5	28	1.9	1.3	2.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
Investigations (10022891)	67	1.2	0.9	1.5	13	0.2	0.1	0.4	66	1.1	0.8	1.4	13	0.2	0.1	0.4	12	0.8	0.4	1.3	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Metabolism and nutrition disorders (10027433)	35	0.6	0.4	0.8	24	0.4	0.3	0.6	82	1.4	1.1	1.7	50	0.8	0.6	1.1	26	1.7	1.1	2.4	20	1.4	0.8	2.1	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Musculoskeletal and connective tissue disorders (10028395)	577	10.0	9.2	10.8	305	5.3	4.8	5.9	548	9.0	8.3	9.8	411	6.6	6.0	7.3	145	9.2	7.8	10.8	105	7.2	5.9	8.6	4	6.8	1.9	16.5	7	9.7	4.0	19.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	23	0.4	0.3	0.6	20	0.3	0.2	0.5	43	0.7	0.5	1.0	37	0.6	0.4	0.8	4	0.3	0.1	0.6	11	0.8	0.4	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Nervous system disorders (10029205)	609	10.5	9.7	11.3	290	5.1	4.5	5.7	495	8.2	7.5	8.9	316	5.1	4.5	5.7	106	6.7	5.5	8.1	75	5.1	4.1	6.4	3	5.1	1.1	14.1	3	4.2	0.9	11.7
Psychiatric disorders (10037175)	66	1.1	0.9	1.4	32	0.6	0.4	0.8	69	1.1	0.9	1.4	48	0.8	0.6	1.0	25	1.6	1.0	2.3	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Renal and urinary disorders (10038359)	24	0.4	0.3	0.6	8	0.1	0.1	0.3	27	0.4	0.3	0.6	22	0.4	0.2	0.5	16	1.0	0.6	1.6	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Reproductive system and breast disorders (10038604)	19	0.3	0.2	0.5	23	0.4	0.3	0.6	26	0.4	0.3	0.6	26	0.4	0.3	0.6	5	0.3	0.1	0.7	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Respiratory, thoracic and mediastinal disorders (10038738)	200	3.5	3.0	4.0	167	2.9	2.5	3.4	200	3.3	2.9	3.8	225	3.6	3.2	4.1	53	3.4	2.5	4.4	63	4.3	3.3	5.5	2	3.4	0.4	11.7	2	2.8	0.3	9.7
Skin and subcutaneous tissue disorders (10040785)	198	3.4	3.0	3.9	173	3.0	2.6	3.5	222	3.7	3.2	4.2	230	3.7	3.2	4.2	72	4.6	3.6	5.7	50	3.4	2.5	4.5	2	3.4	0.4	11.7	4	5.6	1.5	13.6
Social circumstances (10041244)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	3	0.1	0.0	0.2	8	0.1	0.1	0.3	4	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	47	0.8	0.6	1.1	45	0.8	0.6	1.0	86	1.4	1.1	1.7	78	1.3	1.0	1.6	22	1.4	0.9	2.1	36	2.5	1.7	3.4	1	1.7	0.0	9.1	3	4.2	0.9	11.7

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

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Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Primary System Organ Class)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

