VTE Events/100 PY	2.81	0.00	19.88	0.00	6.12
95% CI	0.07, 15.67	0.00, 2.31	0.50, 110.71	0.00, 32.63	0.16, 34.10

Abbreviations: CGDM = Cegedim; CI = confidence intervals; MTX = methotrexate; N = number of patients in the specified category; PY = person-year; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available.

b Concomitant MTX (methotrexate) use is defined as greater than or equal to 2 dispensings of MTX over the follow-up period

c N (%) of subgroups may not always sum precisely to total group N (%) due to rounding

source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\cegedim\4. Table 6.45. Incidence Rate of Event - VTE, Primary Definition [Cegedim THIN (FR) - France] (1)_vrm.docx

Table 48_CGDM_VRM. Comparative Risk of Incident VTE, Primary Definition [CGDM]

	TNFi	Baricitinib		p-value
		HR	95%CI	
Base Model[1]	Ref	-	-	-
Adjusted – Model [1][2,3]	Ref	>999.999	0, ∞	1.00

Abbreviations: CGDM = Cegedim; CI = confidence interval; HR = Cox proportional hazard ratio; Ref = referent group; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

1 Overall, rare outcome events in the exposed and/or referent groups preclude the calculation of the HR

2 Model [1] = propensity score-matched model with outcome and baricitinib exposure, adjusted for any variables that remain unbalanced after PS matching.

3 Zero events in the TNFi referent group preclude the interpretability of the HR.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\cegedim\4. Table 6.48. Comparative Risk of Incident VTE, Primary Definition [Cegedim THIN (FR) - France]_vrm.docx

Table 54_CGDM_VRM. Incidence Rate of Event - MACE [CGDM]

Model	Unmatched		Matched		
	Baricitinib[a] (N=213)	TNFi (N=813)	Baricitinib[a] (N=26)	TNFi (N=37)	Total (N=63)
Overall					
Person-Years	51.27	366.33	6.63	18.72	25.36
MACE	0	0	0	0	0
MACE/100 PY	0.00	0.00	0.00	0.00	0.00
95% CI	0.00, 7.20	0.00, 1.01	0.00, 55.62	0.00, 19.70	0.00, 14.55

Model	Unmatched		Matched		
	Baricitinib[a] (N=213)	TNFi (N=813)	Baricitinib[a] (N=26)	TNFi (N=37)	Total (N=63)
MI					
MI	0	0	0	0	0
Person-Years	51.27	366.33	6.63	18.72	25.36
IR per100 PY	0.00	0.00	0.00	0.00	0.00
95% CI	0.00, 7.20	0.00, 1.01	0.00, 55.62	0.00, 19.70	0.00, 14.55
Stroke, any					
Stroke	0	0	0	0	0
Person-Years	51.27	366.33	6.63	18.72	25.36
IR per 100 PY	0.00	0.00	0.00	0.00	0.00
95% CI	0.00, 7.20	0.00, 1.01	0.00, 55.62	0.00, 19.70	0.00, 14.55
Concomitant MTX Use[b]					
MACE	0	0	0	0	0
Person-Years	15.69	206.37	4.56	8.50	13.07
IR per 100 PY	0.00	0.00	0.00	0.00	0.00
95% CI	0.00, 23.51	0.00, 1.79	0.00, 80.87	0.00, 43.38	0.00, 28.23
No Concomitant MTX Use[b]					
MACE	0	0	0	0	0
Person-Years	35.58	159.96	2.07	10.22	12.29
IR per 100 PY	0.00	0.00	0.00	0.00	0.00
95% CI	0.00, 10.37	0.00, 2.31	0.00, 178.10	0.00, 36.10	0.00, 30.01

Abbreviations: CGDM = Cegedim; CI = confidence interval; IR = incidence rate; MACE = major adverse cardiovascular event, defined based on primary hospital discharge diagnosis codes for acute myocardial infarction, ischemic or hemorrhagic stroke; MI = Myocardial infarction; MTX = methotrexate; N = number of patients in the specified category; PY = person-years; TNFi = tumour necrosis factor inhibitor.

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

b Concomitant MTX (methotrexate) use is defined as greater than or equal to 2 dispensings of MTX over the follow-up period.

c N in subgroups may not always sum precisely to total group N due to rounding.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\cegedim\4. Table 6.54. Incidence Rate of Event - MACE [Cegedim THIN (FR) - France]_vrm.docx

Table 59_CGDM_VRM. Incidence Rate of Event - First Serious Infection [CGDM]

	Unmatched		Matched		
	Baricitinib[a] (N=218)	**TNFi (N=823)**	**Baricitinib[a] (N=40)**	**TNFi (N=48)**	**Total (N=88)**
SI Events	0	1	0	0	0
Person-years	53.86	371.15	11.00	23.09	34.09
IR per 100 PY	0.00	0.27	0.00	0.00	0.00
95% CI	0.00, 6.85	0.01, 1.50	0.00, 33.54	0.00, 15.98	0.00, 10.82

Abbreviations: CGDM = Cegedim; CI = confidence interval; IR = incidence rate; N = number of patients in the specified category; PY = person-years; SI = serious infection; TNFi = tumour necrosis factor inhibitor.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\cegedim\4. Table 6.59. Incidence Rate of Event - First Serious Infection [Cegedim THIN (FR) RA]_vrm.docx

Annex 14. CorEvitas Japan – Additional Results

This annex includes information about results for the following analyses:

I. Additional analysis
These additional results were not presented in the body of the report. These results, like those included in the report body, are based on 1:1 baricitinib:TNFi propensity score matching. Specifically, this section of the annex includes:
- Descriptive tables for unmatched eligible patients.
- Descriptive tables for matched patient cohorts for the serious infection analyses

II. Variable Ratio Matching
These results were not presented in the body of this report. They are based on matching baricitinib:TNFi using Variable Ratio matching, i.e., as many matched 1:3 as possible, then the maximum number matched 1:2, then the remaining patients matched 1:1.

I. Additional Analyses

Table 1_Cor_JP. Baseline Demographics, Pre-matched Population [COR_JP]

	Baricitinib			TNFi	
	Any (N=210)	2mg (N=21)	4mg (N=184)	(N=354)	Std. Diff (Any vs TNFi)
Age [yrs]					
n	210	21	184	354	0.103
Mean ± SD	60.3 ±13.1	70.3 ± 8.9	59.1 ±13.2	61.8 ±15.1	
Median	62.0	71.0	61.0	64.0	
Min, Max	25.0, 85.0	50.0, 84.0	25.0, 85.0	20.0, 90.0	
≥ 65 years	90 (42.9%)	15 (71.4%)	73 (39.7%)	172 (48.6%)	0.115
Gender					
Male	32 (15.4%)	0 (0.0%)	32 (17.6%)	77 (21.8%)	0.166
Female	176 (84.6%)	21 (100.0%)	150 (82.4%)	276 (78.2%)	
BMI					
n	202	17	181	331	0.132
Mean ± SD	23.1 ± 4.6	21.8 ± 4.5	23.1 ± 4.5	22.5 ± 3.8	
Median	22.0	22.0	21.9	22.1	
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1	
Smoking (current)	31 (14.9%)	4 (19.0%)	26 (14.3%)	32 (9.2%)	0.176
Alcohol use	82 (39.0%)	8 (38.1%)	73 (39.7%)	156 (44.1%)	0.102
Education					
Primary	21 (10.0%)	4 (19.0%)	16 (8.7%)	46 (13.0%)	0.094
High School	120 (57.1%)	13 (61.9%)	104 (56.5%)	192 (54.2%)	0.059
College/University	58 (27.6%)	3 (14.3%)	54 (29.3%)	101 (28.5%)	0.020

Abbreviations: BMI = body mass index; COR_JP = CorEvitas Japan; Max = maximum; Min = minimum; N = count of patients in specified category; SD = standard deviation; Std Diff = absolute value of the standardised difference; TNFi = tumour necrosis factor inhibitor.

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Table 4_Cor_JP. Baseline Demographics, Serious infection-matched Population - also excludes patients with a serious infection within 6 months prior to index date [COR_JP]

	Baricitinib			TNFi		
	Any (N=170)	2mg (N=15)	4mg (N=154)	(N=170)	Std. Diff (Any vs TNFi)	Total (N=340)
Age [yrs]						
n	170	15	154	170	0.045	340
Mean ± SD	60.6 ±13.8	71.6 ± 8.1	59.4 ±13.8	61.2 ±15.2		60.9 ±14.5
Median	62.5	73.0	62.0	63.0		63.0
Min, Max	25.0, 85.0	56.0, 84.0	25.0, 85.0	22.0, 84.0		22.0, 85.0
≥ 65 years	78 (45.9%)	12 (80.0%)	65 (42.2%)	81 (47.6%)	0.035	159 (46.8%)
Gender						
Male	25 (14.7%)	0 (0.0%)	25 (16.2%)	32 (18.8%)	0.110	57 (16.8%)
Female	145 (85.3%)	15 (100.0%)	129 (83.8%)	138 (81.2%)		283 (83.2%)
BMI						
n	170	15	154	170	0.017	340
Mean ± SD	22.8 ± 4.5	21.6 ± 4.4	22.8 ± 4.5	22.8 ± 4.2		22.8 ± 4.4
Median	21.8	22.0	21.8	22.2		22.0
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1		14.3, 47.1
Smoking (current)	16 (9.4%)	2 (13.3%)	14 (9.1%)	21 (12.4%)	0.095	37 (10.9%)
Alcohol use	67 (39.4%)	7 (46.7%)	60 (39.0%)	70 (41.2%)	0.036	137 (40.3%)
Education						
Primary	15 (8.8%)	2 (13.3%)	13 (8.4%)	17 (10.0%)	0.040	32 (9.4%)
High School	99 (58.2%)	9 (60.0%)	89 (57.8%)	98 (57.6%)	0.012	197 (57.9%)
College/University	47 (27.6%)	3 (20.0%)	44 (28.6%)	46 (27.1%)	0.013	93 (27.4%)

Abbreviations: BMI = body mass index; COR_JP = CorEvitas Japan; Max = maximum; Min = minimum; N = count of patients in specified categor; SD = standard deviation; Std Diff = absolute value of the standardised difference; TNFi = tumour necrosis factor inhibitor.

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Table 6_Cor_JP. Baseline Clinical Characteristics, Pre-matched Population [COR_JP]

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	10 (4.8%)	27 (7.6%)	0.119
Cancer, NMSC only	0 (0.0%)	1 (0.3%)	0.075
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	19 (9.0%)	39 (11.0%)	0.066
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.5%)	3 (0.8%)	0.046
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.4%)	7 (2.0%)	0.042
Cardiovascular revascularization	2 (1.0%)	1 (0.3%)	0.086
Congestive heart failure (hospitalized)	1 (0.5%)	2 (0.6%)	0.012
Coronary artery disease	0 (0.0%)	2 (0.6%)	0.107
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	5 (2.4%)	6 (1.7%)	0.049
TIA	0 (0.0%)	0 (0.0%)	
Unstable angina	0 (0.0%)	3 (0.8%)	0.131
Ventricular arrhythmia	0 (0.0%)	1 (0.3%)	0.075
Diabetes mellitus	27 (12.9%)	29 (8.2%)	0.152
Hyperlipidemia	28 (13.3%)	50 (14.1%)	0.023
Hypertension (hospitalized & non-hospitalized)	59 (28.1%)	106 (29.9%)	0.041
Immune disorders	16 (7.6%)	36 (10.2%)	0.090
Secondary Sjogren Syndrome	16 (7.6%)	36 (10.2%)	0.090
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	4 (1.9%)	2 (0.6%)	0.122
Obesity, current	18 (8.9%)	13 (3.9%)	0.204
Pregnancy, recent (current or since last visit)	0 (0.0%)	2 (0.6%)	0.107
Smoking (current)	31 (14.9%)	32 (9.2%)	0.176
RA severity (CDAI)			
n	198	338	0.122
Mean ± SD	23.8 ±12.9	22.3 ±12.9	
Median	21.8	20.0	
Min, Max	1.0, 64.2	0.5, 67.2	
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	7 (2.0%)	0.201

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
MACE (at any time in the past)	8 (3.8%)	7 (2.0%)	0.109
Myocardial infarction	3 (1.4%)	4 (1.1%)	0.027
Stroke	5 (2.4%)	3 (0.8%)	0.122
Serious infection (at any time in the past)	23 (11.0%)	36 (10.2%)	0.025
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	
DMARD history			
Number of cDMARDs used(ever)			
0	18 (8.6%)	25 (7.1%)	0.056
1	145 (69.0%)	245 (69.2%)	0.003
2+	47 (22.4%)	84 (23.7%)	0.032
Methotrexate (prior use)	180 (85.7%)	312 (88.1%)	0.072
Number of bDMARDs used (ever)			
0	72 (34.3%)	254 (71.8%)	0.810
1	61 (29.0%)	65 (18.4%)	0.253
2+	77 (36.7%)	35 (9.9%)	0.668
Prior bDMARD use[a]	138 (65.7%)	100 (28.2%)	0.810
Prior TNFi bDMARD use	111 (52.9%)	57 (16.1%)	0.839
Prior non-TNFi bDMARD use	87 (41.4%)	67 (18.9%)	0.506
DMARD, current (baseline)			
cDMARD, concomitant use at baseline	123 (58.6%)	271 (76.6%)	0.391
Methotrexate (current use)	110 (52.4%)	254 (71.8%)	0.407
Prescription medication use, current (baseline)			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	2 (1.0%)	6 (1.7%)	0.064
Antihypertensives (blood pressure lowering medication(s); patient-reported)	50 (23.8%)	93 (26.3%)	0.057
Antiplatelet (Plavix; patient-reported)	2 (1.0%)	5 (1.4%)	0.042
Nitrates (angina/nitrate medications; patient-reported)	2 (1.0%)	3 (0.8%)	0.011
Lipid-lowering agents (cholesterol medication; patient-reported)	35 (17.2%)	55 (15.8%)	0.036
RA-related			
Aspirin (includes non-prescription)	3 (1.5%)	9 (2.6%)	0.079
Prednisone	48 (22.9%)	102 (28.8%)	0.136
Vaccinations			
Shingles (ever)	2 (1.0%)	3 (0.8%)	0.011

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = conventional disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; COR_JP = CorEvitas Japan; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; N = count of patients in specified category; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardised difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

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Table 9_Cor_JP. Baseline Clinical Characteristics, Serious infection-matched Population - also excludes patients with serious infection within 6 months prior to index date [COR_JP]

	Baricitinib (N=170)	TNFi (N=170)	Std. Diff.	Total (N=340)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	8 (4.7%)	16 (9.4%)	0.185	24 (7.1%)
Cancer, NMSC only	0 (0.0%)	1 (0.6%)	0.109	1 (0.3%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	16 (9.4%)	15 (8.8%)	0.020	31 (9.1%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.6%)	1 (0.6%)	0.000	2 (0.6%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.8%)	4 (2.4%)	0.041	7 (2.1%)
Cardiovascular revascularization	2 (1.2%)	0 (0.0%)	0.154	2 (0.6%)
Congestive heart failure (hospitalized)	1 (0.6%)	1 (0.6%)	0.000	2 (0.6%)
Coronary artery disease	0 (0.0%)	1 (0.6%)	0.109	1 (0.3%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	4 (2.4%)	3 (1.8%)	0.041	7 (2.1%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	2 (1.2%)	0.154	2 (0.6%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)		0 (0.0%)
Diabetes mellitus	18 (10.6%)	21 (12.4%)	0.055	39 (11.5%)
Hyperlipidemia	22 (12.9%)	24 (14.1%)	0.034	46 (13.5%)
Hypertension (hospitalized & non-hospitalized)	48 (28.2%)	57 (33.5%)	0.115	105 (30.9%)
Immune disorders	14 (8.2%)	15 (8.8%)	0.021	29 (8.5%)
Secondary Sjogren Syndrome	14 (8.2%)	15 (8.8%)	0.021	29 (8.5%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (0.6%)	1 (0.6%)	0.000	2 (0.6%)
Obesity, current	14 (8.2%)	9 (5.3%)	0.117	23 (6.8%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	1 (0.6%)	0.109	1 (0.3%)
Smoking (current)	16 (9.4%)	21 (12.4%)	0.095	37 (10.9%)
RA severity (CDAI)				
n	170	170	0.027	340
Mean ± SD	23.5 ±13.1	23.9 ±14.1		23.7 ±13.6
Median	20.9	20.5		20.5
Min, Max	1.0, 64.2	0.5, 67.2		0.5, 67.2
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	4 (2.4%)	0.220	4 (1.2%)
MACE (at any time in the past)	4 (2.4%)	4 (2.4%)	0.000	8 (2.4%)
Myocardial infarction	2 (1.2%)	2 (1.2%)	0.000	4 (1.2%)
Stroke	2 (1.2%)	2 (1.2%)	0.000	4 (1.2%)

	Baricitinib (N=170)	TNFi (N=170)	Std. Diff.	Total (N=340)
Serious infection (at any time in the past)	17 (10.0%)	13 (7.6%)	0.083	30 (8.8%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used (ever)				
0	14 (8.2%)	14 (8.2%)	0.000	28 (8.2%)
1	119 (70.0%)	112 (65.9%)	0.088	231 (67.9%)
2+	37 (21.8%)	44 (25.9%)	0.097	81 (23.8%)
Methotrexate (prior use)	145 (85.3%)	148 (87.1%)	0.051	293 (86.2%)
Number of bDMARDs used (ever)				
0	68 (40.0%)	88 (51.8%)	0.238	156 (45.9%)
1	50 (29.4%)	52 (30.6%)	0.026	102 (30.0%)
2+	52 (30.6%)	30 (17.6%)	0.306	82 (24.1%)
Prior bDMARD use[a]	102 (60.0%)	82 (48.2%)	0.238	184 (54.1%)
Prior TNFi bDMARD use	78 (45.9%)	50 (29.4%)	0.345	128 (37.6%)
Prior non-TNFi bDMARD use	63 (37.1%)	54 (31.8%)	0.112	117 (34.4%)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	102 (60.0%)	119 (70.0%)	0.211	221 (65.0%)
Methotrexate (current use)	92 (54.1%)	113 (66.5%)	0.255	205 (60.3%)
Prescription medication use, current (baseline)				
Cardiovascular medications				
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	3 (1.8%)	0.190	3 (0.9%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	40 (23.5%)	49 (28.8%)	0.121	89 (26.2%)
Antiplatelet (Plavix; patient-reported)	1 (0.6%)	1 (0.6%)	0.000	2 (0.6%)
Nitrates (angina/nitrate medications; patient-reported)	2 (1.2%)	1 (0.6%)	0.063	3 (0.9%)
Lipid-lowering agents (cholesterol medication; patient-reported)	29 (17.1%)	30 (17.6%)	0.016	59 (17.4%)
RA-related				
Aspirin (includes non-prescription)	2 (1.2%)	5 (2.9%)	0.125	7 (2.1%)
Prednisone	40 (23.5%)	42 (24.7%)	0.028	82 (24.1%)
Vaccinations				
Shingles (ever)	1 (0.6%)	0 (0.0%)	0.109	1 (0.3%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = conventional disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; Cor_JP = CorEvitas Japan; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardised difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

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Table 16_Cor_JP. Baseline Prevalence of Outcomes [COR_JP]

	Pre-matched			Matched*			
	Baricitinib events (%)/N	TNFi events (%)/N	Std. Diff.	Baricitinib events (%)/N	TNFi events (%)/N	Std. Diff	Total events (%)/N
VTE	0 (0.0%)/210	7 (2.0%)/354	0.201	0 (0.0%)/171	0 (0.0%)/171		0 (0%)/342
MACE	8 (3.8%)/210	7 (2.0%)/354	0.109	4 (2.4%)/168	3 (1.8%)/168	0.042	7 (2.1%)/336
Serious Infection	23 (11.0%)/210	37 (10.5%)/354	0.025	17 (10.0%)/170	13 (7.6%)/170	0.083	30 (8.8%)/340

Abbreviations: Cor_JP = CorEvitas Japan; MACE = major adverse cardiovascular event; N = count of patients in specified category; Std. Diff. = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

* Matched refers to the outcome-specific matched population

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Table 17_Cor_JP. Duration of Exposure (Days), in Pre-matched Population – exposure ends at discontinuation/last follow-up visit [COR_JP]

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
N	210	354	
Mean ± SD	402.7 ±259.5	554.0 ±341.9	0.498
Median	371.0	551.0	
Min, Max	9.0, 1071.0	14.0, 1263.0	

Abbreviations: Cor_JP = CorEvitas Japan; Max = maximum; Min = minimum; N = count of patients in specified category; SD = standard deviation; Std Diff = absolute value of standardised difference; TNFi = tumour necrosis factor inhibitor.

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Table 18_Cor_JP. Duration of Exposure (Days), in VTE-matched Population – exposure ends at discontinuation/last follow-up visit; excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant [COR_JP]

	Baricitinib (N=171)	TNFi (N=171)	Std. Diff.
N	171	171	
Mean ± SD	426.1 ±253.2	529.2 ±348.4	0.339
Median	385.0	491.0	
Min, Max	12.0, 1071.0	14.0, 1225.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	13 (8%)	30 (18%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	17 (10%)	44 (26%)	
End of follow-up for that patient	141 (82%)	97 (57%)	
Death	n/a	n/a	
Incident event (VTE)	0	0	

Abbreviations: Cor_JP = CorEvitas Japan; Max = maximum; Min = minimum; N = count of patients in specified category; n/a = not available; SD = standard deviation; Std Diff = absolute value of standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

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Table 21_Cor_JP. Duration of Exposure (Days), in MACE-matched Population – exposure ends at discontinuation/last follow-up visit; excludes patients with MACE within 6 months prior to index date or taking anticoagulant [COR_JP]

	Baricitinib (N=168)	TNFi (N=168)	Std. Diff.
N	168	209	
Mean ± SD	422.4 ±253.8	508.0 ±344.0	0.283
Median	385.0	486.5	
Min, Max	12.0, 1071.0	14.0, 1210.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	13 (8%)	27 (16%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	17 (10%)	43 (26%)	
End of follow-up for that patient	138 (82%)	98 (58%)	
Death	n/a	n/a	
Incident event (MACE)	0	0	

Abbreviations: b/tsDMARD = biologic or targeted synthetic disease-modifying antirheumatic drug; Cor_JP = CorEvitas Japan; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardised difference; TNFi = tumour necrosis factor inhibitor.

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Table 22_Cor_JP. Duration of Exposure (Days), in Serious Infection-matched Population - exposure ends at discontinuation/last follow-up visit; excludes patients with serious infection within 6 months prior to index date [COR_JP]

	Baricitinib (N=170)	TNFi (N=170)	Std. Diff.
N	170	170	
Mean ± SD	419.2 ±254.3	510.0 ±338.7	0.303
Median	381.5	486.5	
Min, Max	12.0, 1071.0	14.0, 1210.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	10 (6%)	28 (16%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	18 (11%)	42 (25%)	
End of follow-up for that patient	133 (78%)	94 (55%)	
Death	n/a	n/a	
Incident event (serious Infection)	9 (5%)	6 (4%)	

Abbreviations: b/tsDMARD = biologic or targeted synthetic disease-modifying antirheumatic drug; Cor_JP = CorEvitas Japan; Max = maximum; Min = minimum; N =; n/a = not applicable; SD = standard deviation; Std Diff = absolute value of standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism

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Table 24_Cor_JP. Baseline Clinical Characteristics by Exposure Duration, Pre-matched Population - exposure ends at discontinuation/last follow-up visit [COR_JP]

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N=52)	TNFi (N=71)	Std. Diff.	Baricitinib (N=52)	TNFi (N=54)	Std. Diff.	Baricitinib (N=77)	TNFi (N=108)	Std. Diff.	Baricitinib (N=29)	TNFi (N=121)	Std. Diff.
Age [yrs]												
n	52	71	0.20	52	54	0.08	77	108	0.13	29	121	0.01
Mean ± SD	58.5 ± 14.6	61.4 ± 14.0		61.1 ± 12.1	62.4 ± 17.6		60.7 ± 13.0	62.5 ± 14.7		61.2 ± 12.6	61.1 ± 15.0	
Median	61.5	65.0		61.5	68.5		64.0	64.5		65.0	63.0	
Min, Max	25.0, 84.0	20.0, 90.0		34.0, 83.0	22.0, 90.0		30.0, 85.0	25.0, 88.0		38.0, 82.0	25.0, 84.0	
≥ 65 years	21 (40.4%)	36 (50.7%)	0.21	20 (38.5%)	28 (51.9%)	0.27	34 (44.2%)	54 (50.0%)	0.12	15 (51.7%)	54 (44.6%)	0.14
Gender												
Male	5 (9.6%)	13 (18.6%)	0.26	8 (15.7%)	10 (18.5%)	0.08	12 (15.6%)	23 (21.3%)	0.15	7 (25.0%)	31 (25.6%)	0.01
Female	47 (90.4%)	57 (81.4%)		43 (84.3%)	44 (81.5%)		65 (84.4%)	85 (78.7%)		21 (75.0%)	90 (74.4%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (1.9%)	7 (9.9%)	0.34	2 (3.8%)	4 (7.4%)	0.16	1 (1.3%)	8 (7.4%)	0.30	6 (20.7%)	8 (6.6%)	0.42
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	5 (9.6%)	4 (5.6%)	0.15	6 (11.5%)	8 (14.8%)	0.10	5 (6.5%)	15 (13.9%)	0.25	3 (10.3%)	12 (9.9%)	0.01
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.9%)	0.19	1 (1.3%)	1 (0.9%)	0.04	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N=52)	TNFi (N=71)	Std. Diff.	Baricitinib (N=52)	TNFi (N=54)	Std. Diff.	Baricitinib (N=77)	TNFi (N=108)	Std. Diff.	Baricitinib (N=29)	TNFi (N=121)	Std. Diff.
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (1.9%)	3 (4.2%)	0.13	1 (1.9%)	1 (1.9%)	0.01	1 (1.3%)	2 (1.9%)	0.04	0 (0.0%)	1 (0.8%)	0.13
Cardiovascular revascularization	1 (1.9%)	0 (0.0%)	0.20	1 (1.9%)	0 (0.0%)	0.20	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Congestive heart failure (hospitalized)	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.9%)	0.19	1 (1.3%)	0 (0.0%)	0.16	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (3.8%)	2 (2.8%)	0.06	2 (3.8%)	1 (1.9%)	0.12	0 (0.0%)	1 (0.9%)	0.14	1 (3.4%)	2 (1.7%)	0.11
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	1 (0.8%)	0.13
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	3 (5.8%)	6 (8.5%)	0.10	4 (7.7%)	6 (11.1%)	0.12	15 (19.5%)	10 (9.3%)	0.29	5 (17.2%)	7 (5.8%)	0.36
Hyperlipidemia	6 (11.5%)	8 (11.3%)	0.01	6 (11.5%)	9 (16.7%)	0.15	13 (16.9%)	18 (16.7%)	0.01	3 (10.3%)	15 (12.4%)	0.06

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N=52)	TNFi (N=71)	Std. Diff.	Baricitinib (N=52)	TNFi (N=54)	Std. Diff.	Baricitinib (N=77)	TNFi (N=108)	Std. Diff.	Baricitinib (N=29)	TNFi (N=121)	Std. Diff.
Hypertension (hospitalized & non-hospitalized)	12 (23.1%)	14 (19.7%)	0.08	15 (28.8%)	21 (38.9%)	0.21	23 (29.9%)	33 (30.6%)	0.01	9 (31.0%)	38 (31.4%)	0.01
Immune disorders	1 (1.9%)	5 (7.0%)	0.25	3 (5.8%)	6 (11.1%)	0.19	10 (13.0%)	10 (9.3%)	0.12	2 (6.9%)	15 (12.4%)	0.19
Secondary Sjogren Syndrome	1 (1.9%)	5 (7.0%)	0.25	3 (5.8%)	6 (11.1%)	0.19	10 (13.0%)	10 (9.3%)	0.12	2 (6.9%)	15 (12.4%)	0.19
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	2 (2.8%)	0.24	1 (1.9%)	0 (0.0%)	0.20	2 (2.6%)	0 (0.0%)	0.23	1 (3.4%)	0 (0.0%)	0.27
Obesity, current	7 (14.0%)	3 (4.5%)	0.33	3 (6.1%)	3 (5.9%)	0.01	6 (8.0%)	3 (3.1%)	0.22	2 (7.1%)	4 (3.4%)	0.17
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.9%)	0.19	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Smoking (current)	8 (15.4%)	11 (15.5%)	0.00	10 (19.2%)	4 (7.8%)	0.34	10 (13.2%)	9 (8.3%)	0.16	3 (10.7%)	8 (6.8%)	0.14
RA severity (CDAI)												
n	44	68	0.22	49	52	0.09	76	100	0.02	29	118	0.30
Mean ± SD	25.5 ± 12.5	22.8 ± 11.3		22.0 ± 12.8	20.8± 12.9		23.3± 12.7	23.0± 14.9		25.9 ± 14.5	22.0± 12.1	
Median	22.9	22.1		20.0	16.4		22.0	18.9		22.0	19.8	
Min, Max	4.4, 55.0	5.5, 67.2		1.0, 64.2	3.0, 58.3		1.4, 57.3	0.5, 65.5		3.5, 60.0	0.5, 59.7	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.9%)	0.19	0 (0.0%)	4 (3.7%)	0.28	0 (0.0%)	1 (0.8%)	0.13
MACE (at any time in the past)	1 (1.9%)	2 (2.8%)	0.06	2 (3.8%)	1 (1.9%)	0.12	4 (5.2%)	0 (0.0%)	0.33	1 (3.4%)	4 (3.3%)	0.01
Myocardial infarction	0 (0.0%)	1 (1.4%)	0.17	2 (3.8%)	1 (1.9%)	0.12	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	2 (1.7%)	0.11
Stroke	1 (1.9%)	1 (1.4%)	0.04	0 (0.0%)	0 (0.0%)	-	4 (5.2%)	0 (0.0%)	0.33	0 (0.0%)	2 (1.7%)	0.18
Serious infection (at any time in the past)	7 (13.5%)	7 (9.9%)	0.11	4 (7.7%)	4 (7.4%)	0.01	9 (11.7%)	13 (12.0%)	0.01	3 (10.3%)	12 (9.9%)	0.01

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N=52)	TNFi (N=71)	Std. Diff.	Baricitinib (N=52)	TNFi (N=54)	Std. Diff.	Baricitinib (N=77)	TNFi (N=108)	Std. Diff.	Baricitinib (N=29)	TNFi (N=121)	Std. Diff.
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	5 (9.6%)	7 (9.9%)	0.01	5 (9.6%)	5 (9.3%)	0.01	5 (6.5%)	9 (8.3%)	0.07	3 (10.3%)	6 (5.0%)	0.20
1	35 (67.3%)	46 (64.8%)	0.05	38 (73.1%)	34 (63.0%)	0.22	53 (68.8%)	73 (67.6%)	0.03	19 (65.5%)	90 (74.4%)	0.19
2+	12 (23.1%)	18 (25.4%)	0.05	9 (17.3%)	15 (27.8%)	0.25	19 (24.7%)	26 (24.1%)	0.01	7 (24.1%)	25 (20.7%)	0.08
Number of bDMARDs used (ever)												
0	11 (21.2%)	48 (67.6%)	1.06	19 (36.5%)	33 (61.1%)	0.51	31 (40.3%)	75 (69.4%)	0.61	11 (37.9%)	98 (81.0%)	0.98
1	15 (28.8%)	10 (14.1%)	0.37	19 (36.5%)	14 (25.9%)	0.23	22 (28.6%)	23 (21.3%)	0.17	5 (17.2%)	18 (14.9%)	0.06
2+	26 (50.0%)	13 (18.3%)	0.71	14 (26.9%)	7 (13.0%)	0.35	24 (31.2%)	10 (9.3%)	0.57	13 (44.8%)	5 (4.1%)	1.07
Prior bDMARD use[a]	41 (78.8%)	23 (32.4%)	1.06	33 (63.5%)	21 (38.9%)	0.51	46 (59.7%)	33 (30.6%)	0.61	18 (62.1%)	23 (19.0%)	0.98
Prior TNFi bDMARD use	38 (73.1%)	13 (18.3%)	1.32	25 (48.1%)	13 (24.1%)	0.52	34 (44.2%)	18 (16.7%)	0.63	14 (48.3%)	13 (10.7%)	0.90
Prior non-TNFi bDMARD use	25 (48.1%)	18 (25.4%)	0.49	18 (34.6%)	13 (24.1%)	0.23	30 (39.0%)	22 (20.4%)	0.42	14 (48.3%)	14 (11.6%)	0.87
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	26 (50.0%)	51 (71.8%)	0.46	26 (50.0%)	39 (72.2%)	0.47	51 (66.2%)	83 (76.9%)	0.24	20 (69.0%)	98 (81.0%)	0.28
Methotrexate (current use)	26 (50.0%)	47 (66.2%)	0.33	26 (50.0%)	36 (66.7%)	0.34	43 (55.8%)	79 (73.1%)	0.37	15 (51.7%)	92 (76.0%)	0.52
Prescription medication use, current (baseline)												
Cardiovascular medications												

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N=52)	TNFi (N=71)	Std. Diff.	Baricitinib (N=52)	TNFi (N=54)	Std. Diff.	Baricitinib (N=77)	TNFi (N=108)	Std. Diff.	Baricitinib (N=29)	TNFi (N=121)	Std. Diff.
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	2 (2.9%)	0.24	1 (2.0%)	2 (3.7%)	0.11	1 (1.3%)	1 (1.0%)	0.03	0 (0.0%)	1 (0.8%)	0.13
Antihypertensives (blood pressure lowering medication(s); patient-reported)	9 (17.3%)	15 (21.1%)	0.10	12 (23.1%)	16 (29.6%)	0.15	20 (26.0%)	25 (23.1%)	0.07	9 (31.0%)	37 (30.6%)	0.01
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	2 (2.6%)	2 (1.9%)	0.05	0 (0.0%)	3 (2.5%)	0.23
Nitrates (angina/nitrate medications; patient-reported)	1 (1.9%)	1 (1.4%)	0.04	0 (0.0%)	1 (1.9%)	0.19	0 (0.0%)	1 (0.9%)	0.14	1 (3.4%)	0 (0.0%)	0.27
Lipid-lowering agents (cholesterol medication; patient-reported)	6 (12.8%)	13 (18.6%)	0.16	9 (17.6%)	10 (18.5%)	0.02	15 (19.5%)	17 (16.3%)	0.08	5 (17.2%)	15 (12.5%)	0.13
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	5 (7.1%)	0.39	2 (3.9%)	1 (1.9%)	0.12	0 (0.0%)	1 (1.0%)	0.14	1 (3.4%)	2 (1.7%)	0.11
Prednisone	11 (21.2%)	24 (33.8%)	0.29	11 (21.2%)	10 (18.5%)	0.07	19 (24.7%)	30 (27.8%)	0.07	7 (24.1%)	38 (31.4%)	0.16
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (1.9%)	0 (0.0%)	0.20	1 (1.3%)	2 (1.9%)	0.04	0 (0.0%)	1 (0.8%)	0.13

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = conventional disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; Cor_JP = CorEvitas Japan; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; MD = doctor of medicine ; Min = minimum; N = count of patients in specified category; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardised difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

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Table 52_Cor_JP. Pattern of RA Medication Use in Patients with MACE - excludes patients with a MACE within 6 months prior to index date or on anticoagulant [COR_JP]

	Pre-matched		Matched		
	Baricitinib (N=1)	TNFi (N=0)	Baricitinib (N=0)	TNFi (N=0)	Total (N=0)
Baseline Medication					
Number of cDMARDs used (ever)					
0	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
1	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
2+	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Methotrexate (prior use)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Number of bDMARDs used (ever)					
0	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
1	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
2+	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Concomitant non-methotrexate cDMARD use at baseline	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Concomitant methotrexate use at baseline	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Prior bDMARD use[a]	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Prior TNFi bDMARD use	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Prior non-TNFi bDMARD use	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Post-index Medication					
Concomitant methotrexate use during exposure (regardless of use at index date)	1(100.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Concomitant non-methotrexate cDMARD use during exposure (regardless of use at index date)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)
Baricitinib dose change during exposure	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)	0(0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; cDMARD = conventional disease-modifying antirheumatic drugs; Cor_JP = CorEvitas Japan; MACE = major adverse cardiovascular event; N = count of patients in specified category; RA = rheumatoid arthritis; TNFi = tumour necrosis factor inhibitor.

[a] Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table

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Table 53_Cor_JP. Time to First MACE (Days) [COR_JP]

	Pre-matched		Matched		
	Baricitinib (N=1)	**TNFi (N=0)**	**Baricitinib (N=0)**	**TNFi (N=0)**	**Total (N=0)**
n	1	0	0	0	0
Mean ± SD	35.0 ±.	n/a	n/a	n/a	n/a
Median	35.0				
Min, Max	35.0, 35.0				
25th, 75th percentile	35.0, 35.0				

Abbreviations: Cor_JP = CorEvitas Japan; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; N = count of patients in specified category; n/a = not applicable; SD = standard deviation; TNFi = tumour necrosis factor inhibitor

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Table 56_Cor_JP. Baseline Clinical Characteristics of Patients with Serious Infection, Serious Infection-matched Population – excludes patients with a serious infection within 6 months prior to index date [COR_JP]

	Baricitinib (N=9)	TNFi (N=6)	Total (N=15)
Age [yrs]			
n	9	6	15
Mean ± SD	68.9 ±13.7	66.7 ± 5.3	68.0 ±10.9
Median	73.0	67.0	70.0
Min, Max	39.0, 81.0	58.0, 74.0	39.0, 81.0
Gender			
Male	2 (22.2%)	1 (16.7%)	3 (20.0%)
Female	7 (77.8%)	5 (83.3%)	12 (80.0%)
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	0 (0.0%)	1 (16.7%)	1 (6.7%)
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	0 (0.0%)	2 (33.3%)	2 (13.3%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure (hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes mellitus	0 (0.0%)	2 (33.3%)	2 (13.3%)
Hyperlipidemia	0 (0.0%)	1 (16.7%)	1 (6.7%)
Hypertension (hospitalized & non-hospitalized)	4 (44.4%)	2 (33.3%)	6 (40.0%)
Immune disorders	0 (0.0%)	2 (33.3%)	2 (13.3%)
Secondary Sjogren Syndrome	0 (0.0%)	2 (33.3%)	2 (13.3%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Obesity, current	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Baricitinib (N=9)	TNFi (N=6)	Total (N=15)
Smoking (current)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RA severity (CDAI)			
n	9	6	15
Mean ± SD	22.7 ±15.5	25.2 ±11.1	23.7 ±13.5
Median	18.0	26.8	21.3
Min, Max	8.5, 60.0	6.7, 39.5	6.7, 60.0
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	1 (16.7%)	1 (6.7%)
MACE (at any time in the past)	1 (11.1%)	0 (0.0%)	1 (6.7%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stroke	1 (11.1%)	0 (0.0%)	1 (6.7%)
Serious infection (at any time in the past)	3 (33.3%)	2 (33.3%)	5 (33.3%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prescription medication use, current (baseline)			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	1 (11.1%)	1 (16.7%)	2 (13.3%)
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nitrates (angina/nitrate medications; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents (cholesterol medication; patient-reported)	3 (33.3%)	1 (16.7%)	4 (26.7%)
RA-related			
Aspirin (includes non-prescription)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate (current use)	3 (33.3%)	6 (100.0%)	9 (60.0%)
Prednisone	2 (22.2%)	4 (66.7%)	6 (40.0%)
Vaccinations			
Shingles (ever)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: CDAI = clinical disease activity index; cDMARD = conventional disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; Cor_JP = CorEvitas Japan; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; N = count of patients in specified category ; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

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Table 57_Cor_JP. Pattern of RA Medication Use in Patients with Serious Infection – excludes patients with a serious infection within 6 months prior to index date [COR_JP]

	Pre-matched		Matched		
	Baricitinib (N=11)	TNFi (N=15)	Baricitinib (N=9)	TNFi (N=6)	Total (N=15)
Baseline Medication					
BDMARD history					
Number of cDMARDs used (event)					
0	1 (9.1%)	1 (6.7%)	1 (11.1%)	0 (0.0%)	1 (6.7%)
1	9 (81.8%)	9 (60.0%)	7 (77.8%)	3 (50.0%)	10 (66.7%)
2+	1 (9.1%)	5 (33.3%)	1 (11.1%)	3 (50.0%)	4 (26.7%)
Methotrexate (prior use)	9 (81.8%)	13 (86.7%)	7 (77.8%)	6 (100.0%)	13 (86.7%)
Number of bDAMRDs used (ever)					
0	4 (36.4%)	11 (73.3%)	3 (33.3%)	3 (50.0%)	6 (40.0%)
1	1 (9.1%)	2 (13.3%)	1 (11.1%)	1 (16.7%)	2 (13.3%)
2+	6 (54.5%)	2 (13.3%)	5 (55.6%)	2 (33.3%)	7 (46.7%)
Prior bDMARD use[a]	7 (63.6%)	4 (26.7%)	6 (66.7%)	3 (50.0%)	9 (60.0%)
Prior TNFi bDMARD use	6 (54.5%)	3 (20.0%)	5 (55.6%)	3 (50.0%)	8 (53.3%)
Prior non-TNFi bDMARD use	5 (45.5%)	3 (20.0%)	5 (55.6%)	2 (33.3%)	7 (46.7%)
BDMARD, current (baseline)					
Concomittant non-methotrexate cDMARD use at baseline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant methotrexate use at baseline	4 (36.4%)	13 (86.7%)	3 (33.3%)	6 (100.0%)	9 (60.0%)
Post-index Medication					
Concomitant methotrexate use during exposure (regardless of use at index date)	5 (45.5%)	13 (86.7%)	4 (44.4%)	6 (100.0%)	10 (66.7%)
Concomitant non-methotrexate cDMARD use during exposure (regardless of use at index date)	0 (0.0%)	2 (13.3%)	0 (0.0%)	1 (16.7%)	1 (6.7%)
Baricitinib dose change during exposure	0 (0.0%)	2 (13.3%)	0 (0.0%)	2 (33.3%)	2 (13.3%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; cDMARD = conventional disease-modifying antirheumatic drugs; Cor_JP = CorEvitas Japan; MACE = major adverse cardiovascular event; N = count of patients in specified category ; RA = rheumatoid arthritis; TNFi = tumour necrosis factor inhibitor.

a Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table

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Table 58_Cor_JP. Time to First Serious Infection Event (Days) [COR_JP]

	Pre-matched		Matched		
	Baricitinib	**TNFi**	**Baricitinib**	**TNFi**	**Total**
	(N=11)	**(N=15)**	**(N=9)**	**(N=6)**	**(N=15)**
n	11	15	9	6	15
Mean ± SD	208.1 ±249.3	338.3 ±301.0	210.7 ±278.3	409.5 ±253.4	290.2 ±278.1
Median	128.0	300.0	108.0	361.0	153.0
Min, Max	40.0, 902.0	41.0, 903.0	40.0, 902.0	41.0, 716.0	40.0, 902.0
25th, 75th percentile	51.0, 223.0	70.0, 678.0	51.0, 153.0	300.0, 678.0	51.0, 396.0

Abbreviations: Cor_JP = CorEvitas Japan; Min = minimum; Max = maximum; N = count of patients in specified category; SD = standard deviation; TNFi = tumour necrosis factor inhibitor

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Table 68_Cor_JP. Incidence Rates of VTE, by Dose. Pre-matched VTE population [COR_JP]

	Baricitinib 2mg (N=20)	Baricitinib 4mg (N=184)	TNFi (N=346)
VTE Events	0	0	0
Person-Years	22.9	205.7	528.2
IR per 100 PY	0.0	0.0	0.0
95% CI	0, 16.1	0, 1.8	0, 0.7
Incidence rate difference: baricitinib 2mg - TNFi (95% CI)			0.0 (0.0, 0.0)
Incidence rate difference: baricitinib 4mg - TNFi (95% CI)			0.0 (0.0, 0.0)

Abbreviations: CI = confidence interval; Cor_JP = CorEvitas Japan; IR = incidence rate; N = count of patients in specified category; PY = person-years; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

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II. Variable Ratio Matching

All prior tables presented were based on propensity score matched baricitinib:TNFi cohorts using a 1:1 matching strategy. In this section, the tables include results that are based on a variable ratio matching (VRM) approach as described in Section 9.9.6.1 of the final study report.

