

GSK Vaccines R&D	APPENDIX
Statistical Analysis Report	
Study alias & e-track number(s): HPV-094 (207644)	
Analysis ID / Description: ANALYSIS_E1_01/Analysis to investigate the imbalance in incidence of CIN2+ and CIN3+ cases in Efficacy Study	

Detailed Title:	Meta analysis of HPV-associated cases in efficacy studies according to baseline cytology and DNA status.
Scope:	Efficacy data related to the studies HPV-008, HPV-015, HPV-032, HPV-063 Ext HPV-032, HPV-039
Stat Analyst(s):	PPD
Statistician:	PPD
Date of Database Freeze (DBF):	Respective DBF dates used for the final efficacy report for each of the study
Date of Statistical Analysis Report:	30-June-2017

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1. DOCUMENT HISTORY

Date	SAR Validation	Description	Reference Document
30-June-2017	<input checked="" type="checkbox"/> In a SAR validation document <input type="checkbox"/> In this SAR	First version	SAP Dated 31 Jan 2017

2. STATISTICAL METHOD

All the analysis was performed as per the Statistical Analysis Plan.

2.1. Synopsis

Not applicable: the statistical analyses are not for a study report

2.2. Major change for inclusion in the study report

Not applicable: the statistical analyses are not for a study report

2.3. Minor change not for the study report

Not applicable: the statistical analyses have been performed as per approved Statistical Analysis Plan.

3. CONCLUSION FOR CONFIRMATORY OBJECTIVE(S)

Not applicable: the statistical analyses are not aiming to conclude on confirmatory objectives

4. SAR APPENDICES

The results from the analysis are presented in the annexes

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- HPV-094 (207644)- Annex tables E1_01 - Annex 1.docx
- HPV-094 (207644)- Annex tables E1_01 - Annex 2.docx
- HPV-094 (207644)- Annex tables E1_01 - Annex 3.docx
- HPV-094 (207644)- Annex tables E1_01 - Annex 4.docx

5. SUMMARY OF RESULTS

The analysis result indicates that:

- In total, there are 31482 subjects in TVC in the pooled analysis. Approximately 60% of them are from HPV-008 study. Followed by HPV-039 and HPV-015.
- To note that the age groups in the studies are not the same. HPV-008, HPV-039, HPV-032 were in subjects who were ≤ 25 years of age at the vaccination and in study HPV-015 were of the age >25 years of age at the vaccination.
- To note that the control used in the studies are not the same.
- Following categories were considered for cytology status at baseline
 - High: AGC, ASC-H and HSIL
 - Low: ASC-US+ and LSIL
 - Normal: negative or ASC-US/HCII-
- Following categories are considered for HPV DNA status at baseline
 - HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18. That is, a non-vaccine oncogenic HPV type (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, or 68) had to be present and might be co-infected with HPV-16/18.
 - With HPV-16/18 = HPV-16, 18 (including co-infections with other non-vaccine type)
 - With HPV-16/18 Only = HPV-16, 18 (excluding co-infection)
 - With HR-HPV = HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68
 - Without HR-HPV = Subjects who were positive for Low risk HPV DNA or were negative for HPV DNA at the baseline
- 0.8% in HPV group and 0.7% in Control group had high grade cytology at baseline in the pooled analysis.

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- By study, the baseline high grade cytology status was: HPV-015 (1.3% Vs 1.0%), HPV-008 (0.5% Vs 0.5%), HPV-032(0.8% Vs 1.0%), and HPV-039 (1.1% Vs 1.0%). However, to note that the number of subjects was < 50 in each group.
- Overall, there were 18.6% subjects in HPV group and 18.2% in Control group were DNA positive for a high risk (HR) HPV type at baseline.
- 3.4% in HPV group and 3.1 % in control group were positive for HPV-16 and/or HPV-18 only at baseline (excluding co-infections).
- Overall, 2.9% subjects & 3.9% subjects reported CIN2 cases irrespective of HPV type, 3.2% subjects & 4.3% subjects reported CIN2+ cases irrespective of HPV type and 1.3% subjects & 1.6% subjects reported CIN3+ cases irrespective of HPV type.
- The imbalance observed in HPV-015 for high grade could be because of the age group and/or pre-existing disease or infections as the same is not observed when pooling cases from all studies.
- Overall, the majority of CIN2+, CIN3+ cases observed in HPV-015 are associated with HRW-HPV (HR-HPV without HPV-16/18). HPV-16/18-only cases represent 20-24% of cases
- The imbalance of CIN2+ and CIN3+ cases in subjects with high grade cytology or who are HR-DNA positive at baseline is not observed in other age groups than the elderly (26 and above, which are predominantly the subjects from HPV-015). There were a limited number of cases in each category for the younger groups.

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Table 1 Number and Percentage of Subjects in each Study (Total vaccinated cohort)

		HPV N = 15741		Control N = 15741		Total N = 31482	
Characteristics	Categories	n	%	n	%	n	%
Study	008	9319	59.2	9325	59.2	18644	59.2
	015	2877	18.3	2870	18.2	5747	18.3
	032	519	3.3	521	3.3	1040	3.3
	039	3026	19.2	3025	19.2	6051	19.2

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 2 Summary of DNA Status at Baseline (Total vaccinated cohort)

Characteristics	Categories	HPV N = 15741		Control N = 15741		Total N = 31482	
		n	%	n	%	n	%
High Risk HPV Without Vaccine Type	HRW-HPV	2392	15.2	2381	15.1	4773	15.2
Vaccine Type	With HPV-16/18	998	6.3	952	6.0	1950	6.2
Vaccine Type Only	With HPV-16/18 Only	542	3.4	490	3.1	1032	3.3
High Risk HPV Type	With HR-HPV	2934	18.6	2871	18.2	5805	18.4
	Without HR-HPV	12780	81.2	12833	81.5	25613	81.4

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 3 Summary of Cytology Status at Baseline (Total vaccinated cohort)

		HPV N = 15741		Control N = 15741		Total N = 31482	
Characteristics	Categories	n	%	n	%	n	%
Cytology Status at Baseline	High	119	0.8	107	0.7	226	0.7
	Low	1052	6.7	1045	6.6	2097	6.7
	Normal	14547	92.4	14560	92.5	29107	92.5

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 4 Summary of DNA Status at Baseline by Cytology Status (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total			
			N	n	%	N	n	%	N	n	%	
High	High Risk HPV Without Vaccine Type	HRW-HPV	119	66	55.5	107	64	59.8	226	130	57.5	
	Vaccine Type	With HPV-16/18	119	66	55.5	107	59	55.1	226	125	55.3	
	Vaccine Type Only	With HPV-16/18 Only	119	39	32.8	107	28	26.2	226	67	29.6	
	High Risk HPV Type	With HR-HPV	With HR-HPV	119	105	88.2	107	92	86.0	226	197	87.2
			Without HR-HPV	119	14	11.8	107	15	14.0	226	29	12.8
Normal	High Risk HPV Without Vaccine Type	HRW-HPV	14547	1573	10.8	14560	1579	10.8	29107	3152	10.8	
	Vaccine Type	With HPV-16/18	14547	598	4.1	14560	573	3.9	29107	1171	4.0	
	Vaccine Type Only	With HPV-16/18 Only	14547	372	2.6	14560	335	2.3	29107	707	2.4	
	High Risk HPV Type	With HR-HPV	With HR-HPV	14547	1945	13.4	14560	1914	13.1	29107	3859	13.3
			Without HR-HPV	14547	12592	86.6	14560	12638	86.8	29107	25230	86.7
Low	High Risk HPV Without Vaccine Type	HRW-HPV	1052	753	71.6	1045	738	70.6	2097	1491	71.1	
	Vaccine Type	With HPV-16/18	1052	334	31.7	1045	320	30.6	2097	654	31.2	
	Vaccine Type Only	With HPV-16/18 Only	1052	131	12.5	1045	127	12.2	2097	258	12.3	
	High Risk HPV Type	With HR-HPV	With HR-HPV	1052	884	84.0	1045	865	82.8	2097	1749	83.4
			Without HR-HPV	1052	168	16.0	1045	179	17.1	2097	347	16.5
Missing	High Risk HPV Without Vaccine Type	HRW-HPV	23	0	0.0	29	0	0.0	52	0	0.0	
	Vaccine Type	With HPV-16/18	23	0	0.0	29	0	0.0	52	0	0.0	
	Vaccine Type Only	With HPV-16/18 Only	23	0	0.0	29	0	0.0	52	0	0.0	
	High Risk HPV Type	With HR-HPV	With HR-HPV	23	0	0.0	29	0	0.0	52	0	0.0
			Without HR-HPV	23	6	26.1	29	1	3.4	52	7	13.5

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each cytology status category at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 5 Summary of Cytology Status at Baseline by study (Total vaccinated cohort)

Study	Cytology Status at Baseline	HPV			Control			Total		
		N	n	%	N	n	%	N	n	%
008	High	9319	45	0.5	9325	43	0.5	18644	88	0.5
	Low	9319	714	7.7	9325	682	7.3	18644	1396	7.5
	Normal	9319	8544	91.7	9325	8585	92.1	18644	17129	91.9
015	High	2877	36	1.3	2870	30	1.0	5747	66	1.1
	Low	2877	123	4.3	2870	124	4.3	5747	247	4.3
	Normal	2877	2717	94.4	2870	2713	94.5	5747	5430	94.5
032	High	519	4	0.8	521	5	1.0	1040	9	0.9
	Low	519	49	9.4	521	58	11.1	1040	107	10.3
	Normal	519	465	89.6	521	458	87.9	1040	923	88.8
039	High	3026	34	1.1	3025	29	1.0	6051	63	1.0
	Low	3026	166	5.5	3025	181	6.0	6051	347	5.7
	Normal	3026	2821	93.2	3025	2804	92.7	6051	5625	93.0

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 6 Summary of DNA Status at Baseline by study (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	High Risk HPV Without Vaccine Type	HRW-HPV	9319	1552	16.7	9325	1536	16.5	18644	3088	16.6
	Vaccine Type	With HPV-16/18	9319	690	7.4	9325	649	7.0	18644	1339	7.2
	Vaccine Type Only	With HPV-16/18 Only	9319	346	3.7	9325	319	3.4	18644	665	3.6
	High Risk HPV Type	With HR-HPV	9319	1898	20.4	9325	1855	19.9	18644	3753	20.1
		Without HR-HPV	9319	7402	79.4	9325	7447	79.9	18644	14849	79.6
015	High Risk HPV Without Vaccine Type	HRW-HPV	2877	343	11.9	2870	334	11.6	5747	677	11.8
	Vaccine Type	With HPV-16/18	2877	113	3.9	2870	116	4.0	5747	229	4.0
	Vaccine Type Only	With HPV-16/18 Only	2877	73	2.5	2870	74	2.6	5747	147	2.6
	High Risk HPV Type	With HR-HPV	2877	416	14.5	2870	408	14.2	5747	824	14.3
		Without HR-HPV	2877	2458	85.4	2870	2459	85.7	5747	4917	85.6
032	High Risk HPV Without Vaccine Type	HRW-HPV	519	120	23.1	521	129	24.8	1040	249	23.9
	Vaccine Type	With HPV-16/18	519	44	8.5	521	59	11.3	1040	103	9.9
	Vaccine Type Only	With HPV-16/18 Only	519	27	5.2	521	28	5.4	1040	55	5.3
	High Risk HPV Type	With HR-HPV	519	147	28.3	521	157	30.1	1040	304	29.2
		Without HR-HPV	519	372	71.7	521	364	69.9	1040	736	70.8
039	High Risk HPV Without Vaccine Type	HRW-HPV	3026	377	12.5	3025	382	12.6	6051	759	12.5
	Vaccine Type	With HPV-16/18	3026	151	5.0	3025	128	4.2	6051	279	4.6
	Vaccine Type Only	With HPV-16/18 Only	3026	96	3.2	3025	69	2.3	6051	165	2.7
	High Risk HPV Type	With HR-HPV	3026	473	15.6	3025	451	14.9	6051	924	15.3
		Without HR-HPV	3026	2548	84.2	3025	2563	84.7	6051	5111	84.5

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 7 Summary of Demographic characteristics (Total vaccinated cohort)

		HPV N = 15741		Control N = 15741		Total N = 31482	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	23.8	-	23.8	-	23.8	-
	SD	7.5	-	7.5	-	7.5	-
	Median	22.0	-	22.0	-	22.0	-
	Minimum	14.0	-	15.0	-	14.0	-
	Maximum	72.0	-	68.0	-	72.0	-
Gender	F	15741	100	15741	100	31482	100
Race	Arabic/North African	13	0.1	16	0.1	29	0.1
	Asian - Chinese Heritage	3862	24.5	3850	24.5	7712	24.5
	Asian - Japanese Heritage	522	3.3	526	3.3	1048	3.3
	Black	414	2.6	432	2.7	846	2.7
	East & South East Asian	2802	17.8	2793	17.7	5595	17.8
	Hispanic	1469	9.3	1464	9.3	2933	9.3
	Indian	21	0.1	28	0.2	49	0.2
	Malay	32	0.2	29	0.2	61	0.2
	South Asian	14	0.1	15	0.1	29	0.1
	White/Caucasian	6322	40.2	6313	40.1	12635	40.1
	Other	270	1.7	275	1.7	545	1.7
Height in CM	Mean	160.6	-	160.7	-	160.7	-
	SD	7.4	-	7.3	-	7.3	-
	Median	160.0	-	160.0	-	160.0	-
Weight in KG	Mean	59.3	-	59.2	-	59.2	-
	SD	13.6	-	13.3	-	13.5	-
	Median	56.5	-	56.8	-	56.8	-
BMI	Mean	22.9	-	22.9	-	22.9	-
	SD	4.7	-	4.7	-	4.7	-
	Median	21.8	-	21.8	-	21.8	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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**Table 8 Summary of Demographic characteristics - Cytology Status (High)
(Total vaccinated cohort)**

		HPV N = 119		Control N = 107		Total N = 226	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	25.9	-	25.7	-	25.8	-
	SD	8.1	-	8.3	-	8.2	-
	Median	24.0	-	23.0	-	24.0	-
	Minimum	15.0	-	16.0	-	15.0	-
	Maximum	56.0	-	59.0	-	59.0	-
Gender	F	119	100	107	100	226	100
Race	Asian - Chinese Heritage	37	31.1	31	29.0	68	30.1
	Asian - Japanese Heritage	4	3.4	5	4.7	9	4.0
	Black	4	3.4	0	0.0	4	1.8
	East & South East Asian	15	12.6	13	12.1	28	12.4
	Hispanic	16	13.4	10	9.3	26	11.5
	Indian	1	0.8	0	0.0	1	0.4
	Malay	0	0.0	1	0.9	1	0.4
	White/Caucasian	42	35.3	44	41.1	86	38.1
	Other	0	0.0	3	2.8	3	1.3
Height in CM	Mean	161.3	-	160.9	-	161.1	-
	SD	7.6	-	6.8	-	7.2	-
	Median	160.0	-	160.0	-	160.0	-
Weight in KG	Mean	60.6	-	59.0	-	59.8	-
	SD	13.8	-	11.2	-	12.6	-
	Median	58.7	-	57.0	-	57.8	-
BMI	Mean	23.3	-	22.7	-	23.0	-
	SD	5.0	-	3.9	-	4.5	-
	Median	22.1	-	22.0	-	22.0	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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**Table 9 Summary of Demographic characteristics - Cytology Status (Low)
(Total vaccinated cohort)**

Characteristics	Parameters or Categories	HPV N = 1052		Control N = 1045		Total N = 2097	
		Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	21.9	-	22.1	-	22.0	-
	SD	5.6	-	5.6	-	5.6	-
	Median	21.0	-	21.0	-	21.0	-
	Minimum	15.0	-	15.0	-	15.0	-
	Maximum	52.0	-	59.0	-	59.0	-
Gender	F	1052	100	1045	100	2097	100
Race	Arabic/North African	0	0.0	1	0.1	1	0.0
	Asian - Chinese Heritage	196	18.6	220	21.1	416	19.8
	Asian - Japanese Heritage	49	4.7	58	5.6	107	5.1
	Black	53	5.0	59	5.6	112	5.3
	East & South East Asian	97	9.2	104	10.0	201	9.6
	Hispanic	89	8.5	91	8.7	180	8.6
	Indian	1	0.1	1	0.1	2	0.1
	Malay	2	0.2	1	0.1	3	0.1
	South Asian	0	0.0	1	0.1	1	0.0
	White/Caucasian	537	51.0	482	46.1	1019	48.6
	Other	28	2.7	27	2.6	55	2.6
Height in CM	Mean	161.7	-	161.5	-	161.6	-
	SD	7.4	-	7.2	-	7.3	-
	Median	161.0	-	161.0	-	161.0	-
Weight in KG	Mean	59.9	-	59.3	-	59.6	-
	SD	13.6	-	13.1	-	13.3	-
	Median	57.0	-	57.0	-	57.0	-
BMI	Mean	22.8	-	22.7	-	22.8	-
	SD	4.5	-	4.4	-	4.4	-
	Median	21.9	-	21.9	-	21.9	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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**Table 10 Summary of Demographic characteristics - Cytology Status (Normal)
(Total vaccinated cohort)**

		HPV N = 14547		Control N = 14560		Total N = 29107	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	23.9	-	23.9	-	23.9	-
	SD	7.6	-	7.6	-	7.6	-
	Median	22.0	-	22.0	-	22.0	-
	Minimum	14.0	-	15.0	-	14.0	-
	Maximum	72.0	-	68.0	-	72.0	-
Gender	F	14547	100	14560	100	29107	100
Race	Arabic/North African	13	0.1	15	0.1	28	0.1
	Asian - Chinese Heritage	3624	24.9	3587	24.6	7211	24.8
	Asian - Japanese Heritage	468	3.2	463	3.2	931	3.2
	Black	357	2.5	371	2.5	728	2.5
	East & South East Asian	2682	18.4	2669	18.3	5351	18.4
	Hispanic	1363	9.4	1363	9.4	2726	9.4
	Indian	19	0.1	27	0.2	46	0.2
	Malay	30	0.2	27	0.2	57	0.2
	South Asian	14	0.1	14	0.1	28	0.1
	White/Caucasian	5735	39.4	5780	39.7	11515	39.6
	Other	242	1.7	244	1.7	486	1.7
Height in CM	Mean	160.6	-	160.7	-	160.6	-
	SD	7.3	-	7.3	-	7.3	-
	Median	160.0	-	160.0	-	160.0	-
Weight in KG	Mean	59.2	-	59.2	-	59.2	-
	SD	13.6	-	13.4	-	13.5	-
	Median	56.5	-	56.8	-	56.6	-
BMI	Mean	22.9	-	22.9	-	22.9	-
	SD	4.7	-	4.7	-	4.7	-
	Median	21.8	-	21.8	-	21.8	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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Table 11 Summary of Demographic characteristics - Cytology Status (Missing) (Total vaccinated cohort)

		HPV N = 23		Control N = 29		Total N = 52	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	23.3	-	24.2	-	23.8	-
	SD	3.1	-	6.2	-	5.1	-
	Median	23.0	-	24.0	-	23.5	-
	Minimum	18.0	-	16.0	-	16.0	-
	Maximum	34.0	-	43.0	-	43.0	-
Gender	F	23	100	29	100	52	100
Race	Asian - Chinese Heritage	5	21.7	12	41.4	17	32.7
	Asian - Japanese Heritage	1	4.3	0	0.0	1	1.9
	Black	0	0.0	2	6.9	2	3.8
	East & South East Asian	8	34.8	7	24.1	15	28.8
	Hispanic	1	4.3	0	0.0	1	1.9
	White/Caucasian	8	34.8	7	24.1	15	28.8
	Other	0	0.0	1	3.4	1	1.9
Height in CM	Mean	157.0	-	159.0	-	158.1	-
	SD	6.5	-	7.7	-	7.2	-
	Median	157.0	-	160.0	-	157.0	-
Weight in KG	Mean	57.8	-	60.0	-	59.0	-
	SD	14.0	-	13.4	-	13.5	-
	Median	54.6	-	55.0	-	54.8	-
BMI	Mean	23.3	-	23.6	-	23.5	-
	SD	4.5	-	4.3	-	4.4	-
	Median	22.2	-	22.7	-	22.4	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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Table 12 Summary of Demographic characteristics - DNA Status (With HR-HPV) (Total vaccinated cohort)

Characteristics	Parameters or Categories	HPV N = 2934		Control N = 2871		Total N = 5805	
		Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	22.7	-	22.8	-	22.7	-
	SD	6.0	-	6.4	-	6.2	-
	Median	22.0	-	22.0	-	22.0	-
	Minimum	15.0	-	15.0	-	15.0	-
	Maximum	61.0	-	59.0	-	61.0	-
Gender	F	2934	100	2871	100	5805	100
Race	Arabic/North African	1	0.0	5	0.2	6	0.1
	Asian - Chinese Heritage	577	19.7	550	19.2	1127	19.4
	Asian - Japanese Heritage	147	5.0	157	5.5	304	5.2
	Black	135	4.6	146	5.1	281	4.8
	East & South East Asian	325	11.1	352	12.3	677	11.7
	Hispanic	294	10.0	272	9.5	566	9.8
	Indian	3	0.1	2	0.1	5	0.1
	Malay	3	0.1	4	0.1	7	0.1
	South Asian	5	0.2	0	0.0	5	0.1
	White/Caucasian	1366	46.6	1314	45.8	2680	46.2
	Other	78	2.7	69	2.4	147	2.5
Height in CM	Mean	161.5	-	161.5	-	161.5	-
	SD	7.3	-	7.2	-	7.3	-
	Median	161.0	-	161.0	-	161.0	-
Weight in KG	Mean	59.8	-	59.5	-	59.6	-
	SD	13.2	-	13.4	-	13.3	-
	Median	57.5	-	57.0	-	57.3	-
BMI	Mean	22.9	-	22.7	-	22.8	-
	SD	4.5	-	4.5	-	4.5	-
	Median	21.9	-	21.8	-	21.8	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 13 Summary of Demographic characteristics - DNA Status (Without HR-HPV) (Total vaccinated cohort)

		HPV N = 12780		Control N = 12833		Total N = 25613	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	24.0	-	24.0	-	24.0	-
	SD	7.8	-	7.7	-	7.8	-
	Median	23.0	-	23.0	-	23.0	-
	Minimum	14.0	-	15.0	-	14.0	-
	Maximum	72.0	-	68.0	-	72.0	-
Gender	F	12780	100	12833	100	25613	100
Race	Arabic/North African	12	0.1	11	0.1	23	0.1
	Asian - Chinese Heritage	3280	25.7	3288	25.6	6568	25.6
	Asian - Japanese Heritage	375	2.9	369	2.9	744	2.9
	Black	279	2.2	283	2.2	562	2.2
	East & South East Asian	2470	19.3	2433	19.0	4903	19.1
	Hispanic	1174	9.2	1191	9.3	2365	9.2
	Indian	18	0.1	26	0.2	44	0.2
	Malay	29	0.2	25	0.2	54	0.2
	South Asian	9	0.1	15	0.1	24	0.1
	White/Caucasian	4942	38.7	4987	38.9	9929	38.8
	Other	192	1.5	205	1.6	397	1.5
Height in CM	Mean	160.4	-	160.6	-	160.5	-
	SD	7.3	-	7.3	-	7.3	-
	Median	160.0	-	160.0	-	160.0	-
Weight in KG	Mean	59.2	-	59.1	-	59.1	-
	SD	13.7	-	13.3	-	13.5	-
	Median	56.2	-	56.8	-	56.5	-
BMI	Mean	22.9	-	22.9	-	22.9	-
	SD	4.8	-	4.7	-	4.7	-
	Median	21.8	-	21.8	-	21.8	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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**Table 14 Summary of Demographic characteristics - DNA Status (HRW-HPV)
(Total vaccinated cohort)**

Characteristics	Parameters or Categories	HPV N = 2392		Control N = 2381		Total N = 4773	
		Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	22.7	-	22.8	-	22.8	-
	SD	6.1	-	6.3	-	6.2	-
	Median	22.0	-	22.0	-	22.0	-
	Minimum	15.0	-	15.0	-	15.0	-
	Maximum	61.0	-	59.0	-	61.0	-
Gender	F	2392	100	2381	100	4773	100
Race	Arabic/North African	1	0.0	2	0.1	3	0.1
	Asian - Chinese Heritage	470	19.6	468	19.7	938	19.7
	Asian - Japanese Heritage	120	5.0	129	5.4	249	5.2
	Black	113	4.7	123	5.2	236	4.9
	East & South East Asian	255	10.7	295	12.4	550	11.5
	Hispanic	260	10.9	231	9.7	491	10.3
	Indian	3	0.1	2	0.1	5	0.1
	Malay	3	0.1	3	0.1	6	0.1
	South Asian	3	0.1	0	0.0	3	0.1
	White/Caucasian	1103	46.1	1072	45.0	2175	45.6
	Other	61	2.6	56	2.4	117	2.5
Height in CM	Mean	161.3	-	161.4	-	161.4	-
	SD	7.3	-	7.3	-	7.3	-
	Median	161.0	-	161.0	-	161.0	-
Weight in KG	Mean	59.9	-	59.4	-	59.6	-
	SD	13.4	-	13.4	-	13.4	-
	Median	57.4	-	57.0	-	57.0	-
BMI	Mean	23.0	-	22.7	-	22.8	-
	SD	4.6	-	4.6	-	4.6	-
	Median	22.0	-	21.8	-	21.9	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 15 Summary of Demographic characteristics - DNA Status (With HPV-16/18) (Total vaccinated cohort)

		HPV N = 998		Control N = 952		Total N = 1950	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	21.9	-	22.2	-	22.0	-
	SD	5.3	-	6.0	-	5.7	-
	Median	21.0	-	21.0	-	21.0	-
	Minimum	15.0	-	15.0	-	15.0	-
	Maximum	53.0	-	59.0	-	59.0	-
Gender	F	998	100	952	100	1950	100
Race	Arabic/North African	0	0.0	3	0.3	3	0.2
	Asian - Chinese Heritage	172	17.2	151	15.9	323	16.6
	Asian - Japanese Heritage	44	4.4	59	6.2	103	5.3
	Black	46	4.6	49	5.1	95	4.9
	East & South East Asian	91	9.1	88	9.2	179	9.2
	Hispanic	74	7.4	73	7.7	147	7.5
	Indian	1	0.1	0	0.0	1	0.1
	Malay	0	0.0	1	0.1	1	0.1
	South Asian	3	0.3	0	0.0	3	0.2
	White/Caucasian	540	54.1	507	53.3	1047	53.7
	Other	27	2.7	21	2.2	48	2.5
Height in CM	Mean	162.4	-	162.5	-	162.4	-
	SD	7.3	-	7.0	-	7.2	-
	Median	163.0	-	163.0	-	163.0	-
Weight in KG	Mean	59.7	-	59.6	-	59.6	-
	SD	11.9	-	12.6	-	12.2	-
	Median	58.0	-	57.7	-	58.0	-
BMI	Mean	22.6	-	22.5	-	22.5	-
	SD	4.0	-	3.9	-	4.0	-
	Median	21.8	-	21.7	-	21.7	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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Table 16 Summary of Demographic characteristics - DNA Status (With HPV-16/18 only) (Total vaccinated cohort)

		HPV N = 542		Control N = 490		Total N = 1032	
Characteristics	Parameters or Categories	Value or n	%	Value or n	%	Value or n	%
Age in years at Dose 1	Mean	22.5	-	22.7	-	22.6	-
	SD	5.6	-	6.6	-	6.1	-
	Median	22.0	-	22.0	-	22.0	-
	Minimum	15.0	-	15.0	-	15.0	-
	Maximum	51.0	-	56.0	-	56.0	-
Gender	F	542	100	490	100	1032	100
Race	Arabic/North African	0	0.0	3	0.6	3	0.3
	Asian - Chinese Heritage	107	19.7	82	16.7	189	18.3
	Asian - Japanese Heritage	27	5.0	28	5.7	55	5.3
	Black	22	4.1	23	4.7	45	4.4
	East & South East Asian	70	12.9	57	11.6	127	12.3
	Hispanic	34	6.3	41	8.4	75	7.3
	Malay	0	0.0	1	0.2	1	0.1
	South Asian	2	0.4	0	0.0	2	0.2
	White/Caucasian	263	48.5	242	49.4	505	48.9
	Other	17	3.1	13	2.7	30	2.9
Height in CM	Mean	162.0	-	162.0	-	162.0	-
	SD	7.3	-	7.1	-	7.2	-
	Median	162.0	-	162.0	-	162.0	-
Weight in KG	Mean	59.2	-	60.1	-	59.7	-
	SD	12.2	-	13.3	-	12.7	-
	Median	58.0	-	58.7	-	58.0	-
BMI	Mean	22.5	-	22.8	-	22.6	-
	SD	4.1	-	4.1	-	4.1	-
	Median	21.6	-	21.9	-	21.7	-

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

Value = value of the considered parameter

% = n / Number of subjects with available results x 100

SD = Standard deviation

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Table 1 Number and Percentage of Subjects with CIN2, CIN2+, and CIN3+ by Study & Overall (Total vaccinated cohort)

Study	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	CIN2	No	9319	9054	97.2	9325	8933	95.8	18644	17987	96.5
		Yes	9319	265	2.8	9325	392	4.2	18644	657	3.5
	CIN2+	No	9319	9032	96.9	9325	8897	95.4	18644	17929	96.2
		Yes	9319	287	3.1	9325	428	4.6	18644	715	3.8
	CIN3+	No	9319	9233	99.1	9325	9167	98.3	18644	18400	98.7
		Yes	9319	86	0.9	9325	158	1.7	18644	244	1.3
015	CIN2	No	2877	2786	96.8	2870	2777	96.8	5747	5563	96.8
		Yes	2877	91	3.2	2870	93	3.2	5747	184	3.2
	CIN2+	No	2877	2774	96.4	2870	2762	96.2	5747	5536	96.3
		Yes	2877	103	3.6	2870	108	3.8	5747	211	3.7
	CIN3+	No	2877	2827	98.3	2870	2825	98.4	5747	5652	98.3
		Yes	2877	50	1.7	2870	45	1.6	5747	95	1.7
032	CIN2	No	519	501	96.5	521	483	92.7	1040	984	94.6
		Yes	519	18	3.5	521	38	7.3	1040	56	5.4
	CIN2+	No	519	500	96.3	521	480	92.1	1040	980	94.2
		Yes	519	19	3.7	521	41	7.9	1040	60	5.8
	CIN3+	No	519	510	98.3	521	507	97.3	1040	1017	97.8
		Yes	519	9	1.7	521	14	2.7	1040	23	2.2
039	CIN2	No	3026	2942	97.2	3025	2934	97.0	6051	5876	97.1
		Yes	3026	84	2.8	3025	91	3.0	6051	175	2.9
	CIN2+	No	3026	2929	96.8	3025	2927	96.8	6051	5856	96.8
		Yes	3026	97	3.2	3025	98	3.2	6051	195	3.2
	CIN3+	No	3026	2972	98.2	3025	2986	98.7	6051	5958	98.5
		Yes	3026	54	1.8	3025	39	1.3	6051	93	1.5
Overall total	CIN2	No	15741	15283	97.1	15741	15127	96.1	31482	30410	96.6
		Yes	15741	458	2.9	15741	614	3.9	31482	1072	3.4
	CIN2+	No	15741	15235	96.8	15741	15066	95.7	31482	30301	96.2
		Yes	15741	506	3.2	15741	675	4.3	31482	1181	3.8
	CIN3+	No	15741	15542	98.7	15741	15485	98.4	31482	31027	98.6
		Yes	15741	199	1.3	15741	256	1.6	31482	455	1.4

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 2 Number and Percentage of Subjects with CIN2 by HPV DNA status at baseline (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	High Risk HPV Without Vaccine Type	HRW-HPV	265	130	49.1	392	145	37.0	657	275	41.9
	Vaccine Type	With HPV-16/18	265	88	33.2	392	94	24.0	657	182	27.7
	Vaccine Type Only	With HPV-16/18 Only	265	43	16.2	392	40	10.2	657	83	12.6
	High Risk HPV Type	With HR-HPV	265	173	65.3	392	185	47.2	657	358	54.5
		Without HR-HPV	265	92	34.7	392	207	52.8	657	299	45.5
015	High Risk HPV Without Vaccine Type	HRW-HPV	91	50	54.9	93	51	54.8	184	101	54.9
	Vaccine Type	With HPV-16/18	91	28	30.8	93	32	34.4	184	60	32.6
	Vaccine Type Only	With HPV-16/18 Only	91	17	18.7	93	18	19.4	184	35	19.0
	High Risk HPV Type	With HR-HPV	91	67	73.6	93	69	74.2	184	136	73.9
		Without HR-HPV	91	24	26.4	93	24	25.8	184	48	26.1
032	High Risk HPV Without Vaccine Type	HRW-HPV	18	10	55.6	38	17	44.7	56	27	48.2
	Vaccine Type	With HPV-16/18	18	8	44.4	38	16	42.1	56	24	42.9
	Vaccine Type Only	With HPV-16/18 Only	18	4	22.2	38	9	23.7	56	13	23.2
	High Risk HPV Type	With HR-HPV	18	14	77.8	38	26	68.4	56	40	71.4
		Without HR-HPV	18	4	22.2	38	12	31.6	56	16	28.6
039	High Risk HPV Without Vaccine Type	HRW-HPV	84	52	61.9	91	53	58.2	175	105	60.0
	Vaccine Type	With HPV-16/18	84	40	47.6	91	38	41.8	175	78	44.6
	Vaccine Type Only	With HPV-16/18 Only	84	20	23.8	91	19	20.9	175	39	22.3
	High Risk HPV Type	With HR-HPV	84	72	85.7	91	72	79.1	175	144	82.3
		Without HR-HPV	84	12	14.3	91	17	18.7	175	29	16.6
Overall total	High Risk HPV Without Vaccine Type	HRW-HPV	458	242	52.8	614	266	43.3	1072	508	47.4
	Vaccine Type	With HPV-16/18	458	164	35.8	614	180	29.3	1072	344	32.1
	Vaccine Type Only	With HPV-16/18 Only	458	84	18.3	614	86	14.0	1072	170	15.9
	High Risk HPV Type	With HR-HPV	458	326	71.2	614	352	57.3	1072	678	63.2
		Without HR-HPV	458	132	28.8	614	260	42.3	1072	392	36.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2 in each study and overall

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 3 Number and Percentage of Subjects with CIN2+ by HPV DNA status at baseline (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	High Risk HPV Without Vaccine Type	HRW-HPV	287	145	50.5	428	161	37.6	715	306	42.8
	Vaccine Type	With HPV-16/18	287	103	35.9	428	111	25.9	715	214	29.9
	Vaccine Type Only	With HPV-16/18 Only	287	49	17.1	428	47	11.0	715	96	13.4
	High Risk HPV Type	With HR-HPV	287	194	67.6	428	208	48.6	715	402	56.2
		Without HR-HPV	287	93	32.4	428	220	51.4	715	313	43.8
015	High Risk HPV Without Vaccine Type	HRW-HPV	103	57	55.3	108	58	53.7	211	115	54.5
	Vaccine Type	With HPV-16/18	103	36	35.0	108	42	38.9	211	78	37.0
	Vaccine Type Only	With HPV-16/18 Only	103	21	20.4	108	26	24.1	211	47	22.3
	High Risk HPV Type	With HR-HPV	103	78	75.7	108	84	77.8	211	162	76.8
		Without HR-HPV	103	25	24.3	108	24	22.2	211	49	23.2
032	High Risk HPV Without Vaccine Type	HRW-HPV	19	10	52.6	41	19	46.3	60	29	48.3
	Vaccine Type	With HPV-16/18	19	9	47.4	41	19	46.3	60	28	46.7
	Vaccine Type Only	With HPV-16/18 Only	19	5	26.3	41	10	24.4	60	15	25.0
	High Risk HPV Type	With HR-HPV	19	15	78.9	41	29	70.7	60	44	73.3
		Without HR-HPV	19	4	21.1	41	12	29.3	60	16	26.7
039	High Risk HPV Without Vaccine Type	HRW-HPV	97	54	55.7	98	54	55.1	195	108	55.4
	Vaccine Type	With HPV-16/18	97	51	52.6	98	42	42.9	195	93	47.7
	Vaccine Type Only	With HPV-16/18 Only	97	29	29.9	98	22	22.4	195	51	26.2
	High Risk HPV Type	With HR-HPV	97	83	85.6	98	76	77.6	195	159	81.5
		Without HR-HPV	97	14	14.4	98	20	20.4	195	34	17.4
Overall total	High Risk HPV Without Vaccine Type	HRW-HPV	506	266	52.6	675	292	43.3	1181	558	47.2
	Vaccine Type	With HPV-16/18	506	199	39.3	675	214	31.7	1181	413	35.0
	Vaccine Type Only	With HPV-16/18 Only	506	104	20.6	675	105	15.6	1181	209	17.7
	High Risk HPV Type	With HR-HPV	506	370	73.1	675	397	58.8	1181	767	64.9
		Without HR-HPV	506	136	26.9	675	276	40.9	1181	412	34.9

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2+ in each study and overall

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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**Table 4 Number and Percentage of Subjects with CIN3+ by HPV DNA status
(Total vaccinated cohort)**

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	High Risk HPV Without Vaccine Type	HRW-HPV	86	48	55.8	158	72	45.6	244	120	49.2
	Vaccine Type	With HPV-16/18	86	55	64.0	158	61	38.6	244	116	47.5
	Vaccine Type Only	With HPV-16/18 Only	86	28	32.6	158	26	16.5	244	54	22.1
	High Risk HPV Type	With HR-HPV	86	76	88.4	158	98	62.0	244	174	71.3
		Without HR-HPV	86	10	11.6	158	60	38.0	244	70	28.7
015	High Risk HPV Without Vaccine Type	HRW-HPV	50	34	68.0	45	22	48.9	95	56	58.9
	Vaccine Type	With HPV-16/18	50	24	48.0	45	23	51.1	95	47	49.5
	Vaccine Type Only	With HPV-16/18 Only	50	12	24.0	45	18	40.0	95	30	31.6
	High Risk HPV Type	With HR-HPV	50	46	92.0	45	40	88.9	95	86	90.5
		Without HR-HPV	50	4	8.0	45	5	11.1	95	9	9.5
032	High Risk HPV Without Vaccine Type	HRW-HPV	9	5	55.6	14	8	57.1	23	13	56.5
	Vaccine Type	With HPV-16/18	9	6	66.7	14	9	64.3	23	15	65.2
	Vaccine Type Only	With HPV-16/18 Only	9	4	44.4	14	3	21.4	23	7	30.4
	High Risk HPV Type	With HR-HPV	9	9	100	14	11	78.6	23	20	87.0
		Without HR-HPV	9	0	0.0	14	3	21.4	23	3	13.0
039	High Risk HPV Without Vaccine Type	HRW-HPV	54	27	50.0	39	17	43.6	93	44	47.3
	Vaccine Type	With HPV-16/18	54	37	68.5	39	25	64.1	93	62	66.7
	Vaccine Type Only	With HPV-16/18 Only	54	23	42.6	39	16	41.0	93	39	41.9
	High Risk HPV Type	With HR-HPV	54	50	92.6	39	33	84.6	93	83	89.2
		Without HR-HPV	54	4	7.4	39	5	12.8	93	9	9.7
Overall total	High Risk HPV Without Vaccine Type	HRW-HPV	199	114	57.3	256	119	46.5	455	233	51.2
	Vaccine Type	With HPV-16/18	199	122	61.3	256	118	46.1	455	240	52.7
	Vaccine Type Only	With HPV-16/18 Only	199	67	33.7	256	63	24.6	455	130	28.6
	High Risk HPV Type	With HR-HPV	199	181	91.0	256	182	71.1	455	363	79.8
		Without HR-HPV	199	18	9.0	256	73	28.5	455	91	20.0

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN3+ in each study and overall

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 5 Number and Percentage of Subjects with CIN2 by cytology status at baseline (Total vaccinated cohort)

Study	Cytology Status at Baseline	HPV			Control			Total		
		N	n	%	N	n	%	N	n	%
008	High	265	17	6.4	392	22	5.6	657	39	5.9
	Low	265	93	35.1	392	92	23.5	657	185	28.2
	Normal	265	155	58.5	392	277	70.7	657	432	65.8
015	High	91	21	23.1	93	11	11.8	184	32	17.4
	Low	91	27	29.7	93	26	28.0	184	53	28.8
	Normal	91	43	47.3	93	56	60.2	184	99	53.8
032	High	18	3	16.7	38	3	7.9	56	6	10.7
	Low	18	7	38.9	38	12	31.6	56	19	33.9
	Normal	18	8	44.4	38	23	60.5	56	31	55.4
039	High	84	13	15.5	91	19	20.9	175	32	18.3
	Low	84	36	42.9	91	33	36.3	175	69	39.4
	Normal	84	35	41.7	91	37	40.7	175	72	41.1
Overall total	High	458	54	11.8	614	55	9.0	1072	109	10.2
	Low	458	163	35.6	614	163	26.5	1072	326	30.4
	Normal	458	241	52.6	614	393	64.0	1072	634	59.1