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Table 14.3.1.20 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	At least one symptom	2984	51.6	50.3	52.9	1696	29.6	28.4	30.8	3019	49.7	48.5	51.0	2034	32.7	31.5	33.9	754	47.9	45.4	50.4	520	35.5	33.1	38.0	23	39.0	26.5	52.6	22	30.6	20.2	42.5
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	22	0.4	0.2	0.6	5	0.1	0.0	0.2	13	0.2	0.1	0.4	10	0.2	0.1	0.3	5	0.3	0.1	0.7	12	0.8	0.4	1.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia (1002034)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhagic diathesis (10062713)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersplenism (10020769)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iron deficiency anaemia (10022972)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Leukopenia (10024384)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymph node pain (10025182)	6	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenitis (10025188)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenopathy (10025197)	9	0.2	0.1	0.3	2	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macrocytosis (10025382)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Normochromic normocytic anaemia (10029783)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytopenia (10043554)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytosis (10043563)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	24	0.4	0.3	0.6	29	0.5	0.3	0.7	49	0.8	0.6	1.1	52	0.8	0.6	1.1	26	1.7	1.1	2.4	30	2.0	1.4	2.9	2	3.4	0.4	11.7	1	1.4	0.0	7.5
	Acute coronary syndrome (10051592)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute myocardial infarction (10000891)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina pectoris (10002383)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina unstable (10002388)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve incompetence (10002915)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve stenosis (10002918)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arrhythmia (10003119)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	9	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arrhythmia supraventricular (10003130)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Atrial fibrillation (10003658)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrial flutter (10003662)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block (10003671)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block complete (10003673)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block first degree (10003674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bradycardia (10006093)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac discomfort (10054211)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac disorder (10061024)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Cardiac failure (10007554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure acute (10007556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure chronic (10007558)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure congestive (10007559)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac flutter (10052840)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac valve disease (10061406)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiovascular disorder (10007649)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Congestive cardiomyopathy (10056370)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cor pulmonale (10010968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery disease (10011078)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery occlusion (10011086)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Extrasystoles (10015856)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertensive heart disease (10020823)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve disease (10061532)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve incompetence (10027727)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Myocardial infarction (10028596)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocardial ischaemia (10028600)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocarditis (10028606)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Palpitations (10033557)	6	0.1	0.0	0.2	5	0.1	0.0	0.2	11	0.2	0.1	0.3	7	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Right ventricular failure (10039163)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus bradycardia (10040741)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus node dysfunction (10075889)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Supraventricular extrasystoles (10042602)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Supraventricular tachycardia (10042604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachyarrhythmia (10049447)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia (10043071)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia paroxysmal (10043079)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular extrasystoles (10047289)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Congenital, familial and genetic disorders (10010331)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malformation venous (10025532)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	36	0.6	0.4	0.9	26	0.5	0.3	0.7	43	0.7	0.5	1.0	42	0.7	0.5	0.9	14	0.9	0.5	1.5	13	0.9	0.5	1.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerumen impaction (10050337)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness neurosensory (10011891)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear discomfort (10052137)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear disorder (10014004)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear pain (10014020)	15	0.3	0.1	0.4	7	0.1	0.0	0.3	6	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eustachian tube disorder (10061462)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoacusis (10048865)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniere's disease (10027183)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Middle ear effusion (10062545)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Motion sickness (10027990)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Otorrhoea (10033101)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sudden hearing loss (10061373)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinnitus (10043882)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo (10047340)	14	0.2	0.1	0.4	7	0.1	0.0	0.3	23	0.4	0.2	0.6	21	0.3	0.2	0.5	6	0.4	0.1	0.8	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo positional (10047348)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Endocrine disorders (10014698)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	9	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Androgen deficiency (10002261)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Autoimmune thyroiditis (10049046)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basedow's disease (10004161)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Goitre (10018498)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperparathyroidism (10020705)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperthyroidism (10020850)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypogonadism (10058359)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypopituitarism (10021067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypothyroidism (10021114)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	At least one PT related to the corresponding SOC	42	0.7	0.5	1.0	46	0.8	0.6	1.1	60	1.0	0.8	1.3	66	1.1	0.8	1.3	22	1.4	0.9	2.1	15	1.0	0.6	1.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Abnormal sensation in eye (10000173)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenopia (10003552)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blepharitis (10005148)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blepharospasm (10005159)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract (10007739)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	6	0.1	0.0	0.2	13	0.2	0.1	0.4	7	0.4	0.2	0.9	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chalazion (10008388)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chorioretinal atrophy (10008762)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chorioretinopathy (10063118)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chromatopsia (10008795)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival degeneration (10010705)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival haemorrhage (10010719)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival hyperaemia (10051625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Corneal erosion (10011013)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dark circles under eyes (10064729)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic retinopathy (10012689)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diplopia (10013036)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry eye (10013774)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	8	0.1	0.1	0.3	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema eyelids (10014194)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enophthalmos (10014853)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema of eyelid (10015237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye allergy (10015907)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye discharge (10015915)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye disorder (10015916)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye haemorrhage (10015926)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye inflammation (10015943)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye irritation (10015946)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye pain (10015958)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	8	0.1	0.1	0.3	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye pruritus (10052140)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye swelling (10015967)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid function disorder (10061145)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid oedema (10015993)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Eyelid ptosis (10015995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid rash (10074620)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelids pruritus (10051627)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foreign body sensation in eyes (10051116)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glaucoma (10018304)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Keratitis (10023332)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacrimation decreased (10023642)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacrimation increased (10023644)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular degeneration (10025409)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular fibrosis (10071392)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Maculopathy (10025425)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Narrow anterior chamber angle (10068960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neovascular age-related macular degeneration (10071129)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular discomfort (10052143)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular hyperaemia (10030041)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular hypertension (10030043)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ophthalmic vein thrombosis (10074349)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Optic ischaemic neuropathy (10030924)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Panophthalmitis (10033683)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periorbital oedema (10034545)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photopsia (10034962)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Posterior capsule opacification (10036346)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal degeneration (10038845)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal detachment (10038848)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinopathy hypertensive (10038926)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trichiasis (10044604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulcerative keratitis (10064996)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uveitis (10046851)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vision blurred (10047513)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visual acuity reduced (10047531)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visual impairment (10047571)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous detachment (10047650)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous floaters (10047654)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	318	5.5	4.9	6.1	218	3.8	3.3	4.3	310	5.1	4.6	5.7	275	4.4	3.9	5.0	91	5.8	4.7	7.1	79	5.4	4.3	6.7	4	6.8	1.9	16.5	2	2.8	0.3	9.7
	Abdominal discomfort (10000059)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal distension (10000060)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	7	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Abdominal hernia (10060954)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain (10000081)	17	0.3	0.2	0.5	12	0.2	0.1	0.4	15	0.2	0.1	0.4	14	0.2	0.1	0.4	4	0.3	0.1	0.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain lower (10000084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain upper (10000087)	23	0.4	0.3	0.6	28	0.5	0.3	0.7	23	0.4	0.2	0.6	32	0.5	0.4	0.7	6	0.4	0.1	0.8	5	0.3	0.1	0.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Abnormal faeces (10000133)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acid peptic disease (10075494)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aerophagia (10052813)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal fissure (10002153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal haemorrhage (10049555)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal inflammation (10050247)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal pruritus (10068172)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphthous stomatitis (10002958)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aptyalism (10003068)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Change of bowel habit (10008399)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chapped lips (10049047)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cheilitis (10008417)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic gastritis (10008882)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coeliac disease (10009839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis (10009887)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Constipation (10010774)	10	0.2	0.1	0.3	12	0.2	0.1	0.4	18	0.3	0.2	0.5	13	0.2	0.1	0.4	6	0.4	0.1	0.8	7	0.5	0.2	1.0	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Crohn's disease (10011401)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental caries (10012318)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental necrosis (10012327)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diarrhoea (10012735)	56	1.0	0.7	1.3	41	0.7	0.5	1.0	50	0.8	0.6	1.1	53	0.9	0.6	1.1	18	1.1	0.7	1.8	13	0.9	0.5	1.5	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Diverticulum (10013554)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum intestinal (10013559)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry mouth (10013781)	6	0.1	0.0	0.2	1	0.0	0.0	0.1	8	0.1	0.1	0.3	10	0.2	0.1	0.3	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer (10013836)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspepsia (10013946)	14	0.2	0.1	0.4	11	0.2	0.1	0.3	15	0.2	0.1	0.4	16	0.3	0.1	0.4	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphagia (10013950)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enteritis (10014866)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Enterovesical fistula (10062570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epigastric discomfort (10053155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eructation (10015137)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faeces discoloured (10016100)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flatulence (10016766)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Food poisoning (10016952)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Functional gastrointestinal disorder (10071275)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric disorder (10056819)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric ulcer (10017822)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis (10017853)	9	0.2	0.1	0.3	6	0.1	0.0	0.2	15	0.2	0.1	0.4	12	0.2	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis erosive (10017865)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroduodenitis (10048714)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal angiodysplasia (10017928)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal disorder (10017944)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal haemorrhage (10017955)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal pain (10017999)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal sounds abnormal (10067715)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrooesophageal reflux disease (10017885)	7	0.1	0.0	0.2	8	0.1	0.1	0.3	11	0.2	0.1	0.3	10	0.2	0.1	0.3	2	0.1	0.0	0.5	3	0.2	0.0	0.6	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Gastrooesophageal sphincter insufficiency (10062879)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival bleeding (10018276)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival pain (10018286)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival swelling (10018291)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossitis (10018386)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossodynia (10018388)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematochezia (10018836)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoidal haemorrhage (10054787)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoids (10019022)	3	0.1	0.0	0.2	9	0.2	0.1	0.3	11	0.2	0.1	0.3	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hiatus hernia (10020028)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hyperchlorhydria (10020601)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoaesthesia oral (10057371)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ileus (10021328)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infrequent bowel movements (10059158)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inguinal hernia (10022016)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal cyst (10062023)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal perforation (10022694)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal polyp (10048616)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Irritable bowel syndrome (10023003)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine polyp (10051589)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip blister (10049307)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip disorder (10048470)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip dry (10024552)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip pain (10024561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip swelling (10024570)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip ulceration (10024572)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Loose tooth (10065612)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Melanosis coli (10027158)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth haemorrhage (10028024)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth swelling (10075203)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth ulceration (10028034)	7	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.2	0.0	0.6	4	0.3	0.1	0.7	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Nausea (10028813)	92	1.6	1.3	1.9	28	0.5	0.3	0.7	71	1.2	0.9	1.5	32	0.5	0.4	0.7	18	1.1	0.7	1.8	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Noninfective gingivitis (10074863)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Odynophagia (10030094)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal discomfort (10053634)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal spasm (10030184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophagitis (10030216)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral disorder (10067621)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral mucosal blistering (10030995)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Oral pain (10031009)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Pancreatic steatosis (10072787)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis (10033645)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis acute (10033647)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraesthesia oral (10057372)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peptic ulcer (10034341)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periodontal disease (10034536)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal polyp (10038074)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal prolapse (10038077)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retching (10038776)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retroperitoneal haemorrhage (10038980)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland calculus (10039394)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland cyst (10052248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary hypersecretion (10039424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sensitivity of teeth (10040012)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stomatitis (10042128)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Swollen tongue (10042727)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue blistering (10043942)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue coated (10043945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue disorder (10043951)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue pruritus (10070072)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue ulceration (10043991)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth deposit (10044029)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth disorder (10044034)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth erosion (10044038)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth impacted (10044042)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toothache (10044055)	22	0.4	0.2	0.6	25	0.4	0.3	0.6	13	0.2	0.1	0.4	21	0.3	0.2	0.5	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Umbilical hernia (10045458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper gastrointestinal haemorrhage (10046274)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vomiting (10047700)	26	0.4	0.3	0.7	10	0.2	0.1	0.3	19	0.3	0.2	0.5	17	0.3	0.2	0.4	9	0.6	0.3	1.1	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	2118	36.6	35.4	37.9	298	5.2	4.6	5.8	1882	31.0	29.8	32.2	362	5.8	5.3	6.4	439	27.9	25.7	30.2	84	5.7	4.6	7.1	14	23.7	13.6	36.6	7	9.7	4.0	19.0
	Administration site erythema (10074796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site pain (10058049)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site reaction (10001315)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adverse drug reaction (10061623)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenia (10003549)	38	0.7	0.5	0.9	6	0.1	0.0	0.2	26	0.4	0.3	0.6	13	0.2	0.1	0.4	8	0.5	0.2	1.0	3	0.2	0.0	0.6	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Axillary pain (10048750)	6	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest discomfort (10008469)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest pain (10008479)	10	0.2	0.1	0.3	10	0.2	0.1	0.3	19	0.3	0.2	0.5	10	0.2	0.1	0.3	3	0.2	0.0	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chills (10008531)	253	4.4	3.9	4.9	16	0.3	0.2	0.5	189	3.1	2.7	3.6	14	0.2	0.1	0.4	36	2.3	1.6	3.2	2	0.1	0.0	0.5	3	5.1	1.1	14.1	0	0.0	0.0	5.0
	Cyst (10011732)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device breakage (10012575)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Discomfort (10013082)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Face oedema (10016029)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial pain (10016059)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatigue (10016256)	252	4.4	3.8	4.9	47	0.8	0.6	1.1	182	3.0	2.6	3.5	75	1.2	0.9	1.5	34	2.2	1.5	3.0	8	0.5	0.2	1.1	2	3.4	0.4	11.7	1	1.4	0.0	7.5
	Feeling abnormal (10016322)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling cold (10016326)	28	0.5	0.3	0.7	4	0.1	0.0	0.2	20	0.3	0.2	0.5	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling hot (10016334)	27	0.5	0.3	0.7	2	0.0	0.0	0.1	16	0.3	0.2	0.4	7	0.1	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling jittery (10016338)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling of body temperature change (10061458)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gait disturbance (10017577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	General physical health deterioration (10049438)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ill-defined disorder (10061520)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Implant site hypersensitivity (10063858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Induration (10060708)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inflammation (10061218)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza like illness (10022004)	61	1.1	0.8	1.4	21	0.4	0.2	0.6	39	0.6	0.5	0.9	18	0.3	0.2	0.5	8	0.5	0.2	1.0	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site atrophy (10022048)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site bruising (10022052)	16	0.3	0.2	0.4	16	0.3	0.2	0.5	16	0.3	0.2	0.4	13	0.2	0.1	0.4	2	0.1	0.0	0.5	3	0.2	0.0	0.6	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Injection site coldness (10050082)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site discolouration (10051572)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site discomfort (10054266)	10	0.2	0.1	0.3	2	0.0	0.0	0.1	9	0.1	0.1	0.3	1	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site eczema (10066221)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site erythema (10022061)	607	10.5	9.7	11.3	14	0.2	0.1	0.4	535	8.8	8.1	9.6	22	0.4	0.2	0.5	115	7.3	6.1	8.7	1	0.1	0.0	0.4	4	6.8	1.9	16.5	0	0.0	0.0	5.0
	Injection site haematoma (10022066)	9	0.2	0.1	0.3	5	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site haemorrhage (10022067)	5	0.1	0.0	0.2	6	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hyperaesthesia (10073418)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypersensitivity (10022071)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypoaesthesia (10074586)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site induration (10022075)	21	0.4	0.2	0.6	2	0.0	0.0	0.1	25	0.4	0.3	0.6	2	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site inflammation (10022078)	19	0.3	0.2	0.5	0	0.0	0.0	0.1	21	0.3	0.2	0.5	1	0.0	0.0	0.1	9	0.6	0.3	1.1	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site injury (10066083)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site irritation (10022079)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site joint pain (10049261)	21	0.4	0.2	0.6	1	0.0	0.0	0.1	22	0.4	0.2	0.5	3	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site lymphadenopathy (10057665)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site macule (10067255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site mass (10022081)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site movement impairment (10056250)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site nodule (10057880)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site oedema (10022085)	12	0.2	0.1	0.4	0	0.0	0.0	0.1	20	0.3	0.2	0.5	0	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pain (10022086)	1454	25.1	24.0	26.3	94	1.6	1.3	2.0	1334	22.0	20.9	23.0	109	1.8	1.4	2.1	298	18.9	17.0	21.0	29	2.0	1.3	2.8	8	13.6	6.0	25.0	3	4.2	0.9	11.7
	Injection site papule (10066044)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site paraesthesia (10022088)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pruritus (10022093)	144	2.5	2.1	2.9	11	0.2	0.1	0.3	115	1.9	1.6	2.3	16	0.3	0.1	0.4	36	2.3	1.6	3.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site rash (10022094)	30	0.5	0.4	0.7	1	0.0	0.0	0.1	22	0.4	0.2	0.5	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site reaction (10022095)	27	0.5	0.3	0.7	4	0.1	0.0	0.2	27	0.4	0.3	0.6	7	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Injection site swelling (10053425)	455	7.9	7.2	8.6	8	0.1	0.1	0.3	390	6.4	5.8	7.1	8	0.1	0.1	0.3	88	5.6	4.5	6.8	4	0.3	0.1	0.7	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Injection site ulcer (10022105)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site urticaria (10022107)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site vesicles (10022111)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site warmth (10022112)	63	1.1	0.8	1.4	0	0.0	0.0	0.1	66	1.1	0.8	1.4	4	0.1	0.0	0.2	12	0.8	0.4	1.3	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Injury associated with device (10069803)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Local swelling (10024770)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malaise (10025482)	113	2.0	1.6	2.3	19	0.3	0.2	0.5	87	1.4	1.1	1.8	16	0.3	0.1	0.4	20	1.3	0.8	2.0	3	0.2	0.0	0.6	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Metaplasia (10054949)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mucous membrane disorder (10028133)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nodule (10054107)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-cardiac chest pain (10062501)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema (10030095)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema peripheral (10030124)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.2	0.0	0.6	7	0.5	0.2	1.0	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pain (10033371)	98	1.7	1.4	2.1	10	0.2	0.1	0.3	71	1.2	0.9	1.5	17	0.3	0.2	0.4	18	1.1	0.7	1.8	4	0.3	0.1	0.7	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Peripheral swelling (10048959)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	6	0.1	0.0	0.2	5	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyp (10061529)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyrexia (10037660)	561	9.7	8.9	10.5	33	0.6	0.4	0.8	341	5.6	5.1	6.2	29	0.5	0.3	0.7	58	3.7	2.8	4.7	5	0.3	0.1	0.8	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Reactogenicity event (10065109)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sluggishness (10041052)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Swelling (10042674)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temperature intolerance (10057040)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tenderness (10043224)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thirst (10043458)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulcer haemorrhage (10061577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site coldness (10076157)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site discolouration (10069474)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site erythema (10059079)	12	0.2	0.1	0.4	0	0.0	0.0	0.1	19	0.3	0.2	0.5	2	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site haematoma (10069472)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site inflammation (10068878)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site irritation (10069479)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site pain (10068879)	30	0.5	0.4	0.7	0	0.0	0.0	0.1	25	0.4	0.3	0.6	5	0.1	0.0	0.2	5	0.3	0.1	0.7	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Vaccination site pruritus (10068881)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site reaction (10059080)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	8	0.1	0.1	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site swelling (10069620)	8	0.1	0.1	0.3	0	0.0	0.0	0.1	9	0.1	0.1	0.3	1	0.0	0.0	0.1	4	0.3	0.1	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site warmth (10069624)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vessel puncture site erythema (10074760)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vessel puncture site pain (10066951)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	7	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	16	0.3	0.1	0.4	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct stenosis (10051341)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct stone (10004637)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary colic (10004663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangitis (10008604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangitis acute (10008605)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis (10008612)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cholecystitis acute (10008614)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholelithiasis (10008629)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic hepatitis (10008909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gallbladder polyp (10049704)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cirrhosis (10019641)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cyst (10019646)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic function abnormal (10019670)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic steatosis (10019708)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatotoxicity (10019851)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperbilirubinaemia (10020578)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertransaminasaemia (10068237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Jaundice cholestatic (10023129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver disorder (10024670)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	12	0.2	0.1	0.4	14	0.2	0.1	0.4	14	0.2	0.1	0.4	15	0.2	0.1	0.4	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergy to arthropod sting (10058284)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergy to chemicals (10061626)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergy to plants (10054928)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amyloidosis (10002022)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Food allergy (10016946)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity (10020751)	6	0.1	0.0	0.2	9	0.2	0.1	0.3	7	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Milk allergy (10027633)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple allergies (10028164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seasonal allergy (10048908)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	642	11.1	10.3	11.9	653	11.4	10.6	12.2	685	11.3	10.5	12.1	686	11.0	10.3	11.8	183	11.6	10.1	13.3	171	11.7	10.1	13.4	4	6.8	1.9	16.5	6	8.3	3.1	17.3
