	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Comorbidity N (%)	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**
No*	183	57.0	280	58.1	696	66.4	539	42.8	1,569	50.5
Hyperlipidemia										
Yes	99	30.8	150	31.1	282	26.9	546	43.3	1,193	38.4
No*	222	69.2	332	68.9	766	73.1	714	56.7	1,914	61.6
Coronary artery disease										
Yes	30	9.4	43	8.9	86	8.2	291	23.1	489	15.7
No*	291	90.7	439	91.1	962	91.8	969	76.9	2,618	84.3
Serious infections (Hospitalized)										
Yes	13	4.1	17	3.5	33	3.2	224	17.8	253	8.1
No*	308	96.0	465	96.5	1,015	96.9	1,036	82.2	2,854	91.9
Cancer										
Yes	10	3.1	16	3.3	32	3.1	159	12.6	214	6.9
No*	311	96.9	466	96.7	1,016	97.0	1,101	87.4	2,893	93.1
Other immune deficiencies										
Yes	13	4.1	18	3.7	72	6.9	105	8.3	183	5.9
No*	308	96.0	464	96.3	976	93.1	1,155	91.7	2,924	94.1
HIV/AIDS										
Yes	0	0.0	0	0.0	1	0.1	10	0.8	7	0.2
No*	321	100.0	482	100.0	1,047	99.9	1,250	99.2	3,100	99.8
Diabetes										

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	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Comorbidity N (%)	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**
Yes	61	19.0	84	17.4	184	17.6	314	24.9	627	20.2
No*	260	81.0	398	82.6	864	82.4	946	75.1	2,480	79.8
CKD/Dialysis										
Yes	27	8.4	35	7.3	68	6.5	257	20.4	429	13.8
No*	294	91.6	447	92.7	980	93.5	1,003	79.6	2,678	86.2
Liver Disease										
Yes	10	3.1	17	3.5	42	4.0	107	8.5	125	4.0
No*	311	96.9	465	96.5	1,006	96.0	1,153	91.5	2,982	96.0
Corticosteroid Use										
Yes	114	35.5	177	36.7	379	36.2	649	51.5	1,233	39.7
No*	207	64.5	305	63.3	669	63.8	611	48.5	1,874	60.3
History of hospitalization										
Yes	28	8.7	43	8.9	77	7.4	402	31.9	520	16.7
No*	293	91.3	439	91.1	971	92.7	858	68.1	2,587	83.3

ł May not be mutually exclusive for each insurance type. Missing data are not presented
*No=Total number of COVID patients - those with "Yes". Thus, it may include "unknown"

In the PsA sub-cohort, hypertension and hyperlipidemia were interchangeably the first and second-most prevalent comorbidities/clinical characteristics across treatment classes, and corticosteroid use, and diabetes were consistently the third- and fourth-most prevalent (Table 11). Compared with RA patients, prevalence of all four leading comorbidities/clinical characteristics, except hyperlipidemia, was less prevalent in PsA patients.

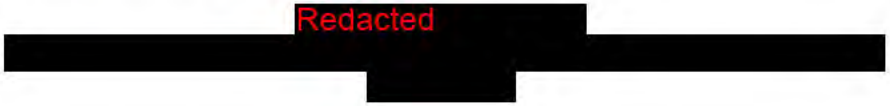
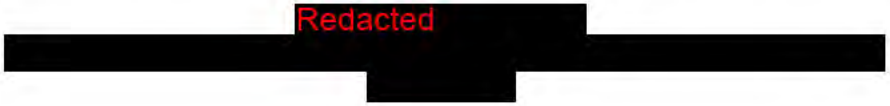


Table 10. Baseline Comorbidities in PsA Cohort Within Baseline Treatment Strata

	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Comorbidity N (%)	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530										
Covid 19 Patients in sub-cohorts										
Sub total	40	100.0	43	100.0	434	100.0	404	100.0	352	100.0
Comorbidity and Clinical Characteristics										
ILD										
Yes	0	0.0	0	0.0	1	0.2	5	1.2	3	0.9
No*	40	100.0	43	100.0	433	99.8	399	98.8	349	99.2
Asthma										
Yes	5	12.5	5	11.6	37	8.5	34	8.4	23	6.5
No*	35	87.5	38	88.4	397	91.5	370	91.6	329	93.5
COPD										
Yes	1	2.5	1	2.3	16	3.7	25	6.2	21	6.0
No*	39	97.5	42	97.7	418	96.3	379	93.8	331	94.0
VTE										
Yes	1	2.5	1	2.3	3	0.7	7	1.7	7	2.0
No*	39	97.5	42	97.7	431	99.3	397	98.3	345	98.0
Hypertension										
Yes	15	37.5	16	37.2	135	31.1	172	42.6	133	37.8
No*	25	62.5	27	62.8	299	68.9	232	57.4	219	62.2



	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Hyperlipidemia										
Yes	15	37.5	17	39.5	120	27.7	155	38.4	120	34.1
No*	25	62.5	26	60.5	314	72.4	249	61.6	232	65.9
Coronary artery disease										
Yes	5	12.5	5	11.6	30	6.9	51	12.6	41	11.7
No*	35	87.5	38	88.4	404	93.1	353	87.4	311	88.4
Serious infections (Hospitalized)										
Yes	3	7.5	3	7.0	7	1.6	28	6.9	11	3.1
No*	37	92.5	40	93.0	427	98.4	376	93.1	341	96.9
Cancer										
Yes	2	5.0	2	4.7	12	2.8	23	5.7	25	7.1
No*	38	95.0	41	95.4	422	97.2	381	94.3	327	92.9
Other immune deficiencies										
Yes	5	12.5	5	11.6	20	4.6	17	4.2	12	3.4
No*	35	87.5	38	88.4	414	95.4	387	95.8	340	96.6
HIV/AIDS										
Yes	0	0.0	0	0.0	2	0.5	1	0.3	0	0.0
No*	40	100.0	43	100.0	432	99.5	403	99.8	352	100.0
Diabetes										
Yes	6	15.0	7	16.3	62	14.3	97	24.0	70	19.9
No*	34	85.0	36	83.7	372	85.7	307	76.0	282	80.1

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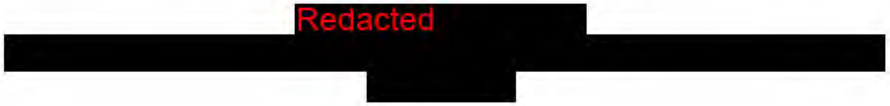
	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
CKD/Dialysis										
Yes	3	7.5	3	7.0	17	3.9	32	7.9	29	8.2
No*	37	92.5	40	93.0	417	96.1	372	92.1	323	91.8
Liver Disease										
Yes	3	7.5	3	7.0	29	6.7	42	10.4	16	4.6
No*	37	92.5	40	93.0	405	93.3	362	89.6	336	95.5
Corticosteroid Use										
Yes	11	27.5	11	25.6	93	21.4	121	30.0	75	21.3
No*	29	72.5	32	74.4	341	78.6	283	70.1	277	78.7
History of hospitalization										
Yes	4	10.0	4	9.3	17	3.9	59	14.6	28	8.0
No*	36	90.0	39	90.7	417	96.1	345	85.4	324	92.1

*No=Total number of COVID patients - those with "Yes". Thus, it may include "unknown"

In the UC patient sub-cohort, the most prevalent comorbidities/clinical characteristics in each of the five treatment groups were less patterned than in the RA and PsA sub-cohorts (Table 12). Corticosteroid use was the most prevalent comorbidity/clinical characteristic in the tofacitinib, JAKi, and TNFi treatment groups whereas hypertension was most prevalent in the non-TNFi and csDMARD treatment groups. Hyperlipidemia, hypertension, asthma, and a history of hospitalization were the second-, third-, and tied for fourth-most common, respectively, in the tofacitinib and JAKi groups. In the TNFi group, hypertension, hyperlipidemia, and history of hospitalization completed the top four most common, respectively. In the non-TNFi group, corticosteroid use, history of hospitalization, and hyperlipidemia completed the four most common, respectively. In the csDMARD group, hyperlipidemia, corticosteroid use, and diabetes, respectively, completed the top four most common comorbidities/clinical characteristics.