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2 in each study and overall

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 6 Number and Percentage of Subjects with CIN2+ by cytology status at baseline (Total vaccinated cohort)

Study	Cytology Status at Baseline	HPV			Control			Total		
		N	n	%	N	n	%	N	n	%
008	High	287	20	7.0	428	25	5.8	715	45	6.3
	Low	287	101	35.2	428	103	24.1	715	204	28.5
	Normal	287	166	57.8	428	299	69.9	715	465	65.0
015	High	103	27	26.2	108	18	16.7	211	45	21.3
	Low	103	27	26.2	108	28	25.9	211	55	26.1
	Normal	103	49	47.6	108	62	57.4	211	111	52.6
032	High	19	3	15.8	41	4	9.8	60	7	11.7
	Low	19	8	42.1	41	13	31.7	60	21	35.0
	Normal	19	8	42.1	41	24	58.5	60	32	53.3
039	High	97	21	21.6	98	20	20.4	195	41	21.0
	Low	97	38	39.2	98	35	35.7	195	73	37.4
	Normal	97	38	39.2	98	41	41.8	195	79	40.5
Overall total	High	506	71	14.0	675	67	9.9	1181	138	11.7
	Low	506	174	34.4	675	179	26.5	1181	353	29.9
	Normal	506	261	51.6	675	426	63.1	1181	687	58.2

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2+ in each study and overall

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

Table 7 Number and Percentage of Subjects with CIN3+ by cytology status at baseline (Total vaccinated cohort)

Study	Cytology Status at Baseline	HPV			Control			Total		
		N	n	%	N	n	%	N	n	%
008	High	86	13	15.1	158	13	8.2	244	26	10.7
	Low	86	33	38.4	158	39	24.7	244	72	29.5
	Normal	86	40	46.5	158	106	67.1	244	146	59.8
015	High	50	25	50.0	45	13	28.9	95	38	40.0
	Low	50	10	20.0	45	9	20.0	95	19	20.0
	Normal	50	15	30.0	45	23	51.1	95	38	40.0
032	High	9	2	22.2	14	2	14.3	23	4	17.4
	Low	9	4	44.4	14	5	35.7	23	9	39.1
	Normal	9	3	33.3	14	7	50.0	23	10	43.5
039	High	54	17	31.5	39	14	35.9	93	31	33.3
	Low	54	22	40.7	39	12	30.8	93	34	36.6
	Normal	54	15	27.8	39	12	30.8	93	27	29.0
Overall total	High	199	57	28.6	256	42	16.4	455	99	21.8
	Low	199	69	34.7	256	65	25.4	455	134	29.5
	Normal	199	73	36.7	256	148	57.8	455	221	48.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN3+ in each study and overall

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 8 Number and Percentage of Subjects with CIN2 by DNA Status and cytology status at baseline (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	High Risk HPV Without Vaccine Type	HRW-HPV	54	32	59.3	55	37	67.3	109	69	63.3
	Vaccine Type	With HPV-16/18	54	33	61.1	55	35	63.6	109	68	62.4
	Vaccine Type Only	With HPV-16/18 Only	54	21	38.9	55	17	30.9	109	38	34.9
	High Risk HPV Type	With HR-HPV	54	53	98.1	55	54	98.2	109	107	98.2
		Without HR-HPV	54	1	1.9	55	1	1.8	109	2	1.8
Normal	High Risk HPV Without Vaccine Type	HRW-HPV	241	84	34.9	393	106	27.0	634	190	30.0
	Vaccine Type	With HPV-16/18	241	51	21.2	393	66	16.8	634	117	18.5
	Vaccine Type Only	With HPV-16/18 Only	241	32	13.3	393	40	10.2	634	72	11.4
	High Risk HPV Type	With HR-HPV	241	116	48.1	393	146	37.2	634	262	41.3
		Without HR-HPV	241	125	51.9	393	247	62.8	634	372	58.7
Low	High Risk HPV Without Vaccine Type	HRW-HPV	163	126	77.3	163	123	75.5	326	249	76.4
	Vaccine Type	With HPV-16/18	163	80	49.1	163	79	48.5	326	159	48.8
	Vaccine Type Only	With HPV-16/18 Only	163	31	19.0	163	29	17.8	326	60	18.4
	High Risk HPV Type	With HR-HPV	163	157	96.3	163	152	93.3	326	309	94.8
		Without HR-HPV	163	6	3.7	163	11	6.7	326	17	5.2
Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	3	0	0.0	3	0	0.0
	Vaccine Type	With HPV-16/18	0	-	-	3	0	0.0	3	0	0.0
	Vaccine Type Only	With HPV-16/18 Only	0	-	-	3	0	0.0	3	0	0.0
	High Risk HPV Type	With HR-HPV	0	-	-	3	0	0.0	3	0	0.0
		Without HR-HPV	0	-	-	3	1	33.3	3	1	33.3

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2 case during the study by cytology status

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 9 Number and Percentage of Subjects with CIN2 by DNA Status and cytology status at baseline - by study (Total vaccinated cohort)

Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
008	High	High Risk HPV Without Vaccine Type	HRW-HPV	17	7	41.2	22	16	72.7	39	23	59.0
		Vaccine Type	With HPV-16/18	17	12	70.6	22	14	63.6	39	26	66.7
		Vaccine Type Only	With HPV-16/18 Only	17	9	52.9	22	5	22.7	39	14	35.9
		High Risk HPV Type	With HR-HPV	17	16	94.1	22	21	95.5	39	37	94.9
			Without HR-HPV	17	1	5.9	22	1	4.5	39	2	5.1
		Normal	High Risk HPV Without Vaccine Type	HRW-HPV	155	49	31.6	277	62	22.4	432	111
	Vaccine Type		With HPV-16/18	155	31	20.0	277	37	13.4	432	68	15.7
	Vaccine Type Only		With HPV-16/18 Only	155	19	12.3	277	19	6.9	432	38	8.8
	High Risk HPV Type		With HR-HPV	155	68	43.9	277	81	29.2	432	149	34.5
			Without HR-HPV	155	87	56.1	277	196	70.8	432	283	65.5
	Low		High Risk HPV Without Vaccine Type	HRW-HPV	93	74	79.6	92	67	72.8	185	141
		Vaccine Type	With HPV-16/18	93	45	48.4	92	43	46.7	185	88	47.6
		Vaccine Type Only	With HPV-16/18 Only	93	15	16.1	92	16	17.4	185	31	16.8
		High Risk HPV Type	With HR-HPV	93	89	95.7	92	83	90.2	185	172	93.0
			Without HR-HPV	93	4	4.3	92	9	9.8	185	13	7.0
		Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	1	0	0.0	1	0
	Vaccine Type		With HPV-16/18	0	-	-	1	0	0.0	1	0	0.0
	Vaccine Type Only		With HPV-16/18 Only	0	-	-	1	0	0.0	1	0	0.0
	High Risk HPV Type		With HR-HPV	0	-	-	1	0	0.0	1	0	0.0
			Without HR-HPV	0	-	-	1	1	100	1	1	100
	015		High	High Risk HPV Without Vaccine Type	HRW-HPV	21	16	76.2	11	7	63.6	32
Vaccine Type		With HPV-16/18		21	8	38.1	11	7	63.6	32	15	46.9
Vaccine Type Only		With HPV-16/18 Only		21	5	23.8	11	4	36.4	32	9	28.1
High Risk HPV Type		With HR-HPV		21	21	100	11	11	100	32	32	100
		Without HR-HPV		21	0	0.0	11	0	0.0	32	0	0.0
Normal		High Risk HPV Without Vaccine Type		HRW-HPV	43	16	37.2	56	23	41.1	99	39
		Vaccine Type	With HPV-16/18	43	5	11.6	56	13	23.2	99	18	18.2
		Vaccine Type Only	With HPV-16/18 Only	43	3	7.0	56	9	16.1	99	12	12.1
		High Risk HPV Type	With HR-HPV	43	19	44.2	56	32	57.1	99	51	51.5
			Without HR-HPV	43	24	55.8	56	24	42.9	99	48	48.5
		Low	High Risk HPV Without Vaccine Type	HRW-HPV	27	18	66.7	26	21	80.8	53	39
Vaccine Type			With HPV-16/18	27	15	55.6	26	12	46.2	53	27	50.9
Vaccine Type Only			With HPV-16/18 Only	27	9	33.3	26	5	19.2	53	14	26.4
High Risk HPV Type			With HR-HPV	27	27	100	26	26	100	53	53	100
			Without HR-HPV	27	0	0.0	26	0	0.0	53	0	0.0

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Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
032	High	High Risk HPV Without Vaccine Type	HRW-HPV	3	1	33.3	3	2	66.7	6	3	50.0
		Vaccine Type	With HPV-16/18	3	3	100	3	1	33.3	6	4	66.7
		Vaccine Type Only	With HPV-16/18 Only	3	2	66.7	3	1	33.3	6	3	50.0
		High Risk HPV Type	With HR-HPV	3	3	100	3	3	100	6	6	100
			Without HR-HPV	3	0	0.0	3	0	0.0	6	0	0.0
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	8	4	50.0	23	7	30.4	31	11	35.5
		Vaccine Type	With HPV-16/18	8	2	25.0	23	7	30.4	31	9	29.0
		Vaccine Type Only	With HPV-16/18 Only	8	1	12.5	23	5	21.7	31	6	19.4
		High Risk HPV Type	With HR-HPV	8	5	62.5	23	12	52.2	31	17	54.8
			Without HR-HPV	8	3	37.5	23	11	47.8	31	14	45.2
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	7	5	71.4	12	8	66.7	19	13	68.4
		Vaccine Type	With HPV-16/18	7	3	42.9	12	8	66.7	19	11	57.9
		Vaccine Type Only	With HPV-16/18 Only	7	1	14.3	12	3	25.0	19	4	21.1
		High Risk HPV Type	With HR-HPV	7	6	85.7	12	11	91.7	19	17	89.5
			Without HR-HPV	7	1	14.3	12	1	8.3	19	2	10.5
039	High	High Risk HPV Without Vaccine Type	HRW-HPV	13	8	61.5	19	12	63.2	32	20	62.5
		Vaccine Type	With HPV-16/18	13	10	76.9	19	13	68.4	32	23	71.9
		Vaccine Type Only	With HPV-16/18 Only	13	5	38.5	19	7	36.8	32	12	37.5
		High Risk HPV Type	With HR-HPV	13	13	100	19	19	100	32	32	100
			Without HR-HPV	13	0	0.0	19	0	0.0	32	0	0.0
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	35	15	42.9	37	14	37.8	72	29	40.3
		Vaccine Type	With HPV-16/18	35	13	37.1	37	9	24.3	72	22	30.6
		Vaccine Type Only	With HPV-16/18 Only	35	9	25.7	37	7	18.9	72	16	22.2
		High Risk HPV Type	With HR-HPV	35	24	68.6	37	21	56.8	72	45	62.5
			Without HR-HPV	35	11	31.4	37	16	43.2	72	27	37.5
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	36	29	80.6	33	27	81.8	69	56	81.2
		Vaccine Type	With HPV-16/18	36	17	47.2	33	16	48.5	69	33	47.8
		Vaccine Type Only	With HPV-16/18 Only	36	6	16.7	33	5	15.2	69	11	15.9
		High Risk HPV Type	With HR-HPV	36	35	97.2	33	32	97.0	69	67	97.1
			Without HR-HPV	36	1	2.8	33	1	3.0	69	2	2.9
Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	2	0	0.0	2	0	0.0	
	Vaccine Type	With HPV-16/18	0	-	-	2	0	0.0	2	0	0.0	
	Vaccine Type Only	With HPV-16/18 Only	0	-	-	2	0	0.0	2	0	0.0	
	High Risk HPV Type	With HR-HPV	0	-	-	2	0	0.0	2	0	0.0	
		Without HR-HPV	0	-	-	2	0	0.0	2	0	0.0	

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2 case during the study by cytology status & study

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n = number of subjects in a given category

% = $n / \text{Number of subjects with available results} \times 100$

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Table 10 Number and Percentage of Subjects with CIN2+ by DNA Status and cytology status at baseline - Overall (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	High Risk HPV Without Vaccine Type	HRW-HPV	71	38	53.5	67	42	62.7	138	80	58.0
	Vaccine Type	With HPV-16/18	71	48	67.6	67	46	68.7	138	94	68.1
	Vaccine Type Only	With HPV-16/18 Only	71	31	43.7	67	24	35.8	138	55	39.9
	High Risk HPV Type	With HR-HPV	71	69	97.2	67	66	98.5	138	135	97.8
		Without HR-HPV	71	2	2.8	67	1	1.5	138	3	2.2
Normal	High Risk HPV Without Vaccine Type	HRW-HPV	261	94	36.0	426	117	27.5	687	211	30.7
	Vaccine Type	With HPV-16/18	261	63	24.1	426	77	18.1	687	140	20.4
	Vaccine Type Only	With HPV-16/18 Only	261	39	14.9	426	46	10.8	687	85	12.4
	High Risk HPV Type	With HR-HPV	261	133	51.0	426	163	38.3	687	296	43.1
		Without HR-HPV	261	128	49.0	426	263	61.7	687	391	56.9
Low	High Risk HPV Without Vaccine Type	HRW-HPV	174	134	77.0	179	133	74.3	353	267	75.6
	Vaccine Type	With HPV-16/18	174	88	50.6	179	91	50.8	353	179	50.7
	Vaccine Type Only	With HPV-16/18 Only	174	34	19.5	179	35	19.6	353	69	19.5
	High Risk HPV Type	With HR-HPV	174	168	96.6	179	168	93.9	353	336	95.2
		Without HR-HPV	174	6	3.4	179	11	6.1	353	17	4.8
Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	3	0	0.0	3	0	0.0
	Vaccine Type	With HPV-16/18	0	-	-	3	0	0.0	3	0	0.0
	Vaccine Type Only	With HPV-16/18 Only	0	-	-	3	0	0.0	3	0	0.0
	High Risk HPV Type	With HR-HPV	0	-	-	3	0	0.0	3	0	0.0
		Without HR-HPV	0	-	-	3	1	33.3	3	1	33.3

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2+ case during the study by cytology status

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 11 Number and Percentage of Subjects with CIN2+ Cases by DNA Status and cytology status at baseline - by study (Total vaccinated cohort)

Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
008	High	High Risk HPV Without Vaccine Type	HRW-HPV	20	7	35.0	25	17	68.0	45	24	53.3
		Vaccine Type	With HPV-16/18	20	15	75.0	25	17	68.0	45	32	71.1
		Vaccine Type Only	With HPV-16/18 Only	20	12	60.0	25	7	28.0	45	19	42.2
		High Risk HPV Type	With HR-HPV	20	19	95.0	25	24	96.0	45	43	95.6
			Without HR-HPV	20	1	5.0	25	1	4.0	45	2	4.4
		Normal	High Risk HPV Without Vaccine Type	HRW-HPV	166	57	34.3	299	68	22.7	465	125
	Vaccine Type		With HPV-16/18	166	38	22.9	299	44	14.7	465	82	17.6
	Vaccine Type Only		With HPV-16/18 Only	166	21	12.7	299	22	7.4	465	43	9.2
	High Risk HPV Type		With HR-HPV	166	78	47.0	299	90	30.1	465	168	36.1
			Without HR-HPV	166	88	53.0	299	209	69.9	465	297	63.9
	Low		High Risk HPV Without Vaccine Type	HRW-HPV	101	81	80.2	103	76	73.8	204	157
		Vaccine Type	With HPV-16/18	101	50	49.5	103	50	48.5	204	100	49.0
		Vaccine Type Only	With HPV-16/18 Only	101	16	15.8	103	18	17.5	204	34	16.7
		High Risk HPV Type	With HR-HPV	101	97	96.0	103	94	91.3	204	191	93.6
			Without HR-HPV	101	4	4.0	103	9	8.7	204	13	6.4
		Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	1	0	0.0	1	0
	Vaccine Type		With HPV-16/18	0	-	-	1	0	0.0	1	0	0.0
	Vaccine Type Only		With HPV-16/18 Only	0	-	-	1	0	0.0	1	0	0.0
	High Risk HPV Type		With HR-HPV	0	-	-	1	0	0.0	1	0	0.0
			Without HR-HPV	0	-	-	1	1	100	1	1	100
015	High		High Risk HPV Without Vaccine Type	HRW-HPV	27	21	77.8	18	10	55.6	45	31
		Vaccine Type	With HPV-16/18	27	13	48.1	18	13	72.2	45	26	57.8
		Vaccine Type Only	With HPV-16/18 Only	27	6	22.2	18	8	44.4	45	14	31.1
		High Risk HPV Type	With HR-HPV	27	27	100	18	18	100	45	45	100
			Without HR-HPV	27	0	0.0	18	0	0.0	45	0	0.0
		Normal	High Risk HPV Without Vaccine Type	HRW-HPV	49	18	36.7	62	27	43.5	111	45
	Vaccine Type		With HPV-16/18	49	8	16.3	62	15	24.2	111	23	20.7
	Vaccine Type Only		With HPV-16/18 Only	49	6	12.2	62	11	17.7	111	17	15.3
	High Risk HPV Type		With HR-HPV	49	24	49.0	62	38	61.3	111	62	55.9
			Without HR-HPV	49	25	51.0	62	24	38.7	111	49	44.1
	Low		High Risk HPV Without Vaccine Type	HRW-HPV	27	18	66.7	28	21	75.0	55	39
		Vaccine Type	With HPV-16/18	27	15	55.6	28	14	50.0	55	29	52.7
		Vaccine Type Only	With HPV-16/18 Only	27	9	33.3	28	7	25.0	55	16	29.1
		High Risk HPV Type	With HR-HPV	27	27	100	28	28	100	55	55	100

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Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
			Without HR-HPV	27	0	0.0	28	0	0.0	55	0	0.0	
032	High	High Risk HPV Without Vaccine Type	HRW-HPV	3	1	33.3	4	2	50.0	7	3	42.9	
		Vaccine Type	With HPV-16/18	3	3	100	4	2	50.0	7	5	71.4	
		Vaccine Type Only	With HPV-16/18 Only	3	2	66.7	4	2	50.0	7	4	57.1	
		High Risk HPV Type	With HR-HPV	3	3	100	4	4	100	7	7	100	
				Without HR-HPV	3	0	0.0	4	0	0.0	7	0	0.0
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	8	4	50.0	24	8	33.3	32	12	37.5	
		Vaccine Type	With HPV-16/18	8	2	25.0	24	8	33.3	32	10	31.3	
		Vaccine Type Only	With HPV-16/18 Only	8	1	12.5	24	5	20.8	32	6	18.8	
		High Risk HPV Type	With HR-HPV	8	5	62.5	24	13	54.2	32	18	56.3	
				Without HR-HPV	8	3	37.5	24	11	45.8	32	14	43.8
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	8	5	62.5	13	9	69.2	21	14	66.7	
		Vaccine Type	With HPV-16/18	8	4	50.0	13	9	69.2	21	13	61.9	
		Vaccine Type Only	With HPV-16/18 Only	8	2	25.0	13	3	23.1	21	5	23.8	
		High Risk HPV Type	With HR-HPV	8	7	87.5	13	12	92.3	21	19	90.5	
				Without HR-HPV	8	1	12.5	13	1	7.7	21	2	9.5
	039	High	High Risk HPV Without Vaccine Type	HRW-HPV	21	9	42.9	20	13	65.0	41	22	53.7
Vaccine Type			With HPV-16/18	21	17	81.0	20	14	70.0	41	31	75.6	
Vaccine Type Only			With HPV-16/18 Only	21	11	52.4	20	7	35.0	41	18	43.9	
High Risk HPV Type			With HR-HPV	21	20	95.2	20	20	100	41	40	97.6	
				Without HR-HPV	21	1	4.8	20	0	0.0	41	1	2.4
Normal		High Risk HPV Without Vaccine Type	HRW-HPV	38	15	39.5	41	14	34.1	79	29	36.7	
		Vaccine Type	With HPV-16/18	38	15	39.5	41	10	24.4	79	25	31.6	
		Vaccine Type Only	With HPV-16/18 Only	38	11	28.9	41	8	19.5	79	19	24.1	
		High Risk HPV Type	With HR-HPV	38	26	68.4	41	22	53.7	79	48	60.8	
				Without HR-HPV	38	12	31.6	41	19	46.3	79	31	39.2
Low		High Risk HPV Without Vaccine Type	HRW-HPV	38	30	78.9	35	27	77.1	73	57	78.1	
		Vaccine Type	With HPV-16/18	38	19	50.0	35	18	51.4	73	37	50.7	
		Vaccine Type Only	With HPV-16/18 Only	38	7	18.4	35	7	20.0	73	14	19.2	
		High Risk HPV Type	With HR-HPV	38	37	97.4	35	34	97.1	73	71	97.3	
				Without HR-HPV	38	1	2.6	35	1	2.9	73	2	2.7
Missing		High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	2	0	0.0	2	0	0.0	
	Vaccine Type	With HPV-16/18	0	-	-	2	0	0.0	2	0	0.0		
	Vaccine Type Only	With HPV-16/18 Only	0	-	-	2	0	0.0	2	0	0.0		
	High Risk HPV Type	With HR-HPV	0	-	-	2	0	0.0	2	0	0.0		
			Without HR-HPV	0	-	-	2	0	0.0	2	0	0.0	

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

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N = number of subjects with CIN2+ case during the study by cytology status & by study
n = number of subjects in a given category
% = $n / \text{Number of subjects with available results} \times 100$

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Table 12 Number and Percentage of Subjects with CIN3+ by DNA Status and cytology status at baseline - Overall (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	High Risk HPV Without Vaccine Type	HRW-HPV	57	28	49.1	42	21	50.0	99	49	49.5
	Vaccine Type	With HPV-16/18	57	38	66.7	42	34	81.0	99	72	72.7
	Vaccine Type Only	With HPV-16/18 Only	57	27	47.4	42	21	50.0	99	48	48.5
	High Risk HPV Type	With HR-HPV	57	55	96.5	42	42	100	99	97	98.0
		Without HR-HPV	57	2	3.5	42	0	0.0	99	2	2.0
Normal	High Risk HPV Without Vaccine Type	HRW-HPV	73	35	47.9	148	51	34.5	221	86	38.9
	Vaccine Type	With HPV-16/18	73	35	47.9	148	47	31.8	221	82	37.1
	Vaccine Type Only	With HPV-16/18 Only	73	22	30.1	148	26	17.6	221	48	21.7
	High Risk HPV Type	With HR-HPV	73	57	78.1	148	77	52.0	221	134	60.6
		Without HR-HPV	73	16	21.9	148	71	48.0	221	87	39.4
Low	High Risk HPV Without Vaccine Type	HRW-HPV	69	51	73.9	65	47	72.3	134	98	73.1
	Vaccine Type	With HPV-16/18	69	49	71.0	65	37	56.9	134	86	64.2
	Vaccine Type Only	With HPV-16/18 Only	69	18	26.1	65	16	24.6	134	34	25.4
	High Risk HPV Type	With HR-HPV	69	69	100	65	63	96.9	134	132	98.5
		Without HR-HPV	69	0	0.0	65	2	3.1	134	2	1.5
Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	1	0	0.0	1	0	0.0
	Vaccine Type	With HPV-16/18	0	-	-	1	0	0.0	1	0	0.0
	Vaccine Type Only	With HPV-16/18 Only	0	-	-	1	0	0.0	1	0	0.0
	High Risk HPV Type	With HR-HPV	0	-	-	1	0	0.0	1	0	0.0
		Without HR-HPV	0	-	-	1	0	0.0	1	0	0.0

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN3+ case during the study by cytology status

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 13 Number and Percentage of Subjects with CIN3+ by DNA Status and cytology status at baseline - by study (Total vaccinated cohort)

Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
008	High	High Risk HPV Without Vaccine Type	HRW-HPV	13	3	23.1	13	8	61.5	26	11	42.3
		Vaccine Type	With HPV-16/18	13	10	76.9	13	11	84.6	26	21	80.8
		Vaccine Type Only	With HPV-16/18 Only	13	9	69.2	13	5	38.5	26	14	53.8
		High Risk HPV Type	With HR-HPV	13	12	92.3	13	13	100	26	25	96.2
			Without HR-HPV	13	1	7.7	13	0	0.0	26	1	3.8
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	40	21	52.5	106	33	31.1	146	54	37.0
		Vaccine Type	With HPV-16/18	40	19	47.5	106	29	27.4	146	48	32.9
		Vaccine Type Only	With HPV-16/18 Only	40	10	25.0	106	14	13.2	146	24	16.4
		High Risk HPV Type	With HR-HPV	40	31	77.5	106	47	44.3	146	78	53.4
			Without HR-HPV	40	9	22.5	106	59	55.7	146	68	46.6
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	33	24	72.7	39	31	79.5	72	55	76.4
		Vaccine Type	With HPV-16/18	33	26	78.8	39	21	53.8	72	47	65.3
		Vaccine Type Only	With HPV-16/18 Only	33	9	27.3	39	7	17.9	72	16	22.2
		High Risk HPV Type	With HR-HPV	33	33	100	39	38	97.4	72	71	98.6
			Without HR-HPV	33	0	0.0	39	1	2.6	72	1	1.4
015	High	High Risk HPV Without Vaccine Type	HRW-HPV	25	19	76.0	13	6	46.2	38	25	65.8
		Vaccine Type	With HPV-16/18	25	12	48.0	13	10	76.9	38	22	57.9
		Vaccine Type Only	With HPV-16/18 Only	25	6	24.0	13	7	53.8	38	13	34.2
		High Risk HPV Type	With HR-HPV	25	25	100	13	13	100	38	38	100
			Without HR-HPV	25	0	0.0	13	0	0.0	38	0	0.0
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	15	7	46.7	23	11	47.8	38	18	47.4
		Vaccine Type	With HPV-16/18	15	5	33.3	23	8	34.8	38	13	34.2
		Vaccine Type Only	With HPV-16/18 Only	15	4	26.7	23	7	30.4	38	11	28.9
		High Risk HPV Type	With HR-HPV	15	11	73.3	23	18	78.3	38	29	76.3
			Without HR-HPV	15	4	26.7	23	5	21.7	38	9	23.7
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	10	8	80.0	9	5	55.6	19	13	68.4
		Vaccine Type	With HPV-16/18	10	7	70.0	9	5	55.6	19	12	63.2
		Vaccine Type Only	With HPV-16/18 Only	10	2	20.0	9	4	44.4	19	6	31.6
		High Risk HPV Type	With HR-HPV	10	10	100	9	9	100	19	19	100
			Without HR-HPV	10	0	0.0	9	0	0.0	19	0	0.0
032	High	High Risk HPV Without Vaccine Type	HRW-HPV	2	0	0.0	2	0	0.0	4	0	0.0
		Vaccine Type	With HPV-16/18	2	2	100	2	2	100	4	4	100
		Vaccine Type Only	With HPV-16/18 Only	2	2	100	2	2	100	4	4	100
		High Risk HPV Type	With HR-HPV	2	2	100	2	2	100	4	4	100
			Without HR-HPV	2	0	0.0	2	0	0.0	4	0	0.0

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Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	3	2	66.7	7	4	57.1	10	6	60.0
		Vaccine Type	With HPV-16/18	3	2	66.7	7	4	57.1	10	6	60.0
		Vaccine Type Only	With HPV-16/18 Only	3	1	33.3	7	1	14.3	10	2	20.0
		High Risk HPV Type	With HR-HPV	3	3	100	7	5	71.4	10	8	80.0
			Without HR-HPV	3	0	0.0	7	2	28.6	10	2	20.0
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	4	3	75.0	5	4	80.0	9	7	77.8
		Vaccine Type	With HPV-16/18	4	2	50.0	5	3	60.0	9	5	55.6
		Vaccine Type Only	With HPV-16/18 Only	4	1	25.0	5	0	0.0	9	1	11.1
		High Risk HPV Type	With HR-HPV	4	4	100	5	4	80.0	9	8	88.9
			Without HR-HPV	4	0	0.0	5	1	20.0	9	1	11.1
039	High	High Risk HPV Without Vaccine Type	HRW-HPV	17	6	35.3	14	7	50.0	31	13	41.9
		Vaccine Type	With HPV-16/18	17	14	82.4	14	11	78.6	31	25	80.6
		Vaccine Type Only	With HPV-16/18 Only	17	10	58.8	14	7	50.0	31	17	54.8
		High Risk HPV Type	With HR-HPV	17	16	94.1	14	14	100	31	30	96.8
			Without HR-HPV	17	1	5.9	14	0	0.0	31	1	3.2
	Normal	High Risk HPV Without Vaccine Type	HRW-HPV	15	5	33.3	12	3	25.0	27	8	29.6
		Vaccine Type	With HPV-16/18	15	9	60.0	12	6	50.0	27	15	55.6
		Vaccine Type Only	With HPV-16/18 Only	15	7	46.7	12	4	33.3	27	11	40.7
		High Risk HPV Type	With HR-HPV	15	12	80.0	12	7	58.3	27	19	70.4
			Without HR-HPV	15	3	20.0	12	5	41.7	27	8	29.6
	Low	High Risk HPV Without Vaccine Type	HRW-HPV	22	16	72.7	12	7	58.3	34	23	67.6
		Vaccine Type	With HPV-16/18	22	14	63.6	12	8	66.7	34	22	64.7
		Vaccine Type Only	With HPV-16/18 Only	22	6	27.3	12	5	41.7	34	11	32.4
		High Risk HPV Type	With HR-HPV	22	22	100	12	12	100	34	34	100
			Without HR-HPV	22	0	0.0	12	0	0.0	34	0	0.0
	Missing	High Risk HPV Without Vaccine Type	HRW-HPV	0	-	-	1	0	0.0	1	0	0.0
		Vaccine Type	With HPV-16/18	0	-	-	1	0	0.0	1	0	0.0
		Vaccine Type Only	With HPV-16/18 Only	0	-	-	1	0	0.0	1	0	0.0
		High Risk HPV Type	With HR-HPV	0	-	-	1	0	0.0	1	0	0.0
			Without HR-HPV	0	-	-	1	0	0.0	1	0	0.0

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN3+ case during the study by cytology status & by study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 14 Number and Percentage of Subjects with CIN2 by DNA Status and Sero status at baseline - Overall (Total vaccinated cohort)

Characteristics	Categories	HPV		Control		Total	
		n	%	n	%	n	%
DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	217	47.4	344	56.0	561	52.3
	DNA Negative and Sero Positive	99	21.6	112	18.2	211	19.7
	DNA Positive and Sero Negative	40	8.7	50	8.1	90	8.4
	DNA Positive and Sero Positive	101	22.1	101	16.4	202	18.8
DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	345	75.3	469	76.4	814	75.9
	DNA Negative and Sero Positive	76	16.6	96	15.6	172	16.0
	DNA Positive and Sero Negative	12	2.6	19	3.1	31	2.9
	DNA Positive and Sero Positive	20	4.4	23	3.7	43	4.0

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2 in each category

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 15 Number and Percentage of Subjects with CIN2 by DNA Status and Sero status at baseline - by study (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	265	141	53.2	392	253	64.5	657	394	60.0
		DNA Negative and Sero Positive	265	49	18.5	392	59	15.1	657	108	16.4
		DNA Positive and Sero Negative	265	24	9.1	392	32	8.2	657	56	8.5
		DNA Positive and Sero Positive	265	50	18.9	392	43	11.0	657	93	14.2
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	265	213	80.4	392	325	82.9	657	538	81.9
		DNA Negative and Sero Positive	265	34	12.8	392	39	9.9	657	73	11.1
		DNA Positive and Sero Negative	265	9	3.4	392	11	2.8	657	20	3.0
		DNA Positive and Sero Positive	265	8	3.0	392	15	3.8	657	23	3.5
015	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	91	41	45.1	93	36	38.7	184	77	41.8
		DNA Negative and Sero Positive	91	30	33.0	93	27	29.0	184	57	31.0
		DNA Positive and Sero Negative	91	5	5.5	93	8	8.6	184	13	7.1
		DNA Positive and Sero Positive	91	15	16.5	93	22	23.7	184	37	20.1
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	91	57	62.6	93	52	55.9	184	109	59.2
		DNA Negative and Sero Positive	91	21	23.1	93	33	35.5	184	54	29.3
		DNA Positive and Sero Negative	91	3	3.3	93	3	3.2	184	6	3.3
		DNA Positive and Sero Positive	91	6	6.6	93	3	3.2	184	9	4.9
032	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	18	6	33.3	38	22	57.9	56	28	50.0
		DNA Negative and Sero Positive	18	4	22.2	38	5	13.2	56	9	16.1
		DNA Positive and Sero Negative	18	4	22.2	38	3	7.9	56	7	12.5
		DNA Positive and Sero Positive	18	4	22.2	38	8	21.1	56	12	21.4
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	18	14	77.8	38	25	65.8	56	39	69.6
		DNA Negative and Sero Positive	18	4	22.2	38	7	18.4	56	11	19.6
		DNA Positive and Sero Negative	18	0	0.0	38	1	2.6	56	1	1.8
		DNA Positive and Sero Positive	18	0	0.0	38	4	10.5	56	4	7.1
039	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	84	29	34.5	91	33	36.3	175	62	35.4

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Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Positive	84	16	19.0	91	21	23.1	175	37	21.1
		DNA Positive and Sero Negative	84	7	8.3	91	7	7.7	175	14	8.0
		DNA Positive and Sero Positive	84	32	38.1	91	28	30.8	175	60	34.3
		DNA Negative and Sero Negative	84	61	72.6	91	67	73.6	175	128	73.1
		DNA Negative and Sero Positive	84	17	20.2	91	17	18.7	175	34	19.4
		DNA Positive and Sero Negative	84	0	0.0	91	4	4.4	175	4	2.3
		DNA Positive and Sero Positive	84	6	7.1	91	1	1.1	175	7	4.0

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2 in each category & study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 16 Number and Percentage of Subjects with CIN2+ by DNA Status and Sero status at baseline - Overall (Total vaccinated cohort)

Characteristics	Categories	HPV		Control		Total	
		n	%	n	%	n	%
DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	230	45.5	364	53.9	594	50.3
	DNA Negative and Sero Positive	103	20.4	120	17.8	223	18.9
	DNA Positive and Sero Negative	47	9.3	58	8.6	105	8.9
	DNA Positive and Sero Positive	125	24.7	125	18.5	250	21.2
DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	377	74.5	510	75.6	887	75.1
	DNA Negative and Sero Positive	87	17.2	110	16.3	197	16.7
	DNA Positive and Sero Negative	15	3.0	22	3.3	37	3.1
	DNA Positive and Sero Positive	21	4.2	24	3.6	45	3.8

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2+ in each category

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 17 Number and Percentage of Subjects with CIN2+ by DNA Status and Sero status at baseline - by study (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	287	149	51.9	428	266	62.1	715	415	58.0
		DNA Negative and Sero Positive	287	49	17.1	428	65	15.2	715	114	15.9
		DNA Positive and Sero Negative	287	28	9.8	428	37	8.6	715	65	9.1
		DNA Positive and Sero Positive	287	60	20.9	428	54	12.6	715	114	15.9
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	287	228	79.4	428	352	82.2	715	580	81.1
		DNA Negative and Sero Positive	287	40	13.9	428	46	10.7	715	86	12.0
		DNA Positive and Sero Negative	287	10	3.5	428	12	2.8	715	22	3.1
		DNA Positive and Sero Positive	287	8	2.8	428	15	3.5	715	23	3.2
015	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	103	44	42.7	108	41	38.0	211	85	40.3
		DNA Negative and Sero Positive	103	33	32.0	108	28	25.9	211	61	28.9
		DNA Positive and Sero Negative	103	6	5.8	108	10	9.3	211	16	7.6
		DNA Positive and Sero Positive	103	20	19.4	108	29	26.9	211	49	23.2
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	103	61	59.2	108	60	55.6	211	121	57.3
		DNA Negative and Sero Positive	103	26	25.2	108	38	35.2	211	64	30.3
		DNA Positive and Sero Negative	103	5	4.9	108	4	3.7	211	9	4.3
		DNA Positive and Sero Positive	103	6	5.8	108	3	2.8	211	9	4.3
032	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	19	6	31.6	41	22	53.7	60	28	46.7
		DNA Negative and Sero Positive	19	4	21.1	41	5	12.2	60	9	15.0
		DNA Positive and Sero Negative	19	4	21.1	41	4	9.8	60	8	13.3
		DNA Positive and Sero Positive	19	5	26.3	41	10	24.4	60	15	25.0
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	19	15	78.9	41	27	65.9	60	42	70.0
		DNA Negative and Sero Positive	19	4	21.1	41	7	17.1	60	11	18.3
		DNA Positive and Sero Negative	19	0	0.0	41	1	2.4	60	1	1.7
		DNA Positive and Sero Positive	19	0	0.0	41	5	12.2	60	5	8.3
039	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	97	31	32.0	98	35	35.7	195	66	33.8

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Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Positive	97	17	17.5	98	22	22.4	195	39	20.0
		DNA Positive and Sero Negative	97	9	9.3	98	7	7.1	195	16	8.2
		DNA Positive and Sero Positive	97	40	41.2	98	32	32.7	195	72	36.9
		DNA Negative and Sero Negative	97	73	75.3	98	71	72.4	195	144	73.8
		DNA Negative and Sero Positive	97	17	17.5	98	19	19.4	195	36	18.5
		DNA Positive and Sero Negative	97	0	0.0	98	5	5.1	195	5	2.6
		DNA Positive and Sero Positive	97	7	7.2	98	1	1.0	195	8	4.1

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN2+ in each category & by study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table18 Number and Percentage of Subjects with CIN3+ by DNA Status and Sero status at baseline - Overall (Total vaccinated cohort)

Characteristics	Categories	HPV		Control		Total	
		n	%	n	%	n	%
DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	60	30.2	105	41.0	165	36.3
	DNA Negative and Sero Positive	32	16.1	43	16.8	75	16.5
	DNA Positive and Sero Negative	26	13.1	29	11.3	55	12.1
	DNA Positive and Sero Positive	80	40.2	77	30.1	157	34.5
DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	135	67.8	179	69.9	314	69.0
	DNA Negative and Sero Positive	40	20.1	54	21.1	94	20.7
	DNA Positive and Sero Negative	7	3.5	9	3.5	16	3.5
	DNA Positive and Sero Positive	12	6.0	11	4.3	23	5.1

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN3+ in each category

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 19 Number and Percentage of Subjects with CIN3+ by DNA Status and Sero status at baseline - by study (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	86	31	36.0	158	78	49.4	244	109	44.7
		DNA Negative and Sero Positive	86	7	8.1	158	24	15.2	244	31	12.7
		DNA Positive and Sero Negative	86	13	15.1	158	19	12.0	244	32	13.1
		DNA Positive and Sero Positive	86	34	39.5	158	36	22.8	244	70	28.7
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	86	65	75.6	158	126	79.7	244	191	78.3
		DNA Negative and Sero Positive	86	12	14.0	158	22	13.9	244	34	13.9
		DNA Positive and Sero Negative	86	3	3.5	158	4	2.5	244	7	2.9
		DNA Positive and Sero Positive	86	5	5.8	158	5	3.2	244	10	4.1
015	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	50	19	38.0	45	12	26.7	95	31	32.6
		DNA Negative and Sero Positive	50	13	26.0	45	12	26.7	95	25	26.3
		DNA Positive and Sero Negative	50	4	8.0	45	6	13.3	95	10	10.5
		DNA Positive and Sero Positive	50	14	28.0	45	15	33.3	95	29	30.5
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	50	28	56.0	45	20	44.4	95	48	50.5
		DNA Negative and Sero Positive	50	12	24.0	45	20	44.4	95	32	33.7
		DNA Positive and Sero Negative	50	4	8.0	45	3	6.7	95	7	7.4
		DNA Positive and Sero Positive	50	2	4.0	45	1	2.2	95	3	3.2
032	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	9	1	11.1	14	7	50.0	23	8	34.8
		DNA Negative and Sero Positive	9	2	22.2	14	2	14.3	23	4	17.4
		DNA Positive and Sero Negative	9	2	22.2	14	2	14.3	23	4	17.4
		DNA Positive and Sero Positive	9	4	44.4	14	3	21.4	23	7	30.4
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	9	5	55.6	14	7	50.0	23	12	52.2
		DNA Negative and Sero Positive	9	4	44.4	14	2	14.3	23	6	26.1
		DNA Positive and Sero Negative	9	0	0.0	14	1	7.1	23	1	4.3
		DNA Positive and Sero Positive	9	0	0.0	14	4	28.6	23	4	17.4
039	DNA Status and Serology Status - HPV-16	DNA Negative and Sero Negative	54	9	16.7	39	8	20.5	93	17	18.3