	Abdominal infection (10056519)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal wall abscess (10000099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Abscess (10000269)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess limb (10050473)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess oral (10000311)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acarodermatitis (10063409)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute sinusitis (10001076)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute tonsillitis (10001093)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alveolar osteitis (10066995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerotic gangrene (10003222)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis bacterial (10053555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis infective (10060968)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacteraemia (10003997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacterial infection (10060945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacteriuria (10004056)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blastocystis infection (10005092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body tinea (10005913)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Borrelia infection (10061591)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast abscess (10006171)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchiolitis (10006448)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis (10006451)	24	0.4	0.3	0.6	32	0.6	0.4	0.8	60	1.0	0.8	1.3	42	0.7	0.5	0.9	16	1.0	0.6	1.6	16	1.1	0.6	1.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Bronchitis viral (10053160)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchopneumonia (10006469)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Candida infection (10074170)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carbuncle (10007247)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cellulitis (10007882)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	11	0.2	0.1	0.3	2	0.1	0.0	0.5	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cellulitis orbital (10007918)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervicitis (10008323)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic hepatitis b (10008910)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic sinusitis (10009137)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctivitis (10010741)	7	0.1	0.0	0.2	4	0.1	0.0	0.2	11	0.2	0.1	0.3	19	0.3	0.2	0.5	11	0.7	0.3	1.2	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctivitis viral (10010755)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystitis (10011781)	14	0.2	0.1	0.4	10	0.2	0.1	0.3	17	0.3	0.2	0.4	15	0.2	0.1	0.4	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dacryocystitis (10011844)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dengue fever (10012310)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatophytosis (10012504)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Diarrhoea infectious (10012742)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulitis (10013538)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear infection (10014011)	6	0.1	0.0	0.2	7	0.1	0.0	0.3	6	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema infected (10014199)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Encephalomyelitis (10014619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometritis (10014791)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enteritis infectious (10058839)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epididymitis (10015000)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erysipelas (10015145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema migrans (10062488)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Escherichia infection (10061126)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye infection (10015929)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid infection (10015988)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Folliculitis (10016936)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fungal infection (10017533)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fungal skin infection (10017543)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Furuncle (10017553)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric infection (10056663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis (10017888)	18	0.3	0.2	0.5	21	0.4	0.2	0.6	21	0.3	0.2	0.5	15	0.2	0.1	0.4	2	0.1	0.0	0.5	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis viral (10017918)	7	0.1	0.0	0.2	5	0.1	0.0	0.2	9	0.1	0.1	0.3	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal fungal infection (10049479)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital candidiasis (10018143)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital herpes (10018150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital infection (10048461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingivitis (10018292)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Groin abscess (10050269)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	H1n1 influenza (10069767)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematoma infection (10051564)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoid infection (10051541)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Helicobacter infection (10054263)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic infection (10056522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes simplex (10019948)	15	0.3	0.1	0.4	20	0.3	0.2	0.5	9	0.1	0.1	0.3	7	0.1	0.0	0.2	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes virus infection (10019973)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hordeolum (10020377)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Impetigo (10021531)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected bites (10021769)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected cyst (10058015)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected varicose vein (10057258)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infection (10021789)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza (10022000)	30	0.5	0.4	0.7	29	0.5	0.3	0.7	21	0.3	0.2	0.5	27	0.4	0.3	0.6	3	0.2	0.0	0.6	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site cellulitis (10050057)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site infection (10022076)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Kidney infection (10023424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Labyrinthitis (10023567)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngitis (10023874)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver abscess (10024652)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lobar pneumonia (10024738)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Localised infection (10024774)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower respiratory tract infection (10024968)	6	0.1	0.0	0.2	6	0.1	0.0	0.2	11	0.2	0.1	0.3	14	0.2	0.1	0.4	15	1.0	0.5	1.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Lung infection (10061229)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lyme disease (10025169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mastitis (10026883)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nail bed infection (10061303)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasopharyngitis (10028810)	211	3.6	3.2	4.2	252	4.4	3.9	5.0	193	3.2	2.8	3.7	208	3.3	2.9	3.8	40	2.5	1.8	3.4	36	2.5	1.7	3.4	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Neuroborreliosis (10052057)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Omphalitis (10030306)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychomycosis (10030338)	6	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	10	0.2	0.1	0.3	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ophthalmic herpes simplex (10073938)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral candidiasis (10030963)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral fungal infection (10061324)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral herpes (10067152)	35	0.6	0.4	0.8	22	0.4	0.2	0.6	25	0.4	0.3	0.6	18	0.3	0.2	0.5	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral infection (10048685)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Orchitis (10031064)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal candidiasis (10050346)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteomyelitis (10031252)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis externa (10033072)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	10	0.2	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis externa fungal (10052557)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media (10033078)	5	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media acute (10033079)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parasitic gastroenteritis (10067720)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paronychia (10034016)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parotitis (10034038)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Perichondritis (10062067)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periodontitis (10034539)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peritonsillar abscess (10034686)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pertussis (10034738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngitis (10034835)	22	0.4	0.2	0.6	18	0.3	0.2	0.5	30	0.5	0.3	0.7	31	0.5	0.3	0.7	5	0.3	0.1	0.7	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pharyngitis bacterial (10057869)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngotonsillitis (10049140)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia (10035664)	8	0.1	0.1	0.3	6	0.1	0.0	0.2	14	0.2	0.1	0.4	11	0.2	0.1	0.3	5	0.3	0.1	0.7	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural infection (10067268)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Postoperative wound infection (10036410)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoas abscess (10056517)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulpitis dental (10037464)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis (10037596)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyuria (10037686)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash pustular (10037888)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract infection (10062352)	17	0.3	0.2	0.5	7	0.1	0.0	0.3	17	0.3	0.2	0.4	9	0.1	0.1	0.3	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinitis (10038910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis (10039083)	17	0.3	0.2	0.5	22	0.4	0.2	0.6	19	0.3	0.2	0.5	18	0.3	0.2	0.5	6	0.4	0.1	0.8	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinolaryngitis (10057442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinovirus infection (10061494)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scrotal abscess (10049571)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sepsis (10040047)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinobronchitis (10048979)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinusitis (10040753)	24	0.4	0.3	0.6	26	0.5	0.3	0.7	30	0.5	0.3	0.7	22	0.4	0.2	0.5	5	0.3	0.1	0.7	9	0.6	0.3	1.2	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin bacterial infection (10052891)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin candida (10054152)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin infection (10040872)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Staphylococcal infection (10058080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subcutaneous abscess (10042343)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea capitis (10043866)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea cruris (10043868)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea infection (10060889)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea manuum (10067197)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea pedis (10043873)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea versicolour (10056131)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillitis (10044008)	5	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillitis bacterial (10065235)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth abscess (10044016)	7	0.1	0.0	0.2	8	0.1	0.1	0.3	5	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth infection (10048762)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Toxoplasmosis (10044272)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tracheitis (10044302)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tracheobronchitis (10044314)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper respiratory tract infection (10046306)	100	1.7	1.4	2.1	77	1.3	1.1	1.7	89	1.5	1.2	1.8	77	1.2	1.0	1.5	24	1.5	1.0	2.3	14	1.0	0.5	1.6	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Urethritis (10046480)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary tract infection (10046571)	28	0.5	0.3	0.7	36	0.6	0.4	0.9	40	0.7	0.5	0.9	42	0.7	0.5	0.9	18	1.1	0.7	1.8	12	0.8	0.4	1.4	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urosepsis (10048709)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal infection (10046914)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicella (10046980)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral infection (10047461)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	10	0.2	0.1	0.3	6	0.1	0.0	0.2	5	0.3	0.1	0.7	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral rash (10047476)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral sinusitis (10051513)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound infection (10048038)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	76	1.3	1.0	1.6	98	1.7	1.4	2.1	112	1.8	1.5	2.2	126	2.0	1.7	2.4	41	2.6	1.9	3.5	28	1.9	1.3	2.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Accident (10000369)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aneurysm perforation (10075395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Animal bite (10002515)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ankle fracture (10002544)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aqueous humour leakage (10070497)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthropod bite (10003399)	8	0.1	0.1	0.3	6	0.1	0.0	0.2	14	0.2	0.1	0.4	8	0.1	0.1	0.3	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthropod sting (10003402)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back injury (10003986)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bite (10004966)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone contusion (10066251)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone fissure (10064210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burns first degree (10006797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Burns second degree (10006802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cartilage injury (10007710)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest injury (10061386)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Clavicle fracture (10009245)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Compression fracture (10010214)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Concussion (10010254)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contrast media reaction (10010836)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contusion (10050584)	3	0.1	0.0	0.2	8	0.1	0.1	0.3	13	0.2	0.1	0.4	16	0.3	0.1	0.4	8	0.5	0.2	1.0	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Corneal abrasion (10010984)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Craniocebral injury (10070976)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Crush injury (10061097)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epicondylitis (10014971)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Excoriation (10049796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye injury (10061128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Face injury (10050392)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial bones fracture (10016042)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fall (10016173)	2	0.0	0.0	0.1	8	0.1	0.1	0.3	10	0.2	0.1	0.3	6	0.1	0.0	0.2	6	0.4	0.1	0.8	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femoral neck fracture (10016450)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femur fracture (10016454)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibula fracture (10016667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foot fracture (10016970)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Forearm fracture (10016997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foreign body (10070245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foreign body in eye (10017012)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fractured sacrum (10017308)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hand fracture (10019114)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Head injury (10019196)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heat stroke (10019345)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hip fracture (10020100)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Humerus fracture (10020462)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injury (10022116)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injury corneal (10022120)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint dislocation (10023204)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Joint injury (10060820)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Kidney contusion (10023413)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laceration (10023572)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament injury (10061223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament rupture (10065433)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament sprain (10024453)	8	0.1	0.1	0.3	12	0.2	0.1	0.4	7	0.1	0.0	0.2	10	0.2	0.1	0.3	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb injury (10061225)	3	0.1	0.0	0.2	8	0.1	0.1	0.3	7	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip injury (10055082)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower limb fracture (10061599)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar vertebral fracture (10049947)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniscus injury (10072970)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth injury (10049294)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple injuries (10028224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle injury (10028314)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle rupture (10028331)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle strain (10050031)	6	0.1	0.0	0.2	3	0.1	0.0	0.2	8	0.1	0.1	0.3	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nerve root injury cervical (10029183)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Open fracture (10030527)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Patella fracture (10034122)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic fracture (10061161)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural haematuria (10066225)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural inflammation (10063101)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural pulmonary embolism (10063909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Procedural pain (10064882)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pubis fracture (10070286)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radius fracture (10037802)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rib fracture (10039117)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Road traffic accident (10039203)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scratch (10039737)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skeletal injury (10061363)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin abrasion (10064990)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Skin injury (10061364)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin wound (10072170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skull fracture (10061365)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue injury (10041291)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal column injury (10069689)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal compression fracture (10041541)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Spinal cord injury (10041552)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal fracture (10041569)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subdural haematoma (10042361)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sunburn (10042496)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon rupture (10043248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thermal burn (10053615)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thoracic vertebral fracture (10049948)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tibia fracture (10043827)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth fracture (10062544)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toxicity to various agents (10070863)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic arthropathy (10044502)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic haematoma (10044522)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulna fracture (10045375)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper limb fracture (10061394)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination complication (10046861)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound (10052428)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wrist fracture (10048049)	2	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Investigations (10022891)	At least one PT related to the corresponding SOC	67	1.2	0.9	1.5	13	0.2	0.1	0.4	66	1.1	0.8	1.4	13	0.2	0.1	0.4	12	0.8	0.4	1.3	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anticoagulation drug level above therapeutic (10060320)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood alkaline phosphatase increased (10059570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood cholesterol increased (10005425)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blood glucose fluctuation (10049803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood glucose increased (10005557)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood iron decreased (10005619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood potassium decreased (10005724)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood potassium increased (10005725)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure abnormal (10005728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure decreased (10005734)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure diastolic increased (10005739)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure increased (10005750)	7	0.1	0.0	0.2	2	0.0	0.0	0.1	7	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood sodium decreased (10005802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood testosterone decreased (10005814)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood thyroid stimulating hormone increased (10005833)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood uric acid increased (10005861)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body temperature decreased (10005910)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body temperature increased (10005911)	54	0.9	0.7	1.2	2	0.0	0.0	0.1	46	0.8	0.6	1.0	2	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac murmur (10007586)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Catheterisation cardiac (10007815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Electrocardiogram abnormal (10014363)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gamma-glutamyltransferase increased (10017693)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Grip strength decreased (10062556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate increased (10019303)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate irregular (10019304)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Helicobacter test positive (10070101)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver function test abnormal (10024690)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Precancerous cells present (10049673)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Protein urine present (10053123)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Serum ferritin decreased (10040249)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transaminases increased (10054889)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urine analysis abnormal (10062226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Weight decreased (10047895)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Weight increased (10047899)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	35	0.6	0.4	0.8	24	0.4	0.3	0.6	82	1.4	1.1	1.7	50	0.8	0.6	1.1	26	1.7	1.1	2.4	20	1.4	0.8	2.1	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Abnormal loss of weight (10000159)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cachexia (10006895)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decreased appetite (10061428)	10	0.2	0.1	0.3	0	0.0	0.0	0.1	16	0.3	0.2	0.4	3	0.0	0.0	0.1	5	0.3	0.1	0.7	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dehydration (10012174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes mellitus (10012601)	6	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes mellitus inadequate control (10012607)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyslipidaemia (10058108)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	11	0.2	0.1	0.3	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeding disorder (10061148)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Folate deficiency (10016880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glucose tolerance impaired (10018429)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Gout (10018627)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	13	0.2	0.1	0.4	4	0.1	0.0	0.2	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypercalcaemia (10020583)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypercholesterolaemia (10020603)	2	0.0	0.0	0.1	7	0.1	0.0	0.3	10	0.2	0.1	0.3	5	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Hyperglycaemia (10020635)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperkalaemia (10020646)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperlipidaemia (10062060)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	7	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperphagia (10020710)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertriglyceridaemia (10020869)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperuricaemia (10020903)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoglycaemia (10020993)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypokalaemia (10021015)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyponatraemia (10021036)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypovitaminosis (10021135)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iron deficiency (10022970)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lactose intolerance (10023681)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Obesity (10029883)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polydipsia (10036067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Type 2 diabetes mellitus (10067585)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	3	0.0	0.0	0.1	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitamin b12 deficiency (10047609)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitamin d deficiency (10047626)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	577	10.0	9.2	10.8	305	5.3	4.8	5.9	548	9.0	8.3	9.8	411	6.6	6.0	7.3	145	9.2	7.8	10.8	105	7.2	5.9	8.6	4	6.8	1.9	16.5	7	9.7	4.0	19.0
	Acquired claw toe (10057689)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthralgia (10003239)	110	1.9	1.6	2.3	68	1.2	0.9	1.5	99	1.6	1.3	2.0	73	1.2	0.9	1.5	22	1.4	0.9	2.1	18	1.2	0.7	1.9	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Arthritis (10003246)	5	0.1	0.0	0.2	4	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthropathy (10003285)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Axillary mass (10049021)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back pain (10003988)	90	1.6	1.3	1.9	63	1.1	0.8	1.4	76	1.3	1.0	1.6	82	1.3	1.1	1.6	26	1.7	1.1	2.4	28	1.9	1.3	2.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Bone disorder (10005956)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone pain (10006002)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone swelling (10053631)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bursitis (10006811)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	7	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cervical spinal stenosis (10008313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chondrocalcinosis (10061761)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chondropathy (10061762)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coccydynia (10009829)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Costochondritis (10011219)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dupuytren's contracture (10013872)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Exostosis (10015688)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibromyalgia (10048439)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flank pain (10016750)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foot deformity (10061159)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gouty arthritis (10018634)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Groin pain (10018735)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iliolumbar syndrome (10063442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc degeneration (10061246)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc protrusion (10050296)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Jaw cyst (10023146)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint effusion (10023215)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint stiffness (10023230)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint swelling (10023232)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament disorder (10061222)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb discomfort (10061224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Lumbar spinal stenosis (10025005)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metatarsalgia (10027487)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mobility decreased (10048334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Monarthritis (10027811)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle contracture (10062575)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle disorder (10028300)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle fatigue (10049565)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle rigidity (10028330)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle spasms (10028334)	10	0.2	0.1	0.3	8	0.1	0.1	0.3	20	0.3	0.2	0.5	12	0.2	0.1	0.3	6	0.4	0.1	0.8	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle tightness (10049816)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle twitching (10028347)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscular weakness (10028372)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Musculoskeletal chest pain (10050819)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal discomfort (10053156)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal pain (10028391)	40	0.7	0.5	0.9	24	0.4	0.3	0.6	44	0.7	0.5	1.0	28	0.5	0.3	0.7	3	0.2	0.0	0.6	9	0.6	0.3	1.2	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Musculoskeletal stiffness (10052904)	13	0.2	0.1	0.4	7	0.1	0.0	0.3	6	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myalgia (10028411)	243	4.2	3.7	4.8	36	0.6	0.4	0.9	177	2.9	2.5	3.4	51	0.8	0.6	1.1	32	2.0	1.4	2.9	9	0.6	0.3	1.2	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Myofascial pain syndrome (10048780)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neck pain (10028836)	32	0.6	0.4	0.8	14	0.2	0.1	0.4	24	0.4	0.3	0.6	23	0.4	0.2	0.6	4	0.3	0.1	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Osteitis (10031149)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoarthritis (10031161)	9	0.2	0.1	0.3	20	0.3	0.2	0.5	42	0.7	0.5	0.9	49	0.8	0.6	1.0	16	1.0	0.6	1.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Osteochondrosis (10031233)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteolysis (10031248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteonecrosis (10031264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteopenia (10049088)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoporosis (10031282)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pain in extremity (10033425)	52	0.9	0.7	1.2	44	0.8	0.6	1.0	67	1.1	0.9	1.4	40	0.6	0.5	0.9	27	1.7	1.1	2.5	14	1.0	0.5	1.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain in jaw (10033433)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periarthritis (10034464)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Plantar fasciitis (10035155)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyarthritis (10036030)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rheumatic disorder (10072736)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rotator cuff syndrome (10039227)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scoliosis (10039722)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue disorder (10061366)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue mass (10071051)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal column stenosis (10041540)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal disorder (10061368)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal osteoarthritis (10041591)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Spinal pain (10072005)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Spondyloarthropathy (10051265)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylolisthesis (10063550)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylolysis (10052013)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovial cyst (10042858)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovitis (10042868)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon disorder (10043239)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon pain (10066371)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendonitis (10043255)	2	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Tenosynovitis (10043261)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tenosynovitis stenosaurs (10056698)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Torticollis (10044074)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigger finger (10044654)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertebral foraminal stenosis (10069690)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	23	0.4	0.3	0.6	20	0.3	0.2	0.5	43	0.7	0.5	1.0	37	0.6	0.4	0.8	4	0.3	0.1	0.6	11	0.8	0.4	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acrochordon (10000591)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma (10001141)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma of colon (10001167)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenoma benign (10001233)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adrenal adenoma (10001323)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anogenital warts (10059313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basal cell carcinoma (10004146)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	6	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign ear neoplasm (10069051)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign neoplasm of skin (10004398)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct cancer (10004593)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder cancer (10005003)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder neoplasm (10005056)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bowen's disease (10006059)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Breast cancer (10006187)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervix carcinoma (10008342)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon adenoma (10048832)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon cancer (10009944)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysplastic naevus (10062805)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibroma (10016629)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibrous histiocytoma (10053717)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatocellular carcinoma (10073071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraductal proliferative breast lesion (10073094)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Invasive ductal breast carcinoma (10073095)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine benign neoplasm (10073394)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lipoma (10024612)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung neoplasm malignant (10058467)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant melanoma (10025650)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant melanoma in situ (10025652)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Melanocytic naevus (10027145)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningioma (10027191)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to liver (10027457)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to lung (10027458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to lymph nodes (10027459)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to peritoneum (10051676)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasopharyngeal neoplasm benign (10028802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm malignant (10028997)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm skin (10029098)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal carcinoma (10030155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic carcinoma (10033609)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraganglion neoplasm (10061332)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleomorphic adenoma (10073372)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer (10060862)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer recurrent (10036911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cancer (10038389)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sarcoma (10039491)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seborrhoeic keratosis (10039796)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin cancer (10040808)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin papilloma (10040907)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma (10041823)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Nervous system disorders (10029205)	Squamous cell carcinoma of skin (10041834)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular neoplasm (10061379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral neoplasm (10062223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	609	10.5	9.7	11.3	290	5.1	4.5	5.7	495	8.2	7.5	8.9	316	5.1	4.5	5.7	106	6.7	5.5	8.1	75	5.1	4.1	6.4	3	5.1	1.1	14.1	3	4.2	0.9	11.7
	Amnesia (10001949)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphonia (10002953)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Balance disorder (10049848)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	6	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burning sensation (10006784)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery stenosis (10007687)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrospinal fluid leakage (10008164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular disorder (10008196)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical myelopathy (10008289)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical radiculopathy (10050217)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cognitive disorder (10057668)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Convulsions local (10010920)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cubital tunnel syndrome (10056473)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dementia (10012267)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic neuropathy (10012680)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disturbance in attention (10013496)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