Table 11. Baseline Comorbidity in UC Cohort within Baseline Treatment Strata

	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Comorbidity N (%)	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530										
Covid 19 Patients in sub-cohorts										
Sub total	38	100.0	38	100.0	401	100.0	639	100.0	1,040	100.0
Comorbidity and Clinical Characteristics										
ILD										
Yes	0	0.0	0	0.0	2	0.5	22	3.4	8	0.8
No*	38	100.0	38	100.0	399	99.5	617	96.6	1,032	99.2
Asthma										
Yes	3	7.9	3	7.9	26	6.5	97	15.2	84	8.1
No*	35	92.1	35	92.1	375	93.5	542	84.8	956	91.9
COPD										
Yes	0	0.0	0	0.0	11	2.7	75	11.7	66	6.4
No*	38	100.0	38	100.0	390	97.3	564	88.3	974	93.7
VTE										
Yes	0	0.0	0	0.0	5	1.3	35	5.5	27	2.6
No*	38	100.0	38	100.0	396	98.8	604	94.5	1,013	97.4
Hypertension										
Yes	5	13.2	5	13.2	79	19.7	259	40.5	355	34.1
No*	33	86.8	33	86.8	322	80.3	380	59.5	685	65.9



	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Comorbidity N (%)	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**
Hyperlipidemia										
Yes	6	15.8	6	15.8	58	14.5	197	30.8	298	28.7
No*	32	84.2	32	84.2	343	85.5	442	69.2	742	71.4
Coronary artery disease										
Yes	0	0.0	0	0.0	8	2.0	118	18.5	98	9.4
No*	38	100.0	38	100.0	393	98.0	521	81.5	942	90.6
Serious infections (Hospitalized)										
Yes	1	2.6	1	2.6	19	4.7	133	20.8	66	6.4
No*	37	97.4	37	97.4	382	95.3	506	79.2	974	93.7
Cancer										
Yes	0	0.0	0	0.0	9	2.2	90	14.1	81	7.8
No*	38	100.0	38	100.0	392	97.8	549	85.9	959	92.2
Other immune deficiencies										
Yes	1	2.6	1	2.6	23	5.7	50	7.8	37	3.6
No*	37	97.4	37	97.4	378	94.3	589	92.2	1,003	96.4
HIV/AIDS										
Yes	0	0.0	0	0.0	0	0.0	4	0.6	4	0.4
No*	38	100.0	38	100.0	401	100.0	635	99.4	1,036	99.6

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	Tofacitinib (Overall)		JAK inhibitors (Overall)		TNFi (Overall)		non-TNFi (Overall)		csDMARD	
Comorbidity N (%)	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**	**Number of patients**	**%**
Diabetes										
Yes	2	5.3	2	5.3	32	8.0	125	19.6	143	13.8
No*	36	94.7	36	94.7	369	92.0	514	80.4	897	86.3
CKD/Dialysis										
Yes	1	2.6	1	2.6	19	4.7	130	20.3	88	8.5
No*	37	97.4	37	97.4	382	95.3	509	79.7	952	91.5
Liver Disease										
Yes	0	0.0	0	0.0	24	6.0	92	14.4	67	6.4
No*	38	100.0	38	100.0	377	94.0	547	85.6	973	93.6
Corticosteroid Use										
Yes	11	29.0	11	29.0	142	35.4	251	39.3	221	21.3
No*	27	71.1	27	71.1	259	64.6	388	60.7	819	78.8
History of hospitalization										
Yes	3	7.9	3	7.9	44	11.0	233	36.5	136	13.1
No*	35	92.1	35	92.1	357	89.0	406	63.5	904	86.9

*No=Total number of COVID patients - those with "Yes". Thus, it may include "unknown"

Redacted

With few exceptions across the three indications, the non-TNFi treatment group had a notably higher prevalence of the most common comorbidities/clinical characteristics compared with the other treatment groups.

10.3. Outcome Data

Among the four sub-cohorts, frequency of all primary and secondary endpoints was always highest in RA patients and most often (though not always) lowest in PsA patients.

10.3.1. Endpoints in the Four Sub-Cohorts

Hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among RA patients (23.88%; 95% CI 23.02%-24.77%) and least frequent among PsA patients (11.75%; 95% CI 10.31%-13.33%), with 14.04% (95% CI 13.99%-14.10%) of the non-indicated sub-cohort being hospitalized during this period (Table 12). ICU admission during this same period was likewise most frequent among RA patients (4.45%; 95% CI 4.04%-4.89%) and least frequent among PsA patients (1.49%; 95% CI 0.98%-2.16%), with 2.60% (95% CI 2.58%-2.63%) of the non-indicated patient sub-cohort being admitted to an ICU.

Table 12. Incidence Proportion of Primary Endpoints For Indicated And Non-Indicated Patients

	RA			PsA			UC			Non-Indicated		
	Number of Patients	**Incidence Proportion**	**95% CI**	**Number of Patients**	**Incidence Proportion**	**95% CI**	**Number of Patients**	**Incidence Proportion**	**95% CI**	**Number of Patients**	**Incidence Proportion**	**95% CI**
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530												
Covid 19 Patients in sub-cohorts												
Sub total	**9,186**	100.00		**1,812**	100.00		**3,354**	100.00		**1,371,178**	100.00	
Primary Endpoints												
Hospitalization												
Yes	2,194	23.88	23.02 - 24.77	213	11.75	10.31 - 13.33	538	16.04	14.81 - 17.33	192,581	14.04	13.99 - 14.10
ICU admission												
Yes	409	4.45	4.04 - 4.89	27	1.49	0.98 - 2.16	72	2.15	1.68 - 2.70	35,678	2.60	2.58 - 2.63

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10.3.2. Secondary Endpoints in the Four Sub-cohorts

Of hospitalized patients, in-hospital death was most frequent for RA patients (17.68%; 95% CI 16.11%-19.35%) and least frequent for UC patients (11.90%; 95% CI 9.28%-14.94%), with 13.04% (95% CI 12.89%-13.19%) of hospitalized non-indicated patients having an in-hospital death (Table 13).

Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was highest for RA patients (6.14%; 95% CI 5.66%-6.65%) and lowest for PsA patients (2.37%; 95% CI 1.72%-3.18%), with 2.76% (95% CI 2.74%-2.79%) of non-indicated patients dying from any cause during this period.

Modal length of hospital stay was 6-10 days for RA patients (28.49%; 95% CI 26.61%-30.43%), 3-5 and 6-10 days for PsA patients (for both: 29.11%; 95% CI 23.10%-35.71%); 6-10 days for UC patients (26.58%; 95% CI 22.89%-30.53%); and 3-5 days for non-indicated patients (31.30%; 95% CI 31.09%-31.51%).

Modal discharge disposition (with non-trivial missingness) was "home" for all four sub-cohorts, ranging from 46.22% (95% CI 44.11%-48.33%) for RA patients to 50.20% (49.97%-50.42%) for non-indicated patients.

Of the six health outcome conditions assessed, the two most prevalent in all four sub-cohorts were pneumonia and acute respiratory distress syndrome (ARDS) (with the rank varying between sub-cohorts). The occurrence of each was never higher than 14.60% or lower than 7.06%. Kidney failure was the third most frequent health outcome in all four sub-cohorts, ranging from 4.54% (95% CI 4.51%-4.58%) in the non-indicated sub-cohort to 8.35% (95% CI 7.79%-8.93%) in RA patients. Thrombotic events, heart failure, and sepsis/septic shock were the three least common health outcomes of those assessed in all four sub-cohorts.

Mechanical ventilation/extracorporeal membrane oxygenation (ECMO) occurred during SARS-CoV-2 hospitalization most frequently in RA patients (2.71%; 95% CI 2.39%-3.06%) and least frequently in PsA patients (1.16%; 95% CI 0.72%-1.77%).

IV Immunoglobulin use occurred during SARS-CoV-2 hospitalization most frequently in RA patients (0.48%; 95% CI 0.35%-0.64%) and least frequently in the non-indicated sub-cohort (0.13%; 95% CI 0.13%-0.14%).