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Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
		DNA Negative and Sero Positive	54	10	18.5	39	5	12.8	93	15	16.1
		DNA Positive and Sero Negative	54	7	13.0	39	2	5.1	93	9	9.7
		DNA Positive and Sero Positive	54	28	51.9	39	23	59.0	93	51	54.8
	DNA Status and Serology Status - HPV-18	DNA Negative and Sero Negative	54	37	68.5	39	26	66.7	93	63	67.7
		DNA Negative and Sero Positive	54	12	22.2	39	10	25.6	93	22	23.7
		DNA Positive and Sero Negative	54	0	0.0	39	1	2.6	93	1	1.1
		DNA Positive and Sero Positive	54	5	9.3	39	1	2.6	93	6	6.5

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with CIN3+ in each category & study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 20 Number and Percentage of Subjects with CIN2 by associated HPV type - Cytology status at baseline (Total vaccinated cohort)

Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	CIN2 associated with HR-HPV	Yes	119	47	39.5	107	50	46.7	226	97	42.9
		No	119	72	60.5	107	57	53.3	226	129	57.1
	CIN2 associated with HRW-HPV	Yes	119	28	23.5	107	31	29.0	226	59	26.1
		No	119	91	76.5	107	76	71.0	226	167	73.9
	CIN2 associated with HPV-16/18	Yes	119	25	21.0	107	33	30.8	226	58	25.7
		No	119	94	79.0	107	74	69.2	226	168	74.3
	CIN2 associated with HPV-16/18 Only	Yes	119	19	16.0	107	19	17.8	226	38	16.8
		No	119	100	84.0	107	88	82.2	226	188	83.2
	CIN2 not associated with HR-HPV	Yes	119	7	5.9	107	5	4.7	226	12	5.3
		No	119	112	94.1	107	102	95.3	226	214	94.7
	CIN2 irrespective of HPV type	Yes	119	54	45.4	107	55	51.4	226	109	48.2
		No	119	65	54.6	107	52	48.6	226	117	51.8
Normal	CIN2 associated with HR-HPV	Yes	14547	186	1.3	14560	352	2.4	29107	538	1.8
		No	14547	14361	98.7	14560	14208	97.6	29107	28569	98.2
	CIN2 associated with HRW-HPV	Yes	14547	154	1.1	14560	241	1.7	29107	395	1.4
		No	14547	14393	98.9	14560	14319	98.3	29107	28712	98.6
	CIN2 associated with HPV-16/18	Yes	14547	48	0.3	14560	194	1.3	29107	242	0.8
		No	14547	14499	99.7	14560	14366	98.7	29107	28865	99.2
	CIN2 associated with HPV-16/18 Only	Yes	14547	32	0.2	14560	111	0.8	29107	143	0.5
		No	14547	14515	99.8	14560	14449	99.2	29107	28964	99.5
	CIN2 not associated with HR-HPV	Yes	14547	55	0.4	14560	41	0.3	29107	96	0.3
		No	14547	14492	99.6	14560	14519	99.7	29107	29011	99.7
	CIN2 irrespective of HPV type	Yes	14547	241	1.7	14560	393	2.7	29107	634	2.2
		No	14547	14306	98.3	14560	14167	97.3	29107	28473	97.8
Low	CIN2 associated with HR-HPV	Yes	1052	142	13.5	1045	143	13.7	2097	285	13.6
		No	1052	910	86.5	1045	902	86.3	2097	1812	86.4
	CIN2 associated with HRW-HPV	Yes	1052	105	10.0	1045	106	10.1	2097	211	10.1
		No	1052	947	90.0	1045	939	89.9	2097	1886	89.9
	CIN2 associated with HPV-16/18	Yes	1052	62	5.9	1045	70	6.7	2097	132	6.3
		No	1052	990	94.1	1045	975	93.3	2097	1965	93.7
	CIN2 associated with HPV-16/18 Only	Yes	1052	37	3.5	1045	37	3.5	2097	74	3.5
		No	1052	1015	96.5	1045	1008	96.5	2097	2023	96.5
	CIN2 not associated with HR-HPV	Yes	1052	21	2.0	1045	20	1.9	2097	41	2.0
		No	1052	1031	97.0	1045	1025	97.1	2097	2056	97.0

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Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
		No	1052	1031	98.0	1045	1025	98.1	2097	2056	98.0
	CIN2 irrespective of HPV type	Yes	1052	163	15.5	1045	163	15.6	2097	326	15.5
		No	1052	889	84.5	1045	882	84.4	2097	1771	84.5
Missing	CIN2 associated with HR-HPV	Yes	23	0	0.0	29	3	10.3	52	3	5.8
		No	23	23	100	29	26	89.7	52	49	94.2
	CIN2 associated with HRW-HPV	Yes	23	0	0.0	29	3	10.3	52	3	5.8
		No	23	23	100	29	26	89.7	52	49	94.2
	CIN2 associated with HPV-16/18	Yes	23	0	0.0	29	2	6.9	52	2	3.8
		No	23	23	100	29	27	93.1	52	50	96.2
	CIN2 associated with HPV-16/18 Only	Yes	23	0	0.0	29	0	0.0	52	0	0.0
		No	23	23	100	29	29	100	52	52	100
	CIN2 not associated with HR-HPV	Yes	23	0	0.0	29	0	0.0	52	0	0.0
		No	23	23	100	29	29	100	52	52	100
	CIN2 irrespective of HPV type	Yes	23	0	0.0	29	3	10.3	52	3	5.8
		No	23	23	100	29	26	89.7	52	49	94.2
Overall total	CIN2 associated with HR-HPV	Yes	15741	375	2.4	15741	548	3.5	31482	923	2.9
		No	15741	15366	97.6	15741	15193	96.5	31482	30559	97.1
	CIN2 associated with HRW-HPV	Yes	15741	287	1.8	15741	381	2.4	31482	668	2.1
		No	15741	15454	98.2	15741	15360	97.6	31482	30814	97.9
	CIN2 associated with HPV-16/18	Yes	15741	135	0.9	15741	299	1.9	31482	434	1.4
		No	15741	15606	99.1	15741	15442	98.1	31482	31048	98.6
	CIN2 associated with HPV-16/18 Only	Yes	15741	88	0.6	15741	167	1.1	31482	255	0.8
		No	15741	15653	99.4	15741	15574	98.9	31482	31227	99.2
	CIN2 not associated with HR-HPV	Yes	15741	83	0.5	15741	66	0.4	31482	149	0.5
		No	15741	15658	99.5	15741	15675	99.6	31482	31333	99.5
	CIN2 irrespective of HPV type	Yes	15741	458	2.9	15741	614	3.9	31482	1072	3.4
		No	15741	15283	97.1	15741	15127	96.1	31482	30410	96.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with respective Cytology Status at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 21 Number and Percentage of Subjects with CIN2+ by associated HPV type - Cytology status at baseline (Total vaccinated cohort)

Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	CIN2+ associated with HR-HPV	Yes	119	68	57.1	107	63	58.9	226	131	58.0
		No	119	51	42.9	107	44	41.1	226	95	42.0
	CIN2+ associated with HRW-HPV	Yes	119	34	28.6	107	37	34.6	226	71	31.4
		No	119	85	71.4	107	70	65.4	226	155	68.6
	CIN2+ associated with HPV-16/18	Yes	119	43	36.1	107	45	42.1	226	88	38.9
		No	119	76	63.9	107	62	57.9	226	138	61.1
	CIN2+ associated with HPV-16/18 Only	Yes	119	34	28.6	107	26	24.3	226	60	26.5
		No	119	85	71.4	107	81	75.7	226	166	73.5
	CIN2+ not associated with HR-HPV	Yes	119	3	2.5	107	4	3.7	226	7	3.1
		No	119	116	97.5	107	103	96.3	226	219	96.9
	CIN2+ irrespective of HPV type	Yes	119	71	59.7	107	67	62.6	226	138	61.1
		No	119	48	40.3	107	40	37.4	226	88	38.9
Normal	CIN2+ associated with HR-HPV	Yes	14547	212	1.5	14560	386	2.7	29107	598	2.1
		No	14547	14335	98.5	14560	14174	97.3	29107	28509	97.9
	CIN2+ associated with HRW-HPV	Yes	14547	172	1.2	14560	267	1.8	29107	439	1.5
		No	14547	14375	98.8	14560	14293	98.2	29107	28668	98.5
	CIN2+ associated with HPV-16/18	Yes	14547	62	0.4	14560	219	1.5	29107	281	1.0
		No	14547	14485	99.6	14560	14341	98.5	29107	28826	99.0
	CIN2+ associated with HPV-16/18 Only	Yes	14547	40	0.3	14560	119	0.8	29107	159	0.5
		No	14547	14507	99.7	14560	14441	99.2	29107	28948	99.5
	CIN2+ not associated with HR-HPV	Yes	14547	49	0.3	14560	40	0.3	29107	89	0.3
		No	14547	14498	99.7	14560	14520	99.7	29107	29018	99.7
	CIN2+ irrespective of HPV type	Yes	14547	261	1.8	14560	426	2.9	29107	687	2.4
		No	14547	14286	98.2	14560	14134	97.1	29107	28420	97.6
Low	CIN2+ associated with HR-HPV	Yes	1052	154	14.6	1045	163	15.6	2097	317	15.1
		No	1052	898	85.4	1045	882	84.4	2097	1780	84.9
	CIN2+ associated with HRW-HPV	Yes	1052	112	10.6	1045	116	11.1	2097	228	10.9
		No	1052	940	89.4	1045	929	88.9	2097	1869	89.1
	CIN2+ associated with HPV-16/18	Yes	1052	75	7.1	1045	87	8.3	2097	162	7.7
		No	1052	977	92.9	1045	958	91.7	2097	1935	92.3
	CIN2+ associated with HPV-16/18 Only	Yes	1052	42	4.0	1045	47	4.5	2097	89	4.2
		No	1052	1010	96.0	1045	998	95.5	2097	2008	95.8

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Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
	CIN2+ not associated with HR-HPV	Yes	1052	20	1.9	1045	16	1.5	2097	36	1.7
		No	1052	1032	98.1	1045	1029	98.5	2097	2061	98.3
	CIN2+ irrespective of HPV type	Yes	1052	174	16.5	1045	179	17.1	2097	353	16.8
		No	1052	878	83.5	1045	866	82.9	2097	1744	83.2
Missing	CIN2+ associated with HR-HPV	Yes	23	0	0.0	29	3	10.3	52	3	5.8
		No	23	23	100	29	26	89.7	52	49	94.2
	CIN2+ associated with HRW-HPV	Yes	23	0	0.0	29	3	10.3	52	3	5.8
		No	23	23	100	29	26	89.7	52	49	94.2
	CIN2+ associated with HPV-16/18	Yes	23	0	0.0	29	2	6.9	52	2	3.8
		No	23	23	100	29	27	93.1	52	50	96.2
	CIN2+ associated with HPV-16/18 Only	Yes	23	0	0.0	29	0	0.0	52	0	0.0
		No	23	23	100	29	29	100	52	52	100
	CIN2+ not associated with HR-HPV	Yes	23	0	0.0	29	0	0.0	52	0	0.0
		No	23	23	100	29	29	100	52	52	100
CIN2+ irrespective of HPV type	Yes	23	0	0.0	29	3	10.3	52	3	5.8	
	No	23	23	100	29	26	89.7	52	49	94.2	
Overall total	CIN2+ associated with HR-HPV	Yes	15741	434	2.8	15741	615	3.9	31482	1049	3.3
		No	15741	15307	97.2	15741	15126	96.1	31482	30433	96.7
	CIN2+ associated with HRW-HPV	Yes	15741	318	2.0	15741	423	2.7	31482	741	2.4
		No	15741	15423	98.0	15741	15318	97.3	31482	30741	97.6
	CIN2+ associated with HPV-16/18	Yes	15741	180	1.1	15741	353	2.2	31482	533	1.7
		No	15741	15561	98.9	15741	15388	97.8	31482	30949	98.3
	CIN2+ associated with HPV-16/18 Only	Yes	15741	116	0.7	15741	192	1.2	31482	308	1.0
		No	15741	15625	99.3	15741	15549	98.8	31482	31174	99.0
	CIN2+ not associated with HR-HPV	Yes	15741	72	0.5	15741	60	0.4	31482	132	0.4
		No	15741	15669	99.5	15741	15681	99.6	31482	31350	99.6
CIN2+ irrespective of HPV type	Yes	15741	506	3.2	15741	675	4.3	31482	1181	3.8	
	No	15741	15235	96.8	15741	15066	95.7	31482	30301	96.2	

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with respective Cytology Status at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 22 Number and Percentage of Subjects with CIN3 by associated HPV type – Cytology status at baseline (Total vaccinated cohort)

Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	CIN3+ associated with HR-HPV	Yes	119	55	46.2	107	41	38.3	226	96	42.5
		No	119	64	53.8	107	66	61.7	226	130	57.5
	CIN3+ associated with HRW-HPV	Yes	119	27	22.7	107	16	15.0	226	43	19.0
		No	119	92	77.3	107	91	85.0	226	183	81.0
	CIN3+ associated with HPV-16/18	Yes	119	35	29.4	107	32	29.9	226	67	29.6
		No	119	84	70.6	107	75	70.1	226	159	70.4
	CIN3+ associated with HPV-16/18 Only	Yes	119	28	23.5	107	25	23.4	226	53	23.5
		No	119	91	76.5	107	82	76.6	226	173	76.5
	CIN3+ not associated with HR-HPV	Yes	119	2	1.7	107	1	0.9	226	3	1.3
		No	119	117	98.3	107	106	99.1	226	223	98.7
	CIN3+ irrespective of HPV type	Yes	119	57	47.9	107	42	39.3	226	99	43.8
		No	119	62	52.1	107	65	60.7	226	127	56.2
Normal	CIN3+ associated with HR-HPV	Yes	14547	67	0.5	14560	133	0.9	29107	200	0.7
		No	14547	14480	99.5	14560	14427	99.1	29107	28907	99.3
	CIN3+ associated with HRW-HPV	Yes	14547	40	0.3	14560	74	0.5	29107	114	0.4
		No	14547	14507	99.7	14560	14486	99.5	29107	28993	99.6
	CIN3+ associated with HPV-16/18	Yes	14547	36	0.2	14560	90	0.6	29107	126	0.4
		No	14547	14511	99.8	14560	14470	99.4	29107	28981	99.6
	CIN3+ associated with HPV-16/18 Only	Yes	14547	27	0.2	14560	59	0.4	29107	86	0.3
		No	14547	14520	99.8	14560	14501	99.6	29107	29021	99.7
	CIN3+ not associated with HR-HPV	Yes	14547	6	0.0	14560	15	0.1	29107	21	0.1
		No	14547	14541	100	14560	14545	99.9	29107	29086	99.9
	CIN3+ irrespective of HPV type	Yes	14547	73	0.5	14560	148	1.0	29107	221	0.8
		No	14547	14474	99.5	14560	14412	99.0	29107	28886	99.2
Low	CIN3+ associated with HR-HPV	Yes	1052	61	5.8	1045	57	5.5	2097	118	5.6
		No	1052	991	94.2	1045	988	94.5	2097	1979	94.4
	CIN3+ associated with HRW-HPV	Yes	1052	33	3.1	1045	32	3.1	2097	65	3.1
		No	1052	1019	96.9	1045	1013	96.9	2097	2032	96.9
	CIN3+ associated with HPV-16/18	Yes	1052	45	4.3	1045	35	3.3	2097	80	3.8
		No	1052	1007	95.7	1045	1010	96.7	2097	2017	96.2
	CIN3+ associated with HPV-16/18 Only	Yes	1052	28	2.7	1045	25	2.4	2097	53	2.5
		No	1052	1024	97.3	1045	1020	97.6	2097	2044	97.5

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Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
	CIN3+ not associated with HR-HPV	Yes	1052	8	0.8	1045	8	0.8	2097	16	0.8
		No	1052	1044	99.2	1045	1037	99.2	2097	2081	99.2
	CIN3+ irrespective of HPV type	Yes	1052	69	6.6	1045	65	6.2	2097	134	6.4
		No	1052	983	93.4	1045	980	93.8	2097	1963	93.6
Missing	CIN3+ associated with HR-HPV	Yes	23	0	0.0	29	1	3.4	52	1	1.9
		No	23	23	100	29	28	96.6	52	51	98.1
	CIN3+ associated with HRW-HPV	Yes	23	0	0.0	29	1	3.4	52	1	1.9
		No	23	23	100	29	28	96.6	52	51	98.1
	CIN3+ associated with HPV-16/18	Yes	23	0	0.0	29	1	3.4	52	1	1.9
		No	23	23	100	29	28	96.6	52	51	98.1
	CIN3+ associated with HPV-16/18 Only	Yes	23	0	0.0	29	0	0.0	52	0	0.0
		No	23	23	100	29	29	100	52	52	100
	CIN3+ not associated with HR-HPV	Yes	23	0	0.0	29	0	0.0	52	0	0.0
		No	23	23	100	29	29	100	52	52	100
CIN3+ irrespective of HPV type	Yes	23	0	0.0	29	1	3.4	52	1	1.9	
	No	23	23	100	29	28	96.6	52	51	98.1	
Overall total	CIN3+ associated with HR-HPV	Yes	15741	183	1.2	15741	232	1.5	31482	415	1.3
		No	15741	15558	98.8	15741	15509	98.5	31482	31067	98.7
	CIN3+ associated with HRW-HPV	Yes	15741	100	0.6	15741	123	0.8	31482	223	0.7
		No	15741	15641	99.4	15741	15618	99.2	31482	31259	99.3
	CIN3+ associated with HPV-16/18	Yes	15741	116	0.7	15741	158	1.0	31482	274	0.9
		No	15741	15625	99.3	15741	15583	99.0	31482	31208	99.1
	CIN3+ associated with HPV-16/18 Only	Yes	15741	83	0.5	15741	109	0.7	31482	192	0.6
		No	15741	15658	99.5	15741	15632	99.3	31482	31290	99.4
	CIN3+ not associated with HR-HPV	Yes	15741	16	0.1	15741	24	0.2	31482	40	0.1
		No	15741	15725	99.9	15741	15717	99.8	31482	31442	99.9
CIN3+ irrespective of HPV type	Yes	15741	199	1.3	15741	256	1.6	31482	455	1.4	
	No	15741	15542	98.7	15741	15485	98.4	31482	31027	98.6	

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects with respective Cytology Status at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

HRW-HPV = All high-risk (oncogenic) HPV types excluding HPV-16 and HPV-18

HR-HPV= High-risk (oncogenic) HPV types: HPV-16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68

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Table 23 Number and Percentage of Subjects with CIN2 by associated HPV type – Cytology status at baseline & study (Total vaccinated cohort)

Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
008	High	CIN2 associated with HR-HPV	Yes	45	14	31.1	43	18	41.9	88	32	36.4	
			No	45	31	68.9	43	25	58.1	88	56	63.6	
		CIN2 associated with HRW-HPV	Yes	45	7	15.6	43	13	30.2	88	20	22.7	
			No	45	38	84.4	43	30	69.8	88	68	77.3	
		CIN2 associated with HPV-16/18	Yes	45	8	17.8	43	14	32.6	88	22	25.0	
			No	45	37	82.2	43	29	67.4	88	66	75.0	
		CIN2 associated with HPV-16/18 Only	Yes	45	7	15.6	43	5	11.6	88	12	13.6	
			No	45	38	84.4	43	38	88.4	88	76	86.4	
		CIN2 not associated with HR-HPV	Yes	45	3	6.7	43	4	9.3	88	7	8.0	
			No	45	42	93.3	43	39	90.7	88	81	92.0	
		CIN2 irrespective of HPV type	Yes	45	17	37.8	43	22	51.2	88	39	44.3	
			No	45	28	62.2	43	21	48.8	88	49	55.7	
		Normal	CIN2 associated with HR-HPV	Yes	8544	120	1.4	8585	247	2.9	17129	367	2.1
				No	8544	8424	98.6	8585	8338	97.1	17129	16762	97.9
	CIN2 associated with HRW-HPV		Yes	8544	103	1.2	8585	171	2.0	17129	274	1.6	
			No	8544	8441	98.8	8585	8414	98.0	17129	16855	98.4	
	CIN2 associated with HPV-16/18		Yes	8544	28	0.3	8585	145	1.7	17129	173	1.0	
			No	8544	8516	99.7	8585	8440	98.3	17129	16956	99.0	
	CIN2 associated with HPV-16/18 Only		Yes	8544	17	0.2	8585	76	0.9	17129	93	0.5	
			No	8544	8527	99.8	8585	8509	99.1	17129	17036	99.5	
	CIN2 not associated with HR-HPV		Yes	8544	35	0.4	8585	30	0.3	17129	65	0.4	
			No	8544	8509	99.6	8585	8555	99.7	17129	17064	99.6	
	CIN2 irrespective of HPV type		Yes	8544	155	1.8	8585	277	3.2	17129	432	2.5	
			No	8544	8389	98.2	8585	8308	96.8	17129	16697	97.5	
Low	CIN2 associated with HR-HPV		Yes	714	77	10.8	682	81	11.9	1396	158	11.3	
			No	714	637	89.2	682	601	88.1	1396	1238	88.7	
	CIN2 associated with HRW-HPV	Yes	714	60	8.4	682	62	9.1	1396	122	8.7		
		No	714	654	91.6	682	620	90.9	1396	1274	91.3		
	CIN2 associated with HPV-16/18	Yes	714	34	4.8	682	39	5.7	1396	73	5.2		
		No	714	680	95.2	682	643	94.3	1396	1323	94.8		
	CIN2 associated with HPV-16/18 Only	Yes	714	17	2.4	682	19	2.8	1396	36	2.6		
		No	714	697	97.6	682	663	97.2	1396	1360	97.4		

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2 not associated with HR-HPV	Yes	714	16	2.2	682	11	1.6	1396	27	1.9	
			No	714	698	97.8	682	671	98.4	1396	1369	98.1	
		CIN2 irrespective of HPV type	Yes	714	93	13.0	682	92	13.5	1396	185	13.3	
			No	714	621	87.0	682	590	86.5	1396	1211	86.7	
	Missing	CIN2 associated with HR-HPV	Yes	16	0	0.0	15	1	6.7	31	1	3.2	
			No	16	16	100	15	14	93.3	31	30	96.8	
		CIN2 associated with HRW-HPV	Yes	16	0	0.0	15	1	6.7	31	1	3.2	
			No	16	16	100	15	14	93.3	31	30	96.8	
		CIN2 associated with HPV-16/18	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN2 associated with HPV-16/18 Only	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN2 not associated with HR-HPV	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
	CIN2 irrespective of HPV type	Yes	16	0	0.0	15	1	6.7	31	1	3.2		
		No	16	16	100	15	14	93.3	31	30	96.8		
	015	High	CIN2 associated with HR-HPV	Yes	36	19	52.8	30	10	33.3	66	29	43.9
				No	36	17	47.2	30	20	66.7	66	37	56.1
CIN2 associated with HRW-HPV			Yes	36	14	38.9	30	5	16.7	66	19	28.8	
			No	36	22	61.1	30	25	83.3	66	47	71.2	
CIN2 associated with HPV-16/18			Yes	36	6	16.7	30	6	20.0	66	12	18.2	
			No	36	30	83.3	30	24	80.0	66	54	81.8	
CIN2 associated with HPV-16/18 Only			Yes	36	5	13.9	30	5	16.7	66	10	15.2	
			No	36	31	86.1	30	25	83.3	66	56	84.8	
CIN2 not associated with HR-HPV			Yes	36	2	5.6	30	1	3.3	66	3	4.5	
			No	36	34	94.4	30	29	96.7	66	63	95.5	
CIN2 irrespective of HPV type			Yes	36	21	58.3	30	11	36.7	66	32	48.5	
			No	36	15	41.7	30	19	63.3	66	34	51.5	
Normal		CIN2 associated with HR-HPV	Yes	2717	29	1.1	2713	48	1.8	5430	77	1.4	
			No	2717	2688	98.9	2713	2665	98.2	5430	5353	98.6	
		CIN2 associated with HRW-HPV	Yes	2717	25	0.9	2713	32	1.2	5430	57	1.0	
			No	2717	2692	99.1	2713	2681	98.8	5430	5373	99.0	
		CIN2 associated with HPV-16/18	Yes	2717	5	0.2	2713	25	0.9	5430	30	0.6	
			No	2717	2712	99.8	2713	2688	99.1	5430	5400	99.4	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2 associated with HPV-16/18 Only	Yes	2717	4	0.1	2713	16	0.6	5430	20	0.4
			No	2717	2713	99.9	2713	2697	99.4	5430	5410	99.6
		CIN2 not associated with HR-HPV	Yes	2717	14	0.5	2713	8	0.3	5430	22	0.4
			No	2717	2703	99.5	2713	2705	99.7	5430	5408	99.6
		CIN2 irrespective of HPV type	Yes	2717	43	1.6	2713	56	2.1	5430	99	1.8
			No	2717	2674	98.4	2713	2657	97.9	5430	5331	98.2
	Low	CIN2 associated with HR-HPV	Yes	123	26	21.1	124	20	16.1	247	46	18.6
			No	123	97	78.9	124	104	83.9	247	201	81.4
		CIN2 associated with HRW-HPV	Yes	123	18	14.6	124	17	13.7	247	35	14.2
			No	123	105	85.4	124	107	86.3	247	212	85.8
		CIN2 associated with HPV-16/18	Yes	123	13	10.6	124	7	5.6	247	20	8.1
			No	123	110	89.4	124	117	94.4	247	227	91.9
		CIN2 associated with HPV-16/18 Only	Yes	123	8	6.5	124	3	2.4	247	11	4.5
			No	123	115	93.5	124	121	97.6	247	236	95.5
		CIN2 not associated with HR-HPV	Yes	123	1	0.8	124	6	4.8	247	7	2.8
			No	123	122	99.2	124	118	95.2	247	240	97.2
		CIN2 irrespective of HPV type	Yes	123	27	22.0	124	26	21.0	247	53	21.5
			No	123	96	78.0	124	98	79.0	247	194	78.5
	Missing	CIN2 associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0
			No	1	1	100	3	3	100	4	4	100
		CIN2 associated with HRW-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0
			No	1	1	100	3	3	100	4	4	100
		CIN2 associated with HPV-16/18	Yes	1	0	0.0	3	0	0.0	4	0	0.0
			No	1	1	100	3	3	100	4	4	100
CIN2 associated with HPV-16/18 Only		Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
CIN2 not associated with HR-HPV		Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
CIN2 irrespective of HPV type		Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
032	High	CIN2 associated with HR-HPV	Yes	4	3	75.0	5	3	60.0	9	6	66.7
			No	4	1	25.0	5	2	40.0	9	3	33.3
		CIN2 associated with HRW-HPV	Yes	4	0	0.0	5	2	40.0	9	2	22.2
			No	4	4	100	5	3	60.0	9	7	77.8

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2 associated with HPV-16/18	Yes	4	3	75.0	5	1	20.0	9	4	44.4
			No	4	1	25.0	5	4	80.0	9	5	55.6
		CIN2 associated with HPV-16/18 Only	Yes	4	3	75.0	5	1	20.0	9	4	44.4
			No	4	1	25.0	5	4	80.0	9	5	55.6
		CIN2 not associated with HR-HPV	Yes	4	0	0.0	5	0	0.0	9	0	0.0
			No	4	4	100	5	5	100	9	9	100
	CIN2 irrespective of HPV type	Yes	4	3	75.0	5	3	60.0	9	6	66.7	
		No	4	1	25.0	5	2	40.0	9	3	33.3	
	Normal	CIN2 associated with HR-HPV	Yes	465	5	1.1	458	20	4.4	923	25	2.7
			No	465	460	98.9	458	438	95.6	923	898	97.3
		CIN2 associated with HRW-HPV	Yes	465	5	1.1	458	12	2.6	923	17	1.8
			No	465	460	98.9	458	446	97.4	923	906	98.2
CIN2 associated with HPV-16/18		Yes	465	1	0.2	458	9	2.0	923	10	1.1	
		No	465	464	99.8	458	449	98.0	923	913	98.9	
CIN2 associated with HPV-16/18 Only		Yes	465	0	0.0	458	8	1.7	923	8	0.9	
		No	465	465	100	458	450	98.3	923	915	99.1	
CIN2 not associated with HR-HPV		Yes	465	3	0.6	458	3	0.7	923	6	0.7	
		No	465	462	99.4	458	455	99.3	923	917	99.3	
CIN2 irrespective of HPV type		Yes	465	8	1.7	458	23	5.0	923	31	3.4	
		No	465	457	98.3	458	435	95.0	923	892	96.6	
Low	CIN2 associated with HR-HPV	Yes	49	5	10.2	58	12	20.7	107	17	15.9	
		No	49	44	89.8	58	46	79.3	107	90	84.1	
	CIN2 associated with HRW-HPV	Yes	49	5	10.2	58	9	15.5	107	14	13.1	
		No	49	44	89.8	58	49	84.5	107	93	86.9	
	CIN2 associated with HPV-16/18	Yes	49	0	0.0	58	6	10.3	107	6	5.6	
		No	49	49	100	58	52	89.7	107	101	94.4	
	CIN2 associated with HPV-16/18 Only	Yes	49	0	0.0	58	3	5.2	107	3	2.8	
		No	49	49	100	58	55	94.8	107	104	97.2	
	CIN2 not associated with HR-HPV	Yes	49	2	4.1	58	0	0.0	107	2	1.9	
		No	49	47	95.9	58	58	100	107	105	98.1	
	CIN2 irrespective of HPV type	Yes	49	7	14.3	58	12	20.7	107	19	17.8	
		No	49	42	85.7	58	46	79.3	107	88	82.2	
Missing	CIN2 associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN2 associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 associated with HPV-16/18	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 associated with HPV-16/18 Only	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		039	High	CIN2 associated with HR-HPV	Yes	34	11	32.4	29	19	65.5	63	30	47.6
					No	34	23	67.6	29	10	34.5	63	33	52.4
				CIN2 associated with HRW-HPV	Yes	34	7	20.6	29	11	37.9	63	18	28.6
					No	34	27	79.4	29	18	62.1	63	45	71.4
CIN2 associated with HPV-16/18	Yes			34	8	23.5	29	12	41.4	63	20	31.7		
	No			34	26	76.5	29	17	58.6	63	43	68.3		
CIN2 associated with HPV-16/18 Only	Yes			34	4	11.8	29	8	27.6	63	12	19.0		
	No			34	30	88.2	29	21	72.4	63	51	81.0		
CIN2 not associated with HR-HPV	Yes			34	2	5.9	29	0	0.0	63	2	3.2		
	No			34	32	94.1	29	29	100	63	61	96.8		
CIN2 irrespective of HPV type	Yes			34	13	38.2	29	19	65.5	63	32	50.8		
	No			34	21	61.8	29	10	34.5	63	31	49.2		
Normal				CIN2 associated with HR-HPV	Yes	2821	32	1.1	2804	37	1.3	5625	69	1.2
					No	2821	2789	98.9	2804	2767	98.7	5625	5556	98.8
		CIN2 associated with HRW-HPV	Yes	2821	21	0.7	2804	26	0.9	5625	47	0.8		
			No	2821	2800	99.3	2804	2778	99.1	5625	5578	99.2		
		CIN2 associated with HPV-16/18	Yes	2821	14	0.5	2804	15	0.5	5625	29	0.5		
			No	2821	2807	99.5	2804	2789	99.5	5625	5596	99.5		
		CIN2 associated with HPV-16/18 Only	Yes	2821	11	0.4	2804	11	0.4	5625	22	0.4		
			No	2821	2810	99.6	2804	2793	99.6	5625	5603	99.6		
		CIN2 not associated with HR-HPV	Yes	2821	3	0.1	2804	0	0.0	5625	3	0.1		
			No	2821	2818	99.9	2804	2804	100	5625	5622	99.9		
		CIN2 irrespective of HPV type	Yes	2821	35	1.2	2804	37	1.3	5625	72	1.3		
			No	2821	2786	98.8	2804	2767	98.7	5625	5553	98.7		

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	Low	CIN2 associated with HR-HPV	Yes	166	34	20.5	181	30	16.6	347	64	18.4
			No	166	132	79.5	181	151	83.4	347	283	81.6
		CIN2 associated with HRW-HPV	Yes	166	22	13.3	181	18	9.9	347	40	11.5
			No	166	144	86.7	181	163	90.1	347	307	88.5
		CIN2 associated with HPV-16/18	Yes	166	15	9.0	181	18	9.9	347	33	9.5
			No	166	151	91.0	181	163	90.1	347	314	90.5
		CIN2 associated with HPV-16/18 Only	Yes	166	12	7.2	181	12	6.6	347	24	6.9
			No	166	154	92.8	181	169	93.4	347	323	93.1
	CIN2 not associated with HR-HPV	Yes	166	2	1.2	181	3	1.7	347	5	1.4	
		No	166	164	98.8	181	178	98.3	347	342	98.6	
	CIN2 irrespective of HPV type	Yes	166	36	21.7	181	33	18.2	347	69	19.9	
		No	166	130	78.3	181	148	81.8	347	278	80.1	
	Missing	CIN2 associated with HR-HPV	Yes	5	0	0.0	11	2	18.2	16	2	12.5
			No	5	5	100	11	9	81.8	16	14	87.5
		CIN2 associated with HRW-HPV	Yes	5	0	0.0	11	2	18.2	16	2	12.5
			No	5	5	100	11	9	81.8	16	14	87.5
CIN2 associated with HPV-16/18		Yes	5	0	0.0	11	2	18.2	16	2	12.5	
		No	5	5	100	11	9	81.8	16	14	87.5	
CIN2 associated with HPV-16/18 Only		Yes	5	0	0.0	11	0	0.0	16	0	0.0	
		No	5	5	100	11	11	100	16	16	100	
CIN2 not associated with HR-HPV	Yes	5	0	0.0	11	0	0.0	16	0	0.0		
	No	5	5	100	11	11	100	16	16	100		
CIN2 irrespective of HPV type	Yes	5	0	0.0	11	2	18.2	16	2	12.5		
	No	5	5	100	11	9	81.8	16	14	87.5		

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study with respective cytology status at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 24 Number and Percentage of Subjects with CIN2+ by associated HPV type – Cytology status at baseline & study (Total vaccinated cohort)

Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
008	High	CIN2+ associated with HR-HPV	Yes	45	18	40.0	43	22	51.2	88	40	45.5
			No	45	27	60.0	43	21	48.8	88	48	54.5
		CIN2+ associated with HRW-HPV	Yes	45	7	15.6	43	16	37.2	88	23	26.1
			No	45	38	84.4	43	27	62.8	88	65	73.9
		CIN2+ associated with HPV-16/18	Yes	45	12	26.7	43	17	39.5	88	29	33.0
			No	45	33	73.3	43	26	60.5	88	59	67.0
		CIN2+ associated with HPV-16/18 Only	Yes	45	11	24.4	43	6	14.0	88	17	19.3
			No	45	34	75.6	43	37	86.0	88	71	80.7
		CIN2+ not associated with HR-HPV	Yes	45	2	4.4	43	3	7.0	88	5	5.7
			No	45	43	95.6	43	40	93.0	88	83	94.3
		CIN2+ irrespective of HPV type	Yes	45	20	44.4	43	25	58.1	88	45	51.1
			No	45	25	55.6	43	18	41.9	88	43	48.9
	Normal	CIN2+ associated with HR-HPV	Yes	8544	135	1.6	8585	269	3.1	17129	404	2.4
			No	8544	8409	98.4	8585	8316	96.9	17129	16725	97.6
		CIN2+ associated with HRW-HPV	Yes	8544	111	1.3	8585	191	2.2	17129	302	1.8
			No	8544	8433	98.7	8585	8394	97.8	17129	16827	98.2
		CIN2+ associated with HPV-16/18	Yes	8544	36	0.4	8585	162	1.9	17129	198	1.2
			No	8544	8508	99.6	8585	8423	98.1	17129	16931	98.8
		CIN2+ associated with HPV-16/18 Only	Yes	8544	24	0.3	8585	78	0.9	17129	102	0.6
			No	8544	8520	99.7	8585	8507	99.1	17129	17027	99.4
		CIN2+ not associated with HR-HPV	Yes	8544	31	0.4	8585	30	0.3	17129	61	0.4
			No	8544	8513	99.6	8585	8555	99.7	17129	17068	99.6
		CIN2+ irrespective of HPV type	Yes	8544	166	1.9	8585	299	3.5	17129	465	2.7
			No	8544	8378	98.1	8585	8286	96.5	17129	16664	97.3
Low	CIN2+ associated with HR-HPV	Yes	714	85	11.9	682	94	13.8	1396	179	12.8	
		No	714	629	88.1	682	588	86.2	1396	1217	87.2	
	CIN2+ associated with HRW-HPV	Yes	714	64	9.0	682	68	10.0	1396	132	9.5	
		No	714	650	91.0	682	614	90.0	1396	1264	90.5	
	CIN2+ associated with HPV-16/18	Yes	714	42	5.9	682	49	7.2	1396	91	6.5	
		No	714	672	94.1	682	633	92.8	1396	1305	93.5	
	CIN2+ associated with HPV-16/18 Only	Yes	714	21	2.9	682	26	3.8	1396	47	3.4	
		No	714	693	97.1	682	656	96.2	1396	1349	96.6	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2+ not associated with HR-HPV	Yes	714	16	2.2	682	9	1.3	1396	25	1.8	
			No	714	698	97.8	682	673	98.7	1396	1371	98.2	
		CIN2+ irrespective of HPV type	Yes	714	101	14.1	682	103	15.1	1396	204	14.6	
			No	714	613	85.9	682	579	84.9	1396	1192	85.4	
	Missing	CIN2+ associated with HR-HPV	Yes	16	0	0.0	15	1	6.7	31	1	3.2	
			No	16	16	100	15	14	93.3	31	30	96.8	
		CIN2+ associated with HRW-HPV	Yes	16	0	0.0	15	1	6.7	31	1	3.2	
			No	16	16	100	15	14	93.3	31	30	96.8	
		CIN2+ associated with HPV-16/18	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN2+ associated with HPV-16/18 Only	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN2+ not associated with HR-HPV	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
	CIN2+ irrespective of HPV type	Yes	16	0	0.0	15	1	6.7	31	1	3.2		
		No	16	16	100	15	14	93.3	31	30	96.8		
	015	High	CIN2+ associated with HR-HPV	Yes	36	27	75.0	30	17	56.7	66	44	66.7
				No	36	9	25.0	30	13	43.3	66	22	33.3
CIN2+ associated with HRW-HPV			Yes	36	19	52.8	30	7	23.3	66	26	39.4	
			No	36	17	47.2	30	23	76.7	66	40	60.6	
CIN2+ associated with HPV-16/18			Yes	36	11	30.6	30	13	43.3	66	24	36.4	
			No	36	25	69.4	30	17	56.7	66	42	63.6	
CIN2+ associated with HPV-16/18 Only			Yes	36	8	22.2	30	10	33.3	66	18	27.3	
			No	36	28	77.8	30	20	66.7	66	48	72.7	
CIN2+ not associated with HR-HPV			Yes	36	0	0.0	30	1	3.3	66	1	1.5	
			No	36	36	100	30	29	96.7	66	65	98.5	
CIN2+ irrespective of HPV type			Yes	36	27	75.0	30	18	60.0	66	45	68.2	
			No	36	9	25.0	30	12	40.0	66	21	31.8	
Normal		CIN2+ associated with HR-HPV	Yes	2717	36	1.3	2713	55	2.0	5430	91	1.7	
			No	2717	2681	98.7	2713	2658	98.0	5430	5339	98.3	
		CIN2+ associated with HRW-HPV	Yes	2717	31	1.1	2713	37	1.4	5430	68	1.3	
			No	2717	2686	98.9	2713	2676	98.6	5430	5362	98.7	
		CIN2+ associated with HPV-16/18	Yes	2717	8	0.3	2713	27	1.0	5430	35	0.6	
			No	2717	2709	99.7	2713	2686	99.0	5430	5395	99.4	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2+ associated with HPV-16/18 Only	Yes	2717	5	0.2	2713	18	0.7	5430	23	0.4	
			No	2717	2712	99.8	2713	2695	99.3	5430	5407	99.6	
		CIN2+ not associated with HR-HPV	Yes	2717	13	0.5	2713	7	0.3	5430	20	0.4	
			No	2717	2704	99.5	2713	2706	99.7	5430	5410	99.6	
		CIN2+ irrespective of HPV type	Yes	2717	49	1.8	2713	62	2.3	5430	111	2.0	
			No	2717	2668	98.2	2713	2651	97.7	5430	5319	98.0	
		Low	CIN2+ associated with HR-HPV	Yes	123	26	21.1	124	24	19.4	247	50	20.2
				No	123	97	78.9	124	100	80.6	247	197	79.8
			CIN2+ associated with HRW-HPV	Yes	123	19	15.4	124	19	15.3	247	38	15.4
				No	123	104	84.6	124	105	84.7	247	209	84.6
			CIN2+ associated with HPV-16/18	Yes	123	14	11.4	124	11	8.9	247	25	10.1
				No	123	109	88.6	124	113	91.1	247	222	89.9
	CIN2+ associated with HPV-16/18 Only		Yes	123	7	5.7	124	5	4.0	247	12	4.9	
			No	123	116	94.3	124	119	96.0	247	235	95.1	
	CIN2+ not associated with HR-HPV		Yes	123	1	0.8	124	4	3.2	247	5	2.0	
			No	123	122	99.2	124	120	96.8	247	242	98.0	
	CIN2+ irrespective of HPV type		Yes	123	27	22.0	124	28	22.6	247	55	22.3	
			No	123	96	78.0	124	96	77.4	247	192	77.7	
	Missing	CIN2+ associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
			No	1	1	100	3	3	100	4	4	100	
		CIN2+ associated with HRW-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
			No	1	1	100	3	3	100	4	4	100	
		CIN2+ associated with HPV-16/18	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
			No	1	1	100	3	3	100	4	4	100	
CIN2+ associated with HPV-16/18 Only		Yes	1	0	0.0	3	0	0.0	4	0	0.0		
		No	1	1	100	3	3	100	4	4	100		
CIN2+ not associated with HR-HPV		Yes	1	0	0.0	3	0	0.0	4	0	0.0		
		No	1	1	100	3	3	100	4	4	100		
CIN2+ irrespective of HPV type		Yes	1	0	0.0	3	0	0.0	4	0	0.0		
		No	1	1	100	3	3	100	4	4	100		
032	High	CIN2+ associated with HR-HPV	Yes	4	3	75.0	5	4	80.0	9	7	77.8	
			No	4	1	25.0	5	1	20.0	9	2	22.2	
		CIN2+ associated with HRW-HPV	Yes	4	0	0.0	5	3	60.0	9	3	33.3	
			No	4	4	100	5	2	40.0	9	6	66.7	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2+ associated with HPV-16/18	Yes	4	3	75.0	5	2	40.0	9	5	55.6
			No	4	1	25.0	5	3	60.0	9	4	44.4
		CIN2+ associated with HPV-16/18 Only	Yes	4	3	75.0	5	1	20.0	9	4	44.4
			No	4	1	25.0	5	4	80.0	9	5	55.6
		CIN2+ not associated with HR-HPV	Yes	4	0	0.0	5	0	0.0	9	0	0.0
			No	4	4	100	5	5	100	9	9	100
	CIN2+ irrespective of HPV type	Yes	4	3	75.0	5	4	80.0	9	7	77.8	
		No	4	1	25.0	5	1	20.0	9	2	22.2	
	Normal	CIN2+ associated with HR-HPV	Yes	465	6	1.3	458	21	4.6	923	27	2.9
			No	465	459	98.7	458	437	95.4	923	896	97.1
		CIN2+ associated with HRW-HPV	Yes	465	6	1.3	458	13	2.8	923	19	2.1
			No	465	459	98.7	458	445	97.2	923	904	97.9
CIN2+ associated with HPV-16/18		Yes	465	2	0.4	458	11	2.4	923	13	1.4	
		No	465	463	99.6	458	447	97.6	923	910	98.6	
CIN2+ associated with HPV-16/18 Only		Yes	465	0	0.0	458	8	1.7	923	8	0.9	
		No	465	465	100	458	450	98.3	923	915	99.1	
CIN2+ not associated with HR-HPV		Yes	465	2	0.4	458	3	0.7	923	5	0.5	
		No	465	463	99.6	458	455	99.3	923	918	99.5	
CIN2+ irrespective of HPV type		Yes	465	8	1.7	458	24	5.2	923	32	3.5	
		No	465	457	98.3	458	434	94.8	923	891	96.5	
Low	CIN2+ associated with HR-HPV	Yes	49	7	14.3	58	13	22.4	107	20	18.7	
		No	49	42	85.7	58	45	77.6	107	87	81.3	
	CIN2+ associated with HRW-HPV	Yes	49	6	12.2	58	10	17.2	107	16	15.0	
		No	49	43	87.8	58	48	82.8	107	91	85.0	
	CIN2+ associated with HPV-16/18	Yes	49	2	4.1	58	7	12.1	107	9	8.4	
		No	49	47	95.9	58	51	87.9	107	98	91.6	
	CIN2+ associated with HPV-16/18 Only	Yes	49	1	2.0	58	3	5.2	107	4	3.7	
		No	49	48	98.0	58	55	94.8	107	103	96.3	
	CIN2+ not associated with HR-HPV	Yes	49	1	2.0	58	0	0.0	107	1	0.9	
		No	49	48	98.0	58	58	100	107	106	99.1	
	CIN2+ irrespective of HPV type	Yes	49	8	16.3	58	13	22.4	107	21	19.6	
		No	49	41	83.7	58	45	77.6	107	86	80.4	
Missing	CIN2+ associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN2+ associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ associated with HPV-16/18	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ associated with HPV-16/18 Only	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		039	High	CIN2+ associated with HR-HPV	Yes	34	20	58.8	29	20	69.0	63	40	63.5
					No	34	14	41.2	29	9	31.0	63	23	36.5
				CIN2+ associated with HRW-HPV	Yes	34	8	23.5	29	11	37.9	63	19	30.2
					No	34	26	76.5	29	18	62.1	63	44	69.8
CIN2+ associated with HPV-16/18	Yes			34	17	50.0	29	13	44.8	63	30	47.6		
	No			34	17	50.0	29	16	55.2	63	33	52.4		
CIN2+ associated with HPV-16/18 Only	Yes			34	12	35.3	29	9	31.0	63	21	33.3		
	No			34	22	64.7	29	20	69.0	63	42	66.7		
CIN2+ not associated with HR-HPV	Yes			34	1	2.9	29	0	0.0	63	1	1.6		
	No			34	33	97.1	29	29	100	63	62	98.4		
CIN2+ irrespective of HPV type	Yes			34	21	61.8	29	20	69.0	63	41	65.1		
	No			34	13	38.2	29	9	31.0	63	22	34.9		
Normal				CIN2+ associated with HR-HPV	Yes	2821	35	1.2	2804	41	1.5	5625	76	1.4
					No	2821	2786	98.8	2804	2763	98.5	5625	5549	98.6
		CIN2+ associated with HRW-HPV	Yes	2821	24	0.9	2804	26	0.9	5625	50	0.9		
			No	2821	2797	99.1	2804	2778	99.1	5625	5575	99.1		
		CIN2+ associated with HPV-16/18	Yes	2821	16	0.6	2804	19	0.7	5625	35	0.6		
			No	2821	2805	99.4	2804	2785	99.3	5625	5590	99.4		
		CIN2+ associated with HPV-16/18 Only	Yes	2821	11	0.4	2804	15	0.5	5625	26	0.5		
			No	2821	2810	99.6	2804	2789	99.5	5625	5599	99.5		
		CIN2+ not associated with HR-HPV	Yes	2821	3	0.1	2804	0	0.0	5625	3	0.1		
			No	2821	2818	99.9	2804	2804	100	5625	5622	99.9		
		CIN2+ irrespective of HPV type	Yes	2821	38	1.3	2804	41	1.5	5625	79	1.4		
			No	2821	2783	98.7	2804	2763	98.5	5625	5546	98.6		

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	Low	CIN2+ associated with HR-HPV	Yes	166	36	21.7	181	32	17.7	347	68	19.6
			No	166	130	78.3	181	149	82.3	347	279	80.4
		CIN2+ associated with HRW-HPV	Yes	166	23	13.9	181	19	10.5	347	42	12.1
			No	166	143	86.1	181	162	89.5	347	305	87.9
		CIN2+ associated with HPV-16/18	Yes	166	17	10.2	181	20	11.0	347	37	10.7
			No	166	149	89.8	181	161	89.0	347	310	89.3
		CIN2+ associated with HPV-16/18 Only	Yes	166	13	7.8	181	13	7.2	347	26	7.5
			No	166	153	92.2	181	168	92.8	347	321	92.5
	CIN2+ not associated with HR-HPV	Yes	166	2	1.2	181	3	1.7	347	5	1.4	
		No	166	164	98.8	181	178	98.3	347	342	98.6	
	CIN2+ irrespective of HPV type	Yes	166	38	22.9	181	35	19.3	347	73	21.0	
		No	166	128	77.1	181	146	80.7	347	274	79.0	
	Missing	CIN2+ associated with HR-HPV	Yes	5	0	0.0	11	2	18.2	16	2	12.5
			No	5	5	100	11	9	81.8	16	14	87.5
		CIN2+ associated with HRW-HPV	Yes	5	0	0.0	11	2	18.2	16	2	12.5
			No	5	5	100	11	9	81.8	16	14	87.5
CIN2+ associated with HPV-16/18		Yes	5	0	0.0	11	2	18.2	16	2	12.5	
		No	5	5	100	11	9	81.8	16	14	87.5	
CIN2+ associated with HPV-16/18 Only		Yes	5	0	0.0	11	0	0.0	16	0	0.0	
		No	5	5	100	11	11	100	16	16	100	
CIN2+ not associated with HR-HPV	Yes	5	0	0.0	11	0	0.0	16	0	0.0		
	No	5	5	100	11	11	100	16	16	100		
CIN2+ irrespective of HPV type	Yes	5	0	0.0	11	2	18.2	16	2	12.5		
	No	5	5	100	11	9	81.8	16	14	87.5		

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study with respective cytology status at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 24 Number and Percentage of Subjects with CIN3+ by associated HPV type – Cytology status at baseline & study (Total vaccinated cohort)

Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
008	High	CIN3+ associated with HR-HPV	Yes	45	12	26.7	43	12	27.9	88	24	27.3
			No	45	33	73.3	43	31	72.1	88	64	72.7
		CIN3+ associated with HRW-HPV	Yes	45	5	11.1	43	6	14.0	88	11	12.5
			No	45	40	88.9	43	37	86.0	88	77	87.5
		CIN3+ associated with HPV-16/18	Yes	45	8	17.8	43	9	20.9	88	17	19.3
			No	45	37	82.2	43	34	79.1	88	71	80.7
		CIN3+ associated with HPV-16/18 Only	Yes	45	7	15.6	43	6	14.0	88	13	14.8
			No	45	38	84.4	43	37	86.0	88	75	85.2
		CIN3+ not associated with HR-HPV	Yes	45	1	2.2	43	1	2.3	88	2	2.3
	No		45	44	97.8	43	42	97.7	88	86	97.7	
	CIN3+ irrespective of HPV type	Yes	45	13	28.9	43	13	30.2	88	26	29.5	
		No	45	32	71.1	43	30	69.8	88	62	70.5	
	Normal	CIN3+ associated with HR-HPV	Yes	8544	37	0.4	8585	95	1.1	17129	132	0.8
			No	8544	8507	99.6	8585	8490	98.9	17129	16997	99.2
		CIN3+ associated with HRW-HPV	Yes	8544	20	0.2	8585	57	0.7	17129	77	0.4
			No	8544	8524	99.8	8585	8528	99.3	17129	17052	99.6
		CIN3+ associated with HPV-16/18	Yes	8544	19	0.2	8585	66	0.8	17129	85	0.5
			No	8544	8525	99.8	8585	8519	99.2	17129	17044	99.5
CIN3+ associated with HPV-16/18 Only		Yes	8544	17	0.2	8585	38	0.4	17129	55	0.3	
		No	8544	8527	99.8	8585	8547	99.6	17129	17074	99.7	
CIN3+ not associated with HR-HPV		Yes	8544	3	0.0	8585	11	0.1	17129	14	0.1	
	No	8544	8541	100	8585	8574	99.9	17129	17115	99.9		
CIN3+ irrespective of HPV type	Yes	8544	40	0.5	8585	106	1.2	17129	146	0.9		
	No	8544	8504	99.5	8585	8479	98.8	17129	16983	99.1		
Low	CIN3+ associated with HR-HPV	Yes	714	29	4.1	682	32	4.7	1396	61	4.4	
		No	714	685	95.9	682	650	95.3	1396	1335	95.6	
	CIN3+ associated with HRW-HPV	Yes	714	17	2.4	682	17	2.5	1396	34	2.4	
		No	714	697	97.6	682	665	97.5	1396	1362	97.6	
	CIN3+ associated with HPV-16/18	Yes	714	24	3.4	682	19	2.8	1396	43	3.1	
		No	714	690	96.6	682	663	97.2	1396	1353	96.9	
	CIN3+ associated with HPV-16/18 Only	Yes	714	12	1.7	682	15	2.2	1396	27	1.9	
		No	714	702	98.3	682	667	97.8	1396	1369	98.1	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN3+ not associated with HR-HPV	Yes	714	4	0.6	682	7	1.0	1396	11	0.8	
			No	714	710	99.4	682	675	99.0	1396	1385	99.2	
		CIN3+ irrespective of HPV type	Yes	714	33	4.6	682	39	5.7	1396	72	5.2	
			No	714	681	95.4	682	643	94.3	1396	1324	94.8	
	Missing	CIN3+ associated with HR-HPV	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN3+ associated with HRW-HPV	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN3+ associated with HPV-16/18	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN3+ associated with HPV-16/18 Only	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
		CIN3+ not associated with HR-HPV	Yes	16	0	0.0	15	0	0.0	31	0	0.0	
			No	16	16	100	15	15	100	31	31	100	
	CIN3+ irrespective of HPV type	Yes	16	0	0.0	15	0	0.0	31	0	0.0		
		No	16	16	100	15	15	100	31	31	100		
	015	High	CIN3+ associated with HR-HPV	Yes	36	25	69.4	30	13	43.3	66	38	57.6
				No	36	11	30.6	30	17	56.7	66	28	42.4
CIN3+ associated with HRW-HPV			Yes	36	17	47.2	30	5	16.7	66	22	33.3	
			No	36	19	52.8	30	25	83.3	66	44	66.7	
CIN3+ associated with HPV-16/18			Yes	36	11	30.6	30	10	33.3	66	21	31.8	
			No	36	25	69.4	30	20	66.7	66	45	68.2	
CIN3+ associated with HPV-16/18 Only			Yes	36	8	22.2	30	8	26.7	66	16	24.2	
			No	36	28	77.8	30	22	73.3	66	50	75.8	
CIN3+ not associated with HR-HPV			Yes	36	0	0.0	30	0	0.0	66	0	0.0	
			No	36	36	100	30	30	100	66	66	100	
CIN3+ irrespective of HPV type		Yes	36	25	69.4	30	13	43.3	66	38	57.6		
		No	36	11	30.6	30	17	56.7	66	28	42.4		
Normal		CIN3+ associated with HR-HPV	Yes	2717	13	0.5	2713	21	0.8	5430	34	0.6	
			No	2717	2704	99.5	2713	2692	99.2	5430	5396	99.4	
		CIN3+ associated with HRW-HPV	Yes	2717	9	0.3	2713	11	0.4	5430	20	0.4	
			No	2717	2708	99.7	2713	2702	99.6	5430	5410	99.6	
		CIN3+ associated with HPV-16/18	Yes	2717	6	0.2	2713	10	0.4	5430	16	0.3	
			No	2717	2711	99.8	2713	2703	99.6	5430	5414	99.7	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN3+ associated with HPV-16/18 Only	Yes	2717	4	0.1	2713	10	0.4	5430	14	0.3	
			No	2717	2713	99.9	2713	2703	99.6	5430	5416	99.7	
		CIN3+ not associated with HR-HPV	Yes	2717	2	0.1	2713	2	0.1	5430	4	0.1	
			No	2717	2715	99.9	2713	2711	99.9	5430	5426	99.9	
		CIN3+ irrespective of HPV type	Yes	2717	15	0.6	2713	23	0.8	5430	38	0.7	
			No	2717	2702	99.4	2713	2690	99.2	5430	5392	99.3	
		Low	CIN3+ associated with HR-HPV	Yes	123	8	6.5	124	9	7.3	247	17	6.9
				No	123	115	93.5	124	115	92.7	247	230	93.1
			CIN3+ associated with HRW-HPV	Yes	123	4	3.3	124	6	4.8	247	10	4.0
				No	123	119	96.7	124	118	95.2	247	237	96.0
			CIN3+ associated with HPV-16/18	Yes	123	6	4.9	124	5	4.0	247	11	4.5
				No	123	117	95.1	124	119	96.0	247	236	95.5
	CIN3+ associated with HPV-16/18 Only		Yes	123	4	3.3	124	3	2.4	247	7	2.8	
			No	123	119	96.7	124	121	97.6	247	240	97.2	
	CIN3+ not associated with HR-HPV		Yes	123	2	1.6	124	0	0.0	247	2	0.8	
			No	123	121	98.4	124	124	100	247	245	99.2	
	CIN3+ irrespective of HPV type		Yes	123	10	8.1	124	9	7.3	247	19	7.7	
			No	123	113	91.9	124	115	92.7	247	228	92.3	
	Missing	CIN3+ associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
			No	1	1	100	3	3	100	4	4	100	
		CIN3+ associated with HRW-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
			No	1	1	100	3	3	100	4	4	100	
		CIN3+ associated with HPV-16/18	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
			No	1	1	100	3	3	100	4	4	100	
CIN3+ associated with HPV-16/18 Only		Yes	1	0	0.0	3	0	0.0	4	0	0.0		
		No	1	1	100	3	3	100	4	4	100		
CIN3+ not associated with HR-HPV		Yes	1	0	0.0	3	0	0.0	4	0	0.0		
		No	1	1	100	3	3	100	4	4	100		
CIN3+ irrespective of HPV type		Yes	1	0	0.0	3	0	0.0	4	0	0.0		
		No	1	1	100	3	3	100	4	4	100		
032	High	CIN3+ associated with HR-HPV	Yes	4	2	50.0	5	2	40.0	9	4	44.4	
			No	4	2	50.0	5	3	60.0	9	5	55.6	
		CIN3+ associated with HRW-HPV	Yes	4	0	0.0	5	1	20.0	9	1	11.1	
			No	4	4	100	5	4	80.0	9	8	88.9	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN3+ associated with HPV-16/18	Yes	4	2	50.0	5	2	40.0	9	4	44.4
			No	4	2	50.0	5	3	60.0	9	5	55.6
		CIN3+ associated with HPV-16/18 Only	Yes	4	2	50.0	5	1	20.0	9	3	33.3
			No	4	2	50.0	5	4	80.0	9	6	66.7
		CIN3+ not associated with HR-HPV	Yes	4	0	0.0	5	0	0.0	9	0	0.0
			No	4	4	100	5	5	100	9	9	100
	CIN3+ irrespective of HPV type	Yes	4	2	50.0	5	2	40.0	9	4	44.4	
		No	4	2	50.0	5	3	60.0	9	5	55.6	
	Normal	CIN3+ associated with HR-HPV	Yes	465	3	0.6	458	5	1.1	923	8	0.9
			No	465	462	99.4	458	453	98.9	923	915	99.1
		CIN3+ associated with HRW-HPV	Yes	465	3	0.6	458	2	0.4	923	5	0.5
			No	465	462	99.4	458	456	99.6	923	918	99.5
CIN3+ associated with HPV-16/18		Yes	465	2	0.4	458	4	0.9	923	6	0.7	
		No	465	463	99.6	458	454	99.1	923	917	99.3	
CIN3+ associated with HPV-16/18 Only		Yes	465	0	0.0	458	3	0.7	923	3	0.3	
		No	465	465	100	458	455	99.3	923	920	99.7	
CIN3+ not associated with HR-HPV		Yes	465	0	0.0	458	2	0.4	923	2	0.2	
		No	465	465	100	458	456	99.6	923	921	99.8	
CIN3+ irrespective of HPV type		Yes	465	3	0.6	458	7	1.5	923	10	1.1	
		No	465	462	99.4	458	451	98.5	923	913	98.9	
Low	CIN3+ associated with HR-HPV	Yes	49	3	6.1	58	5	8.6	107	8	7.5	
		No	49	46	93.9	58	53	91.4	107	99	92.5	
	CIN3+ associated with HRW-HPV	Yes	49	2	4.1	58	5	8.6	107	7	6.5	
		No	49	47	95.9	58	53	91.4	107	100	93.5	
	CIN3+ associated with HPV-16/18	Yes	49	2	4.1	58	3	5.2	107	5	4.7	
		No	49	47	95.9	58	55	94.8	107	102	95.3	
	CIN3+ associated with HPV-16/18 Only	Yes	49	1	2.0	58	0	0.0	107	1	0.9	
		No	49	48	98.0	58	58	100	107	106	99.1	
	CIN3+ not associated with HR-HPV	Yes	49	1	2.0	58	0	0.0	107	1	0.9	
		No	49	48	98.0	58	58	100	107	106	99.1	
	CIN3+ irrespective of HPV type	Yes	49	4	8.2	58	5	8.6	107	9	8.4	
		No	49	45	91.8	58	53	91.4	107	98	91.6	
Missing	CIN3+ associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN3+ associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ associated with HPV-16/18	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ associated with HPV-16/18 Only	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		039	High	CIN3+ associated with HR-HPV	Yes	34	16	47.1	29	14	48.3	63	30	47.6
					No	34	18	52.9	29	15	51.7	63	33	52.4
				CIN3+ associated with HRW-HPV	Yes	34	5	14.7	29	4	13.8	63	9	14.3
					No	34	29	85.3	29	25	86.2	63	54	85.7
CIN3+ associated with HPV-16/18	Yes			34	14	41.2	29	11	37.9	63	25	39.7		
	No			34	20	58.8	29	18	62.1	63	38	60.3		
CIN3+ associated with HPV-16/18 Only	Yes			34	11	32.4	29	10	34.5	63	21	33.3		
	No			34	23	67.6	29	19	65.5	63	42	66.7		
CIN3+ not associated with HR-HPV	Yes			34	1	2.9	29	0	0.0	63	1	1.6		
	No			34	33	97.1	29	29	100	63	62	98.4		
CIN3+ irrespective of HPV type	Yes			34	17	50.0	29	14	48.3	63	31	49.2		
	No			34	17	50.0	29	15	51.7	63	32	50.8		
	Normal			CIN3+ associated with HR-HPV	Yes	2821	14	0.5	2804	12	0.4	5625	26	0.5
					No	2821	2807	99.5	2804	2792	99.6	5625	5599	99.5
		CIN3+ associated with HRW-HPV	Yes	2821	8	0.3	2804	4	0.1	5625	12	0.2		
			No	2821	2813	99.7	2804	2800	99.9	5625	5613	99.8		
		CIN3+ associated with HPV-16/18	Yes	2821	9	0.3	2804	10	0.4	5625	19	0.3		
			No	2821	2812	99.7	2804	2794	99.6	5625	5606	99.7		
		CIN3+ associated with HPV-16/18 Only	Yes	2821	6	0.2	2804	8	0.3	5625	14	0.2		
			No	2821	2815	99.8	2804	2796	99.7	5625	5611	99.8		
		CIN3+ not associated with HR-HPV	Yes	2821	1	0.0	2804	0	0.0	5625	1	0.0		
			No	2821	2820	100	2804	2804	100	5625	5624	100		
		CIN3+ irrespective of HPV type	Yes	2821	15	0.5	2804	12	0.4	5625	27	0.5		
			No	2821	2806	99.5	2804	2792	99.6	5625	5598	99.5		

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Study	Cytology Status at baseline	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	Low	CIN3+ associated with HR-HPV	Yes	166	21	12.7	181	11	6.1	347	32	9.2
			No	166	145	87.3	181	170	93.9	347	315	90.8
		CIN3+ associated with HRW-HPV	Yes	166	10	6.0	181	4	2.2	347	14	4.0
			No	166	156	94.0	181	177	97.8	347	333	96.0
		CIN3+ associated with HPV-16/18	Yes	166	13	7.8	181	8	4.4	347	21	6.1
			No	166	153	92.2	181	173	95.6	347	326	93.9
		CIN3+ associated with HPV-16/18 Only	Yes	166	11	6.6	181	7	3.9	347	18	5.2
			No	166	155	93.4	181	174	96.1	347	329	94.8
	CIN3+ not associated with HR-HPV	Yes	166	1	0.6	181	1	0.6	347	2	0.6	
		No	166	165	99.4	181	180	99.4	347	345	99.4	
	CIN3+ irrespective of HPV type	Yes	166	22	13.3	181	12	6.6	347	34	9.8	
		No	166	144	86.7	181	169	93.4	347	313	90.2	
	Missing	CIN3+ associated with HR-HPV	Yes	5	0	0.0	11	1	9.1	16	1	6.3
			No	5	5	100	11	10	90.9	16	15	93.8
		CIN3+ associated with HRW-HPV	Yes	5	0	0.0	11	1	9.1	16	1	6.3
			No	5	5	100	11	10	90.9	16	15	93.8
CIN3+ associated with HPV-16/18		Yes	5	0	0.0	11	1	9.1	16	1	6.3	
		No	5	5	100	11	10	90.9	16	15	93.8	
CIN3+ associated with HPV-16/18 Only		Yes	5	0	0.0	11	0	0.0	16	0	0.0	
		No	5	5	100	11	11	100	16	16	100	
CIN3+ not associated with HR-HPV	Yes	5	0	0.0	11	0	0.0	16	0	0.0		
	No	5	5	100	11	11	100	16	16	100		
CIN3+ irrespective of HPV type	Yes	5	0	0.0	11	1	9.1	16	1	6.3		
	No	5	5	100	11	10	90.9	16	15	93.8		

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study with respective cytology status at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 1 Number and Percentage of Subjects in each Study by age category (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	Age in Years	15-17 Years	9319	2973	31.9	9325	2984	32.0	18644	5957	32.0
		18-20 Years	9319	2066	22.2	9325	2095	22.5	18644	4161	22.3
		21-25 Years	9319	4265	45.8	9325	4235	45.4	18644	8500	45.6
		26 Years and above	9319	14	0.2	9325	11	0.1	18644	25	0.1
		15-20 Years	9319	5039	54.1	9325	5079	54.5	18644	10118	54.3
		21 Years and above	9319	4279	45.9	9325	4246	45.5	18644	8525	45.7
015	Age in Years	15-17 Years	2877	0	0.0	2870	0	0.0	5747	0	0.0
		18-20 Years	2877	0	0.0	2870	0	0.0	5747	0	0.0
		21-25 Years	2877	3	0.1	2870	0	0.0	5747	3	0.1
		26 Years and above	2877	2874	99.9	2870	2870	100	5747	5744	99.9
		15-20 Years	2877	0	0.0	2870	0	0.0	5747	0	0.0
		21 Years and above	2877	2877	100	2870	2870	100	5747	5747	100
032	Age in Years	15-17 Years	519	0	0.0	521	0	0.0	1040	0	0.0
		18-20 Years	519	75	14.5	521	62	11.9	1040	137	13.2
		21-25 Years	519	444	85.5	521	459	88.1	1040	903	86.8
		26 Years and above	519	0	0.0	521	0	0.0	1040	0	0.0
		15-20 Years	519	75	14.5	521	62	11.9	1040	137	13.2
		21 Years and above	519	444	85.5	521	459	88.1	1040	903	86.8
039	Age in Years	15-17 Years	3026	0	0.0	3025	0	0.0	6051	0	0.0
		18-20 Years	3026	284	9.4	3025	284	9.4	6051	568	9.4
		21-25 Years	3026	2735	90.4	3025	2725	90.1	6051	5460	90.2
		26 Years and above	3026	7	0.2	3025	16	0.5	6051	23	0.4
		15-20 Years	3026	284	9.4	3025	284	9.4	6051	568	9.4
		21 Years and above	3026	2742	90.6	3025	2741	90.6	6051	5483	90.6
Overall total	Age in Years	15-17 Years	15741	2973	18.9	15741	2984	19.0	31482	5957	18.9
		18-20 Years	15741	2425	15.4	15741	2441	15.5	31482	4866	15.5
		21-25 Years	15741	7447	47.3	15741	7419	47.1	31482	14866	47.2
		26 Years and above	15741	2895	18.4	15741	2897	18.4	31482	5792	18.4
		15-20 Years	15741	5398	34.3	15741	5425	34.5	31482	10823	34.4
		21 Years and above	15741	10342	65.7	15741	10316	65.5	31482	20658	65.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each study

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 2 Summary of Cytology Status at Baseline by study and age category (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	Age in Years	15-17 Years	119	12	10.1	107	13	12.1	226	25	11.1
		18-20 Years	119	14	11.8	107	8	7.5	226	22	9.7
		21-25 Years	119	57	47.9	107	56	52.3	226	113	50.0
		26 Years and above	119	36	30.3	107	30	28.0	226	66	29.2
		15-20 Years	119	26	21.8	107	21	19.6	226	47	20.8
		21 Years and above	119	93	78.2	107	86	80.4	226	179	79.2
Normal	Age in Years	15-17 Years	14547	2715	18.7	14560	2759	18.9	29107	5474	18.8
		18-20 Years	14547	2192	15.1	14560	2208	15.2	29107	4400	15.1
		21-25 Years	14547	6904	47.5	14560	6853	47.1	29107	13757	47.3
		26 Years and above	14547	2735	18.8	14560	2740	18.8	29107	5475	18.8
		15-20 Years	14547	4907	33.7	14560	4967	34.1	29107	9874	33.9
		21 Years and above	14547	9639	66.3	14560	9593	65.9	29107	19232	66.1
Low	Age in Years	15-17 Years	1052	246	23.4	1045	210	20.1	2097	456	21.7
		18-20 Years	1052	216	20.5	1045	221	21.1	2097	437	20.8
		21-25 Years	1052	467	44.4	1045	490	46.9	2097	957	45.6
		26 Years and above	1052	123	11.7	1045	124	11.9	2097	247	11.8
		15-20 Years	1052	462	43.9	1045	431	41.2	2097	893	42.6
		21 Years and above	1052	590	56.1	1045	614	58.8	2097	1204	57.4
Missing	Age in Years	15-17 Years	23	0	0.0	29	2	6.9	52	2	3.8
		18-20 Years	23	3	13.0	29	4	13.8	52	7	13.5
		21-25 Years	23	19	82.6	29	20	69.0	52	39	75.0
		26 Years and above	23	1	4.3	29	3	10.3	52	4	7.7
		15-20 Years	23	3	13.0	29	6	20.7	52	9	17.3
		21 Years and above	23	20	87.0	29	23	79.3	52	43	82.7

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 3 Summary of Cytology Status at Baseline by age category (Total vaccinated cohort)

Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
008	High	Age in Years	15-17 Years	45	12	26.7	43	13	30.2	88	25	28.4
			18-20 Years	45	11	24.4	43	6	14.0	88	17	19.3
			21-25 Years	45	22	48.9	43	24	55.8	88	46	52.3
			26 Years and above	45	0	0.0	43	0	0.0	88	0	0.0
			15-20 Years	45	23	51.1	43	19	44.2	88	42	47.7
			21 Years and above	45	22	48.9	43	24	55.8	88	46	52.3
	Normal	Age in Years	15-17 Years	8544	2715	31.8	8585	2759	32.1	17129	5474	32.0
			18-20 Years	8544	1856	21.7	8585	1882	21.9	17129	3738	21.8
			21-25 Years	8544	3958	46.3	8585	3933	45.8	17129	7891	46.1
			26 Years and above	8544	14	0.2	8585	11	0.1	17129	25	0.1
			15-20 Years	8544	4571	53.5	8585	4641	54.1	17129	9212	53.8
			21 Years and above	8544	3972	46.5	8585	3944	45.9	17129	7916	46.2
	Low	Age in Years	15-17 Years	714	246	34.5	682	210	30.8	1396	456	32.7
			18-20 Years	714	196	27.5	682	204	29.9	1396	400	28.7
			21-25 Years	714	272	38.1	682	268	39.3	1396	540	38.7
			26 Years and above	714	0	0.0	682	0	0.0	1396	0	0.0
			15-20 Years	714	442	61.9	682	414	60.7	1396	856	61.3
			21 Years and above	714	272	38.1	682	268	39.3	1396	540	38.7
	Missing	Age in Years	15-17 Years	16	0	0.0	15	2	13.3	31	2	6.5
			18-20 Years	16	3	18.8	15	3	20.0	31	6	19.4
21-25 Years			16	13	81.3	15	10	66.7	31	23	74.2	
26 Years and above			16	0	0.0	15	0	0.0	31	0	0.0	
		15-20 Years	16	3	18.8	15	5	33.3	31	8	25.8	
		21 Years and above	16	13	81.3	15	10	66.7	31	23	74.2	
015	High	Age in Years	15-17 Years	36	0	0.0	30	0	0.0	66	0	0.0
			18-20 Years	36	0	0.0	30	0	0.0	66	0	0.0
			21-25 Years	36	0	0.0	30	0	0.0	66	0	0.0
			26 Years and above	36	36	100	30	30	100	66	66	100
			15-20 Years	36	0	0.0	30	0	0.0	66	0	0.0
			21 Years and above	36	36	100	30	30	100	66	66	100
	Normal	Age in Years	15-17 Years	2717	0	0.0	2713	0	0.0	5430	0	0.0
			18-20 Years	2717	0	0.0	2713	0	0.0	5430	0	0.0
			21-25 Years	2717	3	0.1	2713	0	0.0	5430	3	0.1
			26 Years and above	2717	2714	99.9	2713	2713	100	5430	5427	99.9
			15-20 Years	2717	0	0.0	2713	0	0.0	5430	0	0.0
			21 Years and above	2717	2717	100	2713	2713	100	5430	5430	100
	Low	Age in Years	15-17 Years	123	0	0.0	124	0	0.0	247	0	0.0

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Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
			18-20 Years	123	0	0.0	124	0	0.0	247	0	0.0		
			21-25 Years	123	0	0.0	124	0	0.0	247	0	0.0		
			26 Years and above	123	123	100	124	124	100	247	247	100		
			15-20 Years	123	0	0.0	124	0	0.0	247	0	0.0		
		21 Years and above	123	123	100	124	124	100	247	247	100			
		Missing	Age in Years	15-17 Years	1	0	0.0	3	0	0.0	4	0	0.0	
				18-20 Years	1	0	0.0	3	0	0.0	4	0	0.0	
				21-25 Years	1	0	0.0	3	0	0.0	4	0	0.0	
	26 Years and above			1	1	100	3	3	100	4	4	100		
				15-20 Years	1	0	0.0	3	0	0.0	4	0	0.0	
				21 Years and above	1	1	100	3	3	100	4	4	100	
	032	High	Age in Years	15-17 Years	4	0	0.0	5	0	0.0	9	0	0.0	
18-20 Years				4	0	0.0	5	1	20.0	9	1	11.1		
21-25 Years				4	4	100	5	4	80.0	9	8	88.9		
26 Years and above				4	0	0.0	5	0	0.0	9	0	0.0		
					15-20 Years	4	0	0.0	5	1	20.0	9	1	11.1
					21 Years and above	4	4	100	5	4	80.0	9	8	88.9
Normal			Age in Years	15-17 Years	465	0	0.0	458	0	0.0	923	0	0.0	
				18-20 Years	465	67	14.4	458	56	12.2	923	123	13.3	
		21-25 Years		465	398	85.6	458	402	87.8	923	800	86.7		
		26 Years and above		465	0	0.0	458	0	0.0	923	0	0.0		
					15-20 Years	465	67	14.4	458	56	12.2	923	123	13.3
					21 Years and above	465	398	85.6	458	402	87.8	923	800	86.7
		Low	Age in Years	15-17 Years	49	0	0.0	58	0	0.0	107	0	0.0	
				18-20 Years	49	8	16.3	58	5	8.6	107	13	12.1	
21-25 Years				49	41	83.7	58	53	91.4	107	94	87.9		
26 Years and above				49	0	0.0	58	0	0.0	107	0	0.0		
					15-20 Years	49	8	16.3	58	5	8.6	107	13	12.1
					21 Years and above	49	41	83.7	58	53	91.4	107	94	87.9
Missing			Age in Years	15-17 Years	1	0	0.0	0	-	-	1	0	0.0	
				18-20 Years	1	0	0.0	0	-	-	1	0	0.0	
	21-25 Years	1		1	100	0	-	-	1	1	100			
	26 Years and above	1		0	0.0	0	-	-	1	0	0.0			
				15-20 Years	1	0	0.0	0	-	-	1	0	0.0	
				21 Years and above	1	1	100	0	-	-	1	1	100	
039	High	Age in Years	15-17 Years	34	0	0.0	29	0	0.0	63	0	0.0		
			18-20 Years	34	3	8.8	29	1	3.4	63	4	6.3		
			21-25 Years	34	31	91.2	29	28	96.6	63	59	93.7		
			26 Years and above	34	0	0.0	29	0	0.0	63	0	0.0		

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Study	Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
			15-20 Years	34	3	8.8	29	1	3.4	63	4	6.3
			21 Years and above	34	31	91.2	29	28	96.6	63	59	93.7
	Normal	Age in Years	15-17 Years	2821	0	0.0	2804	0	0.0	5625	0	0.0
			18-20 Years	2821	269	9.5	2804	270	9.6	5625	539	9.6
			21-25 Years	2821	2545	90.2	2804	2518	89.8	5625	5063	90.0
			26 Years and above	2821	7	0.2	2804	16	0.6	5625	23	0.4
			15-20 Years	2821	269	9.5	2804	270	9.6	5625	539	9.6
			21 Years and above	2821	2552	90.5	2804	2534	90.4	5625	5086	90.4
	Low	Age in Years	15-17 Years	166	0	0.0	181	0	0.0	347	0	0.0
			18-20 Years	166	12	7.2	181	12	6.6	347	24	6.9
			21-25 Years	166	154	92.8	181	169	93.4	347	323	93.1
			26 Years and above	166	0	0.0	181	0	0.0	347	0	0.0
			15-20 Years	166	12	7.2	181	12	6.6	347	24	6.9
			21 Years and above	166	154	92.8	181	169	93.4	347	323	93.1
	Missing	Age in Years	15-17 Years	5	0	0.0	11	0	0.0	16	0	0.0
			18-20 Years	5	0	0.0	11	1	9.1	16	1	6.3
			21-25 Years	5	5	100	11	10	90.9	16	15	93.8
			26 Years and above	5	0	0.0	11	0	0.0	16	0	0.0
15-20 Years			5	0	0.0	11	1	9.1	16	1	6.3	
21 Years and above			5	5	100	11	10	90.9	16	15	93.8	

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects by study and cytology at baseline

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 4 Number & percentage of subjects by study and age category – with HR-HPV at baseline (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	Age in Years	15-17 Years	1898	535	28.2	1855	515	27.8	3753	1050	28.0
		18-20 Years	1898	504	26.6	1855	502	27.1	3753	1006	26.8
		21-25 Years	1898	859	45.3	1855	837	45.1	3753	1696	45.2
		26 Years and above	1898	0	0.0	1855	1	0.1	3753	1	0.0
		15-20 Years	1898	1039	54.7	1855	1017	54.8	3753	2056	54.8
		21 Years and above	1898	859	45.3	1855	838	45.2	3753	1697	45.2
015	Age in Years	15-17 Years	416	0	0.0	408	0	0.0	824	0	0.0
		18-20 Years	416	0	0.0	408	0	0.0	824	0	0.0
		21-25 Years	416	0	0.0	408	0	0.0	824	0	0.0
		26 Years and above	416	416	100	408	408	100	824	824	100
		15-20 Years	416	0	0.0	408	0	0.0	824	0	0.0
		21 Years and above	416	416	100	408	408	100	824	824	100
032	Age in Years	15-17 Years	147	0	0.0	157	0	0.0	304	0	0.0
		18-20 Years	147	21	14.3	157	20	12.7	304	41	13.5
		21-25 Years	147	126	85.7	157	137	87.3	304	263	86.5
		26 Years and above	147	0	0.0	157	0	0.0	304	0	0.0
		15-20 Years	147	21	14.3	157	20	12.7	304	41	13.5
		21 Years and above	147	126	85.7	157	137	87.3	304	263	86.5
039	Age in Years	15-17 Years	473	0	0.0	451	0	0.0	924	0	0.0
		18-20 Years	473	32	6.8	451	50	11.1	924	82	8.9
		21-25 Years	473	441	93.2	451	398	88.2	924	839	90.8
		26 Years and above	473	0	0.0	451	3	0.7	924	3	0.3
		15-20 Years	473	32	6.8	451	50	11.1	924	82	8.9
		21 Years and above	473	441	93.2	451	401	88.9	924	842	91.1
Overall total	Age in Years	15-17 Years	2934	535	18.2	2871	515	17.9	5805	1050	18.1
		18-20 Years	2934	557	19.0	2871	572	19.9	5805	1129	19.4
		21-25 Years	2934	1426	48.6	2871	1372	47.8	5805	2798	48.2
		26 Years and above	2934	416	14.2	2871	412	14.4	5805	828	14.3
		15-20 Years	2934	1092	37.2	2871	1087	37.9	5805	2179	37.5
		21 Years and above	2934	1842	62.8	2871	1784	62.1	5805	3626	62.5