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Report Final

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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Dizziness (10013573)	70	1.2	0.9	1.5	34	0.6	0.4	0.8	78	1.3	1.0	1.6	60	1.0	0.7	1.2	24	1.5	1.0	2.3	15	1.0	0.6	1.7	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Dizziness postural (10013578)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysaesthesia (10013886)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysgeusia (10013911)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Encephalopathy (10014625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epilepsy (10015037)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Essential tremor (10015496)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial spasm (10063006)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Head discomfort (10019194)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Headache (10019211)	475	8.2	7.5	8.9	205	3.6	3.1	4.1	329	5.4	4.9	6.0	160	2.6	2.2	3.0	61	3.9	3.0	5.0	30	2.0	1.4	2.9	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Hemiparesis (10019465)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperaesthesia (10020568)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersomnia (10020765)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoesthesia (10020937)	6	0.1	0.0	0.2	9	0.2	0.1	0.3	12	0.2	0.1	0.3	7	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Hypogeusia (10020989)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypotonia (10021118)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intercostal neuralgia (10049949)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacunar infarction (10051078)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lethargy (10024264)	9	0.2	0.1	0.3	4	0.1	0.0	0.2	12	0.2	0.1	0.3	3	0.0	0.0	0.1	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Loss of consciousness (10024855)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar radiculopathy (10050219)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Memory impairment (10027175)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metabolic encephalopathy (10062190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Migraine (10027599)	8	0.1	0.1	0.3	3	0.1	0.0	0.2	6	0.1	0.0	0.2	7	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Motor dysfunction (10061296)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle contractions involuntary (10028293)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nerve compression (10029174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nervous system disorder (10029202)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuralgia (10029223)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraesthesia (10033775)	13	0.2	0.1	0.4	5	0.1	0.0	0.2	9	0.1	0.1	0.3	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parkinson's disease (10061536)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parkinsonism (10034010)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Petit mal epilepsy (10034759)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyneuropathy (10036105)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Poor quality sleep (10062519)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Presyncope (10036653)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radicular pain (10059604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radiculitis brachial (10037778)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radiculopathy (10037779)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restless legs syndrome (10058920)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sciatica (10039674)	6	0.1	0.0	0.2	6	0.1	0.0	0.2	11	0.2	0.1	0.3	21	0.3	0.2	0.5	1	0.1	0.0	0.4	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Seizure (10039906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Senile dementia (10039966)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sensory disturbance (10040026)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sensory loss (10040030)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus headache (10040744)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Somnolence (10041349)	13	0.2	0.1	0.4	2	0.0	0.0	0.1	17	0.3	0.2	0.4	5	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal claudication (10041539)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stupor (10042264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subarachnoid haemorrhage (10042316)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Syncope (10042772)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tension headache (10043269)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thalamic infarction (10064961)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transient global amnesia (10044380)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transient ischaemic attack (10044390)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tremor (10044565)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigeminal neuralgia (10044652)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visual field defect (10047555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	66	1.1	0.9	1.4	32	0.6	0.4	0.8	69	1.1	0.9	1.4	48	0.8	0.6	1.0	25	1.6	1.0	2.3	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Abnormal dreams (10000125)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute stress disorder (10001084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Affective disorder (10001443)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Agitation (10001497)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Agoraphobia (10001502)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Alcohol withdrawal syndrome (10053164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alcoholism (10001639)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anxiety (10002855)	13	0.2	0.1	0.4	3	0.1	0.0	0.2	8	0.1	0.1	0.3	11	0.2	0.1	0.3	4	0.3	0.1	0.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anxiety disorder (10057666)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aversion (10063659)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Confusional state (10010305)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depressed mood (10012374)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depression (10012378)	4	0.1	0.0	0.2	7	0.1	0.0	0.3	9	0.1	0.1	0.3	11	0.2	0.1	0.3	4	0.3	0.1	0.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depressive symptom (10054089)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disorientation (10013395)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphemia (10054964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphoria (10013954)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysthymic disorder (10013982)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Emotional disorder (10014551)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Emotional distress (10049119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hallucination (10019063)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hallucination, visual (10019075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Insomnia (10022437)	34	0.6	0.4	0.8	19	0.3	0.2	0.5	29	0.5	0.3	0.7	14	0.2	0.1	0.4	9	0.6	0.3	1.1	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Irritability (10022998)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Libido decreased (10024419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Listless (10024642)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Major depression (10057840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mental status changes (10048294)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Middle insomnia (10027590)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nervousness (10029216)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nightmare (10029412)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Obsessive thoughts (10029897)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Panic attack (10033664)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psychosomatic disease (10049587)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psychotic disorder (10061920)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restlessness (10038743)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Schizophrenia, paranoid type (10039639)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sleep disorder (10040984)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Somatoform disorder (10054153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stress (10042209)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tension (10043268)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tic (10043833)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	24	0.4	0.3	0.6	8	0.1	0.1	0.3	27	0.4	0.3	0.6	22	0.4	0.2	0.5	16	1.0	0.6	1.6	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute kidney injury (10069339)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder pain (10005063)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder spasm (10048994)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Calculus bladder (10006987)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Calculus ureteric (10007025)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chromaturia (10008796)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic kidney disease (10064848)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystitis interstitial (10011796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysuria (10013990)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematuria (10018867)	6	0.1	0.0	0.2	0	0.0	0.0	0.1	4	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertonic bladder (10020853)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incontinence (10021639)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Micturition disorder (10027561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Micturition urgency (10027566)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephritis (10029117)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephrolithiasis (10029148)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephropathy (10029151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neurogenic bladder (10029279)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nocturia (10029446)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pollakiuria (10036018)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyuria (10036142)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal colic (10038419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cyst (10038423)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Renal failure (10038435)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal impairment (10062237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal pain (10038490)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tubulointerstitial nephritis (10048302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral polyp (10051507)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral stenosis (10065584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urge incontinence (10046494)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary hesitation (10046542)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary incontinence (10046543)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary retention (10046555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary tract disorder (10046566)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urine odour abnormal (10057135)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	19	0.3	0.2	0.5	23	0.4	0.3	0.6	26	0.4	0.3	0.6	26	0.4	0.3	0.6	5	0.3	0.1	0.7	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrophic vulvovaginitis (10003693)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Balanoposthitis (10004078)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign prostatic hyperplasia (10004446)	0	0.0	0.0	0.1	8	0.1	0.1	0.3	8	0.1	0.1	0.3	8	0.1	0.1	0.3	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast cyst (10006220)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast discomfort (10049872)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast enlargement (10006242)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast mass (10006272)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast pain (10006298)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast swelling (10006312)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast tenderness (10006313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical cyst (10008254)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical polyp (10008297)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystocele (10011803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysfunctional uterine bleeding (10013908)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysmenorrhoea (10013935)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometrial hyperplasia (10014755)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Erectile dysfunction (10061461)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital discomfort (10066887)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital tract inflammation (10058821)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital ulceration (10018180)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Male sexual dysfunction (10057672)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Menopausal symptoms (10027304)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Menorrhagia (10027313)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nipple disorder (10029417)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Organic erectile dysfunction (10052004)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic pain (10034263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Penile pain (10034310)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Postmenopausal haemorrhage (10055870)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate induration (10057263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatic disorder (10036956)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatism (10036976)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatitis (10036978)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatomegaly (10051482)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus genital (10037093)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectocele (10038084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scrotal cyst (10065670)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scrotal swelling (10039759)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular mass (10058901)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular pain (10043345)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testis discomfort (10052531)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine prolapse (10046814)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal erosion (10062558)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal haemorrhage (10046910)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal inflammation (10046916)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginal dryness (10047791)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginal pruritus (10056530)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	200	3.5	3.0	4.0	167	2.9	2.5	3.4	200	3.3	2.9	3.8	225	3.6	3.2	4.1	53	3.4	2.5	4.4	63	4.3	3.3	5.5	2	3.4	0.4	11.7	2	2.8	0.3	9.7
	Asthma (10003553)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	10	0.2	0.1	0.3	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atelectasis (10003598)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchial irritation (10006438)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchiectasis (10006445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis chronic (10006458)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Bronchospasm (10006482)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Catarrh (10007774)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic obstructive pulmonary disease (10009033)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	6	0.1	0.0	0.2	6	0.1	0.0	0.2	7	0.4	0.2	0.9	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cough (10011224)	70	1.2	0.9	1.5	64	1.1	0.9	1.4	88	1.4	1.2	1.8	96	1.5	1.3	1.9	18	1.1	0.7	1.8	22	1.5	0.9	2.3	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Dry throat (10013789)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphonia (10013952)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspnoea (10013968)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	9	0.1	0.1	0.3	11	0.2	0.1	0.3	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspnoea exertional (10013971)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Emphysema (10014561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epistaxis (10015090)	7	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemoptysis (10018964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemothorax (10019027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Increased upper airway secretion (10062717)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Increased viscosity of bronchial secretion (10054761)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngeal oedema (10023845)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngitis allergic (10064866)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower respiratory tract congestion (10075565)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung disorder (10025082)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung infiltration (10025102)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal congestion (10028735)	6	0.1	0.0	0.2	12	0.2	0.1	0.4	11	0.2	0.1	0.3	7	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal discomfort (10052437)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal disorder (10062209)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal dryness (10028740)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal obstruction (10028748)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal polyps (10028756)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal pruritus (10076406)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Nasal septum deviation (10028762)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal discomfort (10068318)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal pain (10068319)	81	1.4	1.1	1.7	64	1.1	0.9	1.4	55	0.9	0.7	1.2	56	0.9	0.7	1.2	4	0.3	0.1	0.6	12	0.8	0.4	1.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Paranasal sinus discomfort (10052438)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngeal erythema (10057009)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleural adhesion (10035588)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleural effusion (10035598)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleurisy (10035618)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleuritic pain (10035623)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumothorax (10035759)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Productive cough (10036790)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary bulla (10051688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary embolism (10037377)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary mass (10056342)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rales (10037833)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory disorder (10038683)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory failure (10038695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract congestion (10052251)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinalgia (10051496)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis allergic (10039085)	5	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	9	0.1	0.1	0.3	1	0.1	0.0	0.4	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis hypertrophic (10059235)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinorrhoea (10039101)	19	0.3	0.2	0.5	11	0.2	0.1	0.3	17	0.3	0.2	0.4	14	0.2	0.1	0.4	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus congestion (10040742)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus disorder (10062244)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sleep apnoea syndrome (10040979)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sneezing (10041232)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Snoring (10041235)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sputum discoloured (10041807)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sputum increased (10041812)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Throat irritation (10043521)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Throat tightness (10043528)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillar disorder (10053477)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper respiratory tract inflammation (10049590)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper-airway cough syndrome (10070488)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasomotor rhinitis (10047145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vocal cord thickening (10047676)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wheezing (10047924)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	198	3.4	3.0	3.9	173	3.0	2.6	3.5	222	3.7	3.2	4.2	230	3.7	3.2	4.2	72	4.6	3.6	5.7	50	3.4	2.5	4.5	2	3.4	0.4	11.7	4	5.6	1.5	13.6
Skin and subcutaneous tissue disorders (10040785)	Acne (10000496)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Actinic keratosis (10000614)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Alopecia (10001760)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alopecia areata (10001761)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angioedema (10002424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blister (10005191)	6	0.1	0.0	0.2	3	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cold sweat (10009866)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decubitus ulcer (10011985)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermal cyst (10012426)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Dermatitis (10012431)	5	0.1	0.0	0.2	5	0.1	0.0	0.2	4	0.1	0.0	0.2	13	0.2	0.1	0.4	5	0.3	0.1	0.7	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Dermatitis allergic (10012434)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis atopic (10012438)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Dermatitis contact (10012442)	2	0.0	0.0	0.1	6	0.1	0.0	0.2	7	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatosis (10048768)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic foot (10060734)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug eruption (10013687)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry skin (10013786)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyshidrotic eczema (10013913)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ecchymosis (10014080)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema (10014184)	14	0.2	0.1	0.4	23	0.4	0.3	0.6	26	0.4	0.3	0.6	24	0.4	0.2	0.6	8	0.5	0.2	1.0	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema asteatotic (10014190)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema (10015150)	21	0.4	0.2	0.6	7	0.1	0.0	0.3	20	0.3	0.2	0.5	14	0.2	0.1	0.4	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema nodosum (10015226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hand dermatitis (10058898)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hyperhidrosis (10020642)	16	0.3	0.2	0.4	4	0.1	0.0	0.2	10	0.2	0.1	0.3	8	0.1	0.1	0.3	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperkeratosis (10020649)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypohidrosis (10021013)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Idiopathic urticaria (10021247)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ingrowing nail (10022013)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lichen planus (10024429)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lichen sclerosus (10024434)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Miliaria (10027627)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nail growth abnormal (10064764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neurodermatitis (10029263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Night sweats (10029410)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychalgia (10064251)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychoclasis (10048886)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onycholysis (10030337)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychomadesis (10049274)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain of skin (10033474)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Papule (10033733)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Petechiae (10034754)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pityriasis rosea (10035114)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Precancerous skin lesion (10049422)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prurigo (10037083)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus (10037087)	37	0.6	0.5	0.9	35	0.6	0.4	0.8	45	0.7	0.5	1.0	56	0.9	0.7	1.2	23	1.5	0.9	2.2	13	0.9	0.5	1.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pruritus generalised (10052576)	4	0.1	0.0	0.2	7	0.1	0.0	0.3	4	0.1	0.0	0.2	9	0.1	0.1	0.3	5	0.3	0.1	0.7	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoriasis (10037153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash (10037844)	45	0.8	0.6	1.0	40	0.7	0.5	0.9	42	0.7	0.5	0.9	63	1.0	0.8	1.3	18	1.1	0.7	1.8	9	0.6	0.3	1.2	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Rash erythematous (10037855)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash generalised (10037858)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash macular (10037867)	3	0.1	0.0	0.2	7	0.1	0.0	0.3	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash maculo-papular (10037868)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash papular (10037876)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash pruritic (10037884)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	9	0.1	0.1	0.3	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Rosacea (10039218)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seborrhoea (10039792)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seborrhoeic dermatitis (10039793)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Senile pruritus (10039986)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin burning sensation (10054786)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin discolouration (10040829)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin disorder (10040831)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin exfoliation (10040844)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin fissures (10040849)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin irritation (10040880)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin lesion (10040882)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin necrosis (10040893)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin plaque (10067723)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin striae (10040925)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin swelling (10053262)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin ulcer (10040943)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin warm (10040952)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Solar dermatitis (10041303)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stasis dermatitis (10041955)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urticaria (10046735)	11	0.2	0.1	0.3	6	0.1	0.0	0.2	9	0.1	0.1	0.3	13	0.2	0.1	0.4	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Xeroderma (10048218)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Social circumstances (10041244)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Occupational physical problem (10030026)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	8	0.1	0.1	0.3	4	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal operation (10061609)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac pacemaker replacement (10049434)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract operation (10063797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary arterial stent insertion (10052086)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental implantation (10064143)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endodontic procedure (10051085)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hip arthroplasty (10020096)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniscus operation (10054948)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth cyst excision (10052179)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal polypectomy (10038075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shoulder operation (10062242)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin lesion excision (10062250)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin neoplasm excision (10059443)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth extraction (10062132)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Umbilical hernia repair (10045462)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasectomy (10047133)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	47	0.8	0.6	1.1	45	0.8	0.6	1.0	86	1.4	1.1	1.7	78	1.3	1.0	1.6	22	1.4	0.9	2.1	36	2.5	1.7	3.4	1	1.7	0.0	9.1	3	4.2	0.9	11.7
	Angiopathy (10059245)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic aneurysm (10002882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic stenosis (10002906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerosis (10003210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Behcet's syndrome (10004213)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure fluctuation (10005746)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure inadequately controlled (10051128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deep vein thrombosis (10051055)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Essential hypertension (10015488)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flushing (10016825)	7	0.1	0.0	0.2	0	0.0	0.0	0.1	8	0.1	0.1	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematoma (10018852)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhage (10055798)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hot flush (10060800)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperaemia (10020565)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertension (10020772)	26	0.4	0.3	0.7	30	0.5	0.4	0.7	37	0.6	0.4	0.8	46	0.7	0.5	1.0	8	0.5	0.2	1.0	20	1.4	0.8	2.1	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Hypertensive crisis (10020802)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Hypotension (10021097)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	8	0.1	0.1	0.3	8	0.1	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intra-abdominal haematoma (10056457)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ischaemia (10061255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Labile blood pressure (10023533)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphoedema (10025282)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Orthostatic hypotension (10031127)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral arterial occlusive disease (10062585)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Peripheral artery stenosis (10072563)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral coldness (10034568)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral vascular disorder (10034636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral venous disease (10075049)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Phlebitis (10034879)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Raynaud's phenomenon (10037912)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temporal arteritis (10043207)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombophlebitis (10043570)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombophlebitis superficial (10043595)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis (10043607)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicose vein (10046996)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular pain (10047095)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasculitis (10047115)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Venous thrombosis (10047249)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