The main analysis was modified to use 1:1 matching, as this allows the results in the meta-analysis to be directly proportional to the amount of baricitinib exposure in each data source. For transparency, comparative results generated using VRM prior to the adoption of the 1:1 matching are included here.

Non-interventional Post-authorization Safety Study LY3009104 I4V-MC-B023

Analysis Results from the CorEvitas Japan Rheumatoid Arthritis Registry: 1:3-Matched Population

Prepared for: Lilly

Report Date: 17 August 2021

Prepared by: Nicole Foster, MS, Emily A. Scherer, PhD, Alina Onofrei, MS, Bernice Gershenson, MPH, Robert Magner, MPH, Christine J. Barr, BSN, MPH, and Celeste A. Lemay, RN, MPH.

Available Data through: 31 December 20

COR_JP Table 6.1. Baseline Demographics, Pre-matched Population [CorEvitas Japan]

	Any (N=210)	Baricitinib 2mg (N=21)	4mg (N=184)	TNFi (N=354)	Std. Diff (Any vs TNFi)
Age [yrs]					
n	210	21	184	354	0.103
Mean±SD	60.3 ±13.1	70.3 ± 8.9	59.1 ±13.2	61.8 ±15.1	
Median	62.0	71.0	61.0	64.0	
Min, Max	25.0, 85.0	50.0, 84.0	25.0, 85.0	20.0, 90.0	
≥ 65 years	90 (42.9%)	15 (71.4%)	73 (39.7%)	172 (48.6%)	0.115
Gender					
Male	32 (15.4%)	0 (0.0%)	32 (17.6%)	77 (21.8%)	0.166
Female	176 (84.6%)	21 (100.0%)	150 (82.4%)	276 (78.2%)	
BMI					
n	202	17	181	331	0.132
Mean±SD	23.1 ± 4.6	21.8 ± 4.5	23.1 ± 4.5	22.5 ± 3.8	
Median	22.0	22.0	21.9	22.1	
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1	
Smoking (current)	31 (14.9%)	4 (19.0%)	26 (14.3%)	32 (9.2%)	0.176
Alcohol use	82 (39.0%)	8 (38.1%)	73 (39.7%)	156 (44.1%)	0.102
Education					
Primary	21 (10.0%)	4 (19.0%)	16 (8.7%)	46 (13.0%)	0.094
High School	120 (57.1%)	13 (61.9%)	104 (56.5%)	192 (54.2%)	0.059
College/University	58 (27.6%)	3 (14.3%)	54 (29.3%)	101 (28.5%)	0.020

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.2. Baseline Demographics, VTE-matched Population [CorEvitas Japan] - also excludes patients with VTE within 6 months of index date or currently taking anticoagulant

	Baricitinib			TNFi		
	Any (N=171)	2mg (N=15)	4mg (N=155)	(N=207)	Std. Diff (Any vs TNFi)	Total (N=378)
Age [yrs]						
n	171	15	155	207	0.027	378
Mean±SD	60.9 ±13.6	71.6 ± 8.1	59.8 ±13.7	60.6 ±15.5		60.7 ±14.7
Median	63.0	73.0	62.0	63.0		63.0
Min, Max	25.0, 85.0	56.0, 84.0	25.0, 85.0	22.0, 86.0		22.0, 86.0
≥ 65 years	80 (46.8%)	12 (80.0%)	67 (43.2%)	92 (44.4%)	0.047	172 (45.5%)
Gender						
Male	26 (15.2%)	0 (0.0%)	26 (16.8%)	39 (18.8%)	0.097	65 (17.2%)
Female	145 (84.8%)	15 (100.0%)	129 (83.2%)	168 (81.2%)		313 (82.8%)
BMI						
n	171	15	155	207	0.036	378
Mean±SD	22.8 ± 4.5	21.6 ± 4.4	22.9 ± 4.5	22.6 ± 4.0		22.7 ± 4.2
Median	21.8	22.0	21.8	21.9		21.9
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1		14.3, 47.1
Smoking (current)	18 (10.5%)	2 (13.3%)	16 (10.3%)	22 (10.6%)	0.003	40 (10.6%)
Alcohol use	68 (39.8%)	7 (46.7%)	61 (39.4%)	90 (43.5%)	0.075	158 (41.8%)
Education						
Primary	15 (8.8%)	2 (13.3%)	13 (8.4%)	23 (11.1%)	0.078	38 (10.1%)
High School	99 (57.9%)	9 (60.0%)	89 (57.4%)	115 (55.6%)	0.047	214 (56.6%)
College/University	48 (28.1%)	3 (20.0%)	45 (29.0%)	58 (28.0%)	0.001	106 (28.0%)

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.3. Baseline Demographics, MACE-matched Population [CorEvitas Japan] - also excludes patients with a MACE within 6 months prior to index date or taking anticoagulant

	Baricitinib			TNFi		
	Any (N=168)	2mg (N=15)	4mg (N=152)	(N=209)	Std. Diff (Any vs TNFi)	Total (N=377)
Age [yrs]						
n	168	15	152	209	0.044	377
Mean±SD	60.8 ±13.7	71.6 ± 8.1	59.7 ±13.7	61.5 ±15.8		61.2 ±14.9
Median	63.0	73.0	62.0	64.0		64.0
Min, Max	25.0, 85.0	56.0, 84.0	25.0, 85.0	22.0, 88.0		22.0, 88.0
≥ 65 years	78 (46.4%)	12 (80.0%)	65 (42.8%)	104 (49.8%)	0.067	182 (48.3%)
Gender						
Male	24 (14.3%)	0 (0.0%)	24 (15.8%)	41 (19.6%)	0.142	65 (17.2%)
Female	144 (85.7%)	15 (100.0%)	128 (84.2%)	168 (80.4%)		312 (82.8%)
BMI						
n	168	15	152	209	0.000	377
Mean±SD	22.7 ± 4.4	21.6 ± 4.4	22.8 ± 4.4	22.7 ± 4.0		22.7 ± 4.2
Median	21.8	22.0	21.8	22.2		22.0
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1		14.3, 47.1
Smoking (current)	15 (8.9%)	2 (13.3%)	13 (8.6%)	26 (12.4%)	0.114	41 (10.9%)
Alcohol use	67 (39.9%)	7 (46.7%)	60 (39.5%)	91 (43.5%)	0.074	158 (41.9%)
Education						
Primary	14 (8.3%)	2 (13.3%)	12 (7.9%)	27 (12.9%)	0.149	41 (10.9%)
High School	99 (58.9%)	9 (60.0%)	89 (58.6%)	115 (55.0%)	0.079	214 (56.8%)
College/University	46 (27.4%)	3 (20.0%)	43 (28.3%)	57 (27.3%)	0.002	103 (27.3%)

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.4. Baseline Demographics, Serious infection-matched Population [CorEvitas Japan] - also excludes patients with a serious infection within 6 months prior to index date

	Baricitinib			TNFi		
	Any (N=170)	2mg (N=15)	4mg (N=154)	(N=213)	Std. Diff (Any vs TNFi)	Total (N=383)
Age [yrs]						
n	170	15	154	213	0.056	383
Mean±SD	60.6 ±13.8	71.6 ± 8.1	59.4 ±13.8	61.4 ±15.8		61.1 ±14.9
Median	62.5	73.0	62.0	63.0		63.0
Min, Max	25.0, 85.0	56.0, 84.0	25.0, 85.0	22.0, 90.0		22.0, 90.0
≥ 65 years	78 (45.9%)	12 (80.0%)	65 (42.2%)	101 (47.4%)	0.031	179 (46.7%)
Gender						
Male	25 (14.7%)	0 (0.0%)	25 (16.2%)	38 (17.8%)	0.085	63 (16.4%)
Female	145 (85.3%)	15 (100.0%)	129 (83.8%)	175 (82.2%)		320 (83.6%)
BMI						
n	170	15	154	213	0.054	383
Mean±SD	22.8 ± 4.5	21.6 ± 4.4	22.8 ± 4.5	22.5 ± 4.0		22.6 ± 4.3
Median	21.8	22.0	21.8	22.2		21.9
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1		14.3, 47.1
Smoking (current)	16 (9.4%)	2 (13.3%)	14 (9.1%)	22 (10.3%)	0.031	38 (9.9%)
Alcohol use	67 (39.4%)	7 (46.7%)	60 (39.0%)	86 (40.4%)	0.020	153 (39.9%)
Education						
Primary	15 (8.8%)	2 (13.3%)	13 (8.4%)	25 (11.7%)	0.096	40 (10.4%)
High School	99 (58.2%)	9 (60.0%)	89 (57.8%)	120 (56.3%)	0.038	219 (57.2%)
College/University	47 (27.6%)	3 (20.0%)	44 (28.6%)	57 (26.8%)	0.020	104 (27.2%)

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.5. Baseline Demographics, Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - also excludes patients with a hospitalized TB within 6 months prior to index date

	Baricitinib			TNFi		
	Any (N=169)	2mg (N=15)	4mg (N=153)	(N=213)	Std. Diff (Any vs TNFi)	Total (N=382)
Age [yrs]						
n	169	15	153	213	0.020	382
Mean±SD	60.7 ±13.8	71.6 ± 8.1	59.6 ±13.8	61.0 ±15.6		60.9 ±14.8
Median	63.0	73.0	62.0	63.0		63.0
Min, Max	25.0, 85.0	56.0, 84.0	25.0, 85.0	20.0, 90.0		20.0, 90.0
≥ 65 years	78 (46.2%)	12 (80.0%)	65 (42.5%)	97 (45.5%)	0.012	175 (45.8%)
Gender						
Male	25 (14.8%)	0 (0.0%)	25 (16.3%)	39 (18.3%)	0.095	64 (16.8%)
Female	144 (85.2%)	15 (100.0%)	128 (83.7%)	174 (81.7%)		318 (83.2%)
BMI						
n	169	15	153	213	0.072	382
Mean±SD	22.8 ± 4.5	21.6 ± 4.4	22.8 ± 4.5	22.5 ± 3.9		22.6 ± 4.2
Median	21.8	22.0	21.8	22.0		21.9
Min, Max	16.1, 45.2	16.2, 33.7	16.1, 45.2	14.3, 47.1		14.3, 47.1
Smoking (current)	16 (9.5%)	2 (13.3%)	14 (9.2%)	24 (11.3%)	0.059	40 (10.5%)
Alcohol use	67 (39.6%)	7 (46.7%)	60 (39.2%)	92 (43.2%)	0.072	159 (41.6%)
Education						
Primary	15 (8.9%)	2 (13.3%)	13 (8.5%)	26 (12.2%)	0.109	41 (10.7%)
High School	99 (58.6%)	9 (60.0%)	89 (58.2%)	118 (55.4%)	0.064	217 (56.8%)
College/University	46 (27.2%)	3 (20.0%)	43 (28.1%)	58 (27.2%)	0.000	104 (27.2%)

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.6. Baseline Clinical Characteristics, Pre-matched Population [CorEvitas Japan]

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	10 (4.8%)	27 (7.6%)	0.119
Cancer, NMSC only	0 (0.0%)	1 (0.3%)	0.075
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	19 (9.0%)	39 (11.0%)	0.066
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.5%)	3 (0.8%)	0.046
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.4%)	7 (2.0%)	0.042
Cardiovascular revascularization	2 (1.0%)	1 (0.3%)	0.086
Congestive heart failure (hospitalized)	1 (0.5%)	2 (0.6%)	0.012
Coronary artery disease	0 (0.0%)	2 (0.6%)	0.107
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	5 (2.4%)	6 (1.7%)	0.049
TIA	0 (0.0%)	0 (0.0%)	
Unstable angina	0 (0.0%)	3 (0.8%)	0.131
Ventricular arrhythmia	0 (0.0%)	1 (0.3%)	0.075
Diabetes mellitus	27 (12.9%)	29 (8.2%)	0.152
Hyperlipidemia	28 (13.3%)	50 (14.1%)	0.023
Hypertension (hospitalized & non-hospitalized)	59 (28.1%)	106 (29.9%)	0.041
Immune disorders	16 (7.6%)	36 (10.2%)	0.090
Secondary Sjogren Syndrome	16 (7.6%)	36 (10.2%)	0.090
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	4 (1.9%)	2 (0.6%)	0.122
Obesity, current	18 (8.9%)	13 (3.9%)	0.204
Pregnancy, recent (current or since last visit)	0 (0.0%)	2 (0.6%)	0.107
Smoking (current)	31 (14.9%)	32 (9.2%)	0.176
RA severity (CDAI)			
n	198	338	0.122

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
Mean±SD	23.8 ±12.9	22.3 ±12.9	
Median	21.8	20.0	
Min, Max	1.0, 64.2	0.5, 67.2	
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	7 (2.0%)	0.201
MACE (at any time in the past)	8 (3.8%)	7 (2.0%)	0.109
Myocardial infarction	3 (1.4%)	4 (1.1%)	0.027
Stroke	5 (2.4%)	3 (0.8%)	0.122
Serious infection (at any time in the past)	23 (11.0%)	36 (10.2%)	0.025
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	
DMARD history			
Number of cDMARDs used(ever)			
0	18 (8.6%)	25 (7.1%)	0.056
1	145 (69.0%)	245 (69.2%)	0.003
2+	47 (22.4%)	84 (23.7%)	0.032
Methotrexate (prior use)	180 (85.7%)	312 (88.1%)	0.072
Number of bDMARDs used (ever)			
0	72 (34.3%)	254 (71.8%)	0.810
1	61 (29.0%)	65 (18.4%)	0.253
2+	77 (36.7%)	35 (9.9%)	0.668
Prior bDMARD use[a]	138 (65.7%)	100 (28.2%)	0.810
Prior TNFi bDMARD use	111 (52.9%)	57 (16.1%)	0.839
Prior non-TNFi bDMARD use	87 (41.4%)	67 (18.9%)	0.506
DMARD, current (baseline)			
cDMARD, concomitant use at baseline	123 (58.6%)	271 (76.6%)	0.391
Methotrexate (current use)	110 (52.4%)	254 (71.8%)	0.407
Prescription medication use, current (baseline)			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	2 (1.0%)	6 (1.7%)	0.064
Antihypertensives (blood pressure lowering medication(s); patient-reported)	50 (23.8%)	93 (26.3%)	0.057
Antiplatelet (Plavix; patient-reported)	2 (1.0%)	5 (1.4%)	0.042
Nitrates (angina/nitrate medications; patient-reported)	2 (1.0%)	3 (0.8%)	0.011
Lipid-lowering agents (cholesterol medication; patient-reported)	35 (17.2%)	55 (15.8%)	0.036
RA-related			

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
Aspirin (includes non-prescription)	3 (1.5%)	9 (2.6%)	0.079
Prednisone	48 (22.9%)	102 (28.8%)	0.136
Vaccinations			
Shingles (ever)	2 (1.0%)	3 (0.8%)	0.011

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.7. Baseline Clinical Characteristics, VTE-matched Population [CorEvitas Japan] - also excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant

	Baricitinib (N=171)	TNFi (N=207)	Std. Diff.	Total (N=378)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	9 (5.3%)	16 (7.7%)	0.100	25 (6.6%)
Cancer, NMSC only	0 (0.0%)	1 (0.5%)	0.099	1 (0.3%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	16 (9.4%)	20 (9.7%)	0.010	36 (9.5%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.6%)	1 (0.5%)	0.014	2 (0.5%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.8%)	3 (1.4%)	0.024	6 (1.6%)
Cardiovascular revascularization	2 (1.2%)	0 (0.0%)	0.154	2 (0.5%)
Congestive heart failure (hospitalized)	1 (0.6%)	0 (0.0%)	0.108	1 (0.3%)
Coronary artery disease	0 (0.0%)	1 (0.5%)	0.099	1 (0.3%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	4 (2.3%)	3 (1.4%)	0.065	7 (1.9%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	1 (0.5%)	0.099	1 (0.3%)
Ventricular arrhythmia	0 (0.0%)	1 (0.5%)	0.099	1 (0.3%)
Diabetes mellitus	19 (11.1%)	25 (12.1%)	0.030	44 (11.6%)
Hyperlipidemia	22 (12.9%)	28 (13.5%)	0.020	50 (13.2%)
Hypertension (hospitalized & non-hospitalized)	48 (28.1%)	58 (28.0%)	0.001	106 (28.0%)
Immune disorders	14 (8.2%)	14 (6.8%)	0.054	28 (7.4%)
Secondary Sjogren Syndrome	14 (8.2%)	14 (6.8%)	0.054	28 (7.4%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (0.6%)	1 (0.5%)	0.014	2 (0.5%)
Obesity, current	14 (8.2%)	9 (4.3%)	0.159	23 (6.1%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)		0 (0.0%)
Smoking (current)	18 (10.5%)	22 (10.6%)	0.003	40 (10.6%)

	Baricitinib (N=171)	TNFi (N=207)	Std. Diff.	Total (N=378)
RA severity (CDAI)				
n	171	207	0.110	378
Mean±SD	23.4 ±13.0	22.0 ±13.4		22.6 ±13.2
Median	21.0	19.3		19.6
Min, Max	1.0, 64.2	0.5, 67.2		0.5, 67.2
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
MACE (at any time in the past)	4 (2.3%)	4 (1.9%)	0.028	8 (2.1%)
Myocardial infarction	2 (1.2%)	2 (1.0%)	0.020	4 (1.1%)
Stroke	2 (1.2%)	2 (1.0%)	0.020	4 (1.1%)
Serious infection (at any time in the past)	17 (9.9%)	19 (9.2%)	0.026	36 (9.5%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used(ever)				
0	14 (8.2%)	18 (8.7%)	0.018	32 (8.5%)
1	119 (69.6%)	145 (70.0%)	0.010	264 (69.8%)
2+	38 (22.2%)	44 (21.3%)	0.023	82 (21.7%)
Methotrexate (prior use)	146 (85.4%)	178 (86.0%)	0.017	324 (85.7%)
Number of bDMARDs used (ever)				
0	68 (39.8%)	128 (61.8%)	0.453	196 (51.9%)
1	51 (29.8%)	50 (24.2%)	0.128	101 (26.7%)
2+	52 (30.4%)	29 (14.0%)	0.402	81 (21.4%)
Prior bDMARD use[a]	103 (60.2%)	79 (38.2%)	0.453	182 (48.1%)
Prior TNFi bDMARD use	79 (46.2%)	45 (21.7%)	0.535	124 (32.8%)
Prior non-TNFi bDMARD use	64 (37.4%)	55 (26.6%)	0.234	119 (31.5%)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	105 (61.4%)	144 (69.6%)	0.172	249 (65.9%)
Methotrexate (current use)	94 (55.0%)	134 (64.7%)	0.200	228 (60.3%)
Prescription medication use, current (baseline)				
Cardiovascular medications				
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)		0 (0.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	40 (23.4%)	48 (23.2%)	0.005	88 (23.3%)
Antiplatelet (Plavix; patient-reported)	1 (0.6%)	2 (1.0%)	0.043	3 (0.8%)
Nitrates (angina/nitrate medications; patient-reported)	2 (1.2%)	1 (0.5%)	0.076	3 (0.8%)

	Baricitinib (N=171)	TNFi (N=207)	Std. Diff.	Total (N=378)
Lipid-lowering agents (cholesterol medication; patient-reported)	29 (17.0%)	29 (14.0%)	0.082	58 (15.3%)
RA-related				
Aspirin (includes non-prescription)	2 (1.2%)	5 (2.4%)	0.094	7 (1.9%)
Prednisone	40 (23.4%)	56 (27.1%)	0.084	96 (25.4%)
Vaccinations				
Shingles (ever)	1 (0.6%)	0 (0.0%)	0.108	1 (0.3%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.8. Baseline Clinical Characteristics, MACE-matched Population [CorEvitas Japan] - also excludes patients with MACE within 6 months prior to index date or taking anticoagulant

	Baricitinib (N=168)	TNFi (N=209)	Std. Diff.	Total (N=377)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	8 (4.8%)	18 (8.6%)	0.155	26 (6.9%)
Cancer, NMSC only	0 (0.0%)	1 (0.5%)	0.098	1 (0.3%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	16 (9.5%)	24 (11.5%)	0.064	40 (10.6%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.6%)	0 (0.0%)	0.109	1 (0.3%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.8%)	3 (1.4%)	0.028	6 (1.6%)
Cardiovascular revascularization	2 (1.2%)	1 (0.5%)	0.078	3 (0.8%)
Congestive heart failure (hospitalized)	1 (0.6%)	0 (0.0%)	0.109	1 (0.3%)
Coronary artery disease	0 (0.0%)	2 (1.0%)	0.139	2 (0.5%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	4 (2.4%)	4 (1.9%)	0.032	8 (2.1%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	2 (1.0%)	0.139	2 (0.5%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)		0 (0.0%)
Diabetes mellitus	17 (10.1%)	23 (11.0%)	0.029	40 (10.6%)
Hyperlipidemia	22 (13.1%)	25 (12.0%)	0.034	47 (12.5%)
Hypertension (hospitalized & non-hospitalized)	47 (28.0%)	64 (30.6%)	0.058	111 (29.4%)
Immune disorders	13 (7.7%)	18 (8.6%)	0.032	31 (8.2%)
Secondary Sjogren Syndrome	13 (7.7%)	18 (8.6%)	0.032	31 (8.2%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (0.6%)	1 (0.5%)	0.016	2 (0.5%)
Obesity, current	13 (7.7%)	8 (3.8%)	0.168	21 (5.6%)

	Baricitinib (N=168)	TNFi (N=209)	Std. Diff.	Total (N=377)
Pregnancy, recent (current or since last visit)	0 (0.0%)	2 (1.0%)	0.139	2 (0.5%)
Smoking (current)	15 (8.9%)	26 (12.4%)	0.114	41 (10.9%)
RA severity (CDAI)				
n	168	209	0.009	377
Mean±SD	23.4 ±13.1	23.3 ±13.7		23.4 ±13.5
Median	20.3	20.3		20.3
Min, Max	1.0, 64.2	0.5, 67.2		0.5, 67.2
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	3 (1.4%)	0.171	3 (0.8%)
MACE (at any time in the past)	4 (2.4%)	3 (1.4%)	0.069	7 (1.9%)
Myocardial infarction	2 (1.2%)	1 (0.5%)	0.078	3 (0.8%)
Stroke	2 (1.2%)	2 (1.0%)	0.023	4 (1.1%)
Serious infection (at any time in the past)	16 (9.5%)	18 (8.6%)	0.032	34 (9.0%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used(ever)				
0	14 (8.3%)	17 (8.1%)	0.007	31 (8.2%)
1	117 (69.6%)	143 (68.4%)	0.026	260 (69.0%)
2+	37 (22.0%)	49 (23.4%)	0.034	86 (22.8%)
Methotrexate (prior use)	143 (85.1%)	181 (86.6%)	0.043	324 (85.9%)
Number of bDMARDs used (ever)				
0	68 (40.5%)	127 (60.8%)	0.414	195 (51.7%)
1	49 (29.2%)	54 (25.8%)	0.075	103 (27.3%)
2+	51 (30.4%)	28 (13.4%)	0.419	79 (21.0%)
Prior bDMARD use[a]	100 (59.5%)	82 (39.2%)	0.414	182 (48.3%)
Prior TNFi bDMARD use	76 (45.2%)	48 (23.0%)	0.483	124 (32.9%)
Prior non-TNFi bDMARD use	62 (36.9%)	54 (25.8%)	0.240	116 (30.8%)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	102 (60.7%)	153 (73.2%)	0.268	255 (67.6%)
Methotrexate (current use)	92 (54.8%)	143 (68.4%)	0.284	235 (62.3%)
Prescription medication use, current (baseline)				
Cardiovascular medication				

	Baricitinib (N=168)	TNFi (N=209)	Std. Diff.	Total (N=377)
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)		0 (0.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	40 (23.8%)	54 (25.8%)	0.047	94 (24.9%)
Antiplatelet (Plavix; patient-reported)	1 (0.6%)	2 (1.0%)	0.041	3 (0.8%)
Nitrates (angina/nitrate medications; patient-reported)	2 (1.2%)	0 (0.0%)	0.155	2 (0.5%)
Lipid-lowering agents (cholesterol medication; patient-reported)	28 (16.7%)	33 (15.8%)	0.024	61 (16.2%)
RA-related				
Aspirin (includes non-prescription)	2 (1.2%)	5 (2.4%)	0.091	7 (1.9%)
Prednisone	39 (23.2%)	56 (26.8%)	0.083	95 (25.2%)
Vaccinations				
Shingles (ever)	1 (0.6%)	0 (0.0%)	0.109	1 (0.3%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.9. Baseline Clinical Characteristics, Serious infection-matched Population [CorEvitas Japan] - also excludes patients with serious infection within 6 months prior to index date

	Baricitinib (N=170)	TNFi (N=213)	Std. Diff.	Total (N=383)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	8 (4.7%)	20 (9.4%)	0.184	28 (7.3%)
Cancer, NMSC only	0 (0.0%)	1 (0.5%)	0.097	1 (0.3%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	16 (9.4%)	21 (9.9%)	0.015	37 (9.7%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.6%)	1 (0.5%)	0.016	2 (0.5%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.8%)	5 (2.3%)	0.041	8 (2.1%)
Cardiovascular revascularization	2 (1.2%)	1 (0.5%)	0.078	3 (0.8%)
Congestive heart failure (hospitalized)	1 (0.6%)	1 (0.5%)	0.016	2 (0.5%)
Coronary artery disease	0 (0.0%)	2 (0.9%)	0.138	2 (0.5%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	4 (2.4%)	5 (2.3%)	0.000	9 (2.3%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	3 (1.4%)	0.169	3 (0.8%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)		0 (0.0%)
Diabetes mellitus	18 (10.6%)	22 (10.3%)	0.008	40 (10.4%)
Hyperlipidemia	22 (12.9%)	29 (13.6%)	0.020	51 (13.3%)
Hypertension (hospitalized & non-hospitalized)	48 (28.2%)	70 (32.9%)	0.101	118 (30.8%)
Immune disorders	14 (8.2%)	19 (8.9%)	0.024	33 (8.6%)
Secondary Sjogren Syndrome	14 (8.2%)	19 (8.9%)	0.024	33 (8.6%)

	Baricitinib (N=170)	TNFi (N=213)	Std. Diff.	Total (N=383)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (0.6%)	1 (0.5%)	0.016	2 (0.5%)
Obesity, current	14 (8.2%)	9 (4.2%)	0.166	23 (6.0%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	2 (0.9%)	0.138	2 (0.5%)
Smoking (current)	16 (9.4%)	22 (10.3%)	0.031	38 (9.9%)
RA severity (CDAI)				
n	170	213	0.013	383
Mean±SD	23.5 ±13.1	23.3 ±13.6		23.4 ±13.4
Median	20.9	20.5		20.5
Min, Max	1.0, 64.2	0.5, 67.2		0.5, 67.2
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	5 (2.3%)	0.219	5 (1.3%)
MACE (at any time in the past)	4 (2.4%)	5 (2.3%)	0.000	9 (2.3%)
Myocardial infarction	2 (1.2%)	3 (1.4%)	0.021	5 (1.3%)
Stroke	2 (1.2%)	2 (0.9%)	0.023	4 (1.0%)
Serious infection (at any time in the past)	17 (10.0%)	17 (8.0%)	0.071	34 (8.9%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used(ever)				
0	14 (8.2%)	17 (8.0%)	0.009	31 (8.1%)
1	119 (70.0%)	144 (67.6%)	0.052	263 (68.7%)
2+	37 (21.8%)	52 (24.4%)	0.063	89 (23.2%)
Methotrexate (prior use)	145 (85.3%)	186 (87.3%)	0.059	331 (86.4%)
Number of bDMARDs used (ever)				
0	68 (40.0%)	129 (60.6%)	0.420	197 (51.4%)
1	50 (29.4%)	54 (25.4%)	0.091	104 (27.2%)
2+	52 (30.6%)	30 (14.1%)	0.404	82 (21.4%)
Prior bDMARD use[a]	102 (60.0%)	84 (39.4%)	0.420	186 (48.6%)
Prior TNFi bDMARD use	78 (45.9%)	50 (23.5%)	0.484	128 (33.4%)
Prior non-TNFi bDMARD use	63 (37.1%)	56 (26.3%)	0.233	119 (31.1%)

	Baricitinib (N=170)	TNFi (N=213)	Std. Diff.	Total (N=383)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	102 (60.0%)	153 (71.8%)	0.252	255 (66.6%)
Methotrexate (current use)	92 (54.1%)	146 (68.5%)	0.300	238 (62.1%)
Prescription medication use, current (baseline)				
Cardiovascular medications				
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	4 (1.9%)	0.196	4 (1.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	40 (23.5%)	64 (30.0%)	0.148	104 (27.2%)
Antiplatelet (Plavix; patient-reported)	1 (0.6%)	3 (1.4%)	0.083	4 (1.0%)
Nitrates (angina/nitrate medications; patient-reported)	2 (1.2%)	1 (0.5%)	0.078	3 (0.8%)
Lipid-lowering agents (cholesterol medication; patient-reported)	29 (17.1%)	36 (16.9%)	0.004	65 (17.0%)
RA-related				
Aspirin (includes non-prescription)	2 (1.2%)	7 (3.3%)	0.143	9 (2.3%)
Prednisone	40 (23.5%)	54 (25.4%)	0.042	94 (24.5%)
Vaccinations				
Shingles (ever)	1 (0.6%)	0 (0.0%)	0.109	1 (0.3%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.10. Baseline Clinical Characteristics, hospitalized tuberculosis-matched Population [CorEvitas Japan] - also excludes patients with hospitalized tuberculosis within 6 months prior to index date

	Baricitinib (N=169)	TNFi (N=213)	Std. Diff.	Total (N=382)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	8 (4.7%)	23 (10.8%)	0.228	31 (8.1%)
Cancer, NMSC only	0 (0.0%)	1 (0.5%)	0.097	1 (0.3%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	16 (9.5%)	24 (11.3%)	0.059	40 (10.5%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (0.6%)	1 (0.5%)	0.017	2 (0.5%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	3 (1.8%)	5 (2.3%)	0.040	8 (2.1%)
Cardiovascular revascularization	2 (1.2%)	1 (0.5%)	0.079	3 (0.8%)
Congestive heart failure (hospitalized)	1 (0.6%)	1 (0.5%)	0.017	2 (0.5%)
Coronary artery disease	0 (0.0%)	2 (0.9%)	0.138	2 (0.5%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	4 (2.4%)	5 (2.3%)	0.001	9 (2.4%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	3 (1.4%)	0.169	3 (0.8%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)		0 (0.0%)
Diabetes mellitus	18 (10.7%)	22 (10.3%)	0.011	40 (10.5%)
Hyperlipidemia	22 (13.0%)	28 (13.1%)	0.004	50 (13.1%)
Hypertension (hospitalized & non-hospitalized)	48 (28.4%)	67 (31.5%)	0.067	115 (30.1%)
Immune disorders	14 (8.3%)	20 (9.4%)	0.039	34 (8.9%)
Secondary Sjogren Syndrome	14 (8.3%)	20 (9.4%)	0.039	34 (8.9%)

	Baricitinib (N=169)	TNFi (N=213)	Std. Diff.	Total (N=382)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (0.6%)	1 (0.5%)	0.017	2 (0.5%)
Obesity, current	14 (8.3%)	9 (4.2%)	0.168	23 (6.0%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	1 (0.5%)	0.097	1 (0.3%)
Smoking (current)	16 (9.5%)	24 (11.3%)	0.059	40 (10.5%)
RA severity (CDAI)				
n	169	213	0.025	382
Mean±SD	23.4 ±13.1	23.8 ±13.7		23.6 ±13.4
Median	20.5	20.8		20.6
Min, Max	1.0, 64.2	0.5, 67.2		0.5, 67.2
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	5 (2.3%)	0.219	5 (1.3%)
MACE (at any time in the past)	4 (2.4%)	5 (2.3%)	0.001	9 (2.4%)
Myocardial infarction	2 (1.2%)	3 (1.4%)	0.020	5 (1.3%)
Stroke	2 (1.2%)	2 (0.9%)	0.024	4 (1.0%)
Serious infection (at any time in the past)	17 (10.1%)	22 (10.3%)	0.009	39 (10.2%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used(ever)				
0	14 (8.3%)	16 (7.5%)	0.029	30 (7.9%)
1	118 (69.8%)	145 (68.1%)	0.038	263 (68.8%)
2+	37 (21.9%)	52 (24.4%)	0.060	89 (23.3%)
Methotrexate (prior use)	144 (85.2%)	187 (87.8%)	0.076	331 (86.6%)
Number of bDMARDs used (ever)				
0	68 (40.2%)	129 (60.6%)	0.415	197 (51.6%)
1	50 (29.6%)	54 (25.4%)	0.095	104 (27.2%)
2+	51 (30.2%)	30 (14.1%)	0.395	81 (21.2%)
Prior bDMARD use[a]	101 (59.8%)	84 (39.4%)	0.415	185 (48.4%)
Prior TNFi bDMARD use	77 (45.6%)	50 (23.5%)	0.478	127 (33.2%)
Prior non-TNFi bDMARD use	62 (36.7%)	56 (26.3%)	0.225	118 (30.9%)

	Baricitinib (N=169)	TNFi (N=213)	Std. Diff.	Total (N=382)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	102 (60.4%)	155 (72.8%)	0.265	257 (67.3%)
Methotrexate (current use)	92 (54.4%)	145 (68.1%)	0.283	237 (62.0%)
Current (baseline) prescription medication use				
Cardiovascular medications				
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	3 (1.4%)	0.169	3 (0.8%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	40 (23.7%)	60 (28.2%)	0.103	100 (26.2%)
Antiplatelet (Plavix; patient-reported)	1 (0.6%)	3 (1.4%)	0.082	4 (1.0%)
Nitrates (angina/nitrate medications; patient-reported)	2 (1.2%)	1 (0.5%)	0.079	3 (0.8%)
Lipid-lowering agents (cholesterol medication; patient-reported)	29 (17.2%)	34 (16.0%)	0.032	63 (16.5%)
RA-related				
Aspirin (includes non-prescription)	2 (1.2%)	7 (3.3%)	0.143	9 (2.4%)
Prednisone	40 (23.7%)	56 (26.3%)	0.061	96 (25.1%)
Vaccinations				
Shingles (ever)	1 (0.6%)	0 (0.0%)	0.109	1 (0.3%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.11. Baseline Healthcare Resource Utilization, Unmatched [CorEvitas Japan]

Not available for CorEvitas data.

COR_JP Table 6.12. Baseline Healthcare Resource Utilization Primary VTE Cohorts, Matched [CorEvitas Japan]

Not available for CorEvitas data.

COR_JP Table 6.13. Baseline Healthcare Resource Utilization MACE Cohorts, Matched [CorEvitas Japan]

Not available for CorEvitas data.

COR_JP Table 6.14. Baseline Healthcare Resource Utilization Serious Infection Cohorts, Matched [CorEvitas Japan]

Not available for CorEvitas data.

COR_JP Table 6.15. Baseline Healthcare Resource Utilization Hospitalized Tuberculosis Cohorts, Matched [CorEvitas Japan]

Not available for CorEvitas data.