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 5 Number & percentage of subjects by study and age category – with HRW-HPV at baseline (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	Age in Years	15-17 Years	1552	447	28.8	1536	413	26.9	3088	860	27.8
		18-20 Years	1552	397	25.6	1536	419	27.3	3088	816	26.4
		21-25 Years	1552	708	45.6	1536	703	45.8	3088	1411	45.7
		26 Years and above	1552	0	0.0	1536	1	0.1	3088	1	0.0
		15-20 Years	1552	844	54.4	1536	832	54.2	3088	1676	54.3
		21 Years and above	1552	708	45.6	1536	704	45.8	3088	1412	45.7
015	Age in Years	15-17 Years	343	0	0.0	334	0	0.0	677	0	0.0
		18-20 Years	343	0	0.0	334	0	0.0	677	0	0.0
		21-25 Years	343	0	0.0	334	0	0.0	677	0	0.0
		26 Years and above	343	343	100	334	334	100	677	677	100
		15-20 Years	343	0	0.0	334	0	0.0	677	0	0.0
		21 Years and above	343	343	100	334	334	100	677	677	100
032	Age in Years	15-17 Years	120	0	0.0	129	0	0.0	249	0	0.0
		18-20 Years	120	15	12.5	129	19	14.7	249	34	13.7
		21-25 Years	120	105	87.5	129	110	85.3	249	215	86.3
		26 Years and above	120	0	0.0	129	0	0.0	249	0	0.0
		15-20 Years	120	15	12.5	129	19	14.7	249	34	13.7
		21 Years and above	120	105	87.5	129	110	85.3	249	215	86.3
039	Age in Years	15-17 Years	377	0	0.0	382	0	0.0	759	0	0.0
		18-20 Years	377	24	6.4	382	41	10.7	759	65	8.6
		21-25 Years	377	353	93.6	382	339	88.7	759	692	91.2
		26 Years and above	377	0	0.0	382	2	0.5	759	2	0.3
		15-20 Years	377	24	6.4	382	41	10.7	759	65	8.6
		21 Years and above	377	353	93.6	382	341	89.3	759	694	91.4
Overall total	Age in Years	15-17 Years	2392	447	18.7	2381	413	17.3	4773	860	18.0
		18-20 Years	2392	436	18.2	2381	479	20.1	4773	915	19.2
		21-25 Years	2392	1166	48.7	2381	1152	48.4	4773	2318	48.6
		26 Years and above	2392	343	14.3	2381	337	14.2	4773	680	14.2
		15-20 Years	2392	883	36.9	2381	892	37.5	4773	1775	37.2
		21 Years and above	2392	1509	63.1	2381	1489	62.5	4773	2998	62.8

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 6 Number & percentage of subjects by study and age category – with HPV-16/18 at baseline (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	Age in Years	15-17 Years	690	216	31.3	649	201	31.0	1339	417	31.1
		18-20 Years	690	187	27.1	649	172	26.5	1339	359	26.8
		21-25 Years	690	287	41.6	649	276	42.5	1339	563	42.0
		26 Years and above	690	0	0.0	649	0	0.0	1339	0	0.0
		15-20 Years	690	403	58.4	649	373	57.5	1339	776	58.0
		21 Years and above	690	287	41.6	649	276	42.5	1339	563	42.0
015	Age in Years	15-17 Years	113	0	0.0	116	0	0.0	229	0	0.0
		18-20 Years	113	0	0.0	116	0	0.0	229	0	0.0
		21-25 Years	113	0	0.0	116	0	0.0	229	0	0.0
		26 Years and above	113	113	100	116	116	100	229	229	100
		15-20 Years	113	0	0.0	116	0	0.0	229	0	0.0
		21 Years and above	113	113	100	116	116	100	229	229	100
032	Age in Years	15-17 Years	44	0	0.0	59	0	0.0	103	0	0.0
		18-20 Years	44	8	18.2	59	5	8.5	103	13	12.6
		21-25 Years	44	36	81.8	59	54	91.5	103	90	87.4
		26 Years and above	44	0	0.0	59	0	0.0	103	0	0.0
		15-20 Years	44	8	18.2	59	5	8.5	103	13	12.6
		21 Years and above	44	36	81.8	59	54	91.5	103	90	87.4
039	Age in Years	15-17 Years	151	0	0.0	128	0	0.0	279	0	0.0
		18-20 Years	151	12	7.9	128	15	11.7	279	27	9.7
		21-25 Years	151	139	92.1	128	112	87.5	279	251	90.0
		26 Years and above	151	0	0.0	128	1	0.8	279	1	0.4
		15-20 Years	151	12	7.9	128	15	11.7	279	27	9.7
		21 Years and above	151	139	92.1	128	113	88.3	279	252	90.3
Overall total	Age in Years	15-17 Years	998	216	21.6	952	201	21.1	1950	417	21.4
		18-20 Years	998	207	20.7	952	192	20.2	1950	399	20.5
		21-25 Years	998	462	46.3	952	442	46.4	1950	904	46.4
		26 Years and above	998	113	11.3	952	117	12.3	1950	230	11.8
		15-20 Years	998	423	42.4	952	393	41.3	1950	816	41.8
		21 Years and above	998	575	57.6	952	559	58.7	1950	1134	58.2

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 7 Number & percentage of subjects by study and age category – with HPV-16/18 only at baseline (Total vaccinated cohort)

Study	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
008	Age in Years	15-17 Years	346	88	25.4	319	102	32.0	665	190	28.6
		18-20 Years	346	107	30.9	319	83	26.0	665	190	28.6
		21-25 Years	346	151	43.6	319	134	42.0	665	285	42.9
		26 Years and above	346	0	0.0	319	0	0.0	665	0	0.0
		15-20 Years	346	195	56.4	319	185	58.0	665	380	57.1
		21 Years and above	346	151	43.6	319	134	42.0	665	285	42.9
015	Age in Years	15-17 Years	73	0	0.0	74	0	0.0	147	0	0.0
		18-20 Years	73	0	0.0	74	0	0.0	147	0	0.0
		21-25 Years	73	0	0.0	74	0	0.0	147	0	0.0
		26 Years and above	73	73	100	74	74	100	147	147	100
		15-20 Years	73	0	0.0	74	0	0.0	147	0	0.0
		21 Years and above	73	73	100	74	74	100	147	147	100
032	Age in Years	15-17 Years	27	0	0.0	28	0	0.0	55	0	0.0
		18-20 Years	27	6	22.2	28	1	3.6	55	7	12.7
		21-25 Years	27	21	77.8	28	27	96.4	55	48	87.3
		26 Years and above	27	0	0.0	28	0	0.0	55	0	0.0
		15-20 Years	27	6	22.2	28	1	3.6	55	7	12.7
		21 Years and above	27	21	77.8	28	27	96.4	55	48	87.3
039	Age in Years	15-17 Years	96	0	0.0	69	0	0.0	165	0	0.0
		18-20 Years	96	8	8.3	69	9	13.0	165	17	10.3
		21-25 Years	96	88	91.7	69	59	85.5	165	147	89.1
		26 Years and above	96	0	0.0	69	1	1.4	165	1	0.6
		15-20 Years	96	8	8.3	69	9	13.0	165	17	10.3
		21 Years and above	96	88	91.7	69	60	87.0	165	148	89.7
Overall total	Age in Years	15-17 Years	542	88	16.2	490	102	20.8	1032	190	18.4
		18-20 Years	542	121	22.3	490	93	19.0	1032	214	20.7
		21-25 Years	542	260	48.0	490	220	44.9	1032	480	46.5
		26 Years and above	542	73	13.5	490	75	15.3	1032	148	14.3
		15-20 Years	542	209	38.6	490	195	39.8	1032	404	39.1
		21 Years and above	542	333	61.4	490	295	60.2	1032	628	60.9

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 8 Number & percentage of subjects by cytology status and age category – with HR-HPV at baseline (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	Age in Years	15-17 Years	105	11	10.5	92	13	14.1	197	24	12.2
		18-20 Years	105	11	10.5	92	8	8.7	197	19	9.6
		21-25 Years	105	52	49.5	92	47	51.1	197	99	50.3
		26 Years and above	105	31	29.5	92	24	26.1	197	55	27.9
		15-20 Years	105	22	21.0	92	21	22.8	197	43	21.8
		21 Years and above	105	83	79.0	92	71	77.2	197	154	78.2
Normal	Age in Years	15-17 Years	1945	311	16.0	1914	328	17.1	3859	639	16.6
		18-20 Years	1945	363	18.7	1914	379	19.8	3859	742	19.2
		21-25 Years	1945	983	50.5	1914	921	48.1	3859	1904	49.3
		26 Years and above	1945	288	14.8	1914	286	14.9	3859	574	14.9
		15-20 Years	1945	674	34.7	1914	707	36.9	3859	1381	35.8
		21 Years and above	1945	1271	65.3	1914	1207	63.1	3859	2478	64.2
Low	Age in Years	15-17 Years	884	213	24.1	865	174	20.1	1749	387	22.1
		18-20 Years	884	183	20.7	865	185	21.4	1749	368	21.0
		21-25 Years	884	391	44.2	865	404	46.7	1749	795	45.5
		26 Years and above	884	97	11.0	865	102	11.8	1749	199	11.4
		15-20 Years	884	396	44.8	865	359	41.5	1749	755	43.2
		21 Years and above	884	488	55.2	865	506	58.5	1749	994	56.8

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 9 Number & percentage of subjects by cytology status and age category – with HRW-HPV at baseline (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	Age in Years	15-17 Years	66	6	9.1	64	11	17.2	130	17	13.1
		18-20 Years	66	8	12.1	64	5	7.8	130	13	10.0
		21-25 Years	66	29	43.9	64	33	51.6	130	62	47.7
		26 Years and above	66	23	34.8	64	15	23.4	130	38	29.2
		15-20 Years	66	14	21.2	64	16	25.0	130	30	23.1
		21 Years and above	66	52	78.8	64	48	75.0	130	100	76.9
Normal	Age in Years	15-17 Years	1573	252	16.0	1579	251	15.9	3152	503	16.0
		18-20 Years	1573	282	17.9	1579	318	20.1	3152	600	19.0
		21-25 Years	1573	800	50.9	1579	769	48.7	3152	1569	49.8
		26 Years and above	1573	239	15.2	1579	241	15.3	3152	480	15.2
		15-20 Years	1573	534	33.9	1579	569	36.0	3152	1103	35.0
		21 Years and above	1573	1039	66.1	1579	1010	64.0	3152	2049	65.0
Low	Age in Years	15-17 Years	753	189	25.1	738	151	20.5	1491	340	22.8
		18-20 Years	753	146	19.4	738	156	21.1	1491	302	20.3
		21-25 Years	753	337	44.8	738	350	47.4	1491	687	46.1
		26 Years and above	753	81	10.8	738	81	11.0	1491	162	10.9
		15-20 Years	753	335	44.5	738	307	41.6	1491	642	43.1
		21 Years and above	753	418	55.5	738	431	58.4	1491	849	56.9

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 10 **Number & percentage of subjects by cytology status and age category – with HPV-16/18 at baseline (Total vaccinated cohort)**

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	Age in Years	15-17 Years	66	6	9.1	59	5	8.5	125	11	8.8
		18-20 Years	66	6	9.1	59	6	10.2	125	12	9.6
		21-25 Years	66	39	59.1	59	31	52.5	125	70	56.0
		26 Years and above	66	15	22.7	59	17	28.8	125	32	25.6
	Age category in Years	15-20 Years	66	12	18.2	59	11	18.6	125	23	18.4
		21 Years and above	66	54	81.8	59	48	81.4	125	102	81.6
Normal	Age in Years	15-17 Years	598	121	20.2	573	124	21.6	1171	245	20.9
		18-20 Years	598	124	20.7	573	114	19.9	1171	238	20.3
		21-25 Years	598	286	47.8	573	270	47.1	1171	556	47.5
		26 Years and above	598	67	11.2	573	65	11.3	1171	132	11.3
	Age category in Years	15-20 Years	598	245	41.0	573	238	41.5	1171	483	41.2
		21 Years and above	598	353	59.0	573	335	58.5	1171	688	58.8
Low	Age in Years	15-17 Years	334	89	26.6	320	72	22.5	654	161	24.6
		18-20 Years	334	77	23.1	320	72	22.5	654	149	22.8
		21-25 Years	334	137	41.0	320	141	44.1	654	278	42.5
		26 Years and above	334	31	9.3	320	35	10.9	654	66	10.1
	Age category in Years	15-20 Years	334	166	49.7	320	144	45.0	654	310	47.4
		21 Years and above	334	168	50.3	320	176	55.0	654	344	52.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 11 Number & percentage of subjects by cytology status and age category – with HPV-16/18 only at baseline (Total vaccinated cohort)

Cytology Status at baseline	Characteristics	Categories	HPV			Control			Total		
			N	n	%	N	n	%	N	n	%
High	Age in Years	15-17 Years	39	5	12.8	28	2	7.1	67	7	10.4
		18-20 Years	39	3	7.7	28	3	10.7	67	6	9.0
		21-25 Years	39	23	59.0	28	14	50.0	67	37	55.2
		26 Years and above	39	8	20.5	28	9	32.1	67	17	25.4
		15-20 Years	39	8	20.5	28	5	17.9	67	13	19.4
		21 Years and above	39	31	79.5	28	23	82.1	67	54	80.6
Normal	Age in Years	15-17 Years	372	59	15.9	335	77	23.0	707	136	19.2
		18-20 Years	372	81	21.8	335	61	18.2	707	142	20.1
		21-25 Years	372	183	49.2	335	152	45.4	707	335	47.4
		26 Years and above	372	49	13.2	335	45	13.4	707	94	13.3
		15-20 Years	372	140	37.6	335	138	41.2	707	278	39.3
		21 Years and above	372	232	62.4	335	197	58.8	707	429	60.7
Low	Age in Years	15-17 Years	131	24	18.3	127	23	18.1	258	47	18.2
		18-20 Years	131	37	28.2	127	29	22.8	258	66	25.6
		21-25 Years	131	54	41.2	127	54	42.5	258	108	41.9
		26 Years and above	131	16	12.2	127	21	16.5	258	37	14.3
		15-20 Years	131	61	46.6	127	52	40.9	258	113	43.8
		21 Years and above	131	70	53.4	127	75	59.1	258	145	56.2

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table12 Number and Percentage of Subjects with CIN2 by cytology Status and age category (Total vaccinated cohort)

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
High	15-17 Years	CIN2 associated with HR-HPV	Yes	12	3	25.0	13	4	30.8	25	7	28.0
			No	12	9	75.0	13	9	69.2	25	18	72.0
		CIN2 associated with HRW-HPV	Yes	12	1	8.3	13	4	30.8	25	5	20.0
			No	12	11	91.7	13	9	69.2	25	20	80.0
		CIN2 associated with HPV-16/18	Yes	12	2	16.7	13	3	23.1	25	5	20.0
			No	12	10	83.3	13	10	76.9	25	20	80.0
		CIN2 associated with HPV-16/18 Only	Yes	12	2	16.7	13	0	0.0	25	2	8.0
			No	12	10	83.3	13	13	100	25	23	92.0
		CIN2 not associated with HR-HPV	Yes	12	1	8.3	13	2	15.4	25	3	12.0
			No	12	11	91.7	13	11	84.6	25	22	88.0
		CIN2 irrespective of HPV type	Yes	12	4	33.3	13	6	46.2	25	10	40.0
			No	12	8	66.7	13	7	53.8	25	15	60.0
	18-20 Years	CIN2 associated with HR-HPV	Yes	14	3	21.4	8	4	50.0	22	7	31.8
			No	14	11	78.6	8	4	50.0	22	15	68.2
		CIN2 associated with HRW-HPV	Yes	14	2	14.3	8	2	25.0	22	4	18.2
			No	14	12	85.7	8	6	75.0	22	18	81.8
		CIN2 associated with HPV-16/18	Yes	14	1	7.1	8	3	37.5	22	4	18.2
			No	14	13	92.9	8	5	62.5	22	18	81.8
		CIN2 associated with HPV-16/18 Only	Yes	14	1	7.1	8	2	25.0	22	3	13.6
			No	14	13	92.9	8	6	75.0	22	19	86.4
		CIN2 not associated with HR-HPV	Yes	14	0	0.0	8	0	0.0	22	0	0.0
			No	14	14	100	8	8	100	22	22	100
		CIN2 irrespective of HPV type	Yes	14	3	21.4	8	4	50.0	22	7	31.8
			No	14	11	78.6	8	4	50.0	22	15	68.2
21-25 Years	CIN2 associated with HR-HPV	Yes	57	22	38.6	56	32	57.1	113	54	47.8	
		No	57	35	61.4	56	24	42.9	113	59	52.2	
	CIN2 associated with HRW-HPV	Yes	57	11	19.3	56	20	35.7	113	31	27.4	
		No	57	46	80.7	56	36	64.3	113	82	72.6	
	CIN2 associated with HPV-16/18	Yes	57	16	28.1	56	21	37.5	113	37	32.7	
		No	57	41	71.9	56	35	62.5	113	76	67.3	
	CIN2 associated with HPV-16/18 Only	Yes	57	11	19.3	56	12	21.4	113	23	20.4	
		No	57	46	80.7	56	44	78.6	113	90	79.6	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2 not associated with HR-HPV	Yes	57	4	7.0	56	2	3.6	113	6	5.3	
			No	57	53	93.0	56	54	96.4	113	107	94.7	
		CIN2 irrespective of HPV type	Yes	57	26	45.6	56	34	60.7	113	60	53.1	
			No	57	31	54.4	56	22	39.3	113	53	46.9	
	26 Years and above	CIN2 associated with HR-HPV	Yes	36	19	52.8	30	10	33.3	66	29	43.9	
			No	36	17	47.2	30	20	66.7	66	37	56.1	
		CIN2 associated with HRW-HPV	Yes	36	14	38.9	30	5	16.7	66	19	28.8	
			No	36	22	61.1	30	25	83.3	66	47	71.2	
		CIN2 associated with HPV-16/18	Yes	36	6	16.7	30	6	20.0	66	12	18.2	
			No	36	30	83.3	30	24	80.0	66	54	81.8	
		CIN2 associated with HPV-16/18 Only	Yes	36	5	13.9	30	5	16.7	66	10	15.2	
			No	36	31	86.1	30	25	83.3	66	56	84.8	
		CIN2 not associated with HR-HPV	Yes	36	2	5.6	30	1	3.3	66	3	4.5	
			No	36	34	94.4	30	29	96.7	66	63	95.5	
	CIN2 irrespective of HPV type	Yes	36	21	58.3	30	11	36.7	66	32	48.5		
		No	36	15	41.7	30	19	63.3	66	34	51.5		
	Normal	15-17 Years	CIN2 associated with HR-HPV	Yes	2715	55	2.0	2759	124	4.5	5474	179	3.3
				No	2715	2660	98.0	2759	2635	95.5	5474	5295	96.7
CIN2 associated with HRW-HPV			Yes	2715	51	1.9	2759	92	3.3	5474	143	2.6	
			No	2715	2664	98.1	2759	2667	96.7	5474	5331	97.4	
CIN2 associated with HPV-16/18			Yes	2715	8	0.3	2759	69	2.5	5474	77	1.4	
			No	2715	2707	99.7	2759	2690	97.5	5474	5397	98.6	
CIN2 associated with HPV-16/18 Only			Yes	2715	4	0.1	2759	32	1.2	5474	36	0.7	
			No	2715	2711	99.9	2759	2727	98.8	5474	5438	99.3	
CIN2 not associated with HR-HPV			Yes	2715	12	0.4	2759	19	0.7	5474	31	0.6	
			No	2715	2703	99.6	2759	2740	99.3	5474	5443	99.4	
CIN2 irrespective of HPV type		Yes	2715	67	2.5	2759	143	5.2	5474	210	3.8		
		No	2715	2648	97.5	2759	2616	94.8	5474	5264	96.2		
18-20 Years		CIN2 associated with HR-HPV	Yes	2192	32	1.5	2208	70	3.2	4400	102	2.3	
			No	2192	2160	98.5	2208	2138	96.8	4400	4298	97.7	
		CIN2 associated with HRW-HPV	Yes	2192	26	1.2	2208	38	1.7	4400	64	1.5	
			No	2192	2166	98.8	2208	2170	98.3	4400	4336	98.5	
		CIN2 associated with HPV-16/18	Yes	2192	10	0.5	2208	48	2.2	4400	58	1.3	
			No	2192	2182	99.5	2208	2160	97.8	4400	4342	98.7	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2 associated with HPV-16/18 Only	Yes	2192	6	0.3	2208	32	1.4	4400	38	0.9
			No	2192	2186	99.7	2208	2176	98.6	4400	4362	99.1
		CIN2 not associated with HR-HPV	Yes	2192	7	0.3	2208	6	0.3	4400	13	0.3
			No	2192	2185	99.7	2208	2202	99.7	4400	4387	99.7
		CIN2 irrespective of HPV type	Yes	2192	39	1.8	2208	76	3.4	4400	115	2.6
			No	2192	2153	98.2	2208	2132	96.6	4400	4285	97.4
	21-25 Years	CIN2 associated with HR-HPV	Yes	6904	70	1.0	6853	109	1.6	13757	179	1.3
			No	6904	6834	99.0	6853	6744	98.4	13757	13578	98.7
		CIN2 associated with HRW-HPV	Yes	6904	52	0.8	6853	78	1.1	13757	130	0.9
			No	6904	6852	99.2	6853	6775	98.9	13757	13627	99.1
		CIN2 associated with HPV-16/18	Yes	6904	25	0.4	6853	51	0.7	13757	76	0.6
			No	6904	6879	99.6	6853	6802	99.3	13757	13681	99.4
		CIN2 associated with HPV-16/18 Only	Yes	6904	18	0.3	6853	31	0.5	13757	49	0.4
			No	6904	6886	99.7	6853	6822	99.5	13757	13708	99.6
		CIN2 not associated with HR-HPV	Yes	6904	22	0.3	6853	8	0.1	13757	30	0.2
			No	6904	6882	99.7	6853	6845	99.9	13757	13727	99.8
		CIN2 irrespective of HPV type	Yes	6904	92	1.3	6853	117	1.7	13757	209	1.5
			No	6904	6812	98.7	6853	6736	98.3	13757	13548	98.5
	26 Years and above	CIN2 associated with HR-HPV	Yes	2735	29	1.1	2740	49	1.8	5475	78	1.4
			No	2735	2706	98.9	2740	2691	98.2	5475	5397	98.6
		CIN2 associated with HRW-HPV	Yes	2735	25	0.9	2740	33	1.2	5475	58	1.1
			No	2735	2710	99.1	2740	2707	98.8	5475	5417	98.9
		CIN2 associated with HPV-16/18	Yes	2735	5	0.2	2740	26	0.9	5475	31	0.6
			No	2735	2730	99.8	2740	2714	99.1	5475	5444	99.4
CIN2 associated with HPV-16/18 Only		Yes	2735	4	0.1	2740	16	0.6	5475	20	0.4	
		No	2735	2731	99.9	2740	2724	99.4	5475	5455	99.6	
CIN2 not associated with HR-HPV		Yes	2735	14	0.5	2740	8	0.3	5475	22	0.4	
		No	2735	2721	99.5	2740	2732	99.7	5475	5453	99.6	
CIN2 irrespective of HPV type		Yes	2735	43	1.6	2740	57	2.1	5475	100	1.8	
		No	2735	2692	98.4	2740	2683	97.9	5475	5375	98.2	
Missing	CIN2 associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
	CIN2 associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN2 associated with HPV-16/18	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 associated with HPV-16/18 Only	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2 irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		Low	15-17 Years	CIN2 associated with HR-HPV	Yes	246	28	11.4	210	36	17.1	456	64	14.0
					No	246	218	88.6	210	174	82.9	456	392	86.0
				CIN2 associated with HRW-HPV	Yes	246	23	9.3	210	29	13.8	456	52	11.4
					No	246	223	90.7	210	181	86.2	456	404	88.6
CIN2 associated with HPV-16/18	Yes			246	9	3.7	210	21	10.0	456	30	6.6		
	No			246	237	96.3	210	189	90.0	456	426	93.4		
CIN2 associated with HPV-16/18 Only	Yes			246	5	2.0	210	7	3.3	456	12	2.6		
	No			246	241	98.0	210	203	96.7	456	444	97.4		
CIN2 not associated with HR-HPV	Yes			246	9	3.7	210	6	2.9	456	15	3.3		
	No			246	237	96.3	210	204	97.1	456	441	96.7		
CIN2 irrespective of HPV type	Yes			246	37	15.0	210	42	20.0	456	79	17.3		
	No			246	209	85.0	210	168	80.0	456	377	82.7		
18-20 Years	CIN2 associated with HR-HPV		Yes	216	20	9.3	221	23	10.4	437	43	9.8		
			No	216	196	90.7	221	198	89.6	437	394	90.2		
	CIN2 associated with HRW-HPV		Yes	216	15	6.9	221	16	7.2	437	31	7.1		
			No	216	201	93.1	221	205	92.8	437	406	92.9		
	CIN2 associated with HPV-16/18		Yes	216	10	4.6	221	10	4.5	437	20	4.6		
			No	216	206	95.4	221	211	95.5	437	417	95.4		
	CIN2 associated with HPV-16/18 Only		Yes	216	5	2.3	221	7	3.2	437	12	2.7		
			No	216	211	97.7	221	214	96.8	437	425	97.3		
	CIN2 not associated with HR-HPV		Yes	216	2	0.9	221	2	0.9	437	4	0.9		
			No	216	214	99.1	221	219	99.1	437	433	99.1		
	CIN2 irrespective of HPV type		Yes	216	22	10.2	221	25	11.3	437	47	10.8		
			No	216	194	89.8	221	196	88.7	437	390	89.2		
21-25 Years	CIN2 associated with HR-HPV	Yes	467	68	14.6	490	64	13.1	957	132	13.8			
		No	467	399	85.4	490	426	86.9	957	825	86.2			

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2 associated with HRW-HPV	Yes	467	49	10.5	490	44	9.0	957	93	9.7	
			No	467	418	89.5	490	446	91.0	957	864	90.3	
		CIN2 associated with HPV-16/18	Yes	467	30	6.4	490	32	6.5	957	62	6.5	
			No	467	437	93.6	490	458	93.5	957	895	93.5	
		CIN2 associated with HPV-16/18 Only	Yes	467	19	4.1	490	20	4.1	957	39	4.1	
			No	467	448	95.9	490	470	95.9	957	918	95.9	
		CIN2 not associated with HR-HPV	Yes	467	9	1.9	490	6	1.2	957	15	1.6	
			No	467	458	98.1	490	484	98.8	957	942	98.4	
		CIN2 irrespective of HPV type	Yes	467	77	16.5	490	70	14.3	957	147	15.4	
			No	467	390	83.5	490	420	85.7	957	810	84.6	
		26 Years and above	CIN2 associated with HR-HPV	Yes	123	26	21.1	124	20	16.1	247	46	18.6
				No	123	97	78.9	124	104	83.9	247	201	81.4
	CIN2 associated with HRW-HPV		Yes	123	18	14.6	124	17	13.7	247	35	14.2	
			No	123	105	85.4	124	107	86.3	247	212	85.8	
	CIN2 associated with HPV-16/18		Yes	123	13	10.6	124	7	5.6	247	20	8.1	
			No	123	110	89.4	124	117	94.4	247	227	91.9	
	CIN2 associated with HPV-16/18 Only	Yes	123	8	6.5	124	3	2.4	247	11	4.5		
		No	123	115	93.5	124	121	97.6	247	236	95.5		
CIN2 not associated with HR-HPV	Yes	123	1	0.8	124	6	4.8	247	7	2.8			
	No	123	122	99.2	124	118	95.2	247	240	97.2			
CIN2 irrespective of HPV type	Yes	123	27	22.0	124	26	21.0	247	53	21.5			
	No	123	96	78.0	124	98	79.0	247	194	78.5			
Missing	15-17 Years	CIN2 associated with HR-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2 associated with HRW-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2 associated with HPV-16/18	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2 associated with HPV-16/18 Only	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2 not associated with HR-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2 irrespective of HPV type	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	18-20 Years	CIN2 associated with HR-HPV	Yes	3	0	0.0	4	1	25.0	7	1	14.3
			No	3	3	100	4	3	75.0	7	6	85.7
		CIN2 associated with HRW-HPV	Yes	3	0	0.0	4	1	25.0	7	1	14.3
			No	3	3	100	4	3	75.0	7	6	85.7
		CIN2 associated with HPV-16/18	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN2 associated with HPV-16/18 Only	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN2 not associated with HR-HPV	Yes	3	0	0.0	4	0	0.0	7	0	0.0
	No		3	3	100	4	4	100	7	7	100	
	CIN2 irrespective of HPV type	Yes	3	0	0.0	4	1	25.0	7	1	14.3	
		No	3	3	100	4	3	75.0	7	6	85.7	
	21-25 Years	CIN2 associated with HR-HPV	Yes	19	0	0.0	20	2	10.0	39	2	5.1
			No	19	19	100	20	18	90.0	39	37	94.9
		CIN2 associated with HRW-HPV	Yes	19	0	0.0	20	2	10.0	39	2	5.1
			No	19	19	100	20	18	90.0	39	37	94.9
		CIN2 associated with HPV-16/18	Yes	19	0	0.0	20	2	10.0	39	2	5.1
			No	19	19	100	20	18	90.0	39	37	94.9
		CIN2 associated with HPV-16/18 Only	Yes	19	0	0.0	20	0	0.0	39	0	0.0
			No	19	19	100	20	20	100	39	39	100
		CIN2 not associated with HR-HPV	Yes	19	0	0.0	20	0	0.0	39	0	0.0
	No		19	19	100	20	20	100	39	39	100	
	CIN2 irrespective of HPV type	Yes	19	0	0.0	20	2	10.0	39	2	5.1	
		No	19	19	100	20	18	90.0	39	37	94.9	
26 Years and above	CIN2 associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2 associated with HRW-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2 associated with HPV-16/18	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2 associated with HPV-16/18 Only	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2 not associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
No		1	1	100	3	3	100	4	4	100		

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2 irrespective of HPV type	Yes	1	0	0.0	3	0	0.0	4	0	0.0
			No	1	1	100	3	3	100	4	4	100
Overall total	Overall total	CIN2 associated with HR-HPV	Yes	15741	375	2.4	15741	548	3.5	31482	923	2.9
			No	15741	15366	97.6	15741	15193	96.5	31482	30559	97.1
		CIN2 associated with HRW-HPV	Yes	15741	287	1.8	15741	381	2.4	31482	668	2.1
			No	15741	15454	98.2	15741	15360	97.6	31482	30814	97.9
		CIN2 associated with HPV-16/18	Yes	15741	135	0.9	15741	299	1.9	31482	434	1.4
			No	15741	15606	99.1	15741	15442	98.1	31482	31048	98.6
		CIN2 associated with HPV-16/18 Only	Yes	15741	88	0.6	15741	167	1.1	31482	255	0.8
			No	15741	15653	99.4	15741	15574	98.9	31482	31227	99.2
		CIN2 not associated with HR-HPV	Yes	15741	83	0.5	15741	66	0.4	31482	149	0.5
			No	15741	15658	99.5	15741	15675	99.6	31482	31333	99.5
		CIN2 irrespective of HPV type	Yes	15741	458	2.9	15741	614	3.9	31482	1072	3.4
			No	15741	15283	97.1	15741	15127	96.1	31482	30410	96.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects in each cytology status category

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 13 Number and Percentage of Subjects with CIN2+ by Cytology status at baseline and age category (Total vaccinated cohort)

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
High	15-17 Years	CIN2+ associated with HR-HPV	Yes	12	3	25.0	13	4	30.8	25	7	28.0
			No	12	9	75.0	13	9	69.2	25	18	72.0
		CIN2+ associated with HRW-HPV	Yes	12	1	8.3	13	4	30.8	25	5	20.0
			No	12	11	91.7	13	9	69.2	25	20	80.0
		CIN2+ associated with HPV-16/18	Yes	12	2	16.7	13	3	23.1	25	5	20.0
			No	12	10	83.3	13	10	76.9	25	20	80.0
		CIN2+ associated with HPV-16/18 Only	Yes	12	2	16.7	13	0	0.0	25	2	8.0
			No	12	10	83.3	13	13	100	25	23	92.0
		CIN2+ not associated with HR-HPV	Yes	12	1	8.3	13	2	15.4	25	3	12.0
			No	12	11	91.7	13	11	84.6	25	22	88.0
		CIN2+ irrespective of HPV type	Yes	12	4	33.3	13	6	46.2	25	10	40.0
			No	12	8	66.7	13	7	53.8	25	15	60.0
	18-20 Years	CIN2+ associated with HR-HPV	Yes	14	3	21.4	8	4	50.0	22	7	31.8
			No	14	11	78.6	8	4	50.0	22	15	68.2
		CIN2+ associated with HRW-HPV	Yes	14	2	14.3	8	3	37.5	22	5	22.7
			No	14	12	85.7	8	5	62.5	22	17	77.3
		CIN2+ associated with HPV-16/18	Yes	14	1	7.1	8	3	37.5	22	4	18.2
			No	14	13	92.9	8	5	62.5	22	18	81.8
		CIN2+ associated with HPV-16/18 Only	Yes	14	1	7.1	8	1	12.5	22	2	9.1
			No	14	13	92.9	8	7	87.5	22	20	90.9
		CIN2+ not associated with HR-HPV	Yes	14	0	0.0	8	0	0.0	22	0	0.0
			No	14	14	100	8	8	100	22	22	100
		CIN2+ irrespective of HPV type	Yes	14	3	21.4	8	4	50.0	22	7	31.8
			No	14	11	78.6	8	4	50.0	22	15	68.2
21-25 Years	CIN2+ associated with HR-HPV	Yes	57	35	61.4	56	38	67.9	113	73	64.6	
		No	57	22	38.6	56	18	32.1	113	40	35.4	
	CIN2+ associated with HRW-HPV	Yes	57	12	21.1	56	23	41.1	113	35	31.0	
		No	57	45	78.9	56	33	58.9	113	78	69.0	
	CIN2+ associated with HPV-16/18	Yes	57	29	50.9	56	26	46.4	113	55	48.7	
		No	57	28	49.1	56	30	53.6	113	58	51.3	
	CIN2+ associated with HPV-16/18 Only	Yes	57	23	40.4	56	15	26.8	113	38	33.6	
		No	57	34	59.6	56	41	73.2	113	75	66.4	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2+ not associated with HR-HPV	Yes	57	2	3.5	56	1	1.8	113	3	2.7
			No	57	55	96.5	56	55	98.2	113	110	97.3
		CIN2+ irrespective of HPV type	Yes	57	37	64.9	56	39	69.6	113	76	67.3
			No	57	20	35.1	56	17	30.4	113	37	32.7
	26 Years and above	CIN2+ associated with HR-HPV	Yes	36	27	75.0	30	17	56.7	66	44	66.7
			No	36	9	25.0	30	13	43.3	66	22	33.3
		CIN2+ associated with HRW-HPV	Yes	36	19	52.8	30	7	23.3	66	26	39.4
			No	36	17	47.2	30	23	76.7	66	40	60.6
		CIN2+ associated with HPV-16/18	Yes	36	11	30.6	30	13	43.3	66	24	36.4
			No	36	25	69.4	30	17	56.7	66	42	63.6
		CIN2+ associated with HPV-16/18 Only	Yes	36	8	22.2	30	10	33.3	66	18	27.3
			No	36	28	77.8	30	20	66.7	66	48	72.7
		CIN2+ not associated with HR-HPV	Yes	36	0	0.0	30	1	3.3	66	1	1.5
			No	36	36	100	30	29	96.7	66	65	98.5
CIN2+ irrespective of HPV type	Yes	36	27	75.0	30	18	60.0	66	45	68.2		
	No	36	9	25.0	30	12	40.0	66	21	31.8		
Normal	15-17 Years	CIN2+ associated with HR-HPV	Yes	2715	57	2.1	2759	131	4.7	5474	188	3.4
			No	2715	2658	97.9	2759	2628	95.3	5474	5286	96.6
		CIN2+ associated with HRW-HPV	Yes	2715	53	2.0	2759	100	3.6	5474	153	2.8
			No	2715	2662	98.0	2759	2659	96.4	5474	5321	97.2
		CIN2+ associated with HPV-16/18	Yes	2715	8	0.3	2759	75	2.7	5474	83	1.5
			No	2715	2707	99.7	2759	2684	97.3	5474	5391	98.5
		CIN2+ associated with HPV-16/18 Only	Yes	2715	4	0.1	2759	31	1.1	5474	35	0.6
			No	2715	2711	99.9	2759	2728	98.9	5474	5439	99.4
	CIN2+ not associated with HR-HPV	Yes	2715	11	0.4	2759	19	0.7	5474	30	0.5	
		No	2715	2704	99.6	2759	2740	99.3	5474	5444	99.5	
	CIN2+ irrespective of HPV type	Yes	2715	68	2.5	2759	150	5.4	5474	218	4.0	
		No	2715	2647	97.5	2759	2609	94.6	5474	5256	96.0	
	18-20 Years	CIN2+ associated with HR-HPV	Yes	2192	36	1.6	2208	76	3.4	4400	112	2.5
			No	2192	2156	98.4	2208	2132	96.6	4400	4288	97.5
CIN2+ associated with HRW-HPV		Yes	2192	27	1.2	2208	43	1.9	4400	70	1.6	
		No	2192	2165	98.8	2208	2165	98.1	4400	4330	98.4	
CIN2+ associated with HPV-16/18		Yes	2192	13	0.6	2208	53	2.4	4400	66	1.5	
		No	2192	2179	99.4	2208	2155	97.6	4400	4334	98.5	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2+ associated with HPV-16/18 Only	Yes	2192	9	0.4	2208	33	1.5	4400	42	1.0
			No	2192	2183	99.6	2208	2175	98.5	4400	4358	99.0
		CIN2+ not associated with HR-HPV	Yes	2192	7	0.3	2208	5	0.2	4400	12	0.3
			No	2192	2185	99.7	2208	2203	99.8	4400	4388	99.7
		CIN2+ irrespective of HPV type	Yes	2192	43	2.0	2208	81	3.7	4400	124	2.8
			No	2192	2149	98.0	2208	2127	96.3	4400	4276	97.2
	21-25 Years	CIN2+ associated with HR-HPV	Yes	6904	83	1.2	6853	123	1.8	13757	206	1.5
			No	6904	6821	98.8	6853	6730	98.2	13757	13551	98.5
		CIN2+ associated with HRW-HPV	Yes	6904	61	0.9	6853	86	1.3	13757	147	1.1
			No	6904	6843	99.1	6853	6767	98.7	13757	13610	98.9
		CIN2+ associated with HPV-16/18	Yes	6904	33	0.5	6853	63	0.9	13757	96	0.7
			No	6904	6871	99.5	6853	6790	99.1	13757	13661	99.3
		CIN2+ associated with HPV-16/18 Only	Yes	6904	22	0.3	6853	37	0.5	13757	59	0.4
			No	6904	6882	99.7	6853	6816	99.5	13757	13698	99.6
		CIN2+ not associated with HR-HPV	Yes	6904	18	0.3	6853	9	0.1	13757	27	0.2
			No	6904	6886	99.7	6853	6844	99.9	13757	13730	99.8
		CIN2+ irrespective of HPV type	Yes	6904	101	1.5	6853	132	1.9	13757	233	1.7
			No	6904	6803	98.5	6853	6721	98.1	13757	13524	98.3
	26 Years and above	CIN2+ associated with HR-HPV	Yes	2735	36	1.3	2740	56	2.0	5475	92	1.7
			No	2735	2699	98.7	2740	2684	98.0	5475	5383	98.3
		CIN2+ associated with HRW-HPV	Yes	2735	31	1.1	2740	38	1.4	5475	69	1.3
			No	2735	2704	98.9	2740	2702	98.6	5475	5406	98.7
		CIN2+ associated with HPV-16/18	Yes	2735	8	0.3	2740	28	1.0	5475	36	0.7
			No	2735	2727	99.7	2740	2712	99.0	5475	5439	99.3
CIN2+ associated with HPV-16/18 Only		Yes	2735	5	0.2	2740	18	0.7	5475	23	0.4	
		No	2735	2730	99.8	2740	2722	99.3	5475	5452	99.6	
CIN2+ not associated with HR-HPV		Yes	2735	13	0.5	2740	7	0.3	5475	20	0.4	
		No	2735	2722	99.5	2740	2733	99.7	5475	5455	99.6	
CIN2+ irrespective of HPV type		Yes	2735	49	1.8	2740	63	2.3	5475	112	2.0	
		No	2735	2686	98.2	2740	2677	97.7	5475	5363	98.0	
Missing	CIN2+ associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
	CIN2+ associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN2+ associated with HPV-16/18	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ associated with HPV-16/18 Only	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN2+ irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		Low	15-17 Years	CIN2+ associated with HR-HPV	Yes	246	30	12.2	210	38	18.1	456	68	14.9
					No	246	216	87.8	210	172	81.9	456	388	85.1
				CIN2+ associated with HRW-HPV	Yes	246	24	9.8	210	30	14.3	456	54	11.8
					No	246	222	90.2	210	180	85.7	456	402	88.2
CIN2+ associated with HPV-16/18	Yes			246	11	4.5	210	22	10.5	456	33	7.2		
	No			246	235	95.5	210	188	89.5	456	423	92.8		
CIN2+ associated with HPV-16/18 Only	Yes			246	6	2.4	210	8	3.8	456	14	3.1		
	No			246	240	97.6	210	202	96.2	456	442	96.9		
CIN2+ not associated with HR-HPV	Yes			246	10	4.1	210	6	2.9	456	16	3.5		
	No			246	236	95.9	210	204	97.1	456	440	96.5		
CIN2+ irrespective of HPV type	Yes			246	40	16.3	210	44	21.0	456	84	18.4		
	No			246	206	83.7	210	166	79.0	456	372	81.6		
18-20 Years	CIN2+ associated with HR-HPV		Yes	216	22	10.2	221	28	12.7	437	50	11.4		
			No	216	194	89.8	221	193	87.3	437	387	88.6		
	CIN2+ associated with HRW-HPV		Yes	216	16	7.4	221	18	8.1	437	34	7.8		
			No	216	200	92.6	221	203	91.9	437	403	92.2		
	CIN2+ associated with HPV-16/18		Yes	216	12	5.6	221	14	6.3	437	26	5.9		
			No	216	204	94.4	221	207	93.7	437	411	94.1		
	CIN2+ associated with HPV-16/18 Only		Yes	216	6	2.8	221	10	4.5	437	16	3.7		
			No	216	210	97.2	221	211	95.5	437	421	96.3		
	CIN2+ not associated with HR-HPV		Yes	216	2	0.9	221	0	0.0	437	2	0.5		
			No	216	214	99.1	221	221	100	437	435	99.5		
	CIN2+ irrespective of HPV type		Yes	216	24	11.1	221	28	12.7	437	52	11.9		
			No	216	192	88.9	221	193	87.3	437	385	88.1		
21-25 Years	CIN2+ associated with HR-HPV	Yes	467	76	16.3	490	73	14.9	957	149	15.6			
		No	467	391	83.7	490	417	85.1	957	808	84.4			