Table 13. Incidence Proportion of Secondary Outcomes For Indicated And Non-Indicated Patients

	RA			PsA			UC			Non-Indicated		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530												
Covid 19 Patients in sub-cohorts												
Sub total	**9,186**	100.00		**1,812**	100.00		**3,354**	100.00		**1,371,178**	100.00	
Secondary Endpoints												
SARS diagnosis site												
Inpatient	1,387	15.10	14.37 - 15.85	116	6.40	5.32 - 7.63	350	10.44	9.42 - 11.52	123,436	9.00	8.95 - 9.05
Outpatient	4,969	54.09	53.07 - 55.12	1,021	56.35	54.03 - 58.65	1,861	55.49	53.78 - 57.18	699,133	50.99	50.90 - 51.07
ICU	184	2.00	1.73 - 2.31	12	0.66	0.34 - 1.15	29	0.86	0.58 - 1.24	19,242	1.40	1.38 - 1.42
ER	2,199	23.94	23.07 - 24.82	305	16.83	15.14 - 18.64	693	20.66	19.30 - 22.07	377,487	27.53	27.46 - 27.60
Other/Unknown	5,312	57.83	56.81 - 58.84	1,139	62.86	60.59 - 65.09	2,063	61.51	59.84 - 63.16	720,314	52.53	52.45 - 52.62
In hospital death*												
Yes	388	17.68	16.11 - 19.35	26	12.21	8.13 - 17.37	64	11.90	9.28 - 14.94	25,105	13.04	12.89 - 13.19
All-cause mortality **												
Yes	564	6.14	5.66 - 6.65	43	2.37	1.72 - 3.18	98	2.92	2.38 - 3.55	37,880	2.76	2.74 - 2.79
Length of hospital stay												
1 - 2 days	326	14.86	13.40 - 16.42	30	14.08	9.71 - 19.49	98	18.22	15.04 - 21.74	28,473	14.78	14.63 - 14.94

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	RA			PsA			UC			Non-Indicated		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
3 -5 days	531	24.20	22.42 - 26.05	62	29.11	23.10 - 35.71	142	26.39	22.72 - 30.33	60,279	31.30	31.09 - 31.51
6 - 10 days	625	28.49	26.61 - 30.43	62	29.11	23.10 - 35.71	143	26.58	22.89 - 30.53	53,252	27.65	27.45 - 27.85
11-15 days	296	13.49	12.09 - 14.99	24	11.27	7.35 - 16.30	64	11.90	9.28 - 14.94	22,268	11.56	11.42 - 11.71
16-20 days	188	8.57	7.43 - 9.82	15	7.04	3.99 - 11.35	37	6.88	4.89 - 9.36	10,935	5.68	5.58 - 5.78
>20 days	228	10.39	9.15 - 11.75	20	9.39	5.83 - 14.13	54	10.04	7.63 - 12.89	17,374	9.02	8.89 - 9.15
Discharge Disposition												
Home	1,014	46.22	44.11 - 48.33	106	49.77	42.86 - 56.68	263	48.88	44.58 - 53.20	96,668	50.20	49.97 - 50.42
Nursing facility /ICF	197	8.98	7.82 - 10.25	12	5.63	2.94 - 9.63	47	8.74	6.49 - 11.45	15,029	7.80	7.68 - 7.92
Hospice	45	2.05	1.50 - 2.73	0	0.00	0.00 - 0.00	5	0.93	0.30 - 2.16	3,486	1.81	1.75 - 1.87
Hospital	111	5.06	4.18 - 6.06	9	4.23	1.95 - 7.87	23	4.28	2.73 - 6.35	10,963	5.69	5.59 - 5.80
Other/Unknown	392	17.87	16.28 - 19.54	27	12.68	8.52 - 17.90	68	12.64	9.95 - 15.75	28,548	14.82	14.67 - 14.98
Pneumonia												
Yes	1,274	13.87	13.17 - 14.59	134	7.40	6.23 - 8.70	291	8.68	7.75 - 9.68	107,897	7.87	7.82 - 7.91
Kidney failure												
Yes	767	8.35	7.79 - 8.93	85	4.69	3.76 - 5.77	214	6.38	5.58 - 7.26	62,303	4.54	4.51 - 4.58
Thrombotic event												
Yes	445	4.84	4.41 - 5.30	44	2.43	1.77 - 3.25	124	3.70	3.08 - 4.39	31,408	2.29	2.27 - 2.32

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	RA			PsA			UC			Non-Indicated		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
ARDS												
Yes	1,341	14.60	13.88 - 15.34	128	7.06	5.93 - 8.34	260	7.75	6.87 - 8.71	112,145	8.18	8.13 - 8.22
Heart failure												
Yes	732	7.97	7.42 - 8.54	70	3.86	3.02 - 4.86	145	4.32	3.66 - 5.07	41,681	3.04	3.01 - 3.07
Sepsis/septic shock												
Yes	567	6.17	5.69 - 6.68	53	2.92	2.20 - 3.81	152	4.53	3.85 - 5.29	41,844	3.05	3.02 - 3.08
Mechanical ventilation/ECMO												
Yes	249	2.71	2.39 - 3.06	21	1.16	0.72 - 1.77	54	1.61	1.21 - 2.10	18,230	1.33	1.31 - 1.35
IV immunoglobulin												
Yes	44	0.48	0.35 - 0.64	7	0.39	0.16 - 0.79	11	0.33	0.16 - 0.59	1,838	0.13	0.13 - 0.14

ǂ May not be mutually exclusive. Missing data are not presented
*The denominator is number of patients hospitalized
** within 90 days on or after the index date

10.4. Main Results

10.4.1. Primary Endpoints in the Three Indicated Sub-Cohorts, Stratified By Treatment Category

In the RA sub-cohort, hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among non-TNFi-exposed patients (31.03%; 95% CI 28.48%-33.67%) and least among TNFi-exposed patients (11.8%; 95% CI 9.94%-13.94%) (Table 15). ICU admissions among hospitalized patients were most frequent among tofacitinib-exposed patients (5.30%; 95% CI 3.11%-8.34%) and least among TNFi-exposed patients (1.62%; 95% CI 0.95%-2.58%).

Table 14. Incidence Proportion of Primary Endpoints For RA Indicated Patients Within Baseline Treatment Strata

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530															
Covid 19 Patients in sub-cohorts															
Sub total	**321**	100.00		**482**	100.00		**1048**	100.00		**1260**	100.00		**3107**	100.00	
Primary Endpoints															
Hospitalization															
Yes	62	19.31	15.14 - 24.06	85	17.63	14.34 - 21.34	124	11.83	9.94 - 13.94	391	31.03	28.48 - 33.67	748	24.07	22.58 - 25.62
ICU admission															
Yes	17	5.30	3.11 - 8.34	23	4.77	3.05 - 7.07	17	1.62	0.95 - 2.58	59	4.68	3.58 - 6.00	146	4.70	3.98 - 5.50

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In the PsA sub-cohort, the numbers of patients exposed to tofacitinib and JAKi's were small (40 and 43, respectively, versus >350 in each of the three other exposure groups) and outcome events were rare (<5) with correspondingly wide confidence intervals (Table 16).

Hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among csDMARD-exposed patients (14.49%; 95% CI 10.98%-18.61%) and least among TNFi-exposed patients (7.37%; 95% CI 5.10%-10.25%). ICU admissions among hospitalized patients were most frequent among tofacitinib-exposed patients (5.00%; 95% CI 0.61%-16.92%) and least among TNFi-exposed patients (0.69%; 95% CI 0.14%-2.01%).

Table 15. Incidence Proportion of Primary Endpoints For Psa Indicated Patients Within Baseline Treatment Strata

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530															
Covid 19 Patients in sub-cohorts															
Sub total	**40**	100		**43**	100		**434**	100		**404**	100		**352**	100	
Primary Endpoints															
Hospitalization Yes	4	10.00	2.79 - 23.66	4	9.30	2.59 - 22.14	32	7.37	5.10 - 10.25	57	14.11	10.86 - 17.89	51	14.49	10.98 - 18.61
ICU admission Yes	2	5.00	0.61 - 16.92	2	4.65	0.57 - 15.81	3	0.69	0.14 - 2.01	6	1.49	0.55 - 3.20	6	1.70	0.63 - 3.67

Redacted

In the UC sub-cohort, the numbers of patients exposed to tofacitinib and JAKi's were small (38 in both exposure groups, versus >400 in each of the three other exposure groups) and outcome events were rare (<6) with correspondingly wide confidence intervals (Table 16).

Hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among non-TNFi-exposed patients (26.13%; 95% CI 22.77%-29.72%) and least among TNFi-exposed patients (5.99%; 95% CI 3.87%-8.77%). ICU admissions among hospitalized patients were most frequent among non-TNFi-exposed patients (2.97%; 95% CI 1.80%-4.60%) and least among TNFi-exposed patients (1.00%; 95% CI 0.27%-2.53%).

Table 16. Incidence Proportion of Primary Endpoints For UC Indicated Patients Within Baseline Treatment Strata

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530															
Covid 19 Patients in sub-cohorts															
Sub total	**38**	100		**38**	100		**401**	100		**639**	100		**1040**	100	
Primary Endpoints															
Hospitalization															
Yes	5	13.16	4.41 - 28.09	5	13.16	4.41 - 28.09	24	5.99	3.87 - 8.77	167	26.13	22.77 - 29.72	141	13.56	11.53 - 15.79
ICU admission															
Yes	1	2.63	0.07 - 13.81	1	2.63	0.07 - 13.81	4	1.00	0.27 - 2.53	19	2.97	1.80 - 4.60	23	2.21	1.41 - 3.30

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10.4.2. Secondary Endpoints in the Three Indicated Sub-cohorts, Stratified by Treatment Category

10.4.3. RA Sub-Cohort

In the RA sub-cohort, among hospitalized patients, in-hospital death was most frequent in the csDMARD-exposed (19.65%; 95% CI 16.86%-22.68%) and tofacitinib exposed patients (19.35%; 95% CI 10.42%-31.37%) and least among the TNFi-exposed (7.26%; 95% CI 3.37%-13.33%) (Table 17).

Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was highest for csDMARD-exposed (6.14%; 95% CI 5.96%-7.77%) and lowest for TNFI-exposed patients (1.43%; 95% CI 0.80%-2.35%).

The modal length of hospital stay was 6-10 days for tofacitinib-, non-TNFi-, and csDMARD-exposed patients and 3-5 days for JAKi- and TNFi-exposed patients.

Modal discharge disposition (with non-trivial missingness) was "home" for all five exposure categories, ranging from 43.73% (95% CI 38.75%-48.81%) for non-TNFi-exposed patients to 57.26% (48.06%-66.10%) for TNFi-exposed patients.

Of the six health outcome conditions assessed, the most and second-most frequent outcomes in all exposure classes except TNFi were ARDS and pneumonia, respectively (Table 16). In the TNFi-exposed patients, the most and second-most health outcomes were pneumonia and ARDS, respectively. The non-TNFi-exposed patients had the highest frequency of all six health outcomes and the most frequent outcome among them was ARDS (17.38%; 95% CI 15.33%-19.59%). The TNFi-exposed patients had the lowest frequency of all six outcomes and the least frequent outcome among them was sepsis/septic shock (1.91%; 95% CI 1.17%-2.93%).

Mechanical ventilation/extracorporeal membrane oxygenation (ECMO) occurred during SARS-CoV-2 hospitalization most frequently in tofacitinib-exposed patients (4.05%; 95% CI 2.17%-6.83%) and least frequently in TNFi-exposed patients (0.67%; 95% CI 0.27%-1.37%).

IV Immunoglobulin use occurred during SARS-CoV-2 hospitalization most frequently in non-TNFi-exposed patients (1.27%; 95% CI 0.73%-2.05%) and never occurred in the tofacitinib- and JAKi-exposed patients.

Table 17. Incidence Proportions of Secondary Outcomes in RA Patients Within Baseline Treatment Strata

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530															
Covid 19 Patients in sub-cohorts															
Sub total	**321**	100.00		**482**	100.00		**1048**	100.00		**1260**	100.00		**3107**	100.00	
Secondary Endpoints															
SARS diagnosis site															
Inpatient	33	10.28	7.18 - 14.13	39	8.09	5.82 - 10.90	71	6.77	5.33 - 8.47	247	19.60	17.44 - 21.90	453	14.58	13.36 - 15.87
Outpatient	193	60.12	54.54 - 65.52	293	60.79	56.27 - 65.17	593	56.58	53.52 - 59.61	684	54.29	51.49 - 57.06	1688	54.33	52.56 - 56.09
ICU	6	1.87	0.69 - 4.02	9	1.87	0.86 - 3.51	9	0.86	0.39 - 1.62	21	1.67	1.03 - 2.54	71	2.29	1.79 - 2.87
ER	67	20.87	16.56 - 25.73	100	20.75	17.21 - 24.65	179	17.08	14.85 - 19.50	282	22.38	20.11 - 24.79	774	24.91	23.40 - 26.47
Other/Unknown	197	61.37	55.80 - 66.73	283	58.71	54.17 - 63.15	634	60.50	57.46 - 63.47	773	61.35	58.60 - 64.05	1731	55.71	53.95 - 57.47
In hospital death*															
Yes	12	19.35	10.42 - 31.37	16	18.82	11.16 - 28.76	9	7.26	3.37 - 13.33	63	16.11	12.61 - 20.14	147	19.65	16.86 - 22.68

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
All-cause mortality **															
Yes	15	4.67	2.64 - 7.59	19	3.94	2.39 - 6.09	15	1.43	0.80 - 2.35	85	6.75	5.42 - 8.27	212	6.82	5.96 - 7.77
Length of hospital stay															
1 - 2 days	5	8.06	2.67 - 17.83	11	12.94	6.64 - 21.98	21	16.94	10.80 - 24.72	67	17.14	13.53 - 21.24	114	15.24	12.74 - 18.02
3 -5 days	17	27.42	16.85 - 40.23	24	28.24	19.00 - 39.04	43	34.68	26.36 - 43.75	70	17.90	14.23 - 22.07	183	24.47	21.42 - 27.71
6 - 10 days	19	30.65	19.56 - 43.65	23	27.06	17.99 - 37.79	30	24.19	16.96 - 32.70	103	26.34	22.04 - 31.01	211	28.21	25.01 - 31.58
11-15 days	7	11.29	4.66 - 21.89	9	10.59	4.96 - 19.15	11	8.87	4.51 - 15.32	59	15.09	11.69 - 19.03	105	14.04	11.63 - 16.74
16-20 days	3	4.84	1.01 - 13.50	3	3.53	0.73 - 9.97	8	6.45	2.83 - 12.32	41	10.49	7.63 - 13.96	65	8.69	6.77 - 10.94
>20 days	11	17.74	9.20 - 29.53	15	17.65	10.23 - 27.43	11	8.87	4.51 - 15.32	51	13.04	9.87 - 16.79	70	9.36	7.37 - 11.68
Discharge Disposition															
Home	33	53.23	40.12 - 66.02	44	51.76	40.66 - 62.74	71	57.26	48.06 - 66.10	171	43.73	38.75 - 48.81	331	44.25	40.65 - 47.89
Nursing facility /ICF	1	1.61	0.04 - 8.66	1	1.18	0.03 - 6.38	7	5.65	2.30 - 11.29	41	10.49	7.63 - 13.96	57	7.62	5.82 - 9.76
Hospice	0	0.00	0.00 — 1.18	1	1.18	0.03 - 6.38	1	0.81	0.02 - 4.41	10	2.56	1.23 - 4.65	15	2.01	1.13 - 3.29