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Table 14.3.1.21 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	At least one symptom	4439	39.1	38.2	40.0	1996	17.7	17.0	18.4	4233	35.8	34.9	36.7	2443	20.0	19.3	20.7	1033	34.2	32.5	35.9	624	22.2	20.6	23.7	36	31.9	23.4	41.3	26	19.3	13.0	26.9
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	23	0.2	0.1	0.3	5	0.0	0.0	0.1	13	0.1	0.1	0.2	10	0.1	0.0	0.2	5	0.2	0.1	0.4	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaemia (1002034)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhagic diathesis (10062713)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersplenism (10020769)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iron deficiency anaemia (10022972)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Leukopenia (10024384)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymph node pain (10025182)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenitis (10025188)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenopathy (10025197)	10	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macrocytosis (10025382)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Normochromic normocytic anaemia (10029783)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombocytopenia (10043554)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombocytosis (10043563)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	27	0.2	0.2	0.3	29	0.3	0.2	0.4	50	0.4	0.3	0.6	53	0.4	0.3	0.6	27	0.9	0.6	1.3	32	1.1	0.8	1.6	3	2.7	0.6	7.6	1	0.7	0.0	4.1
	Acute coronary syndrome (10051592)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute myocardial infarction (10000891)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina pectoris (10002383)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina unstable (10002388)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve incompetence (10002915)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve stenosis (10002918)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia (10003119)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia supraventricular (10003130)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Atrial fibrillation (10003658)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrial flutter (10003662)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block (10003671)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block complete (10003673)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block first degree (10003674)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bradycardia (10006093)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac discomfort (10054211)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac disorder (10061024)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Cardiac failure (10007554)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure acute (10007556)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure chronic (10007558)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure congestive (10007559)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac flutter (10052840)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac valve disease (10061406)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiovascular disorder (10007649)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Congestive cardiomyopathy (10056370)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cor pulmonale (10010968)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery disease (10011078)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery occlusion (10011086)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Extrasystoles (10015856)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertensive heart disease (10020823)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mitral valve disease (10061532)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mitral valve incompetence (10027727)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocardial infarction (10028596)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocardial ischaemia (10028600)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocarditis (10028606)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Palpitations (10033557)	7	0.1	0.0	0.1	5	0.0	0.0	0.1	11	0.1	0.0	0.2	7	0.1	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Right ventricular failure (10039163)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus bradycardia (10040741)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus node dysfunction (10075889)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Supraventricular extrasystoles (10042602)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Supraventricular tachycardia (10042604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachyarrhythmia (10049447)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia (10043071)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia paroxysmal (10043079)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ventricular extrasystoles (10047289)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Congenital, familial and genetic disorders (10010331)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malformation venous (10025532)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	37	0.3	0.2	0.4	26	0.2	0.2	0.3	45	0.4	0.3	0.5	44	0.4	0.3	0.5	15	0.5	0.3	0.8	15	0.5	0.3	0.9	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerumen impaction (10050337)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness neurosensory (10011891)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear discomfort (10052137)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear disorder (10014004)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear pain (10014020)	15	0.1	0.1	0.2	7	0.1	0.0	0.1	8	0.1	0.0	0.1	7	0.1	0.0	0.1	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eustachian tube disorder (10061462)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hypoacusis (10048865)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniere's disease (10027183)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Middle ear effusion (10062545)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Motion sickness (10027990)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otorrhoea (10033101)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sudden hearing loss (10061373)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinnitus (10043882)	4	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertigo (10047340)	14	0.1	0.1	0.2	7	0.1	0.0	0.1	23	0.2	0.1	0.3	22	0.2	0.1	0.3	7	0.2	0.1	0.5	9	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertigo positional (10047348)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Endocrine disorders (10014698)	At least one PT related to the corresponding SOC	4	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Androgen deficiency (10002261)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Autoimmune thyroiditis (10049046)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Basedow's disease (10004161)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Goitre (10018498)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperparathyroidism (10020705)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperthyroidism (10020850)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypogonadism (10058359)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypopituitarism (10021067)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypothyroidism (10021114)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Eye disorders (10015919)	At least one PT related to the corresponding SOC	44	0.4	0.3	0.5	48	0.4	0.3	0.6	60	0.5	0.4	0.7	67	0.5	0.4	0.7	22	0.7	0.5	1.1	15	0.5	0.3	0.9	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Abnormal sensation in eye (10000173)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthenopia (10003552)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blepharitis (10005148)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blepharospasm (10005159)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract (10007739)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	6	0.1	0.0	0.1	13	0.1	0.1	0.2	7	0.2	0.1	0.5	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chalazion (10008388)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chorioretinal atrophy (10008762)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chorioretinopathy (10063118)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chromatopsia (10008795)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival degeneration (10010705)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Conjunctival haemorrhage (10010719)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival hyperaemia (10051625)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Corneal erosion (10011013)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dark circles under eyes (10064729)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic retinopathy (10012689)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diplopia (10013036)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry eye (10013774)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema eyelids (10014194)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enophthalmos (10014853)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema of eyelid (10015237)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye allergy (10015907)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye discharge (10015915)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye disorder (10015916)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye haemorrhage (10015926)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye inflammation (10015943)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye irritation (10015946)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pain (10015958)	4	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pruritus (10052140)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye swelling (10015967)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid function disorder (10061145)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid oedema (10015993)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Eyelid ptosis (10015995)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid rash (10074620)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelids pruritus (10051627)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body sensation in eyes (10051116)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glaucoma (10018304)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Keratitis (10023332)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacrimation decreased (10023642)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacrimation increased (10023644)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Macular degeneration (10025409)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular fibrosis (10071392)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Maculopathy (10025425)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Narrow anterior chamber angle (10068960)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neovascular age-related macular degeneration (10071129)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular discomfort (10052143)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hyperaemia (10030041)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hypertension (10030043)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ophthalmic vein thrombosis (10074349)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Optic ischaemic neuropathy (10030924)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Panophthalmitis (10033683)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periorbital oedema (10034545)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photopsia (10034962)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Posterior capsule opacification (10036346)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal degeneration (10038845)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal detachment (10038848)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinopathy hypertensive (10038926)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trichiasis (10044604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ulcerative keratitis (10064996)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uveitis (10046851)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vision blurred (10047513)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual acuity reduced (10047531)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual impairment (10047571)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous detachment (10047650)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous floaters (10047654)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	340	3.0	2.7	3.3	232	2.1	1.8	2.3	335	2.8	2.5	3.1	290	2.4	2.1	2.7	95	3.1	2.5	3.8	83	2.9	2.4	3.6	6	5.3	2.0	11.2	2	1.5	0.2	5.2
	Abdominal discomfort (10000059)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	5	0.0	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal distension (10000060)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal hernia (10060954)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain (10000081)	17	0.1	0.1	0.2	12	0.1	0.1	0.2	15	0.1	0.1	0.2	14	0.1	0.1	0.2	4	0.1	0.0	0.3	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain lower (10000084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain upper (10000087)	24	0.2	0.1	0.3	29	0.3	0.2	0.4	24	0.2	0.1	0.3	34	0.3	0.2	0.4	6	0.2	0.1	0.4	5	0.2	0.1	0.4	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Abnormal faeces (10000133)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acid peptic disease (10075494)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aerophagia (10052813)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal fissure (10002153)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal haemorrhage (10049555)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal inflammation (10050247)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal pruritus (10068172)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aphthous stomatitis (10002958)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aptyalism (10003068)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Change of bowel habit (10008399)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chapped lips (10049047)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cheilitis (10008417)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic gastritis (10008882)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coeliac disease (10009839)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis (10009887)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis ulcerative (10009900)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Constipation (10010774)	10	0.1	0.0	0.2	13	0.1	0.1	0.2	18	0.2	0.1	0.2	13	0.1	0.1	0.2	6	0.2	0.1	0.4	7	0.2	0.1	0.5	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Crohn's disease (10011401)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental caries (10012318)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental necrosis (10012327)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea (10012735)	56	0.5	0.4	0.6	41	0.4	0.3	0.5	52	0.4	0.3	0.6	55	0.5	0.3	0.6	18	0.6	0.4	0.9	14	0.5	0.3	0.8	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Diverticulum (10013554)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Diverticulum intestinal (10013559)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry mouth (10013781)	6	0.1	0.0	0.1	1	0.0	0.0	0.0	8	0.1	0.0	0.1	10	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Duodenal ulcer (10013836)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspepsia (10013946)	14	0.1	0.1	0.2	11	0.1	0.0	0.2	16	0.1	0.1	0.2	17	0.1	0.1	0.2	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphagia (10013950)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enteritis (10014866)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enterovesical fistula (10062570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epigastric discomfort (10053155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eructation (10015137)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Faeces discoloured (10016100)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flatulence (10016766)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Food poisoning (10016952)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Functional gastrointestinal disorder (10071275)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric disorder (10056819)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric ulcer (10017822)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis (10017853)	10	0.1	0.0	0.2	7	0.1	0.0	0.1	17	0.1	0.1	0.2	12	0.1	0.1	0.2	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis erosive (10017865)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroduodenitis (10048714)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal angiodysplasia (10017928)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal disorder (10017944)	6	0.1	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal haemorrhage (10017955)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal pain (10017999)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal sounds abnormal (10067715)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroesophageal reflux disease (10017885)	7	0.1	0.0	0.1	8	0.1	0.0	0.1	11	0.1	0.0	0.2	10	0.1	0.0	0.2	2	0.1	0.0	0.2	3	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Gastroesophageal sphincter insufficiency (10062879)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival bleeding (10018276)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival pain (10018286)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Gingival swelling (10018291)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossitis (10018386)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossodynia (10018388)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematochezia (10018836)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoidal haemorrhage (10054787)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoids (10019022)	3	0.0	0.0	0.1	9	0.1	0.0	0.2	11	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hiatus hernia (10020028)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperchlorhydria (10020601)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia oral (10057371)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ileus (10021328)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infrequent bowel movements (10059158)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inguinal hernia (10022016)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal cyst (10062023)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal perforation (10022694)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal polyp (10048616)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Irritable bowel syndrome (10023003)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Large intestine polyp (10051589)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip blister (10049307)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip disorder (10048470)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip dry (10024552)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip pain (10024561)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip swelling (10024570)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip ulceration (10024572)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loose tooth (10065612)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Melanosis coli (10027158)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth haemorrhage (10028024)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth swelling (10075203)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth ulceration (10028034)	7	0.1	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	3	0.1	0.0	0.3	4	0.1	0.0	0.4	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Nausea (10028813)	103	0.9	0.7	1.1	30	0.3	0.2	0.4	78	0.7	0.5	0.8	33	0.3	0.2	0.4	21	0.7	0.4	1.1	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Noninfective gingivitis (10074863)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Odynophagia (10030094)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal discomfort (10053634)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal spasm (10030184)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophagitis (10030216)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral disorder (10067621)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral mucosal blistering (10030995)	6	0.1	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral pain (10031009)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Pancreatic steatosis (10072787)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatitis (10033645)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatitis acute (10033647)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraesthesia oral (10057372)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peptic ulcer (10034341)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periodontal disease (10034536)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal polyp (10038074)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal prolapse (10038077)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retching (10038776)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retroperitoneal haemorrhage (10038980)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary gland calculus (10039394)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary gland cyst (10052248)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary hypersecretion (10039424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sensitivity of teeth (10040012)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stomatitis (10042128)	1	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swollen tongue (10042727)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue blistering (10043942)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue coated (10043945)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue disorder (10043951)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue pruritus (10070072)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Tongue ulceration (10043991)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth deposit (10044029)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth disorder (10044034)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth erosion (10044038)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth impacted (10044042)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toothache (10044055)	23	0.2	0.1	0.3	25	0.2	0.1	0.3	13	0.1	0.1	0.2	21	0.2	0.1	0.3	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Umbilical hernia (10045458)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper gastrointestinal haemorrhage (10046274)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vomiting (10047700)	26	0.2	0.1	0.3	10	0.1	0.0	0.2	19	0.2	0.1	0.3	19	0.2	0.1	0.2	9	0.3	0.1	0.6	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	3231	28.5	27.6	29.3	323	2.9	2.6	3.2	2713	23.0	22.2	23.7	392	3.2	2.9	3.5	601	19.9	18.5	21.3	92	3.3	2.6	4.0	21	18.6	11.9	27.0	7	5.2	2.1	10.4
	Administration site erythema (10074796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Administration site pain (10058049)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Administration site reaction (10001315)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adverse drug reaction (10061623)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthenia (10003549)	41	0.4	0.3	0.5	6	0.1	0.0	0.1	28	0.2	0.2	0.3	13	0.1	0.1	0.2	9	0.3	0.1	0.6	3	0.1	0.0	0.3	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Axillary pain (10048750)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest discomfort (10008469)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.1	2	0.0	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest pain (10008479)	11	0.1	0.0	0.2	10	0.1	0.0	0.2	19	0.2	0.1	0.3	11	0.1	0.0	0.2	3	0.1	0.0	0.3	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chills (10008531)	298	2.6	2.3	2.9	16	0.1	0.1	0.2	216	1.8	1.6	2.1	14	0.1	0.1	0.2	41	1.4	1.0	1.8	2	0.1	0.0	0.3	4	3.5	1.0	8.8	0	0.0	0.0	2.7
	Cyst (10011732)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Device breakage (10012575)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Discomfort (10013082)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Face oedema (10016029)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial pain (10016059)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fatigue (10016256)	296	2.6	2.3	2.9	47	0.4	0.3	0.6	211	1.8	1.6	2.0	75	0.6	0.5	0.8	41	1.4	1.0	1.8	8	0.3	0.1	0.6	2	1.8	0.2	6.2	1	0.7	0.0	4.1
	Feeling abnormal (10016322)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling cold (10016326)	30	0.3	0.2	0.4	4	0.0	0.0	0.1	20	0.2	0.1	0.3	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling hot (10016334)	29	0.3	0.2	0.4	2	0.0	0.0	0.1	16	0.1	0.1	0.2	7	0.1	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling jittery (10016338)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling of body temperature change (10061458)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gait disturbance (10017577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	General physical health deterioration (10049438)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ill-defined disorder (10061520)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Implant site hypersensitivity (10063858)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Induration (10060708)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inflammation (10061218)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza like illness (10022004)	76	0.7	0.5	0.8	21	0.2	0.1	0.3	42	0.4	0.3	0.5	20	0.2	0.1	0.3	10	0.3	0.2	0.6	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site atrophy (10022048)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site bruising (10022052)	19	0.2	0.1	0.3	17	0.2	0.1	0.2	16	0.1	0.1	0.2	15	0.1	0.1	0.2	2	0.1	0.0	0.2	3	0.1	0.0	0.3	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Injection site coldness (10050082)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site discolouration (10051572)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site discomfort (10054266)	10	0.1	0.0	0.2	2	0.0	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.0	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site eczema (10066221)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site erythema (10022061)	812	7.2	6.7	7.6	14	0.1	0.1	0.2	697	5.9	5.5	6.3	23	0.2	0.1	0.3	138	4.6	3.8	5.4	1	0.0	0.0	0.2	4	3.5	1.0	8.8	0	0.0	0.0	2.7
	Injection site haematoma (10022066)	9	0.1	0.0	0.2	7	0.1	0.0	0.1	4	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site haemorrhage (10022067)	5	0.0	0.0	0.1	6	0.1	0.0	0.1	6	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hyperaesthesia (10073418)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypersensitivity (10022071)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypoaesthesia (10074586)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site induration (10022075)	23	0.2	0.1	0.3	2	0.0	0.0	0.1	29	0.2	0.2	0.4	2	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site inflammation (10022078)	21	0.2	0.1	0.3	0	0.0	0.0	0.0	22	0.2	0.1	0.3	1	0.0	0.0	0.0	9	0.3	0.1	0.6	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site injury (10066083)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site irritation (10022079)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site joint pain (10049261)	25	0.2	0.1	0.3	1	0.0	0.0	0.0	22	0.2	0.1	0.3	3	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site lymphadenopathy (10057665)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site macule (10067255)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site mass (10022081)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site movement impairment (10056250)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site nodule (10057880)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site oedema (10022085)	14	0.1	0.1	0.2	0	0.0	0.0	0.0	21	0.2	0.1	0.3	0	0.0	0.0	0.0	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pain (10022086)	2123	18.7	18.0	19.4	105	0.9	0.8	1.1	1851	15.7	15.0	16.3	118	1.0	0.8	1.2	398	13.2	12.0	14.4	34	1.2	0.8	1.7	12	10.6	5.6	17.8	3	2.2	0.5	6.4
	Injection site papule (10066044)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site paraesthesia (10022088)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pruritus (10022093)	170	1.5	1.3	1.7	13	0.1	0.1	0.2	135	1.1	1.0	1.4	17	0.1	0.1	0.2	39	1.3	0.9	1.8	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site rash (10022094)	32	0.3	0.2	0.4	1	0.0	0.0	0.0	24	0.2	0.1	0.3	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site reaction (10022095)	30	0.3	0.2	0.4	4	0.0	0.0	0.1	30	0.3	0.2	0.4	7	0.1	0.0	0.1	4	0.1	0.0	0.3	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Injection site swelling (10053425)	585	5.2	4.8	5.6	8	0.1	0.0	0.1	489	4.1	3.8	4.5	8	0.1	0.0	0.1	112	3.7	3.1	4.4	6	0.2	0.1	0.5	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Injection site ulcer (10022105)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site urticaria (10022107)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	6	0.1	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site vesicles (10022111)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site warmth (10022112)	68	0.6	0.5	0.8	0	0.0	0.0	0.0	75	0.6	0.5	0.8	4	0.0	0.0	0.1	14	0.5	0.3	0.8	0	0.0	0.0	0.1	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Injury associated with device (10069803)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Local swelling (10024770)	5	0.0	0.0	0.1	8	0.1	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malaise (10025482)	126	1.1	0.9	1.3	19	0.2	0.1	0.3	99	0.8	0.7	1.0	16	0.1	0.1	0.2	21	0.7	0.4	1.1	3	0.1	0.0	0.3	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Metaplasia (10054949)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mucous membrane disorder (10028133)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Nodule (10054107)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-cardiac chest pain (10062501)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema (10030095)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema peripheral (10030124)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	6	0.0	0.0	0.1	3	0.1	0.0	0.3	7	0.2	0.1	0.5	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pain (10033371)	113	1.0	0.8	1.2	10	0.1	0.0	0.2	76	0.6	0.5	0.8	18	0.1	0.1	0.2	20	0.7	0.4	1.0	4	0.1	0.0	0.4	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Peripheral swelling (10048959)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	5	0.0	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polyp (10061529)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyrexia (10037660)	674	5.9	5.5	6.4	33	0.3	0.2	0.4	406	3.4	3.1	3.8	30	0.2	0.2	0.4	66	2.2	1.7	2.8	5	0.2	0.1	0.4	3	2.7	0.6	7.6	0	0.0	0.0	2.7
	Reactogenicity event (10065109)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sluggishness (10041052)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swelling (10042674)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Temperature intolerance (10057040)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tenderness (10043224)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thirst (10043458)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ulcer haemorrhage (10061577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site coldness (10076157)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site discolouration (10069474)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site erythema (10059079)	16	0.1	0.1	0.2	0	0.0	0.0	0.0	23	0.2	0.1	0.3	2	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site haematoma (10069472)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site inflammation (10068878)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site irritation (10069479)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site pain (10068879)	36	0.3	0.2	0.4	0	0.0	0.0	0.0	29	0.2	0.2	0.4	5	0.0	0.0	0.1	5	0.2	0.1	0.4	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Vaccination site pruritus (10068881)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site reaction (10059080)	7	0.1	0.0	0.1	0	0.0	0.0	0.0	11	0.1	0.0	0.2	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site swelling (10069620)	11	0.1	0.0	0.2	0	0.0	0.0	0.0	9	0.1	0.0	0.1	1	0.0	0.0	0.0	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site warmth (10069624)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Vessel puncture site erythema (10074760)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vessel puncture site pain (10066951)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	7	0.1	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	16	0.1	0.1	0.2	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct stenosis (10051341)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct stone (10004637)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Biliary colic (10004663)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholangitis (10008604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholangitis acute (10008605)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis (10008612)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis acute (10008614)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholelithiasis (10008629)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic hepatitis (10008909)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gallbladder polyp (10049704)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic cirrhosis (10019641)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic cyst (10019646)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic function abnormal (10019670)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic steatosis (10019708)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatotoxicity (10019851)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperbilirubinaemia (10020578)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertransaminaemia (10068237)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Jaundice cholestatic (10023129)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Liver disorder (10024670)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	12	0.1	0.1	0.2	14	0.1	0.1	0.2	15	0.1	0.1	0.2	16	0.1	0.1	0.2	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergy to arthropod sting (10058284)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergy to chemicals (10061626)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergy to plants (10054928)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Amyloidosis (10002022)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Food allergy (10016946)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity (10020751)	6	0.1	0.0	0.1	9	0.1	0.0	0.2	7	0.1	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Milk allergy (10027633)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple allergies (10028164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seasonal allergy (10048908)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	702	6.2	5.8	6.6	694	6.1	5.7	6.6	731	6.2	5.8	6.6	738	6.0	5.6	6.5	200	6.6	5.8	7.6	182	6.5	5.6	7.4	4	3.5	1.0	8.8	7	5.2	2.1	10.4
	Abdominal infection (10056519)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal wall abscess (10000099)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess (10000269)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess limb (10050473)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess oral (10000311)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acarodermatitis (10063409)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute sinusitis (10001076)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute tonsillitis (10001093)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alveolar osteitis (10066995)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arteriosclerotic gangrene (10003222)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthritis bacterial (10053555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthritis infective (10060968)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacteraemia (10003997)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacterial infection (10060945)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacteriuria (10004056)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blastocystis infection (10005092)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body tinea (10005913)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Borrelia infection (10061591)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast abscess (10006171)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchiolitis (10006448)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis (10006451)	24	0.2	0.1	0.3	32	0.3	0.2	0.4	63	0.5	0.4	0.7	42	0.3	0.2	0.5	17	0.6	0.3	0.9	16	0.6	0.3	0.9	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Bronchitis viral (10053160)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchopneumonia (10006469)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Candida infection (10074170)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Carbuncle (10007247)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cellulitis (10007882)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	11	0.1	0.0	0.2	2	0.1	0.0	0.2	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cellulitis orbital (10007918)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervicitis (10008323)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic hepatitis b (10008910)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic sinusitis (10009137)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis (10010741)	7	0.1	0.0	0.1	4	0.0	0.0	0.1	11	0.1	0.0	0.2	19	0.2	0.1	0.2	11	0.4	0.2	0.6	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis viral (10010755)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis (10011781)	14	0.1	0.1	0.2	11	0.1	0.0	0.2	17	0.1	0.1	0.2	16	0.1	0.1	0.2	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dacryocystitis (10011844)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dengue fever (10012310)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatophytosis (10012504)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea infectious (10012742)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diverticulitis (10013538)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear infection (10014011)	6	0.1	0.0	0.1	7	0.1	0.0	0.1	6	0.1	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema infected (10014199)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Encephalomyelitis (10014619)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometritis (10014791)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enteritis infectious (10058839)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epididymitis (10015000)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erysipelas (10015145)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema migrans (10062488)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Escherichia infection (10061126)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye infection (10015929)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid infection (10015988)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Folliculitis (10016936)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fungal infection (10017533)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fungal skin infection (10017543)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Furuncle (10017553)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric infection (10056663)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis (10017888)	18	0.2	0.1	0.3	21	0.2	0.1	0.3	21	0.2	0.1	0.3	15	0.1	0.1	0.2	2	0.1	0.0	0.2	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Gastroenteritis viral (10017918)	7	0.1	0.0	0.1	5	0.0	0.0	0.1	9	0.1	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal fungal infection (10049479)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital candidiasis (10018143)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital herpes (10018150)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital infection (10048461)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingivitis (10018292)	5	0.0	0.0	0.1	7	0.1	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin abscess (10050269)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	H1n1 influenza (10069767)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematoma infection (10051564)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoid infection (10051541)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hand-foot-and-mouth disease (10019113)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Helicobacter infection (10054263)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic infection (10056522)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes simplex (10019948)	18	0.2	0.1	0.3	20	0.2	0.1	0.3	10	0.1	0.0	0.2	7	0.1	0.0	0.1	7	0.2	0.1	0.5	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes virus infection (10019973)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hordeolum (10020377)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Impetigo (10021531)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected bites (10021769)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected cyst (10058015)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected varicose vein (10057258)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infection (10021789)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza (10022000)	31	0.3	0.2	0.4	29	0.3	0.2	0.4	22	0.2	0.1	0.3	27	0.2	0.1	0.3	3	0.1	0.0	0.3	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site cellulitis (10050057)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site infection (10022076)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Kidney infection (10023424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Labyrinthitis (10023567)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngitis (10023874)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Liver abscess (10024652)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lobar pneumonia (10024738)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Localised infection (10024774)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower respiratory tract infection (10024968)	6	0.1	0.0	0.1	6	0.1	0.0	0.1	11	0.1	0.0	0.2	15	0.1	0.1	0.2	15	0.5	0.3	0.8	6	0.2	0.1	0.5	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Lung infection (10061229)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lyme disease (10025169)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mastitis (10026883)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nail bed infection (10061303)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngitis (10028810)	228	2.0	1.8	2.3	264	2.3	2.1	2.6	200	1.7	1.5	1.9	221	1.8	1.6	2.1	42	1.4	1.0	1.9	36	1.3	0.9	1.8	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Neuroborreliosis (10052057)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Omphalitis (10030306)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychomycosis (10030338)	6	0.1	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	10	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ophthalmic herpes simplex (10073938)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral candidiasis (10030963)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral fungal infection (10061324)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral herpes (10067152)	36	0.3	0.2	0.4	22	0.2	0.1	0.3	27	0.2	0.2	0.3	18	0.1	0.1	0.2	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral infection (10048685)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Orchitis (10031064)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal candidiasis (10050346)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteomyelitis (10031252)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis externa (10033072)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	11	0.1	0.0	0.2	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis externa fungal (10052557)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media (10033078)	5	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media acute (10033079)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media chronic (10033081)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parasitic gastroenteritis (10067720)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paronychia (10034016)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Parotitis (10034038)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Perichondritis (10062067)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periodontitis (10034539)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peritonsillar abscess (10034686)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pertussis (10034738)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis (10034835)	22	0.2	0.1	0.3	18	0.2	0.1	0.3	30	0.3	0.2	0.4	32	0.3	0.2	0.4	6	0.2	0.1	0.4	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pharyngitis bacterial (10057869)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngotonsillitis (10049140)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia (10035664)	8	0.1	0.0	0.1	6	0.1	0.0	0.1	15	0.1	0.1	0.2	11	0.1	0.0	0.2	5	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural infection (10067268)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Postoperative wound infection (10036410)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psoas abscess (10056517)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulpitis dental (10037464)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis (10037596)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyuria (10037686)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pustular (10037888)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection (10062352)	17	0.1	0.1	0.2	7	0.1	0.0	0.1	17	0.1	0.1	0.2	9	0.1	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinitis (10038910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis (10039083)	18	0.2	0.1	0.3	23	0.2	0.1	0.3	19	0.2	0.1	0.3	19	0.2	0.1	0.2	6	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinolaryngitis (10057442)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinovirus infection (10061494)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scrotal abscess (10049571)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sepsis (10040047)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinobronchitis (10048979)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinusitis (10040753)	24	0.2	0.1	0.3	26	0.2	0.2	0.3	31	0.3	0.2	0.4	23	0.2	0.1	0.3	5	0.2	0.1	0.4	9	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Skin bacterial infection (10052891)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin candida (10054152)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin infection (10040872)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Staphylococcal infection (10058080)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subcutaneous abscess (10042343)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea capitis (10043866)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea cruris (10043868)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea infection (10060889)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea manuum (10067197)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea pedis (10043873)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea versicolour (10056131)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillitis (10044008)	5	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillitis bacterial (10065235)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth abscess (10044016)	7	0.1	0.0	0.1	8	0.1	0.0	0.1	5	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth infection (10048762)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toxoplasmosis (10044272)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tracheitis (10044302)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tracheobronchitis (10044314)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract infection (10046306)	104	0.9	0.7	1.1	82	0.7	0.6	0.9	95	0.8	0.7	1.0	84	0.7	0.5	0.9	24	0.8	0.5	1.2	15	0.5	0.3	0.9	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Urethritis (10046480)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary tract infection (10046571)	28	0.2	0.2	0.4	37	0.3	0.2	0.5	41	0.3	0.2	0.5	43	0.4	0.3	0.5	18	0.6	0.4	0.9	13	0.5	0.2	0.8	1	0.9	0.0	4.8	2	1.5	0.2	5.2
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urosepsis (10048709)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal infection (10046914)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Varicella (10046980)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral infection (10047461)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	10	0.1	0.0	0.2	6	0.0	0.0	0.1	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral rash (10047476)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral sinusitis (10051513)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound infection (10048038)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	79	0.7	0.6	0.9	98	0.9	0.7	1.1	115	1.0	0.8	1.2	128	1.0	0.9	1.2	43	1.4	1.0	1.9	29	1.0	0.7	1.5	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Accident (10000369)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aneurysm perforation (10075395)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Animal bite (10002515)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ankle fracture (10002544)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aqueous humour leakage (10070497)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthropod bite (10003399)	8	0.1	0.0	0.1	6	0.1	0.0	0.1	14	0.1	0.1	0.2	8	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthropod sting (10003402)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back injury (10003986)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bite (10004966)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone contusion (10066251)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone fissure (10064210)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burns first degree (10006797)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burns second degree (10006802)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cartilage injury (10007710)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest injury (10061386)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Clavicle fracture (10009245)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Compression fracture (10010214)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Concussion (10010254)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contrast media reaction (10010836)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contusion (10050584)	3	0.0	0.0	0.1	8	0.1	0.0	0.1	13	0.1	0.1	0.2	16	0.1	0.1	0.2	8	0.3	0.1	0.5	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Corneal abrasion (10010984)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Craniocerebral injury (10070976)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Crush injury (10061097)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epicondylitis (10014971)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Excoriation (10049796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye injury (10061128)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Face injury (10050392)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial bones fracture (10016042)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fall (10016173)	2	0.0	0.0	0.1	8	0.1	0.0	0.1	10	0.1	0.0	0.2	6	0.0	0.0	0.1	6	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Femoral neck fracture (10016450)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Femur fracture (10016454)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibula fracture (10016667)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foot fracture (10016970)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Forearm fracture (10016997)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body (10070245)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body in eye (10017012)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fractured sacrum (10017308)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hand fracture (10019114)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head injury (10019196)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heat stroke (10019345)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hip fracture (10020100)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Humerus fracture (10020462)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury (10022116)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury corneal (10022120)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint dislocation (10023204)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint injury (10060820)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Kidney contusion (10023413)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laceration (10023572)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament injury (10061223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament rupture (10065433)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament sprain (10024453)	8	0.1	0.0	0.1	12	0.1	0.1	0.2	7	0.1	0.0	0.1	10	0.1	0.0	0.2	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb injury (10061225)	3	0.0	0.0	0.1	8	0.1	0.0	0.1	7	0.1	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip injury (10055082)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower limb fracture (10061599)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lumbar vertebral fracture (10049947)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniscus injury (10072970)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth injury (10049294)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple injuries (10028224)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle injury (10028314)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle rupture (10028331)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle strain (10050031)	6	0.1	0.0	0.1	3	0.0	0.0	0.1	8	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nerve root injury cervical (10029183)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Open fracture (10030527)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Patella fracture (10034122)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pelvic fracture (10061161)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural haematuria (10066225)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural inflammation (10063101)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural pulmonary embolism (10063909)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Procedural pain (10064882)	1	0.0	0.0	0.0	5	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pubis fracture (10070286)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radius fracture (10037802)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rib fracture (10039117)	1	0.0	0.0	0.0	5	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Road traffic accident (10039203)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scratch (10039737)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skeletal injury (10061363)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin abrasion (10064990)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin injury (10061364)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin wound (10072170)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skull fracture (10061365)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue injury (10041291)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal column injury (10069689)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal compression fracture (10041541)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Spinal cord injury (10041552)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal fracture (10041569)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subdural haematoma (10042361)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sunburn (10042496)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon rupture (10043248)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thermal burn (10053615)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thoracic vertebral fracture (10049948)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tibia fracture (10043827)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth fracture (10062544)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toxicity to various agents (10070863)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Traumatic arthropathy (10044502)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Traumatic haematoma (10044522)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ulna fracture (10045375)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper limb fracture (10061394)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination complication (10046861)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound (10052428)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wrist fracture (10048049)	2	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Investigations (10022891)	At least one PT related to the corresponding SOC	73	0.6	0.5	0.8	13	0.1	0.1	0.2	73	0.6	0.5	0.8	13	0.1	0.1	0.2	13	0.4	0.2	0.7	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anticoagulation drug level above therapeutic (10060320)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood alkaline phosphatase increased (10059570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood cholesterol increased (10005425)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood glucose fluctuation (10049803)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood glucose increased (10005557)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood iron decreased (10005619)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood potassium decreased (10005724)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood potassium increased (10005725)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure abnormal (10005728)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure decreased (10005734)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure diastolic increased (10005739)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure increased (10005750)	8	0.1	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood sodium decreased (10005802)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood testosterone decreased (10005814)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blood thyroid stimulating hormone increased (10005833)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood uric acid increased (10005861)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body temperature decreased (10005910)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body temperature increased (10005911)	57	0.5	0.4	0.7	2	0.0	0.0	0.1	53	0.4	0.3	0.6	2	0.0	0.0	0.1	8	0.3	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac murmur (10007586)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Catheterisation cardiac (10007815)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Electrocardiogram abnormal (10014363)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gamma-glutamyltransferase increased (10017693)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Grip strength decreased (10062556)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart rate increased (10019303)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart rate irregular (10019304)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Helicobacter test positive (10070101)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Liver function test abnormal (10024690)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Precancerous cells present (10049673)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Protein urine present (10053123)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Serum ferritin decreased (10040249)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transaminases increased (10054889)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urine analysis abnormal (10062226)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Weight decreased (10047895)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Weight increased (10047899)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	35	0.3	0.2	0.4	24	0.2	0.1	0.3	84	0.7	0.6	0.9	50	0.4	0.3	0.5	27	0.9	0.6	1.3	20	0.7	0.4	1.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Abnormal loss of weight (10000159)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cachexia (10006895)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Decreased appetite (10061428)	10	0.1	0.0	0.2	0	0.0	0.0	0.0	16	0.1	0.1	0.2	3	0.0	0.0	0.1	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dehydration (10012174)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetes mellitus (10012601)	6	0.1	0.0	0.1	4	0.0	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetes mellitus inadequate control (10012607)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyslipidaemia (10058108)	7	0.1	0.0	0.1	3	0.0	0.0	0.1	11	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeding disorder (10061148)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Folate deficiency (10016880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glucose tolerance impaired (10018429)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gout (10018627)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	15	0.1	0.1	0.2	4	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypercalcaemia (10020583)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypercholesterolaemia (10020603)	2	0.0	0.0	0.1	7	0.1	0.0	0.1	10	0.1	0.0	0.2	5	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hyperglycaemia (10020635)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperkalaemia (10020646)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperlipidaemia (10062060)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	7	0.1	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperphagia (10020710)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertriglyceridaemia (10020869)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperuricaemia (10020903)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoglycaemia (10020993)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypokalaemia (10021015)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyponatraemia (10021036)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypovitaminosis (10021135)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iron deficiency (10022970)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lactose intolerance (10023681)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Obesity (10029883)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polydipsia (10036067)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Type 2 diabetes mellitus (10067585)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Vitamin b12 deficiency (10047609)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitamin d deficiency (10047626)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	667	5.9	5.5	6.3	325	2.9	2.6	3.2	611	5.2	4.8	5.6	433	3.5	3.2	3.9	160	5.3	4.5	6.1	114	4.0	3.4	4.8	4	3.5	1.0	8.8	7	5.2	2.1	10.4
	Acquired claw toe (10057689)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthralgia (10003239)	117	1.0	0.9	1.2	72	0.6	0.5	0.8	104	0.9	0.7	1.1	77	0.6	0.5	0.8	22	0.7	0.5	1.1	18	0.6	0.4	1.0	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Arthritis (10003246)	5	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthropathy (10003285)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Axillary mass (10049021)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back pain (10003988)	91	0.8	0.6	1.0	65	0.6	0.4	0.7	78	0.7	0.5	0.8	84	0.7	0.5	0.9	27	0.9	0.6	1.3	30	1.1	0.7	1.5	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Bone disorder (10005956)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone pain (10006002)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone swelling (10053631)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bursitis (10006811)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	7	0.1	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical spinal stenosis (10008313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chondrocalcinosis (10061761)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chondropathy (10061762)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coccydynia (10009829)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Costochondritis (10011219)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dupuytren's contracture (10013872)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Exostosis (10015688)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibromyalgia (10048439)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flank pain (10016750)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foot deformity (10061159)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gouty arthritis (10018634)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin pain (10018735)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iliolumbar syndrome (10063442)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc degeneration (10061246)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc protrusion (10050296)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Jaw cyst (10023146)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint effusion (10023215)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Joint stiffness (10023230)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint swelling (10023232)	5	0.0	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament disorder (10061222)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb discomfort (10061224)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Lumbar spinal stenosis (10025005)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metatarsalgia (10027487)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mobility decreased (10048334)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Monarthrits (10027811)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle contracture (10062575)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle disorder (10028300)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle fatigue (10049565)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle rigidity (10028330)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle spasms (10028334)	10	0.1	0.0	0.2	8	0.1	0.0	0.1	21	0.2	0.1	0.3	12	0.1	0.1	0.2	6	0.2	0.1	0.4	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle tightness (10049816)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle twitching (10028347)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscular weakness (10028372)	5	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal chest pain (10050819)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.1	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal discomfort (10053156)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal pain (10028391)	43	0.4	0.3	0.5	25	0.2	0.1	0.3	44	0.4	0.3	0.5	28	0.2	0.2	0.3	3	0.1	0.0	0.3	9	0.3	0.1	0.6	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Musculoskeletal stiffness (10052904)	14	0.1	0.1	0.2	7	0.1	0.0	0.1	7	0.1	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myalgia (10028411)	291	2.6	2.3	2.9	38	0.3	0.2	0.5	202	1.7	1.5	2.0	53	0.4	0.3	0.6	38	1.3	0.9	1.7	11	0.4	0.2	0.7	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Myofascial pain syndrome (10048780)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neck pain (10028836)	33	0.3	0.2	0.4	14	0.1	0.1	0.2	25	0.2	0.1	0.3	23	0.2	0.1	0.3	4	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Osteitis (10031149)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoarthritis (10031161)	9	0.1	0.0	0.2	20	0.2	0.1	0.3	44	0.4	0.3	0.5	49	0.4	0.3	0.5	17	0.6	0.3	0.9	7	0.2	0.1	0.5	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Osteochondrosis (10031233)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteolysis (10031248)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteonecrosis (10031264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteopenia (10049088)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	6	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoporosis (10031282)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pain in extremity (10033425)	54	0.5	0.4	0.6	45	0.4	0.3	0.5	71	0.6	0.5	0.8	42	0.3	0.2	0.5	27	0.9	0.6	1.3	14	0.5	0.3	0.8	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain in jaw (10033433)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Periarthritis (10034464)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Plantar fasciitis (10035155)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polyarthritis (10036030)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rheumatic disorder (10072736)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rotator cuff syndrome (10039227)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scoliosis (10039722)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue disorder (10061366)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue mass (10071051)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal column stenosis (10041540)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal disorder (10061368)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal osteoarthritis (10041591)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Spinal pain (10072005)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondyloarthropathy (10051265)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondylolisthesis (10063550)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondylolysis (10052013)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovial cyst (10042858)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovitis (10042868)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon disorder (10043239)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon pain (10066371)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendonitis (10043255)	2	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Tenosynovitis (10043261)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tenosynovitis stenosaurs (10056698)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Torticollis (10044074)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigger finger (10044654)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertebral foraminal stenosis (10069690)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	23	0.2	0.1	0.3	20	0.2	0.1	0.3	45	0.4	0.3	0.5	39	0.3	0.2	0.4	4	0.1	0.0	0.3	11	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acrochordon (10000591)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma (10001141)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma of colon (10001167)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenoma benign (10001233)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adrenal adenoma (10001323)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anogenital warts (10059313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Basal cell carcinoma (10004146)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign ear neoplasm (10069051)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign neoplasm of skin (10004398)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct cancer (10004593)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder cancer (10005003)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder neoplasm (10005056)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bowen's disease (10006059)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast cancer (10006187)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervix carcinoma (10008342)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colon adenoma (10048832)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colon cancer (10009944)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysplastic naevus (10062805)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibroma (10016629)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibrous histiocytoma (10053717)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatocellular carcinoma (10073071)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intraductal proliferative breast lesion (10073094)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Invasive ductal breast carcinoma (10073095)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