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2+ associated with HRW-HPV	Yes	467	53	11.3	490	49	10.0	957	102	10.7	
			No	467	414	88.7	490	441	90.0	957	855	89.3	
		CIN2+ associated with HPV-16/18	Yes	467	38	8.1	490	40	8.2	957	78	8.2	
			No	467	429	91.9	490	450	91.8	957	879	91.8	
		CIN2+ associated with HPV-16/18 Only	Yes	467	23	4.9	490	24	4.9	957	47	4.9	
			No	467	444	95.1	490	466	95.1	957	910	95.1	
		CIN2+ not associated with HR-HPV	Yes	467	7	1.5	490	6	1.2	957	13	1.4	
			No	467	460	98.5	490	484	98.8	957	944	98.6	
		CIN2+ irrespective of HPV type	Yes	467	83	17.8	490	79	16.1	957	162	16.9	
			No	467	384	82.2	490	411	83.9	957	795	83.1	
		26 Years and above	CIN2+ associated with HR-HPV	Yes	123	26	21.1	124	24	19.4	247	50	20.2
				No	123	97	78.9	124	100	80.6	247	197	79.8
			CIN2+ associated with HRW-HPV	Yes	123	19	15.4	124	19	15.3	247	38	15.4
				No	123	104	84.6	124	105	84.7	247	209	84.6
	CIN2+ associated with HPV-16/18		Yes	123	14	11.4	124	11	8.9	247	25	10.1	
			No	123	109	88.6	124	113	91.1	247	222	89.9	
	CIN2+ associated with HPV-16/18 Only		Yes	123	7	5.7	124	5	4.0	247	12	4.9	
			No	123	116	94.3	124	119	96.0	247	235	95.1	
CIN2+ not associated with HR-HPV	Yes		123	1	0.8	124	4	3.2	247	5	2.0		
	No		123	122	99.2	124	120	96.8	247	242	98.0		
CIN2+ irrespective of HPV type	Yes	123	27	22.0	124	28	22.6	247	55	22.3			
	No	123	96	78.0	124	96	77.4	247	192	77.7			
Missing	15-17 Years	CIN2+ associated with HR-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2+ associated with HRW-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2+ associated with HPV-16/18	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2+ associated with HPV-16/18 Only	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2+ not associated with HR-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN2+ irrespective of HPV type	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	18-20 Years	CIN2+ associated with HR-HPV	Yes	3	0	0.0	4	1	25.0	7	1	14.3
			No	3	3	100	4	3	75.0	7	6	85.7
		CIN2+ associated with HRW-HPV	Yes	3	0	0.0	4	1	25.0	7	1	14.3
			No	3	3	100	4	3	75.0	7	6	85.7
		CIN2+ associated with HPV-16/18	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN2+ associated with HPV-16/18 Only	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN2+ not associated with HR-HPV	Yes	3	0	0.0	4	0	0.0	7	0	0.0
	No		3	3	100	4	4	100	7	7	100	
	CIN2+ irrespective of HPV type	Yes	3	0	0.0	4	1	25.0	7	1	14.3	
		No	3	3	100	4	3	75.0	7	6	85.7	
	21-25 Years	CIN2+ associated with HR-HPV	Yes	19	0	0.0	20	2	10.0	39	2	5.1
			No	19	19	100	20	18	90.0	39	37	94.9
		CIN2+ associated with HRW-HPV	Yes	19	0	0.0	20	2	10.0	39	2	5.1
			No	19	19	100	20	18	90.0	39	37	94.9
		CIN2+ associated with HPV-16/18	Yes	19	0	0.0	20	2	10.0	39	2	5.1
			No	19	19	100	20	18	90.0	39	37	94.9
		CIN2+ associated with HPV-16/18 Only	Yes	19	0	0.0	20	0	0.0	39	0	0.0
			No	19	19	100	20	20	100	39	39	100
		CIN2+ not associated with HR-HPV	Yes	19	0	0.0	20	0	0.0	39	0	0.0
	No		19	19	100	20	20	100	39	39	100	
	CIN2+ irrespective of HPV type	Yes	19	0	0.0	20	2	10.0	39	2	5.1	
		No	19	19	100	20	18	90.0	39	37	94.9	
26 Years and above	CIN2+ associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2+ associated with HRW-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2+ associated with HPV-16/18	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2+ associated with HPV-16/18 Only	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN2+ not associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
No		1	1	100	3	3	100	4	4	100		

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2+ irrespective of HPV type	Yes	1	0	0.0	3	0	0.0	4	0	0.0
			No	1	1	100	3	3	100	4	4	100
Overall total	Overall total	CIN2+ associated with HR-HPV	Yes	15741	434	2.8	15741	615	3.9	31482	1049	3.3
			No	15741	15307	97.2	15741	15126	96.1	31482	30433	96.7
		CIN2+ associated with HRW-HPV	Yes	15741	318	2.0	15741	423	2.7	31482	741	2.4
			No	15741	15423	98.0	15741	15318	97.3	31482	30741	97.6
		CIN2+ associated with HPV-16/18	Yes	15741	180	1.1	15741	353	2.2	31482	533	1.7
			No	15741	15561	98.9	15741	15388	97.8	31482	30949	98.3
		CIN2+ associated with HPV-16/18 Only	Yes	15741	116	0.7	15741	192	1.2	31482	308	1.0
			No	15741	15625	99.3	15741	15549	98.8	31482	31174	99.0
		CIN2+ not associated with HR-HPV	Yes	15741	72	0.5	15741	60	0.4	31482	132	0.4
			No	15741	15669	99.5	15741	15681	99.6	31482	31350	99.6
		CIN2+ irrespective of HPV type	Yes	15741	506	3.2	15741	675	4.3	31482	1181	3.8
			No	15741	15235	96.8	15741	15066	95.7	31482	30301	96.2

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 14 Number and Percentage of Subjects with CIN3+ by Cytology status at baseline and age category (Total vaccinated cohort)

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
High	15-17 Years	CIN3+ associated with HR-HPV	Yes	12	1	8.3	13	3	23.1	25	4	16.0
			No	12	11	91.7	13	10	76.9	25	21	84.0
		CIN3+ associated with HRW-HPV	Yes	12	1	8.3	13	1	7.7	25	2	8.0
			No	12	11	91.7	13	12	92.3	25	23	92.0
		CIN3+ associated with HPV-16/18	Yes	12	0	0.0	13	2	15.4	25	2	8.0
			No	12	12	100	13	11	84.6	25	23	92.0
		CIN3+ associated with HPV-16/18 Only	Yes	12	0	0.0	13	2	15.4	25	2	8.0
			No	12	12	100	13	11	84.6	25	23	92.0
		CIN3+ not associated with HR-HPV	Yes	12	1	8.3	13	0	0.0	25	1	4.0
			No	12	11	91.7	13	13	100	25	24	96.0
		CIN3+ irrespective of HPV type	Yes	12	2	16.7	13	3	23.1	25	5	20.0
			No	12	10	83.3	13	10	76.9	25	20	80.0
	18-20 Years	CIN3+ associated with HR-HPV	Yes	14	1	7.1	8	3	37.5	22	4	18.2
			No	14	13	92.9	8	5	62.5	22	18	81.8
		CIN3+ associated with HRW-HPV	Yes	14	1	7.1	8	2	25.0	22	3	13.6
			No	14	13	92.9	8	6	75.0	22	19	86.4
		CIN3+ associated with HPV-16/18	Yes	14	0	0.0	8	2	25.0	22	2	9.1
			No	14	14	100	8	6	75.0	22	20	90.9
		CIN3+ associated with HPV-16/18 Only	Yes	14	0	0.0	8	1	12.5	22	1	4.5
			No	14	14	100	8	7	87.5	22	21	95.5
		CIN3+ not associated with HR-HPV	Yes	14	0	0.0	8	0	0.0	22	0	0.0
			No	14	14	100	8	8	100	22	22	100
		CIN3+ irrespective of HPV type	Yes	14	1	7.1	8	3	37.5	22	4	18.2
			No	14	13	92.9	8	5	62.5	22	18	81.8
21-25 Years	CIN3+ associated with HR-HPV	Yes	57	28	49.1	56	22	39.3	113	50	44.2	
		No	57	29	50.9	56	34	60.7	113	63	55.8	
	CIN3+ associated with HRW-HPV	Yes	57	8	14.0	56	8	14.3	113	16	14.2	
		No	57	49	86.0	56	48	85.7	113	97	85.8	
	CIN3+ associated with HPV-16/18	Yes	57	24	42.1	56	18	32.1	113	42	37.2	
		No	57	33	57.9	56	38	67.9	113	71	62.8	
	CIN3+ associated with HPV-16/18 Only	Yes	57	20	35.1	56	14	25.0	113	34	30.1	
		No	57	37	64.9	56	42	75.0	113	79	69.9	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN3+ not associated with HR-HPV	Yes	57	1	1.8	56	1	1.8	113	2	1.8	
			No	57	56	98.2	56	55	98.2	113	111	98.2	
		CIN3+ irrespective of HPV type	Yes	57	29	50.9	56	23	41.1	113	52	46.0	
			No	57	28	49.1	56	33	58.9	113	61	54.0	
	26 Years and above	CIN3+ associated with HR-HPV	Yes	36	25	69.4	30	13	43.3	66	38	57.6	
			No	36	11	30.6	30	17	56.7	66	28	42.4	
		CIN3+ associated with HRW-HPV	Yes	36	17	47.2	30	5	16.7	66	22	33.3	
			No	36	19	52.8	30	25	83.3	66	44	66.7	
		CIN3+ associated with HPV-16/18	Yes	36	11	30.6	30	10	33.3	66	21	31.8	
			No	36	25	69.4	30	20	66.7	66	45	68.2	
		CIN3+ associated with HPV-16/18 Only	Yes	36	8	22.2	30	8	26.7	66	16	24.2	
			No	36	28	77.8	30	22	73.3	66	50	75.8	
		CIN3+ not associated with HR-HPV	Yes	36	0	0.0	30	0	0.0	66	0	0.0	
			No	36	36	100	30	30	100	66	66	100	
	CIN3+ irrespective of HPV type	Yes	36	25	69.4	30	13	43.3	66	38	57.6		
		No	36	11	30.6	30	17	56.7	66	28	42.4		
	Normal	15-17 Years	CIN3+ associated with HR-HPV	Yes	2715	10	0.4	2759	39	1.4	5474	49	0.9
				No	2715	2705	99.6	2759	2720	98.6	5474	5425	99.1
CIN3+ associated with HRW-HPV			Yes	2715	9	0.3	2759	28	1.0	5474	37	0.7	
			No	2715	2706	99.7	2759	2731	99.0	5474	5437	99.3	
CIN3+ associated with HPV-16/18			Yes	2715	2	0.1	2759	27	1.0	5474	29	0.5	
			No	2715	2713	99.9	2759	2732	99.0	5474	5445	99.5	
CIN3+ associated with HPV-16/18 Only			Yes	2715	1	0.0	2759	11	0.4	5474	12	0.2	
			No	2715	2714	100	2759	2748	99.6	5474	5462	99.8	
CIN3+ not associated with HR-HPV			Yes	2715	0	0.0	2759	6	0.2	5474	6	0.1	
			No	2715	2715	100	2759	2753	99.8	5474	5468	99.9	
CIN3+ irrespective of HPV type		Yes	2715	10	0.4	2759	45	1.6	5474	55	1.0		
		No	2715	2705	99.6	2759	2714	98.4	5474	5419	99.0		
18-20 Years		CIN3+ associated with HR-HPV	Yes	2192	11	0.5	2208	29	1.3	4400	40	0.9	
			No	2192	2181	99.5	2208	2179	98.7	4400	4360	99.1	
		CIN3+ associated with HRW-HPV	Yes	2192	5	0.2	2208	13	0.6	4400	18	0.4	
			No	2192	2187	99.8	2208	2195	99.4	4400	4382	99.6	
		CIN3+ associated with HPV-16/18	Yes	2192	7	0.3	2208	22	1.0	4400	29	0.7	
			No	2192	2185	99.7	2208	2186	99.0	4400	4371	99.3	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN3+ associated with HPV-16/18 Only	Yes	2192	6	0.3	2208	16	0.7	4400	22	0.5
			No	2192	2186	99.7	2208	2192	99.3	4400	4378	99.5
		CIN3+ not associated with HR-HPV	Yes	2192	2	0.1	2208	3	0.1	4400	5	0.1
			No	2192	2190	99.9	2208	2205	99.9	4400	4395	99.9
		CIN3+ irrespective of HPV type	Yes	2192	13	0.6	2208	32	1.4	4400	45	1.0
			No	2192	2179	99.4	2208	2176	98.6	4400	4355	99.0
	21-25 Years	CIN3+ associated with HR-HPV	Yes	6904	33	0.5	6853	44	0.6	13757	77	0.6
			No	6904	6871	99.5	6853	6809	99.4	13757	13680	99.4
		CIN3+ associated with HRW-HPV	Yes	6904	17	0.2	6853	22	0.3	13757	39	0.3
			No	6904	6887	99.8	6853	6831	99.7	13757	13718	99.7
		CIN3+ associated with HPV-16/18	Yes	6904	21	0.3	6853	31	0.5	13757	52	0.4
			No	6904	6883	99.7	6853	6822	99.5	13757	13705	99.6
		CIN3+ associated with HPV-16/18 Only	Yes	6904	16	0.2	6853	22	0.3	13757	38	0.3
			No	6904	6888	99.8	6853	6831	99.7	13757	13719	99.7
		CIN3+ not associated with HR-HPV	Yes	6904	2	0.0	6853	4	0.1	13757	6	0.0
			No	6904	6902	100	6853	6849	99.9	13757	13751	100
		CIN3+ irrespective of HPV type	Yes	6904	35	0.5	6853	48	0.7	13757	83	0.6
			No	6904	6869	99.5	6853	6805	99.3	13757	13674	99.4
	26 Years and above	CIN3+ associated with HR-HPV	Yes	2735	13	0.5	2740	21	0.8	5475	34	0.6
			No	2735	2722	99.5	2740	2719	99.2	5475	5441	99.4
		CIN3+ associated with HRW-HPV	Yes	2735	9	0.3	2740	11	0.4	5475	20	0.4
			No	2735	2726	99.7	2740	2729	99.6	5475	5455	99.6
		CIN3+ associated with HPV-16/18	Yes	2735	6	0.2	2740	10	0.4	5475	16	0.3
			No	2735	2729	99.8	2740	2730	99.6	5475	5459	99.7
CIN3+ associated with HPV-16/18 Only		Yes	2735	4	0.1	2740	10	0.4	5475	14	0.3	
		No	2735	2731	99.9	2740	2730	99.6	5475	5461	99.7	
CIN3+ not associated with HR-HPV		Yes	2735	2	0.1	2740	2	0.1	5475	4	0.1	
		No	2735	2733	99.9	2740	2738	99.9	5475	5471	99.9	
CIN3+ irrespective of HPV type		Yes	2735	15	0.5	2740	23	0.8	5475	38	0.7	
		No	2735	2720	99.5	2740	2717	99.2	5475	5437	99.3	
Missing	CIN3+ associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
	CIN3+ associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN3+ associated with HPV-16/18	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ associated with HPV-16/18 Only	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		CIN3+ irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
			No	1	1	100	0	-	-	1	1	100		
		Low	15-17 Years	CIN3+ associated with HR-HPV	Yes	246	8	3.3	210	11	5.2	456	19	4.2
					No	246	238	96.7	210	199	94.8	456	437	95.8
				CIN3+ associated with HRW-HPV	Yes	246	7	2.8	210	5	2.4	456	12	2.6
					No	246	239	97.2	210	205	97.6	456	444	97.4
CIN3+ associated with HPV-16/18	Yes			246	5	2.0	210	7	3.3	456	12	2.6		
	No			246	241	98.0	210	203	96.7	456	444	97.4		
CIN3+ associated with HPV-16/18 Only	Yes			246	1	0.4	210	6	2.9	456	7	1.5		
	No			246	245	99.6	210	204	97.1	456	449	98.5		
CIN3+ not associated with HR-HPV	Yes			246	1	0.4	210	2	1.0	456	3	0.7		
	No			246	245	99.6	210	208	99.0	456	453	99.3		
CIN3+ irrespective of HPV type	Yes			246	9	3.7	210	13	6.2	456	22	4.8		
	No			246	237	96.3	210	197	93.8	456	434	95.2		
18-20 Years	CIN3+ associated with HR-HPV		Yes	216	8	3.7	221	10	4.5	437	18	4.1		
			No	216	208	96.3	221	211	95.5	437	419	95.9		
	CIN3+ associated with HRW-HPV		Yes	216	4	1.9	221	4	1.8	437	8	1.8		
			No	216	212	98.1	221	217	98.2	437	429	98.2		
	CIN3+ associated with HPV-16/18		Yes	216	7	3.2	221	7	3.2	437	14	3.2		
			No	216	209	96.8	221	214	96.8	437	423	96.8		
	CIN3+ associated with HPV-16/18 Only		Yes	216	4	1.9	221	6	2.7	437	10	2.3		
			No	216	212	98.1	221	215	97.3	437	427	97.7		
	CIN3+ not associated with HR-HPV		Yes	216	2	0.9	221	1	0.5	437	3	0.7		
			No	216	214	99.1	221	220	99.5	437	434	99.3		
	CIN3+ irrespective of HPV type		Yes	216	10	4.6	221	11	5.0	437	21	4.8		
			No	216	206	95.4	221	210	95.0	437	416	95.2		
21-25 Years	CIN3+ associated with HR-HPV	Yes	467	37	7.9	490	27	5.5	957	64	6.7			
		No	467	430	92.1	490	463	94.5	957	893	93.3			

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN3+ associated with HRW-HPV	Yes	467	18	3.9	490	17	3.5	957	35	3.7	
			No	467	449	96.1	490	473	96.5	957	922	96.3	
		CIN3+ associated with HPV-16/18	Yes	467	27	5.8	490	16	3.3	957	43	4.5	
			No	467	440	94.2	490	474	96.7	957	914	95.5	
		CIN3+ associated with HPV-16/18 Only	Yes	467	19	4.1	490	10	2.0	957	29	3.0	
			No	467	448	95.9	490	480	98.0	957	928	97.0	
		CIN3+ not associated with HR-HPV	Yes	467	3	0.6	490	5	1.0	957	8	0.8	
			No	467	464	99.4	490	485	99.0	957	949	99.2	
		CIN3+ irrespective of HPV type	Yes	467	40	8.6	490	32	6.5	957	72	7.5	
			No	467	427	91.4	490	458	93.5	957	885	92.5	
		26 Years and above	CIN3+ associated with HR-HPV	Yes	123	8	6.5	124	9	7.3	247	17	6.9
				No	123	115	93.5	124	115	92.7	247	230	93.1
	CIN3+ associated with HRW-HPV		Yes	123	4	3.3	124	6	4.8	247	10	4.0	
			No	123	119	96.7	124	118	95.2	247	237	96.0	
	CIN3+ associated with HPV-16/18		Yes	123	6	4.9	124	5	4.0	247	11	4.5	
			No	123	117	95.1	124	119	96.0	247	236	95.5	
CIN3+ associated with HPV-16/18 Only	Yes		123	4	3.3	124	3	2.4	247	7	2.8		
	No		123	119	96.7	124	121	97.6	247	240	97.2		
CIN3+ not associated with HR-HPV	Yes	123	2	1.6	124	0	0.0	247	2	0.8			
	No	123	121	98.4	124	124	100	247	245	99.2			
CIN3+ irrespective of HPV type	Yes	123	10	8.1	124	9	7.3	247	19	7.7			
	No	123	113	91.9	124	115	92.7	247	228	92.3			
Missing	15-17 Years	CIN3+ associated with HR-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN3+ associated with HRW-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN3+ associated with HPV-16/18	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN3+ associated with HPV-16/18 Only	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN3+ not associated with HR-HPV	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	
		CIN3+ irrespective of HPV type	Yes	0	-	-	2	0	0.0	2	0	0.0	
			No	0	-	-	2	2	100	2	2	100	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
	18-20 Years	CIN3+ associated with HR-HPV	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN3+ associated with HRW-HPV	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN3+ associated with HPV-16/18	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN3+ associated with HPV-16/18 Only	Yes	3	0	0.0	4	0	0.0	7	0	0.0
			No	3	3	100	4	4	100	7	7	100
		CIN3+ not associated with HR-HPV	Yes	3	0	0.0	4	0	0.0	7	0	0.0
	No		3	3	100	4	4	100	7	7	100	
	CIN3+ irrespective of HPV type	Yes	3	0	0.0	4	0	0.0	7	0	0.0	
		No	3	3	100	4	4	100	7	7	100	
	21-25 Years	CIN3+ associated with HR-HPV	Yes	19	0	0.0	20	1	5.0	39	1	2.6
			No	19	19	100	20	19	95.0	39	38	97.4
		CIN3+ associated with HRW-HPV	Yes	19	0	0.0	20	1	5.0	39	1	2.6
			No	19	19	100	20	19	95.0	39	38	97.4
		CIN3+ associated with HPV-16/18	Yes	19	0	0.0	20	1	5.0	39	1	2.6
			No	19	19	100	20	19	95.0	39	38	97.4
		CIN3+ associated with HPV-16/18 Only	Yes	19	0	0.0	20	0	0.0	39	0	0.0
			No	19	19	100	20	20	100	39	39	100
		CIN3+ not associated with HR-HPV	Yes	19	0	0.0	20	0	0.0	39	0	0.0
	No		19	19	100	20	20	100	39	39	100	
	CIN3+ irrespective of HPV type	Yes	19	0	0.0	20	1	5.0	39	1	2.6	
		No	19	19	100	20	19	95.0	39	38	97.4	
26 Years and above	CIN3+ associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN3+ associated with HRW-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN3+ associated with HPV-16/18	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN3+ associated with HPV-16/18 Only	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
		No	1	1	100	3	3	100	4	4	100	
	CIN3+ not associated with HR-HPV	Yes	1	0	0.0	3	0	0.0	4	0	0.0	
No		1	1	100	3	3	100	4	4	100		

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN3+ irrespective of HPV type	Yes	1	0	0.0	3	0	0.0	4	0	0.0
			No	1	1	100	3	3	100	4	4	100
Overall total	Overall total	CIN3+ associated with HR-HPV	Yes	15741	183	1.2	15741	232	1.5	31482	415	1.3
			No	15741	15558	98.8	15741	15509	98.5	31482	31067	98.7
		CIN3+ associated with HRW-HPV	Yes	15741	100	0.6	15741	123	0.8	31482	223	0.7
			No	15741	15641	99.4	15741	15618	99.2	31482	31259	99.3
		CIN3+ associated with HPV-16/18	Yes	15741	116	0.7	15741	158	1.0	31482	274	0.9
			No	15741	15625	99.3	15741	15583	99.0	31482	31208	99.1
		CIN3+ associated with HPV-16/18 Only	Yes	15741	83	0.5	15741	109	0.7	31482	192	0.6
			No	15741	15658	99.5	15741	15632	99.3	31482	31290	99.4
		CIN3+ not associated with HR-HPV	Yes	15741	16	0.1	15741	24	0.2	31482	40	0.1
			No	15741	15725	99.9	15741	15717	99.8	31482	31442	99.9
		CIN3+ irrespective of HPV type	Yes	15741	199	1.3	15741	256	1.6	31482	455	1.4
			No	15741	15542	98.7	15741	15485	98.4	31482	31027	98.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 15 Number and Percentage of Subjects with CIN2 by Cytology status at baseline and age category(Total vaccinated cohort)

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
High	15-20 Years	CIN2 associated with HR-HPV	Yes	26	6	23.1	21	8	38.1	47	14	29.8	
			No	26	20	76.9	21	13	61.9	47	33	70.2	
		CIN2 associated with HRW-HPV	Yes	26	3	11.5	21	6	28.6	47	9	19.1	
			No	26	23	88.5	21	15	71.4	47	38	80.9	
		CIN2 associated with HPV-16/18	Yes	26	3	11.5	21	6	28.6	47	9	19.1	
			No	26	23	88.5	21	15	71.4	47	38	80.9	
		CIN2 associated with HPV-16/18 Only	Yes	26	3	11.5	21	2	9.5	47	5	10.6	
			No	26	23	88.5	21	19	90.5	47	42	89.4	
		CIN2 not associated with HR-HPV	Yes	26	1	3.8	21	2	9.5	47	3	6.4	
			No	26	25	96.2	21	19	90.5	47	44	93.6	
		CIN2 irrespective of HPV type	Yes	26	7	26.9	21	10	47.6	47	17	36.2	
			No	26	19	73.1	21	11	52.4	47	30	63.8	
	21 Years an		CIN2 associated with HR-HPV	Yes	93	41	44.1	86	42	48.8	179	83	46.4
				No	93	52	55.9	86	44	51.2	179	96	53.6
			CIN2 associated with HRW-HPV	Yes	93	25	26.9	86	25	29.1	179	50	27.9
				No	93	68	73.1	86	61	70.9	179	129	72.1
			CIN2 associated with HPV-16/18	Yes	93	22	23.7	86	27	31.4	179	49	27.4
				No	93	71	76.3	86	59	68.6	179	130	72.6
CIN2 associated with HPV-16/18 Only			Yes	93	16	17.2	86	17	19.8	179	33	18.4	
			No	93	77	82.8	86	69	80.2	179	146	81.6	
CIN2 not associated with HR-HPV			Yes	93	6	6.5	86	3	3.5	179	9	5.0	
			No	93	87	93.5	86	83	96.5	179	170	95.0	
CIN2 irrespective of HPV type			Yes	93	47	50.5	86	45	52.3	179	92	51.4	
			No	93	46	49.5	86	41	47.7	179	87	48.6	
Normal	15-20 Years	CIN2 associated with HR-HPV	Yes	4907	87	1.8	4967	194	3.9	9874	281	2.8	
			No	4907	4820	98.2	4967	4773	96.1	9874	9593	97.2	
		CIN2 associated with HRW-HPV	Yes	4907	77	1.6	4967	130	2.6	9874	207	2.1	
			No	4907	4830	98.4	4967	4837	97.4	9874	9667	97.9	
		CIN2 associated with HPV-16/18	Yes	4907	18	0.4	4967	117	2.4	9874	135	1.4	
			No	4907	4889	99.6	4967	4850	97.6	9874	9739	98.6	
		CIN2 associated with HPV-16/18 Only	Yes	4907	10	0.2	4967	64	1.3	9874	74	0.7	
			No	4907	4897	99.8	4967	4903	98.7	9874	9800	99.3	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2 not associated with HR-HPV	Yes	4907	19	0.4	4967	25	0.5	9874	44	0.4
			No	4907	4888	99.6	4967	4942	99.5	9874	9830	99.6
		CIN2 irrespective of HPV type	Yes	4907	106	2.2	4967	219	4.4	9874	325	3.3
			No	4907	4801	97.8	4967	4748	95.6	9874	9549	96.7
	21 Years an	CIN2 associated with HR-HPV	Yes	9639	99	1.0	9593	158	1.6	19232	257	1.3
			No	9639	9540	99.0	9593	9435	98.4	19232	18975	98.7
		CIN2 associated with HRW-HPV	Yes	9639	77	0.8	9593	111	1.2	19232	188	1.0
			No	9639	9562	99.2	9593	9482	98.8	19232	19044	99.0
		CIN2 associated with HPV-16/18	Yes	9639	30	0.3	9593	77	0.8	19232	107	0.6
			No	9639	9609	99.7	9593	9516	99.2	19232	19125	99.4
		CIN2 associated with HPV-16/18 Only	Yes	9639	22	0.2	9593	47	0.5	19232	69	0.4
			No	9639	9617	99.8	9593	9546	99.5	19232	19163	99.6
		CIN2 not associated with HR-HPV	Yes	9639	36	0.4	9593	16	0.2	19232	52	0.3
			No	9639	9603	99.6	9593	9577	99.8	19232	19180	99.7
		CIN2 irrespective of HPV type	Yes	9639	135	1.4	9593	174	1.8	19232	309	1.6
			No	9639	9504	98.6	9593	9419	98.2	19232	18923	98.4
	Missing	CIN2 associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0
			No	1	1	100	0	-	-	1	1	100
		CIN2 associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0
			No	1	1	100	0	-	-	1	1	100
CIN2 associated with HPV-16/18		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN2 associated with HPV-16/18 Only		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN2 not associated with HR-HPV		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN2 irrespective of HPV type		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
Low	15-20 Years	CIN2 associated with HR-HPV	Yes	462	48	10.4	431	59	13.7	893	107	12.0
			No	462	414	89.6	431	372	86.3	893	786	88.0
		CIN2 associated with HRW-HPV	Yes	462	38	8.2	431	45	10.4	893	83	9.3
			No	462	424	91.8	431	386	89.6	893	810	90.7
		CIN2 associated with HPV-16/18	Yes	462	19	4.1	431	31	7.2	893	50	5.6
			No	462	443	95.9	431	400	92.8	893	843	94.4

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2 associated with HPV-16/18 Only	Yes	462	10	2.2	431	14	3.2	893	24	2.7	
			No	462	452	97.8	431	417	96.8	893	869	97.3	
		CIN2 not associated with HR-HPV	Yes	462	11	2.4	431	8	1.9	893	19	2.1	
			No	462	451	97.6	431	423	98.1	893	874	97.9	
		CIN2 irrespective of HPV type	Yes	462	59	12.8	431	67	15.5	893	126	14.1	
			No	462	403	87.2	431	364	84.5	893	767	85.9	
		21 Years an	CIN2 associated with HR-HPV	Yes	590	94	15.9	614	84	13.7	1204	178	14.8
				No	590	496	84.1	614	530	86.3	1204	1026	85.2
			CIN2 associated with HRW-HPV	Yes	590	67	11.4	614	61	9.9	1204	128	10.6
				No	590	523	88.6	614	553	90.1	1204	1076	89.4
			CIN2 associated with HPV-16/18	Yes	590	43	7.3	614	39	6.4	1204	82	6.8
				No	590	547	92.7	614	575	93.6	1204	1122	93.2
	CIN2 associated with HPV-16/18 Only		Yes	590	27	4.6	614	23	3.7	1204	50	4.2	
			No	590	563	95.4	614	591	96.3	1204	1154	95.8	
	CIN2 not associated with HR-HPV	Yes	590	10	1.7	614	12	2.0	1204	22	1.8		
		No	590	580	98.3	614	602	98.0	1204	1182	98.2		
	CIN2 irrespective of HPV type	Yes	590	104	17.6	614	96	15.6	1204	200	16.6		
		No	590	486	82.4	614	518	84.4	1204	1004	83.4		
	Missing	15-20 Years	CIN2 associated with HR-HPV	Yes	3	0	0.0	6	1	16.7	9	1	11.1
				No	3	3	100	6	5	83.3	9	8	88.9
CIN2 associated with HRW-HPV			Yes	3	0	0.0	6	1	16.7	9	1	11.1	
			No	3	3	100	6	5	83.3	9	8	88.9	
CIN2 associated with HPV-16/18			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN2 associated with HPV-16/18 Only			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN2 not associated with HR-HPV			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN2 irrespective of HPV type			Yes	3	0	0.0	6	1	16.7	9	1	11.1	
			No	3	3	100	6	5	83.3	9	8	88.9	
21 Years an		CIN2 associated with HR-HPV	Yes	20	0	0.0	23	2	8.7	43	2	4.7	
			No	20	20	100	23	21	91.3	43	41	95.3	
		CIN2 associated with HRW-HPV	Yes	20	0	0.0	23	2	8.7	43	2	4.7	
			No	20	20	100	23	21	91.3	43	41	95.3	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN2 associated with HPV-16/18	Yes	20	0	0.0	23	2	8.7	43	2	4.7		
			No	20	20	100	23	21	91.3	43	41	95.3		
		CIN2 associated with HPV-16/18 Only	Yes	20	0	0.0	23	0	0.0	43	0	0.0		
			No	20	20	100	23	23	100	43	43	100		
		CIN2 not associated with HR-HPV	Yes	20	0	0.0	23	0	0.0	43	0	0.0		
			No	20	20	100	23	23	100	43	43	100		
		CIN2 irrespective of HPV type	Yes	20	0	0.0	23	2	8.7	43	2	4.7		
			No	20	20	100	23	21	91.3	43	41	95.3		
		Overall total	Overall total	CIN2 associated with HR-HPV	Yes	15741	375	2.4	15741	548	3.5	31482	923	2.9
					No	15741	15366	97.6	15741	15193	96.5	31482	30559	97.1
				CIN2 associated with HRW-HPV	Yes	15741	287	1.8	15741	381	2.4	31482	668	2.1
					No	15741	15454	98.2	15741	15360	97.6	31482	30814	97.9
CIN2 associated with HPV-16/18	Yes			15741	135	0.9	15741	299	1.9	31482	434	1.4		
	No			15741	15606	99.1	15741	15442	98.1	31482	31048	98.6		
CIN2 associated with HPV-16/18 Only	Yes			15741	88	0.6	15741	167	1.1	31482	255	0.8		
	No			15741	15653	99.4	15741	15574	98.9	31482	31227	99.2		
CIN2 not associated with HR-HPV	Yes			15741	83	0.5	15741	66	0.4	31482	149	0.5		
	No			15741	15658	99.5	15741	15675	99.6	31482	31333	99.5		
CIN2 irrespective of HPV type	Yes			15741	458	2.9	15741	614	3.9	31482	1072	3.4		
	No			15741	15283	97.1	15741	15127	96.1	31482	30410	96.6		

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 16 Number and Percentage of Subjects with CIN2+ by Cytology status at baseline and age category(Total vaccinated cohort)

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
High	15-20 Years	CIN2+ associated with HR-HPV	Yes	26	6	23.1	21	8	38.1	47	14	29.8
			No	26	20	76.9	21	13	61.9	47	33	70.2
		CIN2+ associated with HRW-HPV	Yes	26	3	11.5	21	7	33.3	47	10	21.3
			No	26	23	88.5	21	14	66.7	47	37	78.7
		CIN2+ associated with HPV-16/18	Yes	26	3	11.5	21	6	28.6	47	9	19.1
			No	26	23	88.5	21	15	71.4	47	38	80.9
		CIN2+ associated with HPV-16/18 Only	Yes	26	3	11.5	21	1	4.8	47	4	8.5
			No	26	23	88.5	21	20	95.2	47	43	91.5
		CIN2+ not associated with HR-HPV	Yes	26	1	3.8	21	2	9.5	47	3	6.4
	No		26	25	96.2	21	19	90.5	47	44	93.6	
	CIN2+ irrespective of HPV type	Yes	26	7	26.9	21	10	47.6	47	17	36.2	
		No	26	19	73.1	21	11	52.4	47	30	63.8	
	21 Years an	CIN2+ associated with HR-HPV	Yes	93	62	66.7	86	55	64.0	179	117	65.4
			No	93	31	33.3	86	31	36.0	179	62	34.6
		CIN2+ associated with HRW-HPV	Yes	93	31	33.3	86	30	34.9	179	61	34.1
			No	93	62	66.7	86	56	65.1	179	118	65.9
		CIN2+ associated with HPV-16/18	Yes	93	40	43.0	86	39	45.3	179	79	44.1
			No	93	53	57.0	86	47	54.7	179	100	55.9
CIN2+ associated with HPV-16/18 Only		Yes	93	31	33.3	86	25	29.1	179	56	31.3	
		No	93	62	66.7	86	61	70.9	179	123	68.7	
CIN2+ not associated with HR-HPV		Yes	93	2	2.2	86	2	2.3	179	4	2.2	
	No	93	91	97.8	86	84	97.7	179	175	97.8		
CIN2+ irrespective of HPV type	Yes	93	64	68.8	86	57	66.3	179	121	67.6		
	No	93	29	31.2	86	29	33.7	179	58	32.4		
Normal	15-20 Years	CIN2+ associated with HR-HPV	Yes	4907	93	1.9	4967	207	4.2	9874	300	3.0
			No	4907	4814	98.1	4967	4760	95.8	9874	9574	97.0
		CIN2+ associated with HRW-HPV	Yes	4907	80	1.6	4967	143	2.9	9874	223	2.3
			No	4907	4827	98.4	4967	4824	97.1	9874	9651	97.7
		CIN2+ associated with HPV-16/18	Yes	4907	21	0.4	4967	128	2.6	9874	149	1.5
			No	4907	4886	99.6	4967	4839	97.4	9874	9725	98.5
		CIN2+ associated with HPV-16/18 Only	Yes	4907	13	0.3	4967	64	1.3	9874	77	0.8
			No	4907	4894	99.7	4967	4903	98.7	9874	9797	99.2