COR_JP Table 6.16. Baseline Prevalence of Outcomes [CorEvitas Japan]

	Pre-matched			Matched*			
	Baricitinib events (%)/N	TNFi events (%)/N	Std. Diff.	Baricitinib events (%)/N	TNFi events (%)/N	Std. Diff	Total events (%)/N
VTE	0 (0.0%)/210	7 (2.0%)/354	0.201	0 (0.0%)/171	0 (0.0%)/207		0 (0%)/378
MACE	8 (3.8%)/210	7 (2.0%)/354	0.109	4 (2.4%)/168	3 (1.4%)/209	0.069	7 (1.9%)/377
Serious Infection	23 (11.0%)/210	37 (10.5%)/354	0.025	17 (10.0%)/170	17 (8.0%)/213	0.071	34 (8.9%)/383
Hospitalized Tuberculosis	0 (0.0%)/210	(0.0%)/354		0 (0.0%)/169	0 (0.0%)/213		0 (0.0%)/382

Abbreviations: VTE = venous thromboembolism; MACE = major adverse cardiovascular event; TNFi = tumor necrosis factor inhibitor.
* Matched refers to the outcome-specific matched population

COR_JP Table 6.17. Duration of Exposure (Days), in Pre-matched Population [CorEvitas Japan] – exposure ends at discontinuation/last follow-up visit

	Baricitinib (N=210)	TNFi (N=354)	Std. Diff.
N	210	354	
Mean±SD	402.7 ±259.5	554.0 ±341.9	0.498
Median	371.0	551.0	
Min, Max	9.0, 1071.0	14.0, 1263.0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.18. Duration of Exposure (Days), in VTE-matched Population [CorEvitas Japan] – exposure ends at discontinuation/last follow-up visit; excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant

	Baricitinib (N=171)	TNFi (N=207)	Std. Diff.
N	171	207	
Mean±SD	426.1 ±253.2	545.1 ±352.4	0.388
Median	385.0	504.0	
Min, Max	12.0, 1071.0	14.0, 1253.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	13 (8%)	41 (20%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	17 (10%)	47 (23%)	
End of follow-up for that patient	141 (82%)	119 (57%)	
Death	n/a	n/a	
Incident event (VTE)	0	0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

COR_JP Table 6.19. Duration of Exposure (Days) in Alternate VTE (Case Definition I) Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.20. Duration of Exposure (Days) in Alternate VTE (Case Definition II) Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.21. Duration of Exposure (Days), in MACE-matched Population [CorEvitas Japan] – exposure ends at discontinuation/last follow-up visit; excludes patients with MACE within 6 months prior to index date or taking anticoagulant

	Baricitinib (N=168)	TNFi (N=209)	Std. Diff.
N	168	209	
Mean±SD	422.4 ±253.8	533.5 ±351.5	0.362
Median	385.0	501.0	
Min, Max	12.0, 1071.0	14.0, 1253.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	13 (8%)	34 (16%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	17 (10%)	49 (23%)	
End of follow-up for that patient	138 (82%)	126 (60%)	
Death	n/a	n/a	
Incident event (MACE)	0	0	

Abbreviations: MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.22. Duration of Exposure (Days), in Serious Infection-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit; excludes patients with serious infection within 6 months prior to index date

	Baricitinib (N=170)	TNFi (N=213)	Std. Diff.
N	170	213	
Mean±SD	419.2 ±254.3	529.2 ±340.2	0.366
Median	381.5	501.0	
Min, Max	12.0, 1071.0	14.0, 1210.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	10 (6%)	32 (15%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	18 (11%)	49 (23%)	
End of follow-up for that patient	133 (78%)	124 (58%)	
Death	n/a	n/a	
Incident event (serious Infection)	9 (5%)	8 (4%)	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.23. Duration of Exposure (Days), in Hospitalized Tuberculosis-matched Population [CorEvitas Japan] exposure ends at discontinuation/last follow-up visit; excludes patients with hospitalized TB within 6 months prior to index date

	Baricitinib (N=169)	TNFi (N=213)	Std. Diff.
N	169	213	
Mean±SD	421.4 ±253.4	527.8 ±344.9	0.352
Median	385.0	502.0	
Min, Max	12.0, 1071.0	14.0, 1210.0	
Reason for censoring			
Discontinue index medication (and did not start another b/tsDMARD within 30 days)	13 (8%)	38 (18%)	
Discontinue index medication (and started another b/tsDMARD within 30 days)	17 (10%)	49 (23%)	
End of follow-up for that patient	139 (82%)	126 (59%)	
Death	n/a	n/a	
Incident event (hospitalized TB)	0	0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TB = tuberculosis; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.24. Baseline Clinical Characteristics by Exposure Duration, Pre-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 52)	TNFi (N= 71)	Std. Diff.	Baricitinib (N= 52)	TNFi (N= 54)	Std. Diff.	Baricitinib (N= 77)	TNFi (N= 108)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 121)	Std. Diff.
Age [yrs]												
n	52	71	0.20	52	54	0.08	77	108	0.13	29	121	0.01
Mean±SD	58.5 ± 14.6	61.4 ± 14.0		61.1 ± 12.1	62.4 ± 17.6		60.7 ± 13.0	62.5 ± 14.7		61.2 ± 12.6	61.1 ± 15.0	
Median	61.5	65.0		61.5	68.5		64.0	64.5		65.0	63.0	
Min, Max	25.0, 84.0	20.0, 90.0		34.0, 83.0	22.0, 90.0		30.0, 85.0	25.0, 88.0		38.0, 82.0	25.0, 84.0	
≥ 65 years	21 (40.4%)	36 (50.7%)	0.21	20 (38.5%)	28 (51.9%)	0.27	34 (44.2%)	54 (50.0%)	0.12	15 (51.7%)	54 (44.6%)	0.14
Gender												
Male	5 (9.6%)	13 (18.6%)	0.26	8 (15.7%)	10 (18.5%)	0.08	12 (15.6%)	23 (21.3%)	0.15	7 (25.0%)	31 (25.6%)	0.01
Female	47 (90.4%)	57 (81.4%)		43 (84.3%)	44 (81.5%)		65 (84.4%)	85 (78.7%)		21 (75.0%)	90 (74.4%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (1.9%)	7 (9.9%)	0.34	2 (3.8%)	4 (7.4%)	0.16	1 (1.3%)	8 (7.4%)	0.30	6 (20.7%)	8 (6.6%)	0.42
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	5 (9.6%)	4 (5.6%)	0.15	6 (11.5%)	8 (14.8%)	0.10	5 (6.5%)	15 (13.9%)	0.25	3 (10.3%)	12 (9.9%)	0.01
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.9%)	0.19	1 (1.3%)	1 (0.9%)	0.04	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (1.9%)	3 (4.2%)	0.13	1 (1.9%)	1 (1.9%)	0.01	1 (1.3%)	2 (1.9%)	0.04	0 (0.0%)	1 (0.8%)	0.13
Cardiovascular revascularization	1 (1.9%)	0 (0.0%)	0.20	1 (1.9%)	0 (0.0%)	0.20	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 52)	TNFi (N= 71)	Std. Diff.	Baricitinib (N= 52)	TNFi (N= 54)	Std. Diff.	Baricitinib (N= 77)	TNFi (N= 108)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 121)	Std. Diff.
Congestive heart failure (hospitalized)	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.9%)	0.19	1 (1.3%)	0 (0.0%)	0.16	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (3.8%)	2 (2.8%)	0.06	2 (3.8%)	1 (1.9%)	0.12	0 (0.0%)	1 (0.9%)	0.14	1 (3.4%)	2 (1.7%)	0.11
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	1 (0.8%)	0.13
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	3 (5.8%)	6 (8.5%)	0.10	4 (7.7%)	6 (11.1%)	0.12	15 (19.5%)	10 (9.3%)	0.29	5 (17.2%)	7 (5.8%)	0.36
Hyperlipidemia	6 (11.5%)	8 (11.3%)	0.01	6 (11.5%)	9 (16.7%)	0.15	13 (16.9%)	18 (16.7%)	0.01	3 (10.3%)	15 (12.4%)	0.06
Hypertension (hospitalized & non-hospitalized)	12 (23.1%)	14 (19.7%)	0.08	15 (28.8%)	21 (38.9%)	0.21	23 (29.9%)	33 (30.6%)	0.01	9 (31.0%)	38 (31.4%)	0.01
Immune disorders	1 (1.9%)	5 (7.0%)	0.25	3 (5.8%)	6 (11.1%)	0.19	10 (13.0%)	10 (9.3%)	0.12	2 (6.9%)	15 (12.4%)	0.19
Secondary Sjogren Syndrome	1 (1.9%)	5 (7.0%)	0.25	3 (5.8%)	6 (11.1%)	0.19	10 (13.0%)	10 (9.3%)	0.12	2 (6.9%)	15 (12.4%)	0.19
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	2 (2.8%)	0.24	1 (1.9%)	0 (0.0%)	0.20	2 (2.6%)	0 (0.0%)	0.23	1 (3.4%)	0 (0.0%)	0.27
Obesity, current	7 (14.0%)	3 (4.5%)	0.33	3 (6.1%)	3 (5.9%)	0.01	6 (8.0%)	3 (3.1%)	0.22	2 (7.1%)	4 (3.4%)	0.17
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.9%)	0.19	0 (0.0%)	1 (0.9%)	0.14	0 (0.0%)	0 (0.0%)	-
Smoking (current)	8 (15.4%)	11 (15.5%)	0.00	10 (19.2%)	4 (7.8%)	0.34	10 (13.2%)	9 (8.3%)	0.16	3 (10.7%)	8 (6.8%)	0.14
RA severity (CDAI)												
n	44	68	0.22	49	52	0.09	76	100	0.02	29	118	0.30
Mean±SD	25.5 ± 12.5	22.8 ± 11.3		22.0 ± 12.8	20.8± 12.9		23.3± 12.7	23.0± 14.9		25.9 ± 14.5	22.0± 12.1	

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 52)	TNFi (N= 71)	Std. Diff.	Baricitinib (N= 52)	TNFi (N= 54)	Std. Diff.	Baricitinib (N= 77)	TNFi (N= 108)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 121)	Std. Diff.
Median	22.9	22.1		20.0	16.4		22.0	18.9		22.0	19.8	
Min, Max	4.4, 55.0	5.5, 67.2		1.0, 64.2	3.0, 58.3		1.4, 57.3	0.5, 65.5		3.5, 60.0	0.5, 59.7	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.9%)	0.19	0 (0.0%)	4 (3.7%)	0.28	0 (0.0%)	1 (0.8%)	0.13
MACE (at any time in the past)	1 (1.9%)	2 (2.8%)	0.06	2 (3.8%)	1 (1.9%)	0.12	4 (5.2%)	0 (0.0%)	0.33	1 (3.4%)	4 (3.3%)	0.01
Myocardial infarction	0 (0.0%)	1 (1.4%)	0.17	2 (3.8%)	1 (1.9%)	0.12	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	2 (1.7%)	0.11
Stroke	1 (1.9%)	1 (1.4%)	0.04	0 (0.0%)	0 (0.0%)	-	4 (5.2%)	0 (0.0%)	0.33	0 (0.0%)	2 (1.7%)	0.18
Serious infection (at any time in the past)	7 (13.5%)	7 (9.9%)	0.11	4 (7.7%)	4 (7.4%)	0.01	9 (11.7%)	13 (12.0%)	0.01	3 (10.3%)	12 (9.9%)	0.01
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	5 (9.6%)	7 (9.9%)	0.01	5 (9.6%)	5 (9.3%)	0.01	5 (6.5%)	9 (8.3%)	0.07	3 (10.3%)	6 (5.0%)	0.20
1	35 (67.3%)	46 (64.8%)	0.05	38 (73.1%)	34 (63.0%)	0.22	53 (68.8%)	73 (67.6%)	0.03	19 (65.5%)	90 (74.4%)	0.19
2+	12 (23.1%)	18 (25.4%)	0.05	9 (17.3%)	15 (27.8%)	0.25	19 (24.7%)	26 (24.1%)	0.01	7 (24.1%)	25 (20.7%)	0.08
Number of bDMARDs used (ever)												
0	11 (21.2%)	48 (67.6%)	1.06	19 (36.5%)	33 (61.1%)	0.51	31 (40.3%)	75 (69.4%)	0.61	11 (37.9%)	98 (81.0%)	0.98
1	15 (28.8%)	10 (14.1%)	0.37	19 (36.5%)	14 (25.9%)	0.23	22 (28.6%)	23 (21.3%)	0.17	5 (17.2%)	18 (14.9%)	0.06
2+	26 (50.0%)	13 (18.3%)	0.71	14 (26.9%)	7 (13.0%)	0.35	24 (31.2%)	10 (9.3%)	0.57	13 (44.8%)	5 (4.1%)	1.07
Prior bDMARD use[a]	41 (78.8%)	23 (32.4%)	1.06	33 (63.5%)	21 (38.9%)	0.51	46 (59.7%)	33 (30.6%)	0.61	18 (62.1%)	23 (19.0%)	0.98
Prior TNFi bDMARD use	38 (73.1%)	13 (18.3%)	1.32	25 (48.1%)	13 (24.1%)	0.52	34 (44.2%)	18 (16.7%)	0.63	14 (48.3%)	13 (10.7%)	0.90
Prior non-TNFi bDMARD use	25 (48.1%)	18 (25.4%)	0.49	18 (34.6%)	13 (24.1%)	0.23	30 (39.0%)	22 (20.4%)	0.42	14 (48.3%)	14 (11.6%)	0.87
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	26 (50.0%)	51 (71.8%)	0.46	26 (50.0%)	39 (72.2%)	0.47	51 (66.2%)	83 (76.9%)	0.24	20 (69.0%)	98 (81.0%)	0.28
Methotrexate (current use)	26 (50.0%)	47 (66.2%)	0.33	26 (50.0%)	36 (66.7%)	0.34	43 (55.8%)	79 (73.1%)	0.37	15 (51.7%)	92 (76.0%)	0.52

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 52)	TNFi (N= 71)	Std. Diff.	Baricitinib (N= 52)	TNFi (N= 54)	Std. Diff.	Baricitinib (N= 77)	TNFi (N= 108)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 121)	Std. Diff.
Prescription medication use, current (baseline)												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	2 (2.9%)	0.24	1 (2.0%)	2 (3.7%)	0.11	1 (1.3%)	1 (1.0%)	0.03	0 (0.0%)	1 (0.8%)	0.13
Antihypertensives (blood pressure lowering medication(s); patient-reported)	9 (17.3%)	15 (21.1%)	0.10	12 (23.1%)	16 (29.6%)	0.15	20 (26.0%)	25 (23.1%)	0.07	9 (31.0%)	37 (30.6%)	0.01
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	2 (2.6%)	2 (1.9%)	0.05	0 (0.0%)	3 (2.5%)	0.23
Nitrates (angina/nitrate medications; patient-reported)	1 (1.9%)	1 (1.4%)	0.04	0 (0.0%)	1 (1.9%)	0.19	0 (0.0%)	1 (0.9%)	0.14	1 (3.4%)	0 (0.0%)	0.27
Lipid-lowering agents (cholesterol medication; patient-reported)	6 (12.8%)	13 (18.6%)	0.16	9 (17.6%)	10 (18.5%)	0.02	15 (19.5%)	17 (16.3%)	0.08	5 (17.2%)	15 (12.5%)	0.13
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	5 (7.1%)	0.39	2 (3.9%)	1 (1.9%)	0.12	0 (0.0%)	1 (1.0%)	0.14	1 (3.4%)	2 (1.7%)	0.11
Prednisone	11 (21.2%)	24 (33.8%)	0.29	11 (21.2%)	10 (18.5%)	0.07	19 (24.7%)	30 (27.8%)	0.07	7 (24.1%)	38 (31.4%)	0.16
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (1.9%)	0 (0.0%)	0.20	1 (1.3%)	2 (1.9%)	0.04	0 (0.0%)	1 (0.8%)	0.13

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.25. Baseline Clinical Characteristics by Exposure Duration, VTE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/VTE event; excludes patients with a VTE within 6 months prior to index date or on anticoagulant

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 44)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 63)	Std. Diff.	Baricitinib (N= 25)	TNFi (N= 67)	Std. Diff.
Age [yrs]												
n	37	44	0.05	41	33	0.07	68	63	0.06	25	67	0.05
Mean±SD	60.2± 16.2	59.5± 14.2		61.6 ± 12.4	60.4 ± 18.2		60.9 ± 13.4	61.7± 14.5		61.0 ± 13.0	60.3± 15.9	
Median	65.0	60.0		61.0	63.0		64.0	63.0		66.0	63.0	
Min, Max	25.0, 84.0	27.0, 85.0		34.0, 83.0	22.0, 84.0		30.0, 85.0	25.0, 86.0		38.0, 82.0	25.0, 84.0	
≥ 65 years	19 (51.4%)	17 (38.6%)	0.26	16 (39.0%)	16 (48.5%)	0.19	31 (45.6%)	31 (49.2%)	0.07	14 (56.0%)	28 (41.8%)	0.29
Gender												
Male	2 (5.4%)	10 (22.7%)	0.51	6 (14.6%)	5 (15.2%)	0.01	11 (16.2%)	12 (19.0%)	0.08	7 (28.0%)	12 (17.9%)	0.24
Female	35 (94.6%)	34 (77.3%)		35 (85.4%)	28 (84.8%)		57 (83.8%)	51 (81.0%)		18 (72.0%)	55 (82.1%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (2.7%)	5 (11.4%)	0.34	2 (4.9%)	3 (9.1%)	0.17	1 (1.5%)	4 (6.3%)	0.25	5 (20.0%)	4 (6.0%)	0.43
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	4 (10.8%)	2 (4.5%)	0.24	4 (9.8%)	2 (6.1%)	0.14	5 (7.4%)	9 (14.3%)	0.22	3 (12.0%)	7 (10.4%)	0.05
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	1 (1.6%)	0.01	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (2.7%)	1 (2.3%)	0.03	1 (2.4%)	0 (0.0%)	0.22	1 (1.5%)	1 (1.6%)	0.01	0 (0.0%)	1 (1.5%)	0.17
Cardiovascular revascularization	1 (2.7%)	0 (0.0%)	0.24	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 44)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 63)	Std. Diff.	Baricitinib (N= 25)	TNFi (N= 67)	Std. Diff.
Congestive heart failure (hospitalized)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (2.3%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (5.4%)	1 (2.3%)	0.16	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	1 (4.0%)	2 (3.0%)	0.06
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.5%)	0.17
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	1 (2.7%)	5 (11.4%)	0.34	2 (4.9%)	5 (15.2%)	0.35	13 (19.1%)	8 (12.7%)	0.18	3 (12.0%)	7 (10.4%)	0.05
Hyperlipidemia	5 (13.5%)	3 (6.8%)	0.22	3 (7.3%)	4 (12.1%)	0.16	11 (16.2%)	12 (19.0%)	0.08	3 (12.0%)	9 (13.4%)	0.04
Hypertension (hospitalized & non-hospitalized)	9 (24.3%)	7 (15.9%)	0.21	12 (29.3%)	11 (33.3%)	0.09	20 (29.4%)	20 (31.7%)	0.05	7 (28.0%)	20 (29.9%)	0.04
Immune disorders	1 (2.7%)	2 (4.5%)	0.10	3 (7.3%)	4 (12.1%)	0.16	9 (13.2%)	3 (4.8%)	0.30	1 (4.0%)	5 (7.5%)	0.15
Secondary Sjogren Syndrome	1 (2.7%)	2 (4.5%)	0.10	3 (7.3%)	4 (12.1%)	0.16	9 (13.2%)	3 (4.8%)	0.30	1 (4.0%)	5 (7.5%)	0.15
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	1 (2.3%)	0.22	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	4 (10.8%)	3 (6.8%)	0.14	2 (4.9%)	1 (3.0%)	0.09	6 (8.8%)	2 (3.2%)	0.24	2 (8.0%)	3 (4.5%)	0.15
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Smoking (current)	3 (8.1%)	9 (20.5%)	0.36	5 (12.2%)	2 (6.1%)	0.21	7 (10.3%)	6 (9.5%)	0.03	3 (12.0%)	5 (7.5%)	0.15
RA severity (CDAI)												
n	37	44	0.20	41	33	0.04	68	63	0.02	25	67	0.45
Mean±SD	25.6± 12.6	23.0± 12.5		20.3 ± 11.9	20.9 ± 13.8		23.0 ± 12.7	23.3± 15.5		26.7 ± 15.4	20.6± 11.6	

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 44)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 63)	Std. Diff.	Baricitinib (N= 25)	TNFi (N= 67)	Std. Diff.
Median	21.9	20.5		19.5	16.2		19.5	19.7		22.0	18.5	
Min, Max	4.4, 55.0	5.5, 67.2		1.0, 64.2	3.0, 58.3		1.4, 57.3	0.5, 65.5		3.5, 60.0	4.0, 55.2	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
MACE (at any time in the past)	1 (2.7%)	0 (0.0%)	0.24	1 (2.4%)	0 (0.0%)	0.22	1 (1.5%)	0 (0.0%)	0.17	1 (4.0%)	4 (6.0%)	0.09
Myocardial infarction	0 (0.0%)	0 (0.0%)	-	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	1 (4.0%)	2 (3.0%)	0.06
Stroke	1 (2.7%)	0 (0.0%)	0.24	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	2 (3.0%)	0.25
Serious infection (at any time in the past)	5 (13.5%)	5 (11.4%)	0.07	1 (2.4%)	2 (6.1%)	0.18	9 (13.2%)	6 (9.5%)	0.12	2 (8.0%)	6 (9.0%)	0.03
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used (ever)												
0	3 (8.1%)	5 (11.4%)	0.11	3 (7.3%)	5 (15.2%)	0.25	5 (7.4%)	5 (7.9%)	0.02	3 (12.0%)	3 (4.5%)	0.28
1	25 (67.6%)	30 (68.2%)	0.01	32 (78.0%)	19 (57.6%)	0.45	46 (67.6%)	48 (76.2%)	0.19	16 (64.0%)	48 (71.6%)	0.16
2+	9 (24.3%)	9 (20.5%)	0.09	6 (14.6%)	9 (27.3%)	0.31	17 (25.0%)	10 (15.9%)	0.23	6 (24.0%)	16 (23.9%)	0.00
Methotrexate (prior use)	33 (89.2%)	36 (81.8%)	0.21	37 (90.2%)	28 (84.8%)	0.16	57 (83.8%)	53 (84.1%)	0.01	19 (76.0%)	61 (91.0%)	0.41
Number of bDMARDs used (ever)												
0	11 (29.7%)	24 (54.5%)	0.52	17 (41.5%)	18 (54.5%)	0.26	30 (44.1%)	39 (61.9%)	0.36	10 (40.0%)	47 (70.1%)	0.64
1	12 (32.4%)	9 (20.5%)	0.27	16 (39.0%)	10 (30.3%)	0.18	20 (29.4%)	16 (25.4%)	0.09	3 (12.0%)	15 (22.4%)	0.28
2+	14 (37.8%)	11 (25.0%)	0.28	8 (19.5%)	5 (15.2%)	0.12	18 (26.5%)	8 (12.7%)	0.35	12 (48.0%)	5 (7.5%)	1.02
Prior bDMARD use[a]	26 (70.3%)	20 (45.5%)	0.52	24 (58.5%)	15 (45.5%)	0.26	38 (55.9%)	24 (38.1%)	0.36	15 (60.0%)	20 (29.9%)	0.64
Prior TNFi bDMARD use	23 (62.2%)	11 (25.0%)	0.81	17 (41.5%)	10 (30.3%)	0.23	26 (38.2%)	13 (20.6%)	0.39	13 (52.0%)	11 (16.4%)	0.81
Prior non-TNF bDMARD use	15 (40.5%)	16 (36.4%)	0.09	13 (31.7%)	9 (27.3%)	0.10	25 (36.8%)	17 (27.0%)	0.21	11 (44.0%)	13 (19.4%)	0.55
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	19 (51.4%)	28 (63.6%)	0.25	22 (53.7%)	22 (66.7%)	0.27	46 (67.6%)	44 (69.8%)	0.05	18 (72.0%)	50 (74.6%)	0.06

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 44)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 63)	Std. Diff.	Baricitinib (N= 25)	TNFi (N= 67)	Std. Diff.
Methotrexate (current use)	19 (51.4%)	25 (56.8%)	0.11	22 (53.7%)	22 (66.7%)	0.27	39 (57.4%)	41 (65.1%)	0.16	14 (56.0%)	46 (68.7%)	0.26
Prescription medication use, current (baseline)												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Antihypertensives (blood pressure lowering medication(s); patient-reported)	6 (16.2%)	8 (18.2%)	0.05	10 (24.4%)	6 (18.2%)	0.15	17 (25.0%)	16 (25.4%)	0.01	7 (28.0%)	18 (26.9%)	0.03
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	2 (3.0%)	0.25
Nitrates (angina/nitrate medications; patient-reported)	1 (2.7%)	0 (0.0%)	0.24	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	1 (4.0%)	0 (0.0%)	0.29
Lipid-lowering agents (cholesterol medication; patient-reported)	6 (16.2%)	7 (15.9%)	0.01	7 (17.1%)	3 (9.1%)	0.24	12 (17.6%)	13 (20.6%)	0.08	4 (16.0%)	6 (9.0%)	0.21
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	3 (6.8%)	0.38	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	1 (4.0%)	2 (3.0%)	0.06
Prednisone	7 (18.9%)	14 (31.8%)	0.30	9 (22.0%)	6 (18.2%)	0.09	17 (25.0%)	16 (25.4%)	0.01	7 (28.0%)	20 (29.9%)	0.04
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = Cardiovascular Disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.26. Baseline Characteristics by Exposure Duration, Alternate VTE Cohorts (Case Definition I) Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.27. Baseline Characteristics by Exposure Duration, Alternate VTE Cohorts (Case Definition II) Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.28. Baseline Clinical Characteristics by Exposure Duration, MACE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/MACE event; excludes patients with a MACE within 6 months prior to index date or on anticoagulant

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 47)	Std. Diff.	Baricitinib (N= 40)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 62)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Age [yrs]												
n	37	47	0.07	40	34	0.11	68	62	0.19	23	66	0.04
Mean±SD	59.8 ± 16.5	60.7 ± 13.6		62.0± 12.1	60.2 ± 18.8		60.9 ± 13.4	63.5± 14.6		60.0± 13.1	60.6± 16.7	
Median	65.0	63.0		61.5	68.5		64.0	65.5		65.0	63.5	
Min, Max	25.0, 84.0	27.0, 85.0		34.0, 83.0	22.0, 84.0		30.0, 85.0	25.0, 88.0		38.0, 82.0	25.0, 84.0	
≥ 65 years	19 (51.4%)	21 (44.7%)	0.13	16 (40.0%)	18 (52.9%)	0.26	31 (45.6%)	33 (53.2%)	0.15	12 (52.2%)	32 (48.5%)	0.07
Gender												
Male	2 (5.4%)	10 (21.3%)	0.48	5 (12.5%)	6 (17.6%)	0.14	11 (16.2%)	10 (16.1%)	0.00	6 (26.1%)	15 (22.7%)	0.08
Female	35 (94.6%)	37 (78.7%)		35 (87.5%)	28 (82.4%)		57 (83.8%)	52 (83.9%)		17 (73.9%)	51 (77.3%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (2.7%)	5 (10.6%)	0.32	2 (5.0%)	3 (8.8%)	0.15	1 (1.5%)	4 (6.5%)	0.26	4 (17.4%)	6 (9.1%)	0.25
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	4 (10.8%)	3 (6.4%)	0.16	4 (10.0%)	5 (14.7%)	0.14	5 (7.4%)	8 (12.9%)	0.18	3 (13.0%)	8 (12.1%)	0.03
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (2.7%)	1 (2.1%)	0.04	1 (2.5%)	0 (0.0%)	0.23	1 (1.5%)	1 (1.6%)	0.01	0 (0.0%)	1 (1.5%)	0.18
Cardiovascular revascularization	1 (2.7%)	0 (0.0%)	0.24	1 (2.5%)	0 (0.0%)	0.23	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 47)	Std. Diff.	Baricitinib (N= 40)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 62)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Congestive heart failure (hospitalized)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (2.1%)	0.21	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (5.4%)	1 (2.1%)	0.17	1 (2.5%)	0 (0.0%)	0.23	0 (0.0%)	1 (1.6%)	0.18	1 (4.3%)	2 (3.0%)	0.07
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	1 (1.5%)	0.18
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	1 (2.7%)	5 (10.6%)	0.32	1 (2.5%)	5 (14.7%)	0.45	13 (19.1%)	8 (12.9%)	0.17	2 (8.7%)	5 (7.6%)	0.04
Hyperlipidemia	5 (13.5%)	3 (6.4%)	0.24	3 (7.5%)	3 (8.8%)	0.05	11 (16.2%)	11 (17.7%)	0.04	3 (13.0%)	8 (12.1%)	0.03
Hypertension (hospitalized & non-hospitalized)	9 (24.3%)	6 (12.8%)	0.30	11 (27.5%)	13 (38.2%)	0.23	20 (29.4%)	23 (37.1%)	0.16	7 (30.4%)	22 (33.3%)	0.06
Immune disorders	1 (2.7%)	4 (8.5%)	0.25	2 (5.0%)	4 (11.8%)	0.25	9 (13.2%)	4 (6.5%)	0.23	1 (4.3%)	6 (9.1%)	0.19
Secondary Sjogren Syndrome	1 (2.7%)	4 (8.5%)	0.25	2 (5.0%)	4 (11.8%)	0.25	9 (13.2%)	4 (6.5%)	0.23	1 (4.3%)	6 (9.1%)	0.19
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	1 (2.1%)	0.21	1 (2.5%)	0 (0.0%)	0.23	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	4 (10.8%)	3 (6.4%)	0.16	1 (2.5%)	1 (2.9%)	0.03	6 (8.8%)	2 (3.2%)	0.24	2 (8.7%)	2 (3.0%)	0.24
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.9%)	0.25	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Smoking (current)	2 (5.4%)	9 (19.1%)	0.43	4 (10.0%)	3 (8.8%)	0.04	7 (10.3%)	6 (9.7%)	0.02	2 (8.7%)	8 (12.1%)	0.11

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 47)	Std. Diff.	Baricitinib (N= 40)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 62)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
RA severity (CDAI)												
n	37	47	0.14	40	34	0.22	68	62	0.07	23	66	0.33
Mean±SD	25.6 ± 12.6	23.9 ± 11.8		20.1± 12.0	23.1 ± 14.5		23.0 ± 12.7	24.0± 15.5		27.1± 16.0	22.3± 13.1	
Median	21.9	23.0		19.4	16.8		19.5	19.3		22.0	19.8	
Min, Max	4.4, 55.0	5.6, 67.2		1.0, 64.2	3.0, 58.3		1.4, 57.3	0.5, 65.5		3.5, 60.0	4.0, 59.7	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (2.1%)	0.21	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	2 (3.2%)	0.26	0 (0.0%)	0 (0.0%)	-
MACE (at any time in the past)	1 (2.7%)	1 (2.1%)	0.04	1 (2.5%)	0 (0.0%)	0.23	1 (1.5%)	0 (0.0%)	0.17	1 (4.3%)	2 (3.0%)	0.07
Myocardial infarction	0 (0.0%)	0 (0.0%)	-	1 (2.5%)	0 (0.0%)	0.23	0 (0.0%)	0 (0.0%)	-	1 (4.3%)	1 (1.5%)	0.17
Stroke	1 (2.7%)	1 (2.1%)	0.04	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	1 (1.5%)	0.18
Serious infection (at any time in the past)	5 (13.5%)	4 (8.5%)	0.16	0 (0.0%)	1 (2.9%)	0.25	9 (13.2%)	5 (8.1%)	0.17	2 (8.7%)	8 (12.1%)	0.11
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	3 (8.1%)	4 (8.5%)	0.01	3 (7.5%)	5 (14.7%)	0.23	5 (7.4%)	5 (8.1%)	0.03	3 (13.0%)	3 (4.5%)	0.30
1	25 (67.6%)	31 (66.0%)	0.03	31 (77.5%)	20 (58.8%)	0.41	46 (67.6%)	44 (71.0%)	0.07	15 (65.2%)	48 (72.7%)	0.16
2+	9 (24.3%)	12 (25.5%)	0.03	6 (15.0%)	9 (26.5%)	0.29	17 (25.0%)	13 (21.0%)	0.10	5 (21.7%)	15 (22.7%)	0.02
Methotrexate (prior use)	33 (89.2%)	40 (85.1%)	0.12	36 (90.0%)	28 (82.4%)	0.22	57 (83.8%)	53 (85.5%)	0.05	17 (73.9%)	60 (90.9%)	0.46
Number of bDMARDs used (ever)												
0	11 (29.7%)	26 (55.3%)	0.54	17 (42.5%)	17 (50.0%)	0.15	30 (44.1%)	35 (56.5%)	0.25	10 (43.5%)	49 (74.2%)	0.66
1	11 (29.7%)	10 (21.3%)	0.19	15 (37.5%)	12 (35.3%)	0.05	20 (29.4%)	19 (30.6%)	0.03	3 (13.0%)	13 (19.7%)	0.18
2+	15 (40.5%)	11 (23.4%)	0.37	8 (20.0%)	5 (14.7%)	0.14	18 (26.5%)	8 (12.9%)	0.35	10 (43.5%)	4 (6.1%)	0.96

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 47)	Std. Diff.	Baricitinib (N= 40)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 62)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Prior bDMARD use[a]	26 (70.3%)	21 (44.7%)	0.54	23 (57.5%)	17 (50.0%)	0.15	38 (55.9%)	27 (43.5%)	0.25	13 (56.5%)	17 (25.8%)	0.66
Prior TNFi bDMARD use	23 (62.2%)	12 (25.5%)	0.79	16 (40.0%)	11 (32.4%)	0.16	26 (38.2%)	15 (24.2%)	0.31	11 (47.8%)	10 (15.2%)	0.75
Prior non-TNFi bDMARD use	15 (40.5%)	16 (34.0%)	0.13	13 (32.5%)	10 (29.4%)	0.07	25 (36.8%)	18 (29.0%)	0.17	9 (39.1%)	10 (15.2%)	0.56
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	18 (48.6%)	32 (68.1%)	0.40	22 (55.0%)	23 (67.6%)	0.26	46 (67.6%)	44 (71.0%)	0.07	16 (69.6%)	54 (81.8%)	0.29
Methotrexate (current use)	18 (48.6%)	29 (61.7%)	0.26	22 (55.0%)	23 (67.6%)	0.26	39 (57.4%)	41 (66.1%)	0.18	13 (56.5%)	50 (75.8%)	0.42
Prescription medication use, current (baseline)												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Antihypertensives (blood pressure lowering medication(s); patient-reported)	6 (16.2%)	7 (14.9%)	0.04	10 (25.0%)	7 (20.6%)	0.11	17 (25.0%)	19 (30.6%)	0.13	7 (30.4%)	21 (31.8%)	0.03
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	2 (3.0%)	0.25
Nitrates (angina/nitrate medications; patient-reported)	1 (2.7%)	0 (0.0%)	0.24	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (4.3%)	0 (0.0%)	0.30
Lipid-lowering agents (cholesterol medication; patient-reported)	6 (16.2%)	8 (17.0%)	0.02	6 (15.0%)	5 (14.7%)	0.01	12 (17.6%)	11 (17.7%)	0.00	4 (17.4%)	9 (13.6%)	0.10
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	3 (6.4%)	0.37	1 (2.5%)	0 (0.0%)	0.23	0 (0.0%)	1 (1.6%)	0.18	1 (4.3%)	1 (1.5%)	0.17
Prednisone	7 (18.9%)	18 (38.3%)	0.44	8 (20.0%)	4 (11.8%)	0.23	17 (25.0%)	15 (24.2%)	0.02	7 (30.4%)	19 (28.8%)	0.04

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 47)	Std. Diff.	Baricitinib (N= 40)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 62)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (2.5%)	0 (0.0%)	0.23	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.29. Baseline Clinical Characteristics by Exposure Duration, Serious infection-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/serious infection event; excludes patients with a serious infection within 6 months prior to index date

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 43)	TNFi (N= 49)	Std. Diff.	Baricitinib (N= 38)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 66)	TNFi (N= 64)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Age [yrs]												
n	43	49	0.03	38	34	0.14	66	64	0.10	23	66	0.17
Mean±SD	60.3 ± 16.6	60.8± 13.7		60.6 ± 12.4	58.5 ± 18.9		61.0 ± 13.1	62.4 ± 15.7		60.0± 13.1	62.5± 15.8	
Median	68.0	63.0		60.5	61.0		64.0	63.0		65.0	64.0	
Min, Max	25.0, 84.0	27.0, 90.0		34.0, 83.0	22.0, 84.0		30.0, 85.0	25.0, 88.0		38.0, 82.0	28.0, 84.0	
≥ 65 years	23 (53.5%)	23 (46.9%)	0.13	13 (34.2%)	16 (47.1%)	0.26	30 (45.5%)	30 (46.9%)	0.03	12 (52.2%)	32 (48.5%)	0.07
Gender												
Male	3 (7.0%)	10 (20.4%)	0.40	6 (15.8%)	4 (11.8%)	0.12	10 (15.2%)	10 (15.6%)	0.01	6 (26.1%)	14 (21.2%)	0.11
Female	40 (93.0%)	39 (79.6%)		32 (84.2%)	30 (88.2%)		56 (84.8%)	54 (84.4%)		17 (73.9%)	52 (78.8%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (2.3%)	6 (12.2%)	0.39	2 (5.3%)	3 (8.8%)	0.14	1 (1.5%)	7 (10.9%)	0.40	4 (17.4%)	4 (6.1%)	0.36
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	4 (9.3%)	3 (6.1%)	0.12	4 (10.5%)	4 (11.8%)	0.04	5 (7.6%)	7 (10.9%)	0.12	3 (13.0%)	7 (10.6%)	0.08
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.18	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (2.3%)	3 (6.1%)	0.19	1 (2.6%)	0 (0.0%)	0.23	1 (1.5%)	1 (1.6%)	0.00	0 (0.0%)	1 (1.5%)	0.18

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 43)	TNFi (N= 49)	Std. Diff.	Baricitinib (N= 38)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 66)	TNFi (N= 64)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Cardiovascular revascularization	1 (2.3%)	0 (0.0%)	0.22	1 (2.6%)	0 (0.0%)	0.23	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Congestive heart failure (hospitalized)	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.18	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (4.7%)	2 (4.1%)	0.03	1 (2.6%)	0 (0.0%)	0.23	0 (0.0%)	1 (1.6%)	0.18	1 (4.3%)	2 (3.0%)	0.07
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	1 (1.5%)	0.18
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	1 (2.3%)	5 (10.2%)	0.33	2 (5.3%)	4 (11.8%)	0.23	13 (19.7%)	9 (14.1%)	0.15	2 (8.7%)	4 (6.1%)	0.10
Hyperlipidemia	5 (11.6%)	5 (10.2%)	0.05	3 (7.9%)	4 (11.8%)	0.13	11 (16.7%)	13 (20.3%)	0.09	3 (13.0%)	7 (10.6%)	0.08
Hypertension (hospitalized & non-hospitalized)	11 (25.6%)	10 (20.4%)	0.12	11 (28.9%)	11 (32.4%)	0.07	19 (28.8%)	24 (37.5%)	0.19	7 (30.4%)	25 (37.9%)	0.16
Immune disorders	1 (2.3%)	3 (6.1%)	0.19	3 (7.9%)	3 (8.8%)	0.03	9 (13.6%)	6 (9.4%)	0.13	1 (4.3%)	7 (10.6%)	0.24
Secondary Sjogren Syndrome	1 (2.3%)	3 (6.1%)	0.19	3 (7.9%)	3 (8.8%)	0.03	9 (13.6%)	6 (9.4%)	0.13	1 (4.3%)	7 (10.6%)	0.24
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	1 (2.0%)	0.20	1 (2.6%)	0 (0.0%)	0.23	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	4 (9.3%)	3 (6.1%)	0.12	2 (5.3%)	1 (2.9%)	0.12	6 (9.1%)	2 (3.1%)	0.25	2 (8.7%)	3 (4.5%)	0.17

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 43)	TNFi (N= 49)	Std. Diff.	Baricitinib (N= 38)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 66)	TNFi (N= 64)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.9%)	0.25	0 (0.0%)	1 (1.6%)	0.18	0 (0.0%)	0 (0.0%)	-
Smoking (current)	2 (4.7%)	9 (18.4%)	0.44	5 (13.2%)	3 (8.8%)	0.14	7 (10.6%)	6 (9.4%)	0.04	2 (8.7%)	4 (6.1%)	0.10
RA severity (CDAI)												
n	43	49	0.01	38	34	0.08	66	64	0.10	23	66	0.35
Mean±SD	24.8 ± 12.4	24.7± 12.1		20.7 ± 12.2	21.7 ± 14.9		23.1 ± 12.8	24.5 ± 15.6		27.1± 16.0	22.1± 12.0	
Median	21.5	24.0		19.8	16.4		19.5	21.1		22.0	20.0	
Min, Max	4.4, 55.0	5.5, 67.2		1.0, 64.2	3.0, 58.3		1.4, 57.3	0.5, 65.5		3.5, 60.0	0.5, 55.2	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	3 (4.7%)	0.31	0 (0.0%)	1 (1.5%)	0.18
MACE (at any time in the past)	1 (2.3%)	2 (4.1%)	0.10	1 (2.6%)	0 (0.0%)	0.23	1 (1.5%)	0 (0.0%)	0.18	1 (4.3%)	3 (4.5%)	0.01
Myocardial infarction	0 (0.0%)	1 (2.0%)	0.20	1 (2.6%)	0 (0.0%)	0.23	0 (0.0%)	0 (0.0%)	-	1 (4.3%)	2 (3.0%)	0.07
Stroke	1 (2.3%)	1 (2.0%)	0.02	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.18	0 (0.0%)	1 (1.5%)	0.18
Serious infection (at any time in the past)	7 (16.3%)	5 (10.2%)	0.18	1 (2.6%)	1 (2.9%)	0.02	7 (10.6%)	6 (9.4%)	0.04	2 (8.7%)	5 (7.6%)	0.04
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	3 (7.0%)	4 (8.2%)	0.04	3 (7.9%)	4 (11.8%)	0.13	5 (7.6%)	6 (9.4%)	0.06	3 (13.0%)	3 (4.5%)	0.30
1	31 (72.1%)	31 (63.3%)	0.19	29 (76.3%)	19 (55.9%)	0.44	44 (66.7%)	46 (71.9%)	0.11	15 (65.2%)	48 (72.7%)	0.16
2+	9 (20.9%)	14 (28.6%)	0.18	6 (15.8%)	11 (32.4%)	0.39	17 (25.8%)	12 (18.8%)	0.17	5 (21.7%)	15 (22.7%)	0.02
Methotrexate (prior use)	38 (88.4%)	42 (85.7%)	0.08	35 (92.1%)	29 (85.3%)	0.22	55 (83.3%)	55 (85.9%)	0.07	17 (73.9%)	60 (90.9%)	0.46
Number of bDMARDs used (ever)												
0	13 (30.2%)	28 (57.1%)	0.56	16 (42.1%)	17 (50.0%)	0.16	29 (43.9%)	38 (59.4%)	0.31	10 (43.5%)	46 (69.7%)	0.55
1	11 (25.6%)	9 (18.4%)	0.17	16 (42.1%)	12 (35.3%)	0.14	20 (30.3%)	18 (28.1%)	0.05	3 (13.0%)	15 (22.7%)	0.25