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Hospital	4	6.45	1.79 - 15.70	4	4.71	1.30 - 11.61	4	3.23	0.89 - 8.05	19	4.86	2.95 - 7.48	29	3.88	2.61 - 5.52
Other/Unknown	9	14.52	6.86 - 25.78	11	12.94	6.64 - 21.98	15	12.10	6.93 - 19.17	62	15.86	12.38 - 19.86	145	19.39	16.61 - 22.40
Pneumonia															
Yes	43	13.40	9.87 - 17.62	59	12.24	9.45 - 15.50	74	7.06	5.58 - 8.78	214	16.98	14.95 - 19.17	435	14.00	12.80 - 15.27
Kidney failure															
Yes	18	5.61	3.36 - 8.72	25	5.19	3.38 - 7.56	35	3.34	2.34 - 4.61	142	11.27	9.58 - 13.15	231	7.43	6.54 - 8.41
Thrombotic event															
Yes	10	3.12	1.50 - 5.65	15	3.11	1.75 - 5.08	25	2.39	1.55 - 3.50	91	7.22	5.85 - 8.79	160	5.15	4.40 - 5.99
ARDS															
Yes	44	13.71	10.14 - 17.96	64	13.28	10.38 - 16.64	71	6.77	5.33 - 8.47	219	17.38	15.33 - 19.59	451	14.52	13.29 - 15.80
Heart failure															
Yes	18	5.61	3.36 - 8.72	24	4.98	3.22 - 7.32	31	2.96	2.02 - 4.17	137	10.87	9.21 - 12.72	259	8.34	7.39 - 9.36
Sepsis/septic shock															
Yes	22	6.85	4.34 - 10.19	25	5.19	3.38 - 7.56	20	1.91	1.17 - 2.93	114	9.05	7.52 - 10.77	188	6.05	5.24 - 6.95
Mechanical ventilation/ECMO															

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Yes	13	4.05	2.17 - 6.83	17	3.53	2.07 - 5.59	7	0.67	0.27 - 1.37	48	3.81	2.82 - 5.02	84	2.70	2.16 - 3.34
IV immunoglobulin															
Yes	0	0.00	0.00 - 1.18	0	0.00	0.00 - 0.79	4	0.38	0.10 - 0.97	16	1.27	0.73 - 2.05	13	0.42	0.22 - 0.71

ǂ May not be mutually exclusive. Missing data are not presented
*The denominator is number of patients hospitalized
** within 90 days on or after the index date

Redacted

10.4.4. PsA Sub-Cohort

In the PsA sub-cohort, the numbers of patients exposed to tofacitinib and JAKi's were small (40 and 43, respectively, versus >350 in each of the three other exposure groups) and outcome events were rare (<4) with correspondingly wide confidence intervals (Table 18).

Among hospitalized patients, in-hospital death was most frequent in the tofacitinib- and JAKi –exposed patients (50.0% in both; 95% CI 6.76%-93.24%) and least in the csDMARD-exposed patients (3.92%; 95% CI 0.48%-13.46%).

Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was highest in tofacitinib-exposed (7.50%; 95% CI 1.57%-20.39%) and lowest in TNFI-exposed patients (1.15%; 95% CI 0.38%-2.67%).

The modal length of hospital stay was 16-20 days in tofacitinib- and JAKi-exposed patients (2 of 4 hospitalized patients in both groups), 6-10 days in the csDMARD group, and 3-5 days in the TNFi and non-TNFi groups.

The modal discharge disposition (with non-trivial missingness) was "home" for all five exposure categories, ranging from 47.06% (95% CI 32.93%-61.54%) for csDMARD patients to 59.38% (40.64%-76.30%) for TNFi-exposed patients.

Of the six health outcome conditions assessed, the most frequent outcome in all exposure classes except the non-TNFi group was pneumonia. ARDS was the most common in the non-TNFi group and was tied for most common among the tofacitinib and JAKi groups. Second-most common was either sepsis/septic shock (in the tofacitinib and JAKi groups), ARDS (in the TNFi and csDMARD groups), and pneumonia (in the non-TNFi group). Kidney failure was the third most common health outcome in all five exposure groups. Across all exposure groups, the most common outcome was pneumonia in the csDMARD group (9.38%; 95% CI 6.54%-12.91%). The non-TNFi group had the highest occurrence in four of the six outcomes.

ECMO and IV Immunoglobulin use occurring during SARS-CoV-2 hospitalization were both rare, never occurring in more than 5 patients in any treatment group or in more than 2.50% of the patients in any treatment group, resulting in consistently unstable estimates.

Table 18. Incidence Proportions of Secondary Outcomes In Psa Patients Within Baseline Treatment Strata

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530															
Covid 19 Patients in sub-cohorts															
Sub total	**40**	100		**43**	100		**434**	100		**404**	100		**352**	100	
Secondary Endpoints															
SARS diagnosis site															
Inpatient	1	2.50	0.06 - 13.16	1	2.33	0.06 - 12.29	18	4.15	2.48 - 6.48	28	6.93	4.65 - 9.86	25	7.10	4.65 - 10.31
Outpatient	22	55.00	38.49 - 70.74	25	58.14	42.13 - 72.99	249	57.37	52.57 - 62.08	218	53.96	48.96 - 58.90	200	56.82	51.46 - 62.06
ICU	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	0	0.00	0.00 - 0.88	4	0.99	0.27 - 2.52	4	1.14	0.31 - 2.88
ER	8	20.00	9.05 - 35.65	8	18.60	8.39 - 33.40	51	11.75	8.88 - 15.16	57	14.11	10.86 - 17.89	62	17.61	13.78 - 22.00

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Other/Unknown	28	70.00	53.47 - 83.44	31	72.09	56.33 - 84.67	280	64.52	59.81 - 69.02	251	62.13	57.20 - 66.88	227	64.49	59.24 - 69.49
In hospital death*															
Yes	2	50.00	6.76 - 93.24	2	50.00	6.76 - 93.24	4	12.50	3.51 - 28.99	9	15.79	7.48 - 27.87	2	3.92	0.48 - 13.46
All-cause mortality **															
Yes	3	7.50	1.57 - 20.39	3	6.98	1.46 - 19.06	5	1.15	0.38 - 2.67	12	2.97	1.54 - 5.13	7	1.99	0.80 - 4.05
Length of hospital stay															
1 - 2 days	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	4	12.50	3.51 - 28.99	13	22.81	12.74 - 35.84	4	7.84	2.18 - 18.88
3 -5 days	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	10	31.25	16.12 - 50.01	17	29.82	18.43 - 43.40	14	27.45	15.89 - 41.74
6 - 10 days	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	6	18.75	7.21 - 36.44	15	26.32	15.54 - 39.66	18	35.29	22.43 - 49.93
11-15 days	1	25.00	0.63 - 80.5	1	25.00	0.63 - 80.5	2	6.25	0.77 - 20.8	5	8.77	2.91 - 19.3	7	13.73	5.70 - 26.2

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
			9			9			1			0			6
16-20 days	2	50.00	6.76 - 93.24	2	50.00	6.76 - 93.24	5	15.63	5.28 - 32.79	2	3.51	0.43 - 12.11	3	5.88	1.23 - 16.24
>20 days	1	25.00	0.63 - 80.59	1	25.00	0.63 - 80.59	5	15.63	5.28 - 32.79	5	8.77	2.91 - 19.30	5	9.80	3.26 - 21.41
Discharge Disposition															
Home	2	50.00	6.76 - 93.24	2	50.00	6.76 - 93.24	19	59.38	40.64 - 76.30	28	49.12	35.63 - 62.71	24	47.06	32.93 - 61.54
Nursing facility /ICF	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	1	3.13	0.08 - 16.22	2	3.51	0.43 - 12.11	5	9.80	3.26 - 21.41
Hospice	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	0	0.00	0.00 - 0.88	0	0.00	0.00 - 0.94	0	0.00	0.00 - 1.08
Hospital	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	1	3.13	0.08 - 16.22	2	3.51	0.43 - 12.11	3	5.88	1.23 - 16.24
Other/Unknown	2	50.00	6.76 - 93.24	2	50.00	6.76 - 93.24	3	9.38	1.98 - 25.02	5	8.77	2.91 - 19.30	6	11.76	4.44 - 23.87
Pneumonia															