22-OCT-2019

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CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Large intestine benign neoplasm (10073394)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lipoma (10024612)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung neoplasm malignant (10058467)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant melanoma (10025650)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant melanoma in situ (10025652)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Melanocytic naevus (10027145)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meningioma (10027191)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to liver (10027457)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to lung (10027458)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to lymph nodes (10027459)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to peritoneum (10051676)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngeal neoplasm benign (10028802)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neoplasm malignant (10028997)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neoplasm skin (10029098)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal carcinoma (10030155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pancreatic carcinoma (10033609)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraganglion neoplasm (10061332)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleomorphic adenoma (10073372)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate cancer (10060862)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate cancer recurrent (10036911)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal cancer (10038389)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sarcoma (10039491)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seborrheic keratosis (10039796)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin cancer (10040808)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin papilloma (10040907)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Squamous cell carcinoma (10041823)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Squamous cell carcinoma of skin (10041834)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular neoplasm (10061379)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral neoplasm (10062223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	753	6.6	6.2	7.1	321	2.8	2.5	3.2	560	4.7	4.4	5.1	336	2.8	2.5	3.1	116	3.8	3.2	4.6	80	2.8	2.3	3.5	5	4.4	1.5	10.0	4	3.0	0.8	7.4
	Amnesia (10001949)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aphonia (10002953)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Balance disorder (10049848)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burning sensation (10006784)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carotid artery stenosis (10007687)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cerebral infarction (10008118)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrospinal fluid leakage (10008164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular disorder (10008196)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical myelopathy (10008289)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical radiculopathy (10050217)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	6	0.1	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cognitive disorder (10057668)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Convulsions local (10010920)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cubital tunnel syndrome (10056473)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dementia (10012267)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic neuropathy (10012680)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disturbance in attention (10013496)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness (10013573)	76	0.7	0.5	0.8	34	0.3	0.2	0.4	80	0.7	0.5	0.8	61	0.5	0.4	0.6	25	0.8	0.5	1.2	15	0.5	0.3	0.9	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Dizziness postural (10013578)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysaesthesia (10013886)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysgeusia (10013911)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Encephalopathy (10014625)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epilepsy (10015037)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Essential tremor (10015496)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial spasm (10063006)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head discomfort (10019194)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Headache (10019211)	599	5.3	4.9	5.7	230	2.0	1.8	2.3	381	3.2	2.9	3.6	175	1.4	1.2	1.7	68	2.2	1.8	2.8	33	1.2	0.8	1.6	1	0.9	0.0	4.8	2	1.5	0.2	5.2
	Hemiparesis (10019465)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaesthesia (10020568)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersomnia (10020765)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia (10020937)	6	0.1	0.0	0.1	10	0.1	0.0	0.2	12	0.1	0.1	0.2	7	0.1	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Hypogeusia (10020989)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypotonia (10021118)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Intercostal neuralgia (10049949)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacunar infarction (10051078)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lethargy (10024264)	10	0.1	0.0	0.2	4	0.0	0.0	0.1	12	0.1	0.1	0.2	3	0.0	0.0	0.1	5	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loss of consciousness (10024855)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lumbar radiculopathy (10050219)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Memory impairment (10027175)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metabolic encephalopathy (10062190)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Migraine (10027599)	9	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.1	0.0	0.1	7	0.1	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Mononeuritis (10027910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Motor dysfunction (10061296)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle contractions involuntary (10028293)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nerve compression (10029174)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nervous system disorder (10029202)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuralgia (10029223)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraesthesia (10033775)	13	0.1	0.1	0.2	5	0.0	0.0	0.1	9	0.1	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parkinson's disease (10061536)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parkinsonism (10034010)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Petit mal epilepsy (10034759)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polynuropathy (10036105)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Poor quality sleep (10062519)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presyncope (10036653)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radicular pain (10059604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radiculitis brachial (10037778)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radiculopathy (10037779)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Restless legs syndrome (10058920)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Sciatica (10039674)	6	0.1	0.0	0.1	7	0.1	0.0	0.1	11	0.1	0.0	0.2	21	0.2	0.1	0.3	1	0.0	0.0	0.2	2	0.1	0.0	0.3	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Seizure (10039906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Senile dementia (10039966)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sensory disturbance (10040026)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sensory loss (10040030)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus headache (10040744)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somnolence (10041349)	17	0.1	0.1	0.2	2	0.0	0.0	0.1	19	0.2	0.1	0.3	6	0.0	0.0	0.1	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal claudication (10041539)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stupor (10042264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subarachnoid haemorrhage (10042316)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Syncope (10042772)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tension headache (10043269)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thalamic infarction (10064961)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transient global amnesia (10044380)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transient ischaemic attack (10044390)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tremor (10044565)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigeminal neuralgia (10044652)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual field defect (10047555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	71	0.6	0.5	0.8	33	0.3	0.2	0.4	71	0.6	0.5	0.8	48	0.4	0.3	0.5	25	0.8	0.5	1.2	19	0.7	0.4	1.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Abnormal dreams (10000125)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute stress disorder (10001084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Affective disorder (10001443)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Agitation (10001497)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Agoraphobia (10001502)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Alcohol withdrawal syndrome (10053164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alcoholism (10001639)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anxiety (10002855)	13	0.1	0.1	0.2	3	0.0	0.0	0.1	8	0.1	0.0	0.1	11	0.1	0.0	0.2	4	0.1	0.0	0.3	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anxiety disorder (10057666)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aversion (10063659)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Confusional state (10010305)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depressed mood (10012374)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Depression (10012378)	4	0.0	0.0	0.1	7	0.1	0.0	0.1	9	0.1	0.0	0.1	11	0.1	0.0	0.2	4	0.1	0.0	0.3	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depressive symptom (10054089)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disorientation (10013395)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphemia (10054964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphoria (10013954)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysthymic disorder (10013982)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Emotional disorder (10014551)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Emotional distress (10049119)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hallucination (10019063)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hallucination, visual (10019075)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Insomnia (10022437)	34	0.3	0.2	0.4	20	0.2	0.1	0.3	30	0.3	0.2	0.4	14	0.1	0.1	0.2	9	0.3	0.1	0.6	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Irritability (10022998)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Libido decreased (10024419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Listless (10024642)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Major depression (10057840)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mental status changes (10048294)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Middle insomnia (10027590)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nervousness (10029216)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nightmare (10029412)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Obsessive thoughts (10029897)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Panic attack (10033664)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psychosomatic disease (10049587)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psychotic disorder (10061920)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Restlessness (10038743)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Schizophrenia, paranoid type (10039639)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sleep disorder (10040984)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somatoform disorder (10054153)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stress (10042209)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tension (10043268)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tic (10043833)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	24	0.2	0.1	0.3	8	0.1	0.0	0.1	27	0.2	0.2	0.3	22	0.2	0.1	0.3	16	0.5	0.3	0.9	10	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute kidney injury (10069339)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder pain (10005063)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder spasm (10048994)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Calculus bladder (10006987)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Calculus ureteric (10007025)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chromaturia (10008796)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic kidney disease (10064848)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis interstitial (10011796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysuria (10013990)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematuria (10018867)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertonic bladder (10020853)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Incontinence (10021639)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Micturition disorder (10027561)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Micturition urgency (10027566)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephritis (10029117)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephrolithiasis (10029148)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephropathy (10029151)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neurogenic bladder (10029279)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nocturia (10029446)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pollakiuria (10036018)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polyuria (10036142)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal colic (10038419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal cyst (10038423)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal failure (10038435)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal impairment (10062237)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal pain (10038490)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tubulointerstitial nephritis (10048302)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral polyp (10051507)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral stenosis (10065584)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urge incontinence (10046494)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary hesitation (10046542)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary incontinence (10046543)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary retention (10046555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Urinary tract disorder (10046566)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urine odour abnormal (10057135)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	19	0.2	0.1	0.3	24	0.2	0.1	0.3	26	0.2	0.1	0.3	26	0.2	0.1	0.3	5	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrophic vulvovaginitis (10003693)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Balanoposthitis (10004078)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign prostatic hyperplasia (10004446)	0	0.0	0.0	0.0	8	0.1	0.0	0.1	8	0.1	0.0	0.1	8	0.1	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast cyst (10006220)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast discomfort (10049872)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast enlargement (10006242)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast mass (10006272)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast pain (10006298)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast swelling (10006312)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast tenderness (10006313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical cyst (10008254)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical polyp (10008297)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystocele (10011803)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysfunctional uterine bleeding (10013908)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysmenorrhoea (10013935)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometrial hyperplasia (10014755)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erectile dysfunction (10061461)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital discomfort (10066887)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital tract inflammation (10058821)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital ulceration (10018180)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Male sexual dysfunction (10057672)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Menopausal symptoms (10027304)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Menorrhagia (10027313)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Nipple disorder (10029417)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Organic erectile dysfunction (10052004)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pelvic pain (10034263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Penile pain (10034310)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Postmenopausal haemorrhage (10055870)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate induration (10057263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatic disorder (10036956)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatism (10036976)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatitis (10036978)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatomegaly (10051482)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus genital (10037093)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectocele (10038084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scrotal cyst (10065670)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scrotal swelling (10039759)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular mass (10058901)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular pain (10043345)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testis discomfort (10052531)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine prolapse (10046814)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal erosion (10062558)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal haemorrhage (10046910)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal inflammation (10046916)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal dryness (10047791)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal pruritus (10056530)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	209	1.8	1.6	2.1	176	1.6	1.3	1.8	204	1.7	1.5	2.0	237	1.9	1.7	2.2	53	1.8	1.3	2.3	66	2.3	1.8	3.0	2	1.8	0.2	6.2	2	1.5	0.2	5.2
	Asthma (10003553)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	10	0.1	0.0	0.2	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atelectasis (10003598)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchial irritation (10006438)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchiectasis (10006445)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis chronic (10006458)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Bronchospasm (10006482)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Catarrh (10007774)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Chronic obstructive pulmonary disease (10009033)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	6	0.0	0.0	0.1	7	0.2	0.1	0.5	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cough (10011224)	73	0.6	0.5	0.8	65	0.6	0.4	0.7	89	0.8	0.6	0.9	100	0.8	0.7	1.0	18	0.6	0.4	0.9	23	0.8	0.5	1.2	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Dry throat (10013789)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphonia (10013952)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	6	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspnoea (10013968)	7	0.1	0.0	0.1	3	0.0	0.0	0.1	9	0.1	0.0	0.1	11	0.1	0.0	0.2	3	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspnoea exertional (10013971)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Emphysema (10014561)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epistaxis (10015090)	7	0.1	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemoptysis (10018964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemothorax (10019027)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Increased upper airway secretion (10062717)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Increased viscosity of bronchial secretion (10054761)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngeal oedema (10023845)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngitis allergic (10064866)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower respiratory tract congestion (10075565)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung disorder (10025082)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung infiltration (10025102)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal congestion (10028735)	6	0.1	0.0	0.1	13	0.1	0.1	0.2	11	0.1	0.0	0.2	8	0.1	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal discomfort (10052437)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal disorder (10062209)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal dryness (10028740)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal obstruction (10028748)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal polyps (10028756)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal pruritus (10076406)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal septum deviation (10028762)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal discomfort (10068318)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal pain (10068319)	83	0.7	0.6	0.9	67	0.6	0.5	0.8	55	0.5	0.4	0.6	58	0.5	0.4	0.6	4	0.1	0.0	0.3	12	0.4	0.2	0.7	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Paranasal sinus discomfort (10052438)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngeal erythema (10057009)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pleural adhesion (10035588)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleural effusion (10035598)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleurisy (10035618)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleuritic pain (10035623)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumothorax (10035759)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Productive cough (10036790)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary bulla (10051688)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary embolism (10037377)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary mass (10056342)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rales (10037833)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory disorder (10038683)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory failure (10038695)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract congestion (10052251)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinalgia (10051496)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis allergic (10039085)	5	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.2	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis hypertrophic (10059235)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinorrhoea (10039101)	21	0.2	0.1	0.3	12	0.1	0.1	0.2	17	0.1	0.1	0.2	14	0.1	0.1	0.2	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus congestion (10040742)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus disorder (10062244)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sleep apnoea syndrome (10040979)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sneezing (10041232)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	6	0.1	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Snoring (10041235)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sputum discoloured (10041807)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sputum increased (10041812)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Throat irritation (10043521)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Throat tightness (10043528)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillar disorder (10053477)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract inflammation (10049590)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper-airway cough syndrome (10070488)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vasomotor rhinitis (10047145)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Skin and subcutaneous tissue disorders (10040785)	Vocal cord thickening (10047676)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wheezing (10047924)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	211	1.9	1.6	2.1	181	1.6	1.4	1.9	230	1.9	1.7	2.2	244	2.0	1.8	2.3	76	2.5	2.0	3.1	51	1.8	1.4	2.4	2	1.8	0.2	6.2	4	3.0	0.8	7.4
	Acne (10000496)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Actinic keratosis (10000614)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Alopecia (10001760)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alopecia areata (10001761)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angioedema (10002424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blister (10005191)	6	0.1	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cold sweat (10009866)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Decubitus ulcer (10011985)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermal cyst (10012426)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Dermatitis (10012431)	5	0.0	0.0	0.1	5	0.0	0.0	0.1	4	0.0	0.0	0.1	13	0.1	0.1	0.2	5	0.2	0.1	0.4	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Dermatitis allergic (10012434)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis atopic (10012438)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Dermatitis contact (10012442)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	8	0.1	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatosis (10048768)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic foot (10060734)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Drug eruption (10013687)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry skin (10013786)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyshidrotic eczema (10013913)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ecchymosis (10014080)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema (10014184)	14	0.1	0.1	0.2	24	0.2	0.1	0.3	27	0.2	0.2	0.3	25	0.2	0.1	0.3	8	0.3	0.1	0.5	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema asteatotic (10014190)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema (10015150)	22	0.2	0.1	0.3	7	0.1	0.0	0.1	20	0.2	0.1	0.3	15	0.1	0.1	0.2	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema nodosum (10015226)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hand dermatitis (10058898)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperhidrosis (10020642)	16	0.1	0.1	0.2	4	0.0	0.0	0.1	10	0.1	0.0	0.2	8	0.1	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperkeratosis (10020649)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypohidrosis (10021013)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Idiopathic urticaria (10021247)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ingrowing nail (10022013)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lichen planus (10024429)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lichen sclerosus (10024434)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Miliaria (10027627)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nail growth abnormal (10064764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neurodermatitis (10029263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Night sweats (10029410)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychalgia (10064251)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychoclasia (10048886)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onycholysis (10030337)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychomadesis (10049274)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain of skin (10033474)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Papule (10033733)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Petechiae (10034754)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pityriasis rosea (10035114)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Precancerous skin lesion (10049422)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prurigo (10037083)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus (10037087)	37	0.3	0.2	0.4	35	0.3	0.2	0.4	45	0.4	0.3	0.5	58	0.5	0.4	0.6	23	0.8	0.5	1.1	13	0.5	0.2	0.8	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pruritus generalised (10052576)	4	0.0	0.0	0.1	8	0.1	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psoriasis (10037153)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash (10037844)	46	0.4	0.3	0.5	42	0.4	0.3	0.5	42	0.4	0.3	0.5	66	0.5	0.4	0.7	19	0.6	0.4	1.0	9	0.3	0.1	0.6	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Rash erythematous (10037855)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash generalised (10037858)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash macular (10037867)	3	0.0	0.0	0.1	7	0.1	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash maculo-papular (10037868)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash papular (10037876)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pruritic (10037884)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	9	0.1	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rosacea (10039218)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seborrhoea (10039792)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seborrhoeic dermatitis (10039793)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Senile pruritus (10039986)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin burning sensation (10054786)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin discolouration (10040829)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin disorder (10040831)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin exfoliation (10040844)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin fissures (10040849)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin irritation (10040880)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin lesion (10040882)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin necrosis (10040893)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin plaque (10067723)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin striae (10040925)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin swelling (10053262)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin ulcer (10040943)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin warm (10040952)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Solar dermatitis (10041303)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stasis dermatitis (10041955)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urticaria (10046735)	11	0.1	0.0	0.2	6	0.1	0.0	0.1	9	0.1	0.0	0.1	13	0.1	0.1	0.2	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Xeroderma (10048218)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Social circumstances (10041244)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Occupational physical problem (10030026)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	3	0.0	0.0	0.1	8	0.1	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal operation (10061609)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac pacemaker replacement (10049434)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract operation (10063797)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary arterial stent insertion (10052086)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental implantation (10064143)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endodontic procedure (10051085)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hip arthroplasty (10020096)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniscus operation (10054948)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth cyst excision (10052179)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Rectal polypectomy (10038075)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Shoulder operation (10062242)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin lesion excision (10062250)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin neoplasm excision (10059443)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth extraction (10062132)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Umbilical hernia repair (10045462)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vasectomy (10047133)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	49	0.4	0.3	0.6	45	0.4	0.3	0.5	86	0.7	0.6	0.9	81	0.7	0.5	0.8	23	0.8	0.5	1.1	37	1.3	0.9	1.8	1	0.9	0.0	4.8	3	2.2	0.5	6.4
Vascular disorders (10047065)	Angiopathy (10059245)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic aneurysm (10002882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic stenosis (10002906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arteriosclerosis (10003210)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Behcet's syndrome (10004213)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure fluctuation (10005746)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure inadequately controlled (10051128)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deep vein thrombosis (10051055)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Essential hypertension (10015488)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flushing (10016825)	8	0.1	0.0	0.1	0	0.0	0.0	0.0	8	0.1	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematoma (10018852)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhage (10055798)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hot flush (10060800)	5	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaemia (10020565)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertension (10020772)	27	0.2	0.2	0.3	30	0.3	0.2	0.4	37	0.3	0.2	0.4	47	0.4	0.3	0.5	8	0.3	0.1	0.5	20	0.7	0.4	1.1	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Hypertensive crisis (10020802)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hypotension (10021097)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	8	0.1	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intra-abdominal haematoma (10056457)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ischaemia (10061255)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Labile blood pressure (10023533)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphoedema (10025282)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Orthostatic hypotension (10031127)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral arterial occlusive disease (10062585)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Peripheral artery stenosis (10072563)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral coldness (10034568)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral vascular disorder (10034636)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral venous disease (10075049)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Phlebitis (10034879)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Raynaud's phenomenon (10037912)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Temporal arteritis (10043207)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombophlebitis (10043570)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombophlebitis superficial (10043595)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombosis (10043607)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Varicose vein (10046996)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular pain (10047095)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vasculitis (10047115)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Venous thrombosis (10047249)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of administered doses

n/% = number/percentage of doses with the symptom

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

22-OCT-2019

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Table 14.3.1.22 Global Summary of unsolicited signs and symptoms reported within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	2984	1696	3019	2034	754	520	23	22	6780	4272
Number of doses followed by at least one unsolicited symptom	4439	1996	4233	2443	1033	624	36	26	9741	5089
Number of unsolicited symptoms classified by MedDRA Preferred Term*	9476	2898	8425	3651	2019	980	65	43	19985	7572
Number of unsolicited symptoms reported**	9674	3023	8573	3772	2046	1005	66	46	20359	7846

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.23 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

Primary System Organ Class (CODE)	Non-Frail								Pre-Frail								Frail								Unknown							
	HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom	429	7.4	6.8	8.1	182	3.2	2.7	3.7	429	7.1	6.4	7.7	242	3.9	3.4	4.4	134	8.5	7.2	10.0	80	5.5	4.4	6.8	5	8.5	2.8	18.7	5	6.9	2.3	15.5
Blood and lymphatic system disorders (10005329)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	4	0.1	0.0	0.2	9	0.2	0.1	0.3	9	0.1	0.1	0.3	9	0.1	0.1	0.3	4	0.3	0.1	0.6	12	0.8	0.4	1.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	39	0.7	0.5	0.9	22	0.4	0.2	0.6	37	0.6	0.4	0.8	24	0.4	0.2	0.6	14	0.9	0.5	1.5	13	0.9	0.5	1.5	0	0.0	0.0	6.1	1	1.4	0.0	7.5
General disorders and administration site conditions (10018065)	226	3.9	3.4	4.4	18	0.3	0.2	0.5	177	2.9	2.5	3.4	25	0.4	0.3	0.6	54	3.4	2.6	4.5	6	0.4	0.2	0.9	2	3.4	0.4	11.7	1	1.4	0.0	7.5
Hepatobiliary disorders (10019805)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	82	1.4	1.1	1.8	68	1.2	0.9	1.5	71	1.2	0.9	1.5	61	1.0	0.8	1.3	25	1.6	1.0	2.3	11	0.8	0.4	1.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
Injury, poisoning and procedural complications (10022117)	21	0.4	0.2	0.6	25	0.4	0.3	0.6	22	0.4	0.2	0.5	21	0.3	0.2	0.5	7	0.4	0.2	0.9	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Investigations (10022891)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Metabolism and nutrition disorders (10027433)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	11	0.2	0.1	0.3	5	0.1	0.0	0.2	6	0.4	0.1	0.8	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Musculoskeletal and connective tissue disorders (10028395)	60	1.0	0.8	1.3	25	0.4	0.3	0.6	78	1.3	1.0	1.6	47	0.8	0.6	1.0	24	1.5	1.0	2.3	15	1.0	0.6	1.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	9	0.2	0.1	0.3	5	0.1	0.0	0.2	15	0.2	0.1	0.4	12	0.2	0.1	0.3	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Nervous system disorders (10029205)	65	1.1	0.9	1.4	15	0.3	0.1	0.4	73	1.2	0.9	1.5	37	0.6	0.4	0.8	20	1.3	0.8	2.0	11	0.8	0.4	1.3	2	3.4	0.4	11.7	0	0.0	0.0	5.0
Psychiatric disorders (10037175)	12	0.2	0.1	0.4	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Renal and urinary disorders (10038359)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Reproductive system and breast disorders (10038604)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Respiratory, thoracic and mediastinal disorders (10038738)	17	0.3	0.2	0.5	4	0.1	0.0	0.2	11	0.2	0.1	0.3	19	0.3	0.2	0.5	4	0.3	0.1	0.6	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Skin and subcutaneous tissue disorders (10040785)	10	0.2	0.1	0.3	7	0.1	0.0	0.3	12	0.2	0.1	0.3	4	0.1	0.0	0.2	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	2	2.8	0.3	9.7

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Primary System Organ Class)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.24 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		429	7.4	6.8	8.1	182	3.2	2.7	3.7	429	7.1	6.4	7.7	242	3.9	3.4	4.4
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Lymphadenopathy (10025197)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	9	0.2	0.1	0.3	9	0.1	0.1	0.3	4	0.3	0.1	0.6
	Acute coronary syndrome (10051592)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Acute myocardial infarction (10000891)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Angina pectoris (10002383)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Angina unstable (10002388)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Aortic valve stenosis (10002918)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Arrhythmia (10003119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Atrial fibrillation (10003658)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Atrioventricular block complete (10003673)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bradycardia (10006093)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cardiac failure (10007554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cardiac failure congestive (10007559)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cor pulmonale (10010968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Coronary artery disease (10011078)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Myocardial infarction (10028596)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Myocardial ischaemia (10028600)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Palpitations (10033557)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5
	Supraventricular tachycardia (10042604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Tachyarrhythmia (10049447)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Tachycardia (10043071)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5
	Deafness neurosensory (10011891)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Ear pain (10014020)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hypoaacusis (10048865)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Tinnitus (10043882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vertigo (10047340)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Eye disorders (10015919)	Vertigo positional (10047348)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6
	Cataract (10007739)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Conjunctival haemorrhage (10010719)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Diplopia (10013036)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Eye disorder (10015916)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Eye pain (10015958)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Eye pruritus (10052140)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Foreign body sensation in eyes (10051116)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Keratitis (10023332)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Ocular hyperaemia (10030041)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Retinal detachment (10038848)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Visual acuity reduced (10047531)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Visual impairment (10047571)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	39	0.7	0.5	0.9	22	0.4	0.2	0.6	37	0.6	0.4	0.8	24	0.4	0.2	0.6
	Abdominal hernia (10060954)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Abdominal pain (10000081)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5
	Abdominal pain lower (10000084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Abdominal pain upper (10000087)	2	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anal inflammation (10050247)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Constipation (10010774)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Diarrhoea (10012735)	7	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	8	0.1	0.1	0.3
	Dry mouth (10013781)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Duodenal ulcer (10013836)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Dyspepsia (10013946)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Enterovesical fistula (10062570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Epigastric discomfort (10053155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Fatulence (10016766)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Food poisoning (10016952)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Gastric ulcer (10017822)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Gastritis (10017853)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Gastrointestinal haemorrhage (10017955)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.3
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Glossitis (10018386)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Haemorrhoids (10019022)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hiatus hernia (10020028)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Ileus (10021328)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Inguinal hernia (10022016)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1
	Intestinal perforation (10022694)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lip pain (10024561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lip swelling (10024570)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Mouth ulceration (10028034)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Nausea (10028813)	10	0.2	0.1	0.3	1	0.0	0.0	0.1	10	0.2	0.1	0.3	3	0.0	0.0	0.1
	Odynophagia (10030094)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Oesophageal spasm (10030184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oesophagitis (10030216)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pancreatitis (10033645)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pancreatitis acute (10033647)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Periodontal disease (10034536)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Retroperitoneal haemorrhage (10038980)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Swollen tongue (10042727)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Tongue coated (10043945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Tongue ulceration (10043991)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Toothache (10044055)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Vomiting (10047700)	8	0.1	0.1	0.3	3	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	226	3.9	3.4	4.4	18	0.3	0.2	0.5	177	2.9	2.5	3.4	25	0.4	0.3	0.6
	Asthenia (10003549)	9	0.2	0.1	0.3	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1
	Chest discomfort (10008469)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Chest pain (10008479)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1
	Chills (10008531)	41	0.7	0.5	1.0	0	0.0	0.0	0.1	30	0.5	0.3	0.7	2	0.0	0.0	0.1
	Face oedema (10016029)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Fatigue (10016256)	29	0.5	0.3	0.7	0	0.0	0.0	0.1	24	0.4	0.3	0.6	6	0.1	0.0	0.2
	Feeling abnormal (10016322)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Feeling cold (10016326)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Feeling hot (10016334)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Gait disturbance (10017577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Inflammation (10061218)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Influenza like illness (10022004)	12	0.2	0.1	0.4	1	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.0	0.0	0.1
	Injection site bruising (10022052)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Injection site erythema (10022061)	21	0.4	0.2	0.6	0	0.0	0.0	0.1	23	0.4	0.2	0.6	0	0.0	0.0	0.1
	Injection site haemorrhage (10022067)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site hypersensitivity (10022071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site hypoaesthesia (10074586)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site induration (10022075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site inflammation (10022078)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site joint pain (10049261)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site movement impairment (10056250)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site nodule (10057880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site oedema (10022085)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site pain (10022086)	80	1.4	1.1	1.7	2	0.0	0.0	0.1	74	1.2	1.0	1.5	2	0.0	0.0	0.1
	Injection site paraesthesia (10022088)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site pruritus (10022093)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6
	Injection site reaction (10022095)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injection site swelling (10053425)	16	0.3	0.2	0.4	0	0.0	0.0	0.1	16	0.3	0.2	0.4	0	0.0	0.0	0.1
	Injection site warmth (10022112)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Injury associated with device (10069803)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Local swelling (10024770)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Malaise (10025482)	11	0.2	0.1	0.3	3	0.1	0.0	0.2	7	0.1	0.0	0.2	0	0.0	0.0	0.1
	Non-cardiac chest pain (10062501)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Oedema peripheral (10030124)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pain (10033371)	14	0.2	0.1	0.4	1	0.0	0.0	0.1	9	0.1	0.1	0.3	1	0.0	0.0	0.1
	Peripheral swelling (10048959)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pyrexia (10037660)	82	1.4	1.1	1.8	6	0.1	0.0	0.2	38	0.6	0.4	0.9	3	0.0	0.0	0.1
	Reactogenicity event (10065109)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vaccination site erythema (10059079)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vaccination site pain (10068879)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vaccination site pruritus (10068881)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bile duct stenosis (10051341)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bile duct stone (10004637)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Biliary colic (10004663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cholangitis (10008604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cholangitis acute (10008605)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cholecystitis (10008612)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cholelithiasis (10008629)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hepatotoxicity (10019851)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Immune system disorders (10021428)	Jaundice cholestatic (10023129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1
	Food allergy (10016946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Hypersensitivity (10020751)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2
	Multiple allergies (10028164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Seasonal allergy (10048908)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	82	1.4	1.1	1.8	68	1.2	0.9	1.5	71	1.2	0.9	1.5	61	1.0	0.8	1.3
	Abscess limb (10050473)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bacteraemia (10003997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bronchiolitis (10006448)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bronchitis (10006451)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	8	0.1	0.1	0.3	6	0.1	0.0	0.6
	Bronchitis viral (10053160)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Candida infection (10074170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cellulitis (10007882)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Conjunctivitis (10010741)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Conjunctivitis viral (10010755)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cystitis (10011781)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Diverticulitis (10013538)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Ear infection (10014011)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5
	Enteritis infectious (10058839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2
	Epididymitis (10015000)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Erysipelas (10015145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2
	Escherichia infection (10061126)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Fungal infection (10017533)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Gastroenteritis (10017888)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	4	0.1	0.0	0.2	4	0.1	0.0	0.4
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastroenteritis viral (10017918)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	7	0.1	0.0	0.2	0	0.0	0.0	0.2
	Gingivitis (10018292)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Groin abscess (10050269)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	H1n1 influenza (10069767)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Herpes simplex (10019948)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Influenza (10022000)	7	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4
	Labyrinthitis (10023567)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Laryngitis (10023874)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4