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 43)	TNFi (N= 49)	Std. Diff.	Baricitinib (N= 38)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 66)	TNFi (N= 64)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
2+	19 (44.2%)	12 (24.5%)	0.42	6 (15.8%)	5 (14.7%)	0.03	17 (25.8%)	8 (12.5%)	0.34	10 (43.5%)	5 (7.6%)	0.90
Prior bDMARD use[a]	30 (69.8%)	21 (42.9%)	0.56	22 (57.9%)	17 (50.0%)	0.16	37 (56.1%)	26 (40.6%)	0.31	13 (56.5%)	20 (30.3%)	0.55
Prior TNFi bDMARD use	27 (62.8%)	13 (26.5%)	0.78	15 (39.5%)	11 (32.4%)	0.15	25 (37.9%)	15 (23.4%)	0.32	11 (47.8%)	11 (16.7%)	0.71
Prior non-TNFi bDMARD use	19 (44.2%)	16 (32.7%)	0.24	11 (28.9%)	10 (29.4%)	0.01	24 (36.4%)	17 (26.6%)	0.21	9 (39.1%)	13 (19.7%)	0.44
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	21 (48.8%)	32 (65.3%)	0.34	21 (55.3%)	25 (73.5%)	0.39	44 (66.7%)	45 (70.3%)	0.08	16 (69.6%)	51 (77.3%)	0.18
Methotrexate (current use)	21 (48.8%)	29 (59.2%)	0.21	21 (55.3%)	24 (70.6%)	0.32	37 (56.1%)	45 (70.3%)	0.30	13 (56.5%)	48 (72.7%)	0.34
Current (baseline) prescription medication use												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	2 (4.1%)	0.29	0 (0.0%)	1 (2.9%)	0.25	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.5%)	0.18
Antihypertensives (blood pressure lowering medication(s); patient-reported)	6 (14.0%)	11 (22.4%)	0.22	10 (26.3%)	5 (14.7%)	0.29	17 (25.8%)	21 (32.8%)	0.16	7 (30.4%)	27 (40.9%)	0.22
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	1 (1.6%)	0.00	0 (0.0%)	2 (3.0%)	0.25
Nitrates (angina/nitrate medications; patient-reported)	1 (2.3%)	1 (2.0%)	0.02	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (4.3%)	0 (0.0%)	0.30
Lipid-lowering agents (cholesterol medication; patient-reported)	8 (18.6%)	11 (22.4%)	0.10	5 (13.2%)	3 (8.8%)	0.14	12 (18.2%)	11 (17.2%)	0.03	4 (17.4%)	11 (16.7%)	0.02
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	4 (8.2%)	0.42	1 (2.6%)	0 (0.0%)	0.23	0 (0.0%)	1 (1.6%)	0.18	1 (4.3%)	2 (3.0%)	0.07
Prednisone	9 (20.9%)	16 (32.7%)	0.27	9 (23.7%)	5 (14.7%)	0.23	15 (22.7%)	15 (23.4%)	0.02	7 (30.4%)	18 (27.3%)	0.07

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 43)	TNFi (N= 49)	Std. Diff.	Baricitinib (N= 38)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 66)	TNFi (N= 64)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 66)	Std. Diff.
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (2.6%)	0 (0.0%)	0.23	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.30. Baseline Clinical Characteristics by Exposure Duration, Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/TB event; excludes patients with a hospitalized TB within 6 months prior to index date

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 50)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 59)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 70)	Std. Diff.
Age [yrs]												
n	37	50	0.02	41	34	0.24	68	59	0.02	23	70	0.25
Mean±SD	59.8 ± 16.5	59.4 ± 14.3		61.6 ± 12.4	57.7± 18.8		60.9 ± 13.4	61.2± 15.5		60.0± 13.1	63.5± 14.9	
Median	65.0	60.5		61.0	58.5		64.0	62.0		65.0	67.5	
Min, Max	25.0, 84.0	20.0, 90.0		34.0, 83.0	22.0, 84.0		30.0, 85.0	25.0, 88.0		38.0, 82.0	28.0, 84.0	
≥ 65 years	19 (51.4%)	20 (40.0%)	0.23	16 (39.0%)	14 (41.2%)	0.04	31 (45.6%)	26 (44.1%)	0.03	12 (52.2%)	37 (52.9%)	0.01
Gender												
Male	2 (5.4%)	10 (20.0%)	0.45	6 (14.6%)	4 (11.8%)	0.08	11 (16.2%)	10 (16.9%)	0.02	6 (26.1%)	15 (21.4%)	0.11
Female	35 (94.6%)	40 (80.0%)		35 (85.4%)	30 (88.2%)		57 (83.8%)	49 (83.1%)		17 (73.9%)	55 (78.6%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (2.7%)	7 (14.0%)	0.42	2 (4.9%)	3 (8.8%)	0.16	1 (1.5%)	6 (10.2%)	0.38	4 (17.4%)	7 (10.0%)	0.22
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.7%)	0.19	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	4 (10.8%)	3 (6.0%)	0.17	4 (9.8%)	5 (14.7%)	0.15	5 (7.4%)	8 (13.6%)	0.20	3 (13.0%)	8 (11.4%)	0.05
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (2.7%)	3 (6.0%)	0.16	1 (2.4%)	0 (0.0%)	0.22	1 (1.5%)	1 (1.7%)	0.02	0 (0.0%)	1 (1.4%)	0.17
Cardiovascular revascularization	1 (2.7%)	0 (0.0%)	0.24	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	1 (1.7%)	0.19	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 50)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 59)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 70)	Std. Diff.
Congestive heart failure (hospitalized)	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.7%)	0.19	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (5.4%)	2 (4.0%)	0.07	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	1 (1.7%)	0.19	1 (4.3%)	2 (2.9%)	0.08
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.7%)	0.19	0 (0.0%)	1 (1.4%)	0.17
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	1 (2.7%)	5 (10.0%)	0.30	2 (4.9%)	2 (5.9%)	0.04	13 (19.1%)	8 (13.6%)	0.15	2 (8.7%)	7 (10.0%)	0.04
Hyperlipidemia	5 (13.5%)	6 (12.0%)	0.05	3 (7.3%)	4 (11.8%)	0.15	11 (16.2%)	10 (16.9%)	0.02	3 (13.0%)	8 (11.4%)	0.05
Hypertension (hospitalized & non-hospitalized)	9 (24.3%)	10 (20.0%)	0.10	12 (29.3%)	11 (32.4%)	0.07	20 (29.4%)	19 (32.2%)	0.06	7 (30.4%)	27 (38.6%)	0.17
Immune disorders	1 (2.7%)	4 (8.0%)	0.24	3 (7.3%)	5 (14.7%)	0.24	9 (13.2%)	4 (6.8%)	0.22	1 (4.3%)	7 (10.0%)	0.22
Secondary Sjogren Syndrome	1 (2.7%)	4 (8.0%)	0.24	3 (7.3%)	5 (14.7%)	0.24	9 (13.2%)	4 (6.8%)	0.22	1 (4.3%)	7 (10.0%)	0.22
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	1 (2.0%)	0.20	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	4 (10.8%)	3 (6.0%)	0.17	2 (4.9%)	2 (5.9%)	0.04	6 (8.8%)	2 (3.4%)	0.23	2 (8.7%)	2 (2.9%)	0.25
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.9%)	0.25	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Smoking (current)	2 (5.4%)	9 (18.0%)	0.40	5 (12.2%)	3 (8.8%)	0.11	7 (10.3%)	6 (10.2%)	0.00	2 (8.7%)	6 (8.6%)	0.00

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 50)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 59)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 70)	Std. Diff.
RA severity (CDAI)												
n	37	50	0.09	41	34	0.13	68	59	0.12	23	70	0.25
Mean±SD	25.6 ± 12.6	24.5 ± 12.0		20.3 ± 11.9	22.0± 14.9		23.0 ± 12.7	24.7± 15.4		27.1± 16.0	23.4± 12.8	
Median	21.9	23.5		19.5	16.4		19.5	22.0		22.0	20.9	
Min, Max	4.4, 55.0	5.5, 67.2		1.0, 64.2	3.0, 58.3		1.4, 57.3	0.5, 65.5		3.5, 60.0	0.5, 59.7	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (2.0%)	0.20	0 (0.0%)	1 (2.9%)	0.25	0 (0.0%)	3 (5.1%)	0.33	0 (0.0%)	0 (0.0%)	-
MACE (at any time in the past)	1 (2.7%)	2 (4.0%)	0.07	1 (2.4%)	0 (0.0%)	0.22	1 (1.5%)	0 (0.0%)	0.17	1 (4.3%)	3 (4.3%)	0.00
Myocardial infarction	0 (0.0%)	1 (2.0%)	0.20	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	1 (4.3%)	2 (2.9%)	0.08
Stroke	1 (2.7%)	1 (2.0%)	0.05	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	0 (0.0%)	0.17	0 (0.0%)	1 (1.4%)	0.17
Serious infection (at any time in the past)	5 (13.5%)	6 (12.0%)	0.05	1 (2.4%)	2 (5.9%)	0.17	9 (13.2%)	6 (10.2%)	0.10	2 (8.7%)	8 (11.4%)	0.09
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used (ever)												
0	3 (8.1%)	4 (8.0%)	0.00	3 (7.3%)	4 (11.8%)	0.15	5 (7.4%)	5 (8.5%)	0.04	3 (13.0%)	2 (2.9%)	0.38
1	25 (67.6%)	34 (68.0%)	0.01	32 (78.0%)	20 (58.8%)	0.42	46 (67.6%)	42 (71.2%)	0.08	15 (65.2%)	50 (71.4%)	0.13
2+	9 (24.3%)	12 (24.0%)	0.01	6 (14.6%)	10 (29.4%)	0.36	17 (25.0%)	12 (20.3%)	0.11	5 (21.7%)	18 (25.7%)	0.09
Methotrexate (prior use)	33 (89.2%)	43 (86.0%)	0.10	37 (90.2%)	29 (85.3%)	0.15	57 (83.8%)	50 (84.7%)	0.03	17 (73.9%)	66 (94.3%)	0.58
Number of bDMARDs used (ever)												
0	11 (29.7%)	29 (58.0%)	0.59	17 (41.5%)	17 (50.0%)	0.17	30 (44.1%)	32 (54.2%)	0.20	10 (43.5%)	51 (72.9%)	0.62
1	11 (29.7%)	9 (18.0%)	0.28	16 (39.0%)	12 (35.3%)	0.08	20 (29.4%)	19 (32.2%)	0.06	3 (13.0%)	14 (20.0%)	0.19
2+	15 (40.5%)	12 (24.0%)	0.36	8 (19.5%)	5 (14.7%)	0.13	18 (26.5%)	8 (13.6%)	0.33	10 (43.5%)	5 (7.1%)	0.92
Prior bDMARD use[a]	26 (70.3%)	21 (42.0%)	0.59	24 (58.5%)	17 (50.0%)	0.17	38 (55.9%)	27 (45.8%)	0.20	13 (56.5%)	19 (27.1%)	0.62

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 50)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 59)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 70)	Std. Diff.
Prior TNFi bDMARD use	23 (62.2%)	13 (26.0%)	0.78	17 (41.5%)	11 (32.4%)	0.19	26 (38.2%)	15 (25.4%)	0.28	11 (47.8%)	11 (15.7%)	0.73
Prior non-TNFi bDMARD use	15 (40.5%)	16 (32.0%)	0.18	13 (31.7%)	10 (29.4%)	0.05	25 (36.8%)	18 (30.5%)	0.13	9 (39.1%)	12 (17.1%)	0.50
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	18 (48.6%)	34 (68.0%)	0.40	22 (53.7%)	22 (64.7%)	0.23	46 (67.6%)	43 (72.9%)	0.11	16 (69.6%)	56 (80.0%)	0.24
Methotrexate (current use)	18 (48.6%)	31 (62.0%)	0.27	22 (53.7%)	22 (64.7%)	0.23	39 (57.4%)	40 (67.8%)	0.22	13 (56.5%)	52 (74.3%)	0.38
Prescription medication use, current (baseline)												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	2 (4.0%)	0.29	0 (0.0%)	1 (2.9%)	0.25	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Antihypertensives (blood pressure lowering medication(s); patient-reported)	6 (16.2%)	11 (22.0%)	0.15	10 (24.4%)	6 (17.6%)	0.17	17 (25.0%)	17 (28.8%)	0.09	7 (30.4%)	26 (37.1%)	0.14
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (1.5%)	1 (1.7%)	0.02	0 (0.0%)	2 (2.9%)	0.24
Nitrates (angina/nitrate medications; patient-reported)	1 (2.7%)	1 (2.0%)	0.05	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (4.3%)	0 (0.0%)	0.30
Lipid-lowering agents (cholesterol medication; patient-reported)	6 (16.2%)	10 (20.0%)	0.10	7 (17.1%)	4 (11.8%)	0.15	12 (17.6%)	11 (18.6%)	0.03	4 (17.4%)	9 (12.9%)	0.13
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	4 (8.0%)	0.42	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	1 (1.7%)	0.19	1 (4.3%)	2 (2.9%)	0.08
Prednisone	7 (18.9%)	16 (32.0%)	0.30	9 (22.0%)	4 (11.8%)	0.27	17 (25.0%)	16 (27.1%)	0.05	7 (30.4%)	20 (28.6%)	0.04

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 37)	TNFi (N= 50)	Std. Diff.	Baricitinib (N= 41)	TNFi (N= 34)	Std. Diff.	Baricitinib (N= 68)	TNFi (N= 59)	Std. Diff.	Baricitinib (N= 23)	TNFi (N= 70)	Std. Diff.
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.31. Baseline Healthcare Resource Utilization by Exposure Duration, pre-matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.32. Baseline Healthcare Resource Utilization by Exposure Duration Primary VTE Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.33. Baseline Healthcare Resource Utilization by Exposure Duration Alternate VTE Cohorts (Case Definition I), Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.34. Baseline Healthcare Resource Utilization by Exposure Duration Alternate VTE Cohorts (Case Definition II), Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.35. Baseline Healthcare Resource Utilization by Exposure Duration MACE Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.36. Baseline Healthcare Resource Utilization by Exposure Duration Serious Infection Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.37. Baseline Healthcare Resource Utilization by Exposure Duration Hospitalized Tuberculosis Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.38. Primary (Main) Case Definition for VTE and Alternate Case Definitions for Sensitivity Analyses [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.39. Pattern of VTE and Related Diagnostic Codes in Patients with RA [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.40. Baseline Characteristics of Patients with VTE, VTE-matched Population [CorEvitas Japan] - excludes patients with a VTE within 6 months prior to index date or on anticoagulant

The table has been omitted as there are no VTE events.

COR_JP Table 6.41. Pattern of RA Medication Use in Patients with VTE [CorEvitas Japan] - excludes patients with a VTE within 6 months prior to index date or on anticoagulant

The table has been omitted as there are no VTE events.

COR_JP Table 6.42. Time to First VTE Event (Days) [CorEvitas Japan]

The table has been omitted as there are no VTE events.

COR_JP Table 6.43. Time to First VTE Event, Alternate Definitions I [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.44. Time to First VTE Event, Alternate Definitions II [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.45. Incidence Rates of First VTE Event [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 210)	**TNFi (N= 354)**	**Baricitinib (N= 171)**	**TNFi (N= 207)**	**Total (N= 378)**
Overall					
VTE Events	0	0	0	0	0
Person-Years	231.6	537.0	199.5	308.9	508.4
VTE Events/100 PY	0.0	0.0	0.0	0.0	0.0
95% CI	0.0, 1.6	0.0, 0.7	0.0, 1.8	0.0, 1.2	0.0, 0.7
Incidence rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)
Concomitant MTX Use at Index Date					
N	110	254	94	134	228
VTE Events	0	0	0	0	0
Person-Years	120.7	398.7	108.5	209.3	317.8
VTE Events/100 PY	0.0	0.0	0.0	0.0	0.0
95% CI	0.0, 3.1	0.0, 0.9	0.0, 3.4	0.0, 1.8	0.0, 1.2
Incidence rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)
No Concomitant MTX Use at Index Date					
N	100	100	77	73	150
VTE Events	0	0	0	0	0
Person-Years	110.8	138.2	91.0	99.6	190.6
VTE Events/100 PY	0.0	0.0	0.0	0.0	0.0
95% CI	0.0, 3.3	0.0, 2.7	0.0, 4.1	0.0, 3.7	0.0, 1.9
Incidence rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)

Abbreviations: bDMARD = biologic disease-modifying anti-rheumatic drug; CI = confidence interval; MTX = methotrexate; PY = person-years; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

COR_JP Table 6.46. Incidence Rates of First VTE for Alternate VTE Definition I [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.47. Incidence Rates of First VTE for Alternate VTE Definition II [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.48. Comparative Risk of Incident VTE, Primary Definition [CorEvitas Japan], VTE-matched population – excludes patients with prior VTE within 6 months prior to index date or on anticoagulant

The table has been omitted as there are no VTE events.

COR_JP Figure 2. Kaplan-Meier Curve of Time-to-First VTE Event [CorEvitas Japan], pre-matched VTE Population – excludes patients with prior VTE within 6 months prior to index date or on anticoagulant

Not applicable for CorEvitas Japan data.

COR_JP Figure 3. Kaplan-Meier Curve of Time-to-First VTE Event [CorEvitas Japan], VTE-matched Population – excludes patients with prior VTE within 6 months prior to index date or on anticoagulant

Not applicable for CorEvitas Japan data.

COR_JP Figure 4. Adjusted Survival Curve of Time-to-First VTE Event [CorEvitas Japan], VTE-matched Population – excludes patients with prior VTE within 6 months prior to index date or on anticoagulant

Not applicable for CorEvitas Japan data.

COR_JP Table 6.49. Comparative Risk of Incident VTE for Alternate VTE Definition I [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.50. Comparative Risk of Incident VTE for Alternate VTE Definition II [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.51. Baseline Clinical Characteristics of Patients with MACE, MACE-matched Population [CorEvitas Japan] – excludes patients with a MACE within 6 months prior to index date or on anticoagulant

The table has been omitted as there are no MACE events in the MACE-matched population.

COR_JP Table 6.52. Pattern of RA Medication Use in Patients with MACE [CorEvitas Japan] - excludes patients with a MACE within 6 months prior to index date or on anticoagulant

	Pre-matched		Matched		
	Baricitinib (N= 1)	TNFi (N= 0)	Baricitinib (N= 0)	TNFi (N= 0)	Total (N= 0)
Baseline Medication					
Number of cDMARDs used(ever)					
0	0(0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2+	0(0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate (prior use)	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of bDMARDs used (ever)					
0	0(0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	0(0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2+	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant non-methotrexate cDMARD use at baseline	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant methotrexate use at baseline	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prior bDMARD use[a]	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prior TNFi bDMARD use	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prior non-TNFi bDMARD use	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-index Medication					
Concomitant methotrexate use during exposure (regardless of use at index date)	1(100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant non-methotrexate cDMARD use during exposure (regardless of use at index date)	0(0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Pre-matched		Matched		
	Baricitinib (N= 1)	TNFi (N= 0)	Baricitinib (N= 0)	TNFi (N= 0)	Total (N= 0)
Baricitinib dose change during exposure	0(0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; cDMARD = classical disease-modifying antirheumatic drugs; MACE = major adverse cardiovascular event; TNFi = tumor necrosis factor inhibitor.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.53. Time to First MACE (Days) [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 1)	**TNFi (N= 0)**	**Baricitinib (N= 0)**	**TNFi (N= 0)**	**Total (N= 0)**
n	1	0	0	0	0
Mean±SD	35.0 ±.	n/a	n/a	n/a	n/a
Median	35.0				
Min, Max	35.0, 35.0				
25th, 75th percentile	35.0, 35.0				

Abbreviations: MACE = major adverse cardiovascular event; Min = minimum; Max = maximum; SD = standard deviation; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.54. Incidence Rates of First MACE [CorEvitas Japan]

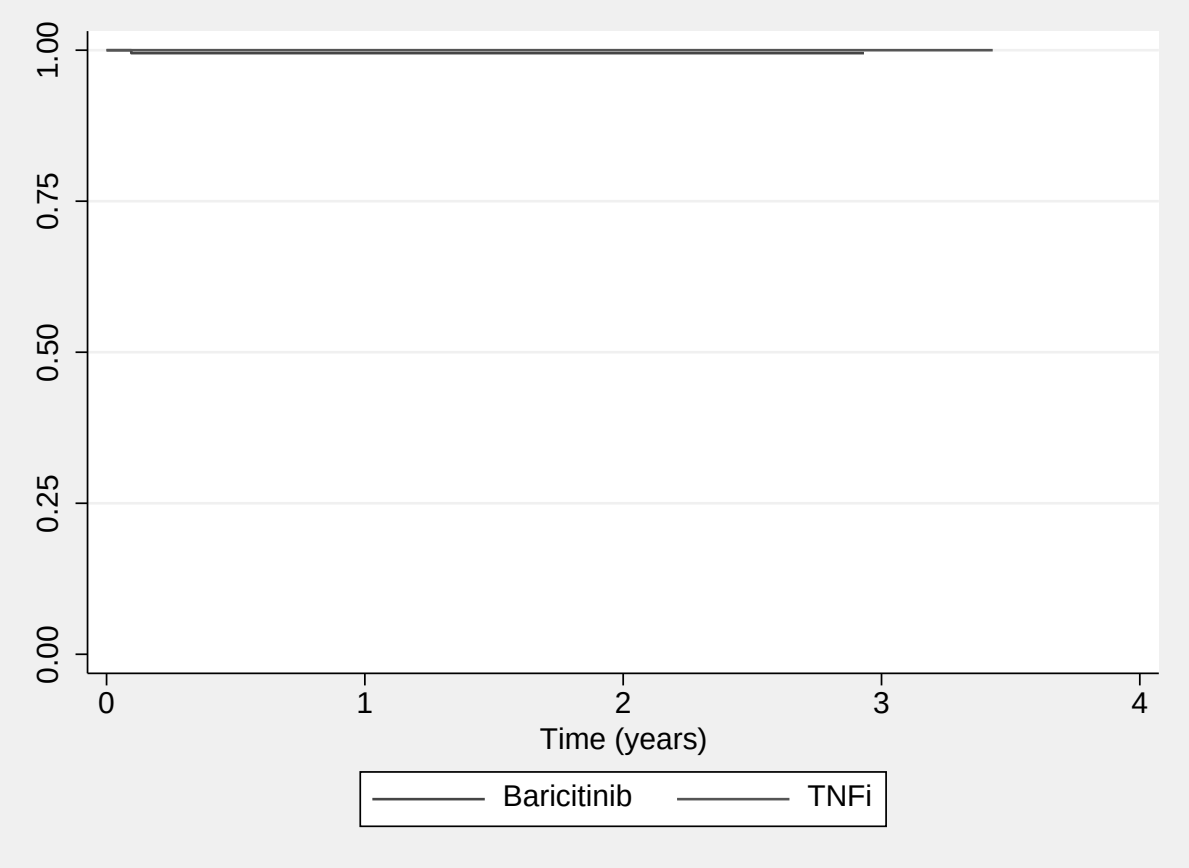
	Pre-matched		Matched		
	Baricitinib (N= 210)	TNFi (N= 354)	Baricitinib (N= 168)	TNFi (N= 209)	Total (N= 377)
Overall					
MACE Events	1	0	0	0	0
Person-Years	231.3	537.0	194.3	305.3	499.5
MACE Events/100 PY	0.4	0.0	0.0	0.0	0.0
95% CI	0.0, 2.4	0.0, 0.7	0.0, 1.9	0.0, 1.2	0.0, 0.7
Incident rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)
MI					
MI Events	0	0	0	0	0
Person-Years	231.6	537.0	194.3	305.3	499.5
MACE Events/100 PY	0.0	0.0	0.0	0.0	0.0
95% CI	0.0, 1.6	0.0, 0.7	0.0, 1.9	0.0, 1.2	0.0, 0.7
Incident rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)
Stroke					
Stroke Events	1	0	0	0	0
Person-Years	231.3	537.0	194.3	305.3	499.5
MACE Events/100 PY	0.4	0.0	0.0	0.0	0.0
95% CI	0.0, 2.4	0.0, 0.7	0.0, 1.9	0.0, 1.2	0.0, 0.7
Incident rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)
Concomitant MTX Use at Index Date					
N	110	254	92	143	235
MACE Events	1	0	0	0	0
Person-Years	120.5	398.7	105.9	221.0	326.9
MACE Events/100 PY	0.8	0.0	0.0	0.0	0.0
95% CI	0.0, 4.6	0.0, 0.9	0.0, 3.5	0.0, 1.7	0.0, 1.1
Incident rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)
No Concomitant MTX Use at Index Date					
N	100	100	76	66	142
MACE Events	0	0	0	0	0
Person-Years	110.8	138.2	88.4	84.3	172.6
MACE Events/100 PY	0.0	0.0	0.0	0.0	0.0
95% CI	0.0, 3.3	0.0, 2.7	0.0, 4.2	0.0, 4.4	0.0, 2.1
Incident rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)

Abbreviations: CI = confidence interval; MI = myocardial infarction; MACE = major adverse cardiovascular event; MTX = methotrexate; PY = person-years; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.55. Comparative Risk of Incident MACE [CorEvitas Japan], MACE-matched population – excludes patients with prior MACE within 6 months prior to index date or on anticoagulant

The table has been omitted as there are no MACE events in the MACE-matched population.

COR_JP Figure 5. Kaplan-Meier Curve of Time-to-First MACE [CorEvitas Japan], pre-matched MACE Population – excludes patients with prior MACE within 6 months prior to index date or on anticoagulant



COR_JP Figure 6. Kaplan-Meier Curve of Time-to-First MACE [CorEvitas Japan], MACE-matched Population – excludes patients with prior MACE within 6 months prior to index date or on anticoagulant

Not applicable to CorEvitas Japan data.

COR_JP Figure 7. Adjusted Survival Curve of Time-to-First MACE [CorEvitas Japan], MACE-matched Population – excludes patients with prior MACE within 6 months prior to index date or on anticoagulant

Not applicable to CorEvitas Japan data.

COR_JP Table 6.56. Baseline Clinical Characteristics of Patients with Serious Infection, Serious Infection-matched Population [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Baricitinib (N=9)	TNFi (N=8)	Total (N=17)
Age [yrs]			
n	9	8	17
Mean±SD	68.9 ±13.7	68.5 ± 6.5	68.7 ±10.6
Median	73.0	68.0	70.0
Min, Max	39.0, 81.0	58.0, 80.0	39.0, 81.0
Gender			
Male	2 (22.2%)	1 (12.5%)	3 (17.6%)
Female	7 (77.8%)	7 (87.5%)	14 (82.4%)
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	0 (0.0%)	2 (25.0%)	2 (11.8%)
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	0 (0.0%)	3 (37.5%)	3 (17.6%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure (hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes mellitus	0 (0.0%)	2 (25.0%)	2 (11.8%)
Hyperlipidemia	0 (0.0%)	2 (25.0%)	2 (11.8%)
Hypertension (hospitalized & non-hospitalized)	4 (44.4%)	3 (37.5%)	7 (41.2%)

	Baricitinib (N=9)	TNFi (N=8)	Total (N=17)
Immune disorders	0 (0.0%)	2 (25.0%)	2 (11.8%)
Secondary Sjogren Syndrome	0 (0.0%)	2 (25.0%)	2 (11.8%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Obesity, current	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Smoking (current)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RA severity (CDAI)			
n	9	8	17
Mean±SD	22.7 ±15.5	23.2 ±10.9	22.9 ±13.1
Median	18.0	25.5	21.3
Min, Max	8.5, 60.0	6.7, 39.5	6.7, 60.0
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	1 (12.5%)	1 (5.9%)
MACE (at any time in the past)	1 (11.1%)	0 (0.0%)	1 (5.9%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stroke	1 (11.1%)	0 (0.0%)	1 (5.9%)
Serious infection (at any time in the past)	3 (33.3%)	2 (25.0%)	5 (29.4%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prescription medication use, current (baseline)			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	1 (11.1%)	2 (25.0%)	3 (17.6%)
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nitrates (angina/nitrate medications; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents (cholesterol medication; patient-reported)	3 (33.3%)	1 (12.5%)	4 (23.5%)
RA-related			
Aspirin (includes non-prescription)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate (current use)	3 (33.3%)	8 (100.0%)	11 (64.7%)

	Baricitinib (N=9)	TNFi (N=8)	Total (N=17)
Prednisone	2 (22.2%)	4 (50.0%)	6 (35.3%)
Vaccinations			
Shingles (ever)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

COR_JP Table 6.57. Pattern of RA Medication Use in Patients with Serious Infection [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Pre-matched		Matched		
	Baricitinib (N= 11)	TNFi (N= 15)	Baricitinib (N= 9)	TNFi (N= 8)	Total (N= 17)
Baseline Medication					
BDMARD history					
Number of cDMARDs used(ever)					
0	1 (9.1%)	1 (6.7%)	1 (11.1%)	0 (0.0%)	1 (5.9%)
1	9 (81.8%)	9 (60.0%)	7 (77.8%)	5 (62.5%)	12 (70.6%)
2+	1 (9.1%)	5 (33.3%)	1 (11.1%)	3 (37.5%)	4 (23.5%)
Methotrexate (prior use)	9 (81.8%)	13 (86.7%)	7 (77.8%)	8 (100.0%)	15 (88.2%)
Number of bDMARDs used (ever)					
0	4 (36.4%)	11 (73.3%)	3 (33.3%)	5 (62.5%)	8 (47.1%)
1	1 (9.1%)	2 (13.3%)	1 (11.1%)	1 (12.5%)	2 (11.8%)
2+	6 (54.5%)	2 (13.3%)	5 (55.6%)	2 (25.0%)	7 (41.2%)
Prior bDMARD use[a]	7 (63.6%)	4 (26.7%)	6 (66.7%)	3 (37.5%)	9 (52.9%)
Prior TNFi bDMARD use	6 (54.5%)	3 (20.0%)	5 (55.6%)	3 (37.5%)	8 (47.1%)
Prior non-TNFi bDMARD use	5 (45.5%)	3 (20.0%)	5 (55.6%)	2 (25.0%)	7 (41.2%)
BDMARD, current (baseline)					
Concomitant non-methotrexate cDMARD use at baseline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant methotrexate use at baseline	4 (36.4%)	13 (86.7%)	3 (33.3%)	8 (100.0%)	11 (64.7%)
Post-index Medication (Prior to Serious Infection)					
Concomitant methotrexate use during exposure (regardless of use at index date)	5 (45.5%)	13 (86.7%)	4 (44.4%)	8 (100.0%)	12 (70.6%)

	Pre-matched		Matched		
	Baricitinib (N= 11)	TNFi (N= 15)	Baricitinib (N= 9)	TNFi (N= 8)	Total (N= 17)
Concomitant non-methotrexate cDMARD use during exposure (regardless of use at index date)	0 (0.0%)	2 (13.3%)	0 (0.0%)	1 (12.5%)	1 (5.9%)
Baricitinib dose change during exposure	0 (0.0%)	2 (13.3%)	0 (0.0%)	2 (25.0%)	2 (11.8%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; cDMARD = classical disease-modifying antirheumatic drugs; TNFi = tumor necrosis factor inhibitor.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.58. Time to First Serious Infection Event (Days) [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 11)	TNFi (N= 15)	Baricitinib (N= 9)	TNFi (N= 8)	Total (N= 17)
n	11	15	9	8	17
Mean±SD	208.1 ±249.3	338.3 ±301.0	210.7 ±278.3	400.1 ±272.0	299.8 ±283.9
Median	128.0	300.0	108.0	361.0	153.0
Min, Max	40.0, 902.0	41.0, 903.0	40.0, 902.0	41.0, 716.0	40.0, 902.0
25th, 75th percentile	51.0, 223.0	70.0, 678.0	51.0, 153.0	180.0, 681.0	60.0, 396.0

Abbreviations: Min = minimum; Max = maximum; SD = standard deviation; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.59. Incidence Rates of First Serious Infection Event [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 210)	**TNFi (N= 354)**	**Baricitinib (N= 170)**	**TNFi (N= 213)**	**Total (N= 383)**
Overall					
SI Events	11	15	9	8	17
Person-Years	225.1	524.5	190.8	303.1	493.8
SI Events/100 PY	4.9	2.9	4.7	2.6	3.4
95% CI	2.4, 8.7	1.6, 4.7	2.2, 9.0	1.1, 5.2	2.0, 5.5
Incidence rate difference: baricitinib – TNFi (95% CI)					2.1 (-1.5, 5.7)

Abbreviations: CI = confidence interval; PY = person-years; SI = Serious Infection defined as infection; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.60. Serious Infection Events Per Patient During Baricitinib and TNF Exposure* [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Pre-matched		Matched		
	Baricitinib (N= 210)	TNFi (N= 354)	Baricitinib (N= 170)	TNFi (N= 213)	Total (N= 383)
0	199 (94.8%)	339 (95.8%)	161 (94.7%)	205 (96.2%)	366 (95.6%)
1	9 (4.3%)	15 (4.2%)	7 (4.1%)	8 (3.8%)	15 (3.9%)
2	2 (1.0%)	0 (0.0%)	2 (1.2%)	0 (0.0%)	2 (0.5%)

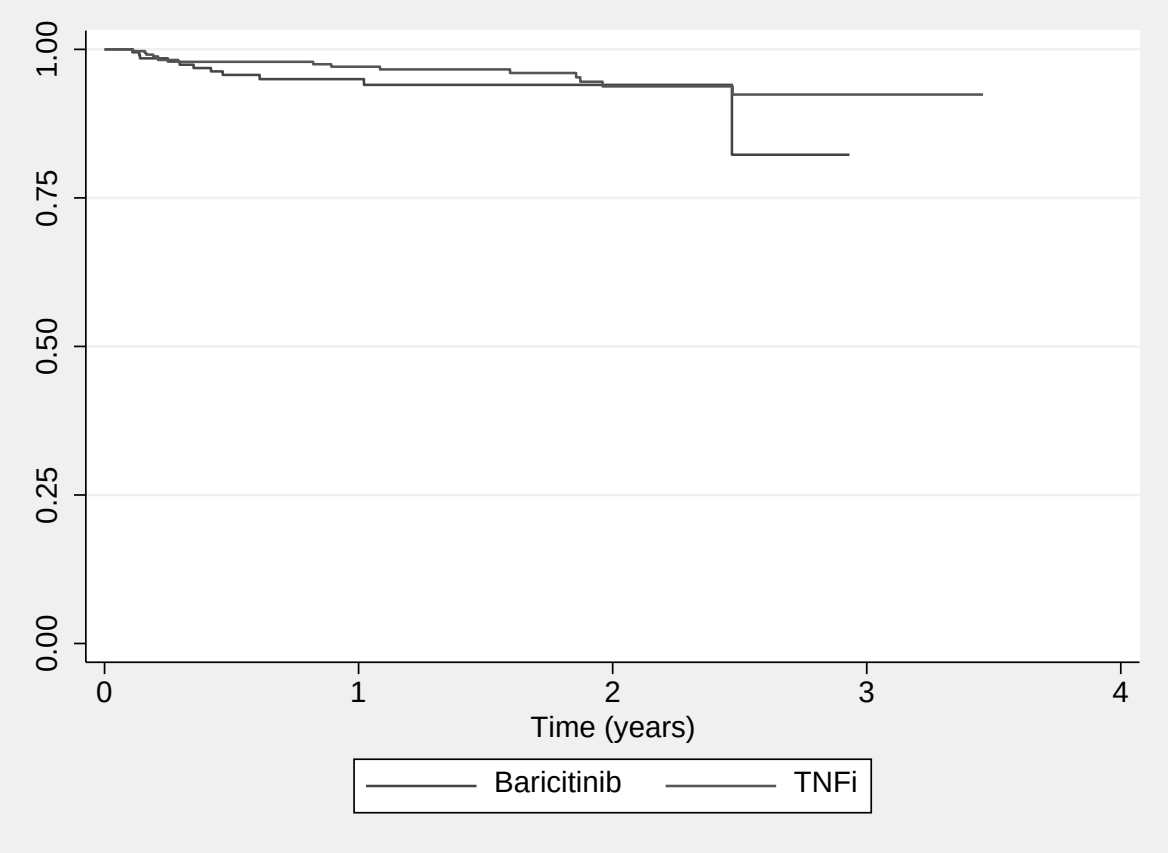
* All events after the first occur after the incident serious infection determining time to first serious infection event
Abbreviation: TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.61. Comparative Risk of Incident Serious Infection [CorEvitas Japan]; Serious Infection-matched population – excludes patients with prior serious infection within 6 months prior to index

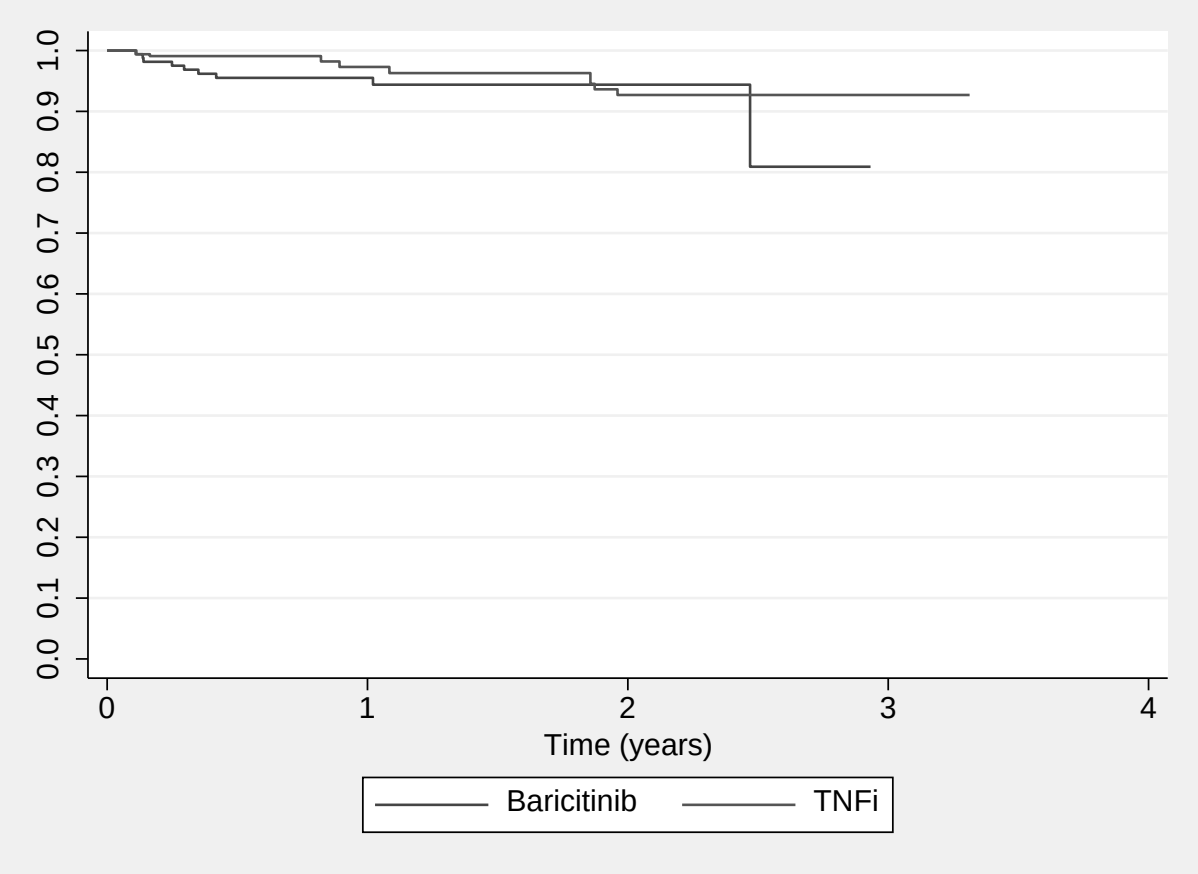
	TNFi	Baricitinib HR (95% CI)	P-Value
Base model	Ref	HR: 1.7 95% CI: [0.61, 4.75]	0.309
Adjusted - Model [1]	Ref	HR: 1.35 95% CI: [0.47, 3.88]	0.579
Adjusted - Model [2]	Ref	HR: 1.41 95% CI: [0.49, 4.07]	0.520
Non-mtx cDMARD use	Ref	HR: .45 95% CI: [0.06, 3.47]	0.442
Mtx cDMARD use	Ref	HR: 1.07 95% CI: [0.38, 3.06]	0.893
Prednisone use	Ref	HR: 1.65 95% CI: [0.56, 4.86]	0.361
Adjusted - Model [3]	Ref	HR: 1.38 95% CI: [0.48, 3.96]	0.544
Prednisone use	Ref	HR: 1.57 95% CI: [0.54, 4.61]	0.410
Adjusted - Model [4]	Ref	HR: 1.36 95% CI: [0.47, 3.92]	0.567
RA severity (CDAI)	Ref	HR: .99 95% CI: [0.96, 1.03]	0.787
Adjusted - Model [5]	Ref	HR: 1.39 95% CI: [0.48, 4.02]	0.543

Abbreviations: CDAI = clinical disease activity index; cDMARD = classical disease-modifying anti-rheumatic drug; CI = confidence interval; HR = hazard ratio mtx = methotrexate; Ref = Referent group; TNFi = tumor necrosis factor inhibitor.
Base model: no adjusting covariates
Model [1]: adjusted with covariates specified in SAP COR_JP Table 66 and remaining imbalanced after matching
Model [2]: Model [1] + time-varying concomitant non-methotrexate cDMARD use + time-varying concomitant methotrexate use + time-varying prednisone use
Model [3]: Model [1] + time-varying prednisone use
Model [4]: Model [1] + RA severity (CDAI)
Model [5]: Model [4] + BMI + smoking status

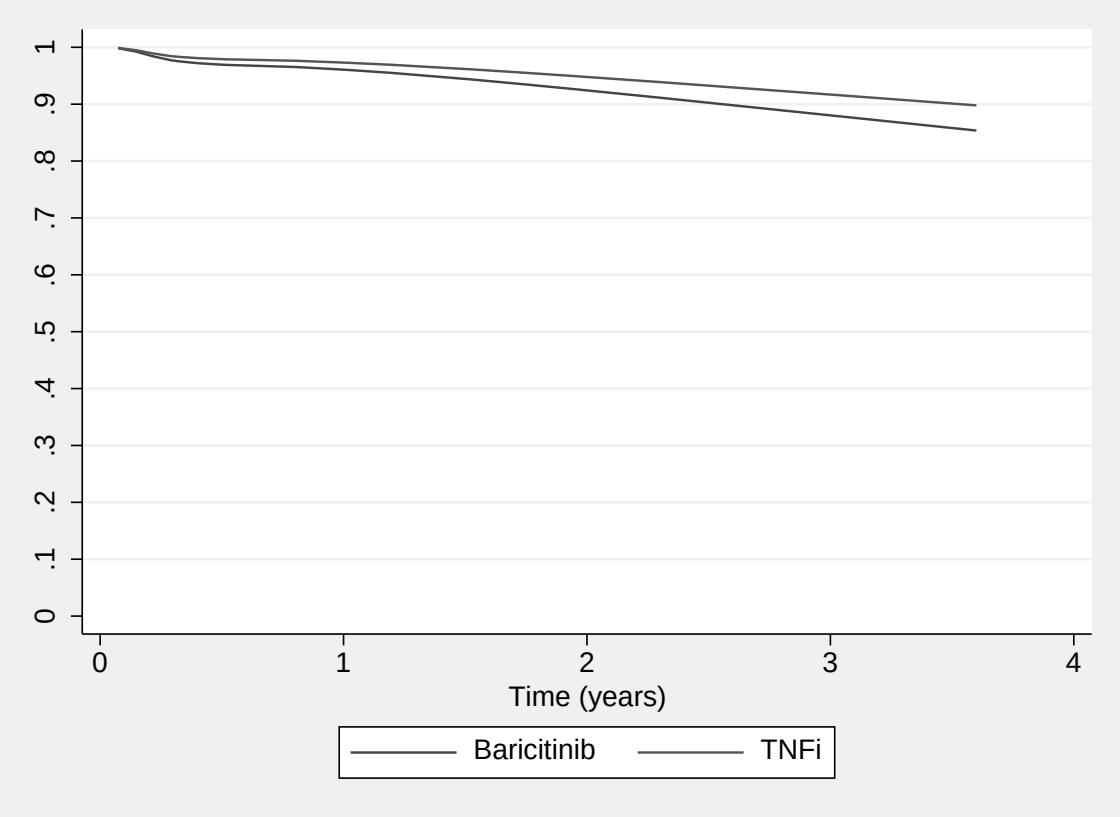
COR_JP Figure 8. Kaplan-Meier Curve of Time-to-First Serious Infection [CorEvitas Japan], pre-matched Serious Infection Population – excludes patients with a serious infection within 6 months prior to index date



COR_JP Figure 9. Kaplan-Meier Curve of Time-to-First Serious Infection [CorEvitas Japan], Serious Infection-matched Population – excludes patients with a serious infection within 6 months prior to index date



COR_JP Figure 10. Adjusted Survival Curve of Time-to-First Serious Infection [CorEvitas Japan], Serious Infection-matched Population – excludes patients with a serious infection within 6 months prior to index date



COR_JP Table 6.62. Pattern of RA Medication Use in Patients with Hospitalized TB Event [CorEvitas Japan]

The table has been omitted as there are no TB events.