Redacted

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Yes	3	7.50	1.57 - 20.39	3	6.98	1.46 - 19.06	21	4.84	3.02 - 7.30	29	7.18	4.86 - 10.15	33	9.38	6.54 - 12.91
Kidney failure															
Yes	1	2.50	0.06 - 13.16	1	2.33	0.06 - 12.29	14	3.23	1.77 - 5.35	28	6.93	4.65 - 9.86	16	4.55	2.62 - 7.28
Thrombotic event															
Yes	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	7	1.61	0.65 - 3.29	13	3.22	1.72 - 5.44	12	3.41	1.77 - 5.88
ARDS															
Yes	3	7.50	1.57 - 20.39	3	6.98	1.46 - 19.06	18	4.15	2.48 - 6.48	31	7.67	5.27 - 10.71	30	8.52	5.82 - 11.94
Heart failure															
Yes	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	7	1.61	0.65 - 3.29	24	5.94	3.84 - 8.71	14	3.98	2.19 - 6.58
Sepsis/septic shock															
Yes	2	5.00	0.61 - 16.92	2	4.65	0.57 - 15.81	10	2.30	1.11 - 4.20	19	4.70	2.85 - 7.25	9	2.56	1.18 - 4.80
Mechanical															

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
ventilation/ECMO															
Yes	1	2.50	0.06 - 13.16	1	2.33	0.06 - 12.29	3	0.69	0.14 - 2.01	4	0.99	0.27 - 2.52	5	1.42	0.46 - 3.28
IV immunoglobulin															
Yes	0	0.00	0.00 - 8.76	0	0.00	0.00 - 8.20	1	0.23	0.01 - 1.28	3	0.74	0.15 - 2.15	2	0.57	0.07 - 2.04

ł May not be mutually exclusive. Missing data are not presented
*The denominator is number of patients hospitalized
** within 90 days on or after the index date

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10.4.5. UC Sub-Cohort

In the UC sub-cohort, the numbers of patients exposed to tofacitinib and JAKi's were small (38 in both groups, versus >400 in each of the three other exposure groups) and outcome events were rare (<4) with correspondingly wide confidence intervals (Table 19).

Among hospitalized patients, in-hospital death was most frequent in the tofacitinib- and JAKi –exposed patients (2 of 5 patients or 40.0% in both; 95% CI 5.27%-85.34%) and least in the TNFi group (8.33%; 95% CI 1.03%-27.00%).

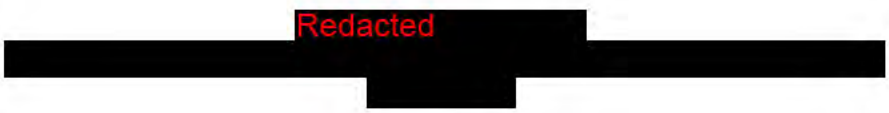
Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was also highest in the tofacitinib and JAKi groups (5.26% in both; 95% CI 0.64%-17.75%) and lowest in the TNFI group (0.50%; 95% CI 0.06%-1.79%).

The modal length of hospital stay was 6-10 days in the TNFi group, tied for 3-5 days and 6-10 days in the tofacitinib and JAKi groups, 1-2 days in the non-TNFi group, and 3-5 days in the csDMARD group.

Modal discharge disposition (with non-trivial missingness) was "home" for the TNFi, non-TNFi, and csDMARD groups, ranging from 43.11% (95% CI 35.49%-50.99%) in the non-TNFi group to 54.17% (95% CI 32.82%-74.45%) in the TNFi group. "Other/Unknown" was the modal discharge disposition category in the tofacitinib and JAKi groups (40% in both; 95% CI 5.27%-85.34%).

As in the PsA sub-cohort, of the six health outcome conditions assessed, the most frequent outcome in all exposure classes except the non-TNFi group was pneumonia. Also, as in the PsA sub-cohort, ARDS was the most common in the non-TNFi group. Kidney failure was the second-most common outcome in the TNFi and non-TNFi groups and ARDS was the second-most common outcome in the csDMARD group. The third most common outcome in the TNFi, non-TNFi, and csDMARD groups were, respectively, ARDS, pneumonia, and kidney failure. Tied for the most frequent health outcomes in the tofacitinib and JAKi groups were pneumonia and sepsis/septic shock (3 events of each in both groups) and tied for second-most common in both groups were kidney failure, thrombotic events, and heart failure (2 events of each in both groups). Across all exposure groups, the most common outcome was ARDS in the non-TNFi group (11.58%; 95% CI 9.20%-14.32%). The non-TNFi group had the highest occurrence of all six outcomes and the TNFi group had the lowest occurrence of five of the six outcomes.

Mechanical ventilation/extracorporeal membrane oxygenation (ECMO) occurred during SARS-CoV-2 hospitalization most frequently in the tofacitinib and JAKi groups (2 patients in each, or 5.26%; 95% CI 0.64%-17.75%) and least frequently in the TNFi group (0.75%; 95% CI 0.15%-2.17%).



IV Immunoglobulin use occurred during SARS-CoV-2 hospitalization most frequently in the non-TNFi group (0.94%; 95% CI 0.35%-2.03%) and never occurred in the tofacitinib and JAKi groups.

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Table 19. Incidence Proportions of Secondary Outcomes In UC Patients Within Baseline Treatment Strata

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Total of Covid-19 patients in ALL indication and non-indication cohorts N=1,385,530															
Covid 19 Patients in sub-cohorts															
Sub total	**38**	100		**38**	100		**401**	100		**639**	100		**1040**	100	
Secondary Endpoints															
SARS diagnosis site															
Inpatient	4	10.53	2.94 - 24.80	4	10.53	2.94 - 24.80	15	3.74	2.11 - 6.09	122	19.09	16.12 - 22.36	86	8.27	6.67 - 10.11
Outpatient	21	55.26	38.30 - 71.38	21	55.26	38.30 - 71.38	229	57.11	52.10 - 62.01	351	54.93	50.98 - 58.84	579	55.67	52.59 - 58.72
ICU	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	0	0.00	0.00 - 0.95	3	0.47	0.10 - 1.37	11	1.06	0.53 - 1.88
ER	3	7.89	1.66 - 21.38	3	7.89	1.66 - 21.38	87	21.70	17.76 - 26.06	132	20.66	17.58 - 24.01	188	18.08	15.78 - 20.55
Other/Unknown	22	57.89	40.82 - 73.69	22	57.89	40.82 - 73.69	272	67.83	63.01 - 72.38	387	60.56	56.65 - 64.37	635	61.06	58.02 - 64.03
In hospital death*															
Yes	2	40.00	5.27 - 85.34	2	40.00	5.27 - 85.34	2	8.33	1.03 - 27.00	21	12.57	7.96 - 18.58	21	14.89	9.46 - 21.86

Redacted

	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
All-cause mortality **															
Yes	2	5.26	0.64 - 17.75	2	5.26	0.64 - 17.75	2	0.50	0.06 - 1.79	27	4.23	2.80 - 6.09	30	2.88	1.95 - 4.09
Length of hospital stay															
1 - 2 days	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	4	16.67	4.74 - 37.38	37	22.16	16.11 - 29.22	21	14.89	9.46 - 21.86
3 -5 days	2	40.00	5.27 - 85.34	2	40.00	5.27 - 85.34	4	16.67	4.74 - 37.38	32	19.16	13.49 - 25.96	47	33.33	25.63 - 41.76
6 - 10 days	2	40.00	5.27 - 85.34	2	40.00	5.27 - 85.34	10	41.67	22.11 - 63.36	34	20.36	14.53 - 27.27	29	20.57	14.23 - 28.18
11-15 days	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	2	8.33	1.03 - 27.00	25	14.97	9.93 - 21.30	19	13.48	8.31 - 20.24
16-20 days	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	1	4.17	0.11 - 21.12	15	8.98	5.11 - 14.38	11	7.80	3.96 - 13.53
>20 days	1	20.00	0.51 - 71.64	1	20.00	0.51 - 71.64	3	12.50	2.66 - 32.36	24	14.37	9.43 - 20.62	14	9.93	5.54 - 16.10
Discharge Disposition															
Home	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	13	54.17	32.82 - 74.45	72	43.11	35.49 - 50.99	74	52.48	43.91 - 60.95
Nursing facility /ICF	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	0	0.00	0.00 - 0.95	17	10.18	6.04 - 15.80	19	13.48	8.31 - 20.24
Hospice	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	0	0.00	0.00 - 0.95	1	0.60	0.02 - 3.29	1	0.71	0.02 - 3.89

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
Hospital	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	1	4.17	0.11 - 21.12	11	6.59	3.33 - 11.48	6	4.26	1.58 - 9.03
Other/Unknown	2	40.00	5.27 - 85.34	2	40.00	5.27 - 85.34	4	16.67	4.74 - 37.38	23	13.77	8.94 - 19.95	16	11.35	6.63 - 17.77
Pneumonia															
Yes	3	7.89	1.66 - 21.38	3	7.89	1.66 - 21.38	18	4.49	2.68 - 7.00	64	10.02	7.80 - 12.61	92	8.85	7.19 - 10.74
Kidney failure															
Yes	1	2.63	0.07 - 13.81	1	2.63	0.07 - 13.81	12	2.99	1.56 - 5.17	73	11.42	9.06 - 14.15	53	5.10	3.84 - 6.61
Thrombotic event															
Yes	1	2.63	0.07 - 13.81	1	2.63	0.07 - 13.81	8	2.00	0.87 - 3.89	35	5.48	3.84 - 7.54	32	3.08	2.11 - 4.32
ARDS															
Yes	2	5.26	0.64 - 17.75	2	5.26	0.64 - 17.75	10	2.49	1.20 - 4.54	74	11.58	9.20 - 14.32	81	7.79	6.23 - 9.59
Heart failure															
Yes	1	2.63	0.07 - 13.81	1	2.63	0.07 - 13.81	1	0.25	0.01 - 1.38	43	6.73	4.91 - 8.96	46	4.42	3.26 - 5.86
Sepsis/septic shock															
Yes	3	7.89	1.66 - 21.38	3	7.89	1.66 - 21.38	5	1.25	0.41 - 2.89	58	9.08	6.96 - 11.58	33	3.17	2.19 - 4.43
Mechanical															

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	Tofacitinib (Overall)			JAK inhibitors (Overall)			TNFi (Overall)			non-TNFi (Overall)			csDMARD		
	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI	Number of Patients	Incidence Proportion	95% CI
ventilation/ECMO															
Yes	2	5.26	0.64 - 17.75	2	5.26	0.64 - 17.75	3	0.75	0.15 - 2.17	17	2.66	1.56 - 4.23	15	1.44	0.81 - 2.37
IV immunoglobulin															
Yes	0	0.00	0.00 - 9.18	0	0.00	0.00 - 9.18	1	0.25	0.01 - 1.38	6	0.94	0.35 - 2.03	4	0.38	0.10 - 0.98

‡ May not be mutually exclusive. Missing data are not presented
*The denominator is number of patients hospitalized
** within 90 days on or after the index date

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10.5. Other Analyses

None.

10.6. Adverse Events/Adverse Reactions

This study involved data that existed as structured data by the time of study start or a combination of existing structured data and unstructured data, which were converted to structured form during the implementation of the protocol solely by a computer using automated/algorithmic methods, such as natural language processing. In these data sources, individual patient data were not retrieved or validated, and it was not possible to link (ie, identify a potential association between) a particular product and medical event for any individual. Thus, the minimum criteria for reporting an adverse event (AE) (ie, identifiable patient, identifiable reporter, a suspect product, and event) cannot be met.

11. DISCUSSION

11.1. Key Results

11.1.1. Baseline Demographics, Comorbidities, and Systemic Treatments in the Four Sub-Cohorts

In this study, there were 9,186 patients in the RA sub-cohort, 1,812 in the PsA sub-cohort, 3,354 in the UC sub-cohort, and 1,371,178 in the non-indicated cohort.

Among the four sub-cohorts, RA patients had the oldest mean age, and the non-indicated cohort had the youngest mean age. Female patients and White patients comprised the majorities in all four cohorts. Relative to their respective distributions in the US population, Black patients were underrepresented among PsA and UC patients and Asian patients were underrepresented in all four patient cohorts. Patients living in the Midwest were the modal geographic group in the four sub-cohorts. Patients receiving commercial insurance were the modal payor group in each of the four sub-cohorts.

In the three indicated sub-cohorts, the most prevalent comorbidities were, in order: hypertension, hyperlipidemia, corticosteroid use, and diabetes. In the non-indicated sub-cohort, the four leading comorbidities were the same, although diabetes was more prevalent than corticosteroid use. Prevalence of all four leading comorbidities was highest in the RA sub-cohort and lowest in the non-indicated sub-cohort.

In the RA and UC sub-cohorts, patients were most likely to have a treatment history with csDMARDs, whereas PsA patients were most likely to have been exposed to TNFi's. Patients in all three indicated sub-cohorts were least likely to have been exposed to tofacitinib. The treatment history of patients in the non-indicated sub-cohort was not ascertained.

11.1.2. Primary Outcomes in the Four Sub-Cohorts

Hospitalization in the 30 days post-SARS-CoV-2 diagnosis, and ICU admission during the same period, were both most frequent among RA patients and least frequent among PsA patients.

11.1.3. Secondary Outcomes in the Four Sub-Cohorts

In the four sub-cohorts, frequency of all secondary endpoints was highest in RA patients and most often (though not always) lowest in PsA patients.

Of hospitalized patients, in-hospital death was most frequent for RA patients and least frequent for UC patients. Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was highest for RA patients and lowest for PsA patients. Modal length of hospital stay was 6-10 days for RA patients, 3-5 and 6-10 days for PsA patients; 6-10 days for UC patients; and 3-5 days for non-indicated patients. Modal discharge disposition was "home" for all four sub-cohorts, though the percentage falling into this

category was lowest for RA patients. Of the six health outcome conditions assessed, the two most prevalent in all four sub-cohorts were pneumonia and acute respiratory distress syndrome (ARDS) (with the order varying between sub-cohorts). The occurrence of each was never higher than 14.60% or lower than 7.06%. Kidney failure was the third most frequent health outcome in all four sub-cohorts. Thrombotic events, heart failure, and sepsis/septic shock were the three least common health outcomes of those assessed in all four sub-cohorts.

Mechanical ventilation/extracorporeal membrane oxygenation (ECMO) occurred during SARS-CoV-2 hospitalization most frequently in RA patients and least frequently in PsA patients. IV Immunoglobulin use occurred during SARS-CoV-2 hospitalization most frequently in RA patients and least frequently in the non-indicated sub-cohort.

11.1.4. Baseline Demographics and Comorbidities in the Three Indicated Sub-Cohorts Within Baseline Treatment Strata

In RA patients, TNFi patients had the youngest mean age and csDMARD patients the oldest. Females comprised a large majority in all treatment groups. The share of patients exposed to tofacitinib, JAKi's, TNFi's, and non-TNFi's who were Black increased and who were White decreased in stepwise fashion across these four treatment categories, respectively. Each group's share of csDMARD patients fell in the middle of these respective ranges. The share of patients who were Asian was smallest in the csDMARD-exposed group and largest in the JAKi group.

In PsA patients, as with RA patients, TNFi-exposed patients had the youngest mean age and csDMARD-exposed patients the oldest. Females comprised a majority in each of the treatment groups. Regarding race groups among PsA patients, baseline treatment data on Black and Asian patients were limited and they comprised ≤ 3.0% of all treatment groups.

In UC patients, as with RA and PsA patients, TNFi-exposed patients had the youngest mean age and csDMARD-exposed patients the oldest. Females comprised a majority in each of the treatment groups. No race patterns were evident in the treatment categories. White patients' share was largest in the csDMARD group and smallest in the JAKi and tofacitinib groups. Black patients' share was largest in the non-TNFi group and smallest in the TNFi group. Asian patients' share was largest in the JAKi and tofacitinib groups and smallest in the non-TNFi group, although their cell sizes across treatment groups were small, ranging from 1 to 20.

11.1.5. Primary Outcomes in the Three Indicated Sub-Cohorts Within Baseline Treatment Strata

In the RA sub-cohort, hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among non-TNFi-exposed patients and least among TNFi-exposed patients. ICU admissions among hospitalized patients were most frequent among tofacitinib-exposed patients and least among TNFi-exposed patients.

In the PsA sub-cohort, hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among csDMARD-exposed patients and least among TNFi-exposed patients. ICU admissions among hospitalized patients were most frequent among tofacitinib-exposed patients and least among TNFi-exposed patients.

In the UC sub-cohort, hospitalization in the 30 days post-SARS-CoV-2 diagnosis was most frequent among non-TNFi-exposed patients and least among TNFi-exposed patients. ICU admissions among hospitalized patients were most frequent among non-TNFi-exposed patients and least among TNFi-exposed patients.

11.1.6. Secondary Outcomes in The Three Indicated Sub-Cohorts Within Baseline Treatment Strata

11.1.6.1. RA Sub-Cohort

In the RA sub-cohort, among hospitalized patients, in-hospital death was most frequent in the csDMARD and tofacitinib patients and least in the TNFi patients. Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was highest in csDMARD patients and lowest in TNFI patients.

Modal length of hospital stay was 6-10 days for tofacitinib, non-TNFi, and csDMARD patients and 3-5 days for JAKi and TNFi patients. Modal discharge disposition was "home" for all five exposure categories.

Of the six health outcome conditions assessed, the most and second-most frequent outcomes were ARDS and pneumonia, respectively, in all treatment classes except TNFi. In the TNFi patients, this order was reversed. The non-TNFi patients had the highest occurrence of all six outcomes and the TNFi patients the lowest.

ECMO occurred during SARS-CoV-2 hospitalization most frequently in the tofacitinib patients and least frequently in TNFi-exposed patients.

IV Immunoglobulin use occurred during SARS-CoV-2 hospitalization most frequently in non-TNFi patients and never occurred in the tofacitinib and JAKi patients.

11.1.6.2. PsA Sub-Cohort

In the PsA sub-cohort, the numbers of patients exposed to tofacitinib and JAKi's were small (40 and 43, respectively, versus >350 in each of the three other exposure groups) and outcome events were rare (<4) with correspondingly wide confidence intervals.

Among hospitalized patients, in-hospital death was most frequent in the tofacitinib and JAKi patients and least frequent in the csDMARD patients. Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was highest in the tofacitinib patients and lowest in the TNFI patients.

Modal length of hospital stay was 16-20 days in tofacitinib and JAKi patients (2 of 4 hospitalized patients in both groups), 6-10 days in the csDMARD patients, and 3-5 days in the TNFi and non-TNFi patients. Modal discharge disposition was "home" for all five treatment groups.

Of the six health outcome conditions assessed, the most frequent outcome in all treatment groups except the non-TNFi group was pneumonia. ARDS was the most common in the non-TNFi group and was tied for most common among the tofacitinib and JAKi groups. Second-most common was either sepsis/septic shock (in the tofacitinib and JAKi groups), ARDS (in the TNFi and csDMARD groups), and pneumonia (in the non-TNFi group). Kidney failure was the third most common health outcome in all five exposure groups.

ECMO and IV Immunoglobulin use occurring during SARS-CoV-2 hospitalization were both rare, never occurring in more than 5 patients, or 2.50%, in any treatment group. In all cases, confidence intervals were wide.

11.1.6.3. UC Sub-Cohort

In the UC sub-cohort, the numbers of patients exposed to tofacitinib and JAKi's were small (38 in both groups, versus >400 in each of the three other exposure groups) and outcome events were rare (<4) in both exposure groups, with correspondingly wide confidence intervals.

Among hospitalized patients, in-hospital death was most frequent in the tofacitinib and JAKi patients and least frequent the TNFi group. Frequency of all-cause mortality within 90 days following SARS-CoV-2 diagnosis was also highest in the tofacitinib and JAKi groups and lowest in the TNFI group.

Modal length of hospital stay was 6-10 days in the TNFi group, tied for 3-5 days and 6-10 days in the tofacitinib and JAKi groups, 1-2 days in the non-TNFi group, and 3-5 days in the csDMARD group. Modal discharge disposition was "home" for the TNFi, non-TNFi, and csDMARD groups. "Other/Unknown" was the modal discharge disposition category in the tofacitinib and JAKi groups.

As in the PsA sub-cohort, of the six health outcome conditions assessed, the most frequent outcome in all exposure classes except the non-TNFi group was pneumonia. Also as in the PsA sub-cohort, ARDS was the most common in the non-TNFi group. Kidney failure was the second-most common outcome in the TNFi and non-TNFi groups and ARDS was the second-most common outcome in the csDMARD group. The third most common outcome in the TNFi, non-TNFi, and csDMARD groups were, respectively, ARDS, pneumonia, and kidney failure. Tied for the most frequent health outcomes in the tofacitinib and JAKi groups were pneumonia and sepsis/septic shock and tied for second-most common in both groups were kidney failure, thrombotic events, and heart failure. The non-TNFi group had the highest occurrence of all six outcomes and the TNFi group had the lowest occurrence of five of the six outcomes.

ECMO occurred during SARS-CoV-2 hospitalization most frequently in the tofacitinib and JAKi groups and least frequently in the TNFi group. IV Immunoglobulin use occurred during SARS-CoV-2 hospitalization most frequently in the non-TNFi group and never occurred in the tofacitinib and JAKi groups.

11.2. Limitations

The Optum database is large and covers all four US geographic regions; however, limitations that are general to all claims database analyses as well as those specific to this study should be noted.

Diagnoses of immune-mediated inflammatory diseases were identified using ICD-10-CM diagnosis codes, which are subject to potential miscoding, though presumably without respect to the treatment or outcomes.

The baseline period of this study was of limited duration and thus baseline comorbidities occurring outside this period may not have been captured, which may have led to an undercount of these factors.

Information on prescriptions for outpatients does not necessarily indicate that the medication was consumed or taken as prescribed; similarly, medications filled over-the-counter or provided as samples by the physician are not recorded in the database. Accordingly, baseline treatment strata are subject to misclassification.

The numbers of PsA and UC patients taking tofacitinib or JAKi's was small (<44 in each condition/treatment subgroup) which resulted in unreliable outcome estimates in these patient groups.

The analyses did not adjust for potential confounding. Therefore, observed associations between drugs and outcomes may be due to confounding and causal inference about these associations would be inappropriate. For example, in all three indicated sub-cohorts, the frequency of most of the comorbidities was greatest in the non-TNFi patients. Accordingly, the worse outcomes generally observed in non-TNFi patients vs. the other treatment groups is likely confounded by their worse baseline health.

11.3. Interpretation

See Section 11.1 and Section 11.2 above.

11.4. Generalizability

Although the sample size in each of the four sub-cohorts was large (>1,812) and was socio-demographically diverse, the Midwest and Northeast regions were overrepresented, and the South and West regions were underrepresented. To the extent the relationships assessed in this study vary across these regions, the results may not generalize to the United States. Further, the results' generalizability outside of the United States should not be assumed.

12. OTHER INFORMATION

Not applicable.

13. CONCLUSIONS

In a sample of patients with SARS-CoV-2 infection, this study assessed clinical outcomes in RA, PsA, and UC patients, and in a comparison sample of patients without these indications. Additionally, clinical outcomes were compared between strata of baseline systemic therapies (tofacitinib, JAKi's, TNFi's, non-TNFi's, and csDMARDs) in each of the three indicated sub-cohorts. Generally, RA patients had the worst outcomes compared with the other three sub-cohorts. Among the indicated sub-cohorts, the number of PsA and UC patients exposed to tofacitinib and JAKi's at baseline was small, resulting in unstable estimates of outcomes in these patients. Those exposed to non-TNFi's at baseline tended to have the worst outcomes and those exposed to TNFi's at baseline tended to have the best outcomes; however, confounding by worse baseline health in non-TNFi-exposed patients likely accounts for non-trivial proportions of the observed differences. Because the study did not adjust for potential confounding, causal inference regarding the observed associations is not warranted.

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15. LIST OF SOURCE TABLES AND FIGURES

Not Applicable.

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Signed By:	Date(GMT)	Signing Capacity
Redacted	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]