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN2+ not associated with HR-HPV	Yes	4907	18	0.4	4967	24	0.5	9874	42	0.4
			No	4907	4889	99.6	4967	4943	99.5	9874	9832	99.6
		CIN2+ irrespective of HPV type	Yes	4907	111	2.3	4967	231	4.7	9874	342	3.5
			No	4907	4796	97.7	4967	4736	95.3	9874	9532	96.5
	21 Years an	CIN2+ associated with HR-HPV	Yes	9639	119	1.2	9593	179	1.9	19232	298	1.5
			No	9639	9520	98.8	9593	9414	98.1	19232	18934	98.5
		CIN2+ associated with HRW-HPV	Yes	9639	92	1.0	9593	124	1.3	19232	216	1.1
			No	9639	9547	99.0	9593	9469	98.7	19232	19016	98.9
		CIN2+ associated with HPV-16/18	Yes	9639	41	0.4	9593	91	0.9	19232	132	0.7
			No	9639	9598	99.6	9593	9502	99.1	19232	19100	99.3
		CIN2+ associated with HPV-16/18 Only	Yes	9639	27	0.3	9593	55	0.6	19232	82	0.4
			No	9639	9612	99.7	9593	9538	99.4	19232	19150	99.6
	CIN2+ not associated with HR-HPV	Yes	9639	31	0.3	9593	16	0.2	19232	47	0.2	
		No	9639	9608	99.7	9593	9577	99.8	19232	19185	99.8	
	CIN2+ irrespective of HPV type	Yes	9639	150	1.6	9593	195	2.0	19232	345	1.8	
		No	9639	9489	98.4	9593	9398	98.0	19232	18887	98.2	
	Missing	CIN2+ associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0
			No	1	1	100	0	-	-	1	1	100
		CIN2+ associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0
			No	1	1	100	0	-	-	1	1	100
CIN2+ associated with HPV-16/18		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN2+ associated with HPV-16/18 Only		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN2+ not associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0		
	No	1	1	100	0	-	-	1	1	100		
CIN2+ irrespective of HPV type	Yes	1	0	0.0	0	-	-	1	0	0.0		
	No	1	1	100	0	-	-	1	1	100		
Low	15-20 Years	CIN2+ associated with HR-HPV	Yes	462	52	11.3	431	66	15.3	893	118	13.2
			No	462	410	88.7	431	365	84.7	893	775	86.8
		CIN2+ associated with HRW-HPV	Yes	462	40	8.7	431	48	11.1	893	88	9.9
			No	462	422	91.3	431	383	88.9	893	805	90.1
		CIN2+ associated with HPV-16/18	Yes	462	23	5.0	431	36	8.4	893	59	6.6
			No	462	439	95.0	431	395	91.6	893	834	93.4

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN2+ associated with HPV-16/18 Only	Yes	462	12	2.6	431	18	4.2	893	30	3.4	
			No	462	450	97.4	431	413	95.8	893	863	96.6	
		CIN2+ not associated with HR-HPV	Yes	462	12	2.6	431	6	1.4	893	18	2.0	
			No	462	450	97.4	431	425	98.6	893	875	98.0	
		CIN2+ irrespective of HPV type	Yes	462	64	13.9	431	72	16.7	893	136	15.2	
			No	462	398	86.1	431	359	83.3	893	757	84.8	
		21 Years an	CIN2+ associated with HR-HPV	Yes	590	102	17.3	614	97	15.8	1204	199	16.5
				No	590	488	82.7	614	517	84.2	1204	1005	83.5
			CIN2+ associated with HRW-HPV	Yes	590	72	12.2	614	68	11.1	1204	140	11.6
				No	590	518	87.8	614	546	88.9	1204	1064	88.4
			CIN2+ associated with HPV-16/18	Yes	590	52	8.8	614	51	8.3	1204	103	8.6
				No	590	538	91.2	614	563	91.7	1204	1101	91.4
	CIN2+ associated with HPV-16/18 Only		Yes	590	30	5.1	614	29	4.7	1204	59	4.9	
			No	590	560	94.9	614	585	95.3	1204	1145	95.1	
	CIN2+ not associated with HR-HPV	Yes	590	8	1.4	614	10	1.6	1204	18	1.5		
		No	590	582	98.6	614	604	98.4	1204	1186	98.5		
	CIN2+ irrespective of HPV type	Yes	590	110	18.6	614	107	17.4	1204	217	18.0		
		No	590	480	81.4	614	507	82.6	1204	987	82.0		
	Missing	15-20 Years	CIN2+ associated with HR-HPV	Yes	3	0	0.0	6	1	16.7	9	1	11.1
				No	3	3	100	6	5	83.3	9	8	88.9
CIN2+ associated with HRW-HPV			Yes	3	0	0.0	6	1	16.7	9	1	11.1	
			No	3	3	100	6	5	83.3	9	8	88.9	
CIN2+ associated with HPV-16/18			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN2+ associated with HPV-16/18 Only			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN2+ not associated with HR-HPV			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN2+ irrespective of HPV type			Yes	3	0	0.0	6	1	16.7	9	1	11.1	
			No	3	3	100	6	5	83.3	9	8	88.9	
21 Years an		CIN2+ associated with HR-HPV	Yes	20	0	0.0	23	2	8.7	43	2	4.7	
			No	20	20	100	23	21	91.3	43	41	95.3	
		CIN2+ associated with HRW-HPV	Yes	20	0	0.0	23	2	8.7	43	2	4.7	
			No	20	20	100	23	21	91.3	43	41	95.3	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total				
				N	n	%	N	n	%	N	n	%		
		CIN2+ associated with HPV-16/18	Yes	20	0	0.0	23	2	8.7	43	2	4.7		
			No	20	20	100	23	21	91.3	43	41	95.3		
		CIN2+ associated with HPV-16/18 Only	Yes	20	0	0.0	23	0	0.0	43	0	0.0		
			No	20	20	100	23	23	100	43	43	100		
		CIN2+ not associated with HR-HPV	Yes	20	0	0.0	23	0	0.0	43	0	0.0		
			No	20	20	100	23	23	100	43	43	100		
		CIN2+ irrespective of HPV type	Yes	20	0	0.0	23	2	8.7	43	2	4.7		
			No	20	20	100	23	21	91.3	43	41	95.3		
		Overall total	Overall total	CIN2+ associated with HR-HPV	Yes	15741	434	2.8	15741	615	3.9	31482	1049	3.3
					No	15741	15307	97.2	15741	15126	96.1	31482	30433	96.7
				CIN2+ associated with HRW-HPV	Yes	15741	318	2.0	15741	423	2.7	31482	741	2.4
					No	15741	15423	98.0	15741	15318	97.3	31482	30741	97.6
CIN2+ associated with HPV-16/18	Yes			15741	180	1.1	15741	353	2.2	31482	533	1.7		
	No			15741	15561	98.9	15741	15388	97.8	31482	30949	98.3		
CIN2+ associated with HPV-16/18 Only	Yes			15741	116	0.7	15741	192	1.2	31482	308	1.0		
	No			15741	15625	99.3	15741	15549	98.8	31482	31174	99.0		
CIN2+ not associated with HR-HPV	Yes			15741	72	0.5	15741	60	0.4	31482	132	0.4		
	No			15741	15669	99.5	15741	15681	99.6	31482	31350	99.6		
CIN2+ irrespective of HPV type	Yes			15741	506	3.2	15741	675	4.3	31482	1181	3.8		
	No			15741	15235	96.8	15741	15066	95.7	31482	30301	96.2		

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

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Table 17 Number and Percentage of Subjects with CIN3+ by Cytology Status at baseline and age category (Total vaccinated cohort)

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
High	15-20 Years	CIN3+ associated with HR-HPV	Yes	26	2	7.7	21	6	28.6	47	8	17.0
			No	26	24	92.3	21	15	71.4	47	39	83.0
		CIN3+ associated with HRW-HPV	Yes	26	2	7.7	21	3	14.3	47	5	10.6
			No	26	24	92.3	21	18	85.7	47	42	89.4
		CIN3+ associated with HPV-16/18	Yes	26	0	0.0	21	4	19.0	47	4	8.5
			No	26	26	100	21	17	81.0	47	43	91.5
		CIN3+ associated with HPV-16/18 Only	Yes	26	0	0.0	21	3	14.3	47	3	6.4
			No	26	26	100	21	18	85.7	47	44	93.6
		CIN3+ not associated with HR-HPV	Yes	26	1	3.8	21	0	0.0	47	1	2.1
	No		26	25	96.2	21	21	100	47	46	97.9	
	CIN3+ irrespective of HPV type	Yes	26	3	11.5	21	6	28.6	47	9	19.1	
		No	26	23	88.5	21	15	71.4	47	38	80.9	
	21 Years an	CIN3+ associated with HR-HPV	Yes	93	53	57.0	86	35	40.7	179	88	49.2
			No	93	40	43.0	86	51	59.3	179	91	50.8
		CIN3+ associated with HRW-HPV	Yes	93	25	26.9	86	13	15.1	179	38	21.2
			No	93	68	73.1	86	73	84.9	179	141	78.8
		CIN3+ associated with HPV-16/18	Yes	93	35	37.6	86	28	32.6	179	63	35.2
			No	93	58	62.4	86	58	67.4	179	116	64.8
CIN3+ associated with HPV-16/18 Only		Yes	93	28	30.1	86	22	25.6	179	50	27.9	
		No	93	65	69.9	86	64	74.4	179	129	72.1	
CIN3+ not associated with HR-HPV		Yes	93	1	1.1	86	1	1.2	179	2	1.1	
	No	93	92	98.9	86	85	98.8	179	177	98.9		
CIN3+ irrespective of HPV type	Yes	93	54	58.1	86	36	41.9	179	90	50.3		
	No	93	39	41.9	86	50	58.1	179	89	49.7		
Normal	15-20 Years	CIN3+ associated with HR-HPV	Yes	4907	21	0.4	4967	68	1.4	9874	89	0.9
			No	4907	4886	99.6	4967	4899	98.6	9874	9785	99.1
		CIN3+ associated with HRW-HPV	Yes	4907	14	0.3	4967	41	0.8	9874	55	0.6
			No	4907	4893	99.7	4967	4926	99.2	9874	9819	99.4
		CIN3+ associated with HPV-16/18	Yes	4907	9	0.2	4967	49	1.0	9874	58	0.6
			No	4907	4898	99.8	4967	4918	99.0	9874	9816	99.4
		CIN3+ associated with HPV-16/18 Only	Yes	4907	7	0.1	4967	27	0.5	9874	34	0.3
			No	4907	4900	99.9	4967	4940	99.5	9874	9840	99.7

CONFIDENTIAL

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN3+ not associated with HR-HPV	Yes	4907	2	0.0	4967	9	0.2	9874	11	0.1
			No	4907	4905	100	4967	4958	99.8	9874	9863	99.9
		CIN3+ irrespective of HPV type	Yes	4907	23	0.5	4967	77	1.6	9874	100	1.0
			No	4907	4884	99.5	4967	4890	98.4	9874	9774	99.0
	21 Years an	CIN3+ associated with HR-HPV	Yes	9639	46	0.5	9593	65	0.7	19232	111	0.6
			No	9639	9593	99.5	9593	9528	99.3	19232	19121	99.4
		CIN3+ associated with HRW-HPV	Yes	9639	26	0.3	9593	33	0.3	19232	59	0.3
			No	9639	9613	99.7	9593	9560	99.7	19232	19173	99.7
		CIN3+ associated with HPV-16/18	Yes	9639	27	0.3	9593	41	0.4	19232	68	0.4
			No	9639	9612	99.7	9593	9552	99.6	19232	19164	99.6
		CIN3+ associated with HPV-16/18 Only	Yes	9639	20	0.2	9593	32	0.3	19232	52	0.3
			No	9639	9619	99.8	9593	9561	99.7	19232	19180	99.7
		CIN3+ not associated with HR-HPV	Yes	9639	4	0.0	9593	6	0.1	19232	10	0.1
			No	9639	9635	100	9593	9587	99.9	19232	19222	99.9
		CIN3+ irrespective of HPV type	Yes	9639	50	0.5	9593	71	0.7	19232	121	0.6
			No	9639	9589	99.5	9593	9522	99.3	19232	19111	99.4
	Missing	CIN3+ associated with HR-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0
			No	1	1	100	0	-	-	1	1	100
		CIN3+ associated with HRW-HPV	Yes	1	0	0.0	0	-	-	1	0	0.0
			No	1	1	100	0	-	-	1	1	100
CIN3+ associated with HPV-16/18		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN3+ associated with HPV-16/18 Only		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN3+ not associated with HR-HPV		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
CIN3+ irrespective of HPV type		Yes	1	0	0.0	0	-	-	1	0	0.0	
		No	1	1	100	0	-	-	1	1	100	
Low	15-20 Years	CIN3+ associated with HR-HPV	Yes	462	16	3.5	431	21	4.9	893	37	4.1
			No	462	446	96.5	431	410	95.1	893	856	95.9
		CIN3+ associated with HRW-HPV	Yes	462	11	2.4	431	9	2.1	893	20	2.2
			No	462	451	97.6	431	422	97.9	893	873	97.8
		CIN3+ associated with HPV-16/18	Yes	462	12	2.6	431	14	3.2	893	26	2.9
			No	462	450	97.4	431	417	96.8	893	867	97.1

CONFIDENTIAL

Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total			
				N	n	%	N	n	%	N	n	%	
		CIN3+ associated with HPV-16/18 Only	Yes	462	5	1.1	431	12	2.8	893	17	1.9	
			No	462	457	98.9	431	419	97.2	893	876	98.1	
		CIN3+ not associated with HR-HPV	Yes	462	3	0.6	431	3	0.7	893	6	0.7	
			No	462	459	99.4	431	428	99.3	893	887	99.3	
		CIN3+ irrespective of HPV type	Yes	462	19	4.1	431	24	5.6	893	43	4.8	
			No	462	443	95.9	431	407	94.4	893	850	95.2	
		21 Years an	CIN3+ associated with HR-HPV	Yes	590	45	7.6	614	36	5.9	1204	81	6.7
				No	590	545	92.4	614	578	94.1	1204	1123	93.3
			CIN3+ associated with HRW-HPV	Yes	590	22	3.7	614	23	3.7	1204	45	3.7
				No	590	568	96.3	614	591	96.3	1204	1159	96.3
			CIN3+ associated with HPV-16/18	Yes	590	33	5.6	614	21	3.4	1204	54	4.5
				No	590	557	94.4	614	593	96.6	1204	1150	95.5
	CIN3+ associated with HPV-16/18 Only		Yes	590	23	3.9	614	13	2.1	1204	36	3.0	
			No	590	567	96.1	614	601	97.9	1204	1168	97.0	
	CIN3+ not associated with HR-HPV		Yes	590	5	0.8	614	5	0.8	1204	10	0.8	
			No	590	585	99.2	614	609	99.2	1204	1194	99.2	
	CIN3+ irrespective of HPV type	Yes	590	50	8.5	614	41	6.7	1204	91	7.6		
		No	590	540	91.5	614	573	93.3	1204	1113	92.4		
	Missing	15-20 Years	CIN3+ associated with HR-HPV	Yes	3	0	0.0	6	0	0.0	9	0	0.0
				No	3	3	100	6	6	100	9	9	100
CIN3+ associated with HRW-HPV			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN3+ associated with HPV-16/18			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN3+ associated with HPV-16/18 Only			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN3+ not associated with HR-HPV			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
CIN3+ irrespective of HPV type			Yes	3	0	0.0	6	0	0.0	9	0	0.0	
			No	3	3	100	6	6	100	9	9	100	
21 Years an		CIN3+ associated with HR-HPV	Yes	20	0	0.0	23	1	4.3	43	1	2.3	
			No	20	20	100	23	22	95.7	43	42	97.7	
		CIN3+ associated with HRW-HPV	Yes	20	0	0.0	23	1	4.3	43	1	2.3	
			No	20	20	100	23	22	95.7	43	42	97.7	

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Cytology Status at baseline	Age in Years	Endpoint	Case	HPV			Control			Total		
				N	n	%	N	n	%	N	n	%
		CIN3+ associated with HPV-16/18	Yes	20	0	0.0	23	1	4.3	43	1	2.3
			No	20	20	100	23	22	95.7	43	42	97.7
		CIN3+ associated with HPV-16/18 Only	Yes	20	0	0.0	23	0	0.0	43	0	0.0
			No	20	20	100	23	23	100	43	43	100
		CIN3+ not associated with HR-HPV	Yes	20	0	0.0	23	0	0.0	43	0	0.0
			No	20	20	100	23	23	100	43	43	100
CIN3+ irrespective of HPV type	Yes	20	0	0.0	23	1	4.3	43	1	2.3		
	No	20	20	100	23	22	95.7	43	42	97.7		
Overall total	Overall total	CIN3+ associated with HR-HPV	Yes	15741	183	1.2	15741	232	1.5	31482	415	1.3
			No	15741	15558	98.8	15741	15509	98.5	31482	31067	98.7
		CIN3+ associated with HRW-HPV	Yes	15741	100	0.6	15741	123	0.8	31482	223	0.7
			No	15741	15641	99.4	15741	15618	99.2	31482	31259	99.3
		CIN3+ associated with HPV-16/18	Yes	15741	116	0.7	15741	158	1.0	31482	274	0.9
			No	15741	15625	99.3	15741	15583	99.0	31482	31208	99.1
		CIN3+ associated with HPV-16/18 Only	Yes	15741	83	0.5	15741	109	0.7	31482	192	0.6
			No	15741	15658	99.5	15741	15632	99.3	31482	31290	99.4
		CIN3+ not associated with HR-HPV	Yes	15741	16	0.1	15741	24	0.2	31482	40	0.1
			No	15741	15725	99.9	15741	15717	99.8	31482	31442	99.9
		CIN3+ irrespective of HPV type	Yes	15741	199	1.3	15741	256	1.6	31482	455	1.4
			No	15741	15542	98.7	15741	15485	98.4	31482	31027	98.6

HPV = Subjects receiving HPV-16/18 L1 VLP ASO4 Vaccine

Control = Subjects receiving the control vaccine

N = number of subjects

n = number of subjects in a given category

% = n / Number of subjects with available results x 100

Cumulative incidence curves irrespective of HPV type in the lesion for subjects (Total vaccinated cohort)

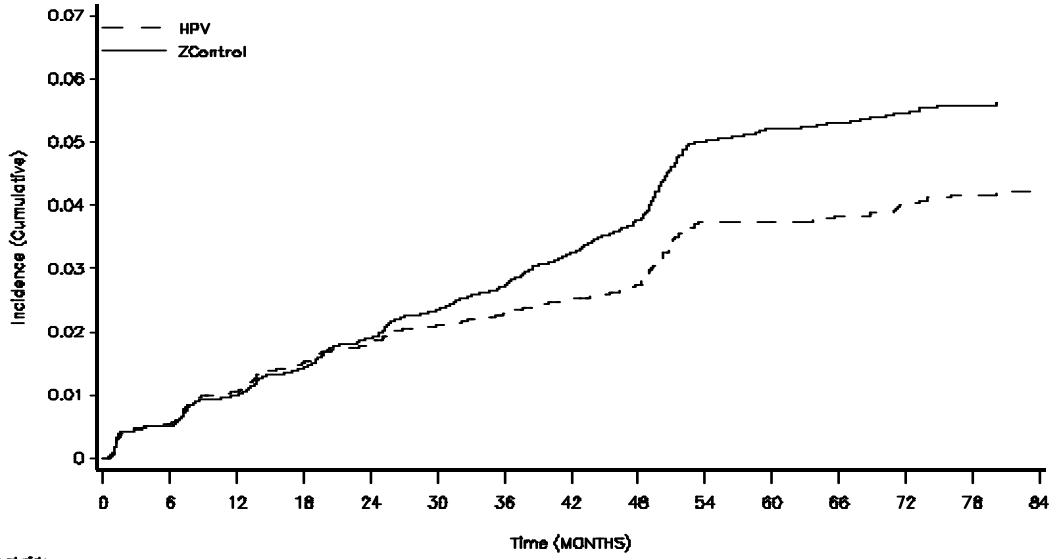
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1. POOLED STUDIES

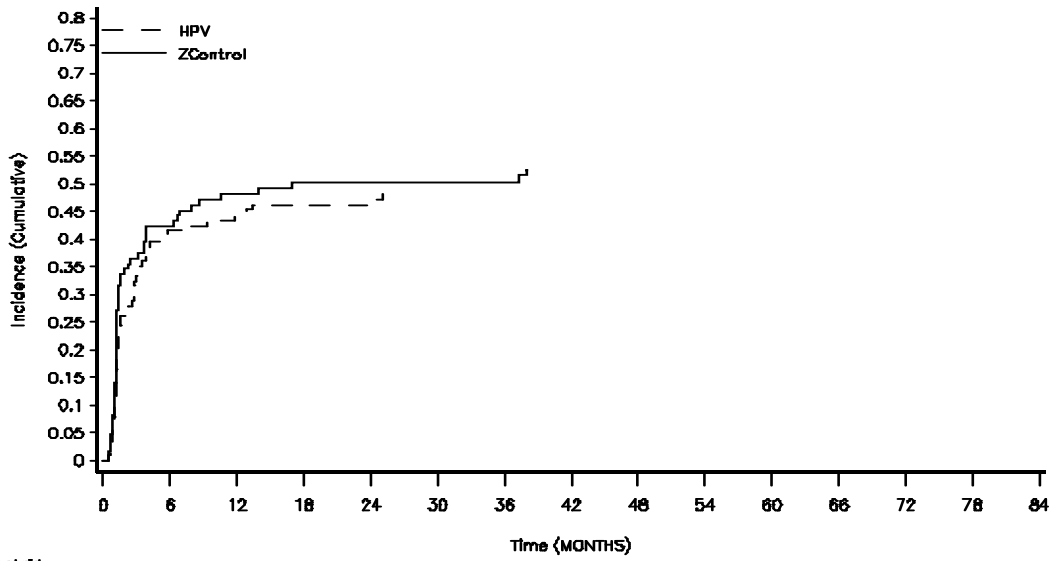
1.1. CIN2:

Overall:



Number at risk																
		0	6	12	18	24	30	36	42	48	54	60	66	72	78	84
HPV		14784	14663	14378	14018	13717	13399	12981	12481	8258	4354	4191	3941	2927	1789	1330
ZControl		14808	14696	14401	14045	13728	13398	12908	12358	8284	4341	4173	3894	2934	1772	1328
Cumulative number of cases																
HPV		0	82	158	223	285	305	330	359	384	439	440	443	450	453	455
ZControl		0	75	148	211	277	339	389	457	519	588	597	602	607	610	611

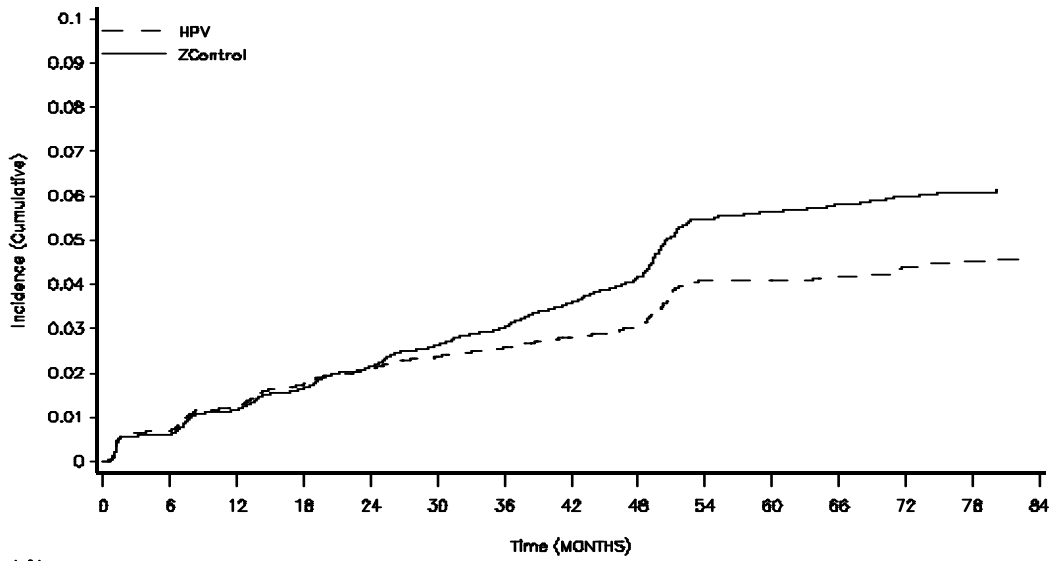
High grade Cytology:



	0	6	12	18	24	30	36	42	48	54	60	66	72	78	84
Number at risk															
HPV	117	84	59	56	53	51	49	48	39	28	25	23	15	10	5
ZControl	107	80	51	47	46	44	43	40	29	22	22	21	17	13	9
Cumulative number of cases															
HPV	0	47	50	52	53	54	54	54	54	54	54	54	54	54	54
ZControl	0	45	51	53	53	53	53	55	55	55	55	55	55	55	55

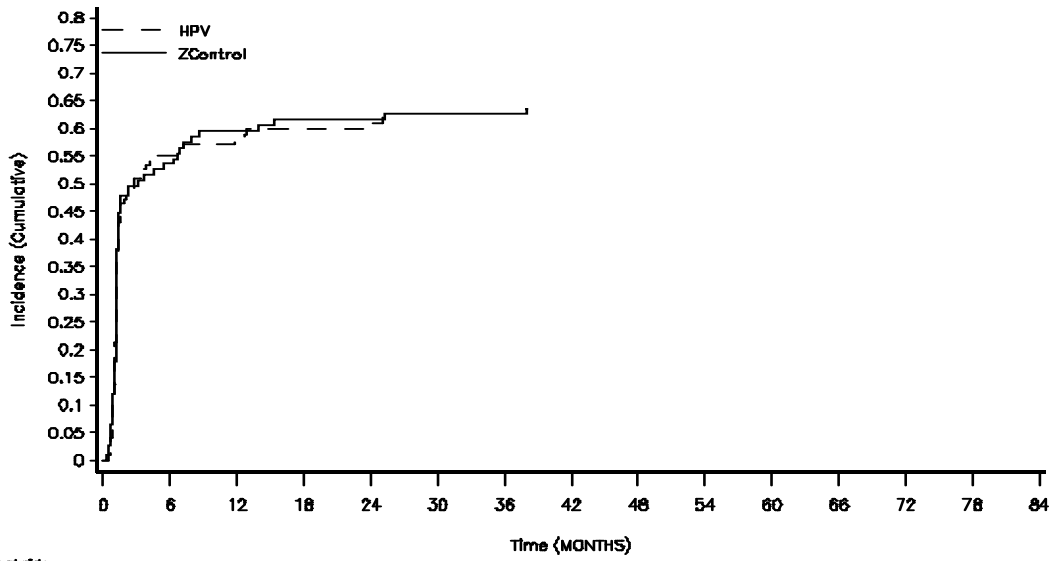
1.2. Cin2+

Overall:



	Time (MONTHS)														
Number at risk															
HPV	14784	14645	14356	13900	13688	13388	12920	12428	8229	4337	4174	3925	2916	1781	1325
ZControl	14808	14681	14378	14018	13702	13367	12873	12325	8239	4326	4160	3882	2922	1764	1320
Cumulative number of cases															
HPV	0	103	181	256	301	344	370	401	429	486	487	490	497	500	502
ZControl	0	91	173	243	311	379	433	507	572	647	656	682	690	671	672

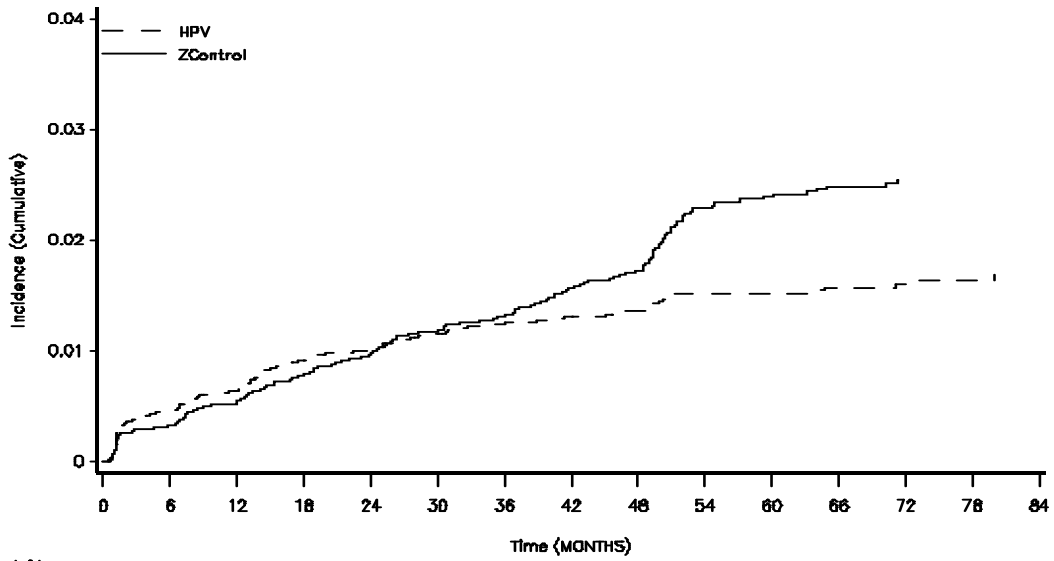
High grade Cytology:



	0	6	12	18	24	30	36	42	48	54	60	66	72	78	84
Number at risk															
HPV	117	50	45	42	39	37	35	34	28	15	14	13	8	5	3
ZControl	107	48	40	37	37	35	35	33	23	17	17	17	13	9	8
Cumulative number of cases															
HPV	0	64	67	69	70	71	71	71	71	71	71	71	71	71	71
ZControl	0	57	63	65	65	66	66	67	67	67	67	67	67	67	67

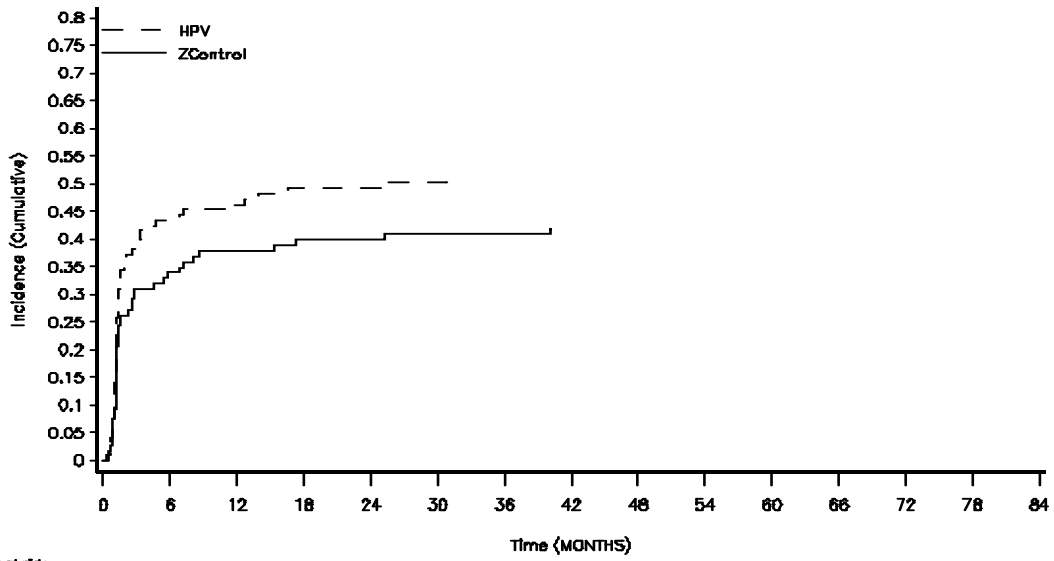
1.3. CIN3+

Overall:



Number at risk		Time (MONTHS)													
	0	6	12	18	24	30	36	42	48	54	60	66	72	78	84
HPV	14784	14677	14434	14102	13829	13530	13102	12616	8378	4408	4237	3987	2971	1814	1348
ZControl	14808	14721	14468	14133	13899	13555	13093	12576	8446	4408	4242	3985	2988	1811	1351
Cumulative number of cases															
HPV	0	66	95	134	145	166	180	187	194	203	203	205	206	207	208
ZControl	0	49	80	116	142	170	188	222	239	271	276	280	282	282	282

High grade Cytology:

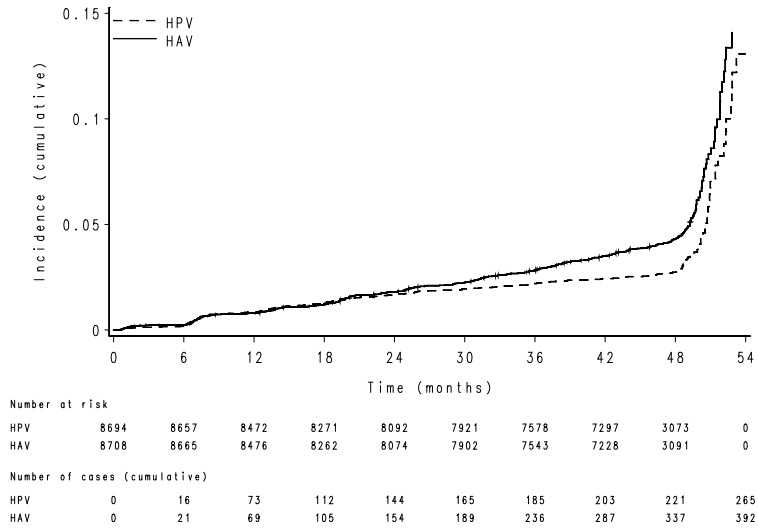


		0	6	12	18	24	30	36	42	48	54	60	66	72	78	84
Number at risk																
HPV	117	82	58	51	48	47	44	42	31	20	18	17	12	8	4	
ZControl	107	88	81	58	58	53	53	50	36	25	25	25	19	14	8	
Cumulative number of cases																
HPV	0	50	53	56	56	57	58	58	58	58	58	58	58	58	58	58
ZControl	0	36	40	42	42	43	43	44	44	44	44	44	44	44	44	44

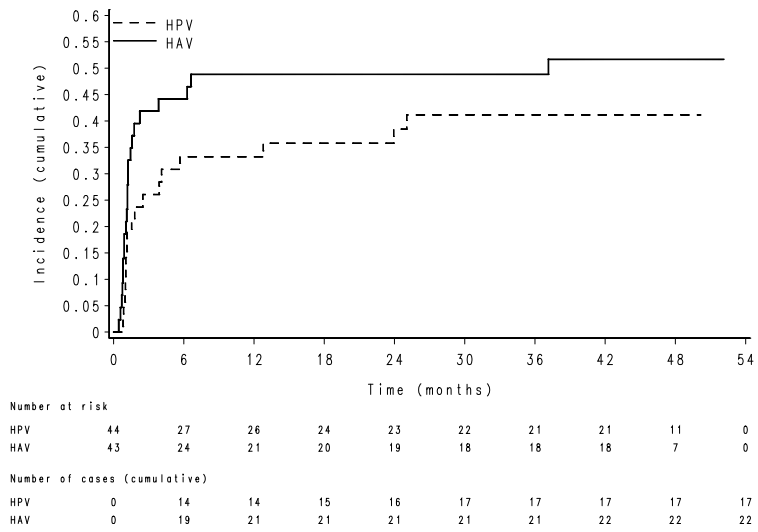
2. HPV-008

2.1. CIN2:

Overall:

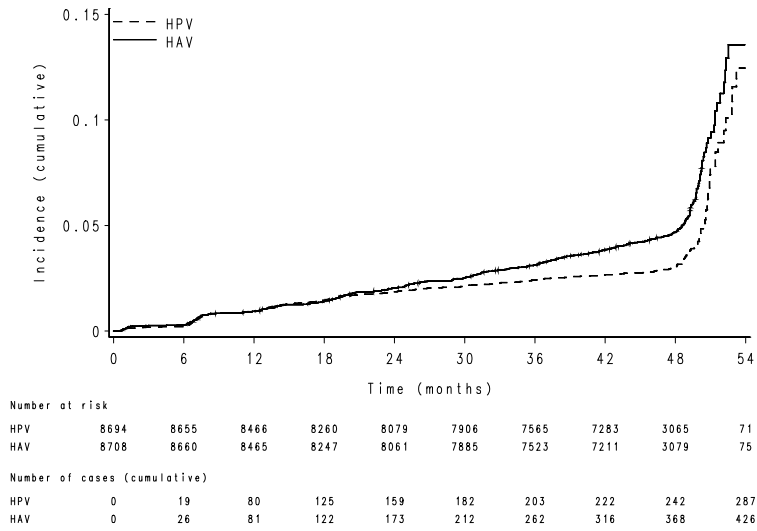


High grade Cytology:

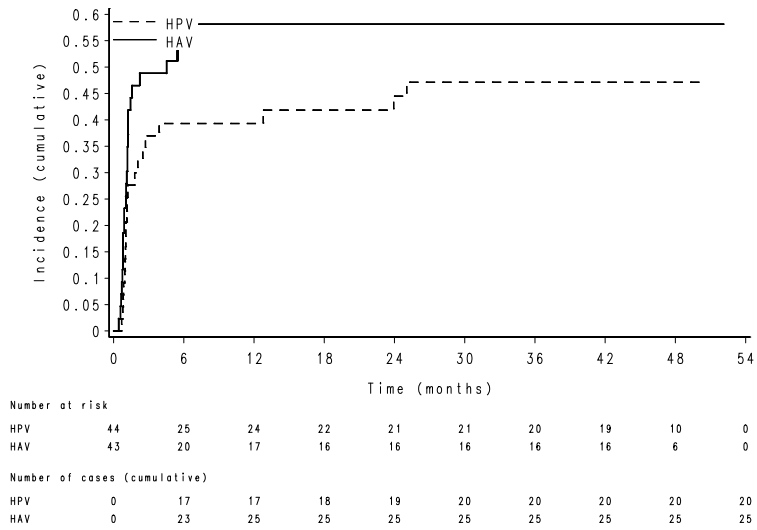


2.2. CIN2+

Overall:

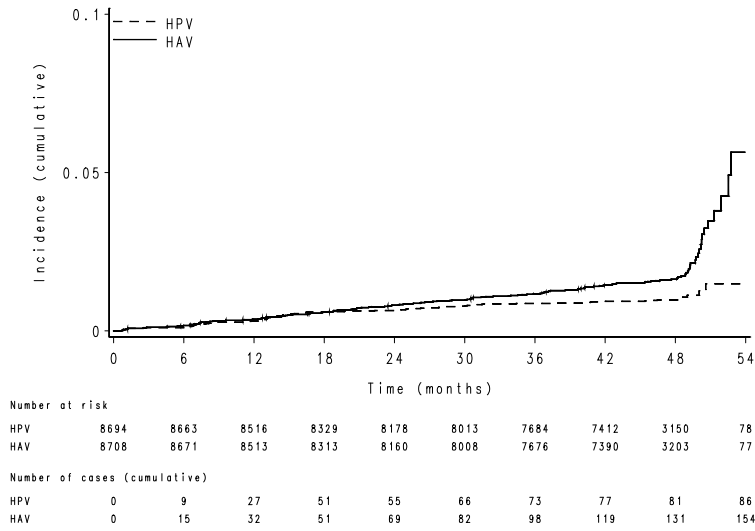


High grade cytology:

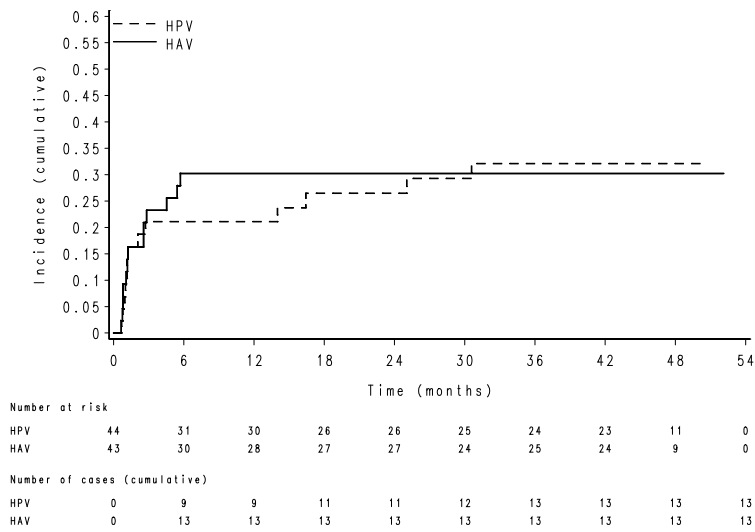


2.3. CIN3+:

Overall:



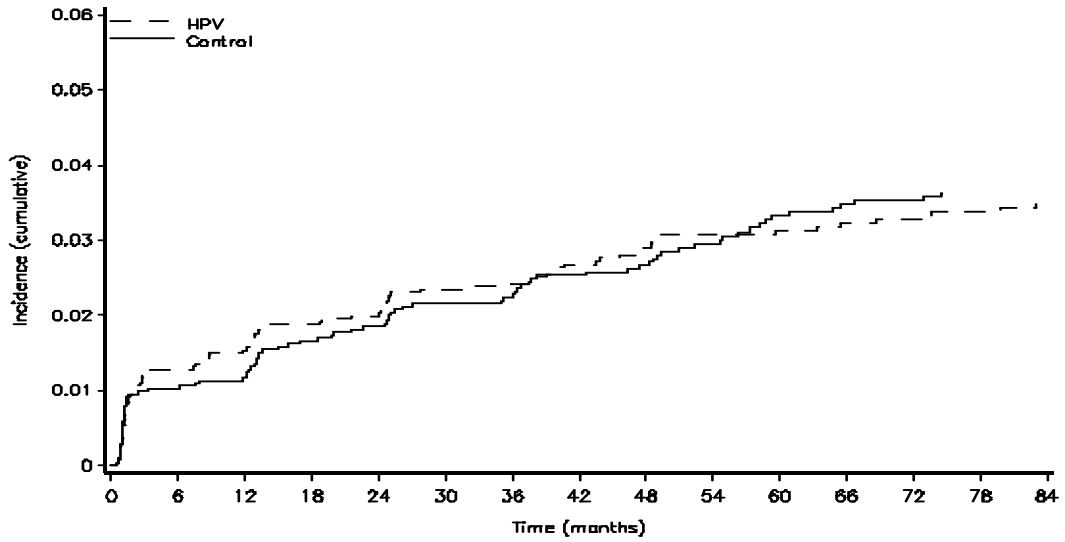
High grade Cytology:



3. HPV-015

3.1. CIN2:

Overall:



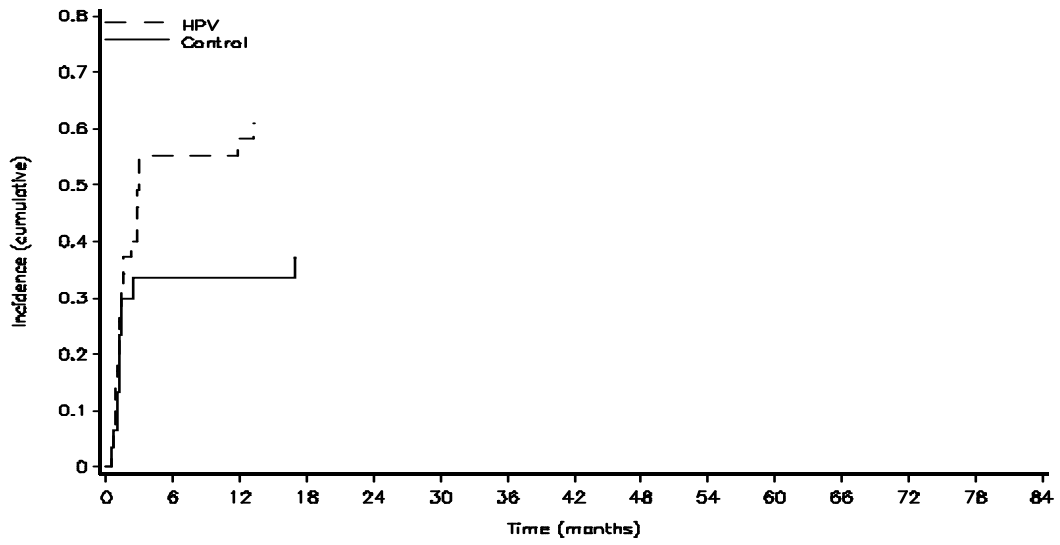
Number at risk

HPV	2733	2689	2635	2575	2534	2494	2403	2287	2177	2033	2007	1957	1891	1776	1251
Control	2736	2698	2658	2599	2549	2502	2387	2253	2152	1995	1987	1910	1851	1751	1242

Cumulative number of cases

HPV	0	36	42	51	54	63	66	71	76	80	81	83	84	86	88
Control	0	28	32	45	50	58	60	67	70	76	84	87	88	90	90

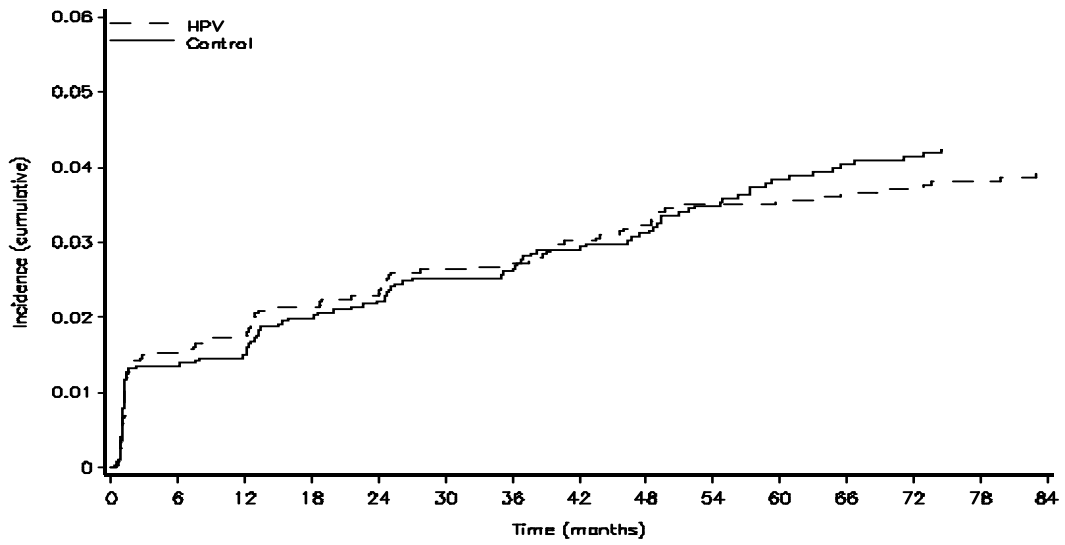
High grade Cytology:



Number at risk	
HPV	35 15 14 13 13 13 12 12 12 12 12 10 10 10 2
Control	30 19 18 16 16 16 14 14 14 14 14 14 13 13 8
Cumulative number of cases	
HPV	0 19 20 21 21 21 21 21 21 21 21 21 21 21 21
Control	0 10 10 11 11 11 11 11 11 11 11 11 11 11 11

3.2. CIN2+:

Overall:



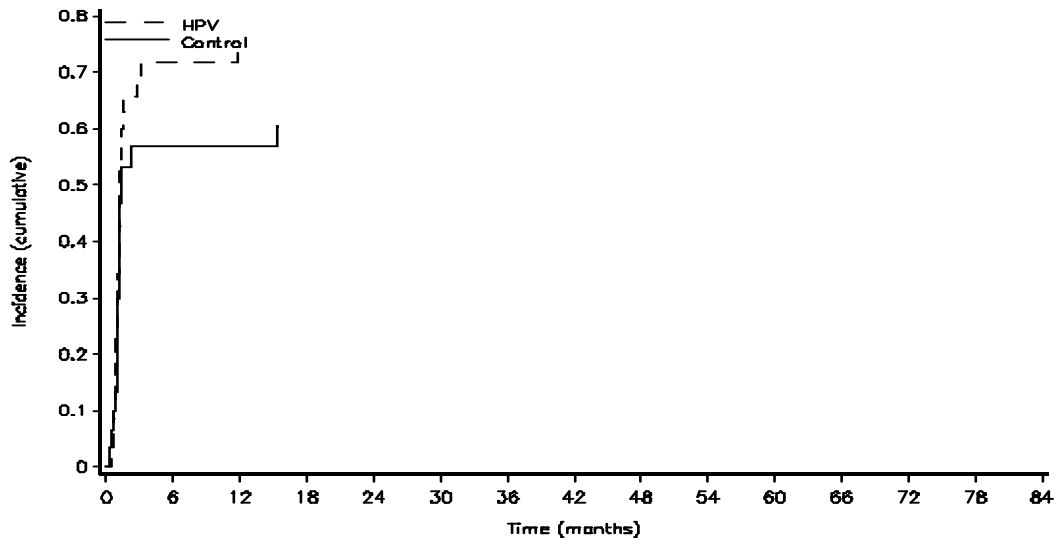
Number at risk

HPV	2733	2682	2629	2569	2527	2487	2398	2279	2170	2024	1998	1949	1883	1768	1247
Control	2735	2687	2648	2592	2541	2494	2381	2248	2147	1988	1961	1903	1843	1743	1236

Cumulative number of cases

HPV	0	42	48	58	63	71	73	80	85	91	92	94	95	97	99
Control	0	37	41	54	60	68	70	77	82	90	97	101	103	105	105

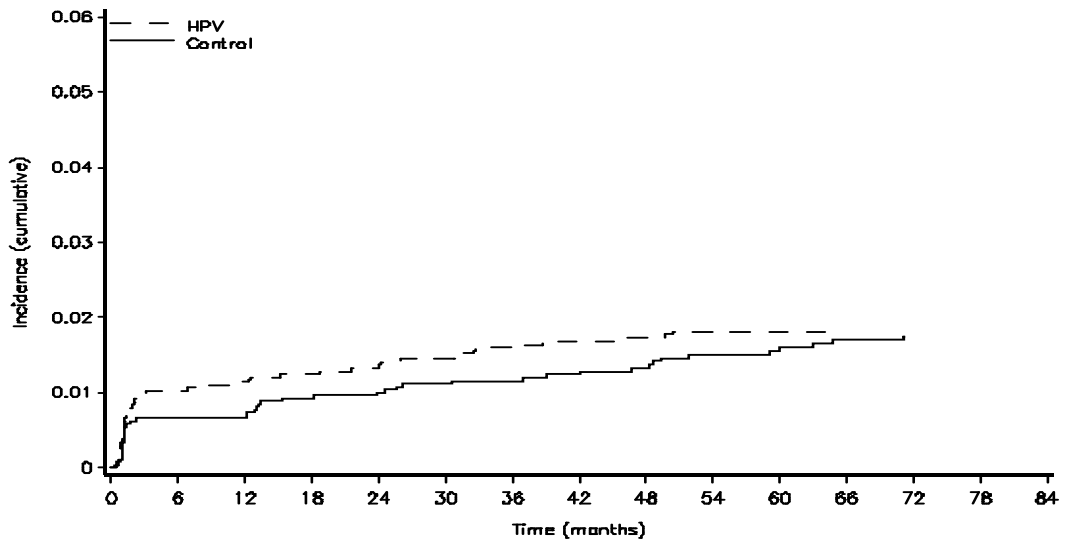
High grade Cytology:



Number at risk	
HPV	35 9 8 7 7 7 6 6 6 6 6 5 5 5 1
Control	30 12 12 11 11 11 10 10 10 10 10 10 9 9 5
Cumulative number of cases	
HPV	0 25 26 27 27 27 27 27 27 27 27 27 27 27 27
Control	0 17 17 18 18 18 18 18 18 18 18 18 18 18 18

3.3. CIN3+:

Overall:



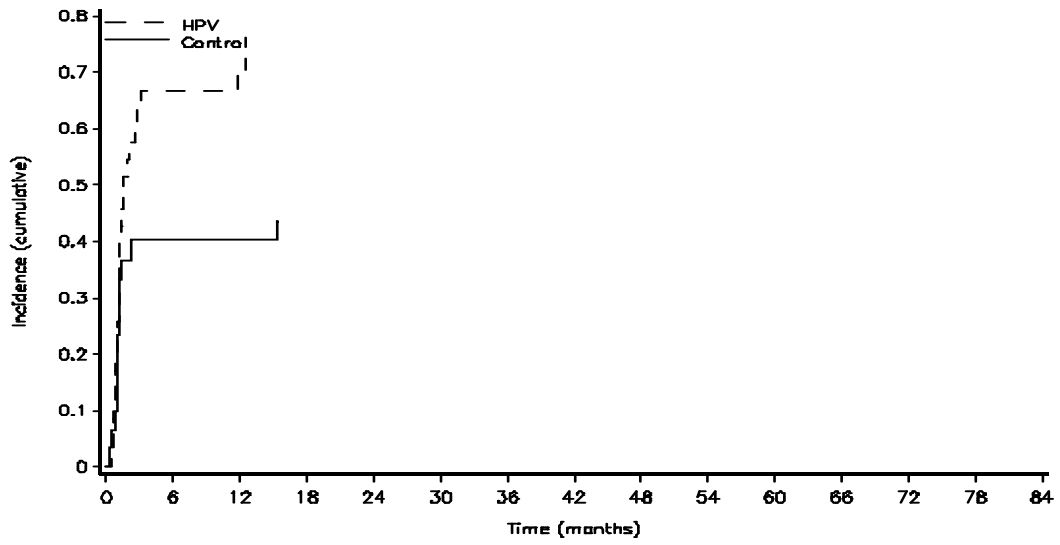
Number at risk

HPV	2733	2695	2643	2590	2550	2516	2421	2309	2201	2058	2031	1983	1916	1799	1268
Control	2735	2705	2670	2619	2570	2526	2412	2283	2185	2028	2006	1950	1889	1790	1264

Cumulative number of cases

HPV	0	28	31	34	37	39	44	45	46	48	48	49	49	49	49
Control	0	18	18	25	27	30	31	33	36	39	41	43	44	44	44

High grade cytology:



Number at risk

HPV	35	11	9	8	8	8	7	7	7	7	7	6	6	6	2
Control	30	17	17	16	16	16	15	15	15	15	15	15	14	14	8

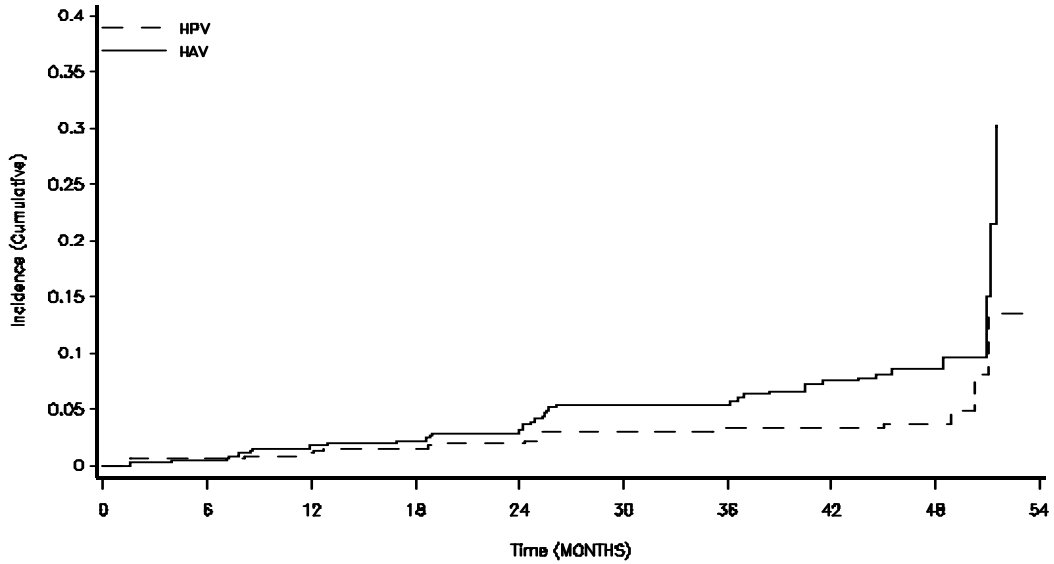
Cumulative number of cases

HPV	0	23	24	25	25	25	25	25	25	25	25	25	25	25	25
Control	0	12	12	13	13	13	13	13	13	13	13	13	13	13	13

4. HPV-032

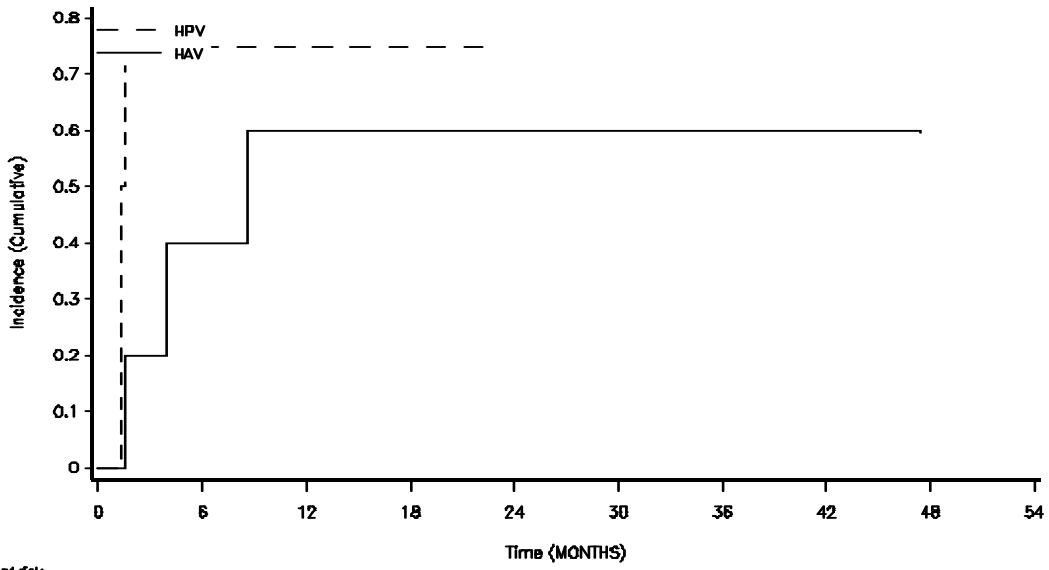
4.1. CIN2:

Overall:



Number at risk		Time (MONTHS)								
	0	6	12	18	24	30	36	42	48	54
HPV	484	480	448	432	381	364	350	339	145	
HAV	483	480	443	428	389	359	334	312	122	
Number of cases (cumulative)										
HPV	0	3	5	7	9	13	14	14	15	
HAV	0	2	8	10	14	23	23	30	33	

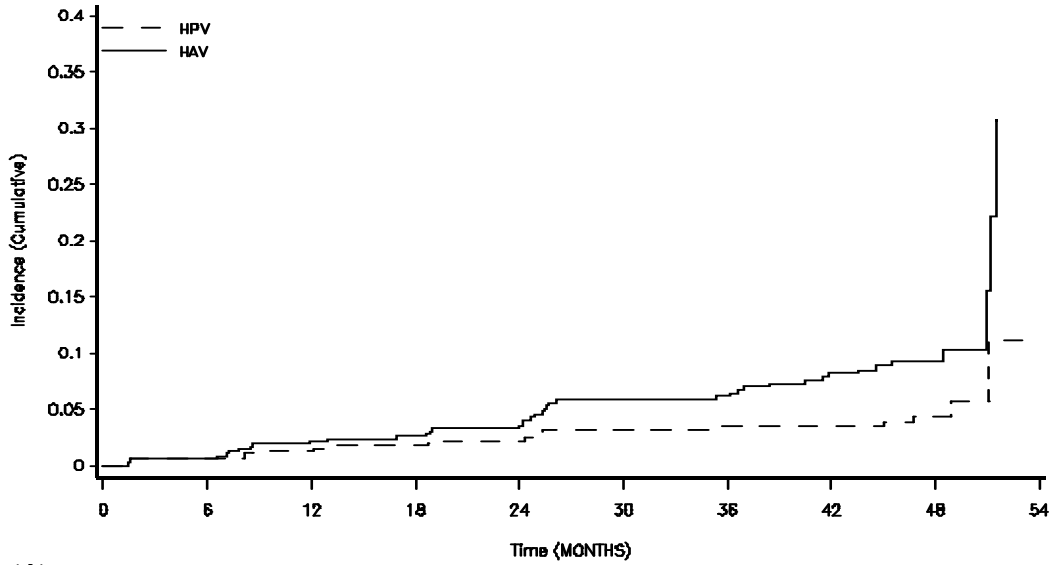
High grade Cytology:



Number at risk		Time (MONTHS)								
	0	6	12	18	24	30	36	42	48	54
HPV	4	1	1	1	0	0	0	0	0	0
HAV	5	3	2	2	2	1	1	1	1	1
Number of cases (cumulative)										
HPV	0	3	3	3	3	3	3	3	3	3
HAV	0	2	3	3	3	3	3	3	3	3

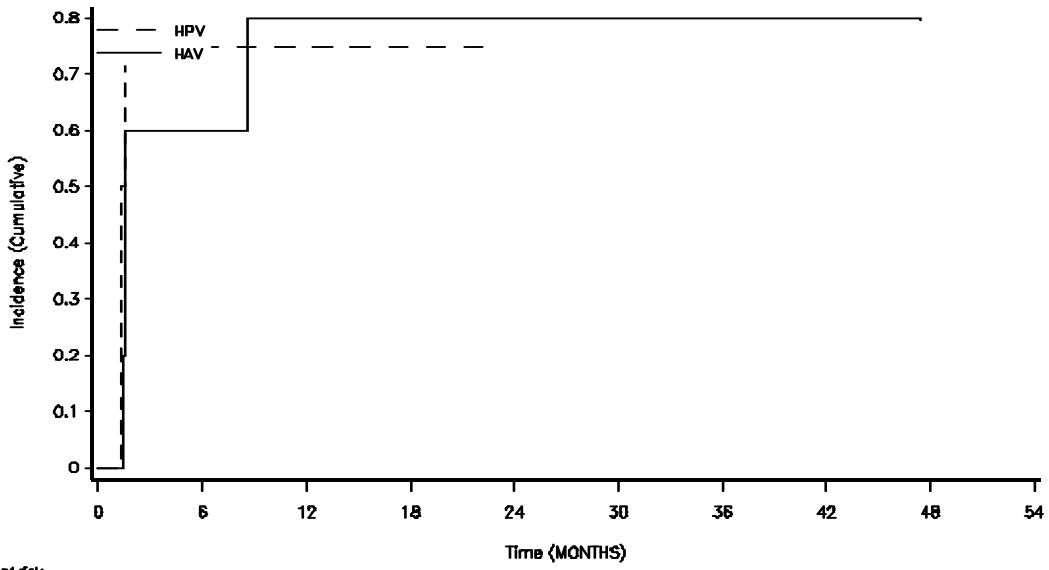
4.2. CIN2+

Overall:



Number at risk		Time (MONTHS)								
	0	6	12	18	24	30	36	42	48	54
HPV	484	480	447	431	380	363	349	338	14.3	
HAV	483	459	441	428	387	358	332	310	121	
Number of cases (cumulative)										
HPV	0	3	8	8	10	14	15	15	17	
HAV	0	3	10	12	18	25	28	33	38	

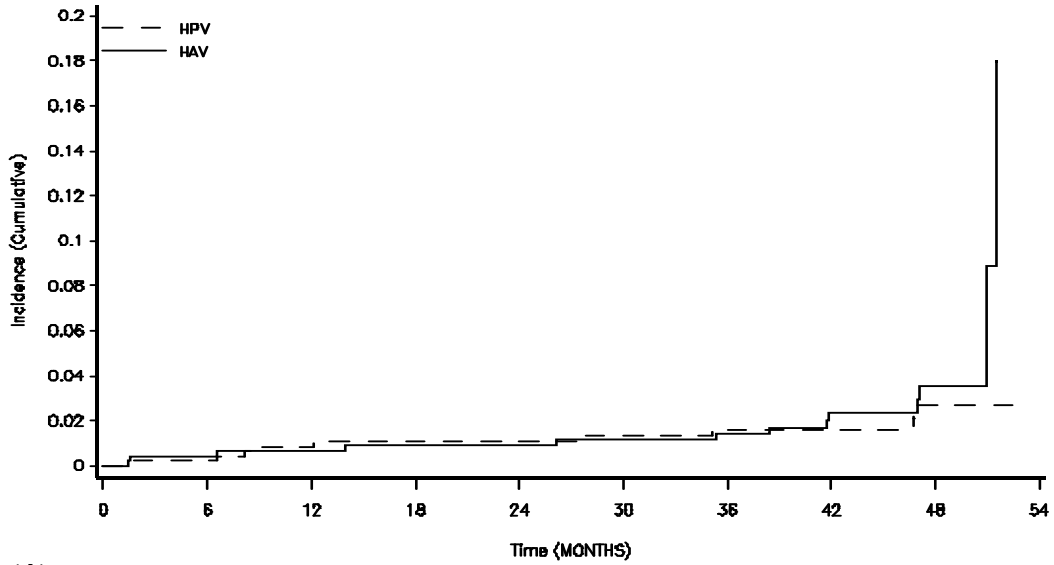
High grade Cytology:



Number at risk		Time (MONTHS)								
	0	6	12	18	24	30	36	42	48	54
HPV	4	1	1	1	0	0	0	0	0	0
HAV	5	2	1	1	1	1	1	1	1	1
Number of cases (cumulative)										
HPV	0	3	3	3	3	3	3	3	3	3
HAV	0	3	4	4	4	4	4	4	4	4

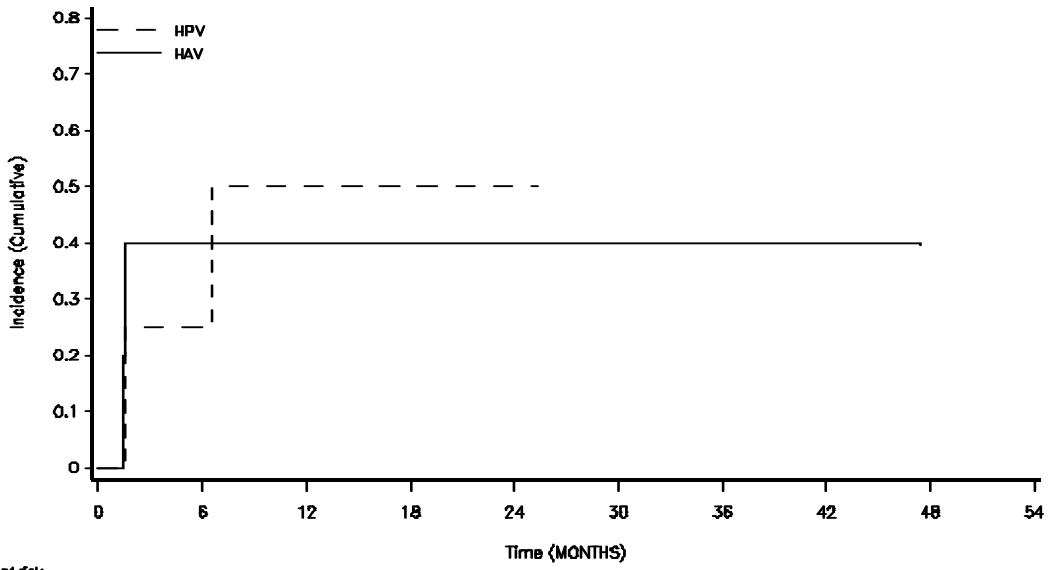
4.3. CIN3+:

Overall:



Number at risk		Time (MONTHS)								
	0	6	12	18	24	30	36	42	48	54
HPV	484	482	449	434	395	370	356	345	148	
HAV	483	480	447	433	394	374	348	328	128	
Number of cases (cumulative)										
HPV	0	1	4	5	5	6	7	7	9	
HAV	0	2	3	4	4	5	6	9	11	

High grade cytology:

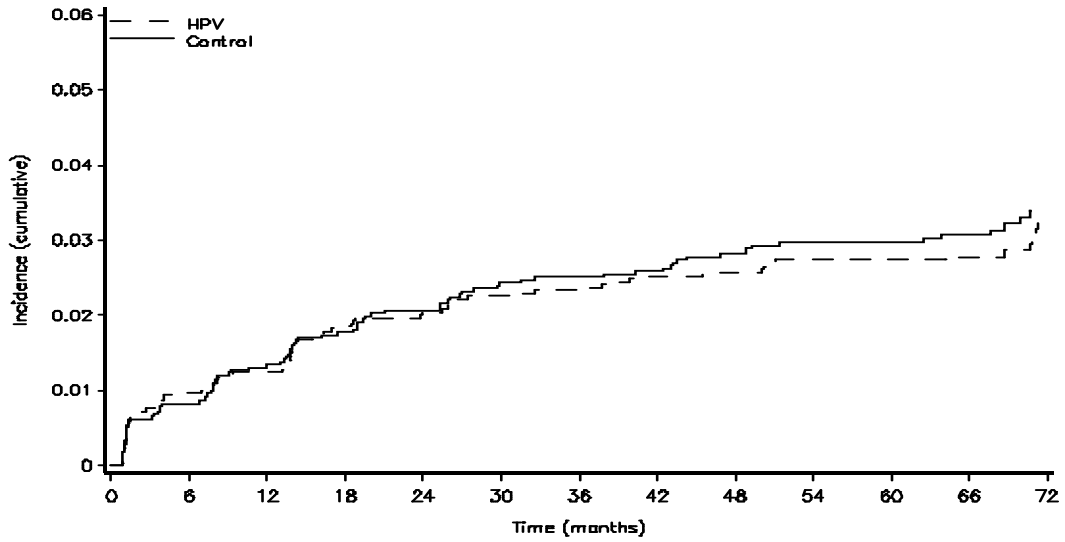


Number at risk		Time (MONTHS)								
	0	3	6	9	12	15	18	21	24	27
HPV	4	3	2	2	1	0	0	0	0	0
HAV	5	3	3	3	1	1	1	1	1	1
Number of cases (cumulative)										
HPV	0	1	2	2	2	2	2	2	2	2
HAV	0	2	2	2	2	2	2	2	2	2

5. HPV-039

5.1. CIN2:

Overall:



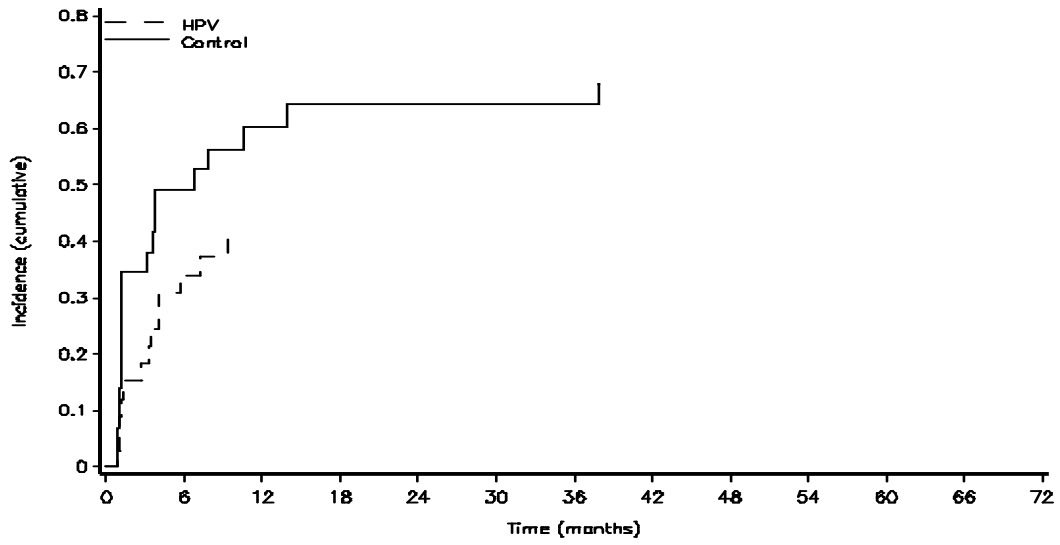
Number at risk

HPV	2893	2852	2802	2736	2683	2616	2562	2534	2431	2243	2179	1908	1028
Control	2902	2870	2802	2749	2699	2630	2597	2560	2460	2285	2194	1907	1076

Cumulative number of cases

HPV	0	28	38	53	58	64	68	71	72	76	76	77	83
Control	0	24	39	51	59	69	71	73	79	83	83	85	89

High grade Cytology:



Number at risk

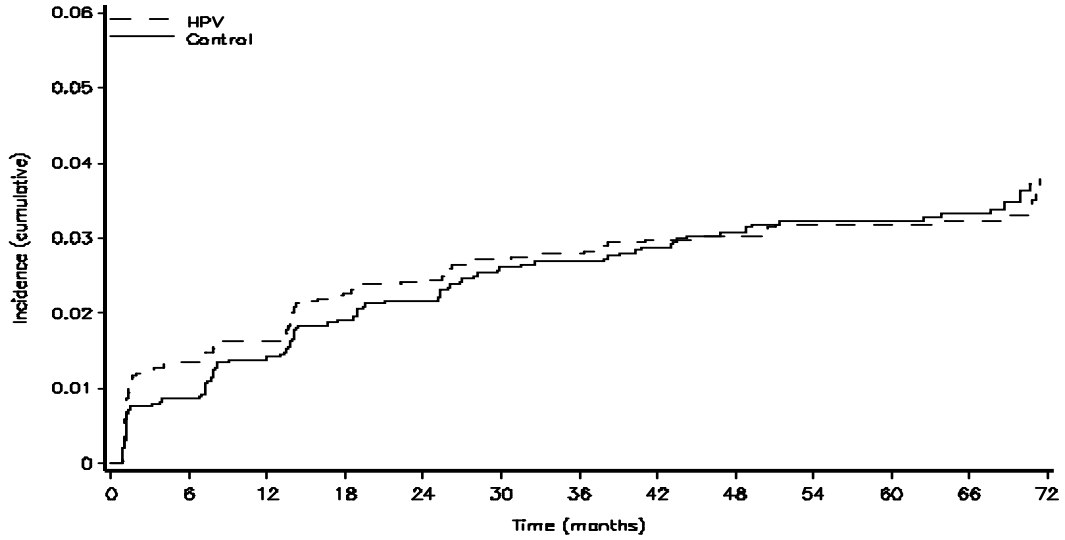
HPV	34	21	18	17	16	16	16	16	16	13	13	12	5
Control	29	14	10	9	9	9	9	8	8	8	8	7	4

Cumulative number of cases

HPV	0	11	13	13	13	13	13	13	13	13	13	13	13
Control	0	14	17	18	18	18	18	19	19	19	19	19	19

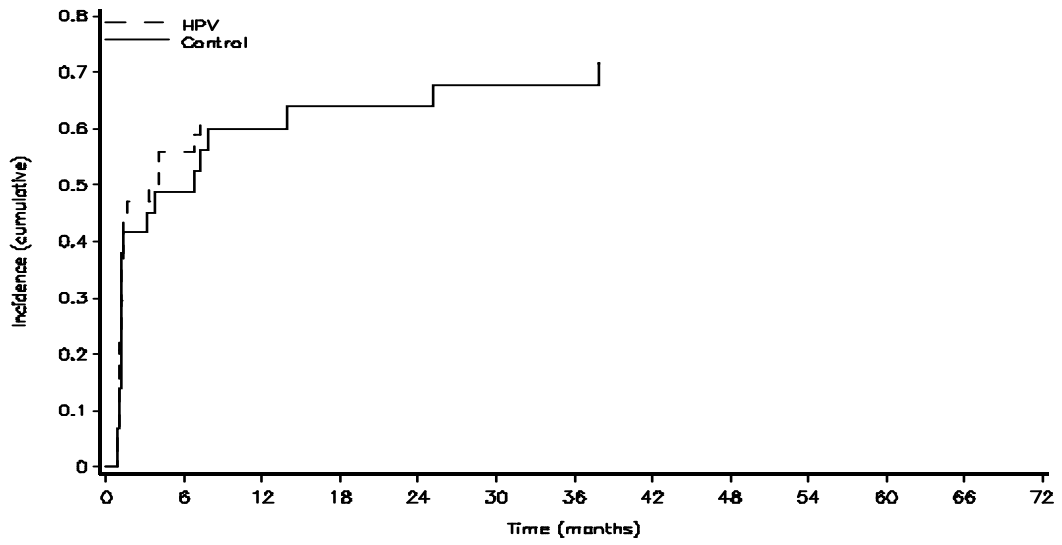
5.2. CIN2+

Overall:



Number at risk													
	0	6	12	18	24	30	36	42	48	54	60	66	72
HPV	2893	2843	2793	2727	2674	2606	2572	2524	2421	2236	2171	1899	1025
Control	2902	2889	2800	2745	2696	2625	2592	2552	2453	2259	2188	1902	1072
Cumulative number of cases													
HPV	0	39	47	65	70	77	79	84	85	89	89	90	96
Control	0	25	41	56	62	74	76	81	86	90	90	92	97

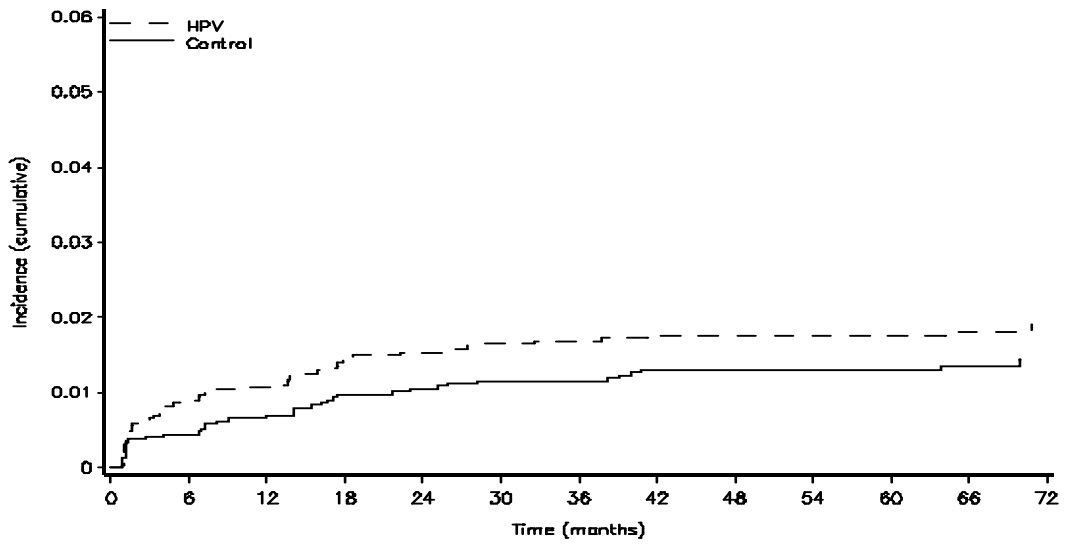
High grade Cytology:



Number at risk													
	0	6	12	18	24	30	36	42	48	54	60	66	72
HPV	34	15	12	11	10	10	10	10	10	8	8	8	3
Control	29	14	10	9	9	8	8	7	7	7	7	7	4
Cumulative number of cases													
HPV	0	19	21	21	21	21	21	21	21	21	21	21	21
Control	0	14	17	18	18	19	19	20	20	20	20	20	20

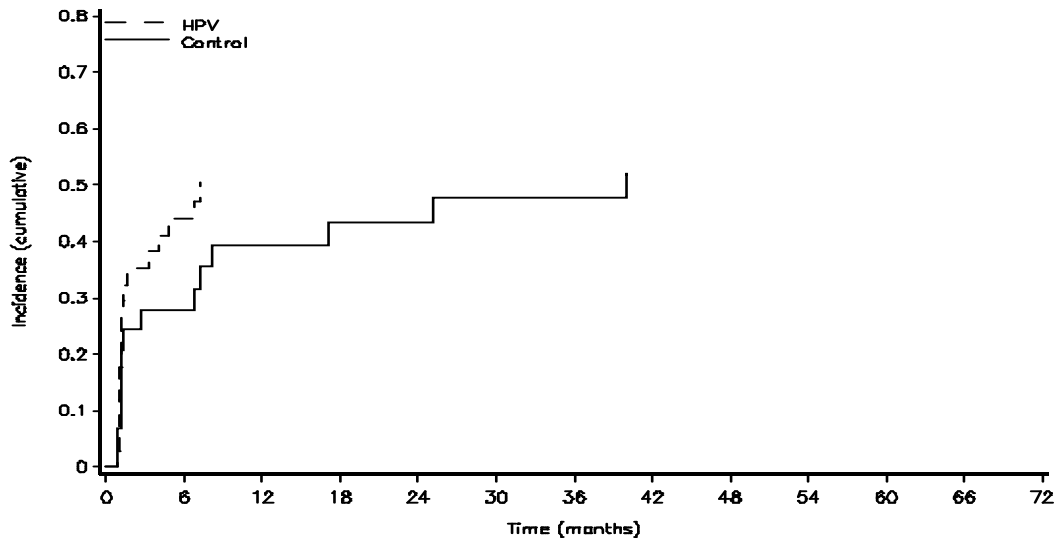
5.3. CIN3+

Overall:



Number at risk													
	0	6	12	18	24	30	36	42	48	54	60	66	72
HPV	2893	2855	2807	2749	2698	2634	2600	2553	2449	2285	2201	1927	1047
Control	2902	2880	2820	2789	2725	2660	2629	2589	2491	2299	2224	1938	1091
Cumulative number of cases													
HPV	0	26	31	41	44	47	48	50	50	50	50	51	52
Control	0	13	20	28	30	33	33	37	37	37	37	38	39

High grade Cytology:



Number at risk													
	0	6	12	18	24	30	36	42	48	54	60	66	72
HPV	34	19	18	15	14	14	13	13	13	11	11	11	8
Control	29	19	15	14	14	12	12	11	11	10	10	10	5
Cumulative number of cases													
HPV	0	15	17	17	17	17	17	17	17	17	17	17	17
Control	0	8	11	12	12	13	13	14	14	14	14	14	14