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		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Lobar pneumonia (10024738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Localised infection (10024774)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.3	0.1	0.7
	Lyme disease (10025169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Mastitis (10026883)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Nasopharyngitis (10028810)	16	0.3	0.2	0.4	14	0.2	0.1	0.3	11	0.2	0.1	0.3	3	0.2	0.0	0.6
	Neuroborreliosis (10052057)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Oral herpes (10067152)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Oral infection (10048685)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Orchitis (10031064)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Oropharyngeal candidiasis (10050346)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Osteomyelitis (10031252)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Otitis media (10033078)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Peritonsillar abscess (10034686)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pertussis (10034738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pharyngitis (10034835)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pneumonia (10035664)	2	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Post procedural infection (10067268)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pulpitis dental (10037464)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pyelonephritis (10037596)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Respiratory tract infection (10062352)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Rhinitis (10039083)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Sepsis (10040047)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Sinusitis (10040753)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4
	Skin bacterial infection (10052891)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Skin candida (10054152)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Subcutaneous abscess (10042343)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Tonsillitis (10044008)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Tooth abscess (10044016)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Upper respiratory tract infection (10046306)	10	0.2	0.1	0.3	9	0.2	0.1	0.3	7	0.1	0.0	0.2	0	0.0	0.0	0.1
	Urethritis (10046480)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Urinary tract infection (10046571)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	4	0.3	0.1	0.6
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Urosepsis (10048709)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Viral infection (10047461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Injury, poisoning and procedural complications (10022117)	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Wound infection (10048038)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	At least one PT related to the corresponding SOC	21	0.4	0.2	0.6	25	0.4	0.3	0.6	22	0.4	0.2	0.5	21	0.3	0.2	0.5
	Accident (10000369)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Aneurysm perforation (10075395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Animal bite (10002515)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Ankle fracture (10002544)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Arthropod bite (10003399)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Back injury (10003986)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bone contusion (10066251)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bone fissure (10064210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Clavicle fracture (10009245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Concussion (10010254)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Contusion (10050584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Crush injury (10061097)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Face injury (10050392)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Fall (10016173)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Femoral neck fracture (10016450)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Femur fracture (10016454)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Fibula fracture (10016667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Foot fracture (10016970)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Forearm fracture (10016997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Foreign body (10070245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Fractured sacrum (10017308)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hand fracture (10019114)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Head injury (10019196)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hip fracture (10020100)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injury (10022116)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Injury corneal (10022120)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Joint dislocation (10023204)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Joint injury (10060820)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Laceration (10023572)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Ligament sprain (10024453)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1
	Limb injury (10061225)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lower limb fracture (10061599)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Meniscus injury (10072970)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Muscle injury (10028314)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Muscle rupture (10028331)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Muscle strain (10050031)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pelvic fracture (10061161)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Procedural pain (10064882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Radius fracture (10037802)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1
	Rib fracture (10039117)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1
	Road traffic accident (10039203)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Skeletal injury (10061363)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Skull fracture (10061365)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Soft tissue injury (10041291)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Subdural haematoma (10042361)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1
	Tendon rupture (10043248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Thoracic vertebral fracture (10049948)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Tibia fracture (10043827)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Upper limb fracture (10061394)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vaccination complication (10046861)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Wrist fracture (10048049)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Investigations (10022891)	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1
	Blood glucose increased (10005557)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Blood pressure increased (10005750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Body temperature increased (10005911)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Weight decreased (10047895)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Weight increased (10047899)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	11	0.2	0.1	0.3	5	0.1	0.0	0.2
	Decreased appetite (10061428)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dehydration (10012174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Diabetes mellitus (10012601)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gout (10018627)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1
	Hyperglycaemia (10020635)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hypoglycaemia (10020993)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Type 2 diabetes mellitus (10067585)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	At least one PT related to the corresponding SOC	60	1.0	0.8	1.3	25	0.4	0.3	0.6	78	1.3	1.0	1.6	47	0.8	0.6	1.0
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	8	0.1	0.1	0.3	5	0.1	0.0	0.2	13	0.2	0.1	0.4	6	0.1	0.0	0.2

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Musculoskeletal system	Arthritis (10003246)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Arthropathy (10003285)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Back pain (10003988)	6	0.1	0.0	0.2	5	0.1	0.0	0.2	17	0.3	0.2	0.4	10	0.2	0.1	0.3
	Bone disorder (10005956)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bone pain (10006002)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bursitis (10006811)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2
	Chondropathy (10061762)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Costochondritis (10011219)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Exostosis (10015688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Groin pain (10018735)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Intervertebral disc protrusion (10050296)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Joint swelling (10023232)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Ligament disorder (10061222)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Lumbar spinal stenosis (10025005)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Muscle contracture (10062575)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Muscle spasms (10028334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4
	Muscular weakness (10028372)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Musculoskeletal chest pain (10050819)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Musculoskeletal pain (10028391)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.4
	Myalgia (10028411)	32	0.6	0.4	0.8	3	0.1	0.0	0.2	21	0.3	0.2	0.5	4	0.1	0.0	0.2
	Neck pain (10028836)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Osteoarthritis (10031161)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2
	Osteoporosis (10031282)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Pain in extremity (10033425)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2
	Pain in jaw (10033433)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Plantar fasciitis (10035155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Rotator cuff syndrome (10039227)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Spinal column stenosis (10041540)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Spinal osteoarthritis (10041591)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Spinal pain (10072005)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Synovial cyst (10042858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Tendonitis (10043255)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.2
	Trigger finger (10044654)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	9	0.2	0.1	0.3	5	0.1	0.0	0.2	15	0.2	0.1	0.4	12	0.2	0.1	0.3
	Adenocarcinoma (10001141)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma of colon (10001167)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2

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		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Basal cell carcinoma (10004146)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bile duct cancer (10004593)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bladder neoplasm (10005056)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Breast cancer (10006187)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Colon cancer (10009944)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Invasive ductal breast carcinoma (10073095)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Lung neoplasm malignant (10058467)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Malignant melanoma (10025650)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Meningioma (10027191)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Metastases to liver (10027457)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Metastases to lymph nodes (10027459)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Metastases to peritoneum (10051676)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Pancreatic carcinoma (10033609)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Prostate cancer (10060862)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Renal cancer (10038389)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Sarcoma (10039491)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Skin cancer (10040808)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Skin papilloma (10040907)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Testicular neoplasm (10061379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Urethral neoplasm (10062223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	65	1.1	0.9	1.4	15	0.3	0.1	0.4	73	1.2	0.9	1.5	37	0.6	0.4	0.8
	Aphonia (10002953)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Burning sensation (10006784)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
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		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cerebral infarction (10008118)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2
	Cervical myelopathy (10008289)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Diabetic neuropathy (10012680)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dizziness (10013573)	9	0.2	0.1	0.3	5	0.1	0.0	0.2	10	0.2	0.1	0.3	5	0.1	0.0	0.2
	Dysaesthesia (10013886)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Dysgeusia (10013911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Encephalopathy (10014625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Epilepsy (10015037)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Head discomfort (10019194)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Headache (10019211)	42	0.7	0.5	1.0	7	0.1	0.0	0.3	32	0.5	0.4	0.7	11	0.6	0.3	1.2
	Hyperaesthesia (10020568)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Hypoaesthesia (10020937)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Lethargy (10024264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.3
	Loss of consciousness (10024855)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2
	Migraine (10027599)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.2
	Neuralgia (10029223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Paraesthesia (10033775)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Presyncope (10036653)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Sciatica (10039674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	8	0.1	0.1	0.3
	Seizure (10039906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Somnolence (10041349)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Spinal claudication (10041539)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Subarachnoid haemorrhage (10042316)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Syncope (10042772)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.2
	Transient global amnesia (10044380)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Transient ischaemic attack (10044390)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4
	Tremor (10044565)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Visual field defect (10047555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	12	0.2	0.1	0.4	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1
	Agoraphobia (10001502)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anxiety (10002855)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Depression (10012378)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2
	Disorientation (10013395)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2

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		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Insomnia (10022437)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2
	Libido decreased (10024419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Nightmare (10029412)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Panic attack (10033664)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Psychotic disorder (10061920)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Chronic kidney disease (10064848)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Nephrolithiasis (10029148)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nocturia (10029446)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pollakiuria (10036018)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Renal colic (10038419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urethral stenosis (10065584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Urinary incontinence (10046543)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.3
	Endometrial hyperplasia (10014755)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Erectile dysfunction (10061461)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pelvic pain (10034263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.3
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	17	0.3	0.2	0.5	4	0.1	0.0	0.2	11	0.2	0.1	0.3	19	0.3	0.2	0.5
	Asthma (10003553)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Chronic obstructive pulmonary disease (10009033)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.4
	Cough (10011224)	8	0.1	0.1	0.3	2	0.0	0.0	0.1	4	0.1	0.1	0.3	0	0.0	0.0	0.2
	Dyspnoea (10013968)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dyspnoea exertional (10013971)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.4
	Epistaxis (10015090)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6
	Haemoptysis (10018964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Haemothorax (10019027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Nasal congestion (10028735)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.3
	Oropharyngeal pain (10068319)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pneumothorax (10035759)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pulmonary bulla (10051688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Pulmonary embolism (10037377)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory disorder (10038683)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Respiratory failure (10038695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Sleep apnoea syndrome (10040979)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.3
	Sneezing (10041232)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.3

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	10	0.2	0.1	0.3	7	0.1	0.0	0.3	12	0.2	0.1	0.3	4	0.1	0.0	0.2	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Actinic keratosis (10000614)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blister (10005191)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cold sweat (10009866)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis (10012431)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis allergic (10012434)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis contact (10012442)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ecchymosis (10014080)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema (10014184)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema (10015150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperhidrosis (10020642)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Night sweats (10029410)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus (10037087)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus generalised (10052576)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoriasis (10037153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash (10037844)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash generalised (10037858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash pruritic (10037884)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urticaria (10046735)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract operation (10063797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth cyst excision (10052179)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shoulder operation (10062242)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth extraction (10062132)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasectomy (10047133)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Aortic stenosis (10002906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deep vein thrombosis (10051055)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flushing (10016825)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertension (10020772)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertensive crisis (10020802)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Hypotension (10021097)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral arterial occlusive disease (10062585)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Phlebitis (10034879)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temporal arteritis (10043207)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.25 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		459	4.0	3.7	4.4	184	1.6	1.4	1.9	458	3.9	3.5	4.2	250	2.0	1.8	2.3	146	4.8	4.1	5.7	84	3.0	2.4	3.7	5	4.4	1.5	10.0	5	3.7	1.2	8.4
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenopathy (10025197)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	4	0.0	0.0	0.1	9	0.1	0.0	0.2	9	0.1	0.0	0.1	9	0.1	0.0	0.1	4	0.1	0.0	0.3	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute coronary syndrome (10051592)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute myocardial infarction (10000891)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina pectoris (10002383)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina unstable (10002388)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve stenosis (10002918)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia (10003119)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrial fibrillation (10003658)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block complete (10003673)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bradycardia (10006093)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure (10007554)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure congestive (10007559)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cor pulmonale (10010968)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery disease (10011078)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocardial infarction (10028596)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocardial ischaemia (10028600)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Palpitations (10033557)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Supraventricular tachycardia (10042604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachyarrhythmia (10049447)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia (10043071)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	5	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness neurosensory (10011891)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear pain (10014020)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoacusis (10048865)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinnitus (10043882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertigo (10047340)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Eye disorders (10015919)	Vertigo positional (10047348)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract (10007739)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival haemorrhage (10010719)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis allergic (10010744)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diplopia (10013036)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye disorder (10015916)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pain (10015958)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pruritus (10052140)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body sensation in eyes (10051116)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Keratitis (10023332)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hyperaemia (10030041)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal detachment (10038848)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual acuity reduced (10047531)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual impairment (10047571)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	39	0.3	0.2	0.5	22	0.2	0.1	0.3	37	0.3	0.2	0.4	25	0.2	0.1	0.3	14	0.5	0.3	0.8	13	0.5	0.2	0.8	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Abdominal hernia (10060954)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain (10000081)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain lower (10000084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain upper (10000087)	2	0.0	0.0	0.1	6	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal inflammation (10050247)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis ulcerative (10009900)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Constipation (10010774)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea (10012735)	7	0.1	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	8	0.1	0.0	0.1	5	0.2	0.1	0.4	3	0.1	0.0	0.3	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Dry mouth (10013781)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Duodenal ulcer (10013836)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspepsia (10013946)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enterovesical fistula (10062570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epigastric discomfort (10053155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flatulence (10016766)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Food poisoning (10016952)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric ulcer (10017822)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis (10017853)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal haemorrhage (10017955)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrooesophageal reflux disease (10017885)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Glossitis (10018386)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoids (10019022)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hiatus hernia (10020028)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ileus (10021328)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inguinal hernia (10022016)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal perforation (10022694)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip pain (10024561)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip swelling (10024570)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth ulceration (10028034)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nausea (10028813)	10	0.1	0.0	0.2	1	0.0	0.0	0.0	10	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Odynophagia (10030094)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal spasm (10030184)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophagitis (10030216)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatitis (10033645)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatitis acute (10033647)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periodontal disease (10034536)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retroperitoneal haemorrhage (10038980)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swollen tongue (10042727)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue coated (10043945)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue ulceration (10043991)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toothache (10044055)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vomiting (10047700)	8	0.1	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	241	2.1	1.9	2.4	18	0.2	0.1	0.3	186	1.6	1.4	1.8	26	0.2	0.1	0.3	64	2.1	1.6	2.7	6	0.2	0.1	0.5	2	1.8	0.2	6.2	1	0.7	0.0	4.1
	Asthenia (10003549)	10	0.1	0.0	0.2	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest discomfort (10008469)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest pain (10008479)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chills (10008531)	41	0.4	0.3	0.5	0	0.0	0.0	0.0	32	0.3	0.2	0.4	2	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Face oedema (10016029)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fatigue (10016256)	29	0.3	0.2	0.4	0	0.0	0.0	0.0	26	0.2	0.1	0.3	6	0.0	0.0	0.1	6	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling abnormal (10016322)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling cold (10016326)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling hot (10016334)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gait disturbance (10017577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inflammation (10061218)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza like illness (10022004)	12	0.1	0.1	0.2	1	0.0	0.0	0.0	8	0.1	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site bruising (10022052)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site erythema (10022061)	21	0.2	0.1	0.3	0	0.0	0.0	0.0	24	0.2	0.1	0.3	0	0.0	0.0	0.0	12	0.4	0.2	0.7	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site haemorrhage (10022067)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypersensitivity (10022071)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypoaesthesia (10074586)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site induration (10022075)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site inflammation (10022078)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site joint pain (10049261)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site movement impairment (10056250)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site nodule (10057880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site oedema (10022085)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pain (10022086)	82	0.7	0.6	0.9	2	0.0	0.0	0.1	77	0.7	0.5	0.8	2	0.0	0.0	0.1	44	1.5	1.1	1.9	0	0.0	0.0	0.1	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Injection site paraesthesia (10022088)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pruritus (10022093)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site reaction (10022095)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site swelling (10053425)	16	0.1	0.1	0.2	0	0.0	0.0	0.0	16	0.1	0.1	0.2	0	0.0	0.0	0.0	9	0.3	0.1	0.6	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site warmth (10022112)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Injury associated with device (10069803)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Local swelling (10024770)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malaise (10025482)	11	0.1	0.0	0.2	3	0.0	0.0	0.1	7	0.1	0.0	0.1	0	0.0	0.0	0.0	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-cardiac chest pain (10062501)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema peripheral (10030124)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain (10033371)	14	0.1	0.1	0.2	1	0.0	0.0	0.0	9	0.1	0.0	0.1	1	0.0	0.0	0.0	5	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral swelling (10048959)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyrexia (10037660)	87	0.8	0.6	0.9	6	0.1	0.0	0.1	38	0.3	0.2	0.4	3	0.0	0.0	0.1	6	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Reactogenicity event (10065109)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site erythema (10059079)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site pain (10068879)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site pruritus (10068881)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct stenosis (10051341)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct stone (10004637)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Biliary colic (10004663)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholangitis (10008604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholangitis acute (10008605)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis (10008612)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholelithiasis (10008629)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatotoxicity (10019851)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Immune system disorders (10021428)	Jaundice cholestatic (10023129)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Food allergy (10016946)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity (10020751)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple allergies (10028164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seasonal allergy (10048908)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	83	0.7	0.6	0.9	68	0.6	0.5	0.8	73	0.6	0.5	0.8	61	0.5	0.4	0.6	25	0.8	0.5	1.2	11	0.4	0.2	0.7	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Abscess limb (10050473)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacteraemia (10003997)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchiolitis (10006448)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis (10006451)	5	0.0	0.0	0.1	7	0.1	0.0	0.1	8	0.1	0.0	0.1	6	0.0	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis viral (10053160)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Candida infection (10074170)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cellulitis (10007882)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis (10010741)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis viral (10010755)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis (10011781)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diverticulitis (10013538)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear infection (10014011)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enteritis infectious (10058839)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epididymitis (10015000)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erysipelas (10015145)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Escherichia infection (10061126)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fungal infection (10017533)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis (10017888)	5	0.0	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis viral (10017918)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingivitis (10018292)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin abscess (10050269)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	H1n1 influenza (10069767)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes simplex (10019948)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza (10022000)	7	0.1	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Labyrinthitis (10023567)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngitis (10023874)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Lobar pneumonia (10024738)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Localised infection (10024774)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lyme disease (10025169)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mastitis (10026883)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngitis (10028810)	17	0.1	0.1	0.2	14	0.1	0.1	0.2	10	0.1	0.0	0.2	11	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Neuroborreliosis (10052057)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral herpes (10067152)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral infection (10048685)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Orchitis (10031064)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal candidiasis (10050346)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteomyelitis (10031252)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media (10033078)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peritonsillar abscess (10034686)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pertussis (10034738)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis (10034835)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis streptococcal (10034839)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia (10035664)	2	0.0	0.0	0.1	5	0.0	0.0	0.1	6	0.1	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural infection (10067268)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulpitis dental (10037464)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis (10037596)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection (10062352)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis (10039083)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sepsis (10040047)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinusitis (10040753)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin bacterial infection (10052891)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin candida (10054152)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subcutaneous abscess (10042343)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillitis (10044008)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth abscess (10044016)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract infection (10046306)	10	0.1	0.0	0.2	9	0.1	0.0	0.2	7	0.1	0.0	0.1	7	0.1	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethritis (10046480)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary tract infection (10046571)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urosepsis (10048709)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral infection (10047461)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Injury, poisoning and procedural complications (10022117)	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound infection (10048038)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	22	0.2	0.1	0.3	25	0.2	0.1	0.3	22	0.2	0.1	0.3	21	0.2	0.1	0.3	7	0.2	0.1	0.5	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Accident (10000369)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aneurysm perforation (10075395)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Animal bite (10002515)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ankle fracture (10002544)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthropod bite (10003399)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back injury (10003986)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone contusion (10066251)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone fissure (10064210)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Clavicle fracture (10009245)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Concussion (10010254)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contusion (10050584)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Crush injury (10061097)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Face injury (10050392)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fall (10016173)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Femoral neck fracture (10016450)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Femur fracture (10016454)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibula fracture (10016667)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foot fracture (10016970)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Forearm fracture (10016997)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body (10070245)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fractured sacrum (10017308)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hand fracture (10019114)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head injury (10019196)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hip fracture (10020100)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury (10022116)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury corneal (10022120)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint dislocation (10023204)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint injury (10060820)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laceration (10023572)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament sprain (10024453)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb injury (10061225)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower limb fracture (10061599)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniscus injury (10072970)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle injury (10028314)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle rupture (10028331)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Muscle strain (10050031)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Pelvic fracture (10061161)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Procedural pain (10064882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Radius fracture (10037802)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Rib fracture (10039117)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Road traffic accident (10039203)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Skeletal injury (10061363)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Skull fracture (10061365)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Soft tissue injury (10041291)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Subdural haematoma (10042361)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Tendon rupture (10043248)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Thoracic vertebral fracture (10049948)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Tibia fracture (10043827)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Upper limb fracture (10061394)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Vaccination complication (10046861)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Wrist fracture (10048049)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
Investigations (10022891)	At least one PT related to the corresponding SOC	3	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Blood glucose increased (10005557)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Blood pressure increased (10005750)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Body temperature increased (10005911)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Weight decreased (10047895)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Weight increased (10047899)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	1	0.0	0.0	0.0	11	0.1	0.0	0.2	5	0.0	0.0	0.1	6	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Decreased appetite (10061428)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Dehydration (10012174)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Diabetes mellitus (10012601)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Gout (10018627)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Hyperglycaemia (10020635)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Hypoglycaemia (10020993)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Type 2 diabetes mellitus (10067585)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	At least one PT related to the corresponding SOC	62	0.5	0.4	0.7	26	0.2	0.2	0.3	80	0.7	0.5	0.8	48	0.4	0.3	0.5	27	0.9	0.6	1.3	15	0.5	0.3	0.9	0	0.0	0.0	0.2	1	0.7	0.0	4.1
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	8	0.1	0.0	0.1	5	0.0	0.0	0.1	13	0.1	0.1	0.2	6	0.0	0.0	0.1	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	0.2	0	0.0	0.0	0.2

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Arthritis (10003246)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthropathy (10003285)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back pain (10003988)	6	0.1	0.0	0.1	5	0.0	0.0	0.1	18	0.2	0.1	0.2	10	0.1	0.0	0.2	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Bone disorder (10005956)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone pain (10006002)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bursitis (10006811)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chondropathy (10061762)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Costochondritis (10011219)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Exostosis (10015688)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin pain (10018735)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc protrusion (10050296)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint swelling (10023232)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament disorder (10061222)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lumbar spinal stenosis (10025005)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle contracture (10062575)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle spasms (10028334)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscular weakness (10028372)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal chest pain (10050819)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal pain (10028391)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myalgia (10028411)	34	0.3	0.2	0.4	3	0.0	0.0	0.1	21	0.2	0.1	0.3	4	0.0	0.0	0.1	8	0.3	0.1	0.5	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neck pain (10028836)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoarthritis (10031161)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoporosis (10031282)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain in extremity (10033425)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain in jaw (10033433)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Plantar fasciitis (10035155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rotator cuff syndrome (10039227)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal column stenosis (10041540)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal osteoarthritis (10041591)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal pain (10072005)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovial cyst (10042858)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendonitis (10043255)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigger finger (10044654)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	9	0.1	0.0	0.2	5	0.0	0.0	0.1	15	0.1	0.1	0.2	12	0.1	0.1	0.2	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma (10001141)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma of colon (10001167)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown											
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135							
			95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI										
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL				
	Basal cell carcinoma (10004146)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Bile duct cancer (10004593)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Bladder neoplasm (10005056)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Breast cancer (10006187)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Colon cancer (10009944)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Invasive ductal breast carcinoma (10073095)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Lung neoplasm malignant (10058467)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Malignant melanoma (10025650)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Meningioma (10027191)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Metastases to liver (10027457)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Metastases to lymph nodes (10027459)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Metastases to peritoneum (10051676)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Pancreatic carcinoma (10033609)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Prostate cancer (10060862)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Renal cancer (10038389)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Sarcoma (10039491)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Skin cancer (10040808)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Skin papilloma (10040907)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Testicular neoplasm (10061379)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Urethral neoplasm (10062223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	70	0.6	0.5	0.8	15	0.1	0.1	0.2	74	0.6	0.5	0.8	39	0.3	0.2	0.4	20	0.7	0.4	1.0	11	0.4	0.2	0.7	2	1.8	0.2	6.2	0	0.0	0.0	0.2				
	Aphonia (10002953)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Burning sensation (10006784)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.2
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.2