COR_JP Table 6.63. Time to First Hospitalized TB Event (Days) [CorEvitas Japan]

The table has been omitted as there are no TB events.

COR_JP Table 6.64. Incidence Rates of First Hospitalized TB Event [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 210)	**TNFi (N= 354)**	**Baricitinib (N= 169)**	**TNFi (N= 213)**	**Total (N= 382)**
Overall					
Person-Years	231.6	537.0	195.0	307.8	502.8
TB Events	0	0	0	0	0
TB Events/100 PY	0.0	0.0	0.0	0.0	0.0
95% CI	0.0, 1.6	0.0, 0.7	0.0, 1.9	0.0, 1.2	0.0, 0.7
Incidence rate difference: baricitinib – TNFi (95% CI)					0.0 (0.0, 0.0)

Abbreviations: CI = confidence interval; PY = person-years; TB = [hospitalized] tuberculosis; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.65. Hospitalized TB Events per Patient During Baricitinib and TNF Exposure [CorEvitas Japan]

The table has been omitted as there are no TB events.

COR_JP Figure 11. Kaplan-Meier Curve of Time-to-First Hospitalized TB Event [CorEvitas Japan], pre-matched Hospitalized TB Population – excludes patients with a hospitalized TB within 6 months prior to index date

Not applicable for CorEvitas Japan data.

COR_JP Figure 12. Kaplan-Meier Curve of Time-to-First Hospitalized TB Event [CorEvitas Japan], Hospitalized TB-matched Population – excludes patients with a hospitalized TB within 6 months prior to index date

Not applicable for CorEvitas Japan data.

COR_JP Figure 13. Adjusted Survival Curve of Time-to-First Hospitalized TB Event [CorEvitas Japan], Hospitalized TB-matched Population – excludes patients with a hospitalized TB within 6 months prior to index date

Not applicable for CorEvitas Japan data.

COR_JP Table 6.67. Incidence Rates of VTE Prior to Cohort Entry [CorEvitas Japan], VTE-matched* Population - does not exclude patients with prior VTE within 6 months prior to index date or patients on anticoagulant

Treatment Group	Patients (N)	Events (n)/PY	Incidence Rate (per 100 PY)	95% CI	Incidence rate difference: baricitinib – TNFi (95% CI)
3 months prior[a]					
baricitinib	n/a	n/a	n/a	n/a	
TNFi	n/a	n/a	n/a	n/a	
6 months prior[b]					
baricitinib	n/a	n/a	n/a	n/a	
TNFi	n/a	n/a	n/a	n/a	
12 months prior					
baricitinib	170	0/170.0	0.0	0.0, 2.2	0.0 (0.0, 0.0)
TNFi	206	0/206.0	0.0	0.0, 1.8	

* Matched population is matched using a propensity score population that excludes the variable indicating history of VTE
Abbreviations: CI = confidence interval; PY = person-years; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
[a] Due to small event counts, incidence rates of VTE in the 3 months prior to cohort entry will not be performed
[b] Due to small event counts, incidence rates of VTE in the 6 months prior to cohort entry will not be performed

COR_JP Table 6.68. Incidence Rates of VTE, by Dose. Pre-matched VTE population [CorEvitas Japan]

	Baricitinib 2mg (N=20)	Baricitinib 4mg (N=184)	TNFi (N=346)
VTE Events	0	0	0
Person-Years	22.9	205.7	528.2
IR per 100 PY	0.0	0.0	0.0
95% CI	0, 16.1	0, 1.8	0, 0.7
Incidence rate difference: baricitinib 2mg - TNFi (95% CI)			0.0 (0.0, 0.0)
Incidence rate difference: baricitinib 4mg - TNFi (95% CI)			0.0 (0.0, 0.0)

Abbreviations: CI = confidence interval; PY = person-years; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

COR_JP Table 6.69. bDMARD Experienced and Naïve Patients[a]: Rates of VTE, by Dose. VTE-matched population [CorEvitas Japan]

	Baricitinib 2mg (N=15)	Baricitinib 4mg (N=155)	TNFi (N=207)
VTE Events	0	0	0
Person-Years	15.6	183.8	308.9
IR per 100 PY	0.0	0.0	0.0
95% CI	0, 23.7	0, 2.0	0, 1.2
Incidence rate difference: baricitinib 2mg - TNFi (95% CI)			0.0 (0.0, 0.0)
Incidence rate difference: baricitinib 4mg - TNFi (95% CI)			0.0 (0.0, 0.0)

Abbreviations: CI = confidence interval; PY = person-years; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Stratified results are not provided because there are 0 events in all groups.

COR_JP Table 6.70. bDMARD-Experienced. Baseline Demographics, Pre-matched Population [CorEvitas Japan]

	Baricitinib			TNFi	
	Any (N=138)	2mg (N=11)	4mg (N=122)	(N=100)	Std. Diff (Any vs TNFi)
Age [yrs]					
n	138	11	122	100	0.172
Mean±SD	60.8 ±12.9	71.1 ±10.9	59.8 ±12.9	63.3 ±15.8	
Median	62.0	73.0	61.0	66.5	
Min, Max	25.0, 85.0	50.0, 84.0	25.0, 85.0	22.0, 90.0	
≥ 65 years	59 (42.8%)	8 (72.7%)	49 (40.2%)	54 (54.0%)	0.226
Gender					
Male	16 (11.7%)	0 (0.0%)	16 (13.2%)	23 (23.0%)	0.302
Female	121 (88.3%)	11 (100.0%)	105 (86.8%)	77 (77.0%)	
BMI					
n	132	9	119	95	0.010
Mean±SD	22.9 ± 4.2	22.1 ± 3.7	22.8 ± 4.0	22.8 ± 4.7	
Median	22.0	22.5	21.8	21.9	
Min, Max	16.1, 39.1	16.8, 27.5	16.1, 35.8	14.3, 47.1	
Smoking (current)	17 (12.4%)	1 (9.1%)	15 (12.4%)	8 (8.2%)	0.137
Alcohol use	47 (34.1%)	4 (36.4%)	42 (34.4%)	37 (37.0%)	0.062
Education					
Primary	13 (9.4%)	1 (9.1%)	11 (9.0%)	12 (12.0%)	0.083
High School	82 (59.4%)	7 (63.6%)	72 (59.0%)	57 (57.0%)	0.049
College/University	39 (28.3%)	3 (27.3%)	35 (28.7%)	26 (26.0%)	0.051

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.71. bDMARD-Naive. Baseline Demographics, Pre-matched Population [CorEvitas Japan]

	Baricitinib			TNFi	Std Diff (Any vs. TNFi)
	Any (N=72)	2mg (N=10)	4mg (N=62)	(N=254)	
Age [yrs]					
n	72	10	62	254	0.122
Mean±SD	59.5 ±13.4	69.5 ± 6.4	57.9 ±13.6	61.2 ±14.8	
Median	62.0	71.0	59.5	63.0	
Min, Max	31.0, 83.0	61.0, 79.0	31.0, 83.0	20.0, 90.0	
≥ 65 years	31 (43.1%)	7 (70.0%)	24 (38.7%)	118 (46.5%)	0.068
Gender					
Male	16 (22.5%)	0 (0.0%)	16 (26.2%)	54 (21.3%)	0.029
Female	55 (77.5%)	10 (100.0%)	45 (73.8%)	199 (78.7%)	
BMI					
n	70	8	62	236	0.230
Mean±SD	23.4 ± 5.4	21.4 ± 5.5	23.7 ± 5.4	22.4 ± 3.4	
Median	22.0	20.5	22.1	22.1	
Min, Max	16.2, 45.2	16.2, 33.7	16.2, 45.2	15.6, 36.0	
Smoking (current)	14 (19.7%)	3 (30.0%)	11 (18.0%)	24 (9.6%)	0.290
Alcohol use	35 (48.6%)	4 (40.0%)	31 (50.0%)	119 (46.9%)	0.035
Education					
Primary	8 (11.1%)	3 (30.0%)	5 (8.1%)	34 (13.4%)	0.069
High School	38 (52.8%)	6 (60.0%)	32 (51.6%)	135 (53.1%)	0.007
College/University	19 (26.4%)	0 (0.0%)	19 (30.6%)	75 (29.5%)	0.070

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.72. bDMARD-Experienced: Baseline Demographics, VTE-matched Population [CorEvitas Japan] - also excludes patients with VTE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.73. bDMARD-Naive: Baseline Demographics, VTE-matched Population [CorEvitas Japan] - also excludes patients with VTE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.74. bDMARD-Experienced: Baseline Demographics, MACE-matched Population [CorEvitas Japan] - also excludes patients with a MACE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.75. bDMARD-Naive: Baseline Demographics, MACE-matched Population [CorEvitas Japan] - also excludes patients with a MACE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.76. bDMARD-Experienced. Baseline Demographics, Serious infection-matched Population [CorEvitas Japan] - also excludes patients with a serious infection within 6 months prior to index date

	Baricitinib			TNFi	Std. Diff (Any vs TNFi)	Total (N=186)
	Any (N=102)	2mg (N=8)	4mg (N=93)	(N=84)		
Age [yrs]						
n	102	8	93	84	0.083	186
Mean±SD	61.6 ±13.9	73.6 ± 9.1	60.4 ±13.8	62.8 ±15.7		62.1 ±14.7
Median	64.0	74.5	62.0	65.5		64.5
Min, Max	25.0, 85.0	56.0, 84.0	25.0, 85.0	22.0, 86.0		22.0, 86.0
≥ 65 years	49 (48.0%)	7 (87.5%)	41 (44.1%)	44 (52.4%)	0.087	93 (50.0%)
Gender						
Male	9 (8.8%)	0 (0.0%)	9 (9.7%)	18 (21.4%)	0.357	27 (14.5%)
Female	93 (91.2%)	8 (100.0%)	84 (90.3%)	66 (78.6%)		159 (85.5%)
BMI						
n	102	8	93	84	0.102	186
Mean±SD	22.3 ± 3.8	21.4 ± 3.3	22.3 ± 3.8	22.7 ± 4.7		22.5 ± 4.2
Median	21.8	22.3	21.6	21.9		21.8
Min, Max	16.1, 35.8	16.8, 26.5	16.1, 35.8	14.3, 47.1		14.3, 47.1
Smoking (current)	3 (2.9%)	0 (0.0%)	3 (3.2%)	6 (7.1%)	0.193	9 (4.8%)
Alcohol use	32 (31.4%)	3 (37.5%)	29 (31.2%)	30 (35.7%)	0.092	62 (33.3%)
Education						
Primary	8 (7.8%)	0 (0.0%)	8 (8.6%)	9 (10.7%)	0.099	17 (9.1%)
High School	63 (61.8%)	5 (62.5%)	57 (61.3%)	49 (58.3%)	0.070	112 (60.2%)
College/University	28 (27.5%)	3 (37.5%)	25 (26.9%)	22 (26.2%)	0.028	50 (26.9%)

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.77. bDMARD-Naive. Baseline Demographics, Serious infection-matched Population [CorEvitas Japan] - also excludes patients with a serious infection within 6 months prior to index date

	Baricitinib			TNFi	Std. Diff	Total
	Any (N=68)	2mg (N=7)	4mg (N=61)	(N=129)	(Any vs TNFi)	(N=197)
Age [yrs]						
n	68	7	61	129	0.095	197
Mean±SD	59.1 ±13.6	69.3 ± 6.6	58.0 ±13.7	60.5 ±15.9		60.0 ±15.1
Median	62.0	71.0	60.0	63.0		63.0
Min, Max	31.0, 83.0	61.0, 79.0	31.0, 83.0	22.0, 90.0		22.0, 90.0
≥ 65 years	29 (42.6%)	5 (71.4%)	24 (39.3%)	57 (44.2%)	0.031	86 (43.7%)
Gender						
Male	16 (23.5%)	0 (0.0%)	16 (26.2%)	20 (15.5%)	0.204	36 (18.3%)
Female	52 (76.5%)	7 (100.0%)	45 (73.8%)	109 (84.5%)		161 (81.7%)
BMI						
n	68	7	61	129	0.229	197
Mean±SD	23.4 ± 5.4	21.9 ± 5.7	23.6 ± 5.4	22.4 ± 3.5		22.8 ± 4.3
Median	22.0	21.5	22.0	22.2		22.1
Min, Max	16.2, 45.2	16.2, 33.7	16.2, 45.2	15.8, 33.7		15.8, 45.2
Smoking (current)	13 (19.1%)	2 (28.6%)	11 (18.0%)	16 (12.4%)	0.185	29 (14.7%)
Alcohol use	35 (51.5%)	4 (57.1%)	31 (50.8%)	56 (43.4%)	0.162	91 (46.2%)
Education						
Primary	7 (10.3%)	2 (28.6%)	5 (8.2%)	16 (12.4%)	0.067	23 (11.7%)
High School	36 (52.9%)	4 (57.1%)	32 (52.5%)	71 (55.0%)	0.042	107 (54.3%)
College/University	19 (27.9%)	0 (0.0%)	19 (31.1%)	35 (27.1%)	0.018	54 (27.4%)

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of the standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.78. bDMARD-Experienced: Baseline Demographics, Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - also excludes patients with a hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.79. bDMARD-Naive: Baseline Demographics, Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - also excludes patients with a hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.80. bDMARD-Experienced. Baseline Clinical Characteristics, Pre-matched Population [CorEvitas Japan]

	Baricitinib (N=138)	TNFi (N=100)	Std. Diff.
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	7 (5.1%)	11 (11.0%)	0.216
Cancer, NMSC only	0 (0.0%)	1 (1.0%)	0.141
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	12 (8.7%)	13 (13.0%)	0.135
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (1.0%)	0.141
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (0.7%)	4 (4.0%)	0.215
Cardiovascular revascularization	1 (0.7%)	0 (0.0%)	0.121
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	1 (1.0%)	0.141
Coronary artery disease	0 (0.0%)	1 (1.0%)	0.141
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	3 (2.2%)	4 (4.0%)	0.104
TIA	0 (0.0%)	0 (0.0%)	
Unstable angina	0 (0.0%)	2 (2.0%)	0.201
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	
Diabetes mellitus	16 (11.6%)	11 (11.0%)	0.022
Hyperlipidemia	19 (13.8%)	18 (18.0%)	0.111
Hypertension (hospitalized & non-hospitalized)	43 (31.2%)	38 (38.0%)	0.136
Immune disorders	15 (10.9%)	13 (13.0%)	0.062
Secondary Sjogren Syndrome	15 (10.9%)	13 (13.0%)	0.062
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	3 (2.2%)	0 (0.0%)	0.211
Obesity, current	10 (7.6%)	7 (7.4%)	0.011
Pregnancy, recent (current or since last visit)	0 (0.0%)	1 (1.0%)	0.141
Smoking (current)	17 (12.4%)	8 (8.2%)	0.140
RA severity (CDAI)			
n	127	95	0.254
Mean±SD	24.4 ±12.6	21.3 ±12.0	
Median	22.0	19.5	

	Baricitinib (N=138)	TNFi (N=100)	Std. Diff.
Min, Max	3.0, 60.0	3.0, 59.0	
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	3 (3.0%)	0.247
MACE (at any time in the past)	5 (3.6%)	3 (3.0%)	0.037
Myocardial infarction	1 (0.7%)	3 (3.0%)	0.169
Stroke	4 (2.9%)	0 (0.0%)	0.244
Serious infection (at any time in the past)	16 (11.6%)	14 (14.0%)	0.096
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	
DMARD history			
Number of cDMARDs used(ever)			
0	15 (10.9%)	10 (10.0%)	0.032
1	95 (68.8%)	59 (59.0%)	0.218
2+	28 (20.3%)	31 (31.0%)	0.262
Methotrexate (prior use)	118 (85.5%)	83 (83.0%)	0.064
Number of bDMARDs used (ever)			
0	0 (0.0%)	0 (0.0%)	
1	61 (44.2%)	65 (65.0%)	0.413
2+	77 (55.8%)	35 (35.0%)	0.413
Prior bDMARD use[a]	138 (100.0%)	100 (100.0%)	
Prior TNFi bDMARD use	111 (80.4%)	57 (57.0%)	0.513
Prior non-TNFi bDMARD use	87 (63.0%)	67 (67.0%)	0.090
DMARD, current (baseline			
cDMARD, concomitant use at baseline	73 (52.9%)	57 (57.0%)	0.091
Methotrexate (current use)	65 (47.1%)	51 (51.0%)	0.088
Current (baseline) prescription medication use			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	2 (1.5%)	1 (1.0%)	0.042
Antihypertensives (blood pressure lowering medication(s); patient-reported)	36 (26.1%)	33 (33.0%)	0.145
Antiplatelet (Plavix; patient-reported)	1 (0.8%)	1 (1.0%)	0.030
Nitrates (angina/nitrate medications; patient-reported)	1 (0.7%)	2 (2.0%)	0.109
Lipid-lowering agents (cholesterol medication; patient-reported)	23 (17.3%)	21 (21.6%)	0.110
RA-related			
Aspirin (includes non-prescription)	1 (0.8%)	7 (7.2%)	0.335
Prednisone	31 (22.5%)	32 (32.0%)	0.209

	Baricitinib (N=138)	TNFi (N=100)	Std. Diff.
Vaccinations			
Shingles (ever)	0 (0.0%)	0 (0.0%)	

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.81. bDMARD-Naive. Baseline Clinical Characteristics, Pre-matched Population [CorEvitas Japan]

	Baricitinib (N=72)	TNFi (N=254)	Std. Diff.
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	3 (4.2%)	16 (6.3%)	0.096
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	7 (9.7%)	26 (10.2%)	0.017
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (1.4%)	2 (0.8%)	0.058
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	2 (2.8%)	3 (1.2%)	0.115
Cardiovascular revascularization	1 (1.4%)	1 (0.4%)	0.106
Congestive heart failure (hospitalized & non-hospitalized)	1 (1.4%)	1 (0.4%)	0.106
Coronary artery disease	0 (0.0%)	1 (0.4%)	0.089
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (2.8%)	2 (0.8%)	0.151
TIA	0 (0.0%)	0 (0.0%)	
Unstable angina	0 (0.0%)	1 (0.4%)	0.089
Ventricular arrhythmia	0 (0.0%)	1 (0.4%)	0.089
Diabetes mellitus	11 (15.3%)	18 (7.1%)	0.262
Hyperlipidemia	9 (12.5%)	32 (12.6%)	0.003
Hypertension (hospitalized & non-hospitalized)	16 (22.2%)	68 (26.8%)	0.106
Immune disorders	1 (1.4%)	23 (9.1%)	0.350
Secondary Sjogren Syndrome	1 (1.4%)	23 (9.1%)	0.350
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (1.4%)	2 (0.8%)	0.058
Obesity, current	8 (11.4%)	6 (2.5%)	0.354
Pregnancy, recent (current or since last visit)	0 (0.0%)	1 (0.4%)	0.089
Smoking (current)	14 (19.7%)	24 (9.6%)	0.290
RA severity (CDAI)			
n	71	243	0.015
Mean±SD	22.9 ±13.5	22.7 ±13.2	
Median	18.8	20.0	
Min, Max	1.0, 64.2	0.5, 67.2	
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	4 (1.6%)	0.179
MACE (at any time in the past)	3 (4.2%)	4 (1.6%)	0.156

	Baricitinib (N=72)	TNFi (N=254)	Std. Diff.
Myocardial infarction	2 (2.8%)	1 (0.4%)	0.192
Stroke	1 (1.4%)	3 (1.2%)	0.018
Serious infection (at any time in the past)	7 (9.7%)	22 (8.7%)	0.037
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	
DMARD history			
Number of cDMARDs used(ever)			
0	3 (4.2%)	17 (6.7%)	0.112
1	50 (69.4%)	184 (72.4%)	0.066
2+	19 (26.4%)	53 (20.9%)	0.130
Methotrexate (prior use)	62 (86.1%)	227 (89.4%)	0.099
Number of bDMARDs used (ever)			
0	72 (100.0%)	254 (100.0%)	
Prior bDMARD use[a]	0 (0.0%)	0 (0.0%)	
Prior TNFi bDMARD use	0 (0.0%)	0 (0.0%)	
Prior non-TNFi bDMARD use	0 (0.0%)	0 (0.0%)	
DMARD, current (baseline)			
cDMARD, concomitant use at baseline	50 (69.4%)	214 (84.3%)	0.357
Methotrexate (current use)	45 (62.5%)	203 (79.9%)	0.392
Current (baseline) prescription medication use			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	5 (2.0%)	0.202
Antihypertensives (blood pressure lowering medication(s); patient-reported)	14 (19.4%)	60 (23.6%)	0.102
Antiplatelet (Plavix; patient-reported)	1 (1.4%)	4 (1.6%)	0.015
Nitrates (angina/nitrate medications; patient-reported)	1 (1.4%)	1 (0.4%)	0.106
Lipid-lowering agents (cholesterol medication; patient-reported)	12 (16.9%)	34 (13.5%)	0.094
RA-related			
Aspirin (includes non-prescription)	2 (2.8%)	2 (0.8%)	0.152
Prednisone	17 (23.6%)	70 (27.6%)	0.091
Vaccinations			
Shingles (ever)	2 (2.8%)	3 (1.2%)	0.115

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.82. bDMARD-Experienced: Baseline Clinical Characteristics, VTE-matched Population [CorEvitas Japan] - also excludes patients with VTE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.83. bDMARD-Naive: Baseline Clinical Characteristics, VTE-matched Population [CorEvitas Japan] - also excludes patients with VTE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.84. bDMARD-Experienced: Baseline Clinical Characteristics, MACE-matched Population [CorEvitas Japan] - also excludes patients with a MACE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.85. bDMARD-Naive: Baseline Clinical Characteristics, MACE-matched Population [CorEvitas Japan] - also excludes patients with a MACE within 6 months of index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.86. bDMARD-Experienced. Baseline Clinical Characteristics, Serious infection-matched Population [CorEvitas Japan] - also excludes patients with serious infection within 6 months prior to index date

	Baricitinib (N=102)	TNFi (N=84)	Std. Diff.	Total (N=186)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	5 (4.9%)	10 (11.9%)	0.254	15 (8.1%)
Cancer, NMSC only	0 (0.0%)	1 (1.2%)	0.155	1 (0.5%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	9 (8.8%)	9 (10.7%)	0.064	18 (9.7%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)		0 (0.0%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (1.0%)	3 (3.6%)	0.174	4 (2.2%)
Cardiovascular revascularization	1 (1.0%)	0 (0.0%)	0.141	1 (0.5%)
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	0 (0.0%)		0 (0.0%)
Coronary artery disease	0 (0.0%)	1 (1.2%)	0.155	1 (0.5%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (2.0%)	3 (3.6%)	0.098	5 (2.7%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	2 (2.4%)	0.221	2 (1.1%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)		0 (0.0%)
Diabetes mellitus	7 (6.9%)	10 (11.9%)	0.174	17 (9.1%)
Hyperlipidemia	14 (13.7%)	12 (14.3%)	0.016	26 (14.0%)
Hypertension (hospitalized & non-hospitalized)	33 (32.4%)	31 (36.9%)	0.096	64 (34.4%)
Immune disorders	13 (12.7%)	12 (14.3%)	0.045	25 (13.4%)
Secondary Sjogren Syndrome	13 (12.7%)	12 (14.3%)	0.045	25 (13.4%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)		0 (0.0%)
Obesity, current	6 (5.9%)	6 (7.1%)	0.051	12 (6.5%)

	Baricitinib (N=102)	TNFi (N=84)	Std. Diff.	Total (N=186)
Pregnancy, recent (current or since last visit)	0 (0.0%)	1 (1.2%)	0.155	1 (0.5%)
Smoking (current)	3 (2.9%)	6 (7.1%)	0.193	9 (4.8%)
RA severity (CDAI)				
n	102	84	0.212	186
Mean±SD	23.7 ±12.7	21.1 ±12.0		22.5 ±12.5
Median	21.4	19.5		20.0
Min, Max	3.0, 60.0	3.0, 59.0		3.0, 60.0
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	3 (3.6%)	0.272	3 (1.6%)
MACE (at any time in the past)	1 (1.0%)	2 (2.4%)	0.109	3 (1.6%)
Myocardial infarction	0 (0.0%)	2 (2.4%)	0.221	2 (1.1%)
Stroke	1 (1.0%)	0 (0.0%)	0.141	1 (0.5%)
Serious infection (at any time in the past)	11 (10.8%)	11 (13.1%)	0.071	22 (11.8%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used(ever)				
0	11 (10.8%)	8 (9.5%)	0.042	19 (10.2%)
1	72 (70.6%)	50 (59.5%)	0.234	122 (65.6%)
2+	19 (18.6%)	26 (31.0%)	0.288	45 (24.2%)
Methotrexate (prior use)	87 (85.3%)	71 (84.5%)	0.022	158 (84.9%)
Number of bDMARDs used (ever)				
0	0 (0.0%)	0 (0.0%)		0 (0.0%)
1	50 (49.0%)	54 (64.3%)	0.312	104 (55.9%)
2+	52 (51.0%)	30 (35.7%)	0.312	82 (44.1%)
Prior bDMARD use[a]	102 (100.0%)	84 (100.0%)		186 (100.0%)
Prior TNFi bDMARD use	78 (76.5%)	50 (59.5%)	0.369	128 (68.8%)
Prior non-TNFi bDMARD use	63 (61.8%)	56 (66.7%)	0.102	119 (64.0%)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	56 (54.9%)	46 (54.8%)	0.003	102 (54.8%)
Methotrexate (current use)	51 (50.0%)	43 (51.2%)	0.024	94 (50.5%)
Current (baseline) prescription medication use				
Cardiovascular medications				

	Baricitinib (N=102)	TNFi (N=84)	Std. Diff.	Total (N=186)
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	1 (1.2%)	0.155	1 (0.5%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	27 (26.5%)	27 (32.1%)	0.125	54 (29.0%)
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	1 (1.2%)	0.155	1 (0.5%)
Nitrates (angina/nitrate medications; patient-reported)	1 (1.0%)	1 (1.2%)	0.020	2 (1.1%)
Lipid-lowering agents (cholesterol medication; patient-reported)	17 (16.7%)	15 (17.9%)	0.032	32 (17.2%)
RA-related				
Aspirin (includes non-prescription)	0 (0.0%)	5 (6.0%)	0.356	5 (2.7%)
Prednisone	23 (22.5%)	25 (29.8%)	0.165	48 (25.8%)
Vaccinations				
Shingles (ever)	0 (0.0%)	0 (0.0%)		0 (0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.87. bDMARD-Naive. Baseline Clinical Characteristics, Serious infection-matched Population [CorEvitas Japan] - also excludes patients with serious infection within 6 months prior to index date

	Baricitinib (N=68)	TNFi (N=129)	Std. Diff.	Total (N=197)
History of MD-reported comorbidities (ever experienced)				
Cancer, non-NMSC	3 (4.4%)	10 (7.8%)	0.140	13 (6.6%)
Cancer, NMSC only	0 (0.0%)	0 (0.0%)		0 (0.0%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	7 (10.3%)	12 (9.3%)	0.033	19 (9.6%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	1 (1.5%)	1 (0.8%)	0.066	2 (1.0%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	2 (2.9%)	2 (1.6%)	0.094	4 (2.0%)
Cardiovascular revascularization	1 (1.5%)	1 (0.8%)	0.066	2 (1.0%)
Congestive heart failure (hospitalized & non-hospitalized)	1 (1.5%)	1 (0.8%)	0.066	2 (1.0%)
Coronary artery disease	0 (0.0%)	1 (0.8%)	0.125	1 (0.5%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (2.9%)	2 (1.6%)	0.094	4 (2.0%)
TIA	0 (0.0%)	0 (0.0%)		0 (0.0%)
Unstable angina	0 (0.0%)	1 (0.8%)	0.125	1 (0.5%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)		0 (0.0%)
Diabetes mellitus	11 (16.2%)	12 (9.3%)	0.207	23 (11.7%)
Hyperlipidemia	8 (11.8%)	17 (13.2%)	0.043	25 (12.7%)
Hypertension (hospitalized & non-hospitalized)	15 (22.1%)	39 (30.2%)	0.187	54 (27.4%)
Immune disorders	1 (1.5%)	7 (5.4%)	0.218	8 (4.1%)
Secondary Sjogren Syndrome	1 (1.5%)	7 (5.4%)	0.218	8 (4.1%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	1 (1.5%)	1 (0.8%)	0.066	2 (1.0%)
Obesity, current	8 (11.8%)	3 (2.3%)	0.375	11 (5.6%)

	Baricitinib (N=68)	TNFi (N=129)	Std. Diff.	Total (N=197)
Pregnancy, recent (current or since last visit)	0 (0.0%)	1 (0.8%)	0.125	1 (0.5%)
Smoking (current)	13 (19.1%)	16 (12.4%)	0.185	29 (14.7%)
RA severity (CDAI)				
n	68	129	0.112	197
Mean±SD	23.3 ±13.7	24.8 ±14.4		24.3 ±14.1
Median	19.8	22.0		21.6
Min, Max	1.0, 64.2	0.5, 67.2		0.5, 67.2
Prevalent outcomes				
VTE (at any time in the past)	0 (0.0%)	2 (1.6%)	0.177	2 (1.0%)
MACE (at any time in the past)	3 (4.4%)	3 (2.3%)	0.116	6 (3.0%)
Myocardial infarction	2 (2.9%)	1 (0.8%)	0.161	3 (1.5%)
Stroke	1 (1.5%)	2 (1.6%)	0.007	3 (1.5%)
Serious infection (at any time in the past)	6 (8.8%)	6 (4.7%)	0.167	12 (6.1%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD history				
Number of cDMARDs used(ever)				
0	3 (4.4%)	9 (7.0%)	0.111	12 (6.1%)
1	47 (69.1%)	94 (72.9%)	0.083	141 (71.6%)
2+	18 (26.5%)	26 (20.2%)	0.150	44 (22.3%)
Methotrexate (prior use)	58 (85.3%)	115 (89.1%)	0.116	173 (87.8%)
Number of bDMARDs used (ever)				
0	68 (100.0%)	129 (100.0%)		197 (100.0%)
Prior bDMARD use[a]	0 (0.0%)	0 (0.0%)		0 (0.0%)
Prior TNFi bDMARD use	0 (0.0%)	0 (0.0%)		0 (0.0%)
Prior non-TNFi bDMARD use	0 (0.0%)	0 (0.0%)		0 (0.0%)
DMARD, current (baseline)				
cDMARD, concomitant use at baseline	46 (67.6%)	107 (82.9%)	0.360	153 (77.7%)
Methotrexate (current use)	41 (60.3%)	103 (79.8%)	0.437	144 (73.1%)
Current (baseline) prescription medication use				
Cardiovascular medications				
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	3 (2.3%)	0.218	3 (1.5%)

	Baricitinib (N=68)	TNFi (N=129)	Std. Diff.	Total (N=197)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	13 (19.1%)	37 (28.7%)	0.226	50 (25.4%)
Antiplatelet (Plavix; patient-reported)	1 (1.5%)	2 (1.6%)	0.007	3 (1.5%)
Nitrates (angina/nitrate medications; patient-reported)	1 (1.5%)	0 (0.0%)	0.173	1 (0.5%)
Lipid-lowering agents (cholesterol medication; patient-reported)	12 (17.6%)	21 (16.3%)	0.036	33 (16.8%)
RA-related				
Aspirin (includes non-prescription)	2 (2.9%)	2 (1.6%)	0.094	4 (2.0%)
Prednisone	17 (25.0%)	29 (22.5%)	0.059	46 (23.4%)
Vaccinations				
Shingles (ever)	1 (1.5%)	0 (0.0%)	0.173	1 (0.5%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 66 for each outcome, e.g., congestive heart failure for VTE. Other factors are included for descriptive purposes only and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., diabetes for VTE.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.88. bDMARD-Experienced: Baseline Clinical Characteristics, hospitalized tuberculosis-matched Population [CorEvitas Japan] - also excludes patients with hospitalized tuberculosis within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.89. bDMARD-Naive: Baseline Clinical Characteristics, hospitalized tuberculosis-matched Population [CorEvitas Japan] - also excludes patients with hospitalized tuberculosis within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.90. bDMARD-Experienced: Baseline Healthcare Resource Utilization, Unmatched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.91. bDMARD-Naive: Baseline Healthcare Resource Utilization, Unmatched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.92. bDMARD-Experienced: Baseline Healthcare Resource Utilization, Primary VTE Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.93. bDMARD-Naive: Baseline Healthcare Resource Utilization, Primary VTE Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.94. bDMARD-Experienced: Baseline Healthcare Resource Utilization, MACE Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.95. bDMARD-Naive: Baseline Healthcare Resource Utilization, MACE Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.96. bDMARD-Experienced: Baseline Healthcare Resource Utilization, Serious Infection Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.97. bDMARD-Naive: Baseline Healthcare Resource Utilization, Serious Infection Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.98. bDMARD-Experienced: Baseline Healthcare Resource Utilization, Hospitalized Tuberculosis Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.99. bDMARD-Naive: Baseline Healthcare Resource Utilization, Hospitalized Tuberculosis Cohorts, Matched [CorEvitas Japan]

Not applicable to CorEvitas data.

COR_JP Table 6.100. bDMARD-Experienced. Baseline Prevalence of Outcomes [CorEvitas Japan]

	Pre-matched			Matched*			
	Baricitinib	TNFi	Std. Diff.	Baricitinib	TNFi	Std. Diff	Total
Serious Infection	16 (11.6%)/138	14 (14.0%)/100	0.072	11 (10.8%)/102	11 (13.1%)/84	0.071	22 (11.8%)/186

Abbreviations: TNFi = tumor necrosis factor inhibitor.
* Matched refers to the outcome-specific matched population

COR_JP Table 6.101. bDMARD-Naive. Baseline Prevalence of Outcomes [CorEvitas Japan]

	Pre-matched			Matched*			
	Baricitinib	**TNFi**	**Std. Diff.**	**Baricitinib**	**TNFi**	**Std. Diff**	**Total**
Serious Infection	7 (9.7%)/72	22 (8.7%)/254	0.037	6 (8.8%)/68	6 (4.7%)/129	0.167	12 (6.1%)/197

Abbreviations: TNFi = tumor necrosis factor inhibitor.
* Matched refers to the outcome-specific matched population

COR_JP Table 6.102. bDMARD-Experienced. Duration of Exposure (Days), in Pre-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit

	Baricitinib (N=138)	TNFi (N=100)	Std. Diff.
N	138	100	
Mean±SD	387.9 ±269.4	479.8 ±329.3	0.307
Median	348.0	406.0	
Min, Max	9.0, 1071.0	21.0, 1210.0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.103. bDMARD-Naive. Duration of Exposure (Days), in Pre-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit

	Baricitinib (N=72)	TNFi (N=254)	Std. Diff.
N	72	254	
Mean±SD	431.2 ±238.6	583.3 ±343.0	0.515
Median	386.0	589.0	
Min, Max	42.0, 957.0	14.0, 1263.0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.104. bDMARD-Experienced: Duration of Exposure (Days) in VTE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit, excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.105. bDMARD-Naive: Duration of Exposure (Days) in VTE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit, excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.106. bDMARD-Experienced: Duration of Exposure (Days) in MACE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit, excludes patients with MACE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.107. bDMARD-Naive: Duration of Exposure (Days) in MACE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit, excludes patients with MACE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.108. bDMARD-Experienced. Duration of Exposure (Days), in Serious Infection-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit; excludes patients with serious infection within 6 months prior to index date

	Baricitinib (N=102)	TNFi (N=84)	Std. Diff.
N	102	84	
Mean±SD	411.7 ±265.4	478.3 ±334.9	0.220
Median	374.5	397.5	
Min, Max	12.0, 1071.0	21.0, 1210.0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.109. bDMARD-Naive. Duration of Exposure (Days), in Serious Infection-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit; excludes patients with serious infection within 6 months prior to index date

	Baricitinib (N=68)	TNFi (N=129)	Std. Diff.
N	68	129	
Mean±SD	430.5 ±238.1	562.3 ±340.9	0.448
Median	386.0	579.0	
Min, Max	42.0, 957.0	14.0, 1204.0	

Abbreviations: Max = maximum; Min = minimum; SD = standard deviation; Std Diff = absolute value of standardized difference; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.110. bDMARD-Experienced: Duration of Exposure (Days) in Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit, excludes patients with hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.111. bDMARD-Naive: Duration of Exposure (Days) in Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit, excludes patients with hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.112. bDMARD-Experienced. Baseline Clinical Characteristics by Exposure Duration, Pre-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 41)	TNFi (N= 23)	Std. Diff.	Baricitinib (N= 33)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 46)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 18)	TNFi (N= 23)	Std. Diff.
Age [yrs]												
n	41	23	0.16	33	21	0.06	46	33	0.37	18	23	0.20
Mean±SD	57.9 ± 14.7	60.3 ± 15.6		60.8 ± 12.7	61.8± 19.8		61.1± 12.6	65.8± 12.9		66.5 ± 8.0	64.0 ± 16.2	
Median	60.0	62.0		61.0	69.0		63.0	68.0		66.5	70.0	
Min, Max	25.0, 84.0	30.0, 85.0		34.0, 82.0	22.0, 90.0		30.0, 85.0	38.0, 86.0		54.0, 82.0	32.0, 84.0	
≥ 65 years	16 (39.0%)	11 (47.8%)	0.18	13 (39.4%)	11 (52.4%)	0.26	18 (39.1%)	20 (60.6%)	0.44	12 (66.7%)	12 (52.2%)	0.30
Gender												
Male	3 (7.3%)	6 (26.1%)	0.52	5 (15.6%)	3 (14.3%)	0.04	4 (8.7%)	7 (21.2%)	0.36	4 (22.2%)	7 (30.4%)	0.19
Female	38 (92.7%)	17 (73.9%)		27 (84.4%)	18 (85.7%)		42 (91.3%)	26 (78.8%)		14 (77.8%)	16 (69.6%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (2.4%)	3 (13.0%)	0.40	2 (6.1%)	2 (9.5%)	0.13	0 (0.0%)	5 (15.2%)	0.60	4 (22.2%)	1 (4.3%)	0.55
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (3.0%)	0.25	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	4 (9.8%)	3 (13.0%)	0.10	3 (9.1%)	2 (9.5%)	0.01	3 (6.5%)	6 (18.2%)	0.36	2 (11.1%)	2 (8.7%)	0.08
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (2.4%)	2 (8.7%)	0.28	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.3%)	0.30
Cardiovascular revascularization	1 (2.4%)	0 (0.0%)	0.22	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 41)	TNFi (N= 23)	Std. Diff.	Baricitinib (N= 33)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 46)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 18)	TNFi (N= 23)	Std. Diff.
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	1 (4.3%)	0.30	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (4.9%)	2 (8.7%)	0.15	1 (3.0%)	1 (4.8%)	0.09	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.3%)	0.30
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	1 (4.3%)	0.30	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.3%)	0.30
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	3 (7.3%)	5 (21.7%)	0.42	3 (9.1%)	1 (4.8%)	0.17	7 (15.2%)	4 (12.1%)	0.09	3 (16.7%)	1 (4.3%)	0.41
Hyperlipidemia	4 (9.8%)	2 (8.7%)	0.04	4 (12.1%)	4 (19.0%)	0.19	9 (19.6%)	9 (27.3%)	0.18	2 (11.1%)	3 (13.0%)	0.06
Hypertension (hospitalized & non-hospitalized)	8 (19.5%)	7 (30.4%)	0.25	12 (36.4%)	8 (38.1%)	0.04	16 (34.8%)	15 (45.5%)	0.22	7 (38.9%)	8 (34.8%)	0.09
Immune disorders	1 (2.4%)	3 (13.0%)	0.40	3 (9.1%)	3 (14.3%)	0.16	9 (19.6%)	5 (15.2%)	0.12	2 (11.1%)	2 (8.7%)	0.08
Secondary Sjogren Syndrome	1 (2.4%)	3 (13.0%)	0.40	3 (9.1%)	3 (14.3%)	0.16	9 (19.6%)	5 (15.2%)	0.12	2 (11.1%)	2 (8.7%)	0.08
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	2 (4.3%)	0 (0.0%)	0.30	1 (5.6%)	0 (0.0%)	0.34
Obesity, current	5 (12.8%)	2 (9.1%)	0.12	2 (6.5%)	2 (10.0%)	0.13	3 (6.7%)	2 (6.3%)	0.02	0 (0.0%)	1 (4.8%)	0.32
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 41)	TNFi (N= 23)	Std. Diff.	Baricitinib (N= 33)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 46)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 18)	TNFi (N= 23)	Std. Diff.
Smoking (current)	7 (17.1%)	5 (21.7%)	0.12	6 (18.2%)	2 (10.5%)	0.22	3 (6.7%)	0 (0.0%)	0.38	1 (5.6%)	1 (4.5%)	0.05
RA severity (CDAI)												
n	33	23	0.35	31	20	0.13	45	29	0.22	18	23	0.34
Mean±SD	25.8 ± 13.6	21.6 ± 10.2		22.0 ± 12.5	20.3±13.3		24.6 ± 11.0	22.0± 13.5		25.3± 14.9	20.9 ± 11.3	
Median	21.9	24.8		20.0	18.0		23.0	18.3		22.6	19.5	
Min, Max	4.4, 55.0	5.6, 36.8		3.0, 50.4	3.0, 49.0		6.6, 52.5	3.6, 59.0		3.5, 60.0	4.0, 42.3	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (4.3%)	0.30	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	2 (6.1%)	0.36	0 (0.0%)	0 (0.0%)	-
MACE (at any time in the past)	0 (0.0%)	1 (4.3%)	0.30	1 (3.0%)	1 (4.8%)	0.09	4 (8.7%)	0 (0.0%)	0.44	0 (0.0%)	1 (4.3%)	0.30
Myocardial infarction	0 (0.0%)	1 (4.3%)	0.30	1 (3.0%)	1 (4.8%)	0.09	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (4.3%)	0.30
Stroke	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	4 (8.7%)	0 (0.0%)	0.44	0 (0.0%)	0 (0.0%)	-
Serious infection (at any time in the past)	6 (14.6%)	4 (17.4%)	0.08	3 (9.1%)	1 (4.8%)	0.17	5 (10.9%)	6 (18.2%)	0.21	2 (11.1%)	3 (13.0%)	0.06
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	4 (9.8%)	2 (8.7%)	0.04	4 (12.1%)	2 (9.5%)	0.08	4 (8.7%)	4 (12.1%)	0.11	3 (16.7%)	2 (8.7%)	0.24
1	30 (73.2%)	14 (60.9%)	0.26	25 (75.8%)	12 (57.1%)	0.40	30 (65.2%)	21 (63.6%)	0.03	10 (55.6%)	12 (52.2%)	0.07
2+	7 (17.1%)	7 (30.4%)	0.32	4 (12.1%)	7 (33.3%)	0.52	12 (26.1%)	8 (24.2%)	0.04	5 (27.8%)	9 (39.1%)	0.24
Methotrexate (prior use)	36 (87.8%)	19 (82.6%)	0.15	28 (84.8%)	17 (81.0%)	0.10	39 (84.8%)	27 (81.8%)	0.08	15 (83.3%)	20 (87.0%)	0.10
Number of bDMARDs used (ever)												
0	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
1	15 (36.6%)	10 (43.5%)	0.14	19 (57.6%)	14 (66.7%)	0.19	22 (47.8%)	23 (69.7%)	0.46	5 (27.8%)	18 (78.3%)	1.17
2+	26 (63.4%)	13 (56.5%)	0.14	14 (42.4%)	7 (33.3%)	0.19	24 (52.2%)	10 (30.3%)	0.46	13 (72.2%)	5 (21.7%)	1.17

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 41)	TNFi (N= 23)	Std. Diff.	Baricitinib (N= 33)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 46)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 18)	TNFi (N= 23)	Std. Diff.
Prior bDMARD use[a]	41 (100.0%)	23(100.0%)	-	33 (100.0%)	21(100.0%)	-	46 (100.0%)	18 (54.5%)	0.41	18(100.0%)	23 (100.0%)	-
Prior TNFi bDMARD use	38 (92.7%)	13 (56.5%)	0.91	25 (75.8%)	13 (61.9%)	0.30	34 (73.9%)	22 (66.7%)	0.03	14 (77.8%)	13 (56.5%)	0.46
Prior non-TNFi bDMARD use	25 (61.0%)	18 (78.3%)	0.38	18 (54.5%)	13 (61.9%)	0.15	30 (65.2%)	0 (0.0%)	-	14 (77.8%)	14 (60.9%)	0.37
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	20 (48.8%)	10 (43.5%)	0.11	12 (36.4%)	14 (66.7%)	0.64	30 (65.2%)	20 (60.6%)	0.10	11 (61.1%)	13 (56.5%)	0.09
Methotrexate (current use)	20 (48.8%)	9 (39.1%)	0.20	12 (36.4%)	12 (57.1%)	0.43	24 (52.2%)	19 (57.6%)	0.11	9 (50.0%)	11 (47.8%)	0.04
Current (baseline) prescription medication use												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	1 (4.3%)	0.30	1 (3.0%)	0 (0.0%)	0.25	1 (2.2%)	0 (0.0%)	0.21	0 (0.0%)	0 (0.0%)	-
Antihypertensives (blood pressure lowering medication(s); patient-reported)	5 (12.2%)	6 (26.1%)	0.36	10 (30.3%)	6 (28.6%)	0.04	15 (32.6%)	13 (39.4%)	0.14	6 (33.3%)	8 (34.8%)	0.03
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (2.2%)	0 (0.0%)	0.21	0 (0.0%)	1 (4.3%)	0.30
Nitrates (angina/nitrate medications; patient-reported)	1 (2.4%)	1 (4.3%)	0.11	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Lipid-lowering agents (cholesterol medication; patient-reported)	3 (8.3%)	6 (26.1%)	0.48	7 (21.2%)	4 (19.0%)	0.05	10 (21.7%)	8 (26.7%)	0.12	3 (16.7%)	3 (13.0%)	0.10
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	3 (13.0%)	0.55	1 (3.0%)	1 (4.8%)	0.09	0 (0.0%)	1 (3.3%)	0.26	0 (0.0%)	2 (8.7%)	0.44
Prednisone	8 (19.5%)	9 (39.1%)	0.44	9 (27.3%)	4 (19.0%)	0.20	11 (23.9%)	13 (39.4%)	0.34	3 (16.7%)	6 (26.1%)	0.23

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 41)	TNFi (N= 23)	Std. Diff.	Baricitinib (N= 33)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 46)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 18)	TNFi (N= 23)	Std. Diff.
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.113. bDMARD-Naive. Baseline Clinical Characteristics by Exposure Duration, Pre-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 11)	TNFi (N= 48)	Std. Diff.	Baricitinib (N= 19)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 31)	TNFi (N= 75)	Std. Diff.	Baricitinib (N= 11)	TNFi (N= 98)	Std. Diff.
Age [yrs]												
n	11	48	0.10	19	33	0.07	31	75	0.06	11	98	0.55
Mean±SD	60.5 ± 14.9	61.9± 13.4		61.8 ± 11.3	62.8± 16.3		60.2 ± 13.7	61.1± 15.3		52.5 ± 14.2	60.4± 14.7	
Median	64.0	66.5		62.0	68.0		65.0	63.0		47.0	62.5	
Min, Max	31.0, 77.0	20.0, 90.0		35.0, 83.0	22.0, 87.0		32.0, 80.0	25.0, 88.0		38.0, 78.0	25.0, 84.0	
≥ 65 years	5 (45.5%)	25 (52.1%)	0.13	7 (36.8%)	17 (51.5%)	0.30	16 (51.6%)	34 (45.3%)	0.13	3 (27.3%)	42 (42.9%)	0.33
Gender												
Male	2 (18.2%)	7 (14.9%)	0.09	3 (15.8%)	7 (21.2%)	0.14	8 (25.8%)	16 (21.3%)	0.11	3 (30.0%)	24 (24.5%)	0.12
Female	9 (81.8%)	40 (85.1%)		16 (84.2%)	26 (78.8%)		23 (74.2%)	59 (78.7%)		7 (70.0%)	74 (75.5%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	0 (0.0%)	4 (8.3%)	0.43	0 (0.0%)	2 (6.1%)	0.36	1 (3.2%)	3 (4.0%)	0.04	2 (18.2%)	7 (7.1%)	0.34
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	1 (9.1%)	1 (2.1%)	0.31	3 (15.8%)	6 (18.2%)	0.06	2 (6.5%)	9 (12.0%)	0.19	1 (9.1%)	10 (10.2%)	0.04
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (2.1%)	0.21	0 (0.0%)	0 (0.0%)	-	1 (3.2%)	1 (1.3%)	0.13	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	0 (0.0%)	1 (2.1%)	0.21	1 (5.3%)	0 (0.0%)	0.33	1 (3.2%)	2 (2.7%)	0.03	0 (0.0%)	0 (0.0%)	-
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	-	1 (5.3%)	0 (0.0%)	0.33	0 (0.0%)	1 (1.3%)	0.16	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 11)	TNFi (N= 48)	Std. Diff.	Baricitinib (N= 19)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 31)	TNFi (N= 75)	Std. Diff.	Baricitinib (N= 11)	TNFi (N= 98)	Std. Diff.
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	1 (2.1%)	0.21	0 (0.0%)	0 (0.0%)	-	1 (3.2%)	0 (0.0%)	0.26	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.3%)	0.16	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	0 (0.0%)	0 (0.0%)	-	1 (5.3%)	0 (0.0%)	0.33	0 (0.0%)	1 (1.3%)	0.16	1 (9.1%)	1 (1.0%)	0.37
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.3%)	0.16	0 (0.0%)	0 (0.0%)	-
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.3%)	0.16	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	0 (0.0%)	1 (2.1%)	0.21	1 (5.3%)	5 (15.2%)	0.33	8 (25.8%)	6 (8.0%)	0.49	2 (18.2%)	6 (6.1%)	0.38
Hyperlipidemia	2 (18.2%)	6 (12.5%)	0.16	2 (10.5%)	5 (15.2%)	0.14	4 (12.9%)	9 (12.0%)	0.03	1 (9.1%)	12 (12.2%)	0.10
Hypertension (hospitalized & non-hospitalized)	4 (36.4%)	7 (14.6%)	0.52	3 (15.8%)	13 (39.4%)	0.55	7 (22.6%)	18 (24.0%)	0.03	2 (18.2%)	30 (30.6%)	0.29
Immune disorders	0 (0.0%)	2 (4.2%)	0.29	0 (0.0%)	3 (9.1%)	0.45	1 (3.2%)	5 (6.7%)	0.16	0 (0.0%)	13 (13.3%)	0.55
Secondary Sjogren Syndrome	0 (0.0%)	2 (4.2%)	0.29	0 (0.0%)	3 (9.1%)	0.45	1 (3.2%)	5 (6.7%)	0.16	0 (0.0%)	13 (13.3%)	0.55
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	2 (4.2%)	0.29	1 (5.3%)	0 (0.0%)	0.33	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	2 (18.2%)	1 (2.3%)	0.54	1 (5.6%)	1 (3.2%)	0.11	3 (10.0%)	1 (1.5%)	0.37	2 (18.2%)	3 (3.1%)	0.50
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.3%)	0.16	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 11)	TNFi (N= 48)	Std. Diff.	Baricitinib (N= 19)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 31)	TNFi (N= 75)	Std. Diff.	Baricitinib (N= 11)	TNFi (N= 98)	Std. Diff.
Smoking (current)	1 (9.1%)	6 (12.5%)	0.11	4 (21.1%)	2 (6.3%)	0.44	7 (22.6%)	9 (12.0%)	0.28	2 (20.0%)	7 (7.3%)	0.38
RA severity (CDAI)												
n	11	45	0.11	18	32	0.06	31	71	0.14	11	95	0.35
Mean±SD	24.6 ± 8.7	23.4± 11.9		22.0 ± 13.7	21.1± 12.8		21.4 ± 14.7	23.5± 15.4		26.9 ± 14.5	22.2± 12.3	
Median	24.0	21.5		20.4	16.1		16.0	19.0		18.0	20.0	
Min, Max	11.6, 42.5	5.5, 67.2		1.0, 64.2	6.0, 58.3		1.4, 57.3	0.5, 65.5		12.0, 51.5	0.5, 59.7	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (3.0%)	0.25	0 (0.0%)	2 (2.7%)	0.23	0 (0.0%)	1 (1.0%)	0.14
MACE (at any time in the past)	1 (9.1%)	1 (2.1%)	0.31	1 (5.3%)	0 (0.0%)	0.33	0 (0.0%)	0 (0.0%)	-	1 (9.1%)	3 (3.1%)	0.25
Myocardial infarction	0 (0.0%)	0 (0.0%)	-	1 (5.3%)	0 (0.0%)	0.33	0 (0.0%)	0 (0.0%)	-	1 (9.1%)	1 (1.0%)	0.37
Stroke	1 (9.1%)	1 (2.1%)	0.31	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	2 (2.0%)	0.20
Serious infection (at any time in the past)	1 (9.1%)	3 (6.3%)	0.11	1 (5.3%)	3 (9.1%)	0.15	4 (12.9%)	7 (9.3%)	0.11	1 (9.1%)	9 (9.2%)	0.00
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	1 (9.1%)	5 (10.4%)	0.04	1 (5.3%)	3 (9.1%)	0.15	1 (3.2%)	5 (6.7%)	0.16	0 (0.0%)	4 (4.1%)	0.29
1	5 (45.5%)	32 (66.7%)	0.44	13 (68.4%)	22 (66.7%)	0.04	23 (74.2%)	52 (69.3%)	0.11	9 (81.8%)	78 (79.6%)	0.06
2+	5 (45.5%)	11 (22.9%)	0.49	5 (26.3%)	8 (24.2%)	0.05	7 (22.6%)	18 (24.0%)	0.03	2 (18.2%)	16 (16.3%)	0.05
Methotrexate (prior use)	10 (90.9%)	42 (87.5%)	0.11	17 (89.5%)	28 (84.8%)	0.14	27 (87.1%)	66 (88.0%)	0.03	8 (72.7%)	91 (92.9%)	0.55
Number of bDMARDs used (ever)												
0	11 (100.0%)	48(100.0%)	-	19 (100.0%)	33(100.0%)	-	31 (100.0%)	75(100.0%)	-	11 (100.0%)	98(100.0%)	-
Prior bDMARD use[a]	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 11)	TNFi (N= 48)	Std. Diff.	Baricitinib (N= 19)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 31)	TNFi (N= 75)	Std. Diff.	Baricitinib (N= 11)	TNFi (N= 98)	Std. Diff.
Prior TNFi bDMARD use	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Prior non-TNFi bDMARD use	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	6 (54.5%)	41 (85.4%)	0.72	14 (73.7%)	25 (75.8%)	0.05	21 (67.7%)	63 (84.0%)	0.39	9 (81.8%)	85 (86.7%)	0.14
Methotrexate (current use)	6 (54.5%)	38 (79.2%)	0.54	14 (73.7%)	24 (72.7%)	0.02	19 (61.3%)	60 (80.0%)	0.42	6 (54.5%)	81 (82.7%)	0.64
Current (baseline) prescription medication use												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	1 (2.1%)	0.21	0 (0.0%)	2 (6.1%)	0.36	0 (0.0%)	1 (1.4%)	0.17	0 (0.0%)	1 (1.0%)	0.14
Antihypertensives (blood pressure lowering medication(s); patient-reported)	4 (36.4%)	9 (18.8%)	0.40	2 (10.5%)	10 (30.3%)	0.51	5 (16.1%)	12 (16.0%)	0.00	3 (27.3%)	29 (29.6%)	0.05
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (3.2%)	2 (2.7%)	0.03	0 (0.0%)	2 (2.1%)	0.21
Nitrates (angina/nitrate medications; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (1.3%)	0.16	1 (9.1%)	0 (0.0%)	0.45
Lipid-lowering agents (cholesterol medication; patient-reported)	3 (27.3%)	7 (14.9%)	0.31	2 (11.1%)	6 (18.2%)	0.20	5 (16.1%)	9 (12.2%)	0.11	2 (18.2%)	12 (12.4%)	0.16
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	2 (4.3%)	0.30	1 (5.6%)	0 (0.0%)	0.34	0 (0.0%)	0 (0.0%)	-	1 (9.1%)	0 (0.0%)	0.45
Prednisone	3 (27.3%)	15 (31.3%)	0.09	2 (10.5%)	6 (18.2%)	0.22	8 (25.8%)	17 (22.7%)	0.07	4 (36.4%)	32 (32.7%)	0.08

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 11)	TNFi (N= 48)	Std. Diff.	Baricitinib (N= 19)	TNFi (N= 33)	Std. Diff.	Baricitinib (N= 31)	TNFi (N= 75)	Std. Diff.	Baricitinib (N= 11)	TNFi (N= 98)	Std. Diff.
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (5.3%)	0 (0.0%)	0.33	1 (3.2%)	2 (2.7%)	0.03	0 (0.0%)	1 (1.0%)	0.14

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.114. bDMARD-Experienced: Baseline Clinical Characteristics by Exposure Duration, VTE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/VTE event, excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.115. bDMARD-Naive: Baseline Clinical Characteristics by Exposure Duration, VTE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/VTE event, excludes patients with VTE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.116. bDMARD-Experienced: Baseline Clinical Characteristics by Exposure Duration, MACE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/MACE event, excludes patients with MACE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.117. bDMARD-Naive: Baseline Clinical Characteristics by Exposure Duration, MACE-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/MACE event, excludes patients with MACE within 6 months prior to index date or currently taking anticoagulant

Not applicable to CorEvitas data.

COR_JP Table 6.118. bDMARD-Experienced. Baseline Clinical Characteristics by Exposure Duration, Serious infection-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/serious infection event; excludes patients with a serious infection within 6 months prior to index date

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 30)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 22)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 37)	TNFi (N= 26)	Std. Diff.	Baricitinib (N= 13)	TNFi (N= 20)	Std. Diff.
Age [yrs]												
n	30	21	0.02	22	17	0.14	37	26	0.31	13	20	0.00
Mean±SD	59.1 ± 17.4	58.9± 15.3		61.0± 13.3	58.6± 19.7		62.4± 12.8	66.4± 12.8		65.8 ± 7.9	65.8± 15.2	
Median	68.5	60.0		60.5	63.0		64.0	68.5		66.0	70.5	
Min, Max	25.0, 84.0	30.0, 83.0		34.0, 82.0	22.0, 84.0		30.0, 85.0	38.0, 86.0		54.0, 82.0	32.0, 84.0	
≥ 65 years	16 (53.3%)	9 (42.9%)	0.21	8 (35.4%)	8 (47.1%)	0.22	16 (43.2%)	16 (61.5%)	0.37	9 (69.2%)	11 (55.0%)	0.30
Gender												
Male	0 (0.0%)	5 (23.8%)	0.79	3 (13.6%)	2 (11.8%)	0.06	3 (8.1%)	5 (19.2%)	0.33	3 (23.1%)	6 (30.0%)	0.16
Female	30 (100.0%)	16 (76.2%)		19 (86.4%)	15 (88.2%)		34 (91.9%)	21 (80.8%)		10 (76.9%)	14 (70.0%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	1 (3.3%)	3 (14.3%)	0.39	2 (9.1%)	2 (11.8%)	0.09	0 (0.0%)	4 (15.4%)	0.60	2 (15.4%)	1 (5.0%)	0.35
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (3.8%)	0.28	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	3 (10.0%)	2 (9.5%)	0.02	1 (4.5%)	1 (5.9%)	0.06	3 (8.1%)	4 (15.4%)	0.23	2 (15.4%)	2 (10.0%)	0.16
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	1 (3.3%)	2 (9.5%)	0.25	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.0%)	0.32
Cardiovascular revascularization	1 (3.3%)	0 (0.0%)	0.26	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 30)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 22)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 37)	TNFi (N= 26)	Std. Diff.	Baricitinib (N= 13)	TNFi (N= 20)	Std. Diff.
Coronary artery disease	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	2 (6.7%)	2 (9.5%)	0.10	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.0%)	0.32
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.0%)	0.32
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	1 (3.3%)	5 (23.8%)	0.63	1 (4.5%)	0 (0.0%)	0.31	5 (13.5%)	4 (15.4%)	0.05	0 (0.0%)	1 (5.0%)	0.32
Hyperlipidemia	3 (10.0%)	1 (4.8%)	0.20	2 (9.1%)	2 (11.8%)	0.09	7 (18.9%)	6 (23.1%)	0.10	2 (15.4%)	3 (15.0%)	0.01
Hypertension (hospitalized & non-hospitalized)	6 (20.0%)	6 (28.6%)	0.20	9 (40.9%)	5 (29.4%)	0.24	13 (35.1%)	12 (46.2%)	0.23	5 (38.5%)	8 (40.0%)	0.03
Immune disorders	1 (3.3%)	3 (14.3%)	0.39	3 (13.6%)	3 (17.6%)	0.11	8 (21.6%)	4 (15.4%)	0.16	1 (7.7%)	2 (10.0%)	0.08
Secondary Sjogren Syndrome	1 (3.3%)	3 (14.3%)	0.39	3 (13.6%)	3 (17.6%)	0.11	8 (21.6%)	4 (15.4%)	0.16	1 (7.7%)	2 (10.0%)	0.08
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	2 (6.7%)	2 (9.5%)	0.10	1 (4.5%)	1 (5.9%)	0.06	3 (8.1%)	2 (7.7%)	0.02	0 (0.0%)	1 (5.0%)	0.32
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.9%)	0.35	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Smoking (current)	1 (3.3%)	4 (19.0%)	0.51	2 (9.1%)	1 (5.9%)	0.12	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.0%)	0.32
RA severity (CDAI)												
n	30	21	0.30	22	17	0.14	37	26	0.19	13	20	0.48
Mean±SD	25.8 ± 13.6	22.1± 10.1		19.2± 10.5	21.0± 14.0		23.7± 11.2	21.4± 13.7		26.5 ± 17.2	19.7± 10.4	
Median	21.7	24.8		19.4	16.5		22.0	18.1		22.0	19.1	
Min, Max	4.4, 55.0	5.6, 36.8		3.0, 44.7	3.0, 49.0		6.6, 52.5	3.6, 59.0		3.5, 60.0	4.0, 42.3	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	2 (7.7%)	0.41	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 30)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 22)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 37)	TNFi (N= 26)	Std. Diff.	Baricitinib (N= 13)	TNFi (N= 20)	Std. Diff.
MACE (at any time in the past)	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	1 (2.7%)	0 (0.0%)	0.24	0 (0.0%)	1 (5.0%)	0.32
Myocardial infarction	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.0%)	0.32
Stroke	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (2.7%)	0 (0.0%)	0.24	0 (0.0%)	0 (0.0%)	-
Serious infection (at any time in the past)	5 (16.7%)	4 (19.0%)	0.06	1 (4.5%)	0 (0.0%)	0.31	4 (10.8%)	4 (15.4%)	0.14	1 (7.7%)	3 (15.0%)	0.23
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used(ever)												
0	2 (6.7%)	2 (9.5%)	0.10	2 (9.1%)	2 (11.8%)	0.09	4 (10.8%)	3 (11.5%)	0.02	3 (23.1%)	1 (5.0%)	0.54
1	24 (80.0%)	13 (61.9%)	0.41	18 (81.8%)	9 (52.9%)	0.65	23 (62.2%)	18 (69.2%)	0.15	7 (53.8%)	10 (50.0%)	0.08
2+	4 (13.3%)	6 (28.6%)	0.38	2 (9.1%)	6 (35.3%)	0.66	10 (27.0%)	5 (19.2%)	0.19	3 (23.1%)	9 (45.0%)	0.48
Methotrexate (prior use)	27 (90.0%)	17 (81.0%)	0.26	20 (90.9%)	15 (88.2%)	0.09	30 (81.1%)	21 (80.8%)	0.01	10 (76.9%)	18 (90.0%)	0.36
Number of bDMARDs used (ever)												
0	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
1	11 (36.7%)	9 (42.9%)	0.13	16 (72.7%)	12 (70.6%)	0.05	20 (54.1%)	18 (69.2%)	0.32	3 (23.1%)	15 (75.0%)	1.22
2+	19 (63.3%)	12 (57.1%)	0.13	6 (27.3%)	5 (29.4%)	0.05	17 (45.9%)	8 (30.8%)	0.32	10 (76.9%)	5 (25.0%)	1.22
Prior bDMARD use[a]	30 (100.0%)	21 (100.0%)	-	22 (100.0%)	17 (100.0%)	-	37 (100.0%)	26 (100.0%)	-	13 (100.0%)	20 (100.0%)	-
Prior TNFi bDMARD use	27 (90.0%)	13 (61.9%)	0.70	15 (68.2%)	11 (64.7%)	0.07	25 (67.6%)	15 (57.7%)	0.21	11 (84.6%)	11 (55.0%)	0.68
Prior non-TNFi bDMARD use	19 (63.3%)	16 (76.2%)	0.28	11 (50.0%)	10 (58.8%)	0.18	24 (64.9%)	17 (65.4%)	0.01	9 (69.2%)	13 (65.0%)	0.09
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	14 (46.7%)	9 (42.9%)	0.08	9 (40.9%)	11 (64.7%)	0.49	25 (67.6%)	15 (57.7%)	0.21	8 (61.5%)	11 (55.0%)	0.13
Methotrexate (current use)	14 (46.7%)	8 (38.1%)	0.17	9 (40.9%)	11 (64.7%)	0.49	20 (54.1%)	15 (57.7%)	0.07	8 (61.5%)	9 (45.0%)	0.34
Current (baseline) prescription medication use												
Cardiovascular medications												

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 30)	TNFi (N= 21)	Std. Diff.	Baricitinib (N= 22)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 37)	TNFi (N= 26)	Std. Diff.	Baricitinib (N= 13)	TNFi (N= 20)	Std. Diff.
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	1 (4.8%)	0.32	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Antihypertensives (blood pressure lowering medication(s); patient-reported)	2 (6.7%)	5 (23.8%)	0.49	8 (36.4%)	3 (17.6%)	0.43	12 (32.4%)	11 (42.3%)	0.21	5 (38.5%)	8 (40.0%)	0.03
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (5.0%)	0.32
Nitrates (angina/nitrate medications; patient-reported)	1 (3.3%)	1 (4.8%)	0.07	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Lipid-lowering agents (cholesterol medication; patient-reported)	4 (13.3%)	5 (23.8%)	0.27	4 (18.2%)	1 (5.9%)	0.38	7 (18.9%)	6 (23.1%)	0.10	2 (15.4%)	3 (15.0%)	0.01
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	2 (9.5%)	0.46	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (3.8%)	0.28	0 (0.0%)	2 (10.0%)	0.47
Prednisone	5 (16.7%)	8 (38.1%)	0.50	7 (31.8%)	3 (17.6%)	0.33	8 (21.6%)	8 (30.8%)	0.21	3 (23.1%)	6 (30.0%)	0.16
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.119. bDMARD-Naive. Baseline Clinical Characteristics by Exposure Duration, Serious infection-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/serious infection event; excludes patients with a serious infection within 6 months prior to index date

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 13)	TNFi (N= 28)	Std. Diff.	Baricitinib (N= 16)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 38)	Std. Diff.	Baricitinib (N= 10)	TNFi (N= 46)	Std. Diff.
Age [yrs]												
n	13	28	0.05	16	17	0.12	29	38	0.03	10	46	0.55
Mean±SD	62.9 ± 14.9	62.3± 12.6		60.2 ± 11.4	58.3± 18.7		59.1± 13.5	59.6± 17.0		52.5± 15.0	61.0± 15.9	
Median	65.0	65.5		60.5	59.0		62.0	59.0		46.5	64.0	
Min, Max	31.0, 80.0	27.0, 90.0		35.0, 83.0	22.0, 82.0		32.0, 79.0	25.0, 88.0		38.0, 78.0	28.0, 84.0	
≥ 65 years	7 (53.8%)	14 (50.0%)	0.08	5 (31.3%)	8 (47.1%)	0.33	14 (48.3%)	14 (36.8%)	0.23	3 (30.0%)	21 (45.7%)	0.33
Gender												
Male	3 (23.1%)	5 (17.9%)	0.13	3 (18.8%)	2 (11.8%)	0.20	7 (24.1%)	5 (13.2%)	0.28	3 (30.0%)	8 (17.4%)	0.30
Female	10 (76.9%)	23 (82.1%)		13 (81.3%)	15 (88.2%)		22 (75.9%)	33 (86.8%)		7 (70.0%)	38 (82.6%)	
History of MD-reported comorbidities (ever experienced)												
Cancer, non-NMSC	0 (0.0%)	3 (10.7%)	0.49	0 (0.0%)	1 (5.9%)	0.35	1 (3.4%)	3 (7.9%)	0.19	2 (20.0%)	3 (6.5%)	0.41
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	1 (7.7%)	1 (3.6%)	0.18	3 (18.8%)	3 (17.6%)	0.03	2 (6.9%)	3 (7.9%)	0.04	1 (10.0%)	5 (10.9%)	0.03
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	1 (3.6%)	0.27	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	0 (0.0%)	0.27	0 (0.0%)	0 (0.0%)	-
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	0 (0.0%)	1 (3.6%)	0.27	1 (6.3%)	0 (0.0%)	0.37	1 (3.4%)	1 (2.6%)	0.05	0 (0.0%)	0 (0.0%)	-
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	-	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	1 (2.6%)	0.23	0 (0.0%)	0 (0.0%)	-

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 13)	TNFi (N= 28)	Std. Diff.	Baricitinib (N= 16)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 38)	Std. Diff.	Baricitinib (N= 10)	TNFi (N= 46)	Std. Diff.
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	1 (3.6%)	0.27	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	0 (0.0%)	0.27	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.6%)	0.23	0 (0.0%)	0 (0.0%)	-
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	0 (0.0%)	0 (0.0%)	-	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	1 (2.6%)	0.23	1 (10.0%)	1 (2.2%)	0.33
TIA	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Unstable angina	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.6%)	0.23	0 (0.0%)	0 (0.0%)	-
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Diabetes mellitus	0 (0.0%)	0 (0.0%)	-	1 (6.3%)	4 (23.5%)	0.50	8 (27.6%)	5 (13.2%)	0.36	2 (20.0%)	3 (6.5%)	0.41
Hyperlipidemia	2 (15.4%)	4 (14.3%)	0.03	1 (6.3%)	2 (11.8%)	0.19	4 (13.8%)	7 (18.4%)	0.13	1 (10.0%)	4 (8.7%)	0.04
Hypertension (hospitalized & non-hospitalized)	5 (38.5%)	4 (14.3%)	0.57	2 (12.5%)	6 (35.3%)	0.55	6 (20.7%)	12 (31.6%)	0.25	2 (20.0%)	17 (37.0%)	0.38
Immune disorders	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	2 (5.3%)	0.09	0 (0.0%)	5 (10.9%)	0.49
Secondary Sjogren Syndrome	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	2 (5.3%)	0.09	0 (0.0%)	5 (10.9%)	0.49
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	1 (3.6%)	0.27	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Obesity, current	2 (15.4%)	1 (3.6%)	0.41	1 (6.3%)	0 (0.0%)	0.37	3 (10.3%)	0 (0.0%)	0.48	2 (20.0%)	2 (4.3%)	0.49
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.6%)	0.23	0 (0.0%)	0 (0.0%)	-
Smoking (current)	1 (7.7%)	5 (17.9%)	0.31	3 (18.8%)	2 (11.8%)	0.20	7 (24.1%)	6 (15.8%)	0.21	2 (20.0%)	3 (6.5%)	0.41
RA severity (CDAI)												
n	13	28	0.35	16	17	0.02	29	38	0.27	10	46	0.33
Mean±SD	22.6 ± 9.4	26.6± 13.2		22.7 ± 14.4	22.4± 16.1		22.3± 14.7	26.6± 16.6		27.8± 15.0	23.2± 12.6	

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 13)	TNFi (N= 28)	Std. Diff.	Baricitinib (N= 16)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 38)	Std. Diff.	Baricitinib (N= 10)	TNFi (N= 46)	Std. Diff.
Median	20.5	23.9		22.3	16.2		17.0	25.9		25.5	20.6	
Min, Max	8.5, 42.5	5.5, 67.2		1.0, 64.2	6.0, 58.3		1.4, 57.3	0.5, 65.5		12.0, 51.5	0.5, 55.2	
Prevalent outcomes												
VTE (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.6%)	0.23	0 (0.0%)	1 (2.2%)	0.21
MACE (at any time in the past)	1 (7.7%)	1 (3.6%)	0.18	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	0 (0.0%)	-	1 (10.0%)	2 (4.3%)	0.22
Myocardial infarction	0 (0.0%)	0 (0.0%)	-	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	0 (0.0%)	-	1 (10.0%)	1 (2.2%)	0.33
Stroke	1 (7.7%)	1 (3.6%)	0.18	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.2%)	0.21
Serious infection (at any time in the past)	2 (15.4%)	1 (3.6%)	0.41	0 (0.0%)	1 (5.9%)	0.35	3 (10.3%)	2 (5.3%)	0.19	1 (10.0%)	2 (4.3%)	0.22
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD history												
Number of cDMARDs used (ever)												
0	1 (7.7%)	2 (7.1%)	0.02	1 (6.3%)	2 (11.8%)	0.19	1 (3.4%)	3 (7.9%)	0.19	0 (0.0%)	2 (4.3%)	0.30
1	7 (53.8%)	18 (64.3%)	0.21	11 (68.8%)	10 (58.8%)	0.21	21 (72.4%)	28 (73.7%)	0.03	8 (80.0%)	38 (82.6%)	0.07
2+	5 (38.5%)	8 (28.6%)	0.21	4 (25.0%)	5 (29.4%)	0.10	7 (24.1%)	7 (18.4%)	0.14	2 (20.0%)	6 (13.0%)	0.19
Methotrexate (prior use)	11 (84.6%)	25 (89.3%)	0.14	15 (93.8%)	14 (82.4%)	0.36	25 (86.2%)	34 (89.5%)	0.10	7 (70.0%)	42 (91.3%)	0.56
Number of bDMARDs used (ever)												
0	13 (100.0%)	28 (100.0%)	-	16 (100.0%)	17 (100.0%)	-	29 (100.0%)	38 (100.0%)	-	10 (100.0%)	46 (100.0%)	-
Prior bDMARD use[a]	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Prior TNFi bDMARD use	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
Prior non-TNFi bDMARD use	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
DMARD, current (baseline)												
cDMARD, concomitant use at baseline	7 (53.8%)	23 (82.1%)	0.64	12 (75.0%)	14 (82.4%)	0.18	19 (65.5%)	30 (78.9%)	0.30	8 (80.0%)	40 (87.0%)	0.19
Methotrexate (current use)	7 (53.8%)	21 (75.0%)	0.45	12 (75.0%)	13 (76.5%)	0.03	17 (58.6%)	30 (78.9%)	0.45	5 (50.0%)	39 (84.8%)	0.80

	<6mos			6 mos to <12 mos			12 mos to <24 mos			>=24 mos		
	Baricitinib (N= 13)	TNFi (N= 28)	Std. Diff.	Baricitinib (N= 16)	TNFi (N= 17)	Std. Diff.	Baricitinib (N= 29)	TNFi (N= 38)	Std. Diff.	Baricitinib (N= 10)	TNFi (N= 46)	Std. Diff.
Current (baseline) prescription medication use												
Cardiovascular medications												
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	1 (3.6%)	0.27	0 (0.0%)	1 (5.9%)	0.35	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	1 (2.2%)	0.21
Antihypertensives (blood pressure lowering medication(s); patient-reported)	4 (30.8%)	6 (21.4%)	0.21	2 (12.5%)	2 (11.8%)	0.02	5 (17.2%)	10 (26.3%)	0.22	2 (20.0%)	19 (41.3%)	0.47
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (3.4%)	1 (2.6%)	0.05	0 (0.0%)	1 (2.2%)	0.21
Nitrates (angina/nitrate medications; patient-reported)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-	1 (10.0%)	0 (0.0%)	0.47
Lipid-lowering agents (cholesterol medication; patient-reported)	4 (30.8%)	6 (21.4%)	0.21	1 (6.3%)	2 (11.8%)	0.19	5 (17.2%)	5 (13.2%)	0.11	2 (20.0%)	8 (17.4%)	0.07
RA-related												
Aspirin (includes non-prescription)	0 (0.0%)	2 (7.1%)	0.39	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	0 (0.0%)	-	1 (10.0%)	0 (0.0%)	0.47
Prednisone	4 (30.8%)	8 (28.6%)	0.05	2 (12.5%)	2 (11.8%)	0.02	7 (24.1%)	7 (18.4%)	0.14	4 (40.0%)	12 (26.1%)	0.30
Vaccinations												
Shingles (ever)	0 (0.0%)	0 (0.0%)	-	1 (6.3%)	0 (0.0%)	0.37	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.
a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.120. bDMARD-Experienced: Baseline Clinical Characteristics by Exposure Duration, Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/TB event, excludes patients with hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.121. bDMARD-Naive: Baseline Clinical Characteristics by Exposure Duration, Hospitalized Tuberculosis-matched Population [CorEvitas Japan] - exposure ends at discontinuation/last follow-up visit/TB event, excludes patients with hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Tables 6.122 - 131. Baseline Healthcare Resource Utilization by Exposure Duration by bDMARD-Experienced/Naive

Not applicable to CorEvitas data.

COR_JP Tables 6.132 - 141. VTE Outcome Tables by bDMARD-Experienced/Naive

Not applicable to CorEvitas data.

COR_JP Tables 6.142 - 151. MACE Outcome Tables by bDMARD-Experienced/Naive

Not applicable to CorEvitas data.

COR_JP Table 6.152. bDMARD-Experienced. Baseline Clinical Characteristics of Patients with Serious Infection, Serious Infection-matched Population [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Baricitinib (N=6)	TNFi (N=3)	Std. Diff.
Age [yrs]			
n	6	3	9
Mean±SD	66.3 ±16.3	63.0 ± 4.4	65.2 ±13.2
Median	74.0	65.0	66.0
Min, Max	39.0, 81.0	58.0, 66.0	39.0, 81.0
Gender			
Male	0 (0.0%)	1 (33.3%)	1 (11.1%)
Female	6 (100.0%)	2 (66.7%)	8 (88.9%)
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	0 (0.0%)	2 (66.7%)	2 (22.2%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes mellitus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperlipidemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypertension (hospitalized & non-hospitalized)	2 (33.3%)	0 (0.0%)	2 (22.2%)
Immune disorders	0 (0.0%)	2 (66.7%)	2 (22.2%)
Secondary Sjogren Syndrome	0 (0.0%)	2 (66.7%)	2 (22.2%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Baricitinib (N=6)	TNFi (N=3)	Std. Diff.
Obesity, current	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Smoking (current)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RA severity (CDAI)			
n	6	3	9
Mean±SD	27.0 ±17.5	18.1 ±10.5	24.0 ±15.5
Median	23.3	20.1	21.3
Min, Max	10.3, 60.0	6.7, 27.5	6.7, 60.0
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	1 (33.3%)	1 (11.1%)
MACE (at any time in the past)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stroke	0 (0.0%)	0 (0.0%)	0 (0.0%)
Serious infection (at any time in the past)	2 (33.3%)	2 (66.7%)	4 (44.4%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prescription medication use, current (baseline)			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nitrates (angina/nitrate medications; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents (cholesterol medication; patient-reported)	2 (33.3%)	0 (0.0%)	2 (22.2%)
RA-related			
Aspirin (includes non-prescription)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prednisone	1 (16.7%)	3 (100.0%)	4 (44.4%)
Vaccinations			
Shingles (ever)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.153. bDMARD-Naive. Baseline Clinical Characteristics of Patients with Serious Infection, Serious Infection-matched Population [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Baricitinib (N=3)	TNFi (N=5)	Std. Diff.
Age [yrs]			
n	3	5	8
Mean±SD	74.0 ± 5.3	71.8 ± 5.2	72.6 ± 5.0
Median	72.0	69.0	71.0
Min, Max	70.0, 80.0	68.0, 80.0	68.0, 80.0
Gender			
Male	2 (66.7%)	0 (0.0%)	2 (25.0%)
Female	1 (33.3%)	5 (100.0%)	6 (75.0%)
History of MD-reported comorbidities (ever experienced)			
Cancer, non-NMSC	0 (0.0%)	2 (40.0%)	2 (25.0%)
Cancer, NMSC only	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic Lung Disease (COPD, pulmonary fibrosis, asthma, interstitial lung disease)	0 (0.0%)	1 (20.0%)	1 (12.5%)
CVD-VTE risk (congestive heart failure, ventricular arrhythmia)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CVD-MACE risk (unstable angina, congestive heart failure, ventricular arrhythmia, cardiovascular revascularization, coronary artery disease, TIA)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure (hospitalized & non-hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease (myocardial infarction, unstable angina, revascularization, coronary artery disease, acute coronary syndrome)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes mellitus	0 (0.0%)	2 (40.0%)	2 (25.0%)
Hyperlipidemia	0 (0.0%)	2 (40.0%)	2 (25.0%)
Hypertension (hospitalized & non-hospitalized)	2 (66.7%)	3 (60.0%)	5 (62.5%)
Immune disorders	0 (0.0%)	0 (0.0%)	0 (0.0%)
Secondary Sjogren Syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
Liver Disorder (hepatic event hospitalized & hepatic event non-hospitalized)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	Baricitinib (N=3)	TNFi (N=5)	Std. Diff.
Obesity, current	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy, recent (current or since last visit)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Smoking (current)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RA severity (CDAI)			
n	3	5	8
Mean±SD	13.9 ± 4.9	26.3 ±11.0	21.7 ±10.8
Median	15.3	26.0	21.5
Min, Max	8.5, 18.0	9.5, 39.5	8.5, 39.5
Prevalent outcomes			
VTE (at any time in the past)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MACE (at any time in the past)	1 (33.3%)	0 (0.0%)	1 (12.5%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stroke	1 (33.3%)	0 (0.0%)	1 (12.5%)
Serious infection (at any time in the past)	1 (33.3%)	0 (0.0%)	1 (12.5%)
TB, hospitalized (at any time in the past)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Current (baseline) prescription medication use			
Cardiovascular medications			
Anticoagulant (coumadin/warfarin; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antihypertensives (blood pressure lowering medication(s); patient-reported)	1 (33.3%)	2 (40.0%)	3 (37.5%)
Antiplatelet (Plavix; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nitrates (angina/nitrate medications; patient-reported)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents (cholesterol medication; patient-reported)	1 (33.3%)	1 (20.0%)	2 (25.0%)
RA-related			
Aspirin (includes non-prescription)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate (current use)	1 (33.3%)	5 (100.0%)	6 (75.0%)
Prednisone	1 (33.3%)	1 (20.0%)	2 (25.0%)
Vaccinations			
Shingles (ever)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; CDAI = clinical disease activity index; cDMARD = classical disease-modifying antirheumatic drugs; COPD = chronic obstructive pulmonary disease; CVD = cardiovascular disease; MACE = major adverse cardiovascular event; Max = maximum; Min = minimum; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; Std Diff = absolute value of the standardized difference; TB = tuberculosis; TIA = transient ischemic attack; TNFi = tumor necrosis factor inhibitor; VTE = venous thromboembolism.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.154. bDMARD-Experienced. Pattern of RA Medication Use in Patients with Serious Infection [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Pre-matched		Matched		
	Baricitinib (N= 7)	TNFi (N= 4)	Baricitinib (N= 6)	TNFi (N= 3)	Total (N= 9)
Baseline Medication					
BDMARD history					
Number of cDMARDs used(ever)					
0	1 (14.3%)	1 (25.0%)	1 (16.7%)	0 (0.0%)	1 (11.1%)
1	5 (71.4%)	1 (25.0%)	4 (66.7%)	1 (33.3%)	5 (55.6%)
2+	1 (14.3%)	2 (50.0%)	1 (16.7%)	2 (66.7%)	3 (33.3%)
Methotrexate (prior use)	6 (85.7%)	3 (75.0%)	5 (83.3%)	3 (100.0%)	8 (88.9%)
Number of bDMARDs used (ever)					
0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	1 (14.3%)	2 (50.0%)	1 (16.7%)	1 (33.3%)	2 (22.2%)
2+	6 (85.7%)	2 (50.0%)	5 (83.3%)	2 (66.7%)	7 (77.8%)
Prior bDMARD use[a]	7 (100.0%)	4 (100.0%)	6 (100.0%)	3 (100.0%)	9 (100.0%)
Prior TNFi bDMARD use	6 (85.7%)	3 (75.0%)	5 (83.3%)	3 (100.0%)	8 (88.9%)
Prior non-TNFi bDMARD use	5 (71.4%)	3 (75.0%)	5 (83.3%)	2 (66.7%)	7 (77.8%)
BDMARD, current (baseline)					
Concomitant non-methotrexate cDMARD use at baseline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant methotrexate use at baseline	2 (28.6%)	3 (75.0%)	2 (33.3%)	3 (100.0%)	5 (55.6%)
Post-index Medication					
Concomitant methotrexate use during exposure (regardless of use at index date)	3 (42.9%)	3 (75.0%)	3 (50.0%)	3 (100.0%)	6 (66.7%)
Concomitant non-methotrexate cDMARD use during exposure (regardless of use at index date)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (33.3%)	1 (11.1%)
Baricitinib dose change during exposure	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (33.3%)	1 (11.1%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; cDMARD = classical disease-modifying antirheumatic drugs; TNFi = tumor necrosis factor inhibitor.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.155. bDMARD-Naive. Pattern of RA Medication Use in Patients with Serious Infection [CorEvitas Japan] – excludes patients with a serious infection within 6 months prior to index date

	Pre-matched		Matched		
	Baricitinib (N= 4)	TNFi (N= 11)	Baricitinib (N= 3)	TNFi (N= 5)	Total (N= 8)
Baseline Medication					
DMARD history					
Number of cDMARDs used(ever)					
0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	4 (100.0%)	8 (72.7%)	3 (100.0%)	4 (80.0%)	7 (87.5%)
2+	0 (0.0%)	3 (27.3%)	0 (0.0%)	1 (20.0%)	1 (12.5%)
Methotrexate (prior use)	3 (75.0%)	10 (90.9%)	2 (66.7%)	5 (100.0%)	7 (87.5%)
Number of bDMARDs used (ever)					
0	4 (100.0%)	11 (100.0%)	3 (100.0%)	5 (100.0%)	8 (100.0%)
1	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2+	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prior bDMARD use[a]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prior TNFi bDMARD use	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Prior non-TNFi bDMARD use	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
DMARD, current (baseline)					
Concomittant non-methotrexate cDMARD use at baseline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Concomitant methotrexate use at baseline	2 (50.0%)	10 (90.9%)	1 (33.3%)	5 (100.0%)	6 (75.0%)
Post-index Medication					
Concomitant methotrexate use during exposure (regardless of use at index date)	2 (50.0%)	10 (90.9%)	1 (33.3%)	5 (100.0%)	6 (75.0%)
Concomitant non-methotrexate cDMARD use during exposure (regardless of use at index date)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Baricitinib dose change during exposure	0 (0.0%)	1 (9.1%)	0 (0.0%)	1 (20.0%)	1 (12.5%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drugs; cDMARD = classical disease-modifying antirheumatic drugs; TNFi = tumor necrosis factor inhibitor.

a. Per CorEvitas' contractual obligations reports on individual drugs are subject to review by individual market authorization holders who are also subscribers to the Corrona registry and have therefore not been included in this table.

COR_JP Table 6.156. bDMARD-Experienced. Time to First Serious Infection Event (Days) [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 7)	TNFi (N= 4)	Baricitinib (N= 6)	TNFi (N= 3)	Total (N= 9)
n	7	4	6	3	9
Mean±SD	275.3 ±295.8	480.5 ±384.4	284.0 ±323.1	339.7 ±320.3	302.6 ±302.8
Median	153.0	489.0	140.5	300.0	153.0
Min, Max	40.0, 902.0	41.0, 903.0	40.0, 902.0	41.0, 678.0	40.0, 902.0
25th, 75th percentile	108.0, 373.0	170.5, 790.5	108.0, 373.0	41.0, 678.0	108.0, 373.0

Abbreviations: Min = minimum; Max = maximum; SD = standard deviation; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.157. bDMARD-Naive. Time to First Serious Infection Event (Days) [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 4)	TNFi (N= 11)	Baricitinib (N= 3)	TNFi (N= 5)	Total (N= 8)
n	4	11	3	5	8
Mean±SD	90.5 ± 56.3	286.6 ±267.3	64.0 ± 23.4	436.4 ±271.6	296.8 ±281.9
Median	71.0	106.0	51.0	396.0	208.5
Min, Max	50.0, 170.0	58.0, 716.0	50.0, 91.0	60.0, 716.0	50.0, 716.0
25th, 75th percentile	50.5, 130.5	70.0, 583.0	50.0, 91.0	326.0, 684.0	55.5, 540.0

Abbreviations: Min = minimum; Max = maximum; SD = standard deviation; TNFi = tumor necrosis factor inhibitor

COR_JP Table 6.158. bDMARD-Experienced. Incidence Rates of First Serious Infection Event [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 138)	**TNFi (N= 100)**	**Baricitinib (N= 102)**	**TNFi (N= 84)**	**Total (N= 9)**
Overall					
SI Events	7	4	6	3	9
Person-Years	142.9	131.8	112.1	109.8	221.9
SI Events/100 PY	4.9	3.0	5.4	2.7	4.1
95% CI	2.0, 10.1	0.8, 7.8	2.0, 11.6	0.6, 8.0	1.9, 7.7
Incidence rate difference: baricitinib – TNFi (95% CI)					2.6 (-2.7, 7.9)

Abbreviations: bDMARD = biologic disease-modifying anti-rheumatic drug; CI = confidence interval; PY = person-years; TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.159. bDMARD-Naive. Incidence Rates of First Serious Infection Event [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 72)	TNFi (N= 254)	Baricitinib (N= 68)	TNFi (N= 129)	Total (N= 8)
Overall					
SI Events	4	11	3	5	8
Person-Years	82.2	394.1	78.7	193.3	272.0
SI Events/100 PY	4.9	2.8	3.8	2.6	2.9
95% CI	1.3, 12.5	1.4, 5.0	0.8, 11.1	0.8, 6.0	1.3, 5.8
Incidence rate difference: baricitinib – TNFi (95% CI)					1.2 (-3.6, 6.1)

Abbreviations: bDMARD = biologic disease-modifying anti-rheumatic drug; CI = confidence interval; PY = person-years; TNFi = tumor necrosis factor inhibitor

COR_JP Table 6.160. bDMARD-Experienced. Serious Infection Events Per Patient During Baricitinib and TNF Exposure* [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 138)	TNFi (N= 100)	Baricitinib (N= 102)	TNFi (N= 84)	Total (N= 186)
0	131 (94.9%)	96 (96.0%)	96 (94.1%)	81 (96.4%)	177 (95.2%)
1	5 (3.6%)	4 (4.0%)	4 (3.9%)	3 (3.6%)	7 (3.8%)
2	2 (1.4%)	0 (0.0%)	2 (2.0%)	0 (0.0%)	2 (1.1%)

* All events after the first occur after the incident serious infection determining time to first serious infection event
Abbreviation: TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.161. bDMARD-Naive. Serious Infection Events Per Patient During Baricitinib and TNF Exposure* [CorEvitas Japan]

	Pre-matched		Matched		
	Baricitinib (N= 72)	TNFi (N= 254)	Baricitinib (N= 68)	TNFi (N= 129)	Total (N= 197)
0	68 (94.4%)	243 (95.7%)	65 (95.6%)	124 (96.1%)	189 (95.9%)
1	4 (5.6%)	11 (4.3%)	3 (4.4%)	5 (3.9%)	8 (4.1%)
2	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

* All events after the first occur after the incident serious infection determining time to first serious infection event
Abbreviation: TNFi = tumor necrosis factor inhibitor.

COR_JP Table 6.162. bDMARD-Experienced. Comparative Risk of Incident Serious Infection [CorEvitas Japan]; Serious Infection-matched population – excludes patients with prior serious infection within 6 months prior to index

	TNFi	Baricitinib HR (95% CI)	P-Value
Base model	Ref	HR: 1.99 95% CI: [0.48, 8.18]	0.342
Adjusted - Model [1]	Ref	HR: 1.33 95% CI: [0.32, 5.57]	0.694
Adjusted - Model [2]	Ref	HR: 1.53 95% CI: [0.36, 6.58]	0.565
Non-mtx cDMARD use	Ref	HR: 0.95 95% CI: [0.11, 8.03]	0.960
Mtx cDMARD use	Ref	HR: 1.11 95% CI: [0.30, 4.17]	0.874
Prednisone use	Ref	HR: 2.28 95% CI: [0.58, 8.95]	0.238
Adjusted - Model [3]	Ref	HR: 1.54 95% CI: [0.36, 6.59]	0.564
Prednisone use	Ref	HR: 2.27 95% CI: [0.59, 8.65]	0.232
Adjusted - Model [4]	Ref	HR: 1.34 95% CI: [0.31, 5.74]	0.694
RA severity (CDAI)	Ref	HR: 1.00 95% CI: [0.95, 1.05]	0.972
Adjusted - Model [5]	Ref	HR: 1.33 95% CI: [0.31, 5.69]	0.704

Abbreviations: CDAI = clinical disease activity index; cDMARD = classical disease-modifying anti-rheumatic drug; CI = confidence interval; HR = hazard ratio mtx = methotrexate; Ref = Referent group; TNFi = tumor necrosis factor inhibitor.

Base model: no adjusting covariates

Model [1]: adjusted with covariates specified in SAP COR_JP Table 66 and remaining imbalanced after matching

Model [2]: Model [1] + time-varying concomitant non-methotrexate cDMARD use + time-varying concomitant methotrexate use + time-varying prednisone use

Model [3]: Model [1] + time-varying prednisone use

Model [4]: Model [1] + RA severity (CDAI)

COR_JP Table 6.163. bDMARD-Naive. Comparative Risk of Incident Serious Infection [CorEvitas Japan]; Serious Infection-matched population – excludes patients with prior serious infection within 6 months prior to index

	TNFi	Baricitinib HR (95% CI)	P-Value
Base model	Ref	HR: 1.32 95% CI: [0.28, 6.27]	0.724
Adjusted - Model [1]	Ref	HR: 1.00 95% CI: [0.20, 5.08]	0.998
Adjusted - Model [2]	Ref	HR: 1.11 95% CI: [0.20, 6.05]	0.908
Non-mtx cDMARD use	Ref	--	--
Mtx cDMARD use	Ref	HR: 1.44 95% CI: [0.21, 9.79]	0.712
Prednisone use	Ref	HR: 0.67 95% CI: [0.07, 6.27]	0.726
Adjusted - Model [3]	Ref	HR: 1.00 95% CI: [0.20, 5.09]	0.997
Prednisone use	Ref	HR: 0.72 95% CI: [0.08, 6.36]	0.767
Adjusted - Model [4]	Ref	HR: 0.96 95% CI: [0.19, 4.92]	0.958
RA severity (CDAI)	Ref	HR: 0.98 95% CI: [0.93, 1.04]	0.522
Adjusted - Model [5]	Ref	HR: 0.94 95% CI: [0.17, 5.10]	0.943

Abbreviations: CDAI = clinical disease activity index; cDMARD = classical disease-modifying anti-rheumatic drug; CI = confidence interval; HR = hazard ratio mtx = methotrexate; Ref = Referent group; TNFi = tumor necrosis factor inhibitor.
Base model: no adjusting covariates
Model [1]: adjusted with covariates specified in SAP COR_JP Table 66 and remaining imbalanced after matching
Model [2]: Model [1] + time-varying concomitant non-methotrexate cDMARD use + time-varying concomitant methotrexate use + time-varying prednisone use
Model [3]: Model [1] + time-varying prednisone use
Model [4]: Model [1] + RA severity (CDAI)

COR_JP Table 6.164. bDMARD-Experienced: Incidence Rates of First Hospitalized TB Event [CorEvitas Japan] - excludes patients with a hospitalized TB within 6 months prior to index date

Not applicable to CorEvitas data.

COR_JP Table 6.165 - 182. Assessment of Potential Class Effect of JAKi on Risk of VTE

Not applicable to CorEvitas Japan data.

COR_JP Table 6.183 - 200. Evaluating the Potential Association between Baricitinib and VTE Regardless of Prior JAKi Use

Not applicable to CorEvitas Japan data.

Annex 15. JMDC – Additional Results

This annex includes information about results for the following analyses:

I. Additional analysis

These additional results were not presented in the body of the report. These results, like those included in the report body, are based on 1:1 baricitinib:TNFi propensity score matching. Specifically, this section of the annex includes:

- Descriptive tables for unmatched eligible patients.
- Descriptive tables for matched patient cohorts for the serious infection analyses

II. Variable Ratio Matching

These results were not presented in the body of this report. They are based on matching baricitinib:TNFi using Variable Ratio matching, i.e., as many matched 1:3 as possible, then the maximum number matched 1:2, then the remaining patients matched 1:1.

I. Additional analysis

Table 1_JMDC. Baseline Demographics, Unmatched [JMDC]

	Baricitinib			TNFi (N=1,721)	Std. Diff. (Any vs TNFi)
	Any (N=243)	4-mg (N=143)	2-mg (N=100)		
Age [yrs]					
N	243	143	100	1,721	
Mean (SD)	52.02 (10.30)	51.82 (10.28)	52.32 (10.38)	47.74 (12.21)	0.38
Median	53.00 [46.00, 59.00]	53.00 [47.00, 59.00]	53.00 [47.00, 59.00]	49.00 [39.00, 57.00]	
Min, Max	19.0, 74.0	23.0, 74.0	19.0, 74.0	18.0, 74.0	
≥ 65 years	21 (8.6%)	11 (7.7%)	10 (10.0%)	128 (7.4%)	0.04
Sex					
Male	51 (21.0%)	25 (17.5%)	26 (26.0%)	441 (25.6%)	0.11
Female	192 (79.0%)	118 (82.5%)	74 (74.0%)	1,280 (74.4%)	0.11

Abbreviations: Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; TNFi = tumour necrosis factor inhibitor; vs = versus.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.1. - Baseline Demographics, Unmatched [Japanese Medical Data Center Payer-Based].docx

Table 4_JMDC. Baseline Demographics Incident Serious Infections, Matched [JMDC]

	Baricitinib			TNFi (N=220)	Std. Diff. (Any vs TNFi)	Total (N=440)
	Any (N=220)	4-mg (N=130)	2-mg (N=90)			
Age [yrs]						
N	220	130	90	220	0.111	440
Mean (SD)	51.78 (9.91)	51.43 (9.76)	52.28 (10.15)	52.91 (10.53)		52.35 (10.23)
Median	52.50 [46.00, 59.00]	53.00 [44.75, 59.00]	52.00 [47.00, 59.00]	55.00 [46.00, 61.00]		53.00 [46.00, 60.00]
Min, Max	19.0, 74.0	23.0, 74.0	19.0, 74.0	23.0, 73.0		19.0, 74.0
≥ 65 years	15 (6.8%)	5 (3.8%)	10 (11.1%)	29 (13.2%)	0.213	44 (10.0%)
Sex						
Male	42 (19.1%)	19 (14.6%)	23 (25.6%)	38 (17.3%)	0.047	80 (18.2%)
Female	178 (80.9%)	111 (85.4%)	67 (74.4%)	182 (82.7%)	0.047	360 (81.8%)

Abbreviations: Max = maximum; Min = minimum; N = number of patients in the specified category; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; vs = versus.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. [Updated 2022.03.15] Table 6.4. - Baseline Demographics Incident Serious Infections, Matched [Japanese Medical Data Center Payer-Based].docx

Table 6_JMDC. Clinical History at Baseline, Unmatched Cohorts [JMDC]

Characteristic[a,b]	Baricitinib[c]			TNFi (N=1,721)	Std. Diff.
	Any (N=243)	2-mg (N=100)	4-mg (N=143)		
Clinical Conditions during baseline					
Cancer	10 (4.1%)	4 (4.0%)	6 (4.2%)	67 (3.9%)	0.01
NMSC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Chronic lung disease	35 (14.4%)	10 (10.0%)	25 (17.5%)	197 (11.4%)	0.09
Cardiovascular conditions					
Atrial arrhythmia/fibrillation	1 (0.4%)	0 (0.0%)	1 (0.7%)	9 (0.5%)	0.02
Cardiovascular revascularization	1 (0.4%)	0 (0.0%)	1 (0.7%)	0 (0.0%)	0.09
Congestive heart failure, hospitalized	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)	0.06
Coronary artery disease	1 (0.4%)	0 (0.0%)	1 (0.7%)	3 (0.2%)	0.04
Ischemic heart disease	1 (0.4%)	0 (0.0%)	1 (0.7%)	3 (0.2%)	0.04
Unstable angina	1 (0.4%)	0 (0.0%)	1 (0.7%)	4 (0.2%)	0.03
Ventricular arrhythmia	1 (0.4%)	0 (0.0%)	1 (0.7%)	5 (0.3%)	0.02
Diabetes Mellitus	7 (2.9%)	2 (2.0%)	5 (3.5%)	22 (1.3%)	0.11
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.1%)	0.05
Type II	7 (2.9%)	2 (2.0%)	5 (3.5%)	20 (1.2%)	0.12
Dyslipidaemia	20 (8.2%)	10 (10.0%)	10 (7.0%)	126 (7.3%)	0.03
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.2%)	0.06
Immune disorders	17 (7.0%)	9 (9.0%)	8 (5.6%)	66 (3.8%)	0.14
AIDS/HIV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Antiphospholipid syndrome	N/A	N/A	N/A	N/A	NA
SLE	13 (5.3%)	7 (7.0%)	6 (4.2%)	25 (1.5%)	0.22
Primary Sjögren syndrome	8 (3.3%)	4 (4.0%)	4 (2.8%)	45 (2.6%)	0.04
Liver disorder	3 (1.2%)	3 (3.0%)	0 (0.0%)	11 (0.6%)	0.06
Obesity	1 (0.4%)	0 (0.0%)	1 (0.7%)	4 (0.2%)	0.03
Pregnancy	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0.03
RA severity (CIRAS Index), mean (SD)	6.53 (1.28)	6.38 (1.39)	6.64 (1.20)	6.86 (1.39)	0.24
Smoking[e]	10 (4.1%)	5 (5.0%)	5 (3.5%)	91 (5.3%)	0.06
Surgery, trauma & hospitalization, recent	24 (9.9%)	9 (9.0%)	15 (10.5%)	194 (11.3%)	0.07
TIA	1 (0.4%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0.09
DMARDs					
cDMARDs, during baseline					
n, total	200 (82.3%)	82 (82.0%)	118 (82.5%)	1,427 (82.9%)	0.02
Mean (SD)	0.99 (0.59)	0.99 (0.59)	0.99 (0.59)	1.02 (0.61)	0.05
Median	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	-
Min, Max	0.0, 3.0	0.00, 2.00	0.00, 3.00	0.0, 4.0	-
>1 cDMARD concomitantly	39 (16.0%)	17 (17.0%)	22 (15.4%)	311 (18.1%)	0.05
Hydroxychloroquine	2 (0.8%)	0 (0.0%)	2 (1.4%)	5 (0.3%)	0.07
Leflunomide	3 (1.2%)	3 (3.0%)	0 (0.0%)	11 (0.6%)	0.06

Characteristic[a,b]	Baricitinib[c]			TNFi (N=1,721)	Std. Diff.
	Any (N=243)	2-mg (N=100)	4-mg (N=143)		
Methotrexate	179 (73.7%)	69 (69.0%)	110 (76.9%)	1,268 (73.7%)	0.00
Minocycline	2 (0.8%)	1 (1.0%)	1 (0.7%)	29 (1.7%)	0.08
Sulfasalazine	42 (17.3%)	20 (20.0%)	22 (15.4%)	389 (22.6%)	0.13
bDMARDs, during baseline[a]					
n, total	136 (56.0%)	48 (48.0%)	88 (61.5%)	203 (11.8%)	1.06
Mean (SD)	0.67 (0.67)	0.57 (0.67)	0.73 (0.66)	0.12 (0.35)	1.01
Median	1.00 [0.00, 1.00]	0.00 [0.00, 1.00]	1.00 [0.00, 1.00]	0.00 [0.00, 0.00]	-
Min, Max	0.0, 3.0	0.00, 3.00	0.00, 2.00	0.0, 3.0	-
cDMARDs, concomitant	97 (39.9%)	35 (35.0%)	62 (43.4%)	145 (8.4%)	0.79
abatacept	27 (11.1%)	9 (9.0%)	18 (12.6%)	43 (2.5%)	0.35
adalimumab[d]	11 (4.5%)	3 (3.0%)	8 (5.6%)	18 (1.0%)	0.21
anakinra	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
certolizumab pegol[d]	10 (4.1%)	4 (4.0%)	6 (4.2%)	5 (0.3%)	0.26
etanercept[d]	29 (11.9%)	11 (11.0%)	18 (12.6%)	26 (1.5%)	0.43
golimumab[d]	19 (7.8%)	4 (4.0%)	15 (10.5%)	8 (0.5%)	0.38
infliximab[d]	4 (1.6%)	0 (0.0%)	4 (2.8%)	38 (2.2%)	0.04
rituximab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
sarilumab	12 (4.9%)	4 (4.0%)	8 (5.6%)	6 (0.3%)	0.29
tocilizumab	50 (20.6%)	22 (22.0%)	28 (19.6%)	71 (4.1%)	0.52
Other Prescription Medications					
Antibiotics	82 (33.7%)	34 (34.0%)	48 (33.6%)	679 (39.5%)	0.12
Antidiabetic agents	15 (6.2%)	9 (9.0%)	6 (4.2%)	108 (6.3%)	0.00
Insulins	1 (0.4%)	0 (0.0%)	1 (0.7%)	25 (1.5%)	0.11
Non-insulins	15 (6.2%)	9 (9.0%)	6 (4.2%)	91 (5.3%)	0.04
Aspirin	2 (0.8%)	0 (0.0%)	2 (1.4%)	30 (1.7%)	0.08
Cardiovascular					
Anticoagulant	7 (2.9%)	3 (3.0%)	4 (2.8%)	68 (4.0%)	0.06
Antihypertensives	61 (25.1%)	27 (27.0%)	34 (23.8%)	297 (17.3%)	0.19
Antiplatelet	14 (5.8%)	7 (7.0%)	7 (4.9%)	82 (4.8%)	0.05
Nitrates	3 (1.2%)	0 (0.0%)	3 (2.1%)	7 (0.4%)	0.09
Hormonal					
HRT	7 (2.9%)	3 (3.0%)	4 (2.8%)	42 (2.4%)	0.03
Oral Contraceptives	N/A	N/A	N/A	N/A	N/A
SERMs	5 (2.1%)	3 (3.0%)	2 (1.4%)	23 (1.3%)	0.06
Lipid-lowering agents					
Bile acid binding	1 (0.4%)	0 (0.0%)	1 (0.7%)	2 (0.1%)	0.06
Cholesterol absorption inhibitor	4 (1.6%)	1 (1.0%)	3 (2.1%)	20 (1.2%)	0.04
Fibrates	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.3%)	0.08
Niacin	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Omega-3 fatty acids	3 (1.2%)	2 (2.0%)	1 (0.7%)	6 (0.3%)	0.10
Statins	28 (11.5%)	17 (17.0%)	11 (7.7%)	183 (10.6%)	0.03
Rheumatoid arthritis-related					
Cox-2 Inhibitor	77 (31.7%)	25 (25.0%)	52 (36.4%)	579 (33.6%)	0.04

Characteristic[a,b]	Baricitinib[c]			TNFi (N=1,721)	Std. Diff.
	Any (N=243)	2-mg (N=100)	4-mg (N=143)		
Glucocorticosteroid	155 (63.8%)	64 (64.0%)	91 (63.6%)	1,026 (59.6%)	0.09
Vaccinations	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.1%)	0.05

Abbreviations: AIDS = acquired immunodeficiency syndrome; bDMARD = biologic disease-modifying antirheumatic drugs; CIRAS = claims-based index for RA severity; cDMARD = conventional disease-modifying antirheumatic drugs; Concom. cDMARDs = concomitant cDMARDs; HIV = human immunodeficiency virus; HRT = hormone replacement therapy; Max = maximum; Min = minimum; N = number of patients in the specified category; N/A = not applicable; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; SERMs = selective estrogen receptor modulators; SLE = systemic lupus erythematosus; Std. Diff. = standardised difference; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a All conditions and characteristics, except for bDMARDs, are measured during the 6 months prior to initiation of study medication including the date at which the qualifying exposure of baricitinib or TNFi occurs (index date). bDMARDs are measured from the 6 months prior to the initiation of study medication until the day prior to baricitinib or the index TNFi exposure, excluding the index date.

b Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 4 in protocol Section 8.3.3 (Annex 19) for each outcome, e.g., hospitalized congestive heart failure for VTE. Other factors are included for descriptive purposes only, and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., Type I diabetes for VTE.

c Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

d TNF inhibitors.

e In JMDC, smoking is defined based on information recorded in the variable “Annual health checkup – Smoking habit”.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.6. - Clinical History at Baseline, Unmatched Cohorts [Japanese Medical Data Center Payer-Based].docx

Table 9_JMDC. Clinical Characteristics Incident Serious Infection Cohorts, Matched [JMDC]

Characteristic[a,b]	Baricitinib[c]			TNFi (N=220)	Std. Diff.
	Any (N=220)	2-mg (N=90)	4-mg (N=130)		
Clinical Conditions during baseline					
Cancer	8 (3.6%)	3 (3.3%)	5 (3.8%)	11 (5.0%)	0.07
NMSC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Chronic lung disease	32 (14.5%)	9 (10.0%)	23 (17.7%)	33 (15.0%)	0.01
Cardiovascular conditions					
Atrial arrhythmia/fibrillation	1 (0.5%)	0 (0.0%)	1 (0.8%)	3 (1.4%)	0.10
Cardiovascular revascularization	1 (0.5%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0.10
Congestive heart failure, hospitalized	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Coronary artery disease	1 (0.5%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0.10
Ischemic heart disease	1 (0.5%)	0 (0.0%)	1 (0.8%)	0 (0.0%)	0.10
Unstable angina	1 (0.5%)	0 (0.0%)	1 (0.8%)	1 (0.5%)	0.0
Ventricular arrhythmia	1 (0.5%)	0 (0.0%)	1 (0.8%)	2 (0.9%)	0.06
Diabetes Mellitus	6 (2.7%)	0 (0.0%)	6 (4.6%)	7 (3.2%)	0.03
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.9%)	0.14
Type II	6 (2.7%)	0 (0.0%)	6 (4.6%)	5 (2.3%)	0.03
Dyslipidaemia	17 (7.7%)	8 (8.9%)	9 (6.9%)	21 (9.5%)	0.07
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Immune disorders	14 (6.4%)	7 (7.8%)	7 (5.4%)	10 (4.5%)	0.08
AIDS/HIV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Antiphospholipid syndrome	N/A	N/A	N/A	N/A	N/A
SLE	11 (5.0%)	6 (6.7%)	5 (3.8%)	3 (1.4%)	0.21
Primary Sjögren syndrome	7 (3.2%)	3 (3.3%)	4 (3.1%)	7 (3.2%)	0.0
Liver disorder	1 (0.5%)	1 (1.1%)	0 (0.0%)	4 (1.8%)	0.13
Obesity	1 (0.5%)	0 (0.0%)	1 (0.8%)	1 (0.5%)	0.0
Pregnancy	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
RA severity (CIRAS Index), mean (SD)	6.56 (1.27)	6.35 (1.39)	6.71 (1.16)	6.52 (1.29)	0.03
Smoking[e]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Surgery, trauma & hospitalization, recent	20 (9.1%)	5 (5.6%)	15 (11.5%)	23 (10.5%)	0.05
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
DMARDs					
cDMARDs, during baseline					
n, total	185 (84.1%)	75 (83.3%)	110 (84.6%)	182 (82.7%)	0.04
Mean (SD)	1.01 (0.58)	1.00 (0.58)	1.02 (0.58)	0.99 (0.59)	0.04

Characteristic[a,b]	Baricitinib[c]			TNFi (N=220)	Std. Diff.
	Any (N=220)	2-mg (N=90)	4-mg (N=130)		
Median	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	-
Min, Max	0.0, 3.0	0.00, 2.00	0.00, 3.00	0.0, 3.0	-
>1 cDMARD concomitantly	36 (16.4%)	15 (16.7%)	21 (16.2%)	32 (14.5%)	0.05
Hydroxychloroquine	2 (0.9%)	0 (0.0%)	2 (1.5%)	2 (0.9%)	0.0
Leflunomide	3 (1.4%)	3 (3.3%)	0 (0.0%)	4 (1.8%)	0.04
Methotrexate	165 (75.0%)	64 (71.1%)	101 (77.7%)	161 (73.2%)	0.04
Minocycline	2 (0.9%)	1 (1.1%)	1 (0.8%)	1 (0.5%)	0.06
Sulfasalazine	39 (17.7%)	17 (18.9%)	22 (16.9%)	45 (20.5%)	0.07
bDMARDs, during baseline[a]					
n, total	110 (50.0%)	37 (41.1%)	73 (56.2%)	220 (100.0%)	1.41
Mean (SD)	0.55 (0.60)	0.44 (0.58)	0.62 (0.60)	0.54 (0.58)	0.02
Median	0.50 [0.00, 1.00]	0.00 [0.00, 1.00]	1.00 [0.00, 1.00]	0.50 [0.00, 1.00]	-
Min, Max	0.0, 3.0	0.00, 3.00	0.00, 2.00	0.0, 3.0	-
cDMARDs, concomitant	79 (35.9%)	27 (30.0%)	52 (40.0%)	158 (71.8%)	0.77
abatacept	21 (9.5%)	7 (7.8%)	14 (10.8%)	28 (12.7%)	0.10
adalimumab[d]	7 (3.2%)	2 (2.2%)	5 (3.8%)	54 (24.5%)	0.65
anakinra	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
certolizumab pegol[d]	9 (4.1%)	4 (4.4%)	5 (3.8%)	34 (15.5%)	0.39
etanercept[d]	22 (10.0%)	8 (8.9%)	14 (10.8%)	72 (32.7%)	0.58
golimumab[d]	15 (6.8%)	3 (3.3%)	12 (9.2%)	76 (34.5%)	0.73
infliximab[d]	1 (0.5%)	0 (0.0%)	1 (0.8%)	31 (14.1%)	0.54
rituximab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
sarilumab	8 (3.6%)	1 (1.1%)	7 (5.4%)	4 (1.8%)	0.11
tocilizumab	38 (17.3%)	15 (16.7%)	23 (17.7%)	40 (18.2%)	0.02
Other Prescription Medications					
Antibiotics	77 (35.0%)	30 (33.3%)	47 (36.2%)	77 (35.0%)	0.0
Antidiabetic agents	10 (4.5%)	6 (6.7%)	4 (3.1%)	19 (8.6%)	0.17
Insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (1.8%)	0.19
Non-insulins	10 (4.5%)	6 (6.7%)	4 (3.1%)	15 (6.8%)	0.10
Aspirin	2 (0.9%)	0 (0.0%)	2 (1.5%)	8 (3.6%)	0.18
Cardiovascular					
Anticoagulant	7 (3.2%)	3 (3.3%)	4 (3.1%)	8 (3.6%)	0.03
Antihypertensives	51 (23.2%)	26 (28.9%)	25 (19.2%)	54 (24.5%)	0.03
Antiplatelet	12 (5.5%)	6 (6.7%)	6 (4.6%)	21 (9.5%)	0.16
Nitrates	3 (1.4%)	0 (0.0%)	3 (2.3%)	0 (0.0%)	0.17
Hormonal					
HRT	6 (2.7%)	3 (3.3%)	3 (2.3%)	6 (2.7%)	0.0
Oral Contraceptives	N/A	N/A	N/A	N/A	N/A
SERMs	4 (1.8%)	3 (3.3%)	1 (0.8%)	9 (4.1%)	0.14
Lipid-lowering agents					

Characteristic[a,b]	Baricitinib[c]			TNFi (N=220)	Std. Diff.
	Any (N=220)	2-mg (N=90)	4-mg (N=130)		
Bile acid binding	1 (0.5%)	0 (0.0%)	1 (0.8%)	1 (0.5%)	0.0
Cholesterol absorption inhibitor	4 (1.8%)	1 (1.1%)	3 (2.3%)	5 (2.3%)	0.03
Fibrates	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0.10
Niacin	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
Omega-3 fatty acids	2 (0.9%)	1 (1.1%)	1 (0.8%)	3 (1.4%)	0.04
Statins	26 (11.8%)	16 (17.8%)	10 (7.7%)	35 (15.9%)	0.12
Rheumatoid arthritis-related					
Cox-2 Inhibitor	69 (31.4%)	22 (24.4%)	47 (36.2%)	65 (29.5%)	0.04
Glucocorticosteroid	136 (61.8%)	55 (61.1%)	81 (62.3%)	145 (65.9%)	0.09
Vaccinations	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-

Abbreviations: AIDS = acquired immunodeficiency syndrome; bDMARD = biologic disease-modifying antirheumatic drugs; CIRAS = claims-based index for RA severity; cDMARD = conventional disease-modifying antirheumatic drugs; Concom. cDMARDs = concomitant cDMARDs; HIV = human immunodeficiency virus; HRT = hormone replacement therapy; Max = maximum; Min = minimum; N = number of patients in the specified category; N/A = not applicable; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; SERMs = selective estrogen receptor modulators; SLE = systemic lupus erythematosus; Std. Diff. = standardised difference; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a All conditions and characteristics, except for bDMARDs, are measured during the 6 months prior to initiation of study medication including the date at which the qualifying exposure of baricitinib or TNFi occurs (index date). bDMARDs are measured from the 6 months prior to the initiation of study medication until the day prior to baricitinib or the index TNFi exposure, excluding the index date.

b Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 4 in protocol Section 8.3.3 (Annex 19) for each outcome, e.g., hospitalized congestive heart failure for VTE. Other factors are included for descriptive purposes only, and may not be balanced across treatment groups but do not contribute to confounding bias, e.g., Type I diabetes for VTE.

c Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

d TNF inhibitors.

e Based on ICD-10 codes used to identify smoking, there were no patients identified. Table 10.2 in body of report contains descriptive information on smoking defined based on “annual health check-up – smoking habits”.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. [Updated 2022.03.15] Table 6.9. - Clinical Characteristics Incident Serious Infection Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 11A_JMDC. Baseline Healthcare Resource Utilization, Unmatched [JMDC]

Type of Resource Use	Baricitinib (N=243)	TNFi (N=1,721)	Std. Diff.
Physician Office Visits			
n, patients	159 (65.4%)	1,292 (75.1%)	0.21
n, events	1145	13389	
Mean (SD)	4.71 (7.18)	7.78 (9.86)	0.36
Median	2.00 [0.00, 6.00]	3.00 [1.00, 12.00]	
Min, Max	0.0, 48.0	0.0, 78.0	
Rheumatologist Visits			
n, patients	20 (8.2%)	219 (12.7%)	0.15
n, events	114	1962	
Mean (SD)	0.47 (2.16)	1.14 (3.98)	0.21
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 20.0	0.0, 34.0	
Other Outpatient Visits			
n, patients	243 (100.0%)	1,720 (99.9%)	0.03
n, events	66344	470418	
Mean (SD)	273.02 (141.76)	273.34 (154.33)	0.00
Median	239.00 [168.00, 342.00]	242.00 [167.00, 348.00]	
Min, Max	31.0, 743.0	0.0, 1154.0	
Inpatient Visits			
n, patients	35 (14.4%)	251 (14.6%)	0.01
n, events	5633	48653	
Mean (SD)	23.18 (83.83)	28.27 (117.67)	0.05
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 873.0	0.0, 1863.0	
ED Visits*			
n, patients	-	-	-
n, events	-	-	-
Mean (SD)	- (-)	- (-)	
Median	- [-, -]	- [-, -]	
Min, Max	-, -	-, -	

Abbreviations: ED = emergency department; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Physician office visits do not include rheumatologist visits.

*Not Applicable

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.11A. Baseline Healthcare Resource Utilization, Unmatched [Japanese Medical Data Center Payer-Based].docx

Table 11B_JMDC. Baseline Healthcare Resource Utilization, Unmatched [JMDC], count at most one visit per day[1]

Type of Resource Use	Baricitinib (N=243)	TNFi (N=1,721)	Std. Diff.
Physician Office Visits[1]			
n, patients	159 (65.4%)	1,292 (75.1%)	0.21
n, events	350	3,287	
Mean (SD)	1.44 (1.54)	1.91 (1.82)	0.28
Median	1.00 [0.00, 2.00]	2.00 [0.00, 3.00]	
Min, Max	0.0, 8.0	0.0, 15.0	
Rheumatologist Visits[1]			
n, patients	20 (8.2%)	219 (12.7%)	0.15
n, events	51	344	
Mean (SD)	0.21 (0.94)	0.20 (0.71)	0.02
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 7.0	0.0, 8.0	
Other Outpatient Visits[1]			
n, patients	243 (100.0%)	1,720 (99.9%)	0.03
n, events	3,494	23,578	
Mean (SD)	14.38 (11.18)	13.70 (10.34)	0.06
Median	12.00 [7.00, 17.00]	11.00 [7.50, 17.00]	
Min, Max	2.0, 113.0	0.0, 119.0	
Inpatient Visits[1]			
n, patients	35 (14.4%)	251 (14.6%)	0.01
n, events	406	3,648	
Mean (SD)	1.67 (5.76)	2.12 (9.43)	0.06
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 47.0	0.0, 154.0	
ED Visits[2]			
n, patients	-	-	-
n, events	-	-	-
Mean (SD)	- (-)	- (-)	
Median	- [-, -]	- [-, -]	
Min, Max	-, -	-, -	

Abbreviations: ED = emergency department; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Physician office visits do not include rheumatologist visits.

1 In this table, results describe utilization of healthcare where a maximum of one event was allowed per day. In the PS matching analyses, multiple claims on the same day were allowed to capture additional information on the amount of services received in a given visit. These results are presented in table 6.11A.

2 Type(s) of healthcare encounter not applicable to the Japanese Medical Data Center Payer-Based database.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\ 3. Table 6.11B (count at most one visit per day). Baseline Healthcare Resource Utilization, Unmatched [Japanese Medical Data Center Payer-Based].docx

Table 12A_JMDC. Baseline Healthcare Resource Utilization Primary VTE Cohorts, Matched [JMDC]

Type of Resource Use	Baricitinib (N=213)	TNFi (N=213)	Std. Diff.
Physician Office Visits			
n, patients	141 (66.2%)	143 (67.1%)	0.02
n, events	1080	993	
Mean (SD)	5.07 (7.54)	4.66 (7.29)	0.06
Median	2.00 [0.00, 7.00]	1.00 [0.00, 6.00]	
Min, Max	0.0, 48.0	0.0, 36.0	
Rheumatologist Visits			
n, patients	18 (8.5%)	18 (8.5%)	0.00
n, events	104	77	
Mean (SD)	0.49 (2.26)	0.36 (1.59)	0.07
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 20.0	0.0, 16.0	
Other Outpatient Visits			
n, patients	213 (100.0%)	213 (100.0%)	0
n, events	57329	56920	
Mean (SD)	269.15 (139.22)	267.23 (137.39)	0.01
Median	239.00 [164.50, 339.50]	244.00 [172.00, 322.50]	
Min, Max	31.0, 743.0	35.0, 1029.0	
Inpatient Visits			
n, patients	27 (12.7%)	29 (13.6%)	0.03
n, events	3781	4931	
Mean (SD)	17.75 (62.40)	23.15 (85.91)	0.07
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 426.0	0.0, 582.0	
ED Visits*			
n, patients	-	-	-
n, events	-	-	-
Mean (SD)	- (-)	- (-)	
Median	- [-, -]	- [-, -]	
Min, Max	-, -	-, -	

Abbreviations: ED = emergency department; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Physician office visits do not include rheumatologist visits.

*Not Applicable

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.12A. Baseline Healthcare Resource Utilization, Primary VTE Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 13A_JMDC. Baseline Healthcare Resource Utilization MACE Cohorts, Matched [JMDC]

Type of Resource Use	Baricitinib (N=224)	TNFi (N=224)	Std. Diff.
Physician Office Visits			
n, patients	146 (65.2%)	161 (71.9%)	0.15
n, events	1098	959	
Mean (SD)	4.90 (7.30)	4.28 (6.56)	0.09
Median	2.00 [0.00, 7.00]	2.00 [0.00, 5.75]	
Min, Max	0.0, 48.0	0.0, 36.0	
Rheumatologist Visits			
n, patients	18 (8.0%)	11 (4.9%)	0.13
n, events	85	49	
Mean (SD)	0.38 (1.75)	0.22 (1.12)	0.10
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 19.0	0.0, 8.0	
Other Outpatient Visits			
n, patients	224 (100.0%)	223 (99.6%)	0.10
n, events	59907	55496	
Mean (SD)	267.44 (137.39)	247.75 (110.57)	0.16
Median	234.00 [164.25, 340.75]	238.50 [160.25, 309.00]	
Min, Max	31.0, 739.0	0.0, 600.0	
Inpatient Visits			
n, patients	32 (14.3%)	28 (12.5%)	0.05
n, events	5943	6059	
Mean (SD)	26.53 (97.37)	27.05 (151.11)	0.004
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 873.0	0.0, 1863.0	
ED Visits*			
n, patients	-	-	-
n, events	-	-	
Mean (SD)	- (-)	- (-)	
Median	- [-, -]	- [-, -]	
Min, Max	-, -	-, -	

Abbreviations: ED = emergency department; MACE = major adverse cardiovascular event, defined based on primary hospital discharge diagnosis codes for acute myocardial infarction, ischemic or haemorrhagic stroke; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor.

Note: Physician office visits do not include rheumatologist visits.

*Not Applicable

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\ 3. Table 6.13A. Baseline Healthcare Resource Utilization MACE Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 14A_JMDC Baseline Healthcare Resource Utilization Serious Infection Cohorts, Matched [JMDC]

Type of Resource Use	Baricitinib (N=220)	TNFi (N=220)	Std. Diff.
Physician Office Visits			
n, patients	146 (66.4%)	147 (66.8%)	0.01
n, events	1111	1208	
Mean (SD)	5.05 (7.43)	5.49 (8.68)	0.06
Median	2.00 [0.00, 7.00]	2.00 [0.00, 7.00]	
Min, Max	0.0, 48.0	0.0, 50.0	
Rheumatologist Visits			
n, patients	18 (8.2%)	17 (7.7%)	0.02
n, events	103	73	
Mean (SD)	0.47 (2.21)	0.33 (1.52)	0.07
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 20.0	0.0, 15.0	
Other Outpatient Visits			
n, patients	220 (100.0%)	220 (100.0%)	0
n, events	59783	59653	
Mean (SD)	271.74 (144.16)	271.15 (151.07)	0.00
Median	232.50 [164.25, 352.75]	239.50 [172.00, 340.50]	
Min, Max	31.0, 743.0	20.0, 1034.0	
Inpatient Visits			
n, patients	33 (15.0%)	31 (14.1%)	0.03
n, events	5507	4886	
Mean (SD)	25.03 (95.54)	22.21 (80.55)	0.03
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 873.0	0.0, 579.0	
ED Visits*			
n, patients	-	-	-
n, events	-	-	-
Mean (SD)	- (-)	- (-)	
Median	- [-, -]	- [-, -]	
Min, Max	-, -	-, -	

Abbreviations: ED = emergency department; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Physician office visits do not include rheumatologist visits.

*Not Applicable

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.14A. Baseline Healthcare Resource Utilization Incident Serious Infection Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 14B_JMDC Baseline Healthcare Resource Utilization Serious Infection Cohorts, Matched [JMCD], count at most one visit per day[1]

Type of Resource Use	Baricitinib (N=220)	TNFi (N=220)	Std. Diff.
Physician Office Visits[1]			
n, patients	146 (66.4%)	143 (65.0%)	0.03
n, events	321	334	
Mean (SD)	1.46 (1.56)	1.52 (1.61)	0.03
Median	1.00 [0.00, 2.00]	1.00 [0.00, 2.00]	
Min, Max	0.0, 8.0	0.0, 8.0	
Rheumatologist Visits[1]			
n, patients	18 (8.2%)	17 (7.7%)	0.02
n, events	42	33	
Mean (SD)	0.19 (0.84)	0.15 (0.72)	0.05
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 6.0	0.0, 7.0	
Other Outpatient Visits[1]			
n, patients	220 (100.0%)	220 (100.0%)	0.00
n, events	3164	3183	
Mean (SD)	14.38 (11.50)	14.47 (11.15)	0.01
Median	12.00 [7.00, 17.00]	12.00 [8.00, 17.00]	
Min, Max	2.0, 113.0	1.0, 91.0	
Inpatient Visits[1]			
n, patients	30 (13.6%)	31 (14.1%)	0.01
n, events	383	339	
Mean (SD)	1.74 (6.57)	1.54 (5.59)	0.03
Median	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]	
Min, Max	0.0, 51.0	0.0, 42.0	
ED Visits[2]			
n, patients	-	-	-
n, events	-	-	-
Mean (SD)	- (-)	- (-)	
Median	- [-, -]	- [-, -]	
Min, Max	-, -	-, -	

Abbreviations: ED = emergency department; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

Note: Physician office visits do not include rheumatologist visits.

1 In this table, results describe utilization of healthcare where a maximum of one event was allowed per day. In the PS matching analyses, multiple claims on the same day were allowed to capture additional information on the amount of services received in a given visit. These results are presented in table 6.14A.

2 Type(s) of healthcare encounter not applicable to the Japanese Medical Data Center Payer-Based database.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. [Upd.3.15] Table 6.14B (count at most one visit per day). Baseline HCRU Serious Infection Cohorts, Matched [JMDC Payer-Based].docx

Table 16_JMDC. Baseline Prevalence of Outcomes [JMDC]

Outcome in Each Matched Cohort[a,c,d]	Unmatched					Matched					
	Baricitinib[b]			TNFi	Std. Diff	Baricitinib[b]			TNFi	Std. Diff	Total
	Any	2mg	4mg			Any	2mg	4mg			
VTE	**N=246**	**N=101**	**N=145**	**N=1,726**	**-**	**N=217**	**N= 93**	**N=124**	**N=217**	**-**	**N=434**
Main case definition in baseline	3 (1.2%)	1 (1.0%)	2 (1.4%)	5 (0.3%)	0.11	3 (1.4%)	1 (1.1%)	2 (1.6%)	0 (0.0%)	0.17	3 (0.7%)
Alternate case definition I in baseline	1 (0.4%)	1 (1.0%)	0 (0.0%)	1 (0.1%)	0.09	1 (0.5%)	1 (1.1%)	0 (0.0%)	0 (0.0%)	0.13	1 (0.2%)
Alternative case definition II in baseline	4 (1.6%)	1 (1.0%)	3 (2.1%	11 (0.6%)	0.07	4 (1.8%)	1 (1.1%)	3 (2.4%)	1 (0.5%)	0.10	5 (1.2%)
MACE	**N=246**	**N=101**	**N=145**	**N=1,726**	**-**	**N=220**	**N=92**	**N=128**	**N=220**	**-**	**N=440**
MACE in baseline	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.3%)	0.08	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	0.10	1 (0.2%)
Serious Infection	**N=248**	**N=102**	**N=146**	**N=1,761**	**-**	**N=223**	**N=91**	**N=132**	**N=223**	**-**	**N=446**
Serious Infection in baseline	2 (0.8%)	2 (2.0%)	0 (0.0%)	11 (0.6%)	0.02	2 (0.9%)	2 (2.2%)	0 (0.0%)	3 (1.3%)	0.04	5 (1.1%)
Hospitalized Tuberculosis	**N=248**	**N=102**	**N=146**	**N=1,761**	**-**	**N=223**	**N=91**	**N=132**	**N=223**	**-**	**N=446**
Hospitalized Tuberculosis in baseline	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0.03	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-	0 (0.0%)

Abbreviations: MACE = major adverse cardiovascular event, defined as hospital primary discharge diagnosis code of acute MI or hospital primary discharge diagnosis code of ischemic or hemorrhagic stroke; N = number of patients in specified category; Std. Diff = standardised difference; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism, defined based on the case definitions.

a Baseline prevalence was calculated for each distinct matched cohort for VTE, MACE, serious infection and hospitalized tuberculosis.

b Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

c Patients with the prevalent outcomes enumerated in this table are those excluded from the main analyses of each outcome, except for VTE alternative case definitions I and II. Only the VTE main case definition was used as an exclusion criterion in the main analyses.

d In the VTE and MACE analyses, cohorts additionally excluded the use of anticoagulants at the time of cohort entry (see protocol Section 8.7.7), resulting in a different N compared to the Serious Infection and Hospitalized Tuberculosis cohorts.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.16. Baseline Prevalence of Outcomes [Japanese Medical Data Center Payer-Based]_.docx

Table 17_JMDC. Duration of Follow-up Period (Days), Unmatched [JMDC]

	Baricitinib[a]			TNFi (N=1,721)	Std. Diff.
	Any (N=213)	4-mg (N= 143)	2-mg (N= 100)		
N	243	143	100	1,721	
Mean (SD)	256.79 (206.82)	285.25 (209.59)	216.09 (196.73)	183.55 (211.05)	1.25
Median	212.00 [69.00, 415.00]	282.00 [86.00, 454.00]	138.00 [58.00, 338.00]	97.00 [52.00, 223.00]	
Min, Max	2.0, 934.0	5.0, 934.0	2.0, 825.0	1.0, 1153.0	

Abbreviations: Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff. = Standarised difference; TNFi = tumour necrosis factor inhibitor.

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be reported for each dose where numbers of patients are sufficient to warrant separate reporting.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.17. Duration of Follow-up Period (Days), Unmatched [Japanese Medical Data Center Payer-Based].docx

Table 18_JMDC. Duration of Follow-up Period (Days) Primary VTE Cohorts, Matched [JMDC]

	Baricitinib[a]				
	Any (N=213)	4mg (N=121)	2mg (N=92)	TNFi (N=213)	Std. Diff.
N	213	121	92	213	0
Mean (SD)	263.93 (209.95)	292.83 (213.00)	225.91 (200.72)	197.09 (223.65)	0.31
Median	216.00 [72.00, 421.50]	286.00 [87.50, 461.00]	162.50 [58.00, 351.50]	115.00 [59.00, 228.50]	
Min, Max	2.0, 934.0	5.0, 934.0	2.0, 825.0	9.0, 1,101.0	
Reasons for censoring [b]					
Incident event	0	0	0	1	-
Medication discontinued	40 (18.8%)	20 (16.5%)	20 (21.7%)	139 (65.3%)	-
Initiated b/tsDMARD	15 (7.0%)	11 (9.1%)	4 (4.3%)	11 (5.2%)	-
End of patient record	143 (67.1%)	82 (67.8%)	61 (66.3%)	60 (28.2%)	-
Death (where available)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
End of study period (12/31/2020)	130 (61.0%)	76 (62.8%)	54 (58.7%)	51 (23.9%)	-

Abbreviations: b/tsDMARD = biologic or targeted synthetic disease-modifying antirheumatic drug; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff. = Standarised difference; TNFi = tumour necrosis factor inhibitor.

[a] Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be reported for each dose where numbers of patients are sufficient to warrant separate reporting.

[b] A single patient can be censored on the same day for multiple reasons, e.g., medication discontinued could also be the same day as initiated b/tsDMARD. Further, additional censoring criteria (e.g., switching medication) were specified in the SAP. For these reasons, the total number of reasons for censoring may be less than or greater than the total number of patients.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.18. Duration of Follow-up Period (Days) Primary VTE Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 21_JMDC. Duration of Follow-up Period (Days) MACE Cohorts, Matched [JMDC]

	Baricitinib[a]				
	Any (N=224)	**4mg (N=131)**	**2mg (N=93)**	**TNFi (N=224)**	**Std. Diff.**
N	224	131	93	224	
Mean (SD)	258.36 (200.39)	291.08 (204.50)	212.27 (185.93)	186.78 (216.78)	0.34
Median	219.00 [72.00, 408.00]	289.00 [93.00, 457.00]	146.00 [58.00, 337.00]	108.00 [59.00, 207.50]	
Min, Max	2.0, 934.0	2.0, 744.0	5.0, 934.0	3.0, 1094.0	
Reasons for censoring					
Incident event	0	0	0	0	-
Medication discontinued	40 (17.9%)	21 (16.0%)	19 (20.4%)	149 (66.5%)	-
Initiated b/tsDMARD	13 (5.8%)	8 (6.1%)	5 (5.4%)	15 (6.7%)	-
End of patient record	154 (68.8%)	93 (71.0%)	61 (65.6%)	60 (26.8%)	-
Death (where available)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	-
End of study period (12/31/2020)	140 (62.5%)	86 (65.6%)	54 (58.1%)	51 (22.8%)	-

Abbreviations: b/tsDMARD = biologic or targeted synthetic disease-modifying antirheumatic drug; MACE = Major adverse cardiovascular event; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; TNFi = tumour necrosis factor inhibitor.

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be reported for each dose where numbers of patients are sufficient to warrant separate reporting.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.21. Duration of Follow-up Period (Days) MACE Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 22_JMDC. Duration of Follow-up Period (Days) Incident Serious Infection Cohorts, Matched [JMDC]

	Baricitinib[a]			TNFi (N=220)	Std. Diff.
	Any (N=220)	4-mg (N=130)	2-mg (N=90)		
N	220	130	90	220	
Mean (SD)	258.25 (198.66)	286.00 (203.04)	218.17 (186.04)	212.59 (230.95)	0.21
Median	223.00 [72.00, 413.25]	287.50 [86.75, 451.00]	177.50 [58.00, 340.25]	122.00 [59.00, 280.75]	
Min, Max	2.0, 934.0	5.0, 934.0	2.0, 744.0	3.0, 1101.0	
Reasons for censoring[b]					
Incident event	0	0	0	1	-
Medication discontinued	42 (19.1%)	21 (16.2%)	21 (23.3%)	142 (64.5%)	-
Initiated b/tsDMARD	12 (5.5%)	9 (6.9%)	3 (3.3%)	8 (3.6%)	-
End of patient record	150 (68.2%)	92 (70.8%)	58 (64.4%)	67 (30.5%)	-
Death (where available)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.5%)	-
End of study period (12/31/2020)	135 (61.4%)	84 (64.6%)	51 (56.7%)	58 (26.4%)	-

Abbreviations: b/tsDMARD = biologic or targeted synthetic disease-modifying antirheumatic drug; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; Std. Diff. = Standardised difference; TNFi = tumour necrosis factor inhibitor.

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

b A single patient can be censored on the same day for multiple reasons, e.g., medication discontinued could also be the same day as initiated b/tsDMARD. Further, additional censoring criteria (e.g., switching medication) were specified in the SAP. For these reasons, the total number of reasons for censoring may be less than or greater than the total number of patients.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. [Updated 2022.03.15] Table 6.22. Duration of Follow-up Period (Days) SI Cohorts, Matched [Japanese Medical Data Center Payer-Based].docx

Table 39_JMDC. Pattern of VTE and Related Diagnostic Codes in Patients with RA [JMDC]

Code	Total Patients (N=3)
Pulmonary Embolism	
I26 - Pulmonary embolism	0 (0.0%)
I26.0 - Pulmonary embolism with mention of acute cor pulmonale	0 (0.0%)
I26.9 - Pulmonary embolism without mention of acute cor pulmonale	0 (0.0%)
Deep Vein Thrombosis, lower	
I80.3 - Phlebitis and thrombophlebitis of lower extremities, unspecified	0 (0.0%)
I80 - Phlebitis and thrombophlebitis	0 (0.0%)
I80.0 - Phlebitis and thrombophlebitis of superficial vessels of lower extremities	0 (0.0%)
I80.1 - Phlebitis and thrombophlebitis of femoral vein	0 (0.0%)
I80.2 - Phlebitis and thrombophlebitis of other deep vessels of lower extremities	3 (100.0%)
Deep Vein Thrombosis, upper	
I82.2 - Embolism and thrombosis of vena cava	0 (0.0%)
Other Venous Thrombosis	
I82.0 - Budd-Chiari syndrome	0 (0.0%)
I82.1 - Thrombophlebitis migrans	0 (0.0%)
I82.3 - Embolism and thrombosis of renal vein	0 (0.0%)
I80.8 - Phlebitis and thrombophlebitis of other sites	0 (0.0%)
I80.9 - Phlebitis and thrombophlebitis of unspecified site	0 (0.0%)
I81 - Portal vein thrombosis	0 (0.0%)

Abbreviations: ICD-10 = International Classification of Disease, 10th Revision; RA = rheumatoid arthritis; VTE = venous thromboembolism

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.39. Pattern of VTE and Related Diagnostic Codes in Patients with RA [Japanese Medical Data Center Payer-Based].docx

Table 40_JMDC. Clinical Characteristics of RA Patients with VTE, Primary Definition [JMDC]

Characteristica,b	Baricitinibc (N=0)	TNFi (N=1)	Total (N=1)
Age (mean) [SD]	- (-)	63.00 (0.00)	63.00 (0.00)
Sex			
Female	0 (0.0%)	1 (100.0%)	1 (100.0%)
Male	0 (0.0%)	0 (0.0%)	0 (0.0%)
Clinical Conditions during baseline			
Cancer	0 (0.0%)	0 (0.0%)	0 (0.0%)
NMSC	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic Lung disease Disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular conditions			
Atrial arrhythmia/ fibrillation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure, hospitalized	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes Mellitus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dyslipidaemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)
Immune disorders	0 (0.0%)	0 (0.0%)	0 (0.0%)
AIDS/HIV	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antiphospholipid syndrome	N/A	N/A	N/A
SLE	0 (0.0%)	0 (0.0%)	0 (0.0%)
Primary Sjögren Syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
Liver Disorder	0 (0.0%)	0 (0.0%)	0 (0.0%)
Obesity	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy	0 (0.0%)	0 (0.0%)	0 (0.0%)
RA Severity (CIRAS Index), mean (SD)	- (-)	6.68 (0.00)	6.68 (0.00)
Smoking	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgery, trauma, & hospitalization, recent	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Prescription Medication			
Antibiotics	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antidiabetic agents	0 (0.0%)	0 (0.0%)	0 (0.0%)
Insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aspirin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular			
Antihypertensives	0 (0.0%)	0 (0.0%)	0 (0.0%)

Nitrates	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anticoagulant	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antiplatelet	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hormonal			
Oral contraceptives	N/A	N/A	N/A
HRT	0 (0.0%)	0 (0.0%)	0 (0.0%)
SERM	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents			
Bile acid binding	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cholesterol absorption inhibitor	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fibrates	0 (0.0%)	0 (0.0%)	0 (0.0%)
Niacin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Omega-3 fatty acids	0 (0.0%)	0 (0.0%)	0 (0.0%)
Statins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rheumatoid arthritis-related			
Cox-2 Inhibitor	0 (0.0%)	1 (100.0%)	1 (100.0%)
Glucocorticosteroid	0 (0.0%)	1 (100.0%)	1 (100.0%)
Vaccinations	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-index Occurrence[d]			
Cancer	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hospitalization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgery	0 (0.0%)	0 (0.0%)	0 (0.0%)
Trauma	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: AIDS = acquired immunodeficiency syndrome; bDMARD = biologic disease-modifying antirheumatic drugs; CIRAS = claims-based index for RA severity; cDMARD = conventional disease-modifying antirheumatic drugs; Concom. cDMARDs = concomitant cDMARDs; HIV = human immunodeficiency virus; HRT = hormone replacement therapy; Max = maximum; Min = minimum; N = number of patients in the specified category; N/A = not applicable; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; SERMs = selective estrogen receptor modulators; SLE = systemic lupus erythematosus; Std. Diff. = standardised difference; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a All conditions and characteristics are measured during the 6 months prior to initiation of study medication until and including the day prior to baricitinib or the index TNFi exposure that qualifies the patient for the cohort.

b Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 4 in protocol Section 8.3.3 (Annex 19) for each outcome, e.g., hospitalized congestive heart failure for VTE. Other factors are included for descriptive purposes only, may not be balanced across treatment groups but do not contribute to confounding bias, e.g., Type I diabetes for VTE.

c Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

d Except for cancer diagnosed within 90 days of VTE diagnosis, events in this category must have occurred in the 4 weeks immediately prior to VTE (Kline et al. 2017).

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.40. - Clinical Characteristics of RA Patients with VTE, Primary Definition [Japanese Medical Data Center Payer-Based].docx

Table 41_JMDC. Pattern of RA Medication Use in Patients with VTE, Primary Definition [JMDC]

Characteristic[a]	Unmatched		Matched		
	Baricitinib[b] (N=0)	TNFi (N=3)	Baricitinib[b] (N=0)	TNFi (N=1)	Total (N=1)
Baseline Medication					
cDMARDs, during baseline					
n, total	0 (0.0%)	2 (66.7%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Mean (SD)	- (-)	1.00 (1.00)	- (-)	1.00 (0.00)	1.00 (0.00)
Median	- [-, -]	1.00 [0.00, 2.00]	- [-, -]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]
Min, Max	-, -	0.0, 2.0	-, -	1.0, 1.0	1.0, 1.0
>1 cDMARD concomitantly	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hydroxychloroquine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Leflunomide	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate	0 (0.0%)	2 (66.7%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Minocycline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sulfasalazine	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
bDMARDs, during baseline					
n, total	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean (SD)	- (-)	0.00 (0.00)	- (-)	0.00 (0.00)	0.00 (0.00)
Median	- [-, -]	0.00 [0.00, 0.00]	- [-, -]	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]
Min, Max	-, -	0.0, 0.0	-, -		
cDMARDs, concomitant	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abatacept	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Adalimumab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anakinra	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Certolizumab pegol[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Etanercept[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Golimumab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infliximab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rituximab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Tocilizumab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-index Medication[d]					
Methotrexate, concomitant	0 (0.0%)	2 (66.7%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Other Concomitant cDMARD	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dose change, baricitinib	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drug; cDMARD = conventional disease-modifying antirheumatic drug; Max = maximum; Min = minimum; N = number of patients in the specified category; NA = not applicable; RA = rheumatoid arthritis; SD = standard deviation; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a All conditions and characteristics are measured during the 6 months prior to initiation of study medication until and including the day prior to baricitinib or the index TNFi exposure that qualifies the patient for the cohort.

b Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

c TNF inhibitors.

d Only baricitinib 2-mg dose is available in the US, so the baricitinib cells should be marked 'NA' as necessary. Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.41. - Pattern of RA Medication Use in Patients with VTE, Primary Definition [Japanese Medical Data Center Payer-Based].docx

Table 42_JMDC. Time to First Event Outcome (days) - VTE, Primary Definition [JMDC]

Time	Unmatched				Matched				
	Baricitinib[a]			TNFi	Baricitinib[a]			TNFi	Total
	Any (N=243)	4mg (N= 143)	2mg (N= 100)	(N=1,721)	Any (N=213)	4mg (N=121)	2mg (N=92)	(N=213)	(N=426)
n	243	143	100	1,721	213	121	92	213	426
Mean (SD)	- (-)	- (-)	- (-)	76.00 (31.43)	- (-)	- (-)	- (-)	70.00 (0.00)	70.00 (0.00)
Median	- [-, -]	- [-, -]	- [-, -]	70.00 [48.00, 110.00]	- [-, -]	- [-, -]	- [-, -]	70.00 [70.00, 70.00]	70.00 [70.00, 70.00]
Min, Max	-,-	-,-	-,-	48.0, 110.0	-,-	-,-	-,-	70.0, 70.0	70.0, 70.0

Abbreviations: Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.42. Time to First Event Outcome (days) - VTE, Primary Definition [JMDC].docx

Table 6.48 Comparative Risk of Incident VTE, Primary Definition [JMDC]

	TNFi	Baricitinib		p-value
		HR	95%CI	
Base Model[1,2]	Ref	-	-	-
Adjusted – Model [1][3]	Ref	-	-	-
Adjusted – Model [n][4]	Ref	-	-	-

Abbreviations: CI = confidence interval; HR = Cox proportional hazard ratio; Ref = referent group; TNFi = tumour necrosis factor inhibitor ; VTE = venous thromboembolism.

1 Base model = propensity score-matched model with confounders, outcome and baricitinib exposure.

2 Zero events in the baricitinib exposure group preclude analyzing models with additional parameters. The model did not converge.

3 Model [1] = propensity score-matched model with outcome and baricitinib exposure, adjusted for any variables that remain unbalanced after PS matching.

4 Models [n] may include additional variables that remain unbalanced after propensity-score matching. Overall, rare outcome events in the exposure and/or referent groups preclude analyzing models with additional parameters.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.48. Comparative Risk of Incident VTE, Primary Definition [Japanese Medical Data Center Payer-Based], updated base model = PS matched.docx

Table 51_JMDC. Clinical Characteristics of RA Patients with MACE [JMDC]

Characteristic[a,b]	Baricitinibc (N=0)	TNFi (N=0)	Total (N=0)
Age (mean) [SD]	- (-)	- (-)	- (-)
Sex			
Female	0 (0.0%)	0 (0.0%)	0 (0.0%)
Male	0 (0.0%)	0 (0.0%)	0 (0.0%)
Clinical Conditions during baseline			
Cancer	0 (0.0%)	0 (0.0%)	0 (0.0%)
NMSC	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic lung disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular conditions			
Atrial arrhythmia/fibrillation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive heart failure, hospitalized	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes Mellitus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dyslipidaemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)
Immune disorders	0 (0.0%)	0 (0.0%)	0 (0.0%)
AIDS/HIV	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antiphospholipid syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
SLE	0 (0.0%)	0 (0.0%)	0 (0.0%)
Primary Sjögren Syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
Liver Disorder	0 (0.0%)	0 (0.0%)	0 (0.0%)
Obesity	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy	0 (0.0%)	0 (0.0%)	0 (0.0%)
RA Severity (CIRAS Index), mean (SD)	- (-)	- (-)	- (-)
Smoking	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgery, Trauma, & Hospitalization, recent	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Prescription Medications			
Antibiotics	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antidiabetic agents	0 (0.0%)	0 (0.0%)	0 (0.0%)
Insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aspirin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular			
Anticoagulant	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antihypertensives	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antiplatelet	0 (0.0%)	0 (0.0%)	0 (0.0%)

Characteristic[a,b]	Baricitinibc (N=0)	TNFi (N=0)	Total (N=0)
Nitrates	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hormonal			
Oral contraceptives	0 (0.0%)	0 (0.0%)	0 (0.0%)
HRT	0 (0.0%)	0 (0.0%)	0 (0.0%)
SERM	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents			
Bile acid binding	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cholesterol absorption inhibitor	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fibrates	0 (0.0%)	0 (0.0%)	0 (0.0%)
Niacin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Omega-3 fatty acids	0 (0.0%)	0 (0.0%)	0 (0.0%)
Statins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rheumatoid arthritis-related			
Cox-2 Inhibitor	0 (0.0%)	0 (0.0%)	0 (0.0%)
Glucocorticosteroid	0 (0.0%)	0 (0.0%)	0 (0.0%)
Vaccinations	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-index Occurrence[d]			
Methotrexate, concomitant	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: AIDS = acquired immunodeficiency syndrome; bDMARD = biologic disease-modifying antirheumatic drugs; CIRAS = claims-based index for RA severity; cDMARD = conventional disease-modifying antirheumatic drugs; Concom. cDMARDs = concomitant cDMARDs; HIV = human immunodeficiency virus; HRT = hormone replacement therapy; Max = maximum; Min = minimum; N = number of patients in the specified category; N/A = not applicable; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; SERMs = selective estrogen receptor modulators; SLE = systemic lupus erythematosus; Std. Diff. = standardised difference; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a All conditions and characteristics are measured during the 6 months prior to initiation of study medication until and including the day prior to baricitinib or the index TNFi exposure that qualifies the patient for the cohort.

b Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 4 in protocol Section 8.3.3 (Annex 19) for each outcome, e.g., hospitalized congestive heart failure for VTE. Other factors are included for descriptive purposes only, may not be balanced across treatment groups but do not contribute to confounding bias, e.g., Type I diabetes for VTE.

c Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

d Events in this category must have occurred in the 7 days immediately prior to MACE.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.51. - Clinical Characteristics of RA Patients with MACE [Japanese Medical Data Center Payer-Based]_.docx

Table 52_JMDC. Pattern of RA Medication Use in Patients with MACE [JMDC]

Characteristic[a]	Unmatched		Matched		
	Baricitinib[b] (N=0)	TNFi (N=3)	Baricitinib[b] (N=0)	TNFi (N=0)	Total (N=0)
Baseline Medication					
cDMARDs, during baseline					
n, total	0 (0.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean (SD)	- (-)	1.00 (1.00)	- (-)	- (-)	- (-)
Median	- [-, -]	1.00 [0.00, 2.00]	- [-, -]	- [-, -]	- [-, -]
Min, Max	-, -	0.0, 2.0	-, -	-, -	-, -
>1 cDMARD concomitantly	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hydroxychloroquine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Leflunomide	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate	0 (0.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Minocycline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sulfasalazine	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
bDMARDs, during baseline					
n, total	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Mean (SD)	- (-)	0.00 (0.00)	- (-)	- (-)	- (-)
Median	- [-, -]	0.00 [0.00, 0.00]	- [-, -]	- [-, -]	- [-, -]
Min, Max	-, -	0.0, 0.0	-, -	-, -	-, -
cDMARDs, concomitant	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abatacept	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Adalimumab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anakinra	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Certolizumab pegol[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Etanercept[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Golimumab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Infliximab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rituximab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Tocilizumab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-index Medication[d]					
Methotrexate, concomitant	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Concomitant cDMARD	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dose change, baricitinib	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: bDMARD = biologic disease-modifying antirheumatic drug; cDMARD = conventional disease-modifying antirheumatic drug; Max = maximum; Min = minimum; N = number of patients in the specified category; NA = not applicable; RA = rheumatoid arthritis; SD = standard deviation; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

a All conditions and characteristics are measured during the 6 months prior to initiation of study medication until and including the day prior to baricitinib or the index TNFi exposure that qualifies the patient for the cohort.

b Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

c TNF inhibitors.

d Only baricitinib 2-mg dose is available in the US, so the baricitinib cells should be marked 'NA' as necessary.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.52. - Pattern of RA Medication Use in Patients with MACE [JMDC].docx

Table 53_JMDC. Time to First Event Outcome (days) - MACE [JMDC]

Time	Unmatched				Matched				
	Baricitinib[a]			TNFi	Baricitinib[a]			TNFi	Total
	Any (N=246)	4mg (N= 145)	2mg (N=101)	(N=1,720)	Any (N=224)	4mg (N= 131)	2mg (N= 93)	(N=224)	(N=448)
n	246	145	101	1,720	224	131	93	224	448
Mean (SD)	- (-)	- (-)	- (-)	235.00 (258.03)	- (-)	- (-)	- (-)	- (-)	- (-)
Median	- [-, -]	- [-, -]	- [-, -]	107.00 [66.00, 532.00]	- [-, -]	- [-, -]	- [-, -]	- [-, -]	- [-, -]
Min, Max	-,-	-,-	-,-	66.0, 532.0	-,-	-,-	-,-	-,-	-,-

Abbreviations: MACE = major adverse cardiovascular event, defined as hospital primary discharge diagnosis code of acute MI or hospital primary discharge diagnosis code of ischemic or hemorrhagic stroke; Max = maximum; Min = minimum; N = number of patients in the specified category; SD = standard deviation; VTE = venous thromboembolism.

a Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.53. Time to First Event Outcome (days) - MACE [JMDC].docx

Table 55_JMDC. Comparative Risk of MACE [JMDC]

	TNFi	Baricitinib		p-value
		HR	95%CI	
Base Model[1,2]	Ref	-	-	-

Abbreviations: CI = confidence interval; HR = Cox proportional hazard ratio; Ref = referent group; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolism.

1 Base model = propensity score-matched model with confounders, outcome and baricitinib exposure.

2 Zero events in the TNFi group preclude analyzing models with additional parameters. The model did not converge.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. Table 6.55. - Comparative Risk of MACE [Japanese Medical Data Center Payer-Based].docx

Table 56_JMDC. Clinical Characteristics of RA Patients with Incident Serious Infections [JMDC]

Characteristics[a,b]	Baricitinib[c] (N=0)	TNFi (N=1)	Total (N=1)
Age (mean) [SD]	- (-)	60.00 (0.00)	60.00 (0.00)
Sex			
Female	0 (0.0%)	1 (100.0%)	1 (100.0%)
Male	0 (0.0%)	0 (0.0%)	0 (0.0%)
Clinical Conditions during baseline			
Cancer	0 (0.0%)	0 (0.0%)	0 (0.0%)
NMSC	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chronic Lung disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular conditions			
Atrial arrhythmia/fibrillation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular revascularization	0 (0.0%)	0 (0.0%)	0 (0.0%)
Congestive Heart Failure, hospitalized	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ischemic heart disease	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unstable angina	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular arrhythmia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diabetes Mellitus	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type I	0 (0.0%)	0 (0.0%)	0 (0.0%)
Type II	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dyslipidaemia	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hypertension	0 (0.0%)	0 (0.0%)	0 (0.0%)
Immune disorders	0 (0.0%)	0 (0.0%)	0 (0.0%)
AIDS/HIV	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antiphospholipid syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
SLE	0 (0.0%)	0 (0.0%)	0 (0.0%)
Primary Sjögren Syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)
Liver Disorder	0 (0.0%)	0 (0.0%)	0 (0.0%)
Obesity	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pregnancy			
RA Severity (CIRAS Index), mean (SD)	- [-, -]	6.32 (0.00)	6.32 (0.00)
Smoking	0 (0.0%)	0 (0.0%)	0 (0.0%)
Surgery, Trauma, & Hospitalization, recent	0 (0.0%)	0 (0.0%)	0 (0.0%)
TIA	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other Prescription Medications			
Antibiotics	0 (0.0%)	1 (100.0%)	1 (100.0%)
Antidiabetic agents	0 (0.0%)	0 (0.0%)	0 (0.0%)
Insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-insulins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Aspirin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiovascular			
Anticoagulant	0 (0.0%)	0 (0.0%)	0 (0.0%)
Antihypertensives	0 (0.0%)	0 (0.0%)	0 (0.0%)

Characteristics[a,b]	Baricitinib[c] (N=0)	TNFi (N=1)	Total (N=1)
Antiplatelet	0 (0.0%)	1 (100.0%)	1 (100.0%)
Nitrates	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hormonal			
HRT	0 (0.0%)	1 (100.0%)	1 (100.0%)
Oral Contraceptives	0 (0.0%)	0 (0.0%)	0 (0.0%)
SERMs	0 (0.0%)	0 (0.0%)	0 (0.0%)
Lipid-lowering agents			
Bile acid binding	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cholesterol absorption inhibitor	0 (0.0%)	0 (0.0%)	0 (0.0%)
Fibrates	0 (0.0%)	0 (0.0%)	0 (0.0%)
Niacin	0 (0.0%)	0 (0.0%)	0 (0.0%)
Omega-3 fatty acids	0 (0.0%)	0 (0.0%)	0 (0.0%)
Statins	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rheumatoid arthritis-related			
Cox-2 Inhibitor	0 (0.0%)	0 (0.0%)	0 (0.0%)
Glucocorticosteroid	0 (0.0%)	1 (100.0%)	1 (100.0%)
Vaccinations	0 (0.0%)	0 (0.0%)	0 (0.0%)

Abbreviations: AIDS = acquired immunodeficiency syndrome; bDMARD = biologic disease-modifying antirheumatic drugs; CIRAS = claims-based index for RA severity; cDMARD = conventional disease-modifying antirheumatic drugs; Concom. cDMARDs = concomitant cDMARDs; HIV = human immunodeficiency virus; HRT = hormone replacement therapy; Max = maximum; Min = minimum; N = number of patients in the specified category; N/A = not applicable; NMSC = non-melanoma skin cancer; RA = rheumatoid arthritis; SD = standard deviation; SERMs = selective estrogen receptor modulators; SLE = systemic lupus erythematosus; Std. Diff. = standardised difference; TIA = transient ischemic attack; TNFi = tumour necrosis factor inhibitor; VTE = venous thromboembolisma All conditions and characteristics are measured during the 6 months prior to initiation of study medication until and including the day prior to baricitinib or the index TNFi exposure that qualifies the patient for the cohort.

b Many characteristics of the cohort are included in this table, but propensity score matching is only expected to balance those risk factors listed in Table 4 in protocol Section 8.3.3 (Annex 19) for each outcome, e.g., hospitalized congestive heart failure for VTE. Other factors are included for descriptive purposes only, may not be balanced across treatment groups but do not contribute to confounding bias, e.g., Type I diabetes for VTE.

c Both 2- and 4-mg baricitinib doses are included when the 4-mg dose is available. Alternatively, additional columns may be added for each dose where numbers of patients are sufficient to warrant separate reporting.

Source: lillyce\prd\ly3009104\i4v_mc_b023\final\output\shared\tfl\jmdc_JMDC\3. [Updated 2022.03.15] Table 6.56. Clinical Characteristics of RA Patients with Incident Serious Infections [Japanese Medical Data Center Payer-Based].docx

Table 57_JMDC. Pattern of RA Medication Use in Patients with Serious Infection Event [JMDC]

Characteristic[a]	Unmatched		Matched		
	Baricitinib[b] (N=0)	TNFi (N=2)	Baricitinib[b] (N=0)	TNFi (N=1)	Total (N=1)
Baseline Medication DMARDS					
cDMARDs, during baseline					
n, total	0 (0.0%)	2 (100.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Mean (SD)	- (-)	1.00 (0.00)	- (-)	1.00 (0.00)	1.00 (0.00)
Median	- [-, -]	1.00 [1.00, 1.00]	- [-, -]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]
Min, Max	-, -	1.0, 1.0	-, -	1.0, 1.0	1.0, 1.0
>1 cDMARD concomitantly	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hydroxychloroquine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Leflunomide	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Methotrexate	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Minocycline	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sulfasalazine	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
bDMARDs, during baseline					
n, total	0 (0.0%)	2 (100.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Mean (SD)	- (-)	0.00 (0.00)	- (-)	0.00 (0.00)	0.00 (0.00)
Median	- [-, -]	0.00 [0.00, 0.00]	- [-, -]	0.00 [0.00, 0.00]	0.00 [0.00, 0.00]
Min, Max	-, -	0.0, 0.0	-, -	0.0, 0.0	0.0, 0.0
cDMARDs, concomitant	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abatacept	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Adalimumab[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Anakinra	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Certolizumab pegol[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Etanercept[c]	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Golimumab[c]	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Infliximab[c]	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Rituximab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Tocilizumab	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-index Medication					
Methotrexate, concomitant	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)
Other Concomitant cDMARD	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dose change, baricitinib	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)