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral infarction (10008118)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical myelopathy (10008289)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic neuropathy (10012680)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness (10013573)	9	0.1	0.0	0.2	5	0.0	0.0	0.1	10	0.1	0.0	0.2	5	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Dysaesthesia (10013886)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysgeusia (10013911)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Encephalopathy (10014625)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epilepsy (10015037)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head discomfort (10019194)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Headache (10019211)	46	0.4	0.3	0.5	7	0.1	0.0	0.1	33	0.3	0.2	0.4	13	0.1	0.1	0.2	10	0.3	0.2	0.6	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaesthesia (10020568)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia (10020937)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lethargy (10024264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loss of consciousness (10024855)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Migraine (10027599)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuralgia (10029223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraesthesia (10033775)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presyncope (10036653)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sciatica (10039674)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	8	0.1	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Seizure (10039906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somnolence (10041349)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal claudication (10041539)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subarachnoid haemorrhage (10042316)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Syncope (10042772)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transient global amnesia (10044380)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transient ischaemic attack (10044390)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tremor (10044565)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual field defect (10047555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	12	0.1	0.1	0.2	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Agoraphobia (10001502)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Anxiety (10002855)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depression (10012378)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disorientation (10013395)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Insomnia (10022437)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Libido decreased (10024419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nightmare (10029412)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Panic attack (10033664)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psychotic disorder (10061920)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic kidney disease (10064848)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephrolithiasis (10029148)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nocturia (10029446)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pollakiuria (10036018)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal colic (10038419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral stenosis (10065584)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary incontinence (10046543)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometrial hyperplasia (10014755)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erectile dysfunction (10061461)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pelvic pain (10034263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	17	0.1	0.1	0.2	4	0.0	0.0	0.1	11	0.1	0.0	0.2	19	0.2	0.1	0.2	4	0.1	0.0	0.3	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthma (10003553)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic obstructive pulmonary disease (10009033)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cough (10011224)	8	0.1	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspnoea (10013968)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspnoea exertional (10013971)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epistaxis (10015090)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemoptysis (10018964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemothorax (10019027)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal congestion (10028735)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal pain (10068319)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumothorax (10035759)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary bulla (10051688)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary embolism (10037377)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory disorder (10038683)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory failure (10038695)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sleep apnoea syndrome (10040979)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sneezing (10041232)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	10	0.1	0.0	0.2	7	0.1	0.0	0.1	12	0.1	0.1	0.2	4	0.0	0.0	0.1	7	0.2	0.1	0.5	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Actinic keratosis (10000614)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blister (10005191)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cold sweat (10009866)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis (10012431)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis allergic (10012434)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis contact (10012442)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ecchymosis (10014080)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema (10014184)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema (10015150)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperhidrosis (10020642)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Night sweats (10029410)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus (10037087)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus generalised (10052576)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psoriasis (10037153)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash (10037844)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash generalised (10037858)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pruritic (10037884)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urticaria (10046735)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract operation (10063797)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth cyst excision (10052179)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Shoulder operation (10062242)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth extraction (10062132)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vasectomy (10047133)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	3	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Aortic stenosis (10002906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deep vein thrombosis (10051055)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flushing (10016825)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertension (10020772)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertensive crisis (10020802)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hypotension (10021097)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral arterial occlusive disease (10062585)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Phlebitis (10034879)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Temporal arteritis (10043207)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of administered doses

n/% = number/percentage of doses with the symptom

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.26 Global Summary of grade 3 unsolicited signs and symptoms reported within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	429	182	429	242	134	80	5	5	997	509
Number of doses followed by at least one unsolicited symptom	459	184	458	250	146	84	5	5	1068	523
Number of unsolicited symptoms classified by MedDRA Preferred Term*	711	224	668	324	245	104	7	6	1631	658
Number of unsolicited symptoms reported**	721	226	676	327	246	106	7	6	1650	665

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.27 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		2223	38.4	37.2	39.7	386	6.7	6.1	7.4	1962	32.3	31.1	33.5	420	6.8	6.1	7.4	449	28.5	26.3	30.8	91	6.2	5.0	7.6	16	27.1	16.4	40.3	6	8.3	3.1	17.3
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	14	0.2	0.1	0.4	2	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymph node pain (10025182)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenitis (10025188)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenopathy (10025197)	8	0.1	0.1	0.3	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytosis (10043563)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	7	0.1	0.0	0.2	2	0.0	0.0	0.1	8	0.1	0.1	0.3	3	0.0	0.0	0.1	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute myocardial infarction (10000891)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina pectoris (10002383)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arrhythmia (10003119)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Palpitations (10033557)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia (10043071)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	8	0.1	0.1	0.3	2	0.0	0.0	0.1	11	0.2	0.1	0.3	1	0.0	0.0	0.1	5	0.3	0.1	0.7	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness neurosensory (10011891)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear pain (10014020)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Middle ear effusion (10062545)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinnitus (10043882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo (10047340)	6	0.1	0.0	0.2	1	0.0	0.0	0.1	7	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	At least one PT related to the corresponding SOC	8	0.1	0.1	0.3	4	0.1	0.0	0.2	10	0.2	0.1	0.3	5	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenopia (10003552)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blepharospasm (10005159)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival haemorrhage (10010719)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dark circles under eyes (10064729)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry eye (10013774)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye pain (10015958)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye pruritus (10052140)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Eye swelling (10015967)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid oedema (10015993)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelids pruritus (10051627)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacrimation increased (10023644)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular discomfort (10052143)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular hyperaemia (10030041)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periorbital oedema (10034545)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photopsia (10034962)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vision blurred (10047513)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	141	2.4	2.1	2.9	32	0.6	0.4	0.8	103	1.7	1.4	2.1	47	0.8	0.6	1.0	29	1.8	1.2	2.6	12	0.8	0.4	1.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Abdominal discomfort (10000059)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal distension (10000060)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain (10000081)	8	0.1	0.1	0.3	1	0.0	0.0	0.1	7	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain lower (10000084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain upper (10000087)	8	0.1	0.1	0.3	6	0.1	0.0	0.2	13	0.2	0.1	0.4	8	0.1	0.1	0.3	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphthous stomatitis (10002958)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cheilitis (10008417)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Constipation (10010774)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diarrhoea (10012735)	18	0.3	0.2	0.5	6	0.1	0.0	0.2	20	0.3	0.2	0.5	13	0.2	0.1	0.4	6	0.4	0.1	0.8	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry mouth (10013781)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspepsia (10013946)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faeces discoloured (10016100)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatulence (10016766)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis (10017853)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal disorder (10017944)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal pain (10017999)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossitis (10018386)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossodynia (10018388)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoaesthesia oral (10057371)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip disorder (10048470)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Lip swelling (10024570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth ulceration (10028034)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Nausea (10028813)	84	1.5	1.2	1.8	13	0.2	0.1	0.4	56	0.9	0.7	1.2	13	0.2	0.1	0.4	15	1.0	0.5	1.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral mucosal blistering (10030995)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral pain (10031009)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraesthesia oral (10057372)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periodontal disease (10034536)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Swollen tongue (10042727)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue coated (10043945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue disorder (10043951)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue pruritus (10070072)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue ulceration (10043991)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toothache (10044055)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vomiting (10047700)	18	0.3	0.2	0.5	1	0.0	0.0	0.1	10	0.2	0.1	0.3	5	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	2053	35.5	34.3	36.7	201	3.5	3.0	4.0	1808	29.8	28.6	30.9	258	4.1	3.7	4.7	414	26.3	24.2	28.6	45	3.1	2.3	4.1	14	23.7	13.6	36.6	5	6.9	2.3	15.5
	Administration site erythema (10074796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site pain (10058049)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site reaction (10001315)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenia (10003549)	32	0.6	0.4	0.8	3	0.1	0.0	0.2	22	0.4	0.2	0.5	8	0.1	0.1	0.3	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Axillary pain (10048750)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest discomfort (10008469)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest pain (10008479)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chills (10008531)	244	4.2	3.7	4.8	10	0.2	0.1	0.3	181	3.0	2.6	3.4	11	0.2	0.1	0.3	35	2.2	1.6	3.1	2	0.1	0.0	0.5	3	5.1	1.1	14.1	0	0.0	0.0	5.0
	Discomfort (10013082)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Face oedema (10016029)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial pain (10016059)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatigue (10016256)	225	3.9	3.4	4.4	31	0.5	0.4	0.8	160	2.6	2.2	3.1	44	0.7	0.5	0.9	26	1.7	1.1	2.4	4	0.3	0.1	0.7	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Feeling abnormal (10016322)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling cold (10016326)	28	0.5	0.3	0.7	2	0.0	0.0	0.1	17	0.3	0.2	0.4	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling hot (10016334)	25	0.4	0.3	0.6	1	0.0	0.0	0.1	12	0.2	0.1	0.3	4	0.1	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling of body temperature change (10061458)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gait disturbance (10017577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	General physical health deterioration (10049438)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza like illness (10022004)	46	0.8	0.6	1.1	5	0.1	0.0	0.2	30	0.5	0.3	0.7	9	0.1	0.1	0.3	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site atrophy (10022048)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site bruising (10022052)	16	0.3	0.2	0.4	16	0.3	0.2	0.5	16	0.3	0.2	0.4	12	0.2	0.1	0.3	2	0.1	0.0	0.5	1	0.1	0.0	0.4	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Injection site coldness (10050082)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site discolouration (10051572)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site discomfort (10054266)	10	0.2	0.1	0.3	2	0.0	0.0	0.1	9	0.1	0.1	0.3	1	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site eczema (10066221)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site erythema (10022061)	607	10.5	9.7	11.3	14	0.2	0.1	0.4	535	8.8	8.1	9.6	22	0.4	0.2	0.5	114	7.2	6.0	8.6	1	0.1	0.0	0.4	4	6.8	1.9	16.5	0	0.0	0.0	5.0
	Injection site haematoma (10022066)	9	0.2	0.1	0.3	5	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site haemorrhage (10022067)	5	0.1	0.0	0.2	6	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hyperaesthesia (10073418)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypersensitivity (10022071)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypoaesthesia (10074586)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site induration (10022075)	21	0.4	0.2	0.6	2	0.0	0.0	0.1	25	0.4	0.3	0.6	2	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site inflammation (10022078)	19	0.3	0.2	0.5	0	0.0	0.0	0.1	21	0.3	0.2	0.5	1	0.0	0.0	0.1	9	0.6	0.3	1.1	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site injury (10066083)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site irritation (10022079)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site joint pain (10049261)	21	0.4	0.2	0.6	1	0.0	0.0	0.1	22	0.4	0.2	0.5	3	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site lymphadenopathy (10057665)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site macule (10067255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site mass (10022081)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site movement impairment (10056250)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site nodule (10057880)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site oedema (10022085)	12	0.2	0.1	0.4	0	0.0	0.0	0.1	20	0.3	0.2	0.5	0	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pain (10022086)	1452	25.1	24.0	26.2	94	1.6	1.3	2.0	1333	22.0	20.9	23.0	109	1.8	1.4	2.1	298	18.9	17.0	21.0	29	2.0	1.3	2.8	8	13.6	6.0	25.0	3	4.2	0.9	11.7
	Injection site papule (10066044)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site paraesthesia (10022088)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pruritus (10022093)	142	2.5	2.1	2.9	11	0.2	0.1	0.3	114	1.9	1.6	2.3	16	0.3	0.1	0.4	35	2.2	1.6	3.1	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site rash (10022094)	30	0.5	0.4	0.7	1	0.0	0.0	0.1	22	0.4	0.2	0.5	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site reaction (10022095)	27	0.5	0.3	0.7	4	0.1	0.0	0.2	27	0.4	0.3	0.6	7	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Injection site swelling (10053425)	455	7.9	7.2	8.6	8	0.1	0.1	0.3	390	6.4	5.8	7.1	8	0.1	0.1	0.3	88	5.6	4.5	6.8	4	0.3	0.1	0.7	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Injection site ulcer (10022105)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site urticaria (10022107)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site vesicles (10022111)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site warmth (10022112)	63	1.1	0.8	1.4	0	0.0	0.0	0.1	66	1.1	0.8	1.4	4	0.1	0.0	0.2	12	0.8	0.4	1.3	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Local swelling (10024770)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malaise (10025482)	109	1.9	1.5	2.3	10	0.2	0.1	0.3	77	1.3	1.0	1.6	10	0.2	0.1	0.3	19	1.2	0.7	1.9	0	0.0	0.0	0.3	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Nodule (10054107)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema (10030095)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema peripheral (10030124)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pain (10033371)	85	1.5	1.2	1.8	2	0.0	0.0	0.1	55	0.9	0.7	1.2	7	0.1	0.0	0.2	16	1.0	0.6	1.6	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Peripheral swelling (10048959)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyrexia (10037660)	538	9.3	8.6	10.1	12	0.2	0.1	0.4	317	5.2	4.7	5.8	13	0.2	0.1	0.4	51	3.2	2.4	4.2	3	0.2	0.0	0.6	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Reactogenicity event (10065109)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sluggishness (10041052)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Swelling (10042674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temperature intolerance (10057040)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tenderness (10043224)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Thirst (10043458)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site coldness (10076157)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site discolouration (10069474)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site erythema (10059079)	12	0.2	0.1	0.4	0	0.0	0.0	0.1	18	0.3	0.2	0.5	1	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site haematoma (10069472)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site inflammation (10068878)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site irritation (10069479)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site pain (10068879)	29	0.5	0.3	0.7	0	0.0	0.0	0.1	23	0.4	0.2	0.6	5	0.1	0.0	0.2	5	0.3	0.1	0.7	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Vaccination site pruritus (10068881)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site reaction (10059080)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	8	0.1	0.1	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site swelling (10069620)	8	0.1	0.1	0.3	0	0.0	0.0	0.1	9	0.1	0.1	0.3	0	0.0	0.0	0.1	4	0.3	0.1	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site warmth (10069624)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity (10020751)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple allergies (10028164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	63	1.1	0.8	1.4	44	0.8	0.6	1.0	69	1.1	0.9	1.4	25	0.4	0.3	0.6	7	0.4	0.2	0.9	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis (10006451)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Candida infection (10074170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystitis (10011781)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erysipelas (10015145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis (10017888)	0	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes simplex (10019948)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infection (10021789)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Influenza (10022000)	10	0.2	0.1	0.3	2	0.0	0.0	0.1	7	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site cellulitis (10050057)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site infection (10022076)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasopharyngitis (10028810)	34	0.6	0.4	0.8	16	0.3	0.2	0.5	29	0.5	0.3	0.7	15	0.2	0.1	0.4	3	0.2	0.0	0.6	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral herpes (10067152)	6	0.1	0.0	0.2	7	0.1	0.0	0.3	8	0.1	0.1	0.3	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngitis (10034835)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract infection (10062352)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis (10039083)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper respiratory tract infection (10046306)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	11	0.2	0.1	0.3	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary tract infection (10046571)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral infection (10047461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral rash (10047476)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contusion (10050584)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epicondylitis (10014971)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination complication (10046861)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Investigations (10022891)	At least one PT related to the corresponding SOC	52	0.9	0.7	1.2	3	0.1	0.0	0.2	49	0.8	0.6	1.1	2	0.0	0.0	0.1	6	0.4	0.1	0.8	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood glucose increased (10005557)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure increased (10005750)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body temperature decreased (10005910)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Body temperature increased (10005911)	52	0.9	0.7	1.2	2	0.0	0.0	0.1	44	0.7	0.5	1.0	1	0.0	0.0	0.1	6	0.4	0.1	0.8	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Grip strength decreased (10062556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate increased (10019303)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate irregular (10019304)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	6	0.1	0.0	0.2	0	0.0	0.0	0.1	13	0.2	0.1	0.4	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decreased appetite (10061428)	6	0.1	0.0	0.2	0	0.0	0.0	0.1	11	0.2	0.1	0.3	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dehydration (10012174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypercalcaemia (10020583)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polydipsia (10036067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	345	6.0	5.4	6.6	35	0.6	0.4	0.8	241	4.0	3.5	4.5	61	1.0	0.8	1.3	53	3.4	2.5	4.4	9	0.6	0.3	1.2	3	5.1	1.1	14.1	0	0.0	0.0	5.0
	Arthralgia (10003239)	75	1.3	1.0	1.6	13	0.2	0.1	0.4	37	0.6	0.4	0.8	10	0.2	0.1	0.3	9	0.6	0.3	1.1	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Arthritis (10003246)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Axillary mass (10049021)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back pain (10003988)	26	0.4	0.3	0.7	2	0.0	0.0	0.1	11	0.2	0.1	0.3	13	0.2	0.1	0.4	5	0.3	0.1	0.7	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone disorder (10005956)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone pain (10006002)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone swelling (10053631)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibromyalgia (10048439)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flank pain (10016750)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint stiffness (10023230)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint swelling (10023232)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb discomfort (10061224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mobility decreased (10048334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle fatigue (10049565)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle rigidity (10028330)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle spasms (10028334)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle tightness (10049816)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle twitching (10028347)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscular weakness (10028372)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal chest pain (10050819)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal discomfort (10053156)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Musculoskeletal pain (10028391)	17	0.3	0.2	0.5	2	0.0	0.0	0.1	10	0.2	0.1	0.3	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal stiffness (10052904)	8	0.1	0.1	0.3	1	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myalgia (10028411)	220	3.8	3.3	4.3	11	0.2	0.1	0.3	160	2.6	2.2	3.1	26	0.4	0.3	0.6	27	1.7	1.1	2.5	3	0.2	0.0	0.6	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Neck pain (10028836)	15	0.3	0.1	0.4	2	0.0	0.0	0.1	9	0.1	0.1	0.3	5	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteitis (10031149)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoarthritis (10031161)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain in extremity (10033425)	18	0.3	0.2	0.5	3	0.1	0.0	0.2	20	0.3	0.2	0.5	6	0.1	0.0	0.2	11	0.7	0.3	1.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovial cyst (10042858)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovitis (10042868)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Torticollis (10044074)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acrochordon (10000591)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	460	8.0	7.3	8.7	96	1.7	1.4	2.0	303	5.0	4.5	5.6	108	1.7	1.4	2.1	57	3.6	2.8	4.7	26	1.8	1.2	2.6	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Balance disorder (10049848)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burning sensation (10006784)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disturbance in attention (10013496)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dizziness (10013573)	52	0.9	0.7	1.2	13	0.2	0.1	0.4	42	0.7	0.5	0.9	26	0.4	0.3	0.6	11	0.7	0.3	1.2	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dizziness postural (10013578)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysgeusia (10013911)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Head discomfort (10019194)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Headache (10019211)	390	6.7	6.1	7.4	77	1.3	1.1	1.7	242	4.0	3.5	4.5	61	1.0	0.8	1.3	42	2.7	1.9	3.6	13	0.9	0.5	1.5	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Hyperaesthesia (10020568)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hypersomnia (10020765)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoaesthesia (10020937)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypotonia (10021118)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lethargy (10024264)	7	0.1	0.0	0.2	1	0.0	0.0	0.1	11	0.2	0.1	0.3	2	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Loss of consciousness (10024855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Memory impairment (10027175)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Migraine (10027599)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraesthesia (10033775)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Poor quality sleep (10062519)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Presyncope (10036653)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restless legs syndrome (10058920)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sciatica (10039674)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Somnolence (10041349)	9	0.2	0.1	0.3	1	0.0	0.0	0.1	14	0.2	0.1	0.4	4	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Syncope (10042772)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tension headache (10043269)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tremor (10044565)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigeminal neuralgia (10044652)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	32	0.6	0.4	0.8	9	0.2	0.1	0.3	20	0.3	0.2	0.5	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Agitation (10001497)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anxiety (10002855)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aversion (10063659)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depressed mood (10012374)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depression (10012378)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disorientation (10013395)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphemia (10054964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphoria (10013954)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hallucination (10019063)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Insomnia (10022437)	17	0.3	0.2	0.5	7	0.1	0.0	0.3	12	0.2	0.1	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Irritability (10022998)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Libido decreased (10024419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Listless (10024642)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Middle insomnia (10027590)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nightmare (10029412)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restlessness (10038743)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Renal and urinary disorders (10038359)	Sleep disorder (10040984)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysuria (10013990)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pollakiuria (10036018)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyuria (10036142)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary incontinence (10046543)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast pain (10006298)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erectile dysfunction (10061461)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic pain (10034263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	33	0.6	0.4	0.8	21	0.4	0.2	0.6	19	0.3	0.2	0.5	15	0.2	0.1	0.4	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cough (10011224)	7	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphonia (10013952)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspnoea (10013968)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epistaxis (10015090)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal congestion (10028735)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal obstruction (10028748)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal discomfort (10068318)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal pain (10068319)	15	0.3	0.1	0.4	13	0.2	0.1	0.4	10	0.2	0.1	0.3	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paranasal sinus discomfort (10052438)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Productive cough (10036790)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinorrhoea (10039101)	8	0.1	0.1	0.3	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sneezing (10041232)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Throat irritation (10043521)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasomotor rhinitis (10047145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wheezing (10047924)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	73	1.3	1.0	1.6	30	0.5	0.4	0.7	54	0.9	0.7	1.2	47	0.8	0.6	1.0	21	1.3	0.8	2.0	12	0.8	0.4	1.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Alopecia areata (10001761)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blister (10005191)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cold sweat (10009866)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis (10012431)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis allergic (10012434)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Dermatitis contact (10012442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ecchymosis (10014080)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema (10014184)	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema (10015150)	12	0.2	0.1	0.4	2	0.0	0.0	0.1	12	0.2	0.1	0.3	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema nodosum (10015226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperhidrosis (10020642)	15	0.3	0.1	0.4	1	0.0	0.0	0.1	7	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypohidrosis (10021013)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Night sweats (10029410)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychalgia (10064251)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain of skin (10033474)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Papule (10033733)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus (10037087)	19	0.3	0.2	0.5	10	0.2	0.1	0.3	11	0.2	0.1	0.3	16	0.3	0.1	0.4	11	0.7	0.3	1.2	5	0.3	0.1	0.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pruritus generalised (10052576)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoriasis (10037153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash (10037844)	12	0.2	0.1	0.4	5	0.1	0.0	0.2	8	0.1	0.1	0.3	12	0.2	0.1	0.3	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash generalised (10037858)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash macular (10037867)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash pruritic (10037884)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin burning sensation (10054786)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin exfoliation (10040844)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin lesion (10040882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin swelling (10053262)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin warm (10040952)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urticaria (10046735)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth extraction (10062132)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	14	0.2	0.1	0.4	3	0.1	0.0	0.2	9	0.1	0.1	0.3	4	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angiopathy (10059245)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Behcet's syndrome (10004213)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blood pressure fluctuation (10005746)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flushing (10016825)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hot flush (10060800)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperaemia (10020565)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertension (10020772)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypotension (10021097)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral coldness (10034568)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicose vein (10046996)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit