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PROPRIETARY DRUG NAME® / GENERIC DRUG NAME: Xeljanz® / Tofacitinib

PROTOCOL NO.: A3921064

PROTOCOL TITLE: Phase 3 Randomized, Double-Blind, Active Comparator, Placebo-Controlled Study of the Efficacy and Safety of 2 Doses of CP-690,550 in Patients with Active Rheumatoid Arthritis on Background Methotrexate

Study Centers: In total 105 centers took part in the study and randomized subjects: 25 centers in the United States, 8 centers in Czech Republic, 7 centers in Germany, 7 centers in Poland, 6 centers in Slovakia, 6 centers in Bulgaria, 6 centers in Canada, 5 centers in Spain, 4 centers in Republic of Korea, 4 centers in Australia, 4 centers in Mexico, 4 centers in Chile, 3 centers in Costa Rica, 3 centers in Croatia, 3 centers in United Kingdom, 3 centers in Philippines, 2 centers in Denmark, 2 centers in Thailand, 1 center in Dominican Republic, 1 center in Bosnia and Herzegovina, and 1 center in Finland.

Study Initiation and Final Completion Dates: 20 May 2009 to 10 March 2011

Phase of Development: Phase 3

Study Objectives:

Primary Objectives:

There were 4 primary objectives, to be assessed in the following sequence:

- To compare the efficacy of tofacitinib in doses of 5 and 10 mg twice daily (BID) versus placebo for the treatment of signs and symptoms of rheumatoid arthritis (RA) in subjects with active RA on a stable background of methotrexate (MTX), as measured by American College of Rheumatology (ACR) definition for improvement in RA, calculated as a ≥20% improvement in tender and swollen joint counts and ≥20% improvement in 3 of the 5 remaining ACR core set measures (ACR20) response rates at Month 6.

- To compare physical function status of subjects after administration of 5 and 10 mg BID of tofacitinib versus placebo using the Health Assessment Questionnaire-Disability Index (HAQ-DI) at Month 3 compared to Baseline in subjects with active RA on a stable background of MTX.

- To compare the rate of achieving DAS28-4 (erythrocyte sedimentation rate [ESR]) <2.6 at Month 6 after administration of 5 and 10 mg BID of tofacitinib versus placebo in subjects with active RA on stable background MTX.

- To evaluate the safety and tolerability over 12 months of tofacitinib in doses of 5 and 10 mg BID versus placebo in subjects with active RA on a stable background of MTX.

Secondary Objectives:

- To compare the efficacy of oral tofacitinib in doses of 5 and 10 mg BID plus MTX versus placebo plus MTX for the treatment of signs and symptoms of RA at all other time points as measured by ACR20, ACR50 (ACR definition for calculating improvement in RA; calculated as a ≥50% improvement in tender and swollen joint counts and ≥50% improvement in 3 of the 5 remaining ACR core set measures), ACR70 (ACR definition for calculating improvement in RA, calculated as a ≥70% improvement in tender and swollen joint counts and ≥70% improvement in 3 of the 5 remaining ACR core set measures), and Disease Activity Score (DAS)28 response rates.

- To compare the efficacy of adalimumab 40 mg administered subcutaneously (SC) every 2 weeks versus placebo for the treatment of signs and symptoms in subjects with active RA on a stable background of MTX at all time points as measured by ACR20, ACR50, ACR70, and DAS28 response rates.

- To compare the durability of ACR20, ACR50, ACR70, and DAS28 response rates.

- To compare the incidence of DAS28 remission and low disease activity state at each visit.

- To compare effects on all health outcomes measures in the study at each visit, as appropriate for the specific outcome, compared to Baseline.

- To estimate the efficacy of adalimumab 40 mg subcutaneous (SC) every 2 weeks versus tofacitinib in doses of 5 and 10 mg BID for the treatment of signs and symptoms in subjects with active RA on a stable background of MTX at all time points as measured by ACR20, ACR50, ACR70, and DAS28 response rates.

METHODS

Study Design: This was a Phase 3 randomized, 1-year, double-blind, placebo-controlled, parallel-group study. Subjects were randomized in a 4:4:1:1:4 ratio to 1 of the 5 parallel treatment sequences, as indicated in Table 1. At the Month 3 visit, the tender/painful and swollen joint counts were calculated and compared to the subject's individual baseline values. If there was not a 20% improvement in both the tender/painful and swollen joint counts, the subject was considered a nonresponder subject. If a nonresponder subject was randomized to active treatment (Treatment Sequences 1, 2, or 5), that subject was to remain on the same treatment, at the same dose, for the duration of the study. If a nonresponder subject was randomized to Treatment Sequences 3 or 4, that subject was to be advanced to the second predetermined treatment in a blinded manner for the remainder of the study by the drug allocation system. At the end of Month 6, all subjects were automatically advanced to their second predetermined treatment in a blinded fashion for the remainder of the study.

The schedule of activities is shown in Table 2.

Table 1. Randomization Treatment Sequences

Treatment Sequence	N	Double-Blind Placebo-Controlled Period[a]	Double-Blind Active-Extension Period[b]
Sequence 1	200	Tofacitinib 5 mg BID + q2w placebo SC injections	Tofacitinib 5 mg BID + q2w placebo SC injections
Sequence 2	200	Tofacitinib 10 mg BID + q2w placebo SC injections	Tofacitinib 10 mg BID + q2w week placebo SC injections
Sequence 3	50	Placebo + q2w placebo SC injections	Tofacitinib 5 mg BID + q2w placebo SC injections
Sequence 4	50	Placebo + q2w placebo SC injections	Tofacitinib 10 mg BID + q2w placebo SC injections
Sequence 5	200	Placebo + adalimumab 40 mg q2w SC injections	Placebo + adalimumab 40 mg q2w SC injections

BID = twice daily; N = the planned number of subjects for each treatment sequence; q2w = every 2 weeks; SC = subcutaneous.

a. 3 to 6-month duration; response was assessed at Month 3, and nonresponsive subjects were advanced to the double-blind, active-extension period.

b. All subjects had entered this period by Month 6.

Table 2. Schedule of Activities

	Screening[a]	Visits					
		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
		Baseline Day 0	Month 1	Month 3	Month 6	Month 9	Month 12/End of the Study
Informed consent	X						
RA diagnosis, medical history[b]	X						
Concomitant medications	X	X	X	X	X	X	X
Complete physical examination	X	X					X
Targeted physical examination[c]			X	X	X	X	
Vital signs, temperature	X	X	X	X	X	X	X
QuantiFERON-TB Gold or PPD	X						
Radiograph of chest[d]	X						
12-lead electrocardiogram	X						X
Blood/Urine							
Rheumatoid factor, anti-CCP		X					X
Hematology[e] and chemistry panel[f]	X	X	X	X	X	X	X
Lipid profile (fasting)[g]		X	X	X	X	X	X
Hematology & chemistry laboratory tests[h]		← As appropriate for standard of care →					
Urinalysis/urine pregnancy test (HCG)[i]	X	X	X	X	X	X	X
Stool examination for parasites (Brazil only)	X						
Molecular profiling sampling (pharmacogenomic)[j]		X	X	X	X		X
Tofacitinib and adalimumab pharmacokinetics[k]				X	X		X
HIV serology, HbsAg, HCV Ab	X						
ACR/DAS							
C-reactive protein	X	X	X	X	X	X	X
Erythrocyte sedimentation rate[l]	X	X	X	X	X	X	X
Tender/painful joint count, swollen joint count	X	X	X	X	X	X	X
Patient Assessment of Arthritis Pain		X	X	X	X	X	X
Patient Global Assessment of Arthritis		X	X	X	X	X	X

Table 2. Schedule of Activities

	Screening[a]	Visits					
		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
		Baseline Day 0	Month 1	Month 3	Month 6	Month 9	Month 12/End of the Study
Physician Global Assessment of Arthritis		X	X	X	X	X	X
Health Assessment Questionnaire – Disability Index		X	X	X	X	X	X
SF-36 (version 2, acute)		X	X	X	X	X	X
MOS Sleep Scale/FACIT - Fatigue Scale		X	X	X	X		X
EuroQoL EQ-5D		X	X	X	X		X
RA Healthcare Resource Utilization Questionnaire		X		X	X		X
Work Limitations Questionnaire		X		X	X		X
Randomization		X					
Drug dispensing		X		X	X	X	
Drug accountability				X	X	X	X
Adverse event reporting		X	X	X	X	X	X
Review entry criteria for extension study (NCT00413699, a long-term, open-label follow-up study of tofacitinib (for treatment of rheumatoid arthritis)							X

ACR = American College of Rheumatology; CCP = cyclic citrullinated peptide; DAS = disease activity score; EQ-5D = Self-Report Questionnaire (quality of life instrument) developed by the European Quality of Life (EuroQoL) Group; EuroQoL = European Quality of Life [Group]; FACIT = Functional Assessment of Chronic Illness Therapy; HBsAg = hepatitis B surface antigen; HCG = human chorionic gonadotrophin; HCV Ab = hepatitis C virus antibody; HIV = human immunodeficiency virus; MOS = Medical Outcomes Study; pH = -log of hygrogen; PPD = purified protein derivative Tuberculin test; RA = rheumatoid arthritis; SF-36 = Short Form-36; TB = tuberculosis.

a. Screening Visit occurred within 1 month prior to the Baseline Visit.
b. Medical history included smoking status, average weekly alcohol consumption, and family history of premature coronary heart disease.
c. Targeted physical examination consisted of weight, examination of heart, lungs, abdomen, lower extremities for peripheral edema, and lymph nodes.
d. Radiograph of chest was to be performed unless performed and documented within 3 months of Screening Visit.
e. Hematology included red blood cell count, white blood cell count (with differential), hemoglobin, hematocrit, and platelet count.
f. Safety chemistry laboratories included: sodium, potassium, chloride, bicarbonate, calcium, glucose, blood urea nitrogen, total protein, creatinine, creatine kinase, bilirubin (direct, indirect, and total), alkaline phosphatase, gamma-glutamyl transferase, aspartate aminotransferase, alanine aminotransferase, albumin and serum creatinine.
g. Lipid profile included fasting total cholesterol, low- and high-density lipoprotein cholesterol, and triglycerides, and might have included fasting apolipoprotein A-1 and B and other lipoprotein tests, potentially including particle size measurements.

Table 2. Schedule of Activities

	Screening[a]	Visits					
		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
		Baseline Day 0	Month 1	Month 3	Month 6	Month 9	Month 12/End of the Study

h. Hematology and safety chemistry laboratory tests as appropriate for standard of care in subjects receiving methotrexate; may have included creatinine, albumin, and liver function tests.
i. Urinalysis included specific gravity, pH, protein, glucose, ketones, and blood. Urinary pregnancy testing (HCG) was required only for women who were of childbearing potential, and may have been repeated more frequently if required by local practices, if a menstrual cycle was missed, or if potential pregnancy was otherwise suspected.
j. Only at participating sites.
k. Serum samples were collected to determine tofacitinib or adalimumab pharmacokinetics prior to dosing.
l. Collected only at sites where local laboratory had the capability of reporting results to the central laboratory.

Number of Subjects (Planned and Analyzed): In total, 700 subjects were planned to be enrolled in this study. A total of 717 subjects were randomized to treatment (204 to tofacitinib 5 mg group, 201 to tofacitinib 10 mg group, 56 to placebo→tofacitinib 5 mg BID, 52 to placebo→tofacitinib 10 mg BID, and 204 to adalimumab 40 mg group). All 717 subjects received at least 1 dose of study medication; 556 subjects (77.5%) completed the study.

Diagnosis and Main Criteria for Inclusion:

Inclusion Criteria: Males and females at least 18 years of age with diagnosis of RA based upon ACR 1987 revised criteria, with an inadequate response to MTX and active disease (as defined by both: ≥6 joints tender or painful on motion; and: ≥6 joints swollen), who fulfilled 1 of the following 2 criteria at screening: 1) erythrocyte sedimentation rate (ESR, Westergren method) >28 mm in the local laboratory; 2) C-reactive protein (CRP) >7 mg/L in the central laboratory, with no evidence of active or latent or inadequately treated infection with *Mycobacterium tuberculosis* were enrolled in the study. Subjects must have been on a stable dose of 7.5 mg to 25 mg weekly of MTX and washed out of all other disease-modifying anti-rheumatic drugs (DMARDs).

Exclusion Criteria: Subjects with blood dyscrasias including confirmed: 1) hemoglobin <9 g/dL or hematocrit <30%; 2) white blood cell count <3000 mm^3; 3) absolute neutrophil count <1200 mm^3; 4) platelet count <100,000/L, subjects with history of any other autoimmune rheumatic disease other than Sjogren's syndrome, subjects with malignancy or history of malignancy, subjects with history of infection requiring hospitalization, parenteral antimicrobial therapy, or as otherwise judged clinically significant by the Investigator within the 6 months prior to the first dose of study drug, subjects who had failed any tumor necrosis factor inhibitor (TNFi) for either lack of efficacy or a TNFi mechanism-related adverse event, subjects who had previously received adalimumab therapy for any reason, subjects who were contraindicated for treatment with adalimumab in accordance with the approved local label, and subjects meeting the NewYork Heart Association Class III and Class IV congestive heart failure were excluded from the study.

Study Treatment:

The subjects were randomized in a 4:4:1:1:4 ratio to 1 of the following treatment sequences: tofacitinib 5 mg BID; tofacitinib 10 mg BID; placebo → tofacitinib 5 mg; placebo → tofacitinib 10 mg, or adalimumab, respectively. Tofacitinib (citrate salt formulation) was provided as tablets with corresponding matching placebo. Study medication was self-administered by the subject. Tablet study drug was permitted to be taken with or without food, other than on study visit days where fasting was required. Subjects were instructed to take their tablet study drug twice daily (once in the morning and once in the evening) and it was suggested that tablet study drug be administered approximately 12 hours apart. Subjects were instructed to administer their injectable study drug once every other week; on weeks when study visits were scheduled, the injection was to occur after their study visit was completed. Background MTX was to be administered either orally or parenterally in a dose and frequency consistent with the requirements of the inclusion criteria. Study treatment was administered for 12 months in this study.

Efficacy Endpoints:

Signs & Symptoms:

- ACR20 responder rates analyzed at all timepoints;
- ACR50 and ACR70 responder rates at all timepoints;
- Disease activity score (DAS)28-3 and DAS28-4 (CRP) at all timepoints;
- DAS28-3 and DAS28-4 (ESR) at all timepoints at participating sites (dependent upon availability of a local laboratory that could report directly to the central laboratory, to ensure blinding of data).

Physical Function and Patient Reported Outcomes:

Assessed at Baseline and Months 1, 3, 6, 9, and 12 / Early Termination:

- HAQ-DI;
- Patient Assessment of Arthritis Pain;
- Patient Global Assessment of Arthritis;
- Physician Global Assessment of Arthritis;
- SF-36 (Version 2, Acute).

Assessed at Baseline and Months 1, 3, 6, and 12 / Early Termination:

- FACIT – Fatigue Scale;
- Medical Outcomes Study (MOS) Sleep Scale.
- EuroQol EQ-5D;

Assessed at Baseline and Months 3, 6, and 12 / Early Termination:

- RA Healthcare Resource Utilization Questionnaire (RA-HCRU);
- Work Limitations Questionnaire;
- Rates of clinically meaningful decrease in the HAQ-DI (decrease of at least 0.22, 0.3, 0.5, or 0.8 units) “HAQ-DI (0.22)”, “HAQ-DI (0.30)”, “HAQ-DI (0.5)”, “HAQ-DI (0.8), respectively;
- Rate of advancement at Month 3;

- Rate of erroneous advancement at Month 3.

Safety Evaluations: Safety evaluations included monitoring for AEs, serious adverse events (SAEs), infections, serious infections, treated infections, potential Hy's Law Cases, as well as laboratory evaluations including abnormal test findings, physical examinations, vital signs, body weight, and electrocardiograms.

Statistical Methods:

Analysis Populations:

- The full analysis set (FAS) included all subjects who were randomized to the study and received at least 1 dose of the randomized study drug (tofacitinib, adalimumab, or placebo). The primary analysis population for this study was defined by the FAS.

- FAS subjects who had a protocol deviation thought to affect the efficacy analysis were excluded from the per-protocol (PP) efficacy analysis. Protocol deviations that would have excluded subjects from the PP set were defined before the randomization blind was broken.

- The safety analysis set was defined as those subjects who received at least 1 dose of the study drug (tofacitinib, adalimumab, or placebo).

Analysis of Primary Endpoints:

The 3 primary endpoints were analyzed for both dose groups of tofacitinib, as well as for the adalimumab and the placebo groups. The analyses were based on the FAS. For ACR20 and incidence of DAS28-4 (ESR) <2.6 at Month 6, the normal approximation for the difference in binomial proportions was used. For the change from Baseline in the HAQ-DI at Month 3, the mixed-effect model with repeated measures as "Treatment Effect Model" was used. To support the interpretation of the primary analyses, some robustness or sensitivity analyses were performed for each primary endpoint. However, the conclusions (statistical significance/superiority) for comparisons of all 3 primary endpoints between each dose of tofacitinib and placebo were purely based on results of the primary analyses. One of the robustness analyses was the PP analysis, that is, the same primary analysis for all 3 primary endpoints was conducted using the PP dataset rather than the FAS.

Analysis of Secondary Endpoints:

All the secondary analyses were based on the FAS.

Secondary analyses include the normal approximation for the difference in binomial proportions for the ACR variables (ACR20, ACR50, and ACR70) done in separate analyses. The binomial variables: DAS28 $\leq$3.2, DAS28 <2.6, DAS28 responses, and clinically meaningful decrease in HAQ-DI, were analyzed by considering the proportion of subjects responding to each endpoint and using the same normal approximation to the binomial for the analyses.

For change in HAQ-DI from Baseline to Month 6, the mixed-effect model with repeated measures as the Treatment Effect Model was used. In addition, change in HAQ-DI from Baseline after Month 6 was also analyzed for descriptive purposes; and the mixed effect model with repeated measures ("Sequence Effect Model") was applied as well to evaluate the effect post Month 6. Further analyses were conducted for the HAQ-DI actual values at each visit.

The durability of ACR20, ACR50, ACR70, and DAS28 response rates, as measured by the proportion of subjects who had sustained response at each visit was summarized by treatment sequence and by visit at which the response first started. The maximum consecutive visits after any response during the study were also summarized.

The number and percent of subjects for advancement at Month 3 and erroneous advancement at Month 3 was presented.

The other 6 components of the ACR criteria, DAS28, the 8 domains and 2 scores of SF-36, MOS-sleep scales, EuroQol EQ-5D, the 4 domain scores and the work loss index of Work Limitation Questionnaire (WLQ) and FACIT fatigue scale were each analyzed in the same way that HAQ-DI was analyzed. The data from the RA-HCRU was listed, and some summary statistics were generated.

Safety: Safety was summarized descriptively.

RESULTS

Subject Disposition and Demography:

Table 3 provides a summary of subject disposition by treatment sequence.

Table 3. Subject Disposition by Treatment Sequence

Number (%) of Subjects	Tofacitinib 5 mg	Tofacitinib 10 mg	Placebo → Tofacitinib 5 mg BID	Placebo → Tofacitinib 10 mg BID	Adalimumab 40 mg SC q2W
Screened: 1042					
Assigned to study treatment	204	201	56	52	204
Treated	204	201	56	52	204
Completed	150 (73.5)	158 (78.6)	47 (83.9)	39 (75.0)	162 (79.4)
Discontinued	54 (26.5)	43 (21.4)	9 (16.1)	13 (25.0)	42 (20.6)
Subject died	0	0	0	0	1 (0.5)
Related to study drug	25 (12.3)	22 (10.9)	5 (8.9)	5 (9.6)	22 (10.8)
Adverse event	19 (9.3)	15 (7.5)	2 (3.6)	2 (3.8)	16 (7.8)
Lack of efficacy	6 (2.9)	7 (3.5)	3 (5.4)	3 (5.8)	6 (2.9)
Not related to study drug	29 (14.2)	21 (10.4)	4 (7.1)	8 (15.4)	19 (9.3)
Adverse event	5 (2.5)	9 (4.5)	0	3 (5.8)	6 (2.9)
Lost to follow-up	2 (1.0)	1 (0.5)	0	0	0
Other	18 (8.8)	9 (4.5)	4 (7.1)	4 (7.7)	12 (5.9)
Subject no longer willing to participate in study	4 (2.0)	2 (1.0)	0	1 (1.9)	1 (0.5)
Analyzed for efficacy					
Per protocol analysis set	187 (91.7)	188 (93.5)	53 (94.6)	45 (86.5)	192 (94.1)
Full analysis set	201 (98.5)	199 (99.0)	56 (100.0)	51 (98.1)	201 (98.5)
Analyzed for safety					
Adverse events	204 (100.0)	201 (100.0)	56 (100.0)	52 (100.0)	204 (100.0)
Laboratory data	203 (99.5)	201 (100.0)	56 (100.0)	49 (94.2)	204 (100.0)

Discontinuations occurring outside the lag period were attributed to the last study treatment received.
BID = twice daily; q2w = every 2 weeks; SC = subcutaneous.

The demographic characteristics of the subjects in each sequence were similar to one another and to the overall study population (Table 4, Table 5 and Table 6, respectively).

Table 4. Demographic Characteristics (Tofacitinib BID)

Demographic Characteristic Parameter	Tofacitinib BID					
	5 mg			10 mg		
	Male N=30	Female N=174	Total N=204	Male N=33	Female N=168	Total N=201
Age (years), n (%):						
18-44	6 (20.0)	40 (23.0)	46 (22.5)	6 (18.2)	42 (25.0)	48 (23.9)
45-64	18 (60.0)	104 (59.8)	122 (59.8)	23 (69.7)	97 (57.7)	120 (59.7)
≥65	6 (20.0)	30 (17.2)	36 (17.6)	4 (12.1)	29 (17.3)	33 (16.4)
Mean (SD)	53.9 (12.5)	52.9 (11.9)	53.0 (11.9)	53.3 (9.2)	52.8 (12.3)	52.9 (11.8)
Range	30-74	22-83	22-83	35-70	19-75	19-75
Race, n (%):						
White	26 (86.7)	125 (71.8)	151 (74.0)	26 (78.8)	117 (69.6)	143 (71.1)
Black	0.0	4 (2.3)	4 (2.0)	0.0	3 (1.8)	3 (1.5)
Asian	3 (10.0)	28 (16.1)	31 (15.2)	5 (15.2)	23 (13.7)	28 (13.9)
Other	1 (3.3)	17 (9.8)	18 (8.8)	2 (6.1)	25 (14.9)	27 (13.4)
Weight (kg):						
Mean (SD)	82.2 (14.8)	70.0 (18.9)	71.8 (18.9)	81.6 (17.6)	71.5 (17.4)	73.1 (17.8)
Range	49.0-122.2	38.0-162.0	38.0-162.0	48.0-113.0	34.5-145.1	34.5-145.1
Body mass index (kg/m^2):						
Mean (SD)	26.7 (4.5)	27.1 (6.9)	27.0 (6.6)	26.8 (4.9)	27.7 (6.4)	27.5 (6.2)
Range	18.7-40.8	17.8-53.4	17.8-53.4	17.2-33.7	16.2-46.3	16.2-46.3
Height (cm):						
Mean (SD)	175.3 (7.4)	160.7 (7.7)	162.9 (9.2)	174.2 (7.2)	160.7 (7.6)	162.9 (9.1)
Range	162.0-190.0	140.0-183.0	140.0-190.0	164.0-190.0	140.0-180.0	140.0-190.0

Body mass index computed as weight/$(height/100)^2$.
BID = twice daily; N = number of subjects; n = number of subjects meeting prespecified criteria; SD = standard deviation.

Table 5. Demographic Characteristics (Placebo → Tofacitinib)

Demographic Characteristic Parameter	Placebo → Tofacitinib					
	5 mg			10 mg		
	Male N=13	Female N=43	Total N=56	Male N=13	Female N=39	Total N=52
Age (years), n (%):						
18-44	3 (23.1)	10 (23.3)	13 (23.2)	4 (30.8)	9 (23.1)	13 (25.0)
45-64	4 (30.8)	22 (51.2)	26 (46.4)	6 (46.2)	25 (64.1)	31 (59.6)
≥65	6 (46.2)	11 (25.6)	17 (30.4)	3 (23.1)	5 (12.8)	8 (15.4)
Mean (SD)	56.7 (15.8)	55.1 (13.2)	55.5 (13.7)	54.6 (13.5)	51.0 (13.7)	51.9 (13.7)
Range	26-74	23-76	23-76	33-79	18-75	18-79
Race, n (%):						
White	113 (100.0)	27 (62.8)	40 (71.4)	13 (100.0)	22 (56.4)	35 (67.3)
Black	0.0	1 (2.3)	1 (1.8)	0.0	2 (5.1)	2 (3.8)
Asian	0.0	9 (20.9)	9 (16.1)	0.0	11 (28.2)	11 (21.2)
Other	0.0	6 (14.0)	6 (10.7)	0.0	4 (10.3)	4 (7.7)
Weight (kg):						
Mean (SD)	76.8 (13.1)	64.9 (13.5)	67.7 (14.2)	87.6 (28.9)	66.0 (20.3)	71.4 (24.3)
Range	50.2-105.0	40.0-106.0	40.0-106.0	66.7-151.9	35.0-135.2	35.0-151.9
Body mass index (kg/m^2):						
Mean (SD)	25.5 (3.9)	25.0 (4.4)	25.1 (4.3)	28.5 (7.1)	25.7 (5.5)	26.4 (6.0)
Range	19.1-33.4	16.4-38.0	16.4-38.0	22.4-43.0	16.6-41.7	16.6-43.0
Height (cm):						
Mean (SD)	173.5 (6.1)	160.8 (6.8)	163.8 (8.5)	173.9 (7.0)	159.2 (9.6)	162.9 (11.0)
Range	162.0-181.0	149.0-176.0	149.0-181.0	164.0-188.0	141.0-180.0	141.0-188.0

Body mass index computed as $weight/(height/100)^2$.
N = number of subjects; n = number of subjects meeting prespecified criteria; SD = standard deviation.

Table 6. Demographic Characteristics (Adalimumab 40 mg SC q2w

Demographic Characteristic Parameter	Adalimumab 40 mg SC q2W Male N=42	Adalimumab 40 mg SC q2W Female N=162	Adalimumab 40 mg SC q2W Total N=204	Total Male N=131	Total Female N=586	Total Total N=717
Age (years), n (%):						
18-44	6 (14.3)	44 (27.2)	50 (24.5)	25 (19.1)	145 (24.7)	170 (23.7)
45-64	30 (71.4)	94 (58.0)	124 (60.8)	81 (61.8)	342 (58.4)	423 (59.0)
≥65	6 (14.3)	24 (14.8)	30 (14.7)	25 (19.1)	99 (16.9)	124 (17.3)
Mean (SD)	54.8 (11.5)	51.9 (11.7)	52.5 (11.7)	54.4 (11.8)	52.6 (12.2)	52.9 (12.1)
Range	23-77	23-75	23-77	23-79	18-83	18-83
Race, n (%):						
White	33 (78.6)	115 (71.0)	148 (72.5)	111 (84.7)	406 (69.3)	517 (72.1)
Black	0.0	3 (1.9)	3 (1.5)	0.0	13 (2.2)	13 (1.8)
Asian	6 (14.3)	23 (14.2)	29 (14.2)	14 (10.7)	94 (16.0)	108 (15.1)
Other	3 (7.1)	21 (13.0)	24 (11.8)	6 (4.6)	73 (12.5)	79 (11.0)
Weight (kg):						
Mean (SD)	79.3 (14.6)	70.7 (16.0)	72.4 (16.1)	81.1 (17.1)	70.0 (17.5)	72.0 (18.0)
Range	53.2-111.5	36.3-115.0	36.3-115.0	48.0-151.9	34.5-162.0	34.5-162.0
Body mass index (kg/m^2):						
Mean (SD)	26.1 (4.1)	27.4 (5.8)	27.1 (5.5)	26.6 (4.7)	27.1 (6.3)	27.0 (6.0)
Range	18.4-40.0	13.9-45.7	13.9-45.7	17.2-43.0	13.9-53.4	13.9-53.4
Height (cm):						
Mean (SD)	173.9 (7.9)	160.6 (7.3)	163.4 (9.2)	174.3 (7.3)	160.6 (7.6)	163.1 (9.2)
Range	156.0-194.0	144.0-180.0	144.0-194.0	156.0-194.0	140.0-183.0	140.0-194.0

Body mass index computed as weight/$(height/100)^2$.
N = number of subjects; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous; SD = standard deviation.

Efficacy Results:

Statistical significance for the 3 primary endpoints, ACR20 at Month 6, HAQ-DI at Month 3 and incidence of DAS28-4 (ESR) <2.6 at Month 6, of the primary objectives for efficacy was determined using the step-down procedure. Both tofacitinib doses demonstrated statistically significant and clinically meaningful reductions in signs and symptoms of RA over placebo as measured by the ACR20 at Month 6 and the HAQ-DI at Month 3. The rate of subjects achieving DAS28-4 (ESR) <2.6 at Month 6 was also statistically significant for both tofacitinib doses. Improvements over time were observed for ACR50, ACR70, and in the change from Baseline in DAS28-4 (ESR) for both tofacitinib doses and for adalimumab.

Primary Efficacy Results:

ACR20 Response Rates at Month 6:

Results for ACR20 are presented in Table 7.

Table 7. Normal Approximation to ACR20 Response Rates at Month 6 (FAS, NRI, Difference From Placebo)

Treatment	N	n	%	Difference From Placebo			
				Difference	95% CI for Difference		p-Value
					Lower	Upper	
Tofacitinib 5 mg BID	196	101	51.53	23.22	12.16	34.29	<0.0001
Tofacitinib 10 mg BID	196	103	52.55	24.24	13.18	35.31	<0.0001
Adalimumab 40 mg SC q2w	199	94	47.24	18.93	7.90	29.96	0.0007
Placebo	106	30	28.30	-			

ACR20 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis; calculated as a ≥20% improvement in tender and swollen joint counts and ≥20% improvement in 3 of the 5 remaining ACR core set measures; BID = twice daily; CI = confidence interval; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Changes From Baseline in HAQ-DI at Month 3:

Results for HAQ-DI are presented in Table 8.

Table 8. Summary of LS Mean Changes From Baseline in HAQ-DI at Month 3 (FAS, Differences From Placebo)

Treatment	N	LS Mean	Difference From Placebo			
			LS Mean Difference	95% CI for Difference		p-Value
				Lower	Upper	
Tofacitinib 5 mg BID	188	-0.55	-0.31	-0.43	-0.19	<0.0001
Tofacitinib 10 mg BID	185	-0.61	-0.38	-0.50	-0.25	<0.0001
Adalimumab 40 mg SC q2w	190	-0.49	-0.25	-0.37	-0.13	<0.0001
Placebo	98	-0.24	-			

BID = twice daily; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire - Disability Index; LS = least squares; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Rate of Subjects Achieving DAS28-4 (ESR) <2.6 at Month 6:

The rate of subjects achieving DAS28-4 (ESR) <2.6 at Month 6 compared to placebo was statistically significant for both tofacitinib doses (Table 9).

Table 9. Summary of Subjects Achieving DAS28-4 (ESR) <2.6 at Month 6 (FAS, NRI, Comparisons to Placebo)

Treatment	N	n	%	Difference From Placebo			
				Difference	95% CI for Difference		p-Value
					Lower	Upper	
Tofacitinib 5 mg BID	177	11	6.21	5.12	0.98	9.26	0.0151
Tofacitinib 10 mg BID	176	22	12.50	11.41	6.08	16.73	<0.0001
Adalimumab 40 mg SC q2w	178	12	6.74	5.65	1.40	9.90	0.0091
Placebo	92	1	1.09		-		

BID = twice daily; CI = confidence interval; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Secondary Efficacy Results:

Signs and Symptoms:

ACR20 Response Rates at All Time Points:

ACR20 response rates are summarized by visit in Table 10. The durability of ACR20 response is summarized in Table 11.

Table 10. Normal Approximation to ACR20 Response Rates per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Values
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	80	41.24	3.53	11.66	34.31	48.16	<0.0001
	Tofacitinib 10 mg BID	196	90	45.92	3.55	12.90	38.94	52.89	<0.0001
	Placebo→5 mg	56	10	17.86	5.11	3.48	7.82	27.88	0.0004
	Placebo→10 mg	50	7	14.00	4.90	2.85	4.38	23.61	0.0043
	Adalimumab 40 mg SC q2w	198	75	37.88	3.44	10.98	31.12	44.63	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	196	119	60.71	3.48	17.4	53.87	67.55	<0.0001
	Tofacitinib 10 mg BID	196	115	58.67	3.51	16.68	51.77	65.56	<0.0001
	Placebo→5 mg	56	16	28.57	6.03	4.73	16.73	40.4	<0.0001
	Placebo→10 mg	50	12	24.00	6.03	3.97	12.16	35.83	<0.0001
	Adalimumab 40 mg SC q2w	199	112	56.28	3.51	16.00	49.38	63.17	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	97	49.49	3.57	13.85	42.49	56.48	<0.0001
	Tofacitinib 10 mg BID	196	99	50.51	3.57	14.14	43.51	57.50	<0.0001
	Placebo→5 mg	56	17	30.36	6.14	4.94	18.31	42.40	<0.0001
	Placebo→10 mg	50	18	36.00	6.78	5.30	22.69	49.30	<0.0001
	Adalimumab 40 mg SC q2w	199	94	47.24	3.53	13.34	40.29	54.17	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	97	49.49	3.57	13.85	42.49	56.48	<0.0001
	Tofacitinib 10 mg BID	196	97	49.49	3.57	13.85	42.49	56.48	<0.0001
	Placebo→5 mg	56	19	33.93	6.32	5.36	21.52	46.32	<0.0001
	Placebo→10 mg	50	17	34.00	6.69	5.07	20.86	47.13	<0.0001
	Adalimumab 40 mg SC q2w	199	98	49.25	3.54	13.89	42.29	56.19	<0.0001

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo →5 mg BID or placebo →10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; N = number of subjects; n = number of subjects meeting ACR20 response criteria; NRI = nonresponder imputation; q2w = every; SC = subcutaneous.

Table 11. Rates of Consecutive Visits With an ACR20 Response (No Imputation)

Treatment Sequence	N	Most Consecutive Visits of Response			
		2 Consecutive n (%)	3 Consecutive n (%)	4 Consecutive n (%)	5 Consecutive n (%)
Tofacitinib 5 mg BID	201	35 (17.4%)	29 (14.4%)	34 (16.9%)	40 (19.9%)
Tofacitinib 10 mg BID	199	29 (14.6%)	32 (16.1%)	24 (12.1%)	51 (25.6%)
Placebo→5 mg	56	12 (21.4%)	7 (12.5%)	7 (12.5%)	4 (7.1%)
Placebo→10 mg	51	11 (21.6%)	10 (19.6%)	5 (9.8%)	3 (5.9%)
Adalimumab 40 mg SC q2w	201	36 (17.9%)	27 (13.4%)	30 (14.9%)	36 (17.9%)

N refered to the number in each sequence at Baseline, with percent =100 (n/N).
A subject was represented only once in each cell.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo →5 mg BID or placebo →10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous.

ACR50 Responder Rates at All Time Points:

ACR50 responder rates are summarized by visit in Table 12. Durability of ACR50 response is summarized in Table 13.

Table 12. Normal Approximation to ACR50 Response Rates per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Values
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	29	14.95	2.55	5.83	9.93	19.96	<0.0001
	Tofacitinib 10 mg BID	196	32	16.33	2.64	6.18	11.15	21.50	<0.0001
	Placebo→5 mg	56	2	3.57	2.47	1.44	-1.28	8.43	0.1498
	Placebo→10 mg	50	3	6.00	3.35	1.78	-0.58	12.58	0.074
	Adalimumab 40 mg SC q2w	198	24	12.12	2.31	5.22	7.57	16.66	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	196	67	34.18	3.38	10.08	27.54	40.82	<0.0001
	Tofacitinib 10 mg BID	196	54	27.55	3.19	8.63	21.29	33.80	<0.0001
	Placebo→5 mg	56	6	10.71	4.13	2.59	2.61	18.81	0.0095
	Placebo→10 mg	50	1	2.00	1.97	1.01	-1.88	5.88	0.3124
	Adalimumab 40 mg SC q2w	199	47	23.62	3.01	7.84	17.71	29.51	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	72	36.73	3.44	10.66	29.98	43.48	<0.0001
	Tofacitinib 10 mg BID	196	68	34.69	3.39	10.20	28.02	41.35	<0.0001
	Placebo→5 mg	56	7	12.50	4.41	2.82	3.83	21.16	0.0046
	Placebo→10 mg	50	6	12.00	4.59	2.61	2.99	21.00	0.0090
	Adalimumab 40 mg SC q2w	199	55	27.64	3.17	8.71	21.42	33.85	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	70	35.71	3.42	10.43	29.00	42.42	<0.0001
	Tofacitinib 10 mg BID	196	73	37.24	3.45	10.78	30.47	44.01	<0.0001
	Placebo→5 mg	56	10	17.86	5.11	3.48	7.82	27.88	0.0004
	Placebo→10 mg	50	13	26.00	6.20	4.19	13.84	38.15	<0.0001
	Adalimumab 40 mg SC q2w	199	58	29.15	3.22	9.04	22.83	35.45	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	72	36.73	3.44	10.66	29.98	43.48	<0.0001
	Tofacitinib 10 mg BID	196	70	35.71	3.42	10.43	29.00	42.42	<0.0001
	Placebo→5 mg	56	12	21.43	5.48	3.90	10.68	32.17	<0.0001
	Placebo→10 mg	50	14	28.00	6.34	4.40	15.55	40.44	<0.0001
	Adalimumab 40 mg SC q2w	199	67	33.67	3.34	10.05	27.10	40.23	<0.0001

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; N = number of subjects; n = number of subjects meeting ACR50 response criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 13. Rates of Consecutive Visits With an ACR50 Response (No Imputation)

Treatment Sequence	N	Most Consecutive Visits of Response			
		2 Consecutive n (%)	3 Consecutive n (%)	4 Consecutive n (%)	5 Consecutive n (%)
Tofacitinib 5 mg BID	201	28 (13.9%)	28 (13.9%)	17 (8.5%)	14 (7.0%)
Tofacitinib 10 mg BID	199	31 (15.6%)	22 (11.1%)	12 (6.0%)	18 (9.0%)
Placebo→5 mg	56	8 (14.3%)	5 (8.9%)	3 (5.4%)	0.0
Placebo→10 mg	51	15 (29.4%)	4 (7.8%)	1 (2.0%)	0.0
Adalimumab 40 mg SC q2w	201	26 (12.9%)	13 (6.5%)	12 (6.0%)	10 (5.0%)

N referred to the number in each sequence at Baseline, with percent = 100 (n/N).
A subject was represented only once in each cell.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous.

ACR70 Responder Rates at All Timepoints:

ACR70 responder rates are summarized by visit in Table 14. Durability of ACR70 response is summarized in Table 15. ACR70 response for at least 6 months was not analyzed.

Table 14. Normal Approximation to ACR70 Response Rates per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	5	2.58	1.13	2.26	0.34	4.80	0.0234
	Tofacitinib 10 mg BID	196	8	4.08	1.41	2.88	1.31	6.85	0.0038
	Placebo→5 mg	56	1	1.79	1.76	1.00	-1.68	5.25	0.3129
	Placebo→10 mg	50	0	0.00					
	Adalimumab 40 mg SC q2w	198	6	3.03	1.21	2.48	0.64	5.41	0.0128
Month 3 (NRI)	Tofacitinib 5 mg BID	196	24	12.24	2.34	5.22	7.65	16.83	<0.0001
	Tofacitinib 10 mg BID	196	29	14.80	2.53	5.83	9.82	19.76	<0.0001
	Placebo→5 mg	56	1	1.79	1.76	1.00	-1.68	5.25	0.3129
	Placebo→10 mg	50	1	2.00	1.97	1.01	-1.88	5.88	0.3124
	Adalimumab 40 mg SC q2w	199	17	8.54	1.98	4.31	4.65	12.42	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	39	19.90	2.85	6.97	14.30	25.48	<0.0001
	Tofacitinib 10 mg BID	196	43	21.94	2.95	7.42	16.14	27.73	<0.0001
	Placebo→5 mg	56	2	3.57	2.47	1.44	-1.28	8.43	0.1498
	Placebo→10 mg	50	0	0.00	-	-	-	-	-
	Adalimumab 40 mg SC q2w	199	18	9.05	2.03	4.44	5.06	13.03	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	36	18.37	2.76	6.64	12.94	23.78	<0.0001
	Tofacitinib 10 mg BID	196	43	21.94	2.95	7.42	16.14	27.73	<0.0001
	Placebo→5 mg	56	5	8.93	3.81	2.34	1.45	16.39	0.0191
	Placebo→10 mg	50	5	10.00	4.24	2.35	1.68	18.31	0.0184
	Adalimumab 40 mg SC q2w	199	22	11.06	2.22	4.97	6.69	15.41	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	45	22.96	3.00	7.64	17.07	28.84	<0.0001
	Tofacitinib 10 mg BID	196	46	23.47	3.02	7.75	17.53	29.40	<0.0001
	Placebo→5 mg	56	6	10.71	4.13	2.59	2.61	18.81	0.0095
	Placebo→10 mg	50	7	14.00	4.90	2.85	4.38	23.61	0.0043
	Adalimumab 40 mg SC q2w	199	33	16.58	2.63	6.28	11.41	21.75	<0.0001

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; N = number of subjects; n = number of subjects meeting ACR70 response criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 15. Rates of Consecutive Visits With an ACR70 Response (No Imputation)

Treatment Sequence	N	Most Consecutive Visits of Response			
		2 Consecutive n (%)	3 Consecutive n (%)	4 Consecutive n (%)	5 Consecutive n (%)
Tofacitinib 5 mg BID	201	12 (6.0%)	9 (4.5%)	12 (6.0%)	2 (<1.0%)
Tofacitinib 10 mg BID	199	18 (9.0%)	13 (6.5%)	8 (4.0%)	4 (2.0%)
Placebo→5 mg	56	6 (10.7%)	2 (3.6%)	0.0	0.0
Placebo→10 mg	51	3 (5.9%)	0.0	0.0	0.0
Adalimumab 40 mg SC q2w	201	12 (6.0%)	3 (1.5%)	4 (2.0%)	2 (<1.0%)

N referred to the number in each sequence at Baseline, with percent =100 (n/N).
A subject was represented only once in each cell.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous.

Individual Components of the ACR Criteria:

Tender Joint Count: Results for tender joint counts are summarized in Table 16 and Table 17.

Swollen Joint Count: Results for swollen joint counts are summarized in Table 18 and Table 19.

Patient Assessment of Arthritis Pain: Results for patient assessment of arthritis pain are summarized in Table 20 and Table 21.

Physician Global Assessment of Arthritis: Results for physician global assessment of arthritis are summarized in Table 22 and Table 23.

Patient Global Assessment of Arthritis: Results for patient global assessment of arthritis are summarized in Table 24. Results at Baseline, Month 1, Month 3, Month 6, Month 9 and Month 12 are presented in Table 25.

CRP: Results of CRP are summarized in Table 26 and Table 27.

HAQ-DI: Descriptive statistics for HAQ-DI are presented by visit in Table 28 and Table 29.

Table 16. Descriptive Statistics of Tender-Joint Counts per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	28.48	15.03	0.00	16.00	26.00	36.00	68.00
	Tofacitinib 10 mg BID	199	26.09	14.13	6.00	15.00	23.00	34.00	66.00
	Placebo→5 mg	55	26.58	14.36	9.00	17.00	22.00	31.00	68.00
	Placebo→10 mg	51	28.10	14.43	7.00	18.00	25.00	39.00	60.00
	Adalimumab 40 mg SC q2w	201	26.65	15.34	6.00	14.00	23.00	37.00	67.00
Month 1	Tofacitinib 5 mg BID	194	19.46	15.90	0.00	8.00	16.00	25.00	68.00
	Tofacitinib 10 mg BID	196	17.34	13.75	0.00	7.00	13.00	25.00	66.00
	Placebo→5 mg	56	23.30	15.70	2.00	12.00	20.50	30.00	68.00
	Placebo→10 mg	50	24.02	15.97	0.00	12.00	18.50	36.00	57.00
	Adalimumab 40 mg SC q2w	198	17.62	13.07	0.00	7.00	15.00	26.00	60.00
Month 3	Tofacitinib 5 mg BID	188	14.81	14.11	0.00	4.00	11.00	21.50	68.00
	Tofacitinib 10 mg BID	185	12.63	11.67	0.00	4.00	10.00	18.00	61.00
	Placebo→5mg	55	20.51	13.83	3.00	10.00	17.00	26.00	68.00
	Placebo→10mg	44	21.2	15.34	0.00	8.50	15.00	37.00	50.00
	Adalimumab 40 mg SC q2w	190	14.44	13.61	0.00	4.00	11.00	20.00	61.00
Month 6	Tofacitinib 5 mg BID	174	12.55	14.01	0.00	3.00	7.50	15.00	67.00
	Tofacitinib 10 mg BID	181	9.63	11.61	0.00	2.00	6.00	13.00	64.00
	Placebo→5 mg	52	12.13	10.74	0.00	5.50	9.00	17.50	62.00
	Placebo→10 mg	42	12.00	13.45	0.00	3.00	8.00	14.00	64.00
	Adalimumab 40 mg SC q2w	182	12.13	12.40	0.00	3.00	8.00	18.00	58.00
Month 9	Tofacitinib 5 mg BID	160	9.23	11.09	0.00	2.50	5.00	12.50	56.00
	Tofacitinib 10 mg BID	167	8.77	11.04	0.00	2.00	5.00	11.00	61.00
	Placebo→5 mg	49	8.53	12.63	0.00	2.00	5.00	8.00	59.00
	Placebo→10 mg	41	7.39	9.60	0.00	1.00	5.00	7.00	47.00
	Adalimumab 40 mg SC q2w	172	11.27	13.49	0.00	2.50	6.00	16.00	68.00
Month 12	Tofacitinib 5 mg BID	150	8.15	10.55	0.00	2.00	4.00	11.00	66.00
	Tofacitinib 10 mg BID	151	7.07	9.12	0.00	1.00	4.00	11.00	60.00
	Placebo→5 mg	49	8.06	9.81	0.00	3.00	5.00	9.00	53.00
	Placebo→10 mg	38	7.16	10.48	0.00	2.00	3.00	9.00	49.00

Table 16. Descriptive Statistics of Tender-Joint Counts per Visit, Comparisons Within Sequence

Adalimumab 40 mg SC q2w	160	8.98	12.64	0.00	1.00	5.00	10.00	63.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 17. Descriptive Statistics of Change From Baseline of Tender-Joint Counts per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	194	-9.18	12.92	-52.00	-16.00	-7.00	-2.00	66.00
	Tofacitinib 10 mg BID	196	-8.79	10.52	-59.00	-15.00	-7.00	-2.00	13.00
	Placebo→5 mg	55	-3.18	9.77	-35.00	-7.00	-3.00	0.00	24.00
	Placebo→10 mg	50	-4.12	11.22	-36.00	-8.00	-1.00	1.00	17.00
	Adalimumab 40 mg SC q2w	198	-8.99	10.69	-49.00	-14.00	-7.00	-2.00	19.00
Month 3	Tofacitinib 5 mg BID	188	-13.86	14.79	-54.00	-22.50	-12.00	-4.50	34.00
	Tofacitinib 10 mg BID	185	-13.51	13.08	-63.00	-20.00	-11.00	-6.00	30.00
	Placebo→5 mg	54	-6.20	14.09	-42.00	-14.00	-5.50	3.00	20.00
	Placebo→10 mg	44	-5.23	10.56	-31.00	-12.50	-4.00	2.00	22.00
	Adalimumab 40 mg SC q2w	190	-12.47	12.68	-51.00	-18.00	-10.00	-5.00	28.00
Month 6	Tofacitinib 5 mg BID	174	-16.30	14.82	-65.00	-23.00	-14.00	-7.00	22.00
	Tofacitinib 10 mg BID	181	-16.37	13.47	-64.00	-23.00	-14.00	-8.00	15.00
	Placebo→5 mg	51	-13.59	13.19	-41.00	-21.00	-13.00	-3.00	13.00
	Placebo→10 mg	42	-13.83	11.79	-43.00	-18.00	-14.50	-7.00	13.00
	Adalimumab 40 mg SC q2w	182	-14.71	13.85	-58.00	-21.00	-13.00	-6.00	46.00
Month 9	Tofacitinib 5 mg BID	160	-18.54	14.24	-58.00	-26.00	-17.00	-9.00	42.00
	Tofacitinib 10 mg BID	167	-16.91	13.15	-64.00	-23.00	-14.00	-7.00	7.00
	Placebo→5 mg	48	-16.94	12.04	-44.00	-25.00	-16.00	-9.00	17.00
	Placebo→10 mg	41	-18.80	11.89	-52.00	-23.00	-18.00	-9.00	2.00
	Adalimumab 40 mg SC q2w	172	-15.78	14.90	-61.00	-21.50	-14.00	-7.00	46.00
Month 12	Tofacitinib 5 mg BID	150	-19.24	14.01	-59.00	-27.00	-17.00	-10.00	21.00
	Tofacitinib 10 mg BID	151	-18.93	14.47	-64.00	-26.00	-16.00	-9.00	14.00
	Placebo→5 mg	48	-17.38	13.67	-63.00	-23.50	-15.50	-9.00	11.00
	Placebo→10 mg	38	-18.71	12.41	-45.00	-24.00	-18.00	-8.00	4.00
	Adalimumab 40 mg SC q2w	160	-18.19	14.04	-58.00	-26.00	-15.50	-9.00	14.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo →10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 18. Descriptive Statistics of Swollen-Joint Counts per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	16.66	8.76	0.00	10.00	14.00	21.00	54.00
	Tofacitinib 10 mg BID	199	15.80	7.82	6.00	10.00	14.00	20.00	48.00
	Placebo→5 mg	55	16.93	9.98	6.00	10.00	14.00	22.00	58.00
	Placebo→10 mg	51	16.37	7.51	6.00	11.00	14.00	23.00	34.00
	Adalimumab 40 mg SC q2w	201	16.35	8.65	6.00	10.00	14.00	21.00	50.00
Month 1	Tofacitinib 5 mg BID	194	9.46	7.13	0.00	4.00	8.00	13.00	36.00
	Tofacitinib 10 mg BID	196	9.38	6.63	0.00	4.00	8.00	13.00	36.00
	Placebo→5 mg	56	13.20	8.75	0.00	8.00	11.00	16.00	45.00
	Placebo→10 mg	50	12.06	6.71	0.00	7.00	11.50	18.00	28.00
	Adalimumab 40 mg SC q2w	198	10.55	8.09	0.00	4.00	8.00	15.00	36.00
Month 3	Tofacitinib 5 mg BID	188	6.88	6.80	0.00	2.00	5.00	10.00	31.00
	Tofacitinib 10 mg BID	185	6.75	6.03	0.00	2.00	5.00	10.00	29.00
	Placebo→5 mg	55	11.35	9.04	0.00	5.00	8.00	16.00	47.00
	Placebo→10 mg	44	10.50	8.26	0.00	4.50	8.50	16.00	36.00
	Adalimumab 40 mg SC q2w	190	7.59	6.27	0.00	3.00	7.00	10.00	33.00
Month 6	Tofacitinib 5 mg BID	174	5.43	6.33	0.00	1.00	4.00	7.00	33.00
	Tofacitinib 10 mg BID	181	4.56	5.35	0.00	0.00	3.00	7.00	24.00
	Placebo→5 mg	52	6.88	6.14	0.00	2.00	5.00	11.00	25.00
	Placebo→10 mg	42	6.24	5.53	0.00	2.00	5.00	9.00	23.00
	Adalimumab 40 mg SC q2w	182	6.12	6.74	0.00	1.00	4.00	9.00	41.00
Month 9	Tofacitinib 5 mg BID	160	3.78	4.49	0.00	0.00	2.00	6.00	21.00
	Tofacitinib 10 mg BID	167	4.06	4.9	0.00	0.00	2.00	5.00	23.00
	Placebo→5 mg	49	4.04	7.47	0.00	0.00	2.00	5.00	49.00
	Placebo→10 mg	41	4.12	5.02	0.00	1.00	3.00	6.00	26.00
	Adalimumab 40 mg SC q2w	172	6.01	8.72	0.00	1.00	4.00	8.00	66.00
Month 12	Tofacitinib 5 mg BID	150	3.37	4.52	0.00	0.00	2.00	5.00	30.00
	Tofacitinib 10 mg BID	151	3.05	3.85	0.00	0.00	2.00	4.00	15.00
	Placebo→5 mg	49	3.02	3.36	0.00	0.00	2.00	5.00	14.00
	Placebo→10 mg	38	3.68	5.35	0.00	0.00	1.50	4.00	22.00

Table 18. Descriptive Statistics of Swollen-Joint Counts per Visit, Comparisons Within Sequence

Adalimumab 40 mg SC q2w	160	4.31	5.15	0.00	0.00	2.50	7.00	29.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 19. Descriptive Statistics of Change From Baseline of Swollen-Joint Counts per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	194	-7.31	7.82	-48.00	-10.00	-6.00	-3.00	9.00
	Tofacitinib 10 mg BID	196	-6.49	8.01	-48.00	-10.00	-5.50	-1.00	9.00
	Placebo→5 mg	55	-3.65	8.38	-37.00	-7.00	-3.00	0.00	16.00
	Placebo→10 mg	50	-4.34	6.55	-22.00	-7.00	-4.00	0.00	8.00
	Adalimumab 40 mg SC q2w	198	-5.80	6.88	-38.00	-9.00	-5.00	-2.00	11.00
Month 3	Tofacitinib 5 mg BID	188	-9.82	9.36	-50.00	-14.50	-8.00	-4.00	16.00
	Tofacitinib 10 mg BID	185	-9.05	8.28	-48.00	-13.00	-8.00	-4.00	13.00
	Placebo→5 mg	54	-5.65	11.17	-50.00	-11.00	-4.50	3.00	14.00
	Placebo→10 mg	44	-5.70	10.11	-28.00	-11.00	-5.50	-1.00	28.00
	Adalimumab 40 mg SC q2w	190	-8.87	7.97	-38.00	-14.00	-8.00	-3.00	9.00
Month 6	Tofacitinib 5 mg BID	174	-11.37	9.29	-54.00	-16.00	-10.00	-6.00	8.00
	Tofacitinib 10 mg BID	181	-11.03	8.14	-43.00	-16.00	-10.00	-6.00	8.00
	Placebo→5 mg	51	-9.80	10.41	-50.00	-13.00	-9.00	-4.00	9.00
	Placebo→10 mg	42	-9.60	7.28	-32.00	-12.00	-9.00	-6.00	3.00
	Adalimumab 40 mg SC q2w	182	-10.27	7.74	-44.00	-14.00	-9.00	-5.00	7.00
Month 9	Tofacitinib 5 mg BID	160	-12.53	8.86	-54.00	-16.00	-11.00	-7.00	4.00
	Tofacitinib 10 mg BID	167	-11.68	8.13	-43.00	-16.00	-10.00	-6.00	5.00
	Placebo→5 mg	48	-12.40	10.64	-56.00	-15.00	-11.00	-7.50	22.00
	Placebo→10 mg	41	-11.83	8.58	-33.00	-18.00	-11.00	-7.00	18.00
	Adalimumab 40 mg SC q2w	172	-10.37	10.90	-46.00	-16.00	-10.00	-5.50	60.00
Month 12	Tofacitinib 5 mg BID	150	-12.77	9.20	-54.00	-18.00	-11.00	-7.00	18.00
	Tofacitinib 10 mg BID	151	-13.01	8.20	-40.00	-18.00	-11.00	-8.00	6.00
	Placebo→5mg mg	48	-13.40	9.66	-57.00	-16.00	-11.00	-7.00	0.00
	Placebo→10 mg	38	-11.71	8.21	-33.00	-16.00	-10.00	-8.00	14.00
	Adalimumab 40 mg SC q2w	160	-11.91	7.44	-34.00	-17.00	-11.50	-6.00	6.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 20. Descriptive Statistics of Pain VAS per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	59.29	20.95	10.00	47.00	62.00	76.00	97.00
	Tofacitinib 10 mg BID	199	59.01	22.18	2.00	45.00	63.00	74.00	100.00
	Placebo→5 mg	55	57.60	20.64	14.00	48.00	63.00	72.00	90.00
	Placebo→10 mg	51	52.61	21.84	6.00	39.00	54.00	68.00	96.00
	Adalimumab 40 mg SC q2w	201	56.46	21.92	6.00	42.00	57.00	73.00	100.00
Month 1	Tofacitinib 5 mg BID	194	39.71	22.60	0.00	23.00	35.00	52.00	100.00
	Tofacitinib 10 mg BID	196	36.77	22.63	0.00	20.00	32.00	53.00	96.00
	Placebo→5 mg	56	50.18	24.89	5.00	30.50	50.50	70.00	98.00
	Placebo→10 mg	50	49.62	23.07	1.00	34.00	50.50	64.00	97.00
	Adalimumab 40 mg SC q2w	198	39.27	24.29	0.00	18.00	39.50	59.00	97.00
Month 3	Tofacitinib 5 mg BID	188	32.98	23.09	0.00	15.50	27.00	49.00	96.00
	Tofacitinib 10 mg BID	185	31.27	22.39	0.00	12.00	27.00	49.00	96.00
	Placebo→5 mg	55	48.81	23.45	6.00	32.00	48.00	66.00	97.00
	Placebo→10 mg	44	48.18	23.66	3.00	27.00	48.00	67.50	96.00
	Adalimumab 40 mg SC q2w	190	36.27	25.67	0.00	14.00	32.00	55.00	100.00
Month 6	Tofacitinib 5 mg BID	174	30.40	23.26	1.00	11.00	24.00	46.00	94.00
	Tofacitinib 10 mg BID	181	28.36	22.52	1.00	10.00	22.00	44.00	95.00
	Placebo→5 mg	52	36.96	22.38	0.00	18.00	34.00	54.50	76.00
	Placebo→10 mg	42	32.67	20.30	1.00	16.00	32.50	51.00	71.00
	Adalimumab 40 mg SC q2w	179	32.78	22.57	0.00	15.00	27.00	50.00	95.00
Month 9	Tofacitinib 5 mg BID	158	27.04	21.35	1.00	10.00	20.50	43.00	91.00
	Tofacitinib 10 mg BID	167	27.99	22.97	0.00	10.00	21.00	45.00	96.00
	Placebo→5 mg	49	31.31	22.66	2.00	11.00	31.00	47.00	86.00
	Placebo→10 mg	41	24.93	19.38	1.00	12.00	18.00	35.00	71.00
	Adalimumab 40 mg SC q2w	171	32.70	24.18	0.00	11.00	28.00	48.00	96.00
Month 12	Tofacitinib 5 mg BID	150	26.99	21.97	0.00	9.00	19.50	40.00	94.00
	Tofacitinib 10 mg BID	150	24.55	20.68	0.00	6.00	18.00	40.00	98.00
	Placebo→5 mg	49	28.23	17.86	3.00	14.00	27.00	37.00	73.00
	Placebo→10 mg	38	29.37	20.57	2.00	17.00	24.00	45.00	77.00

Table 20. Descriptive Statistics of Pain VAS per Visit, Comparisons Within Sequence

Adalimumab 40 mg SC q2w	160	27.94	22.70	0.00	9.50	24.00	44.50	84.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; VAS = Visual Anlogue Scale.

Table 21. Descriptive Statistics of Change From Baseline of Pain VAS per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	194	-19.82	24.35	-86.00	-35.00	-18.00	-4.00	55.00
	Tofacitinib 10 mg BID	196	-22.16	24.84	-88.00	-43.00	-18.00	-3.69	39.00
	Placebo→5 mg	55	-7.64	23.42	-67.00	-18.00	-4.00	9.00	40.00
	Placebo→10 mg	50	-2.12	17.35	-50.00	-11.00	0.00	9.00	27.00
	Adalimumab 40 mg SC q2w	198	-17.19	24.91	-92.00	-30.00	-14.00	-2.00	51.00
Month 3	Tofacitinib 5 mg BID	188	-26.27	27.37	-86.00	-47.00	-24.50	-5.50	42.00
	Tofacitinib 10 mg BID	185	-27.68	25.88	-91.00	-49.00	-25.00	-8.00	27.00
	Placebo→5 mg	54	-9.62	22.35	-73.00	-17.00	-6.50	7.00	35.00
	Placebo→10 mg	44	-2.91	21.01	-47.00	-16.00	-2.00	11.50	49.00
	Adalimumab 40 mg SC q2w	190	-20.12	24.77	-86.00	-38.00	-19.50	-3.00	48.00
Month 6	Tofacitinib 5 mg BID	174	-29.32	28.56	-89.00	-51.00	-29.00	-7.00	42.00
	Tofacitinib 10 mg BID	181	-30.51	27.35	-90.00	-53.00	-30.00	-9.00	36.00
	Placebo→5 mg	51	-20.75	23.45	-72.00	-35.00	-21.00	0.00	20.00
	Placebo→10 mg	42	-18.05	23.28	-66.00	-36.00	-15.00	0.00	39.00
	Adalimumab 40 mg SC q2w	179	-23.64	24.51	-81.00	-40.00	-22.00	-7.00	57.00
Month 9	Tofacitinib 5 mg BID	158	-31.87	28.29	-86.00	-56.00	-32.50	-12.00	41.00
	Tofacitinib 10 mg BID	167	-30.36	29.07	-94.00	-55.00	-31.00	-5.00	51.00

Table 21. Descriptive Statistics of Change From Baseline of Pain VAS per Visit, Comparisons Within Sequence

	Placebo→5 mg	48	-25.77	25.22	-79.00	-39.50	-22.00	-9.00	25.00
	Placebo→10 mg	41	-25.88	27.38	-91.00	-41.00	-30.00	-4.00	34.00
	Adalimumab 40 mg SC q2w	171	-23.66	27.16	-94.00	-44.00	-23.00	-5.00	39.00
Month 12	Tofacitinib 5 mg BID	150	-32.56	28.70	-87.00	-53.00	-33.00	-14.00	56.00
	Tofacitinib 10 mg BID	150	-33.84	28.73	-91.00	-57.00	-35.50	-13.00	54.00
	Placebo→ mg	48	-29.31	23.25	-85.00	-47.00	-29.00	-13.50	20.00
	Placebo→10 mg	38	-21.63	27.03	-71.00	-41.00	-20.00	-6.00	57.00
	Adalimumab 40 mg SC q2w	160	-28.58	25.11	-93.00	-45.00	-29.00	-12.00	45.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; VAS = Visual Analogue Scale.

Table 22. Descriptive Statistics of Physician Global Assessment per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	199	59.92	16.77	3.00	50.00	62.00	72.00	98.00
	Tofacitinib 10 mg BID	199	59.56	16.70	9.00	49.00	62.00	70.00	98.00
	Placebo→5 mg	55	62.40	18.74	12.00	50.00	64.00	71.00	100.00
	Placebo→10 mg	51	58.00	13.64	28.00	48.00	60.00	68.00	90.00
	Adalimumab 40 mg SC q2w	201	58.64	15.98	13.00	47.00	60.00	71.00	96.00
Month 1	Tofacitinib 5 mg BID	193	38.90	18.56	0.00	25.00	37.00	50.00	81.00
	Tofacitinib 10 mg BID	195	36.16	19.27	0.00	21.00	35.00	53.00	80.00
	Placebo→5 mg	56	49.18	23.45	7.00	32.50	50.50	67.00	96.00
	Placebo→10 mg	50	52.46	20.54	0.00	39.00	52.50	69.00	92.00
	Adalimumab 40 mg SC q2w	197	38.81	20.08	0.00	24.00	38.00	52.00	100.00
Month 3	Tofacitinib 5 mg BID	186	30.28	20.71	0.00	16.00	25.00	41.00	92.00
	Tofacitinib 10 mg BID	185	29.91	21.04	0.00	13.00	25.00	41.00	88.00
	Placebo→5 mg	55	44.32	24.58	7.00	22.00	43.00	65.00	92.00
	Placebo→10 mg	44	46.11	20.52	2.00	29.50	45.50	63.00	91.00
	Adalimumab 40 mg SC q2w	189	32.40	21.08	2.00	15.00	29.00	46.00	91.00
Month 6	Tofacitinib 5 mg BID	174	24.97	19.26	2.00	10.00	20.00	35.00	80.00
	Tofacitinib 10 mg BID	180	24.46	19.78	0.00	9.00	20.00	35.50	89.00
	Placebo→5 mg	52	30.62	20.29	0.00	14.00	26.50	41.00	95.00
	Placebo→10 mg	42	32.02	18.69	3.00	18.00	26.50	48.00	73.00
	Adalimumab 40 mg SC q2w	178	27.77	18.36	0.00	14.00	25.00	38.00	84.00
Month 9	Tofacitinib 5 mg BID	160	19.93	16.20	0.00	7.00	16.50	26.00	92.00
	Tofacitinib 10 mg BID	167	21.92	17.87	0.00	8.00	17.00	31.00	87.00
	Placebo→5 mg	49	25.82	20.32	2.00	9.00	23.00	35.00	90.00
	Placebo→10 mg	41	23.78	15.54	1.00	13.00	18.00	35.00	68.00
	Adalimumab 40 mg SC q2w	170	25.45	19.94	0.00	10.00	21.50	34.00	92.00
Month 12	Tofacitinib 5 mg BID	149	18.67	16.18	0.00	7.00	14.00	24.00	95.00

Table 22. Descriptive Statistics of Physician Global Assessment per Visit, Comparisons Within Sequence

	Tofacitinib 10 mg BID	150	18.87	16.05	0.00	6.00	15.00	26.00	70.00
	Placebo→5 mg	48	19.77	13.88	0.00	9.50	17.50	23.50	59.00
	Placebo→10 mg	38	20.68	14.51	1.00	10.00	16.50	29.00	62.00
	Adalimumab 40 mg SC q2w	157	20.44	16.94	0.00	9.00	16.00	27.00	83.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 23. Descriptive Statistics of Change From Baseline of Physician Global Assessment per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	192	-21.20	20.74	-82.00	-33.50	-19.00	-8.00	38.00
	Tofacitinib 10 mg BID	195	-23.25	20.55	-88.00	-38.00	-21.00	-9.00	34.00
	Placebo→5 mg	55	-13.35	19.80	-59.00	-28.00	-13.00	1.00	27.00
	Placebo→10 mg	50	-5.00	19.48	-52.00	-19.00	-3.00	6.00	51.00
	Adalimumab 40 mg SC q2w	197	-20.02	20.76	-91.00	-32.00	-19.00	-6.00	30.00
Month 3	Tofacitinib 5 mg BID	184	-29.88	23.31	-82.00	-48.00	-32.00	-13.00	35.00
	Tofacitinib 10 mg BID	185	-29.61	24.31	-89.00	-47.00	-32.00	-15.00	54.00
	Placebo→5 mg	54	-18.67	22.22	-67.00	-37.00	-14.50	-1.00	12.00
	Placebo→10 mg	44	-11.55	21.69	-60.00	-25.00	-15.50	6.00	28.00
	Adalimumab 40 mg SC q2w	189	-26.28	21.81	-80.00	-39.00	-26.00	-12.00	32.00
Month 6	Tofacitinib 5 mg BID	173	-35.09	24.77	-86.00	-53.00	-37.00	-21.00	56.00
	Tofacitinib 10 mg BID	180	-34.92	23.92	-85.00	-53.50	-37.00	-19.50	48.00
	Placebo→5 mg	51	-31.16	22.72	-81.00	-45.00	-33.00	-12.00	17.00
	Placebo→10 mg	42	-25.93	20.66	-67.00	-39.00	-25.50	-14.00	27.00
	Adalimumab 40 mg SC q2w	178	-31.27	21.06	-88.00	-45.00	-32.00	-18.00	47.00
Month 9	Tofacitinib 5 mg BID	159	-39.72	22.21	-88.00	-55.00	-41.00	-29.00	58.00
	Tofacitinib 10 mg BID	167	-37.71	22.06	-89.00	-57.00	-38.00	-23.00	46.00
	Placebo→5 mg	48	-36.23	22.21	-74.00	-52.00	-38.50	-21.00	10.00
	Placebo→10 mg	41	-34.20	17.66	-71.00	-47.00	-34.00	-22.00	11.00
	Adalimumab 40 mg SC q2w	170	-33.74	21.63	-96.00	-48.00	-37.50	-20.00	32.00
Month 12	Tofacitinib 5 mg BID	148	-41.45	22.41	-86.00	-57.00	-42.00	-29.00	26.00
	Tofacitinib 10 mg BID	150	-40.82	21.68	-83.00	-57.00	-45.00	-29.00	26.00
	Placebo→5 mg	47	-42.55	19.96	-93.00	-53.00	-45.00	-25.00	-4.00
	Placebo→10 mg	38	-37.24	19.10	-75.00	-50.00	-36.50	-26.00	3.00
	Adalimumab 40 mg SC q2w	157	-38.76	20.08	-85.00	-54.00	-39.00	-26.00	23.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 24. Descriptive Statistics of Patient Global Assessment per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	59.86	21.38	5.00	47.00	61.00	77.00	100.00
	Tofacitinib 10 mg BID	199	56.55	23.83	0.00	40.00	59.00	75.00	98.00
	Placebo→5 mg	55	59.13	20.71	3.00	47.00	57.00	73.00	97.00
	Placebo→10 mg	51	49.43	20.90	5.00	40.00	51.00	64.00	100.00
	Adalimumab 40 mg SC q2w	201	57.22	22.22	5.00	44.00	60.00	73.00	100.00
Month 1	Tofacitinib 5 mg BID	194	41.85	23.02	0.00	23.00	43.00	55.00	98.00
	Tofacitinib 10 mg BID	196	36.61	23.51	2.00	19.50	33.00	54.50	98.00
	Placebo→5 mg	56	50.79	24.18	1.00	33.50	52.00	69.00	95.00
	Placebo→10 mg	49	50.59	24.56	2.00	30.00	53.00	69.00	94.00
	Adalimumab 40 mg SC q2w	197	39.32	23.83	0.00	18.00	42.00	57.00	96.00
Month 3	Tofacitinib 5 mg BID	188	35.56	23.81	0.00	18.00	30.50	51.00	96.00
	Tofacitinib 10 mg BID	185	31.25	22.23	0.00	12.00	27.00	48.00	91.00
	Placebo→5 mg	55	49.91	22.15	2.00	37.00	47.00	64.00	98.00
	Placebo→10 mg	44	49.75	23.07	1.00	29.00	51.00	67.00	97.00
	Adalimumab 40 mg SC q2w	190	36.97	25.28	0.00	15.00	34.50	55.00	100.00
Month 6	Tofacitinib 5 mg BID	174	32.79	25.56	2.00	11.00	25.50	52.00	100.00
	Tofacitinib 10 mg BID	181	29.74	22.41	1.00	10.00	25.00	46.00	96.00
	Placebo→5 mg	52	38.60	20.57	5.00	20.50	37.50	51.50	82.00
	Placebo→10 mg	42	34.48	19.54	7.00	16.00	29.00	52.00	80.00
	Adalimumab 40 mg SC q2w	180	33.50	21.97	0.00	15.00	31.50	50.00	95.00
Month 9	Tofacitinib 5 mg BID	158	28.39	22.31	1.00	10.00	23.50	44.00	98.00
	Tofacitinib 10 mg BID	167	29.47	21.99	0.00	10.00	26.00	46.00	96.00
	Placebo→5 mg	49	31.78	20.75	2.00	13.00	32.00	42.00	85.00
	Placebo→10 mg	41	30.00	20.31	1.00	15.00	24.00	44.00	75.00
	Adalimumab 40 mg SC q2w	171	34.38	24.93	0.00	12.00	29.00	50.00	96.00
Month 12	Tofacitinib 5 mg BID	149	26.86	22.44	0.00	9.00	21.00	39.00	95.00
	Tofacitinib 10 mg BID	150	27.70	22.09	0.00	9.00	23.50	45.00	98.00
	Placebo→5 mg	49	30.78	17.65	3.00	17.00	27.00	46.00	67.00

Table 24. Descriptive Statistics of Patient Global Assessment per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→10 mg	37	29.70	20.69	1.00	17.00	24.00	42.00	89.00
	Adalimumab 40 mg SC q2w	160	30.33	24.46	0.00	9.00	25.00	47.00	94.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 25. Descriptive Statistics of Changes From Baseline of Patient Global Assessment per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	194	-18.23	24.15	-83.00	-33.00	-17.00	-1.00	44.00
	Tofacitinib 10 mg BID	196	-19.87	26.85	-91.00	-37.00	-15.00	-1.50	50.00
	Placebo→5 mg	55	-8.60	21.74	-69.00	-19.00	-5.00	2.00	38.00
	Placebo→10 mg	49	1.39	19.86	-46.00	-8.00	4.00	14.00	47.00
	Adalimumab 40 mg SC q2w	197	-17.91	25.81	-94.00	-35.00	-14.00	-2.00	83.00
Month 3	Tofacitinib 5 mg BID	188	-24.02	27.36	-94.00	-45.00	-23.00	-6.00	49.00
	Tofacitinib 10 mg BID	185	-25.20	25.59	-90.00	-45.00	-22.00	-5.00	35.00
	Placebo→5 mg	54	-9.65	22.33	-64.00	-25.00	-7.00	3.00	37.00
	Placebo→10 mg	44	1.14	20.30	-36.00	-10.00	-0.50	12.00	50.00
	Adalimumab 40 mg SC q2w	190	-20.39	25.49	-86.00	-41.00	-18.50	-3.00	52.00
Month 6	Tofacitinib 5 mg BID	174	-26.93	31.16	-93.00	-49.00	-31.50	-6.00	61.00
	Tofacitinib 10 mg BID	181	-26.27	28.14	-89.00	-48.00	-25.00	-6.00	49.00
	Placebo→5 mg	51	-19.73	23.67	-71.00	-34.00	-19.00	-3.00	38.00
	Placebo→10 mg	42	-13.71	22.31	-65.00	-27.00	-11.50	-1.00	47.00
	Adalimumab 40 mg SC q2w	180	-24.41	26.10	-92.00	-39.50	-24.00	-6.00	67.00
Month 9	Tofacitinib 5 mg BID	158	-30.70	26.96	-87.00	-51.00	-29.00	-11.00	38.00
	Tofacitinib 10 mg BID	167	-25.77	29.15	-91.00	-45.00	-24.00	-4.00	61.00
	Placebo→5 mg	48	-25.69	26.52	-76.00	-41.00	-27.50	-6.00	35.00
	Placebo→10 mg	41	-18.22	23.06	-79.00	-32.00	-15.00	-6.00	37.00
	Adalimumab 40 mg SC q2w	171	-23.17	26.29	-94.00	-39.00	-22.00	-4.00	33.00
Month 12	Tofacitinib 5 mg BID	149	-32.17	27.17	-84.00	-54.00	-32.00	-14.00	36.00
	Tofacitinib 10 mg BID	150	-27.60	29.99	-92.00	-51.00	-27.00	-6.00	63.00
	Placebo→5 mg	48	-27.10	25.81	-89.00	-45.00	-28.00	-7.50	31.00
	Placebo→10 mg	37	-20.54	27.18	-64.00	-33.00	-24.00	-12.00	82.00
	Adalimumab 40 mg SC q2w	160	-27.39	28.86	-92.00	-47.00	-27.00	-10.00	59.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 26. Descriptive Statistics of C-Reactive Protein (mg/L) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	14.89	18.58	0.20	3.05	7.62	19.25	142.00
	Tofacitinib 10 mg BID	199	17.27	19.52	0.30	3.50	9.21	26.00	99.10
	Placebo→5 mg	56	20.29	20.07	0.77	3.93	15.25	29.95	79.00
	Placebo→10 mg	51	11.57	16.25	0.31	2.33	6.33	16.70	92.40
	Adalimumab 40 mg SC q2w	201	17.48	22.48	0.20	3.46	9.21	24.10	171.00
Month 1	Tofacitinib 5 mg BID	193	6.70	17.89	0.20	0.67	1.76	5.53	198.00
	Tofacitinib 10 mg BID	196	5.76	12.16	0.20	0.68	1.72	5.94	115.00
	Placebo→5 mg	56	21.75	30.41	0.36	3.03	11.10	32.80	183.00
	Placebo→10 mg	48	13.42	16.84	0.76	3.97	8.40	13.85	91.40
	Adalimumab 40 mg SC q2w	197	8.65	16.04	0.20	1.07	2.77	9.28	108.00
Month 3	Tofacitinib 5 mg BID	187	6.37	15.32	0.20	0.66	1.81	6.39	181.00
	Tofacitinib 10 mg BID	184	7.39	18.23	0.20	0.83	3.01	8.69	229.00
	Placebo→5 mg	55	19.74	32.91	0.37	3.00	7.74	21.80	194.00
	Placebo→10 mg	44	15.28	21.48	0.51	3.83	9.07	17.30	129.00
	Adalimumab 40 mg SC q2w	190	8.29	16.79	0.20	0.95	2.30	8.04	151.00
Month 6	Tofacitinib 5 mg BID	174	4.58	7.31	0.20	0.70	1.61	5.46	63.50
	Tofacitinib 10 mg BID	180	5.53	8.91	0.20	0.78	1.65	6.10	50.00
	Placebo→5 mg	52	8.85	15.24	0.20	1.21	3.97	8.45	87.10
	Placebo→10 mg	42	7.40	9.85	0.20	1.05	3.26	9.01	43.60
	Adalimumab 40 mg SC q2w	181	8.02	14.27	0.20	1.13	2.91	8.34	114.00
Month 9	Tofacitinib 5 mg BID	160	4.25	6.38	0.20	0.68	1.70	5.76	48.20
	Tofacitinib 10 mg BID	168	7.56	16.94	0.20	0.76	2.01	6.37	115.00
	Placebo→5 mg	49	4.31	4.85	0.20	0.77	2.57	6.32	25.80
	Placebo→10 mg	41	5.82	9.22	0.20	0.70	2.31	5.73	45.20
	Adalimumab 40 mg SC q2w	171	8.58	18.42	0.20	0.88	2.55	7.42	137.00
Month 12	Tofacitinib 5 mg BID	149	5.87	12.25	0.20	0.80	2.30	5.81	93.30
	Tofacitinib 10 mg BID	150	7.04	14.65	0.20	0.66	2.32	7.49	136.00
	Placebo→5 mg	48	5.51	7.19	0.20	0.57	2.74	7.61	28.30

Table 26. Descriptive Statistics of C-Reactive Protein (mg/L) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→10 mg	37	4.60	9.01	0.20	0.68	1.39	4.25	47.90
	Adalimumab 40 mg SC q2w	160	8.19	15.50	0.20	0.80	2.19	8.05	116.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 27. Descriptive Statistics of Change From Baseline of C-Reactive Protein (mg/L) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	192	-8.32	22.97	-97.30	-14.21	-4.68	-0.75	191.06
	Tofacitinib 10 mg BID	196	-11.58	19.40	-95.33	-16.45	-5.54	-1.46	78.80
	Placebo→5 mg	56	1.48	22.44	-26.70	-7.19	-0.26	2.86	139.60
	Placebo→10 mg	48	2.19	10.63	-22.37	-0.99	0.34	5.28	35.49
	Adalimumab 40 mg SC q2w	197	-9.07	17.91	-129.20	-14.20	-4.22	-0.98	102.51
Month 3	Tofacitinib 5 mg BID	186	-9.07	23.11	-138.90	-15.15	-4.98	-0.50	175.47
	Tofacitinib 10 mg BID	184	-10.01	26.16	-98.32	-16.15	-4.04	-0.79	227.01
	Placebo→5 mg	55	-0.28	25.50	-74.25	-8.36	-1.57	3.66	118.40
	Placebo→10 mg	44	4.46	11.18	-15.80	-0.98	2.15	7.64	38.07
	Adalimumab 40 mg SC q2w	190	-9.08	20.27	-133.00	-15.79	-4.06	-0.61	56.90
Month 6	Tofacitinib 5 mg BID	173	-10.44	18.39	-135.80	-15.17	-3.80	-0.58	22.70
	Tofacitinib 10 mg BID	180	-11.99	20.48	-98.44	-16.40	-4.98	-1.36	45.00
	Placebo→5 mg	52	-11.22	21.22	-78.40	-20.10	-5.97	-0.34	53.40
	Placebo→10 mg	42	-3.75	16.34	-90.58	-4.76	-0.44	0.46	22.60
	Adalimumab 40 mg SC q2w	181	-9.47	22.32	-167.30	-14.15	-4.26	-0.20	80.20
Month 9	Tofacitinib 5 mg BID	159	-11.16	18.96	-140.80	-15.45	-4.53	-0.57	10.90
	Tofacitinib 10 mg BID	168	-10.15	25.60	-97.58	-16.78	-4.68	-1.11	103.10
	Placebo→5 mg	49	-16.53	19.81	-73.13	-27.13	-9.79	-1.27	4.71
	Placebo→10 mg	41	-5.45	18.84	-91.86	-7.11	-1.91	0.48	36.86
	Adalimumab 40 mg SC q2w	171	-8.69	24.75	-170.10	-14.56	-4.40	-0.51	128.91
Month 12	Tofacitinib 5 mg BID	148	-9.89	21.93	-141.70	-16.48	-4.04	-0.33	69.00
	Tofacitinib 10 mg BID	150	-10.61	25.17	-95.36	-19.72	-4.58	-0.70	130.95
	Placebo→5 mg	48	-15.71	19.48	-76.43	-26.06	-10.04	-1.37	13.90
	Placebo→10 mg	37	-6.21	18.23	-91.80	-9.59	-2.67	0.33	31.00
	Adalimumab 40 mg SC q2w	160	-9.63	23.74	-170.40	-14.03	-5.48	-0.65	75.60

Table 27. Descriptive Statistics of Change From Baseline of C-Reactive Protein (mg/L) per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous. .

Table 28. Descriptive Statistics of HAQ-DI per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	1.50	0.64	0.00	1.13	1.50	2.00	3.00
	Tofacitinib 10 mg BID	199	1.53	0.63	0.00	1.13	1.63	2.00	3.00
	Placebo→5 mg	55	1.47	0.68	0.13	1.00	1.50	2.00	3.00
	Placebo→10 mg	51	1.36	0.68	0.00	0.88	1.38	1.75	3.00
	Adalimumab 40 mg SC q2w	201	1.50	0.59	0.00	1.00	1.50	1.88	2.75
Month 1	Tofacitinib 5 mg BID	194	1.15	0.66	0.00	0.63	1.25	1.63	2.63
	Tofacitinib 10 mg BID	196	1.11	0.67	0.00	0.63	1.13	1.63	2.88
	Placebo→5 mg	56	1.33	0.7	0.00	0.75	1.31	1.88	2.63
	Placebo→10 mg	50	1.32	0.68	0.00	1.00	1.19	1.75	3.00
	Adalimumab 40 mg SC q2w	198	1.12	0.64	0.00	0.63	1.13	1.50	2.88
Month 3	Tofacitinib 5 mg BID	188	1.00	0.72	0.00	0.38	1.00	1.56	2.75
	Tofacitinib 10 mg BID	185	0.94	0.75	0.00	0.25	0.88	1.50	3.00
	Placebo→5 mg	55	1.22	0.71	0.00	0.75	1.13	1.75	2.75
	Placebo→10 mg	44	1.29	0.62	0.13	0.88	1.31	1.69	2.75
	Adalimumab 40 mg SC q2w	190	1.05	0.64	0.00	0.50	1.00	1.50	2.63
Month 6	Tofacitinib 5 mg BID	174	0.92	0.72	0.00	0.25	0.94	1.38	3.00
	Tofacitinib 10 mg BID	181	0.89	0.69	0.00	0.25	0.88	1.38	2.88
	Placebo→5 mg	52	1.03	0.71	0.00	0.44	1.00	1.50	2.63
	Placebo→10 mg	42	1.04	0.67	0.00	0.50	1.00	1.50	2.75
	Adalimumab 40 mg SC q2w	180	0.98	0.65	0.00	0.50	1.00	1.50	2.25
Month 9	Tofacitinib 5 mg BID	158	0.86	0.66	0.00	0.25	0.75	1.25	2.75
	Tofacitinib 10 mg BID	167	0.85	0.66	0.00	0.25	0.88	1.38	2.50
	Placebo→5 mg	49	0.89	0.69	0.00	0.25	0.88	1.25	2.50
	Placebo→10 mg	41	0.90	0.64	0.00	0.50	0.88	1.25	2.75
	Adalimumab 40 mg SC q2w	171	0.97	0.67	0.00	0.38	1.00	1.50	2.88
Month 12	Tofacitinib 5 mg BID	149	0.83	0.68	0.00	0.25	0.75	1.25	2.75
	Tofacitinib 10 mg BID	149	0.81	0.71	0.00	0.13	0.75	1.25	2.75
	Placebo→5 mg	49	0.88	0.71	0.00	0.25	0.88	1.25	2.38
	Placebo→10 mg	38	0.91	0.72	0.00	0.38	0.88	1.38	2.75
	Adalimumab 40 mg SC q2w	159	0.90	0.67	0.00	0.25	0.88	1.50	2.38

Table 28. Descriptive Statistics of HAQ-DI per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; HAQ-DI = Health Assessment Questionnaire – Disability Index; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 29. Descriptive Statistics of Change From Baseline of HAQ-DI per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	194	-0.34	0.53	-2.38	-0.50	-0.25	0.00	1.50
	Tofacitinib 10 mg BID	196	-0.41	0.49	-2.00	-0.75	-0.38	0.00	0.75
	Placebo→5 mg	55	-0.15	0.36	-1.00	-0.38	-0.13	0.00	0.75
	Placebo→10 mg	50	-0.04	0.45	-1.38	-0.25	-0.06	0.13	1.00
	Adalimumab 40 mg SC q2w	198	-0.37	0.48	-2.00	-0.63	-0.38	0.00	0.88
Month 3	Tofacitinib 5 mg BID	188	-0.49	0.59	-2.50	-0.88	-0.38	-0.06	0.75
	Tofacitinib 10 mg BID	185	-0.59	0.58	-2.50	-1.00	-0.50	-0.13	0.88
	Placebo→5 mg	54	-0.25	0.52	-1.75	-0.50	-0.13	0.13	1.13
	Placebo→10 mg	44	-0.07	0.60	-1.38	-0.38	-0.06	0.25	2.00
	Adalimumab 40 mg SC q2w	190	-0.45	0.52	-2.25	-0.88	-0.38	0.00	1.00
Month 6	Tofacitinib 5 mg BID	174	-0.58	0.61	-2.50	-1.00	-0.50	-0.13	1.50
	Tofacitinib 10 mg BID	181	-0.64	0.58	-2.25	-1.00	-0.50	-0.25	0.38
	Placebo→5 mg	51	-0.40	0.55	-1.63	-0.75	-0.25	0.00	0.63
	Placebo→10 mg	42	-0.31	0.56	-1.63	-0.63	-0.25	0.00	0.88
	Adalimumab 40 mg SC q2w	180	-0.52	0.56	-2.63	-0.88	-0.50	-0.13	0.75
Month 9	Tofacitinib 5 mg BID	158	-0.64	0.58	-2.25	-1.00	-0.63	-0.25	0.88
	Tofacitinib 10 mg BID	167	-0.66	0.58	-2.50	-1.00	-0.63	-0.25	0.50
	Placebo→5 mg	48	-0.57	0.57	-2.25	-0.88	-0.50	-0.19	0.50
	Placebo→10 mg	41	-0.48	0.61	-2.00	-0.75	-0.38	-0.13	0.63
	Adalimumab 40 mg SC q2w	171	-0.55	0.58	-2.50	-0.88	-0.50	-0.13	1.00
Month 12	Tofacitinib 5 mg BID	149	-0.67	0.62	-2.13	-1.13	-0.63	-0.25	0.75
	Tofacitinib 10 mg BID	149	-0.69	0.65	-2.50	-1.13	-0.63	-0.25	0.75
	Placebo→5 mg	48	-0.59	0.60	-2.38	-0.88	-0.63	-0.13	0.38
	Placebo→10 mg	38	-0.44	0.52	-1.38	-1.00	-0.44	0.00	0.50
	Adalimumab 40 mg SC q2w	159	-0.62	0.53	-2.25	-1.00	-0.63	-0.13	0.50

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; HAQ-DI = Health Assessment Questionnaire – Disability Index; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

DAS28-3(CRP):

Table 30 presents the descriptive statistics of DAS28-3 (CRP) per visit (Baseline, Months 1, 3 6, 9 and 12). Table 31 present the results of change from Baseline DAS28-3 (CRP). Table 32 presents the rate of subjects achieving DAS28-3 (CRP) ≤3.2 through Month 12. Table 33 presents the rate of subjects achieving DAS28-3 (CRP) <2.6 through Month 12. Table 34 presents the rates of DAS28-3 (CRP) response ('good' or 'moderate') through Month 12. Durability of DAS28-3 (CRP) <2.6 response is summarized in Table 35.

Data was not analyzed for DAS28-4 (CRP) due to change in planned analyses.

Table 30. Descriptive Statistics of DAS28-3 (CRP) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	5.43	0.89	2.08	4.87	5.48	6.07	7.18
	Tofacitinib 10 mg BID	199	5.43	0.83	3.10	4.79	5.46	6.04	7.58
	Placebo→5 mg	55	5.55	0.95	3.72	4.82	5.54	6.29	7.34
	Placebo→10 mg	51	5.32	0.79	3.81	4.64	5.32	6.05	6.72
	Adalimumab 40mg SC q2w	201	5.33	0.92	2.39	4.76	5.26	6.02	7.30
Month 1	Tofacitinib 5 mg BID	193	4.26	1.09	1.30	3.61	4.17	5.05	7.57
	Tofacitinib 10 mg BID	196	4.21	1.05	1.29	3.51	4.16	5.02	6.88
	Placebo→5 mg	56	5.21	1.15	2.47	4.37	5.22	6.03	7.43
	Placebo→10 mg	48	4.95	1.15	1.57	4.39	5.09	5.79	6.94
	Adalimumab 40mg SC q2w	197	4.27	1.06	1.22	3.59	4.30	4.96	6.91
Month 3	Tofacitinib 5 mg BID	187	3.78	1.21	1.22	2.85	3.66	4.66	6.88
	Tofacitinib 10 mg BID	184	3.77	1.21	1.23	2.93	3.87	4.58	6.46
	Placebo→5 mg	55	4.90	1.23	2.34	4.21	4.88	5.78	7.66
	Placebo→10 mg	44	4.75	1.28	1.72	3.81	4.94	5.63	6.81
	Adalimumab 40mg SC q2w	190	3.88	1.15	1.30	3.07	3.90	4.66	6.85
Month 6	Tofacitinib 5 mg BID	174	3.51	1.27	1.27	2.61	3.32	4.44	6.83
	Tofacitinib 10 mg BID	180	3.29	1.22	1.22	2.34	3.20	4.10	6.58
	Placebo→5 mg	52	3.87	1.01	1.22	3.36	3.72	4.57	6.14
	Placebo→10 mg	42	3.69	1.07	1.79	2.68	3.68	4.26	6.71
	Adalimumab 40mg SC q2w	181	3.63	1.19	1.22	2.84	3.61	4.47	6.56
Month 9	Tofacitinib 5 mg BID	160	3.13	1.11	1.22	2.32	3.04	3.72	6.15
	Tofacitinib 10 mg BID	167	3.20	1.20	1.22	2.27	3.00	3.76	6.58
	Placebo→5 mg	49	3.11	1.11	1.23	2.42	3.09	3.57	6.71
	Placebo→10 mg	41	3.03	1.1	1.22	2.24	2.93	3.65	5.55
	Adalimumab 40mg SC q2w	171	3.46	1.21	1.22	2.60	3.50	4.08	7.67
Month 12	Tofacitinib 5 mg BID	149	3.05	1.13	1.22	2.25	3.00	3.60	6.33
	Tofacitinib 10 mg BID	150	3.00	1.18	1.22	2.09	2.86	3.78	6.00
	Placebo→5 mg	48	3.12	0.96	1.22	2.33	3.32	3.88	5.54
	Placebo→10 mg	37	3.02	1.28	1.22	1.99	2.93	3.84	5.94
	Adalimumab 40mg SC q2w	160	3.18	1.25	1.22	2.23	3.01	4.04	6.80

Table 30. Descriptive Statistics of DAS28-3 (CRP) per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 31. Descriptive Statistics of Change From Baseline of DAS28-3 (CRP) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	192	-1.18	1.03	-4.65	-1.78	-1.06	-0.53	3.43
	Tofacitinib 10 mg BID	196	-1.23	0.97	-5.21	-1.71	-1.17	-0.53	0.74
	Placebo→5 mg	55	-0.32	0.73	-2.11	-0.65	-0.33	-0.05	1.46
	Placebo→10 mg	48	-0.33	1.02	-3.87	-0.70	-0.10	0.24	1.51
	Adalimumab 40 mg SC q2w	197	-1.05	0.84	-3.49	-1.53	-0.94	-0.51	1.21
Month 3	Tofacitinib 5 mg BID	186	-1.67	1.25	-5.14	-2.43	-1.54	-0.83	1.52
	Tofacitinib 10 mg BID	184	-1.68	1.24	-5.15	-2.55	-1.57	-0.73	1.24
	Placebo→5 mg	54	-0.64	1.05	-3.00	-1.38	-0.54	0.13	2.28
	Placebo→10 mg	44	-0.48	1.10	-3.28	-1.17	-0.25	0.23	2.73
	Adalimumab 40 mg SC q2w	190	-1.46	1.03	-3.94	-2.16	-1.43	-0.84	1.32
Month 6	Tofacitinib 5 mg BID	173	-1.93	1.30	-4.75	-2.75	-2.04	-0.90	1.11
	Tofacitinib 10 mg BID	180	-2.16	1.33	-5.42	-3.17	-2.18	-1.07	0.78
	Placebo→5 mg	51	-1.63	1.18	-6.12	-2.37	-1.61	-0.82	0.30
	Placebo→10 mg	42	-1.51	1.02	-3.78	-2.11	-1.60	-0.88	0.38
	Adalimumab 40 mg SC q2w	181	-1.70	1.19	-4.86	-2.43	-1.67	-0.92	1.11
Month 9	Tofacitinib 5 mg BID	159	-2.28	1.16	-5.01	-3.20	-2.38	-1.46	1.12
	Tofacitinib 10 mg BID	167	-2.23	1.26	-5.35	-3.20	-2.17	-1.34	0.95
	Placebo→5 mg	48	-2.42	1.31	-4.78	-3.42	-2.35	-1.68	0.54
	Placebo→10 mg	41	-2.18	1.18	-5.14	-2.92	-2.22	-1.51	0.54
	Adalimumab 40 mg SC q2w	171	-1.88	1.25	-6.08	-2.63	-1.79	-1.11	3.05
Month 12	Tofacitinib 5 mg BID	148	-2.36	1.23	-5.13	-3.23	-2.61	-1.42	1.20
	Tofacitinib 10 mg BID	150	-2.46	1.33	-5.40	-3.39	-2.55	-1.36	1.02
	Placebo→5 mg	47	-2.42	1.26	-5.43	-3.22	-2.05	-1.58	-0.5
	Placebo→10 mg	37	-2.15	1.40	-4.86	-3.16	-2.13	-1.45	1.86
	Adalimumab 40 mg SC q2w	160	-2.17	1.28	-4.96	-2.92	-2.10	-1.42	2.37

Table 31. Descriptive Statistics of Change From Baseline of DAS28-3 (CRP) per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 32. Normal Approximation to DAS28-3 (CRP) ≤3.2 Rates per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	193	30	15.54	2.60	5.95	10.43	20.65	<0.0001
	Tofacitinib 10 mg BID	196	34	17.35	2.70	6.41	12.04	22.64	<0.0001
	Placebo→5 mg	56	1	1.79	1.76	1.00	-1.68	5.25	0.3129
	Placebo→10 mg	48	5	10.42	4.40	2.36	1.77	19.05	0.0181
	Adalimumab 40 mg SC q2w	197	31	15.74	2.59	6.06	10.65	20.82	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	196	65	33.16	3.36	9.86	26.57	39.75	<0.0001
	Tofacitinib 10 mg BID	196	60	30.61	3.29	9.29	24.15	37.06	<0.0001
	Placebo→5 mg	56	4	7.14	3.44	2.07	0.39	13.88	0.0379
	Placebo→10 mg	48	6	12.50	4.77	2.61	3.14	21.85	0.0088
	Adalimumab 40 mg SC q2w	199	53	26.63	3.13	8.49	20.49	32.77	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	71	36.22	3.43	10.55	29.49	42.95	<0.0001
	Tofacitinib 10 mg BID	196	73	37.24	3.45	10.78	30.47	44.01	<0.0001
	Placebo→5 mg	56	3	5.36	3.00	1.78	-0.54	11.25	0.075
	Placebo→10 mg	48	7	14.58	5.09	2.86	4.59	24.56	0.0042
	Adalimumab 40 mg SC q2w	199	52	26.13	3.11	8.39	20.02	32.23	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	81	41.33	3.51	11.74	34.43	48.22	<0.0001
	Tofacitinib 10 mg BID	196	79	40.31	3.50	11.50	33.43	47.17	<0.0001
	Placebo→5 mg	56	15	26.79	5.91	4.52	15.18	38.38	<0.0001
	Placebo→10 mg	48	14	29.17	6.56	4.44	16.30	42.02	<0.0001
	Adalimumab 40 mg SC q2w	199	57	28.64	3.20	8.93	22.36	34.92	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	71	36.22	3.43	10.55	29.49	42.95	<0.0001
	Tofacitinib 10 mg BID	196	81	41.33	3.51	11.74	34.43	48.22	<0.0001
	Placebo→5 mg	56	13	23.21	5.64	4.11	12.15	34.27	<0.0001
	Placebo→10 mg	48	14	29.17	6.56	4.44	16.30	42.02	<0.0001
	Adalimumab 40 mg SC q2w	199	74	37.19	3.42	10.85	30.47	43.90	<0.0001

Table 32. Normal Approximation to DAS28-3 (CRP) ≤3.2 Rates per Visit (FAS, NRI), Comparisons Within Sequence

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 had their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 33. Normal Approximation to DAS28-3 (CRP) <2.6 Rates per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	193	11	5.70	1.66	3.41	2.42	8.97	0.0006
	Tofacitinib 10 mg BID	196	12	6.12	1.71	3.57	2.76	9.47	0.0003
	Placebo→5 mg	56	1	1.79	1.76	1.00	-1.68	5.25	0.3129
	Placebo→10 mg	48	2	4.17	2.88	1.44	-1.48	9.81	0.1485
	Adalimumab 40 mg SC q2w	197	10	5.08	1.56	3.24	2.01	8.14	0.0011
Month 3 (NRI)	Tofacitinib 5 mg BID	196	30	15.31	2.57	5.95	10.26	20.34	<0.0001
	Tofacitinib 10 mg BID	196	36	18.37	2.76	6.64	12.94	23.78	<0.0001
	Placebo→5 mg	56	0	0.00	-	-	-	-	-
	Placebo→10 mg	48	3	6.25	3.49	1.78	-0.59	13.09	0.0736
	Adalimumab 40 mg SC q2w	199	26	13.07	2.38	5.46	8.38	17.74	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	36	18.37	2.76	6.64	12.94	23.78	<0.0001
	Tofacitinib 10 mg BID	196	50	25.51	3.11	8.19	19.40	31.61	<0.0001
	Placebo→5 mg	56	2	3.57	2.47	1.44	-1.28	8.43	0.1498
	Placebo→10 mg	48	5	10.42	4.40	2.36	1.77	19.05	0.0181
	Adalimumab 40 mg SC q2w	199	33	16.58	2.63	6.28	11.41	21.75	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	43	21.94	2.95	7.42	16.14	27.73	<0.0001
	Tofacitinib 10 mg BID	196	51	26.02	3.13	8.30	19.87	32.16	<0.0001
	Placebo→5 mg	56	9	16.07	4.90	3.27	6.45	25.69	0.001
	Placebo→10 mg	48	9	18.75	5.63	3.32	7.70	29.79	0.0008
	Adalimumab 40 mg SC q2w	199	37	18.59	2.75	6.74	13.18	23.99	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	43	21.94	2.95	7.42	16.14	27.73	<0.0001
	Tofacitinib 10 mg BID	196	59	30.10	3.27	9.18	23.68	36.52	<0.0001
	Placebo→5 mg	56	9	16.07	4.90	3.27	6.45	25.69	0.001
	Placebo→10 mg	48	10	20.83	5.86	3.55	9.34	32.32	0.0003
	Adalimumab 40 mg SC q2w	199	50	25.13	3.07	8.17	19.09	31.15	<0.0001

Table 33. Normal Approximation to DAS28-3 (CRP) <2.6 Rates per Visit (FAS, NRI), Comparisons Within Sequence

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have had their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 34. Normal Approximation to DAS28-3 (CRP) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRINAP), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRINAP)	Tofacitinib 5 mg BID	192	119	61.98	3.50	17.69	55.11	68.84	<0.0001
	Tofacitinib 10 mg BID	196	129	65.82	3.38	19.42	59.17	72.45	<0.0001
	Placebo→5 mg	55	13	23.64	5.72	4.12	12.40	34.86	<0.0001
	Placebo→10 mg	48	8	16.67	5.37	3.09	6.12	27.20	0.0019
	Adalimumab 40 mg SC q2w	197	126	63.96	3.42	18.69	57.25	70.66	<0.0001
Month 3 (NRINAP)	Tofacitinib 5 mg BID	195	142	72.82	3.18	22.85	66.57	79.06	<0.0001
	Tofacitinib 10 mg BID	196	135	68.88	3.30	20.82	62.39	75.35	<0.0001
	Placebo→5 mg	55	23	41.82	6.65	6.28	28.78	54.85	<0.0001
	Placebo→10 mg	48	16	33.33	6.80	4.89	19.99	46.66	<0.0001
	Adalimumab 40 mg SC q2w	199	147	73.87	3.11	23.71	67.76	79.97	<0.0001
Month 6 (NRINAP)	Tofacitinib 5 mg BID	195	134	68.72	3.32	20.69	62.21	75.22	<0.0001
	Tofacitinib 10 mg BID	196	149	76.02	3.04	24.92	70.04	81.99	<0.0001
	Placebo→5 mg	55	38	69.09	6.23	11.08	56.87	81.30	<0.0001
	Placebo→10 mg	48	31	64.58	6.90	9.35	51.05	78.11	<0.0001
	Adalimumab 40 mg SC q2w	199	142	71.36	3.20	22.26	65.07	77.63	<0.0001
Month 9 (NRINAP)	Tofacitinib 5 mg BID	195	139	71.28	3.24	22.00	64.93	77.63	<0.0001
	Tofacitinib 10 mg BID	196	145	73.98	3.13	23.6	67.83	80.12	<0.0001
	Placebo→5 mg	55	43	78.18	5.56	14.03	67.26	89.09	<0.0001
	Placebo→10 mg	48	37	77.08	6.06	12.70	65.19	88.97	<0.0001
	Adalimumab 40 mg SC q2w	199	140	70.35	3.23	21.73	64.00	76.69	<0.0001
Month 12 (NRINAP)	Tofacitinib 5 mg BID	195	132	67.69	3.34	20.21	61.12	74.25	<0.0001
	Tofacitinib 10 mg BID	196	142	72.45	3.19	22.7	66.19	78.70	<0.0001
	Placebo→5 mg	55	44	80.00	5.39	14.83	69.42	90.57	<0.0001

Table 34. Normal Approximation to DAS28-3 (CRP) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRINAP), Comparisons Within Sequence

Placebo→10 mg	48	36	75.00	6.25	12.00	62.75	87.25	<0.0001
Adalimumab 40 mg SC q2w	199	142	71.36	3.20	22.26	65.07	77.63	<0.0001

Subjects who withdrew for any reason are set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRINAP = nonresponder imputation no advancement penalty; q = every; SC = subcutaneous; w = weeks.

Table 35. Rates of Consecutive Visits With a DAS28-3 (CRP) <2.6 (No Imputation)

Treatment Sequence	N	Most Consecutive Visits of Response			
		2 Consecutive n (%)	3 Consecutive n (%)	4 Consecutive n (%)	5 Consecutive n (%)
Tofacitinib 5 mg BID	201	24 (11.9%)	12 (6.0%)	7 (3.5%)	3 (1.5%)
Tofacitinib 10 mg BID	199	24 (12.1%)	18 (9.0%)	11 (5.5%)	3 (1.5%)
Placebo→5 mg	56	10 (17.9%)	1 (1.8%)	0.0	0.0
Placebo→10 mg	51	6 (11.8%)	6 (11.8%)	0.0	0.0
Adalimumab 40 mg SC q2w	201	19 (9.5%)	10 (5.0%)	9 (4.5%)	4 (2.0%)

N refered to the number in each sequence at Baseline, with percent = 100(n/N).
A subject was represented only once in each cell.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; N = number of subjects; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous.

DAS28-4 (ESR):

Table 36 and Table 37 present the descriptive statisitcs of change from baseline of DAS28-4 (ESR) per visit (Baseline, Months 1, 3 6, 9 and 12). Table 38 presents the rate of subjects achieving DAS28-4 (ESR) ≤3.2 through Month 12. Table 39 presents the rate of subjects achieving DAS28-4 (ESR) <2.6 through Month 12. Table 40 presents the rates of subjects with DAS28-4 (ESR) response ('good' or 'moderate') through Month 12. Durability of DAS28-4 (ESR) <2.6 response is summarized in Table 41.

Data was not analyzed for DAS28-3 (ESR) due to change in planned analyses.

Table 36. Descriptive Statistics of DAS28-4 (ESR) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	195	6.56	0.93	3.43	5.89	6.56	7.22	8.44
	Tofacitinib 10 mg BID	194	6.48	0.89	4.19	5.88	6.52	7.06	9.04
	Placebo→5 mg	54	6.56	1.00	4.34	5.93	6.45	7.33	8.36
	Placebo→10 mg	49	6.33	0.75	4.55	5.70	6.49	6.88	7.43
	Adalimumab 40mg SC q2w	194	6.36	0.93	3.40	5.76	6.41	6.95	8.68
Month 1	Tofacitinib 5 mg BID	172	5.23	1.19	1.63	4.43	5.21	6.05	8.10
	Tofacitinib 10 mg BID	175	5.14	1.26	1.48	4.28	5.28	5.99	7.97
	Placebo→5 mg	49	6.02	1.20	2.74	5.19	5.99	6.90	8.74
	Placebo→10 mg	41	5.81	1.24	1.39	5.03	6.10	6.73	7.73
	Adalimumab 40mg SC q2w	176	5.13	1.21	1.99	4.49	5.14	6.07	7.70
Month 3	Tofacitinib 5 mg BID	170	4.64	1.33	1.61	3.67	4.62	5.56	8.39
	Tofacitinib 10 mg BID	166	4.66	1.39	1.52	3.68	4.69	5.57	8.15
	Placebo→5 mg	49	5.69	1.34	2.61	4.97	5.70	6.58	8.77
	Placebo→10 mg	38	5.49	1.29	1.69	4.66	5.43	6.51	7.63
	Adalimumab 40mg SC q2w	167	4.66	1.28	1.73	3.67	4.58	5.54	7.93
Month 6	Tofacitinib 5 mg BID	155	4.40	1.38	0.81	3.42	4.22	5.25	8.04
	Tofacitinib 10 mg BID	162	4.21	1.38	1.03	3.28	4.20	5.16	7.66
	Placebo→5 mg	47	4.68	1.11	2.30	4.07	4.57	5.32	7.60
	Placebo→10 mg	36	4.45	1.18	2.06	3.61	4.63	4.99	7.96
	Adalimumab 40mg SC q2w	158	4.37	1.30	1.46	3.42	4.32	5.19	7.91
Month 9	Tofacitinib 5 mg BID	140	4.00	1.21	1.28	3.19	3.93	4.78	6.88
	Tofacitinib 10 mg BID	151	4.08	1.33	1.30	3.16	3.98	4.77	7.26
	Placebo→5 mg	45	3.99	1.25	1.80	3.29	3.91	4.32	8.74
	Placebo→10 mg	35	3.93	1.17	1.78	3.03	3.84	4.93	6.37
	Adalimumab 40mg SC q2w	149	4.20	1.39	0.66	3.32	4.19	5.07	7.95
Month 12	Tofacitinib 5 mg BID	134	3.85	1.22	1.07	3.10	3.86	4.53	7.87
	Tofacitinib 10 mg BID	136	3.88	1.35	1.34	3.00	3.82	4.67	7.19

Table 36. Descriptive Statistics of DAS28-4 (ESR) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	44	4.00	0.95	2.29	3.28	3.88	4.86	5.66
	Placebo→10 mg	32	3.70	1.24	0.99	2.95	3.71	4.52	6.42
	Adalimumab 40mg SC q2w	139	3.95	1.48	0.98	2.73	3.98	4.91	7.77

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 37. Descriptive Statistics of Change From Baseline of DAS28-4 (ESR) per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	172	-1.30	1.08	-5.00	-1.84	-1.22	-0.62	3.67
	Tofacitinib 10 mg BID	175	-1.33	1.12	-5.42	-1.92	-1.19	-0.51	0.78
	Placebo→5 mg	48	-0.51	0.84	-2.17	-1.12	-0.53	-0.06	1.42
	Placebo→10 mg	41	-0.43	1.15	-4.86	-0.61	-0.19	0.32	0.89
	Adalimumab 40 mg SC q2w	176	-1.19	1.01	-3.96	-1.83	-1.09	-0.44	2.04
Month 3	Tofacitinib 5 mg BID	170	-1.87	1.34	-5.94	-2.67	-1.76	-1.02	1.74
	Tofacitinib 10 mg BID	166	-1.82	1.31	-5.65	-2.64	-1.71	-0.96	1.27
	Placebo→5 mg	48	-0.85	1.23	-3.97	-1.90	-0.72	0.01	2.21
	Placebo→10 mg	38	-0.67	1.38	-3.84	-1.49	-0.57	0.25	3.01
	Adalimumab 40 mg SC q2w	167	-1.69	1.14	-4.49	-2.48	-1.68	-0.95	1.17
Month 6	Tofacitinib 5 mg BID	155	-2.13	1.35	-5.67	-3.00	-2.13	-1.31	1.10
	Tofacitinib 10 mg BID	162	-2.27	1.33	-5.23	-3.24	-2.26	-1.25	0.59
	Placebo→5 mg	46	-1.81	1.22	-5.54	-2.69	-1.47	-0.99	0.32
	Placebo→10 mg	36	-1.67	1.06	-3.63	-2.54	-1.57	-1.04	0.71
	Adalimumab 40 mg SC q2w	158	-1.95	1.24	-5.97	-2.62	-2.08	-1.03	0.75
Month 9	Tofacitinib 5 mg BID	140	-2.47	1.20	-6.31	-3.33	-2.53	-1.72	0.76
	Tofacitinib 10 mg BID	151	-2.37	1.28	-5.34	-3.19	-2.35	-1.49	0.46
	Placebo→5 mg	44	-2.46	1.41	-4.65	-3.82	-2.55	-1.55	1.03
	Placebo→10 mg	35	-2.21	1.26	-4.49	-3.26	-2.01	-1.30	0.32
	Adalimumab 40 mg SC q2w	149	-2.13	1.35	-5.84	-2.88	-2.07	-1.39	2.66
Month 12	Tofacitinib 5 mg BID	134	-2.61	1.30	-5.78	-3.46	-2.77	-1.77	1.57
	Tofacitinib 10 mg BID	136	-2.62	1.37	-5.60	-3.51	-2.85	-1.67	1.51
	Placebo→5 mg	43	-2.47	1.26	-5.32	-3.33	-2.27	-1.51	-0.05
	Placebo→10 mg	32	-2.42	1.40	-5.75	-3.46	-2.30	-1.54	1.87
	Adalimumab 40 mg SC q2w	139	-2.40	1.49	-5.69	-3.32	-2.41	-1.34	2.07

Table 37. Descriptive Statistics of Change From Baseline of DAS28-4 (ESR) per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 38. Normal Approximation to DAS28-4 (ESR) ≤3.2 Rates per Visit (FAS, NRINAP) Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRINAP)	Tofacitinib 5 mg BID	172	6	3.49	1.39	2.49	0.74	6.23	0.0126
	Tofacitinib 10 mg BID	175	10	5.71	1.75	3.25	2.27	9.15	0.0011
	Placebo→5 mg	49	1	2.04	2.01	1.01	-1.91	5.99	0.3123
	Placebo→10 mg	41	1	2.44	2.40	1.01	-2.28	7.16	0.3113
	Adalimumab 40 mg SC q2w	176	14	7.95	2.03	3.89	3.95	11.95	<0.0001
Month 3 (NRINAP)	Tofacitinib 5 mg BID	177	26	14.69	2.66	5.52	9.47	19.90	<0.0001
	Tofacitinib 10 mg BID	176	24	13.64	2.58	5.27	8.56	18.70	<0.0001
	Placebo→5 mg	50	1	2.00	1.97	1.01	-1.88	5.88	0.3124
	Placebo→10 mg	42	1	2.38	2.35	1.01	-2.22	6.99	0.3114
	Adalimumab 40 mg SC q2w	178	27	15.17	2.68	5.64	9.89	20.43	<0.0001
Month 6 (NRINAP)	Tofacitinib 5 mg BID	177	30	16.95	2.82	6.01	11.42	22.47	<0.0001
	Tofacitinib 10 mg BID	176	36	20.45	3.04	6.72	14.49	26.41	<0.0001
	Placebo→5 mg	50	4	8.00	3.83	2.08	0.48	15.51	0.0370
	Placebo→10 mg	42	4	9.52	4.52	2.10	0.64	18.40	0.0354
	Adalimumab 40 mg SC q2w	178	31	17.42	2.84	6.12	11.84	22.98	<0.0001
Month 9 (NRINAP)	Tofacitinib 5 mg BID	177	37	20.90	3.05	6.83	14.91	26.89	<0.0001
	Tofacitinib 10 mg BID	176	39	22.16	3.13	7.07	16.02	28.29	<0.0001
	Placebo→5 mg	50	10	20.00	5.65	3.53	8.91	31.08	0.0004
	Placebo→10 mg	42	10	23.81	6.57	3.62	10.92	36.69	0.0002
	Adalimumab 40 mg SC q2w	178	28	15.73	2.72	5.76	10.38	21.07	<0.0001
Month 12 (NRINAP)	Tofacitinib 5 mg BID	177	37	20.90	3.05	6.83	14.91	26.89	<0.0001
	Tofacitinib 10 mg BID	176	44	25.00	3.26	7.65	18.60	31.39	<0.0001
	Placebo→5 mg	50	10	20.00	5.65	3.53	8.91	31.08	0.0004
	Placebo→10 mg	42	11	26.19	6.78	3.86	12.89	39.48	0.0001
	Adalimumab 40 mg SC q2w	178	51	28.65	3.38	8.45	22.00	35.29	<0.0001

Table 38. Normal Approximation to DAS28-4 (ESR) ≤3.2 Rates per Visit (FAS, NRINAP) Comparisons Within Sequence

Subjects who withdrew for any reason are set to non-response in this analysis on or after withdrawing.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRINAP = nonresponder imputation no advancement penalty; q2w = every 2 weeks; SC = subcutaneous.

Table 39. Normal Approximation to DAS28-4 (ESR) <2.6 Rates per Visit (FAS, NRINAP) Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRINAP)	Tofacitinib 5 mg BID	172	3	1.74	0.99	1.74	-0.21	3.70	0.0805
	Tofacitinib 10 mg BID	175	5	2.86	1.25	2.26	0.38	5.32	0.0232
	Placebo→5 mg	49	0	0.00	-	-	-	-	-
	Placebo→10 mg	41	1	2.44	2.40	1.01	-2.28	7.16	0.3113
	Adalimumab 40 mg SC q2w	176	6	3.41	1.36	2.49	0.72	6.09	0.0126
Month 3 (NRINAP)	Tofacitinib 5 mg BID	177	10	5.65	1.73	3.25	2.24	9.05	0.0011
	Tofacitinib 10 mg BID	176	12	6.82	1.89	3.58	3.09	10.54	0.0003
	Placebo→5 mg	50	0	0.00	-	-	-	-	-
	Placebo→10 mg	42	1	2.38	2.35	1.01	-2.22	6.99	0.3114
	Adalimumab 40 mg SC q2w	178	8	4.49	1.55	2.89	1.45	7.53	0.0038
Month 6 (NRINAP)	Tofacitinib 5 mg BID	177	11	6.21	1.81	3.42	2.65	9.77	0.0006
	Tofacitinib 10 mg BID	176	23	13.07	2.54	5.14	8.08	18.04	<0.0001
	Placebo→5 mg	50	1	2.00	1.97	1.01	-1.88	5.88	0.3124
	Placebo→10 mg	42	1	2.38	2.35	1.01	-2.22	6.99	0.3114
	Adalimumab 40 mg SC q2w	178	13	7.30	1.95	3.74	3.48	11.12	0.0001
Month 9 (NRINAP)	Tofacitinib 5 mg BID	177	15	8.47	2.09	4.04	4.37	12.57	<0.0001
	Tofacitinib 10 mg BID	176	23	13.07	2.54	5.14	8.08	18.04	<0.0001
	Placebo→5 mg	50	5	10.00	4.24	2.35	1.68	18.31	0.0184
	Placebo→10 mg	42	6	14.29	5.39	2.64	3.70	24.86	0.0081
	Adalimumab 40 mg SC q2w	178	20	11.24	2.36	4.74	6.59	15.87	<0.0001
Month 12 (NRINAP)	Tofacitinib 5 mg BID	177	19	10.73	2.32	4.61	6.17	15.29	<0.0001
	Tofacitinib 10 mg BID	176	26	14.77	2.67	5.52	9.53	20.01	<0.0001
	Placebo→5 mg	50	2	4.00	2.77	1.44	-1.43	9.43	0.1489
	Placebo→10 mg	42	5	11.90	4.99	2.38	2.11	21.69	0.0172
	Adalimumab 40 mg SC q2w	178	33	18.54	2.91	6.36	12.83	24.24	<0.0001

Table 39. Normal Approximation to DAS28-4 (ESR) <2.6 Rates per Visit (FAS, NRINAP) Comparisons Within Sequence

Subjects who withdrew for any reason are set to non-response in this analysis on or after withdrawing.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRINAP = nonresponder imputation no advancement penalty; q2w = every 2 weeks; SC = subcutaneous.

Table 40. Normal Approximation to DAS28-4 (ESR) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRINAP) Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRINAP)	Tofacitinib 5 mg BID	172	95	55.23	3.79	14.56	47.80	62.66	<0.0001
	Tofacitinib 10 mg BID	175	99	56.57	3.74	15.09	49.22	63.91	<0.0001
	Placebo→5 mg	48	12	25.00	6.25	4.00	12.75	37.25	<0.0001
	Placebo→10 mg	41	8	19.51	6.18	3.15	7.38	31.64	0.0016
	Adalimumab 40 mg SC q2w	176	96	54.55	3.75	14.53	47.18	61.90	<0.0001
Month 3 (NRINAP)	Tofacitinib 5 mg BID	177	128	72.32	3.36	21.50	65.72	78.90	<0.0001
	Tofacitinib 10 mg BID	176	121	68.75	3.49	19.67	61.90	75.59	<0.0001
	Placebo→5 mg	49	20	40.82	7.02	5.81	27.05	54.57	<0.0001
	Placebo→10 mg	42	15	35.71	7.39	4.83	21.22	50.20	<0.0001
	Adalimumab 40 mg SC q2w	178	126	70.79	3.40	20.76	64.10	77.46	<0.0001
Month 6 (NRINAP)	Tofacitinib 5 mg BID	177	120	67.80	3.51	19.30	60.91	74.68	<0.0001
	Tofacitinib 10 mg BID	176	130	73.86	3.31	22.30	67.37	80.35	<0.0001
	Placebo→5 mg	49	32	65.31	6.79	9.60	51.97	78.63	<0.0001
	Placebo→10 mg	42	30	71.43	6.97	10.24	57.76	85.09	<0.0001
	Adalimumab 40 mg SC q2w	178	122	68.54	3.48	19.69	61.71	75.36	<0.0001
Month 9 (NRINAP)	Tofacitinib 5 mg BID	177	126	71.19	3.40	20.91	64.51	77.85	<0.0001
	Tofacitinib 10 mg BID	176	123	69.89	3.45	20.21	63.10	76.66	<0.0001
	Placebo→5 mg	49	38	77.55	5.96	13.01	65.86	89.23	<0.0001
	Placebo→10 mg	42	29	69.05	7.13	9.67	55.06	83.02	<0.0001
	Adalimumab 40 mg SC q2w	178	121	67.98	3.49	19.43	61.12	74.83	<0.0001
Month 12 (NRINAP)	Tofacitinib 5 mg BID	177	122	68.93	3.47	19.81	62.10	75.74	<0.0001
	Tofacitinib 10 mg BID	176	125	71.02	3.41	20.76	64.32	77.72	<0.0001
	Placebo→5 mg	49	38	77.55	5.96	13.01	65.86	89.23	<0.0001
	Placebo→10 mg	42	31	73.81	6.78	10.87	60.51	87.10	<0.0001
	Adalimumab 40 mg SC q2w	178	119	66.85	3.52	18.94	59.93	73.76	<0.0001

Table 40. Normal Approximation to DAS28-4 (ESR) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRINAP) Comparisons Within Sequence

Subjects who withdrew for any reason are set to non-response in this analysis on or after withdrawing.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria; NRINAP = nonresponder imputation no advancement penalty; q2w = every 2 weeks; SC = subcutaneous.

Table 41. Rates of Consecutive Visits With a DAS28-4 (ESR) <2.6 (No Imputation)

Treatment Sequence	N	Most Consecutive Visits of Response			
		2 Consecutive n (%)	3 Consecutive n (%)	4 Consecutive n (%)	5 Consecutive n (%)
Tofacitinib 5 mg BID	201	6 (3.0%)	3 (1.5%)	2 (<1.0%)	1 (<1.0%)
Tofacitinib 10 mg BID	199	11 (5.5%)	5 (2.5%)	5 (2.5%)	0.0
Placebo→5 mg	56	1 (1.8%)	0.0	0.0	0.0
Placebo→10 mg	51	1 (2.0%)	0.0	1 (2.0%)	0.0
Adalimumab 40 mg SC q2w	201	10 (5.0%)	7 (3.5%)	4 (2.0%)	0.0

N refered to the number in each sequence at Baseline, with percent = 100 (n/N).
A subject was represented only once in each cell.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either.
Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; DAS = Disease Activity Score; ESR = erythrocytes sedimentation rate; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous.

Patient Reported Outcomes:

SF-36 (Version 2, Acute):

SF-36 results based upon physical functioning, role physical, social functioning, bodily pain, mental health, role emotional, vitality, general health, mental component and physical component are presented in Table 42, Table 43, Table 44, Table 45, Table 46, Table 47, Table 48, Table 49, Table 50 and Table 51 respectively.

Work Limitations Questionnaire (WLQ):

Results based on 4 domain scores: Time Management Score, Physical Demands Scale, Mental-Interpersonal Demands Scale, Output Demands Scale and the Work Loss Index are summarized in Table 52, Table 53, Table 54, Table 55 and Table 56 respectively.

EuroQol EQ-5D:

The EuroQoL EQ-5D questionnaire results are summarized in Table 57.

Medical Outcomes Study (MOS) Sleep Scale:

Based on 8 subscales, results are presented in Table 58, Table 59, Table 60, Table 61, Table 62, Table 63, Table 64, Table 65, and Table 66. The number of subjects with optimal sleep assessing using the MOS sleep scale is presented in Table 67.

FACIT Fatigue Scale:

Results for this scale are given in Table 68.

Rates of Clinically Meaningful Decrease in the HAQ-DI:

Rates of at least 0.22, 0.3 and 0.5 units improvement (decrease) in the HAQ-DI are presented in Table 69, Table 70 and Table 71, respectively. Rates of at least 0.8 units improvement (decrease) in the HAQ-DI were not analyzed.

Work Productivity and Healthcare Resource Utilization (HCRU): Results at Baseline, Month 1, Month 3, Month 6, Month 9 and Month 12 are presented in Table 72, Table 73, Table 74, Table 75, Table 76, Table 77, Table 78, Table 79, Table 80, Table 81, Table 82, Table 83, Table 84, Table 85, Table 86, Table 87, Table 88, Table 89, Table 90, Table 91, Table 92, Table 93, Table 94, Table 95, Table 96, Table 97, Table 98 Table 99, Table 100, Table 101, Table 102, Table 103, Table 104, Table 105, Table 106, Table 107, Table 108, Table 109, Table 110, Table 111, Table 112, Table 113, Table 114, Table 115, Table 116, Table 117, Table 118, Table 119, Table 120, Table 121, and Table 122.

Table 42. Descriptive Statistics of SF-36 Physical Functioning per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	32.02	9.48	16.18	24.37	30.51	38.69	57.11
	Tofacitinib 10 mg BID	199	31.06	9.52	16.18	24.37	30.51	36.65	57.11
	Placebo→5 mg	55	31.74	9.20	16.18	24.37	30.51	38.69	48.93
	Placebo→10 mg	51	32.75	9.74	16.18	26.41	32.55	38.69	53.02
	Adalimumab 40 mg SC q2w	201	31.74	8.95	16.18	24.37	30.51	36.65	57.11
Month 1	Tofacitinib 5 mg BID	194	35.29	9.94	16.18	28.46	34.60	40.74	57.11
	Tofacitinib 10 mg BID	196	35.23	10.57	16.18	26.41	34.60	42.79	57.11
	Placebo→5 mg	56	33.76	9.79	16.18	26.41	33.58	40.74	53.02
	Placebo→10 mg	50	34.27	9.65	16.18	26.41	34.60	40.74	53.02
	Adalimumab 40 mg SC q2w	198	35.38	9.79	16.18	28.46	34.60	42.79	57.11
Month 3	Tofacitinib 5 mg BID	187	38.11	10.39	16.18	30.51	38.69	46.88	57.11
	Tofacitinib 10 mg BID	185	38.49	11.12	16.18	30.51	38.69	46.88	57.11
	Placebo→5 mg	55	34.60	9.30	16.18	26.41	34.60	40.74	55.07
	Placebo→10 mg	44	34.97	8.53	16.18	28.46	35.62	40.74	55.07
	Adalimumab 40 mg SC q2w	190	36.56	10.24	16.18	28.46	36.65	42.79	57.11
Month 6	Tofacitinib 5 mg BID	173	39.31	10.92	16.18	30.51	40.74	48.93	57.11
	Tofacitinib 10 mg BID	181	38.56	11.35	16.18	30.51	38.69	48.93	57.11
	Placebo→5 mg	52	36.61	9.21	20.27	29.48	36.65	44.83	57.11
	Placebo→10 mg	42	38.64	9.27	16.18	30.51	40.74	44.83	57.11
	Adalimumab 40 mg SC q2w	179	37.29	10.40	16.18	28.46	36.65	44.83	57.11
Month 9	Tofacitinib 5 mg BID	158	39.77	10.29	16.18	32.55	40.74	48.93	57.11
	Tofacitinib 10 mg BID	167	38.74	11.31	16.18	30.51	38.69	48.93	57.11
	Placebo→5 mg	49	38.94	9.81	20.27	34.60	38.69	46.88	57.11
	Placebo→10 mg	41	38.59	10.08	16.18	32.55	36.65	46.88	57.11
	Adalimumab 40 mg SC q2w	171	38.75	10.23	16.18	32.55	38.69	46.88	57.11
Month 12	Tofacitinib 5 mg BID	149	40.16	10.25	16.18	32.55	40.74	48.93	57.11
	Tofacitinib 10 mg BID	149	40.34	11.59	16.18	30.51	42.79	50.97	57.11

Table 42. Descriptive Statistics of SF-36 Physical Functioning per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	39.24	10.07	20.27	32.55	38.69	48.93	57.11
	Placebo→10 mg	38	40.42	9.84	16.18	32.55	42.79	46.88	57.11
	Adalimumab 40 mg SC q2w	160	39.21	10.63	16.18	32.55	40.74	46.88	57.11

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 43. Descriptive Statistics of SF-36 Role Physical Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	34.00	9.11	18.45	27.99	35.15	37.53	56.62
	Tofacitinib 10 mg BID	199	33.54	9.12	18.45	27.99	32.76	39.92	56.62
	Placebo→5 mg	55	34.80	7.89	18.45	27.99	37.53	37.53	54.24
	Placebo→10 mg	51	34.59	8.22	18.45	27.99	35.15	39.92	51.85
	Adalimumab 40 mg SC q2w	201	34.79	8.69	18.45	27.99	35.15	39.92	56.62
Month 1	Tofacitinib 5 mg BID	194	38.19	9.34	18.45	32.76	37.53	44.69	56.62
	Tofacitinib 10 mg BID	196	38.45	10.01	18.45	30.38	37.53	47.08	56.62
	Placebo→5 mg	56	37.53	9.66	18.45	30.38	37.53	44.69	56.62
	Placebo→10 mg	50	35.96	9.10	18.45	27.99	36.34	39.92	56.62
	Adalimumab 40 mg SC q2w	198	38.37	9.06	18.45	32.76	37.53	44.69	56.62
Month 3	Tofacitinib 5 mg BID	188	39.79	9.55	18.45	33.96	37.53	47.08	56.62
	Tofacitinib 10 mg BID	185	40.93	10.40	18.45	32.76	39.92	49.47	56.62
	Placebo→5 mg	55	37.58	9.04	18.45	32.76	37.53	42.31	56.62
	Placebo→10 mg	44	36.83	8.77	18.45	29.18	37.53	42.31	56.62
	Adalimumab 40 mg SC q2w	190	39.51	8.89	20.83	32.76	37.53	47.08	56.62
Month 6	Tofacitinib 5 mg BID	173	40.42	10.03	18.45	32.76	39.92	47.08	56.62
	Tofacitinib 10 mg BID	181	41.29	9.73	18.45	35.15	42.31	47.08	56.62
	Placebo→5 mg	52	39.78	8.47	18.45	35.15	38.73	47.08	56.62
	Placebo→10 mg	42	39.81	7.99	25.60	32.76	37.53	47.08	56.62
	Adalimumab 40 mg SC q2w	179	39.99	9.14	18.45	35.15	37.53	47.08	56.62
Month 9	Tofacitinib 5 mg BID	159	41.66	9.62	18.45	35.15	39.92	49.47	56.62
	Tofacitinib 10 mg BID	167	40.55	10.15	18.45	35.15	39.92	47.08	56.62
	Placebo→5 mg	49	41.77	8.36	23.22	37.53	42.31	47.08	56.62
	Placebo→10 mg	41	39.75	9.20	25.60	32.76	37.53	47.08	56.62
	Adalimumab 40 mg SC q2w	171	41.12	9.44	18.45	35.15	39.92	47.08	56.62
Month 12	Tofacitinib 5 mg BID	150	41.15	9.35	18.45	35.15	39.92	47.08	56.62
	Tofacitinib 10 mg BID	150	42.34	10.32	18.45	37.53	42.31	51.85	56.62

Table 43. Descriptive Statistics of SF-36 Role Physical Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	40.16	8.73	23.22	32.76	39.92	47.08	56.62
	Placebo→10 mg	38	41.18	9.30	18.45	37.53	39.92	47.08	56.62
	Adalimumab 40 mg SC q2w	160	41.07	9.29	18.45	35.15	38.73	49.47	56.62

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 44. Descriptive Statistics of SF-36 Social Functioning Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	36.15	10.76	13.38	29.52	34.89	40.27	56.40
	Tofacitinib 10 mg BID	199	36.27	11.59	13.38	29.52	34.89	45.65	56.40
	Placebo→5 mg	55	38.51	11.62	13.38	29.52	34.89	45.65	56.40
	Placebo→10 mg	51	40.27	10.70	18.76	34.89	40.27	51.03	56.40
	Adalimumab 40 mg SC q2w	201	36.23	11.52	13.38	24.14	34.89	45.65	56.40
Month 1	Tofacitinib 5 mg BID	194	40.77	10.53	13.38	34.89	40.27	45.65	56.40
	Tofacitinib 10 mg BID	196	42.22	10.64	13.38	34.89	40.27	51.03	56.40
	Placebo→5 mg	56	41.42	10.54	24.14	34.89	40.27	51.03	56.40
	Placebo→10 mg	50	42.10	11.01	24.14	34.89	45.65	51.03	56.40
	Adalimumab 40 mg SC q2w	198	40.98	10.41	13.38	34.89	40.27	51.03	56.40
Month 3	Tofacitinib 5 mg BID	188	41.59	11.04	13.38	34.89	42.96	51.03	56.40
	Tofacitinib 10 mg BID	185	44.34	11.00	13.38	34.89	45.65	56.40	56.40
	Placebo→5 mg	55	41.54	10.90	13.38	34.89	40.27	51.03	56.40
	Placebo→10 mg	44	41.25	9.08	24.14	34.89	40.27	45.65	56.40
	Adalimumab 40 mg SC q2w	190	40.84	10.92	13.38	34.89	40.27	51.03	56.40
Month 6	Tofacitinib 5 mg BID	173	43.85	11.17	13.38	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	181	43.98	11.30	13.38	34.89	45.65	56.40	56.40
	Placebo→5 mg	52	44.30	10.15	18.76	34.89	45.65	56.40	56.40
	Placebo→10 mg	42	42.58	9.88	24.14	34.89	42.96	51.03	56.40
	Adalimumab 40 mg SC q2w	180	42.36	10.43	13.38	34.89	40.27	51.03	56.40
Month 9	Tofacitinib 5 mg BID	159	43.52	10.65	13.38	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	167	44.42	9.96	13.38	34.89	45.65	56.40	56.40
	Placebo→5 mg	49	44.55	9.82	24.14	34.89	45.65	51.03	56.40
	Placebo→10 mg	41	42.76	9.78	24.14	40.27	45.65	51.03	56.40
	Adalimumab 40 mg SC q2w	171	42.03	11.55	13.38	34.89	40.27	56.40	56.40
Month 12	Tofacitinib 5 mg BID	150	43.14	10.46	13.38	34.89	45.65	51.03	56.40
	Tofacitinib 10 mg BID	150	44.07	10.44	18.76	34.89	45.65	56.40	56.40

Table 44. Descriptive Statistics of SF-36 Social Functioning Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	43.78	9.97	24.14	34.89	45.65	51.03	56.40
	Placebo→10 mg	38	44.94	9.78	24.14	40.27	45.65	56.40	56.40
	Adalimumab 40 mg SC q2w	160	42.96	10.92	18.76	34.89	40.27	56.40	56.40

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 45. Descriptive Statistics of SF-36 Bodily Pain Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	33.42	7.51	19.23	28.40	32.56	36.31	54.22
	Tofacitinib 10 mg BID	199	33.29	7.42	19.23	28.40	32.14	36.31	54.22
	Placebo→5 mg	55	33.86	6.96	19.23	28.40	36.31	36.31	49.22
	Placebo→10 mg	51	35.26	6.11	24.23	32.14	36.31	36.31	54.22
	Adalimumab 40 mg SC q2w	201	33.14	7.33	19.23	28.40	32.14	36.31	54.22
Month 1	Tofacitinib 5 mg BID	194	40.14	8.54	19.23	36.31	40.47	45.06	60.88
	Tofacitinib 10 mg BID	196	40.73	8.46	19.23	36.31	40.47	45.06	60.88
	Placebo→5 mg	56	36.72	7.34	23.40	32.14	36.31	40.89	54.22
	Placebo→10 mg	50	35.57	7.76	19.23	28.40	36.31	40.47	54.22
	Adalimumab 40 mg SC q2w	198	39.58	8.36	19.23	36.31	36.31	45.06	60.88
Month 3	Tofacitinib 5 mg BID	187	41.08	9.15	19.23	36.31	40.89	45.89	60.88
	Tofacitinib 10 mg BID	185	43.09	9.58	19.23	36.31	45.06	50.05	60.88
	Placebo→5 mg	55	37.57	7.76	19.23	32.14	36.31	40.89	54.22
	Placebo→10 mg	44	36.39	8.14	19.23	30.27	36.31	40.89	54.22
	Adalimumab 40 mg SC q2w	190	40.60	9.54	19.23	32.56	40.47	45.89	60.88
Month 6	Tofacitinib 5 mg BID	173	42.79	9.41	19.23	36.31	45.06	50.05	60.88
	Tofacitinib 10 mg BID	181	43.63	9.31	19.23	36.31	45.06	50.05	60.88
	Placebo→5 mg	52	40.29	8.21	19.23	36.31	40.47	45.06	60.88
	Placebo→10 mg	42	40.58	7.29	24.23	36.31	40.68	45.06	54.22
	Adalimumab 40 mg SC q2w	180	41.59	8.95	23.40	36.31	40.89	50.05	60.88
Month 9	Tofacitinib 5 mg BID	159	43.45	9.02	23.40	36.31	45.06	50.05	60.88
	Tofacitinib 10 mg BID	166	42.75	9.50	23.40	36.31	45.06	50.05	60.88
	Placebo→5 mg	49	44.68	8.86	24.23	40.47	44.64	50.05	60.88
	Placebo→10 mg	41	42.26	7.77	28.40	36.31	40.89	45.06	60.88
	Adalimumab 40 mg SC q2w	171	41.81	9.73	19.23	36.31	40.89	50.05	60.88
Month 12	Tofacitinib 5 mg BID	150	43.44	9.48	19.23	36.31	45.06	50.05	60.88
	Tofacitinib 10 mg BID	150	44.02	10.02	19.23	36.31	45.06	50.05	60.88

Table 45. Descriptive Statistics of SF-36 Bodily Pain Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	43.90	8.28	32.14	36.31	45.06	50.05	60.88
	Placebo→10 mg	38	43.18	7.76	28.40	36.31	45.06	50.05	60.88
	Adalimumab 40 mg SC q2w	160	42.73	9.77	24.23	36.31	45.06	50.05	60.88

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 46. Descriptive Statistics of SF-36 Mental Health Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	39.04	11.42	10.79	32.96	38.50	46.81	63.43
	Tofacitinib 10 mg BID	199	39.15	11.19	8.02	32.96	38.50	46.81	63.43
	Placebo→5 mg	55	40.76	9.73	21.87	35.73	41.27	46.81	60.66
	Placebo→10 mg	51	41.48	11.38	19.10	32.96	41.27	52.35	60.66
	Adalimumab 40 mg SC q2w	201	39.64	11.19	16.33	32.96	38.50	49.58	63.43
Month 1	Tofacitinib 5 mg BID	194	42.31	10.3	10.79	35.73	41.27	49.58	63.43
	Tofacitinib 10 mg BID	196	43.35	11.13	8.02	35.73	44.04	52.35	63.43
	Placebo→5 mg	56	41.81	10.30	13.56	34.34	44.04	49.58	63.43
	Placebo→10 mg	50	41.77	11.66	16.33	35.73	41.27	49.58	60.66
	Adalimumab 40 mg SC q2w	198	42.83	10.93	8.02	35.73	41.27	52.35	63.43
Month 3	Tofacitinib 5 mg BID	188	42.43	11.02	10.79	35.73	44.04	50.96	63.43
	Tofacitinib 10 mg BID	185	44.79	11.25	8.02	35.73	44.04	55.12	63.43
	Placebo→5 mg	55	42.43	10.35	16.33	35.73	41.27	49.58	63.43
	Placebo→10 mg	44	42.46	9.75	19.10	35.73	42.65	49.58	57.89
	Adalimumab 40 mg SC q2w	190	43.05	10.45	16.33	35.73	41.27	52.35	63.43
Month 6	Tofacitinib 5 mg BID	173	44.31	11.29	10.79	35.73	46.81	52.35	63.43
	Tofacitinib 10 mg BID	181	45.32	11.43	8.02	35.73	46.81	52.35	63.43
	Placebo→5 mg	52	41.96	10.59	16.33	35.73	41.27	49.58	60.66
	Placebo→10 mg	42	42.32	12.16	10.79	35.73	41.27	52.35	60.66
	Adalimumab 40 mg SC q2w	180	43.13	11.35	16.33	35.73	44.04	52.35	63.43
Month 9	Tofacitinib 5 mg BID	159	44.47	10.27	13.56	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	166	45.42	10.44	10.79	38.50	46.81	52.35	63.43
	Placebo→5 mg	49	44.83	10.70	16.33	38.50	44.04	52.35	63.43
	Placebo→10 mg	41	43.70	10.16	13.56	35.73	46.81	49.58	57.89
	Adalimumab 40 mg SC q2w	171	43.44	12.04	8.02	35.73	44.04	52.35	63.43
Month 12	Tofacitinib 5 mg BID	150	44.83	10.02	21.87	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	149	45.06	10.49	21.87	35.73	46.81	52.35	63.43

Table 46. Descriptive Statistics of SF-36 Mental Health Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	44.09	9.20	21.87	35.73	46.81	49.58	57.89
	Placebo→10 mg	38	45.28	10.94	16.33	41.27	46.81	52.35	60.66
	Adalimumab 40 mg SC q2w	159	44.23	10.93	19.10	35.73	44.04	52.35	63.43

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 47. Descriptive Statistics of SF-36 Role Emotional Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	34.15	12.49	10.25	25.39	32.96	44.32	55.68
	Tofacitinib 10 mg BID	199	34.11	12.63	10.25	25.39	32.96	40.54	55.68
	Placebo→5 mg	55	37.44	12.39	10.25	29.18	36.75	48.11	55.68
	Placebo→10 mg	51	37.20	11.62	10.25	29.18	36.75	44.32	55.68
	Adalimumab 40 mg SC q2w	201	35.54	12.05	10.25	25.39	32.96	44.32	55.68
Month 1	Tofacitinib 5 mg BID	194	38.29	12.54	10.25	32.96	36.75	48.11	55.68
	Tofacitinib 10 mg BID	196	38.64	12.05	10.25	32.96	40.54	48.11	55.68
	Placebo→5 mg	56	38.30	11.84	10.25	29.18	36.75	48.11	55.68
	Placebo→10 mg	50	38.04	12.06	17.82	29.18	36.75	48.11	55.68
	Adalimumab 40 mg SC q2w	198	39.10	11.55	10.25	32.96	36.75	48.11	55.68
Month 3	Tofacitinib 5 mg BID	188	38.74	12.56	10.25	32.96	36.75	51.89	55.68
	Tofacitinib 10 mg BID	185	41.76	12.66	10.25	32.96	44.32	55.68	55.68
	Placebo→5 mg	55	38.20	11.51	10.25	29.18	36.75	44.32	55.68
	Placebo→10 mg	44	39.07	13.59	10.25	27.29	40.54	51.89	55.68
	Adalimumab 40 mg SC q2w	190	39.24	11.53	10.25	32.96	40.54	48.11	55.68
Month 6	Tofacitinib 5 mg BID	173	40.78	12.03	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	181	40.68	11.77	10.25	32.96	40.54	51.89	55.68
	Placebo→5 mg	52	39.73	10.74	17.82	32.96	40.54	46.21	55.68
	Placebo→10 mg	42	39.90	12.11	14.03	32.96	36.75	51.89	55.68
	Adalimumab 40 mg SC q2w	179	39.54	11.85	10.25	32.96	40.54	48.11	55.68
Month 9	Tofacitinib 5 mg BID	159	39.98	11.99	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	167	40.58	12.07	10.25	32.96	44.32	51.89	55.68
	Placebo→5 mg	49	39.84	11.40	10.25	32.96	40.54	48.11	55.68
	Placebo→10 mg	41	41.46	11.81	21.61	32.96	44.32	55.68	55.68
	Adalimumab 40 mg SC q2w	171	40.07	12.15	10.25	32.96	40.54	51.89	55.68
Month 12	Tofacitinib 5 mg BID	150	40.18	11.46	10.25	32.96	40.54	48.11	55.68
	Tofacitinib 10 mg BID	150	42.25	11.68	10.25	32.96	44.32	55.68	55.68

Table 47. Descriptive Statistics of SF-36 Role Emotional Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	40.23	10.79	21.61	32.96	36.75	51.89	55.68
	Placebo→10 mg	38	41.03	12.67	10.25	32.96	44.32	51.89	55.68
	Adalimumab 40 mg SC q2w	159	39.89	11.63	10.25	32.96	40.54	48.11	55.68

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 48. Descriptive Statistics of SF-36 Vitality Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	40.62	9.23	22.02	33.99	39.98	45.97	66.92
	Tofacitinib 10 mg BID	199	40.79	9.36	22.02	33.99	39.98	48.96	60.93
	Placebo→5 mg	55	43.52	7.90	28.01	36.99	42.97	48.96	60.93
	Placebo→10 mg	51	41.76	9.77	22.02	33.99	39.98	51.95	57.94
	Adalimumab 40 mg SC q2w	201	39.95	9.54	22.02	33.99	39.98	45.97	60.93
Month 1	Tofacitinib 5 mg BID	194	45.24	9.33	22.02	39.98	45.97	51.95	69.92
	Tofacitinib 10 mg BID	196	46.99	9.58	22.02	39.98	47.46	54.95	69.92
	Placebo→5 mg	56	44.36	8.17	22.02	36.99	45.97	48.96	63.93
	Placebo→10 mg	50	42.97	9.37	22.02	36.99	42.97	48.96	57.94
	Adalimumab 40 mg SC q2w	198	44.44	10.00	22.02	36.99	45.97	51.95	69.92
Month 3	Tofacitinib 5 mg BID	188	45.63	9.91	22.02	39.98	45.97	51.95	69.92
	Tofacitinib 10 mg BID	185	48.09	10.79	22.02	39.98	48.96	57.94	69.92
	Placebo→5 mg	55	44.28	8.96	22.02	36.99	45.97	48.96	69.92
	Placebo→10 mg	44	43.79	9.63	22.02	36.99	42.97	51.95	60.93
	Adalimumab 40 mg SC q2w	190	45.57	9.76	22.02	39.98	45.97	51.95	69.92
Month 6	Tofacitinib 5 mg BID	173	47.35	10.37	22.02	42.97	48.96	54.95	69.92
	Tofacitinib 10 mg BID	181	48.66	10.08	22.02	39.98	48.96	54.95	69.92
	Placebo→5 mg	52	45.33	8.72	22.02	36.99	45.97	51.95	57.94
	Placebo→10 mg	42	45.90	9.17	22.02	39.98	45.97	51.95	60.93
	Adalimumab 40 mg SC q2w	180	45.93	9.88	22.02	39.98	45.97	51.95	69.92
Month 9	Tofacitinib 5 mg BID	159	47.76	9.51	22.02	42.97	48.96	54.95	69.92
	Tofacitinib 10 mg BID	166	48.69	9.68	22.02	42.97	48.96	54.95	69.92
	Placebo→5 mg	49	47.80	8.94	22.02	45.97	48.96	54.95	60.93
	Placebo→10 mg	41	46.41	10.03	22.02	39.98	48.96	51.95	63.93
	Adalimumab 40 mg SC q2w	171	46.11	10.28	22.02	39.98	45.97	54.95	69.92
Month 12	Tofacitinib 5 mg BID	150	47.60	9.01	22.02	42.97	45.97	54.95	63.93
	Tofacitinib 10 mg BID	149	49.12	9.95	25.01	42.97	48.96	54.95	69.92

Table 48. Descriptive Statistics of SF-36 Vitality Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	47.31	9.13	22.02	42.97	45.97	54.95	63.93
	Placebo→10 mg	38	48.17	9.36	22.02	45.97	47.46	54.95	63.93
	Adalimumab 40 mg SC q2w	159	46.27	9.65	22.02	39.98	45.97	54.95	69.92

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 49. Descriptive Statistics of SF-36 General Health Perception Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	35.22	8.95	16.75	28.49	34.13	41.18	56.68
	Tofacitinib 10 mg BID	199	35.81	8.93	16.75	28.49	34.13	41.18	62.31
	Placebo→5 mg	55	36.16	8.30	19.10	30.84	35.54	43.53	52.92
	Placebo→10 mg	51	36.44	8.55	22.39	30.84	37.89	40.24	62.31
	Adalimumab 40 mg SC q2w	201	35.18	7.96	16.75	28.49	35.54	38.83	55.27
Month 1	Tofacitinib 5 mg BID	194	38.53	9.24	16.75	33.19	38.83	43.53	63.72
	Tofacitinib 10 mg BID	196	39.98	9.16	16.75	34.13	40.24	45.40	62.31
	Placebo→5 mg	56	38.24	9.27	19.10	31.31	37.18	44.70	57.62
	Placebo→10 mg	50	36.48	7.78	19.10	30.84	35.54	41.18	55.27
	Adalimumab 40 mg SC q2w	198	38.35	8.43	16.75	33.19	37.89	43.53	62.31
Month 3	Tofacitinib 5 mg BID	188	39.15	9.52	16.75	30.84	37.89	45.87	63.72
	Tofacitinib 10 mg BID	185	41.35	8.93	16.75	36.48	41.18	47.28	63.72
	Placebo→5 mg	55	37.40	8.65	19.10	30.84	35.54	43.53	55.27
	Placebo→10 mg	44	37.65	7.42	22.39	31.31	36.01	43.53	52.92
	Adalimumab 40 mg SC q2w	189	39.33	9.32	16.75	33.19	37.89	45.87	63.72
Month 6	Tofacitinib 5 mg BID	173	40.53	9.44	19.10	33.19	41.18	48.22	62.31
	Tofacitinib 10 mg BID	180	41.95	8.89	19.10	36.48	42.59	48.22	62.31
	Placebo→5 mg	52	39.70	8.88	19.10	31.78	41.18	48.22	52.92
	Placebo→10 mg	42	38.40	7.51	24.74	33.19	38.36	41.18	57.62
	Adalimumab 40 mg SC q2w	180	39.91	8.72	21.45	34.13	38.83	45.87	62.31
Month 9	Tofacitinib 5 mg BID	159	41.15	9.79	19.10	33.19	41.18	49.63	63.72
	Tofacitinib 10 mg BID	166	41.34	9.20	19.10	36.48	41.18	45.87	63.72
	Placebo→5 mg	49	41.39	8.54	23.80	36.48	41.18	48.22	55.27
	Placebo→10 mg	41	40.57	9.34	19.10	34.13	38.83	45.87	62.31
	Adalimumab 40 mg SC q2w	171	40.12	9.58	16.75	33.19	40.24	45.87	63.72
Month 12	Tofacitinib 5 mg BID	150	41.07	9.85	19.10	33.19	41.18	48.22	63.72
	Tofacitinib 10 mg BID	150	42.33	9.05	21.45	36.48	41.18	48.22	63.72

Table 49. Descriptive Statistics of SF-36 General Health Perception Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	40.47	9.44	19.10	30.84	41.18	48.22	62.31
	Placebo→10 mg	38	40.77	8.31	24.74	34.13	41.18	45.87	59.97
	Adalimumab 40 mg SC q2w	160	40.40	9.13	16.75	33.19	40.24	45.87	62.31

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 50. Descriptive Statistics of SF-36 Mental Component Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	39.82	11.68	9.07	31.46	39.60	47.85	66.33
	Tofacitinib 10 mg BID	199	40.21	11.14	10.46	33.33	39.33	47.78	67.93
	Placebo→5 mg	55	43.31	9.96	25.19	36.91	41.10	49.87	65.60
	Placebo→10 mg	51	43.26	11.30	18.52	33.90	44.28	50.30	72.57
	Adalimumab 40 mg SC q2w	201	40.58	11.64	17.25	31.56	38.87	49.99	68.30
Month 1	Tofacitinib 5 mg BID	194	43.56	10.60	17.40	36.49	42.96	52.01	64.16
	Tofacitinib 10 mg BID	196	44.92	11.21	11.90	36.88	45.53	53.68	72.01
	Placebo→5 mg	56	44.06	10.50	16.21	35.97	42.62	53.10	64.73
	Placebo→10 mg	50	43.99	11.72	22.13	36.45	43.64	52.72	69.14
	Adalimumab 40 mg SC q2w	198	44.05	10.79	9.25	36.15	42.54	53.10	66.80
Month 3	Tofacitinib 5 mg BID	187	43.31	11.47	5.27	34.97	43.88	52.73	64.49
	Tofacitinib 10 mg BID	185	46.49	11.45	11.11	38.87	45.92	55.82	69.03
	Placebo→5 mg	55	44.06	9.85	19.86	37.32	45.01	51.30	62.05
	Placebo→10 mg	44	44.38	11.69	14.59	36.14	44.53	53.07	69.24
	Adalimumab 40 mg SC q2w	189	43.90	10.84	14.09	35.47	43.18	52.36	64.41
Month 6	Tofacitinib 5 mg BID	173	45.44	11.19	12.84	38.09	46.18	54.33	66.91
	Tofacitinib 10 mg BID	180	46.14	11.43	10.55	37.65	47.15	55.01	69.56
	Placebo→5 mg	52	44.46	9.92	21.94	37.32	44.40	53.09	65.44
	Placebo→10 mg	42	43.89	11.48	20.56	35.31	42.58	54.09	66.71
	Adalimumab 40 mg SC q2w	179	44.24	11.69	19.23	35.45	44.33	53.41	65.01
Month 9	Tofacitinib 5 mg BID	158	44.79	10.76	12.48	37.48	46.20	52.25	65.68
	Tofacitinib 10 mg BID	165	46.55	10.52	17.58	39.88	47.32	55.01	66.75
	Placebo→5 mg	49	45.31	9.75	20.84	39.88	45.40	52.85	62.82
	Placebo→10 mg	41	45.23	11.22	13.07	38.58	45.09	54.33	70.88
	Adalimumab 40 mg SC q2w	171	44.08	11.45	9.57	35.70	44.59	53.65	65.25
Month 12	Tofacitinib 5 mg BID	149	45.02	10.14	15.08	38.32	46.08	52.12	64.77
	Tofacitinib 10 mg BID	149	46.29	10.56	15.64	37.68	47.13	55.25	66.64

Table 50. Descriptive Statistics of SF-36 Mental Component Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	45.02	9.29	27.00	37.84	45.51	52.39	59.33
	Placebo→10 mg	38	46.12	11.75	16.61	38.92	47.11	55.44	65.08
	Adalimumab 40 mg SC q2w	158	44.42	10.70	20.20	36.54	44.23	52.76	63.10

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 51. Descriptive Statistics of SF-36 Physical Component Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	33.10	7.69	10.12	27.75	32.67	37.95	54.63
	Tofacitinib 10 mg BID	199	32.62	7.78	14.76	26.88	31.89	38.84	56.02
	Placebo→5 mg	55	32.69	6.17	21.06	27.70	32.90	37.40	49.19
	Placebo→10 mg	51	33.39	6.33	20.34	28.51	33.52	37.95	49.71
	Adalimumab 40 mg SC q2w	201	32.74	6.83	9.69	27.89	32.01	37.64	48.43
Month 1	Tofacitinib 5 mg BID	194	37.50	7.99	16.59	31.76	37.45	42.61	59.03
	Tofacitinib 10 mg BID	196	37.86	8.11	16.66	31.82	38.02	44.10	59.47
	Placebo→5 mg	56	35.54	7.26	22.99	30.57	34.79	41.75	55.85
	Placebo→10 mg	50	34.42	7.50	17.72	29.74	33.73	39.56	52.39
	Adalimumab 40 mg SC q2w	198	37.08	7.88	15.46	32.18	37.25	41.97	59.39
Month 3	Tofacitinib 5 mg BID	187	39.57	8.76	16.67	33.43	40.03	45.09	59.97
	Tofacitinib 10 mg BID	185	40.30	8.94	19.70	33.96	40.30	47.15	60.46
	Placebo→5 mg	55	35.85	7.57	22.22	29.14	35.91	40.85	56.11
	Placebo→10 mg	44	35.25	7.10	19.76	31.15	36.21	39.05	52.13
	Adalimumab 40 mg SC q2w	189	38.58	8.36	10.79	33.22	38.25	43.69	67.72
Month 6	Tofacitinib 5 mg BID	173	40.45	9.29	10.90	35.16	40.63	47.18	57.47
	Tofacitinib 10 mg BID	180	40.86	8.71	16.28	35.14	41.37	47.92	58.34
	Placebo→5 mg	52	38.74	7.34	19.47	33.90	37.25	43.75	52.95
	Placebo→10 mg	42	39.29	6.11	27.57	34.80	38.59	43.96	52.76
	Adalimumab 40 mg SC q2w	179	39.36	8.39	17.36	33.50	38.63	45.93	65.29
Month 9	Tofacitinib 5 mg BID	158	41.55	8.57	17.01	35.61	42.05	47.52	62.14
	Tofacitinib 10 mg BID	165	40.32	9.44	17.46	33.05	41.23	47.11	58.70
	Placebo→5 mg	49	41.65	8.20	23.91	37.25	40.52	47.31	57.55
	Placebo→10 mg	41	39.73	7.73	25.59	35.32	39.40	45.78	56.69
	Adalimumab 40 mg SC q2w	171	40.35	8.31	16.22	34.56	40.79	45.88	58.66
Month 12	Tofacitinib 5 mg BID	149	41.44	8.81	16.90	35.83	40.93	48.34	62.52
	Tofacitinib 10 mg BID	149	41.96	9.40	17.57	35.87	42.54	49.39	59.30

Table 51. Descriptive Statistics of SF-36 Physical Component Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Placebo→5 mg	49	40.82	8.01	23.69	34.62	41.23	47.10	57.20
	Placebo→10 mg	38	41.12	6.49	27.25	37.40	41.44	46.78	53.20
	Adalimumab 40 mg SC q2w	158	40.72	8.84	18.64	34.33	41.73	47.36	59.02

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous; SF-36 = Short Form-36.

Table 52. Descriptive Statistics of Work Limitation Questionnaire: Time Management Scale per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	79	41.46	23.42	0.00	25.00	40.00	60.00	100.00
	Tofacitinib 10 mg BID	77	42.09	28.98	0.00	16.67	40.00	65.00	100.00
	Placebo→5 mg	21	38.93	20.88	0.00	25.00	43.75	55.00	75.00
	Placebo→10 mg	19	36.23	26.98	0.00	10.00	25.00	65.00	80.00
	Adalimumab 40 mg SC q2w	76	46.43	25.94	0.00	27.50	50.00	66.88	100.00
Month 3	Tofacitinib 5 mg BID	74	31.31	25.50	0.00	10.00	25.00	50.00	90.00
	Tofacitinib 10 mg BID	68	21.97	25.52	0.00	0.00	10.00	36.25	90.00
	Placebo→5 mg	24	37.81	29.82	5.00	10.00	35.00	55.00	100.00
	Placebo→10 mg	16	28.93	19.96	5.00	15.00	22.50	50.00	65.00
	Adalimumab 40 mg SC q2w	70	35.73	28.50	0.00	5.00	32.29	55.00	100.00
Month 6	Tofacitinib 5 mg BID	68	29.87	26.81	0.00	5.00	25.00	50.00	100.00
	Tofacitinib 10 mg BID	65	21.30	27.67	0.00	0.00	10.00	25.00	100.00
	Placebo→5 mg	19	29.34	28.06	0.00	10.00	20.00	50.00	80.00
	Placebo→10 mg	11	25.45	24.54	0.00	5.00	20.00	30.00	75.00
	Adalimumab 40 mg SC q2w	67	29.70	25.24	0.00	5.00	25.00	50.00	85.00
Month 12	Tofacitinib 5 mg BID	55	25.59	25.10	0.00	0.00	20.00	45.00	80.00
	Tofacitinib 10 mg BID	53	20.77	28.68	0.00	0.00	5.00	30.00	100.00
	Placebo→5 mg	20	32.69	29.07	0.00	10.00	24.38	55.00	90.00
	Placebo→10 mg	14	28.75	28.26	0.00	10.00	20.00	62.50	80.00
	Adalimumab 40 mg SC q2w	57	26.57	26.68	0.00	0.00	20.00	50.00	95.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 53. Descriptive Statistics of Work Limitation Questionnaire: Physical Demands Scale per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	85	49.99	23.16	0.00	37.50	50.00	70.00	100.00
	Tofacitinib 10 mg BID	76	52.14	24.22	0.00	36.25	50.00	70.42	100.00
	Placebo→5 mg	22	51.95	21.07	8.33	37.50	50.00	68.75	83.33
	Placebo→10 mg	18	54.81	26.95	8.33	30.00	58.33	75.00	100.00
	Adalimumab 40 mg SC q2w	77	44.51	21.15	0.00	29.17	41.67	58.33	100.00
Month 3	Tofacitinib 5 mg BID	77	53.03	26.21	0.00	37.50	54.17	75.00	100.00
	Tofacitinib 10 mg BID	72	47.04	33.97	0.00	16.67	41.67	77.08	100.00
	Placebo→5 mg	24	61.37	27.46	20.00	35.42	54.17	90.00	100.00
	Placebo→10 mg	15	46.28	25.43	15.00	20.83	45.83	66.67	95.83
	Adalimumab 40 mg SC q2w	76	54.38	28.15	0.00	34.17	55.21	75.00	100.00
Month 6	Tofacitinib 5 mg BID	66	55.62	30.05	0.00	35.00	57.29	80.00	100.00
	Tofacitinib 10 mg BID	65	53.57	36.13	0.00	12.50	56.25	85.00	100.00
	Placebo→5 mg	18	49.10	29.45	0.00	25.00	40.83	75.00	93.75
	Placebo→10 mg	10	57.92	29.30	12.50	25.00	75.00	79.17	87.50
	Adalimumab 40 mg SC q2w	71	52.17	28.69	0.00	29.17	50.00	75.00	100.00
Month 12	Tofacitinib 5 mg BID	55	54.35	32.96	0.00	25.00	56.25	83.33	100.00
	Tofacitinib 10 mg BID	52	55.69	38.22	0.00	20.42	63.75	95.83	100.00
	Placebo→5 mg	18	51.81	32.57	0.00	25.00	50.00	87.50	95.83
	Placebo→10 mg	14	59.02	36.59	4.17	30.00	70.83	95.83	100.00
	Adalimumab 40 mg SC q2w	58	50.41	33.98	0.00	16.67	51.04	79.17	100.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 54. Descriptive Statistics of Work Limitation Questionnaire: Mental/Interpersonal Demands Scale per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	82	26.80	22.80	0.00	8.33	22.22	41.67	100.00
	Tofacitinib 10 mg BID	79	27.30	22.32	0.00	8.33	25.00	44.44	81.25
	Placebo→5 mg	22	26.36	28.21	0.00	5.56	13.89	36.11	100.00
	Placebo→10 mg	19	23.10	29.15	0.00	0.00	5.56	50.00	91.67
	Adalimumab 40 mg SC q2w	77	28.45	23.77	0.00	5.56	22.22	44.44	91.67
Month 3	Tofacitinib 5 mg BID	78	21.45	22.03	0.00	2.78	16.67	30.56	87.50
	Tofacitinib 10 mg BID	72	15.14	20.53	0.00	0.00	8.33	22.05	94.44
	Placebo→5 mg	24	27.14	27.61	0.00	4.17	19.05	40.28	100.00
	Placebo→10 mg	17	17.63	23.31	0.00	0.00	5.56	27.78	66.67
	Adalimumab 40 mg SC q2w	73	22.64	21.97	0.00	2.78	19.44	33.33	89.29
Month 6	Tofacitinib 5 mg BID	70	17.50	21.18	0.00	0.00	11.11	25.00	86.11
	Tofacitinib 10 mg BID	68	12.87	22.77	0.00	0.00	2.78	15.28	97.22
	Placebo→5 mg	19	26.30	29.96	0.00	2.78	19.44	50.00	94.44
	Placebo→10 mg	11	14.39	21.18	0.00	0.00	2.78	22.22	63.89
	Adalimumab 40 mg SC q2w	71	22.61	22.38	0.00	0.00	16.67	41.67	84.38
Month 12	Tofacitinib 5 mg BID	55	14.72	19.96	0.00	0.00	5.56	21.43	88.89
	Tofacitinib 10 mg BID	51	13.96	23.76	0.00	0.00	5.56	16.67	100.00
	Placebo→5 mg	21	21.46	27.11	0.00	0.00	12.50	29.17	97.22
	Placebo→10 mg	14	19.44	24.29	0.00	0.00	5.56	33.33	72.22
	Adalimumab 40 mg SC q2w	58	17.99	20.10	0.00	0.00	11.63	33.33	69.44

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 55. Descriptive Statistics of Work Limitation Questionnaire: Output Demands Scale per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	80	36.34	26.55	0.00	15.00	31.25	52.50	100.00
	Tofacitinib 10 mg BID	74	37.29	28.16	0.00	10.00	35.00	55.00	100.00
	Placebo→5 mg	22	28.69	23.95	0.00	15.00	20.00	35.00	95.00
	Placebo→10 mg	18	30.00	29.85	0.00	5.00	25.00	50.00	100.00
	Adalimumab 40 mg SC q2w	77	36.82	22.71	0.00	25.00	35.00	45.00	95.00
Month 3	Tofacitinib 5 mg BID	75	26.64	23.61	0.00	6.25	25.00	40.00	90.00
	Tofacitinib 10 mg BID	70	19.31	23.89	0.00	0.00	10.00	25.00	100.00
	Placebo→5 mg	24	32.71	27.14	0.00	12.50	22.50	45.00	100.00
	Placebo→10 mg	15	19.00	19.66	0.00	5.00	10.00	30.00	70.00
	Adalimumab 40 mg SC q2w	76	26.57	22.50	0.00	5.00	25.00	40.00	95.00
Month 6	Tofacitinib 5 mg BID	67	23.18	25.53	0.00	5.00	15.00	30.00	100.00
	Tofacitinib 10 mg BID	67	16.44	23.79	0.00	0.00	10.00	25.00	100.00
	Placebo→5 mg	19	27.70	28.55	0.00	5.00	20.00	35.00	90.00
	Placebo→0 mg	11	17.27	21.84	0.00	5.00	10.00	25.00	75.00
	Adalimumab 40 mg SC q2w	69	25.82	22.93	0.00	0.00	25.00	40.00	80.00
Month 12	Tofacitinib 5 mg BID	57	20.51	23.13	0.00	0.00	15.00	25.00	80.00
	Tofacitinib 10 mg BID	50	17.35	27.77	0.00	0.00	5.00	20.00	100.00
	Placebo→5 mg	19	27.11	27.29	0.00	5.00	18.75	50.00	90.00
	Placebo→10 mg	14	25.36	29.64	0.00	0.00	12.50	35.00	90.00
	Adalimumab 40 mg SC q2w	58	21.55	22.63	0.00	0.00	20.00	30.00	85.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 56. Descriptive Statistics of Work Limitation Questionnaire: Work Loss Index per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	85	9.76	5.34	0.00	6.30	8.90	13.20	22.90
	Tofacitinib 10 mg BID	81	9.85	5.67	0.00	4.60	9.30	13.30	23.10
	Placebo→5 mg	23	8.82	5.62	0.00	5.00	7.20	11.60	23.10
	Placebo→10 mg	19	8.85	6.37	1.70	3.70	6.90	13.80	23.80
	Adalimumab 40 mg SC q2w	81	9.92	5.01	1.30	6.20	10.10	13.30	20.90
Month 1	Tofacitinib 10 mg BID	1	8.00	-	8.00	8.00	8.00	8.00	8.00
	Placebo→5 mg	1	7.20	-	7.20	7.20	7.20	7.20	7.20
	Placebo→10 mg	2	4.90	1.98	3.50	3.50	4.90	6.30	6.30
Month 3	Tofacitinib 5 mg BID	80	7.89	5.12	0.00	4.15	7.25	9.80	21.90
	Tofacitinib 10 mg BID	74	5.92	5.17	0.00	1.80	4.75	8.10	22.00
	Placebo→5 mg	24	9.92	6.04	2.50	5.70	8.40	11.80	28.60
	Placebo→10 mg	17	6.24	4.59	0.80	3.30	4.70	8.20	17.80
	Adalimumab 40 mg SC q2w	78	8.23	5.47	0.00	4.00	8.05	11.90	23.40
Month 6	Tofacitinib 5 mg BID	70	7.32	5.47	0.00	3.80	5.65	9.20	21.70
	Tofacitinib 10 mg BID	69	5.69	5.54	0.00	2.70	3.80	7.40	24.30
	Placebo→5 mg	19	8.56	6.54	0.60	3.70	6.90	11.30	23.20
	Placebo→10 mg	11	6.34	5.01	0.00	3.40	5.00	8.40	18.60
	Adalimumab 40 mg SC q2w	73	7.84	5.04	0.00	3.60	6.70	12.40	19.40
Month 9	Tofacitinib 5 mg BID	2	1.15	1.63	0.00	0.00	1.15	2.30	2.30
	Tofacitinib 10 mg BID	2	2.80	1.27	1.90	1.90	2.80	3.70	3.70
	Adalimumab 40 mg SC q2w	3	12.33	1.60	10.80	10.80	12.20	14.00	14.00
Month 12	Tofacitinib 5 mg BID	57	6.61	5.07	0.00	3.60	5.10	8.20	21.70
	Tofacitinib 10 mg BID	55	5.78	5.59	0.00	2.70	4.20	7.40	24.30
	Placebo→5 mg	21	7.75	6.53	0.00	3.20	6.40	9.00	23.50
	Placebo→10 mg	14	8.06	6.01	0.50	3.90	6.30	10.90	21.40
	Adalimumab 40 mg SC q2w	60	6.85	5.21	0.20	2.55	5.60	11.40	18.70

Table 56. Descriptive Statistics of Work Limitation Questionnaire: Work Loss Index per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 57. Descriptive Statistics of EuroQol EQ-5D Health State Profile-Utility Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	0.43	0.32	-0.59	0.12	0.55	0.69	1.00
	Tofacitinib 10 mg BID	199	0.43	0.32	-0.59	0.09	0.52	0.69	1.00
	Placebo→5 mg	55	0.45	0.30	-0.24	0.26	0.59	0.69	0.80
	Placebo→10 mg	51	0.55	0.25	-0.18	0.52	0.59	0.73	0.80
	Adalimumab 40 mg SC q2w	201	0.45	0.29	-0.29	0.19	0.52	0.69	0.85
Month 1	Tofacitinib 5 mg BID	192	0.61	0.23	-0.43	0.52	0.62	0.73	1.00
	Tofacitinib 10 mg BID	195	0.60	0.25	-0.35	0.52	0.62	0.73	1.00
	Placebo→5 mg	56	0.55	0.24	-0.24	0.52	0.60	0.69	0.85
	Placebo→10 mg	50	0.57	0.27	-0.07	0.52	0.60	0.73	1.00
	Adalimumab 40 mg SC q2w	198	0.58	0.27	-0.32	0.52	0.62	0.73	1.00
Month 3	Tofacitinib 5 mg BID	187	0.62	0.28	-0.59	0.52	0.69	0.80	1.00
	Tofacitinib 10 mg BID	184	0.64	0.28	-0.35	0.52	0.69	0.80	1.00
	Placebo→5 mg	55	0.52	0.30	-0.18	0.52	0.59	0.73	1.00
	Placebo→10 mg	44	0.58	0.22	-0.13	0.52	0.60	0.73	1.00
	Adalimumab 40 mg SC q2w	189	0.61	0.26	-0.32	0.52	0.66	0.76	1.00
Month 6	Tofacitinib 5 mg BID	172	0.66	0.26	-0.59	0.59	0.69	0.80	1.00
	Tofacitinib 10 mg BID	180	0.65	0.25	-0.35	0.52	0.69	0.80	1.00
	Placebo→5 mg	52	0.62	0.23	-0.08	0.52	0.67	0.76	1.00
	Placebo→10 mg	42	0.66	0.20	-0.09	0.59	0.69	0.76	1.00
	Adalimumab 40 mg SC q2w	178	0.64	0.24	-0.18	0.52	0.69	0.80	1.00
Month 12	Tofacitinib 5 mg BID	147	0.69	0.22	-0.36	0.59	0.71	0.80	1.00
	Tofacitinib 10 mg BID	151	0.69	0.22	-0.02	0.52	0.69	0.85	1.00
	Placebo→5 mg	49	0.68	0.20	-0.06	0.59	0.66	0.80	1.00
	Placebo→10 mg	38	0.66	0.19	-0.02	0.59	0.69	0.80	1.00
	Adalimumab 40 mg SC q2w	159	0.66	0.27	-0.18	0.52	0.69	0.81	1.00

Table 57. Descriptive Statistics of EuroQol EQ-5D Health State Profile-Utility Score per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; EuroQoL = European Quality of Life; EQ-5D = a self-report questionnaire (a quality of life instrument) developed by the European Quality of Life (EuroQoL) Group; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 58. Descriptive Statistics of Medical Outcome Study Overall Sleep Problem Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	199	43.24	19.91	0.00	27.22	43.33	57.22	91.11
	Tofacitinib 10 mg BID	198	42.27	19.32	6.67	27.22	41.11	56.11	93.33
	Placebo→5 mg	55	40.40	17.97	7.22	28.89	38.89	53.33	80.00
	Placebo→10 mg	50	42.22	21.15	2.22	27.22	36.11	58.89	88.89
	Adalimumab 40 mg SC q2w	200	43.12	19.50	2.22	27.50	40.83	59.44	84.44
Month 1	Tofacitinib 5 mg BID	194	36.70	18.13	0.00	22.78	36.11	49.44	85.56
	Tofacitinib 10 mg BID	195	34.81	18.64	0.00	20.56	32.22	46.67	88.89
	Placebo→5 mg	56	38.03	18.02	6.67	26.11	37.78	51.67	79.44
	Placebo→10 mg	49	39.63	19.09	0.00	26.67	36.11	52.22	80.00
	Adalimumab 40 mg SC q2w	198	39.18	19.67	2.22	24.44	38.33	52.22	86.67
Month 3	Tofacitinib 5 mg BID	186	35.74	18.30	0.00	22.22	33.89	46.11	82.22
	Tofacitinib 10 mg BID	185	33.44	20.23	0.00	17.78	31.67	45.00	95.56
	Placebo→5 mg	55	38.61	18.86	6.67	25.00	33.89	51.67	81.67
	Placebo→10 mg	44	38.48	19.33	2.22	28.61	36.39	51.67	75.56
	Adalimumab 40 mg SC q2w	190	38.32	20.05	0.00	22.22	36.67	53.33	88.89
Month 6	Tofacitinib 5 mg BID	173	33.28	17.93	0.00	18.33	30.00	45.00	74.44
	Tofacitinib 10 mg BID	181	32.46	18.50	0.00	20.56	29.44	44.44	95.56
	Placebo→5 mg	52	34.80	16.16	6.67	22.50	31.67	46.39	79.44
	Placebo→10 mg	42	38.70	20.39	4.44	22.78	38.89	56.11	82.22
	Adalimumab 40 mg SC q2w	179	36.73	19.04	0.00	22.78	33.89	47.78	82.22
Month 12	Tofacitinib 5 mg BID	148	34.86	17.87	0.00	20.00	33.33	50.00	72.78
	Tofacitinib 10 mg BID	150	31.49	17.90	0.00	17.78	29.44	43.89	84.44
	Placebo→5 mg	49	36.00	17.63	5.00	22.78	38.89	47.22	72.22
	Placebo→10 mg	37	35.38	20.40	4.44	18.33	32.22	51.11	86.67
	Adalimumab 40 mg SC q2w	158	36.52	19.68	0.00	21.11	33.89	48.33	84.44

Table 58. Descriptive Statistics of Medical Outcome Study Overall Sleep Problem Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 59. Descriptive Statistics of Change From Baseline of Medical Outcome Study Overall Sleep Problem Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Month 1	Tofacitinib 5 mg BID	192	-6.68	13.98	-48.33	-15.56	-4.72	1.67	35.56
	Tofacitinib 10 mg BID	195	-7.36	15.45	-62.78	-15.56	-6.67	0.00	44.44
	Placebo→5 mg	55	-2.76	14.42	-46.67	-10.56	-1.67	6.67	32.22
	Placebo→10 mg	49	-2.80	13.58	-50.00	-8.89	-0.56	4.44	38.89
	Adalimumab 40 mg SC q2w	197	-3.76	13.44	-43.33	-11.11	-4.44	2.22	50.00
Month 3	Tofacitinib 5 mg BID	184	-7.41	15.36	-50.56	-16.11	-7.22	2.22	31.67
	Tofacitinib 10 mg BID	184	-8.59	17.15	-60.56	-17.50	-6.94	2.22	40.56
	Placebo→5 mg	54	-2.00	15.80	-46.67	-8.89	0.00	7.22	25.56
	Placebo→>10 mg	43	-4.07	17.85	-45.56	-13.33	-0.56	8.89	31.11
	Adalimumab 40 mg SC q2w	189	-4.49	13.91	-47.78	-11.67	-4.44	4.44	54.44
Month 6	Tofacitinib 5 mg BID	171	-9.49	17.23	-63.89	-18.89	-7.22	2.22	33.33
	Tofacitinib 10 mg BID	180	-9.35	16.46	-66.11	-17.50	-8.61	2.22	32.78
	Placebo→5 mg	51	-5.22	16.79	-52.22	-15.56	-2.22	4.44	24.44
	Placebo→10 mg	41	-2.75	16.00	-43.33	-11.67	0.00	6.67	42.22
	Adalimumab 40 mg SC q2w	179	-5.96	16.45	-61.67	-15.56	-5.00	4.44	57.22
Month 12	Tofacitinib 5 mg BID	147	-7.63	16.92	-72.78	-16.11	-4.44	3.89	36.11
	Tofacitinib 10 mg BID	150	-9.74	15.66	-53.89	-18.33	-8.33	0.56	24.44
	Placebo→5 mg	48	-4.07	19.47	-57.22	-14.72	-2.50	7.22	39.44
	Placebo→10 mg	37	-5.74	14.48	-36.67	-15.56	-6.67	4.44	20.56
	Adalimumab 40 mg SC q2w	158	-6.38	15.38	-52.22	-15.56	-5.00	3.33	30.56

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 60. Descriptive Statistics of Medical Outcome Study Sleep Problem Summary Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	199	42.13	20.58	0.00	26.67	43.33	56.67	100.00
	Tofacitinib 10 mg BID	198	40.20	19.48	0.00	26.67	40.00	53.33	90.00
	Placebo→5 mg	55	38.79	17.58	3.33	26.67	36.67	53.33	76.67
	Placebo→10 mg	50	39.53	20.70	3.33	26.67	33.33	56.67	86.67
	Adalimumab 40 mg SC q2w	200	40.90	19.68	0.00	26.67	41.67	56.67	83.33
Month 1	Tofacitinib 5 mg BID	194	36.25	19.19	0.00	23.33	36.67	50.00	90.00
	Tofacitinib 10 mg BID	195	34.03	18.74	0.00	20.00	33.33	46.67	86.67
	Placebo→5 mg	56	37.20	18.71	6.67	23.33	36.67	50.00	76.67
	Placebo→10 mg	49	38.10	19.14	0.00	23.33	36.67	50.00	73.33
	Adalimumab 40 mg SC q2w	198	38.16	20.30	0.00	23.33	40.00	50.00	83.33
Month 3	Tofacitinib 5 mg BID	186	35.39	18.66	0.00	20.00	36.67	46.67	90.00
	Tofacitinib 10 mg BID	185	32.86	20.91	0.00	13.33	30.00	46.67	93.33
	Placebo→5 mg	55	38.00	19.65	3.33	23.33	33.33	53.33	83.33
	Placebo→10 mg	44	36.97	18.77	0.00	23.33	36.67	48.33	76.67
	Adalimumab 40 mg SC q2w	190	37.21	20.47	0.00	20.00	36.67	53.33	86.67
Month 6	Tofacitinib 5 mg BID	173	32.66	18.60	0.00	20.00	30.00	46.67	76.67
	Tofacitinib 10 mg BID	181	31.79	18.64	0.00	16.67	30.00	43.33	93.33
	Placebo→5 mg	52	33.97	17.34	3.33	21.67	31.67	50.00	83.33
	Placebo→10 mg	42	38.17	21.16	0.00	23.33	40.00	53.33	80.00
	Adalimumab 40 mg SC q2w	179	36.31	19.25	0.00	20.00	36.67	46.67	80.00
Month 12	Tofacitinib 5 mg BID	148	34.62	18.58	0.00	20.00	33.33	50.00	76.67
	Tofacitinib 10 mg BID	150	30.64	18.42	0.00	16.67	26.67	46.67	80.00
	Placebo→5 mg	49	34.69	19.10	0.00	16.67	36.67	46.67	80.00
	Placebo→10 mg	37	34.68	21.32	0.00	16.67	30.00	50.00	83.33
	Adalimumab 40 mg SC q2w	159	35.72	20.25	0.00	20.00	33.33	46.67	83.33

Table 60. Descriptive Statistics of Medical Outcome Study Sleep Problem Summary Score per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every2 weeks; SC = subcutaneous.

Table 61. Descriptive Statistics of Medical Outcome Study Somnolence Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	199	36.52	21.22	0.00	20.00	33.33	53.33	93.33
	Tofacitinib 10 mg BID	198	35.66	22.28	0.00	20.00	33.33	46.67	100.00
	Placebo→5 mg	55	34.30	18.57	0.00	20.00	33.33	46.67	86.67
	Placebo→10 mg	50	39.33	22.43	0.00	26.67	33.33	53.33	100.00
	Adalimumab 40 mg SC q2w	199	33.47	19.68	0.00	20.00	33.33	46.67	93.33
Month 1	Tofacitinib 5 mg BID	194	31.68	21.26	0.00	13.33	26.67	40.00	93.33
	Tofacitinib 10 mg BID	195	31.04	22.02	0.00	13.33	26.67	46.67	100.00
	Placebo→5 mg	56	33.33	20.26	0.00	20.00	33.33	40.00	86.67
	Placebo→10 mg	49	34.56	23.64	0.00	13.33	33.33	53.33	86.67
	Adalimumab 40 mg SC q2w	198	33.91	19.60	0.00	20.00	33.33	46.67	93.33
Month 3	Tofacitinib 5 mg BID	187	29.41	19.66	0.00	13.33	26.67	40.00	100.00
	Tofacitinib 10 mg BID	185	30.74	22.65	0.00	13.33	26.67	40.00	100.00
	Placebo→5 mg	55	36.24	18.93	0.00	20.00	33.33	53.33	86.67
	Placebo→10 mg	44	36.82	21.69	0.00	20.00	33.33	53.33	93.33
	Adalimumab 40 mg SC q2w	190	31.05	20.26	0.00	13.33	26.67	40.00	100.00
Month 6	Tofacitinib 5 mg BID	173	28.17	17.55	0.00	13.33	26.67	40.00	86.67
	Tofacitinib 10 mg BID	181	30.39	22.37	0.00	13.33	26.67	40.00	100.00
	Placebo	52	31.92	17.48	6.67	20.00	26.67	40.00	73.33
	Placebo→5 mg	42	32.70	17.10	0.00	20.00	30.00	46.67	86.67
	Placebo→10 mg	179	31.84	20.38	0.00	13.33	26.67	40.00	100.00
	Adalimumab 40 mg SC q2w								
Month 12	Tofacitinib 5 mg BID	148	29.41	18.95	0.00	13.33	26.67	40.00	93.33
	Tofacitinib 10 mg BID	150	27.07	19.36	0.00	13.33	20.00	40.00	100.00
	Placebo→5 mg	49	32.38	17.53	6.67	20.00	26.67	40.00	73.33
	Placebo→10 mg	37	29.37	22.25	0.00	13.33	26.67	40.00	100.00
	Adalimumab 40 mg SC q2w	158	30.00	21.21	0.00	13.33	26.67	40.00	100.00

Table 61. Descriptive Statistics of Medical Outcome Study Somnolence Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 62. Descriptive Statistics of Medical Outcome Study Snoring Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	198	36.06	31.78	0.00	0.00	40.00	60.00	100.00
	Tofacitinib 10 mg BID	197	34.62	31.71	0.00	0.00	20.00	40.00	100.00
	Placebo→5 mg	55	24.73	25.52	0.00	0.00	20.00	40.00	100.00
	Placebo→10 mg	50	36.00	29.97	0.00	20.00	40.00	60.00	100.00
	Adalimumab 40 mg SC q2w	199	34.77	30.50	0.00	20.00	20.00	60.00	100.00
Month 1	Tofacitinib 5 mg BID	194	36.08	32.53	0.00	0.00	40.00	60.00	100.00
	Tofacitinib 10 mg BID	193	34.30	29.56	0.00	20.00	40.00	40.00	100.00
	Placebo→5 mg	55	28.73	26.32	0.00	0.00	20.00	40.00	100.00
	Placebo→10 mg	49	34.29	27.99	0.00	20.00	40.00	40.00	100.00
	Adalimumab 40 mg SC q2w	196	32.76	28.19	0.00	20.00	20.00	40.00	100.00
Month 3	Tofacitinib 5 mg BID	186	33.66	30.78	0.00	0.00	20.00	40.00	100.00
	Tofacitinib 10 mg BID	184	34.35	30.06	0.00	0.00	40.00	40.00	100.00
	Placebo→5 mg	55	25.82	21.66	0.00	0.00	20.00	40.00	100.00
	Placebo→10 mg	44	35.45	23.57	0.00	20.00	40.00	60.00	80.00
	Adalimumab 40 mg SC q2w	189	34.60	27.80	0.00	20.00	40.00	40.00	100.00
Month 6	Tofacitinib 5 mg BID	171	31.46	31.43	0.00	0.00	20.00	40.00	100.00
	Tofacitinib 10 mg BID	180	35.00	29.13	0.00	20.00	40.00	40.00	100.00
	Placebo	52	24.62	23.30	0.00	0.00	20.00	40.00	100.00
	Placebo→5 mg	42	33.81	26.31	0.00	20.00	40.00	40.00	100.00
	Placebo→10 mg Adalimumab 40 mg SC q2w	179	33.18	27.32	0.00	20.00	40.00	40.00	100.00
Month 12	Tofacitinib 5 mg BID	148	33.78	29.95	0.00	0.00	20.00	60.00	100.00
	Tofacitinib 10 mg BID	150	30.53	27.29	0.00	0.00	20.00	40.00	100.00
	Placebo→5 mg	48	27.50	22.83	0.00	0.00	30.00	40.00	80.00
	Placebo→10 mg	37	32.43	26.81	0.00	0.00	40.00	40.00	100.00
	Adalimumab 40 mg SC q2w	159	34.47	30.01	0.00	20.00	40.00	40.00	100.00

Table 62. Descriptive Statistics of Medical Outcome Study Snoring Score per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 63. Descriptive Statistics of Medical Outcome Study Quantity Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	6.46	1.36	2.00	6.00	7.00	7.00	10.00
	Tofacitinib 10 mg BID	198	6.61	1.70	1.00	6.00	7.00	8.00	12.00
	Placebo→5 mg	54	6.61	1.41	3.00	6.00	7.00	7.00	11.00
	Placebo→10 mg	50	6.80	1.62	2.00	6.00	7.00	8.00	10.00
	Adalimumab 40 mg SC q2w	199	6.65	1.82	1.00	6.00	7.00	8.00	18.00
Month 1	Tofacitinib 5 mg BID	193	6.70	1.38	3.00	6.00	7.00	8.00	11.00
	Tofacitinib 10 mg BID	195	6.97	1.49	2.00	6.00	7.00	8.00	11.00
	Placebo→5 mg	56	6.63	1.32	3.00	6.00	7.00	8.00	9.00
	Placebo→10 mg	49	6.88	1.67	2.00	6.00	7.00	8.00	10.00
	Adalimumab 40 mg SC q2w	197	6.89	1.55	3.00	6.00	7.00	8.00	15.00
Month 3	Tofacitinib 5 mg BID	188	6.82	1.32	3.00	6.00	7.00	8.00	10.00
	Tofacitinib 10 mg BID	185	7.03	1.45	2.00	6.00	7.00	8.00	12.00
	Placebo→5 mg	55	6.47	1.59	2.00	6.00	6.00	7.00	11.00
	Placebo→10 mg	44	6.55	1.55	2.00	6.00	6.00	8.00	9.00
	Adalimumab 40 mg SC q2w	190	6.83	1.47	3.00	6.00	7.00	8.00	15.00
Month 6	Tofacitinib 5 mg BID	173	6.86	1.18	4.00	6.00	7.00	8.00	10.00
	Tofacitinib 10 mg BID	181	7.10	1.60	2.00	6.00	7.00	8.00	12.00
	Placebo→5 mg	51	6.75	1.55	3.00	6.00	7.00	8.00	11.00
	Placebo→10 mg	42	6.71	1.60	2.00	6.00	7.00	8.00	11.00
	Adalimumab 40 mg SC q2w	178	6.81	1.36	3.00	6.00	7.00	8.00	11.00
Month 12	Tofacitinib 5 mg BID	148	6.78	1.19	4.00	6.00	7.00	8.00	10.00
	Tofacitinib 10 mg BID	150	7.03	1.47	3.00	6.00	7.00	8.00	12.00
	Placebo→5 mg	49	6.86	1.34	4.00	6.00	7.00	8.00	10.00
	Placebo→10 mg	37	6.84	1.34	3.00	6.00	7.00	8.00	9.00
	Adalimumab 40 mg SC q2w	158	6.72	1.31	4.00	6.00	7.00	8.00	10.00

Table 63. Descriptive Statistics of Medical Outcome Study Quantity Score per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 64. Descriptive Statistics of Medical Outcome Study Sleep Disturbance Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	45.46	26.30	0.00	25.00	43.13	65.00	100.00
	Tofacitinib 10 mg BID	198	44.67	25.96	0.00	25.00	42.50	62.50	100.00
	Placebo→5 mg	55	42.36	26.55	0.00	20.00	41.25	61.25	95.00
	Placebo→10 mg	50	45.70	28.47	0.00	26.25	37.50	67.50	100.00
	Adalimumab 40 mg SC q2w	200	46.55	26.31	0.00	26.25	42.50	69.38	100.00
Month 1	Tofacitinib 5 mg BID	194	36.52	23.48	0.00	16.25	36.25	53.75	100.00
	Tofacitinib 10 mg BID	195	35.46	24.25	0.00	15.00	31.25	47.50	95.00
	Placebo→5 mg	56	39.67	26.07	0.00	20.00	37.50	58.13	93.75
	Placebo→10 mg	49	41.30	26.44	0.00	25.00	37.50	57.50	100.00
	Adalimumab 40 mg SC q2w	198	39.41	25.42	0.00	16.25	36.25	55.00	100.00
Month 3	Tofacitinib 5 mg BID	186	35.93	24.29	0.00	16.25	31.25	52.50	100.00
	Tofacitinib 10 mg BID	185	32.86	25.10	0.00	11.25	26.25	46.25	100.00
	Placebo→5 mg	55	39.23	27.33	0.00	20.00	36.25	57.50	100.00
	Placebo→10 mg	44	37.95	25.11	0.00	15.00	35.00	56.88	90.00
	Adalimumab 40 mg SC q2w	190	39.95	25.83	0.00	16.25	36.25	60.00	95.00
Month 6	Tofacitinib 5 mg BID	173	32.95	23.76	0.00	15.00	30.00	47.50	90.00
	Tofacitinib 10 mg BID	181	32.00	24.30	0.00	11.25	30.00	43.75	100.00
	Placebo→5 mg	52	36.37	22.24	0.00	15.63	36.25	52.50	90.00
	Placebo→10 mg	42	39.35	27.96	0.00	16.25	36.25	62.50	95.00
	Adalimumab 40 mg SC q2w	179	36.39	24.20	0.00	20.00	31.25	52.50	100.00
Month 9	Tofacitinib 5 mg BID	5	35.75	20.13	15.00	16.25	41.25	43.75	62.50
	Tofacitinib 10 mg BID	7	38.75	34.38	10.00	10.00	15.00	73.75	78.75
	Adalimumab 40 mg SC q2w	5	53.25	29.99	16.25	40.00	42.50	77.50	90.00
Month 12	Tofacitinib 5 mg BID	149	34.82	23.95	0.00	15.00	30.00	52.50	95.00
	Tofacitinib 10 mg BID	150	32.32	22.41	0.00	15.00	26.25	47.50	95.00
	Placebo→5 mg	49	37.12	23.55	0.00	20.00	32.50	52.50	82.50
	Placebo→10 mg	37	34.86	23.94	0.00	15.00	27.50	53.75	85.00

Table 64. Descriptive Statistics of Medical Outcome Study Sleep Disturbance Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
	Adalimumab 40 mg SC q2w	159	37.36	25.19	0.00	16.25	32.50	52.50	100.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 65. Descriptive Statistics of Medical Outcome Study Awaken Short of Breath Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	19.10	24.91	0.00	0.00	20.00	40.00	100.00
	Tofacitinib 10 mg BID	198	15.96	21.70	0.00	0.00	0.00	20.00	80.00
	Placebo→5 mg	55	21.45	26.90	0.00	0.00	0.00	40.00	100.00
	Placebo→10 mg	50	15.60	21.49	0.00	0.00	0.00	20.00	100.00
	Adalimumab 40 mg SC q2w	200	20.00	24.31	0.00	0.00	20.00	40.00	100.00
Month 1	Tofacitinib 5 mg BID	194	18.35	22.52	0.00	0.00	20.00	20.00	100.00
	Tofacitinib 10 mg BID	195	14.56	20.13	0.00	0.00	0.00	40.00	80.00
	Placebo→5 mg	56	21.79	25.66	0.00	0.00	20.00	40.00	80.00
	Placebo→10 mg	49	17.55	21.46	0.00	0.00	20.00	20.00	100.00
	Adalimumab 40 mg SC q2w	198	18.69	25.26	0.00	0.00	0.00	20.00	100.00
Month 3	Tofacitinib 5 mg BID	187	18.18	22.12	0.00	0.00	20.00	40.00	100.00
	Tofacitinib 10 mg BID	185	14.81	20.62	0.00	0.00	0.00	20.00	80.00
	Placebo→5 mg	55	19.27	21.42	0.00	0.00	20.00	40.00	80.00
	Placebo→10 mg	44	17.73	20.33	0.00	0.00	10.00	40.00	60.00
	Adalimumab 40 mg SC q2w	190	18.42	24.42	0.00	0.00	0.00	40.00	100.00
Month 6	Tofacitinib 5 mg BID	173	16.65	22.00	0.00	0.00	0.00	20.00	100.00
	Tofacitinib 10 mg BID	181	13.48	20.21	0.00	0.00	0.00	20.00	100.00
	Placebo→5 mg	52	14.62	19.04	0.00	0.00	0.00	20.00	80.00
	Placebo→10 mg	42	19.05	17.64	0.00	0.00	20.00	40.00	60.00
	Adalimumab 40 mg SC q2w	179	19.22	22.37	0.00	0.00	20.00	40.00	100.00
Month 12	Tofacitinib 5 mg BID	149	16.78	19.74	0.00	0.00	20.00	20.00	80.00
	Tofacitinib 10 mg BID	150	14.13	20.67	0.00	0.00	0.00	20.00	80.00
	Placebo→5 mg	49	21.22	22.14	0.00	0.00	20.00	40.00	100.00
	Placebo→10 mg	37	18.38	18.49	0.00	0.00	20.00	40.00	60.00
	Adalimumab 40 mg SC q2w	159	17.48	21.79	0.00	0.00	20.00	40.00	100.00

Table 65. Descriptive Statistics of Medical Outcome Study Awaken Short of Breath Score per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 66. Descriptive Statistics of Medical Outcome Study Adequacy Score per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	200	42.95	27.92	0.00	20.00	40.00	60.00	100.00
	Tofacitinib 10 mg BID	198	44.04	28.21	0.00	20.00	40.00	60.00	100.00
	Placebo→5 mg	55	46.18	25.49	0.00	20.00	40.00	60.00	100.00
	Placebo→10 mg	50	48.80	26.85	0.00	20.00	50.00	70.00	90.00
	Adalimumab 40 mg SC q2w	200	44.25	27.83	0.00	20.00	40.00	70.00	100.00
Month 1	Tofacitinib 5 mg BID	194	48.97	27.11	0.00	30.00	50.00	70.00	100.00
	Tofacitinib 10 mg BID	195	52.62	27.62	0.00	30.00	50.00	80.00	100.00
	Placebo→5 mg	56	51.61	25.64	0.00	30.00	50.00	70.00	100.00
	Placebo→10 mg	49	47.76	26.24	0.00	30.00	50.00	60.00	100.00
	Adalimumab 40 mg SC q2w	198	46.87	27.30	0.00	30.00	40.00	70.00	100.00
Month 3	Tofacitinib 5 mg BID	187	50.59	27.67	0.00	30.00	50.00	80.00	100.00
	Tofacitinib 10 mg BID	185	53.24	28.90	0.00	30.00	50.00	80.00	100.00
	Placebo→5 mg	55	49.27	28.92	0.00	30.00	40.00	70.00	100.00
	Placebo→10 mg	44	48.64	27.50	0.00	30.00	40.00	70.00	100.00
	Adalimumab 40 mg SC q2w	190	49.21	28.65	0.00	30.00	50.00	70.00	100.00
Month 6	Tofacitinib 5 mg BID	173	53.12	28.85	0.00	30.00	50.00	80.00	100.00
	Tofacitinib 10 mg BID	181	53.76	27.87	0.00	30.00	50.00	80.00	100.00
	Placebo→5 mg	52	53.46	25.81	0.00	30.00	50.00	80.00	100.00
	Placebo→10 mg	42	47.62	28.01	0.00	20.00	40.00	80.00	100.00
	Adalimumab 40 mg SC q2w	179	50.22	27.33	0.00	30.00	50.00	70.00	100.00
Month 12	Tofacitinib 5 mg BID	149	51.21	26.96	0.00	30.00	50.00	80.00	100.00
	Tofacitinib 10 mg BID	150	57.20	28.48	0.00	40.00	60.00	80.00	100.00
	Placebo→5 mg	49	54.29	27.84	0.00	30.00	60.00	80.00	100.00
	Placebo→10 mg	37	50.00	30.18	0.00	20.00	50.00	80.00	100.00
	Adalimumab 40 mg SC q2w	159	49.81	27.20	0.00	30.00	50.00	80.00	100.00

Table 66. Descriptive Statistics of Medical Outcome Study Adequacy Score per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 67. Normal Approximation to Optimal Sleep Rates in Medical Outcome Study Optimal Sleep Scale per Visit (FAS), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Values
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	93	47.94	3.58	13.36	40.90	54.96	<0.0001
	Tofacitinib 10 mg BID	196	107	54.59	3.55	15.35	47.62	61.56	<0.0001
	Placebo→5 mg	56	30	53.57	6.66	8.03	40.50	66.63	<0.0001
	Placebo→10 mg	50	25	50.00	7.07	7.07	36.14	63.85	<0.0001
	Adalimumab 40 mg SC q2w	198	95	47.98	3.55	13.51	41.02	54.93	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	188	100	53.19	3.63	14.61	46.05	60.32	<0.0001
	Tofacitinib 10 mg BID	185	110	59.46	3.60	16.47	52.38	66.53	<0.0001
	Placebo→5 mg	55	20	36.36	6.48	5.60	23.65	49.07	<0.0001
	Placebo→10 mg	44	17	38.64	7.34	5.26	24.24	53.02	<0.0001
	Adalimumab 40 mg SC q2w	190	93	48.95	3.62	13.49	41.83	56.05	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	174	100	57.47	3.74	15.33	50.12	64.81	<0.0001
	Tofacitinib 10 mg BID	181	100	55.25	3.69	14.94	48.00	62.49	<0.0001
	Placebo→5 mg	52	27	51.92	6.92	7.49	38.34	65.50	<0.0001
	Placebo→10 mg	42	19	45.24	7.68	5.89	30.18	60.29	<0.0001
	Adalimumab 40 mg SC q2w	182	93	51.10	3.70	13.79	43.83	58.36	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	150	80	53.33	4.07	13.09	45.34	61.31	<0.0001
	Tofacitinib 10 mg BID	151	84	55.63	4.04	13.75	47.70	63.55	<0.0001
	Placebo→5 mg	49	28	57.14	7.06	8.08	43.28	70.99	<0.0001
	Placebo→10 mg	38	19	50.00	8.11	6.16	34.10	65.89	<0.0001
	Adalimumab 40 mg SC q2w	160	75	46.88	3.94	11.88	39.14	54.60	<0.0001

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; N = number of subjects; n = number of subjects meeting predefined criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 68. Descriptive Statistics of FACIT - Fatigue Scale per Visit, Comparisons Within Sequence

Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Baseline	Tofacitinib 5 mg BID	201	28.18	10.48	4.00	21.00	28.00	36.00	50.00
	Tofacitinib 10 mg BID	199	28.56	10.84	1.00	21.00	29.00	37.00	51.00
	Placebo→5 mg	55	29.93	10.09	9.00	24.00	31.00	36.00	48.00
	Placebo→10 mg	51	31.10	10.44	0.00	26.00	34.00	37.00	48.00
	Adalimumab 40 mg SC q2w	201	27.95	10.07	2.00	21.00	27.00	36.00	49.00
Month 1	Tofacitinib 5 mg BID	192	32.54	9.94	6.00	26.00	33.00	40.00	50.00
	Tofacitinib 10 mg BID	196	33.95	10.54	0.00	27.00	35.50	42.50	51.00
	Placebo→5 mg	56	31.13	9.97	0.00	24.00	31.50	38.50	47.00
	Placebo→10 mg	50	32.26	10.30	5.00	27.00	33.00	40.00	48.00
	Adalimumab 40 mg SC q2w	198	31.94	10.48	5.00	24.00	32.00	40.00	51.00
Month 3	Tofacitinib 5 mg BID	187	33.86	10.18	5.00	28.00	35.00	42.00	52.00
	Tofacitinib 10 mg BID	185	35.12	11.07	1.00	29.00	37.00	44.00	52.00
	Placebo→5 mg	55	31.33	10.17	2.00	24.00	35.00	38.00	46.00
	Placebo→10 mg	44	30.50	10.36	8.00	22.50	31.00	38.50	50.00
	Adalimumab 40 mg SC q2w	190	32.72	10.27	9.00	25.00	33.00	41.00	51.00
Month 6	Tofacitinib 5 mg BID	173	34.58	10.53	6.00	28.00	37.00	43.00	51.00
	Tofacitinib 10 mg BID	181	36.09	10.07	1.00	29.00	37.00	44.00	52.00
	Placebo→5 mg	52	34.27	9.24	15.00	28.00	34.50	42.00	49.00
	Placebo→10 mg	42	34.02	8.92	8.00	29.00	34.00	40.00	50.00
	Adalimumab 40 mg SC q2w	180	33.69	10.58	8.00	26.00	35.00	42.00	52.00
Month 12	Tofacitinib 5 mg BID	150	35.76	9.53	9.00	29.00	36.00	44.00	52.00
	Tofacitinib 10 mg BID	151	37.53	10.41	7.00	31.00	40.00	46.00	52.00
	Placebo→5 mg	49	36.71	7.81	18.00	32.00	37.00	42.00	51.00
	Placebo→10 mg	38	35.71	9.65	3.00	30.00	36.00	43.00	52.00
	Adalimumab 40 mg SC q2w	159	34.30	9.83	10.00	27.00	35.00	43.00	51.00

Table 68. Descriptive Statistics of FACIT - Fatigue Scale per Visit, Comparisons Within Sequence

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→ 5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FACIT = Functional Assessment of Chronic Illness Therapy; N = number of subjects; q2w = every 2 weeks; SC = subcutaneous.

Table 69. Normal Approximation to Rates of at Least 0.22 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	109	56.19	3.56	15.77	49.20	63.16	<0.0001
	Tofacitinib 10 mg BID	196	119	60.71	3.48	17.40	53.87	67.55	<0.0001
	Placebo→ mg	55	18	32.73	6.32	5.17	20.32	45.12	<0.0001
	Placebo→10 mg	50	17	34.00	6.69	5.07	20.86	47.13	<0.0001
	Adalimumab 40 mg SC q2w	198	114	57.58	3.51	16.39	50.69	64.45	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	196	103	52.55	3.56	14.73	45.56	59.54	<0.0001
	Tofacitinib 10 mg BID	196	109	55.61	3.54	15.67	48.65	62.56	<0.0001
	Placebo→5 mg	55	12	21.82	5.56	3.91	10.90	32.73	<0.0001
	Placebo→10 mg	50	14	28.00	6.34	4.40	15.55	40.44	<0.0001
	Adalimumab 40 mg SC q2w	199	96	48.24	3.54	13.61	41.29	55.18	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	95	48.47	3.56	13.57	41.47	55.46	<0.0001
	Tofacitinib 10 mg BID	196	104	53.06	3.56	14.88	46.07	60.04	<0.0001
	Placebo→5 mg	55	14	25.45	5.87	4.33	13.94	36.96	<0.0001
	Placebo→10 mg	50	13	26.00	6.20	4.19	13.84	38.15	<0.0001
	Adalimumab 40 mg SC q2w	199	101	50.75	3.54	14.32	43.80	57.70	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	93	47.45	3.56	13.30	40.45	54.43	<0.0001
	Tofacitinib 10 mg BID	196	103	52.55	3.56	14.73	45.56	59.54	<0.0001
	Placebo→5 mg	55	15	27.27	6.00	4.54	15.50	39.04	<0.0001
	Placebo→10 mg	50	16	32.00	6.59	4.85	19.06	44.93	<0.0001
	Adalimumab 40 mg SC q2w	199	92	46.23	3.53	13.08	39.30	53.15	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	92	46.94	3.56	13.16	39.95	53.92	<0.0001
	Tofacitinib 10 mg BID	196	100	51.02	3.57	14.28	44.02	58.01	<0.0001
	Placebo→5 mg	55	13	23.64	5.72	4.12	12.40	34.86	<0.0001
	Placebo→0 mg	50	15	30.00	6.48	4.62	17.29	42.70	<0.0001
	Adalimumab 40 mg SC q2w	199	96	48.24	3.54	13.61	41.29	55.18	<0.0001

Table 69. Normal Approximation to Rates of at Least 0.22 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons Within Sequence

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting HAQ-DI response criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 70. Normal Approximation to Rates of at Least 0.3 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	89	45.88	3.57	12.82	38.86	52.88	<0.0001
	Tofacitinib 10 mg BID	196	100	51.02	3.57	14.28	44.02	58.01	<0.0001
	Placebo→5 mg	55	16	29.09	6.12	4.75	17.08	41.09	<0.0001
	Placebo→10 mg	50	11	22.00	5.85	3.75	10.51	33.48	0.0001
	Adalimumab 40 mg SC q2w	198	100	50.51	3.55	14.21	43.54	57.46	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	196	90	45.92	3.55	12.90	38.94	52.89	<0.0001
	Tofacitinib 10 mg BID	196	100	51.02	3.57	14.28	44.02	58.01	<0.0001
	Placebo→5 mg	55	10	18.18	5.20	3.49	7.98	28.37	0.0004
	Placebo→10 mg	50	12	24.00	6.03	3.97	12.16	35.83	<0.0001
	Adalimumab 40 mg SC q2w	199	88	44.22	3.52	12.56	37.32	51.12	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	88	44.90	3.55	12.63	37.93	51.86	<0.0001
	Tofacitinib 10 mg BID	196	94	47.96	3.56	13.43	40.96	54.95	<0.0001
	Placebo→5 mg	55	10	18.18	5.20	3.49	7.98	28.37	0.0004
	Placebo→10 mg	50	11	22.00	5.85	3.75	10.51	33.48	0.0001
	Adalimumab 40 mg SC q2w	199	87	43.72	3.51	12.43	36.82	50.61	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	87	44.39	3.54	12.50	37.43	51.34	<0.0001
	Tofacitinib 10 mg BID	196	91	46.43	3.56	13.03	39.44	53.41	<0.0001
	Placebo→5 mg	55	13	23.64	5.72	4.12	12.40	34.86	<0.0001
	Placebo→10 mg	50	14	28.00	6.34	4.40	15.55	40.44	<0.0001
	Adalimumab 40 mg SC q2w	199	83	41.71	3.49	11.93	34.85	48.55	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	77	39.29	3.48	11.26	32.44	46.12	<0.0001
	Tofacitinib 10 mg BID	196	93	47.45	3.56	13.30	40.45	54.43	<0.0001
	Placebo→5 mg	55	12	21.82	5.56	3.91	10.90	32.73	<0.0001
	Placebo→10 mg	50	14	28.00	6.34	4.40	15.55	40.44	<0.0001
	Adalimumab 40 mg SC q2w	199	89	44.72	3.52	12.68	37.81	51.63	<0.0001

Table 70. Normal Approximation to Rates of at Least 0.3 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons Within Sequence

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting HAQ-DI response criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 71. Normal Approximation to Rates of at Least 0.5 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons Within Sequence

Visit	Treatment Sequence	N	n	Response Rate	Standard Error	Z	95% Confidence Interval		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	194	65	33.51	3.38	9.88	26.86	40.14	<0.0001
	Tofacitinib 10 mg BID	196	82	41.84	3.52	11.87	34.93	48.74	<0.0001
	Placebo→5 mg	55	13	23.64	5.72	4.12	12.40	34.86	<0.0001
	Placebo→10 mg	50	5	10.00	4.24	2.35	1.68	18.31	0.0184
	Adalimumab 40 mg SC q2w	198	80	40.40	3.48	11.58	33.56	47.23	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	196	79	40.31	3.50	11.50	33.43	47.17	<0.0001
	Tofacitinib 10 mg BID	196	88	44.90	3.55	12.63	37.93	51.86	<0.0001
	Placebo→5 mg	55	6	10.91	4.20	2.59	2.66	19.14	0.0094
	Placebo→10 mg	50	9	18.00	5.43	3.31	7.35	28.64	0.0009
	Adalimumab 40 mg SC q2w	199	73	36.68	3.41	10.73	29.98	43.37	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	196	76	38.78	3.48	11.14	31.95	45.59	<0.0001
	Tofacitinib 10 mg BID	196	81	41.33	3.51	11.74	34.43	48.22	<0.0001
	Placebo→5 mg	55	9	16.36	4.98	3.28	6.58	26.14	0.0010
	Placebo→10 mg	50	10	20.00	5.65	3.53	8.91	31.08	0.0004
	Adalimumab 40 mg SC q2w	199	80	40.20	3.47	11.56	33.38	47.01	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	196	78	39.80	3.49	11.38	32.94	46.64	<0.0001
	Tofacitinib 10 mg BID	196	81	41.33	3.51	11.74	34.43	48.22	<0.0001
	Placebo→5 mg	55	10	18.18	5.20	3.49	7.98	28.37	0.0004
	Placebo→10 mg	50	11	22.00	5.85	3.75	10.51	33.48	0.0001
	Adalimumab 40 mg SC q2w	199	74	37.19	3.42	10.85	30.47	43.90	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	196	69	35.20	3.41	10.31	28.51	41.89	<0.0001
	Tofacitinib 10 mg BID	196	84	42.86	3.53	12.12	35.92	49.78	<0.0001
	Placebo→5 mg	55	11	20.00	5.39	3.70	9.42	30.57	0.0002
	Placebo→10 mg	50	12	24.00	6.03	3.97	12.16	35.83	<0.0001
	Adalimumab 40 mg SC q2w	199	77	38.69	3.45	11.20	31.92	45.46	<0.0001

Table 71. Normal Approximation to Rates of at Least 0.5 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons Within Sequence

Subjects who withdrew for any reason before Month 6, or subjects who were advanced to active tofacitinib after Month 3 have their values on or after withdrawing or advancing set to non-response in this analysis.
Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting HAQ-DI response criteria; NRI = nonresponder imputation; q2w = every 2 weeks; SC = subcutaneous.

Table 72. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Seen a Doctor/Healthcare Professional in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Seen any doctor/healthcare professional in past 3 months	Baseline	Tofacitinib 5 mg BID	201	1.16	0.37	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	199	1.13	0.34	1.00	1.00	1.00	1.00	2.00
		Placebo	106	1.15	0.36	1.00	1.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	201	1.15	0.36	1.00	1.00	1.00	1.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 10 mg BID	3	1.33	0.58	1.00	1.00	1.00	2.00	2.00
		Placebo	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	186	1.27	0.45	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.28	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo	99	1.22	0.42	1.00	1.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	190	1.29	0.45	1.00	1.00	1.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.25	0.43	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	180	1.28	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo	45	1.27	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	28	1.18	0.39	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	20	1.20	0.41	1.00	1.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	179	1.31	0.46	1.00	1.00	1.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.40	0.55	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	7	1.14	0.38	1.00	1.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	1.31	0.46	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.27	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	49	1.24	0.43	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	38	1.24	0.43	1.00	1.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	160	1.23	0.42	1.00	1.00	1.00	1.00	2.00

Table 72. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Seen a Doctor/Healthcare Professional in Past 3 Months

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 73. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Total Visits to Doctor/Healthcare Professional in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Total visits to doctor/healthcare professional in past 3 months	Baseline	Tofacitinib 5 mg BID	168	4.26	3.51	1.00	2.00	3.00	5.00	23.00
		Tofacitinib 10 mg BID	174	4.06	3.57	1.00	2.00	3.00	5.00	21.00
		Placebo	90	4.50	5.32	1.00	2.00	3.00	5.00	45.00
		Adalimumab 40 mg SC q2w	172	3.87	3.74	1.00	2.00	3.00	4.00	35.00
	Month 1	Tofacitinib 5 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	2	5.50	0.71	5.00	5.00	5.50	6.00	6.00
		Placebo	5	4.20	2.59	1.00	3.00	4.00	5.00	8.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	136	3.62	4.25	1.00	1.00	3.00	4.00	33.00
		Tofacitinib 10 mg BID	138	2.86	2.99	0.00	1.00	2.00	3.00	33.00
		Placebo	78	3.27	3.93	1.00	1.00	2.00	3.00	27.00
		Adalimumab 40 mg SC q2w	136	3.05	2.87	0.00	1.00	2.00	4.00	19.00
	Month 6	Tofacitinib 5 mg BID	132	3.30	4.17	1.00	1.00	2.00	4.00	29.00
		Tofacitinib 10 mg BID	131	2.86	4.23	1.00	1.00	2.00	3.00	44.00
		Placebo	33	2.52	1.91	1.00	1.00	2.00	3.00	7.00
		Placebo→5 mg	23	2.87	3.17	1.00	1.00	2.00	4.00	15.00
		Placebo→10 mg	16	2.88	2.00	1.00	2.00	2.00	3.50	9.00
		Adalimumab 40 mg SC q2w	128	2.73	2.96	0.00	1.00	2.00	3.00	21.00
	Month 9	Tofacitinib 5 mg BID	3	3.67	1.53	2.00	2.00	4.00	5.00	5.00
		Tofacitinib 10 mg BID	6	3.83	4.62	1.00	1.00	2.00	4.00	13.00
		Adalimumab 40 mg SC q2w	5	3.80	2.39	1.00	2.00	4.00	5.00	7.00
	Month 12	Tofacitinib 5 mg BID	102	2.73	2.78	1.00	1.00	2.00	3.00	19.00
		Tofacitinib 10 mg BID	111	2.80	2.46	1.00	1.00	2.00	3.00	15.00
		Placebo→5 mg	37	3.92	5.97	1.00	1.00	2.00	4.00	31.00
		Placebo→10 mg	30	3.50	3.34	1.00	1.00	3.00	4.00	17.00
		Adalimumab 40 mg SC q2w	125	2.94	3.93	1.00	1.00	2.00	3.00	31.00

Table 73. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Total Visits to Doctor/Healthcare Professional in Past 3 Months

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 74. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
RA related	Baseline	Tofacitinib 5 mg BID	169	1.33	1.03	0.00	1.00	1.00	2.00	9.00
		Tofacitinib 10 mg BID	175	1.17	0.70	0.00	1.00	1.00	1.00	4.00
		Placebo	91	1.26	0.81	0.00	1.00	1.00	2.00	4.00
		Adalimumab 40 mg SC q2w	172	1.19	0.73	0.00	1.00	1.00	1.00	4.00
	Month 1	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	5	0.80	0.84	0.00	0.00	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	136	0.91	0.75	0.00	1.00	1.00	1.00	5.00
		Tofacitinib 10 mg BID	138	0.92	0.67	0.00	1.00	1.00	1.00	4.00
		Placebo	78	0.90	0.71	0.00	1.00	1.00	1.00	4.00
		Adalimumab 40 mg SC q2w	136	0.93	0.65	0.00	1.00	1.00	1.00	3.00
	Month 6	Tofacitinib 5 mg BID	132	0.81	0.63	0.00	0.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	131	0.96	0.74	0.00	1.00	1.00	1.00	4.00
		Placebo	33	0.88	0.86	0.00	1.00	1.00	1.00	5.00
		Placebo→5 mg	24	1.00	0.51	0.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	16	0.81	0.54	0.00	0.50	1.00	1.00	2.00
		Adalimumab 40 mg SC q2w	129	1.00	0.56	0.00	1.00	1.00	1.00	3.00
	Month 9	Tofacitinib 5 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	6	1.67	0.82	1.00	1.00	1.50	2.00	3.00
		Adalimumab 40 mg SC q2w	5	1.60	0.55	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	104	0.82	0.59	0.00	0.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	111	0.93	0.57	0.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	37	0.89	0.52	0.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	30	0.87	0.68	0.00	0.00	1.00	1.00	3.00
		Adalimumab 40 mg SC q2w	125	0.84	0.80	0.00	0.00	1.00	1.00	6.00

Table 74. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Rheumatoid Arthritis Related

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 75. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Treated in a Hospital Emergency Room in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Treated in a hospital ER in past 3 months	Baseline	Tofacitinib 5 mg BID	201	1.95	0.23	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.94	0.25	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	186	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo	99	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.95	0.22	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo	46	1.91	0.28	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	179	1.98	0.15	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	149	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.97	0.16	1.00	2.00	2.00	2.00	2.00

Table 75. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Treated in a Hospital Emergency Room in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	1.96	0.19	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; ER = emergency room; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 76. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Number of Visits to Hospital Emergency Room in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of visits to hospital ER in past 3 months	Baseline	Tofacitinib 5 mg BID	12	1.08	0.51	0.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	14	1.93	1.59	1.00	1.00	1.50	2.00	7.00
		Placebo	7	1.57	0.79	1.00	1.00	1.00	2.00	3.00
		Adalimumab 40 mg SC q2w	12	1.58	1.73	1.00	1.00	1.00	1.00	7.00
	Month 3	Tofacitinib 5 mg BID	8	1.38	0.74	1.00	1.00	1.00	1.50	3.00
		Tofacitinib 10 mg BID	8	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	4	1.75	1.50	1.00	1.00	1.00	2.50	4.00
		Adalimumab 40 mg SC q2w	10	1.90	1.10	1.00	1.00	1.50	3.00	4.00
	Month 6	Tofacitinib 5 mg BID	12	1.08	0.29	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
		Placebo	4	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→5 mg Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
			4	1.75	0.96	1.00	1.00	1.50	2.50	3.00
	Month 12	Tofacitinib 5 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	5	2.40	1.34	1.00	1.00	3.00	3.00	4.00
		Placebo→10 mg Adalimumab 40 mg SC q2w	1	3.00	-	3.00	3.00	3.00	3.00	3.00
			6	1.00	0.00	1.00	1.00	1.00	1.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; ER = emergency room; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 77. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Admitted for Overnight Stay

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Admitted for overnight stay	Baseline	Tofacitinib 5 mg BID	11	0.45	0.82	0.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	14	0.21	0.43	0.00	0.00	0.00	0.00	1.00
		Placebo	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
		Adalimumab 40 mg SC q2w	12	0.08	0.29	0.00	0.00	0.00	0.00	1.00
	Month 3	Tofacitinib 5 mg BID	8	0.25	0.46	0.00	0.00	0.00	0.50	1.00
		Tofacitinib 10 mg BID	8	0.88	0.99	0.00	0.00	0.50	2.00	2.00
		Placebo	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	9	0.22	0.44	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	12	0.58	0.67	0.00	0.00	0.50	1.00	2.00
		Tofacitinib 10 mg BID	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
		Placebo	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 12	Tofacitinib 5 mg BID	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	5	0.20	0.45	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 78. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Emergency Room Visit Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
ER visit RA related	Baseline	Tofacitinib 5 mg BID	11	0.64	0.81	0.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	14	0.64	0.74	0.00	0.00	0.50	1.00	2.00
		Placebo	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
		Adalimumab 40 mg SC q2w	12	0.25	0.45	0.00	0.00	0.00	0.50	1.00
	Month 3	Tofacitinib 5 mg BID	8	0.25	0.46	0.00	0.00	0.00	0.50	1.00
		Tofacitinib 10 mg BID	8	0.50	0.76	0.00	0.00	0.00	1.00	2.00
		Placebo	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	9	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	12	0.25	0.62	0.00	0.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	6	0.67	0.82	0.00	0.00	0.50	1.00	2.00
		Placebo	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→ mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 12	Tofacitinib 5 mg BID	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	5	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; ER = emergency room; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 79. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hospitalized in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Hospitalized in past 3 months	Baseline	Tofacitinib 5 mg BID	201	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.95	0.23	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Placebo	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	185	1.98	0.15	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo	99	1.99	0.10	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.98	0.12	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	172	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo	46	1.96	0.21	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	179	1.99	0.07	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.97	0.16	1.00	2.00	2.00	2.00	2.00

Table 79. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hospitalized in Past 3 Months

	Adalimumab 40 mg SC q2w	160	1.98	0.14	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 80. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Number of Visits Hospitalized in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of visits hospitalized in past 3 months	Baseline	Tofacitinib 5 mg BID	11	2.82	5.71	1.00	1.00	1.00	1.00	20.00
		Tofacitinib 10 mg BID	5	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	7	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	11	1.27	0.90	1.00	1.00	1.00	1.00	4.00
	Month 1	Tofacitinib 10 mg BID	1	1.00	1.00	1.00	1.00	1.00	1.00	1.00
		Placebo	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	4	1.50	1.00	1.00	1.00	1.00	2.00	3.00
		Tofacitinib 10 mg BID	6	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	9	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	5	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→5 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	5	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→5 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Placebo→10 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 81. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hospitalized Length of Stay

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Hospitalized length of stay	Baseline	Tofacitinib 5 mg BID	11	13.64	12.91	2.00	3.00	11.00	15.00	42.00
		Tofacitinib 10 mg BID	6	10.83	9.89	2.00	3.00	9.00	13.00	29.00
		Placebo	7	13.43	9.78	4.00	6.00	10.00	20.00	32.00
		Adalimumab 40 mg SC q2w	11	12.82	10.93	3.00	5.00	13.00	15.00	42.00
	Month 1	Tofacitinib 10 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Placebo	2	2.50	2.12	1.00	1.00	2.50	4.00	4.00
	Month 3	Tofacitinib 5 mg BID	4	6.25	4.03	3.00	3.50	5.00	9.00	12.00
		Tofacitinib 10 mg BID	6	10.00	10.75	1.00	4.00	5.50	14.00	30.00
		Placebo	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	3	10.33	8.14	1.00	1.00	14.00	16.00	16.00
	Month 6	Tofacitinib 5 mg BID	9	10.00	8.20	2.00	4.00	7.00	18.00	22.00
		Tofacitinib 10 mg BID	5	12.80	16.71	2.00	2.00	8.00	10.00	42.00
		Placebo	2	8.50	2.12	7.00	7.00	8.50	10.00	10.00
		Placebo→5 mg	1	3.00	-	3.00	3.00	3.00	3.00	3.00
		Adalimumab 40 mg SC q2w	1	6.00	-	6.00	6.00	6.00	6.00	6.00
	Month 12	Tofacitinib 5 mg BID	3	8.00	6.93	4.00	4.00	4.00	16.00	16.00
		Tofacitinib 10 mg BID	5	5.60	2.70	3.00	4.00	4.00	8.00	9.00
		Placebo→5 mg	1	15.00	-	15.00	15.00	15.00	15.00	15.00
		Placebo→10 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	3	15.33	4.51	11.00	11.00	15.00	20.00	20.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 82. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hospitalized Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Hospitalized RA related	Baseline	Tofacitinib 5 mg BID	11	0.91	0.83	0.00	0.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	6	0.67	0.52	0.00	0.00	1.00	1.00	1.00
		Placebo	7	0.57	0.79	0.00	0.00	0.00	1.00	2.00
		Adalimumab 40 mg SC q2w	11	0.82	0.60	0.00	0.00	1.00	1.00	2.00
	Month 1	Tofacitinib 10 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Placebo	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
		Placebo	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	9	0.22	0.67	0.00	0.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	5	0.40	0.89	0.00	0.00	0.00	0.00	2.00
		Placebo	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	1	0.00	-	0.00	0.00	0.00	0.00	0.00
	Month 12	Tofacitinib 5 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	5	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	3	0.67	0.58	0.00	0.00	1.00	1.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 83. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Had Any Outpatient Surgeries in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Had any outpatient surgeries in past 3 months	Baseline	Tofacitinib 5 mg BID	200	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.97	0.18	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	185	1.98	0.13	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.98	0.15	1.00	2.00	2.00	2.00	2.00
		Placebo	99	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.97	0.18	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.98	0.15	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo	46	1.98	0.15	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	178	1.99	0.11	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.99	0.11	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.95	0.23	1.00	2.00	2.00	2.00	2.00

Table 83. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Had Any Outpatient Surgeries in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	1.97	0.17	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 84. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of Outpatient Surgeries in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of outpatient surgeries in past 3 months	Baseline	Tofacitinib 5 mg BID	8	1.13	0.35	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	6	1.33	0.82	1.00	1.00	1.00	1.00	3.00
		Placebo	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	7	2.57	4.16	1.00	1.00	1.00	1.00	12.00
	Month 3	Tofacitinib 5 mg BID	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	4	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	4	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	6	1.33	0.52	1.00	1.00	1.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	4	1.25	0.50	1.00	1.00	1.00	1.50	2.00
		Tofacitinib 10 mg BID	7	1.14	0.38	1.00	1.00	1.00	1.00	2.00
		Placebo	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	5	1.40	0.89	1.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Placebo→10 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	5	2.20	2.17	1.00	1.00	1.00	2.00	6.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 85. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Outpatient Surgery Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Outpatient surgery RA related	Baseline	Tofacitinib 5 mg BID	7	0.43	0.79	0.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	6	0.33	0.82	0.00	0.00	0.00	0.00	2.00
		Placebo	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
		Adalimumab 40 mg SC q2w	7	0.43	0.79	0.00	0.00	0.00	1.00	2.00
	Month 3	Tofacitinib 5 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	4	0.25	0.50	0.00	0.00	0.00	0.50	1.00
		Placebo	4	0.25	0.50	0.00	0.00	0.00	0.50	1.00
		Adalimumab 40 mg SC q2w	6	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	7	0.43	0.79	0.00	0.00	0.00	1.00	2.00
		Placebo	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	2	1.00	1.41	0.00	0.00	1.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	5	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	5	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 86. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib versus Controls – Had Any Non-Study Diagnostic Tests in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Had any non-study diagnostic tests in past 3 months	Baseline	Tofacitinib 5 mg BID	200	1.81	0.39	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.83	0.37	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.82	0.39	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	200	1.82	0.39	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	1.83	0.41	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	184	1.90	0.30	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.87	0.34	1.00	2.00	2.00	2.00	2.00
		Placebo	99	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.89	0.31	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.87	0.33	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.86	0.35	1.00	2.00	2.00	2.00	2.00
		Placebo	46	1.89	0.31	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.90	0.31	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	178	1.89	0.31	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	149	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.87	0.33	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.88	0.33	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.84	0.37	1.00	2.00	2.00	2.00	2.00

Table 86. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib versus Controls – Had Any Non-Study Diagnostic Tests in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	159	1.86	0.35	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 87. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of Non-Study Diagnostic Tests

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of non-study diagnostic tests	Baseline	Tofacitinib 5 mg BID	37	1.73	1.04	1.00	1.00	1.00	2.00	5.00
		Tofacitinib 10 mg BID	33	1.79	1.17	1.00	1.00	1.00	2.00	5.00
		Placebo	19	1.21	0.54	1.00	1.00	1.00	1.00	3.00
		Adalimumab 40 mg SC q2w	36	1.64	1.10	1.00	1.00	1.00	2.00	6.00
	Month 1	Placebo	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	18	1.72	1.41	1.00	1.00	1.00	2.00	6.00
		Tofacitinib 10 mg BID	23	1.52	0.79	1.00	1.00	1.00	2.00	4.00
		Placebo	9	1.56	0.88	1.00	1.00	1.00	2.00	3.00
		Adalimumab 40 mg SC q2w	20	1.45	0.83	1.00	1.00	1.00	2.00	4.00
	Month 6	Tofacitinib 5 mg BID	21	2.33	3.89	1.00	1.00	1.00	2.00	19.00
		Tofacitinib 10 mg BID	25	1.96	1.31	1.00	1.00	1.00	3.00	5.00
		Placebo	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Placebo→10 mg	2	2.00	1.41	1.00	1.00	2.00	3.00	3.00
		Adalimumab 40 mg SC q2w	19	1.53	0.61	1.00	1.00	1.00	2.00	3.00
	Month 9	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	8	1.13	0.35	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	19	1.95	1.31	1.00	1.00	1.00	3.00	5.00
		Placebo→5 mg	6	3.17	2.64	1.00	1.00	2.50	4.00	8.00
		Placebo→10 mg	6	1.33	0.82	1.00	1.00	1.00	1.00	3.00
		Adalimumab 40 mg SC q2w	22	1.64	0.90	1.00	1.00	1.00	2.00	4.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 88. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Diagnostic Tests Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Diagnostic tests RA related	Baseline	Tofacitinib 5 mg BID	38	0.50	0.76	0.00	0.00	0.00	1.00	3.00
		Tofacitinib 10 mg BID	33	0.55	0.62	0.00	0.00	0.00	1.00	2.00
		Placebo	19	0.47	0.61	0.00	0.00	0.00	1.00	2.00
		Adalimumab 40 mg SC q2w	37	0.84	0.73	0.00	0.00	1.00	1.00	3.00
	Month 1	Placebo	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	19	0.11	0.32	0.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	24	0.21	0.51	0.00	0.00	0.00	0.00	2.00
		Placebo	9	0.11	0.33	0.00	0.00	0.00	0.00	1.00
		Adalimumab 40 mg SC q2w	21	0.24	0.44	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	22	0.18	0.50	0.00	0.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	25	0.16	0.37	0.00	0.00	0.00	0.00	1.00
		Placebo	5	0.20	0.45	0.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Adalimumab 40 mg SC q2w	19	0.11	0.32	0.00	0.00	0.00	0.00	1.00
	Month 9	Tofacitinib 5 mg BID	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	9	0.11	0.33	0.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	19	0.21	0.42	0.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	6	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	22	0.05	0.21	0.00	0.00	0.00	0.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 89. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Subject in a Nursing Home in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Subject in a nursing home in past 3 months	Baseline	Tofacitinib 5 mg BID	201	1.99	0.12	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	106	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.98	0.14	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	185	1.99	0.07	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	99	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.99	0.10	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.99	0.11	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	46	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	178	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	149	1.99	0.12	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	2.00	0.00	2.00	2.00	2.00	2.00	2.00

Table 89. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Subject in a Nursing Home in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	159	1.99	0.08	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 90. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of Days in Nursing Home in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of days in nursing home in past 3 months	Baseline	Tofacitinib 5 mg BID	3	19.33	17.56	1.00	1.00	21.00	36.00	36.00
		Adalimumab 40 mg SC q2w	4	14.25	9.95	6.00	7.00	11.50	21.50	28.00
	Month 3	Adalimumab 40 mg SC q2w	2	17.5	4.95	14.00	14.00	17.50	21.00	21.00
	Month 6	Tofacitinib 5 mg BID	2	27.00	18.38	14.00	14.00	27.00	40.00	40.00
	Month 12	Tofacitinib 5 mg BID	2	24.50	4.95	21.00	21.00	24.50	28.00	28.00
		Adalimumab 40 mg SC q2w	1	10.00	-	10.00	10.00	10.00	10.00	10.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 91. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Used Home Healthcare Services in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Used home healthcare services in past 2 months	Baseline	Tofacitinib 5 mg BID	201	1.99	0.10	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	198	1.99	0.10	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.99	0.10	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.99	0.12	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	184	1.99	0.07	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	99	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.99	0.11	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.99	0.11	1.00	2.00	2.00	2.00	2.00
		Placebo	46	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	177	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	2.00	0.00	2.00	2.00	2.00	2.00	2.00

Table 91. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Used Home Healthcare Services in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	159	1.99	0.08	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 92. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Home Healthcare Services Hours per Day

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Home healthcare services hours per day	Baseline	Tofacitinib 5 mg BID	2	3.00	2.83	1.00	1.00	3.00	5.00	5.00
		Tofacitinib 10 mg BID	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Placebo	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	2	2.50	2.12	1.00	1.00	2.50	4.00	4.00
		Tofacitinib 10 mg BID	2	16.00	5.66	12.00	12.00	16.00	20.00	20.00
	Month 12	Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 93. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Home Healthcare Services Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Home healthcare services RA related	Baseline	Tofacitinib 5 mg BID	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Tofacitinib 10 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	1	0.00	-	0.00	0.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	2	1.00	1.41	0.00	0.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
	Month 12	Adalimumab 40 mg SC q2w	1	1.00	0.00	1.00	1.00	1.00	1.00	1.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 94. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Required Aids/Devices for Daily Functioning in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Required aids/devices for daily functioning in past 3 months	Baseline	Tofacitinib 5 mg BID	201	1.92	0.28	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.86	0.35	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.92	0.28	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.91	0.29	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	1.83	0.41	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	185	1.94	0.25	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Placebo	99	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.92	0.28	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.91	0.28	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Placebo	46	1.87	0.34	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.89	0.31	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	178	1.92	0.27	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	1.71	0.49	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.92	0.27	1.00	2.00	2.00	2.00	2.00

Table 94. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Required Aids/Devices for Daily Functioning in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	1.91	0.29	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 95. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Aids/Devices Used Days

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Aids/devices used days	Baseline	Tofacitinib 5 mg BID	17	133.88	111.17	1.00	90.00	90.00	180.00	368.00
		Tofacitinib 10 mg BID	28	67.32	61.88	1.00	5.50	90.00	90.00	186.00
		Placebo	8	172.75	94.28	90.00	90.00	136.00	270.00	300.00
		Adalimumab 40 mg SC q2w	16	66.13	65.33	1.00	10.00	47.50	91.50	200.00
	Month 1	Placebo	1	90.00	-	90.00	90.00	90.00	90.00	90.00
	Month 3	Tofacitinib 5 mg BID	11	117.91	112.91	1.00	28.00	90.00	180.00	380.00
		Tofacitinib 10 mg BID	17	60.41	88.79	4.00	7.00	21.00	90.00	360.00
		Placebo	6	163.83	153.63	44.00	90.00	102.50	180.00	464.00
		Adalimumab 40 mg SC q2w	15	91.80	95.18	1.00	20.00	90.00	120.00	356.00
	Month 6	Tofacitinib 5 mg BID	14	102.29	115.01	1.00	32.00	90.00	110.00	450.00
		Tofacitinib 10 mg BID	16	126.25	134.08	2.00	51.50	90.00	153.00	450.00
		Placebo	5	80.20	73.45	10.00	15.00	90.00	96.00	190.00
		Placebo→5 mg	3	57.33	48.18	2.00	2.00	80.00	90.00	90.00
		Placebo→10 mg	1	90.00	-	90.00	90.00	90.00	90.00	90.00
		Adalimumab 40 mg SC q2w	14	94.21	76.92	0.00	30.00	92.00	115.00	270.00
	Month 9	Tofacitinib 10 mg BID	2	270.00	127.28	180.00	180.00	270.00	360.00	360.00
		Adalimumab 40 mg SC q2w	2	13.00	4.24	10.00	10.00	13.00	16.00	16.00
	Month 12	Tofacitinib 5 mg BID	11	144.55	258.85	2.00	10.00	85.00	180.00	900.00
		Tofacitinib 10 mg BID	12	51.75	41.51	5.00	9.50	53.00	90.00	112.00
		Placebo→5 mg	3	163.67	173.70	30.00	30.00	101.00	360.00	360.00
		Placebo→10 mg	2	321.5	327.39	90.00	90.00	321.50	553.00	553.00
		Adalimumab 40 mg SC q2w	15	79.33	74.00	1.00	6.00	90.00	105.00	270.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 96. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Aids/Devices Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Aids/devices RA related	Baseline	Tofacitinib 5 mg BID	17	1.76	1.15	0.00	1.00	1.00	2.00	4.00
		Tofacitinib 10 mg BID	28	1.39	0.69	1.00	1.00	1.00	2.00	4.00
		Placebo	9	2.33	1.66	1.00	1.00	2.00	3.00	5.00
		Adalimumab 40 mg SC q2w	17	1.65	1.06	0.00	1.00	1.00	2.00	4.00
	Month 1	Placebo	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	12	1.75	1.22	1.00	1.00	1.00	2.00	5.00
		Tofacitinib 10 mg BID	17	1.12	1.36	0.00	1.00	1.00	1.00	6.00
		Placebo	8	2.38	1.60	1.00	1.50	2.00	2.50	6.00
		Adalimumab 40 mg SC q2w	16	1.81	0.98	0.00	1.00	2.00	2.00	4.00
	Month 6	Tofacitinib 5 mg BID	15	2.00	1.73	0.00	1.00	2.00	2.00	6.00
		Tofacitinib 10 mg BID	16	1.56	1.46	0.00	1.00	1.00	2.00	5.00
		Placebo	6	2.17	1.83	1.00	1.00	1.00	4.00	5.00
		Placebo→5 mg	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	14	2.07	1.27	1.00	1.00	2.00	2.00	6.00
	Month 9	Tofacitinib 10 mg BID	2	2.00	2.83	0.00	0.00	2.00	4.00	4.00
		Adalimumab 40 mg SC q2w	2	3.00	1.41	2.00	2.00	3.00	4.00	4.00
	Month 12	Tofacitinib 5 mg BID	11	2.18	2.79	0.00	1.00	1.00	2.00	10.00
		Tofacitinib 10 mg BID	12	0.75	0.62	0.00	0.00	1.00	1.00	2.00
		Placebo→5 mg	3	2.33	1.53	1.00	1.00	2.00	4.00	4.00
		Placebo→10 mg	3	3.00	2.65	0.00	0.00	4.00	5.00	5.00
		Adalimumab 40 mg SC q2w	15	1.53	0.74	1.00	1.00	1.00	2.00	3.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 97. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Seen Any Non-Medical Practitioner in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Seen any non-medical practitioner in past 3 months	Baseline	Tofacitinib 5 mg BID	201	1.99	0.12	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.97	0.17	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	185	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	99	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.98	0.12	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.98	0.13	1.00	2.00	2.00	2.00	2.00
		Placebo	45	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	178	1.99	0.07	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	149	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.95	0.23	1.00	2.00	2.00	2.00	2.00

Table 97. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Seen Any Non-Medical Practitioner in Past 3 Months

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	2.00	0.00	2.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 98. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls - Non-Medical Practitioner Emergency Room Visits

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Non-medical practitioner ER visit	Baseline	Tofacitinib 5 mg BID	3	1.33	0.58	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	6	3.00	1.79	1.00	2.00	2.50	4.00	6.00
		Placebo	2	4.50	4.95	1.00	1.00	4.50	8.00	8.00
		Adalimumab 40 mg SC q2w	6	10.00	10.51	2.00	2.00	7.00	12.00	30.00
	Month 3	Tofacitinib 5 mg BID	5	2.4	0.89	2.00	2.00	2.00	2.00	4.00
		Placebo	2	17.00	21.21	2.00	2.00	17.00	32.00	32.00
		Adalimumab 40 mg SC q2w	2	7.50	9.19	1.00	1.00	7.50	14.00	14.00
	Month 6	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	3	2.67	2.89	1.00	1.00	1.00	6.00	6.00
		Placebo→5 mg	1	3.00	-	3.00	3.00	3.00	3.00	3.00
		Placebo→10 mg	1	8.00	-	8.00	8.00	8.00	8.00	8.00
		Adalimumab 40 mg SC q2w	1	14.00	-	14.00	14.00	14.00	14.00	14.00
	Month 12	Tofacitinib 5 mg BID	3	10.67	11.72	2.00	2.00	6.00	24.00	24.00
		Tofacitinib 10 mg BID	4	9.75	10.97	2.00	3.50	5.50	16.00	26.00
		Placebo→5 mg	1	192.00	-	192.00	192.00	192.00	192.00	192.00
		Placebo→10 mg	2	10.50	6.36	6.00	6.00	10.50	15.00	15.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; ER = emergency room; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 99. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Non-Medical Practitioner Emergency Room Visit Rheumatoid Arthritis Related

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Non-medical practitioner ER RA related	Baseline	Tofacitinib 5 mg BID	3	0.67	0.58	0.00	0.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	6	0.50	0.84	0.00	0.00	0.00	1.00	2.00
		Placebo	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	6	1.00	0.63	0.00	1.00	1.00	1.00	2.00
	Month 3	Tofacitinib 5 mg BID	5	0.60	0.89	0.00	0.00	0.00	1.00	2.00
		Placebo	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Adalimumab 40 mg SC q2w	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00
		Placebo→5 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Placebo→10 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Adalimumab 40 mg SC q2w	1	0.00	-	0.00	0.00	0.00	0.00	0.00
	Month 12	Tofacitinib 5 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	4	0.50	1.00	0.00	0.00	0.00	1.00	2.00
		Placebo→5 mg	1	0.00	-	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; ER = emergency room; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 100. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Are You Currently Employed

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Are you currently employed	Baseline	Tofacitinib 5 mg BID	201	1.64	0.48	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.65	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo	106	1.64	0.48	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.65	0.48	1.00	1.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Placebo	6	1.50	0.55	1.00	1.00	1.50	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	185	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	185	1.64	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo	99	1.63	0.49	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.64	0.48	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	173	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo	46	1.63	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.68	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.90	0.31	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	179	1.63	0.48	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.60	0.55	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	7	1.71	0.49	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	1.50	0.55	1.00	1.00	1.50	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	1.59	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.68	0.47	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.61	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.61	0.50	1.00	1.00	2.00	2.00	2.00

Table 100. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Are You Currently Employed

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	1.64	0.48	1.00	1.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 101. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hours of Work per Day

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Hours of work per day	Baseline	Tofacitinib 5 mg BID	72	7.76	2.40	0.00	6.50	8.00	8.00	15.00
		Tofacitinib 10 mg BID	69	7.54	2.25	1.00	6.00	8.00	8.00	13.00
		Placebo	38	7.79	1.76	4.00	7.00	8.00	9.00	12.00
		Adalimumab 40 mg SC q2w	70	8.16	2.85	3.00	8.00	8.00	9.00	24.00
	Month 1	Tofacitinib 10 mg BID	1	5.00	-	5.00	5.00	5.00	5.00	5.00
		Placebo	3	8.67	1.15	8.00	8.00	8.00	10.00	10.00
	Month 3	Tofacitinib 5 mg BID	70	8.06	3.59	3.00	6.00	8.00	8.00	32.00
		Tofacitinib 10 mg BID	66	7.53	1.92	3.00	7.00	8.00	8.00	12.00
		Placebo	38	8.53	5.62	3.00	6.00	8.00	10.00	40.00
		Adalimumab 40 mg SC q2w	68	8.38	4.89	2.00	8.00	8.00	8.00	40.00
	Month 6	Tofacitinib 5 mg BID	65	8.35	4.46	3.00	7.00	8.00	9.00	40.00
		Tofacitinib 10 mg BID	61	7.72	2.24	3.00	7.00	8.00	8.00	20.00
		Placebo	17	9.71	7.59	5.00	6.00	8.00	10.00	38.00
		Placebo→5 mg	9	7.44	2.65	4.00	5.00	8.00	9.00	12.00
		Placebo→10 mg	2	8.00	0.00	8.00	8.00	8.00	8.00	8.00
		Adalimumab 40 mg SC q2w	66	8.00	4.27	2.00	7.00	8.00	8.00	32.00
	Month 9	Tofacitinib 5 mg BID	2	9.00	4.24	6.00	6.00	9.00	12.00	12.00
		Tofacitinib 10 mg BID	2	3.50	4.95	0.00	0.00	3.50	7.00	7.00
		Adalimumab 40 mg SC q2w	3	14.67	13.32	6.00	6.00	8.00	30.00	30.00
	Month 12	Tofacitinib 5 mg BID	60	7.52	2.27	2.00	6.50	8.00	8.00	13.00
		Tofacitinib 10 mg BID	49	7.82	1.60	4.00	8.00	8.00	8.00	12.00
		Placebo→5 mg	19	9.53	7.65	4.00	6.00	8.00	10.00	40.00
		Placebo→10 mg	15	7.73	2.40	3.00	7.00	8.00	9.00	12.00
		Adalimumab 40 mg SC q2w	58	7.93	3.12	2.00	8.00	8.00	8.00	24.00

Table 101. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hours of Work per Day

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 102. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Days of Work per Week

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Days of work per week	Baseline	Tofacitinib 5 mg BID	71	4.94	1.18	0.00	5.00	5.00	5.00	8.00
		Tofacitinib 10 mg BID	69	4.80	1.05	1.00	5.00	5.00	5.00	7.00
		Placebo	38	4.95	0.98	2.00	5.00	5.00	5.00	7.00
		Adalimumab 40 mg SC q2w	70	5.01	1.04	1.00	5.00	5.00	5.00	7.00
	Month 1	Tofacitinib 10 mg BID	1	7.00	-	7.00	7.00	7.00	7.00	7.00
		Placebo	3	5.33	0.58	5.00	5.00	5.00	6.00	6.00
	Month 3	Tofacitinib 5 mg BID	70	4.83	0.95	2.00	5.00	5.00	5.00	7.00
		Tofacitinib 10 mg BID	66	4.68	1.18	1.00	5.00	5.00	5.00	7.00
		Placebo	38	4.95	0.80	3.00	5.00	5.00	5.00	6.00
		Adalimumab 40 mg SC q2w	68	4.75	1.25	0.00	5.00	5.00	5.00	7.00
	Month 6	Tofacitinib 5 mg BID	65	4.94	0.85	2.00	5.00	5.00	5.00	7.00
		Tofacitinib 10 mg BID	61	4.70	1.09	1.00	5.00	5.00	5.00	7.00
		Placebo	17	5.35	0.93	4.00	5.00	5.00	6.00	7.00
		Placebo→5 mg	9	5.00	0.50	4.00	5.00	5.00	5.00	6.00
		Placebo→10 mg	2	5.00	0.00	5.00	5.00	5.00	5.00	5.00
		Adalimumab 40 mg SC q2w	66	4.95	0.92	2.00	5.00	5.00	5.00	7.00
	Month 9	Tofacitinib 5 mg BID	2	4.00	0.00	4.00	4.00	4.00	4.00	4.00
		Tofacitinib 10 mg BID	2	5.50	0.71	5.00	5.00	5.50	6.00	6.00
		Adalimumab 40 mg SC q2w	3	4.67	0.58	4.00	4.00	5.00	5.00	5.00
	Month 12	Tofacitinib 5 mg BID	60	4.83	1.04	2.00	5.00	5.00	5.00	7.00
		Tofacitinib 10 mg BID	49	5.04	0.93	2.00	5.00	5.00	5.00	7.00
		Placebo→5 mg	19	5.16	0.90	3.00	5.00	5.00	6.00	7.00
		Placebo→10 mg	15	4.93	0.70	3.00	5.00	5.00	5.00	6.00
		Adalimumab 40 mg SC q2w	58	4.95	1.07	2.00	5.00	5.00	5.00	8.00

Table 102. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Days of Work per Week

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 103. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Feel Well Enough to Work if Jobs Were Available

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Feel well enough to work if jobs were available	Baseline	Tofacitinib 5 mg BID	73	1.90	0.30	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	83	1.89	0.31	1.00	2.00	2.00	2.00	2.00
		Placebo	39	1.82	0.39	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	81	1.80	0.40	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 10 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Placebo	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	74	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	79	1.73	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo	41	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	80	1.74	0.44	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	72	1.75	0.44	1.00	1.50	2.00	2.00	2.00
		Tofacitinib 10 mg BID	81	1.77	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo	23	1.83	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	12	1.75	0.45	1.00	1.50	2.00	2.00	2.00
		Placebo→10 mg	14	1.57	0.51	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	76	1.71	0.46	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	61	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	79	1.75	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	19	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	19	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	76	1.68	0.47	1.00	1.00	2.00	2.00	2.00

Table 103. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Feel Well Enough to Work if Jobs Were Available

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 104. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Unable to Work due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Unable to work due to RA	Baseline	Tofacitinib 5 mg BID	76	1.36	0.48	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	84	1.37	0.49	1.00	1.00	1.00	2.00	2.00
		Placebo	40	1.45	0.50	1.00	1.00	1.00	2.00	2.00
		Adalimumab 40 mg SC q2w	78	1.37	0.49	1.00	1.00	1.00	2.00	2.00
	Month 1	Tofacitinib 10 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Placebo	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	76	1.42	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	83	1.46	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo	44	1.45	0.50	1.00	1.00	1.00	2.00	2.00
		Adalimumab 40 mg SC q2w	77	1.58	0.50	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	73	1.51	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	83	1.54	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo	23	1.48	0.51	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	12	1.58	0.51	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	14	1.50	0.52	1.00	1.00	1.50	2.00	2.00
		Adalimumab 40 mg SC q2w	74	1.57	0.50	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	59	1.56	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	77	1.61	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	19	1.58	0.51	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	19	1.58	0.51	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	77	1.57	0.50	1.00	1.00	2.00	2.00	2.00

Table 104. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Unable to Work due to Rheumatoid Arthritis

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 105. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Lost Job or Retired Early due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Lost job or retired early due to RA	Baseline	Tofacitinib 5 mg BID	66	1.50	0.50	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 10 mg BID	82	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo	39	1.74	0.44	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	81	1.57	0.50	1.00	1.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Placebo	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	73	1.55	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	78	1.59	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo	40	1.75	0.44	1.00	1.50	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	79	1.65	0.48	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	70	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	82	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo	22	1.68	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	12	1.83	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	12	1.75	0.45	1.00	1.50	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	72	1.67	0.47	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	58	1.53	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	75	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	19	1.68	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	18	1.78	0.43	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	75	1.67	0.47	1.00	1.00	2.00	2.00	2.00

Table 105. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Lost Job or Retired Early due to Rheumatoid Arthritis

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 106. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Work Disabled due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Work disabled due to RA	Baseline	Tofacitinib 5 mg BID	66	1.56	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	82	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo	40	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	79	1.65	0.48	1.00	1.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Placebo	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	71	1.63	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	82	1.68	0.47	1.00	1.00	2.00	2.00	2.00
		Placebo	41	1.61	0.49	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	73	1.74	0.44	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	67	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	80	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo	22	1.73	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	12	1.50	0.52	1.00	1.00	1.50	2.00	2.00
		Placebo→10 mg	13	1.77	0.44	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	72	1.72	0.45	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	58	1.64	0.48	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	76	1.75	0.44	1.00	1.50	2.00	2.00	2.00
		Placebo→5 mg	19	1.79	0.42	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	18	1.67	0.49	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	75	1.67	0.47	1.00	1.00	2.00	2.00	2.00

Table 106. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Work Disabled due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 107. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – I am Retired

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
I am retired	Baseline	Tofacitinib 5 mg BID	80	1.41	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	88	1.41	0.49	1.00	1.00	1.00	2.00	2.00
		Placebo	45	1.40	0.50	1.00	1.00	1.00	2.00	2.00
		Adalimumab 40 mg SC q2w	89	1.39	0.49	1.00	1.00	1.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Placebo	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	80	1.39	0.49	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	86	1.34	0.48	1.00	1.00	1.00	2.00	2.00
		Placebo	47	1.38	0.49	1.00	1.00	1.00	2.00	2.00
		Adalimumab 40 mg SC q2w	86	1.38	0.49	1.00	1.00	1.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	77	1.32	0.47	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	87	1.30	0.46	1.00	1.00	1.00	2.00	2.00
		Placebo	22	1.32	0.48	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	14	1.50	0.52	1.00	1.00	1.50	2.00	2.00
		Placebo→10 mg	13	1.54	0.52	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	82	1.35	0.48	1.00	1.00	1.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	64	1.25	0.44	1.00	1.00	1.00	1.50	2.00
		Tofacitinib 10 mg BID	84	1.31	0.47	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	21	1.19	0.40	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	19	1.53	0.51	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	80	1.35	0.48	1.00	1.00	1.00	2.00	2.00

Table 107. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – I am Retired

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 108. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Sick Leave in Past 3 Months From Work due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Sick leave in past 3 months from work due to RA	Baseline	Tofacitinib 5 mg BID	167	1.85	0.36	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	166	1.86	0.35	1.00	2.00	2.00	2.00	2.00
		Placebo	92	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	167	1.83	0.38	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	4	1.75	0.50	1.00	1.50	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	153	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	146	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo	85	1.81	0.39	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	157	1.90	0.29	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	138	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	134	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Placebo	38	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	22	1.95	0.21	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	16	1.75	0.45	1.00	1.50	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	144	1.94	0.24	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	118	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	112	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	37	1.95	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	30	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	124	1.97	0.18	1.00	2.00	2.00	2.00	2.00

Table 108. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Sick Leave in Past 3 Months From Work due to Rheumatoid Arthritis

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 109. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of Days on Sick Leave due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of days on sick leave due to RA	Baseline	Tofacitinib 5 mg BID	24	19.58	27.78	1.00	2.00	5.50	30.00	90.00
		Tofacitinib 10 mg BID	24	16.33	27.21	1.00	2.00	5.50	13.00	90.00
		Placebo	15	29.60	34.88	1.00	4.00	10.00	60.00	90.00
		Adalimumab 40 mg SC q2w	29	16.31	26.05	1.00	2.00	3.00	12.00	90.00
	Month 1	Placebo	1	90.00	-	90.00	90.00	90.00	90.00	90.00
	Month 3	Tofacitinib 5 mg BID	11	24.27	33.73	1.00	1.00	10.00	27.00	90.00
		Tofacitinib 10 mg BID	9	18.44	29.37	1.00	4.00	5.00	10.00	90.00
		Placebo	17	27.12	31.42	1.00	2.00	10.00	52.00	90.00
		Adalimumab 40 mg SC q2w	15	5.13	4.60	1.00	2.00	4.00	8.00	15.00
	Month 6	Tofacitinib 5 mg BID	7	29.57	41.48	2.00	2.00	5.00	90.00	90.00
		Tofacitinib 10 mg BID	9	12.44	14.60	1.00	2.00	3.00	19.00	42.00
		Placebo	3	3.00	2.00	1.00	1.00	3.00	5.00	5.00
		Placebo→5 mg	1	90.00	-	90.00	90.00	90.00	90.00	90.00
		Placebo→10 mg	4	15.00	12.25	5.00	5.00	12.50	25.00	30.00
		Adalimumab 40 mg SC q2w	9	8.67	13.13	1.00	2.00	3.00	5.00	40.00
	Month 9	Tofacitinib 5 mg BID	1	90.00	-	90.00	90.00	90.00	90.00	90.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	5	10.40	11.41	2.00	3.00	7.00	10.00	30.00
		Tofacitinib 10 mg BID	3	36.00	45.97	7.00	7.00	12.00	89.00	89.00
		Placebo→5 mg	2	50.00	56.57	10.00	10.00	50.00	90.00	90.00
		Adalimumab 40 mg SC q2w	4	18.25	14.06	2.00	6.50	20.50	30.00	30.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 110. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Performed Part Time Work in Past 3 Months due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Performed part time work in past 3 months due to RA	Baseline	Tofacitinib 5 mg BID	169	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	166	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Placebo	92	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	167	1.94	0.24	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	4	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	153	1.95	0.21	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	145	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo	85	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	155	1.94	0.25	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	135	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	134	1.96	0.21	1.00	2.00	2.00	2.00	2.00
		Placebo	37	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	22	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	16	1.94	0.25	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	142	1.95	0.22	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	5	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	117	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	112	1.99	0.09	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	37	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	30	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	123	1.99	0.09	1.00	2.00	2.00	2.00	2.00

Table 110. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Performed Part Time Work in Past 3 Months due to Rheumatoid Arthritis

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 111. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of Days Performed Part Time Work due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of days performed part time work due to RA	Baseline	Tofacitinib 5 mg BID	13	13.31	18.94	2.00	3.00	6.00	8.00	60.00
		Tofacitinib 10 mg BID	13	25.31	61.19	1.00	2.00	4.00	10.00	222.00
		Placebo	6	5.33	3.44	1.00	2.00	5.50	8.00	10.00
		Adalimumab 40 mg SC q2w	10	18.50	26.88	2.00	4.00	6.00	24.00	90.00
	Month 3	Tofacitinib 5 mg BID	7	13.29	13.76	3.00	5.00	6.00	24.00	40.00
		Tofacitinib 10 mg BID	4	25.50	27.77	3.00	3.00	19.50	48.00	60.00
		Placebo	6	5.50	3.27	3.00	4.00	4.50	5.00	12.00
		Adalimumab 40 mg SC q2w	10	14.90	27.04	2.00	3.00	4.50	14.00	90.00
	Month 6	Tofacitinib 5 mg BID	7	7.57	6.80	1.00	3.00	4.00	12.00	20.00
		Tofacitinib 10 mg BID	6	24.67	33.07	2.00	4.00	14.00	24.00	90.00
		Placebo	1	4.00	-	4.00	4.00	4.00	4.00	4.00
		Placebo→10 mg Adalimumab 40 mg SC q2w	1	0.00	-	0.00	0.00	0.00	0.00	0.00
			7	9.29	8.67	1.00	2.00	4.00	20.00	20.00
	Month 9	Adalimumab 40 mg SC q2w	1	6	-	6.00	6.00	6.00	6.00	6.00
	Month 12	Tofacitinib 5 mg BID	6	11.33	12.55	0.00	3.00	5.50	24.00	30.00
		Tofacitinib 10 mg BID	1	33.00	-	33.00	33.00	33.00	33.00	33.00
		Adalimumab 40 mg SC q2w	1	30.00	-	30.00	30.00	30.00	30.00	30.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 112. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Average Hours of Missed Work per day due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Average hours of missed work per day due to RA	Baseline	Tofacitinib 5 mg BID	13	6.38	7.22	0.00	2.00	4.00	4.00	24.00
		Tofacitinib 10 mg BID	13	5.00	5.85	0.00	2.00	3.00	5.00	19.00
		Placebo	6	4.00	1.26	2.00	3.00	4.50	5.00	5.00
		Adalimumab 40 mg SC q2w	10	4.00	4.11	0.00	2.00	3.00	4.00	15.00
	Month 3	Tofacitinib 5 mg BID	7	4.57	5.03	0.00	1.00	4.00	6.00	15.00
		Tofacitinib 10 mg BID	4	20.75	39.51	0.00	0.50	1.50	41.00	80.00
		Placebo	6	5.50	5.01	1.00	2.00	4.50	6.00	15.00
		Adalimumab 40 mg SC q2w	9	3.56	1.59	2.00	3.00	3.00	4.00	7.00
	Month 6	Tofacitinib 5 mg BID	7	4.57	5.19	0.00	0.00	3.00	7.00	15.00
		Tofacitinib 10 mg BID	6	3.17	2.32	0.00	1.00	3.50	5.00	6.00
		Placebo	1	5.00	-	5.00	5.00	5.00	5.00	5.00
		Placebo→10 mg	1	8.00	-	8.00	8.00	8.00	8.00	8.00
		Adalimumab 40 mg SC q2w	7	3.29	1.70	0.00	2.00	4.00	4.00	5.00
	Month 9	Adalimumab 40 mg SC q2w	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	6	2.00	1.67	0.00	0.00	2.50	3.00	4.00
		Tofacitinib 10 mg BID	1	4.00	-	4.00	4.00	4.00	4.00	4.00
		Adalimumab 40 mg SC q2w	1	4.00	-	4.00	4.00	4.00	4.00	4.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 113. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Performed Paid Work in Past 3 Months While Bothered by Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Performed paid work in past 3 months while bothered by RA	Baseline	Tofacitinib 5 mg BID	169	1.69	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	166	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo	91	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	167	1.67	0.47	1.00	1.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	4	1.75	0.50	1.00	1.50	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	153	1.73	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	145	1.81	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo	85	1.68	0.47	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	157	1.70	0.46	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	136	1.75	0.43	1.00	1.50	2.00	2.00	2.00
		Tofacitinib 10 mg BID	136	1.80	0.40	1.00	2.00	2.00	2.00	2.00
		Placebo	38	1.74	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	22	1.73	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	16	1.81	0.40	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	142	1.76	0.43	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	5	1.60	0.55	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	118	1.83	0.38	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	114	1.82	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	37	1.78	0.42	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	31	1.71	0.46	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	123	1.82	0.38	1.00	2.00	2.00	2.00	2.00

Table 113. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Performed Paid Work in Past 3 Months While Bothered by Rheumatoid Arthritis

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 114. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of days Performed Paid Work While Bothered by Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of days performed paid work while bothered by RA	Baseline	Tofacitinib 5 mg BID	51	29.10	27.47	2.00	10.00	15.00	50.00	92.00
		Tofacitinib 10 mg BID	47	29.45	31.37	2.00	6.00	12.00	48.00	92.00
		Placebo	31	28.74	28.76	2.00	7.00	15.00	40.00	90.00
		Adalimumab 40 mg SC q2w	53	42.74	31.81	3.00	12.00	40.00	70.00	90.00
	Month 1	Placebo	1	10.00	-	10.00	10.00	10.00	10.00	10.00
	Month 3	Tofacitinib 5 mg BID	39	16.08	21.77	1.00	4.00	8.00	15.00	90.00
		Tofacitinib 10 mg BID	28	26.57	32.41	0.00	5.00	10.00	45.00	90.00
		Placebo	28	19.93	20.79	2.00	5.00	14.50	25.00	90.00
		Adalimumab 40 mg SC q2w	44	33.61	30.31	1.00	7.00	25.00	60.00	90.00
	Month 6	Tofacitinib 5 mg BID	31	14.71	18.47	1.00	4.00	7.00	15.00	60.00
		Tofacitinib 10 mg BID	25	20.40	25.93	1.00	4.00	8.00	24.00	90.00
		Placebo	10	11.00	9.13	3.00	5.00	6.50	20.00	30.00
		Placebo→5 mg	5	18.00	16.19	2.00	8.00	10.00	30.00	40.00
		Placebo→10 mg	3	21.00	25.36	3.00	3.00	10.00	50.00	50.00
		Adalimumab 40 mg SC q2w	33	24.55	26.88	2.00	5.00	10.00	30.00	90.00
	Month 9	Tofacitinib 5 mg BID	1	5.00	-	5.00	5.00	5.00	5.00	5.00
		Tofacitinib 10 mg BID	1	7.00	-	7.00	7.00	7.00	7.00	7.00
		Adalimumab 40 mg SC q2w	2	12.50	3.54	10.00	10.00	12.50	15.00	15.00
	Month 12	Tofacitinib 5 mg BID	20	24.10	30.75	1.00	5.00	8.50	30.00	91.00
		Tofacitinib 10 mg BID	20	20.40	27.90	1.00	4.00	6.50	20.00	90.00
		Placebo→5 mg	7	11.43	8.60	4.00	7.00	10.00	12.00	30.00
		Placebo→10 mg	9	12.33	12.32	2.00	5.00	8.00	14.00	36.00
		Adalimumab 40 mg SC q2w	22	22.86	24.20	3.00	8.00	12.00	30.00	90.00

Table 114. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of days Performed Paid Work While Bothered by Rheumatoid Arthritis

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 115. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Work Performance in Past 3 Months on Days Bothered

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Work performance in past 3 months on days bothered	Baseline	Tofacitinib 5 mg BID	139	4.16	3.05	0.00	1.00	5.00	7.00	10.00
		Tofacitinib 10 mg BID	141	4.16	3.33	0.00	0.00	4.00	7.00	10.00
		Placebo	83	4.08	3.32	0.00	0.00	4.00	7.00	10.00
		Adalimumab 40 mg SC q2w	142	4.19	3.09	0.00	0.00	5.00	7.00	10.00
	Month 1	Tofacitinib 5 mg BID	2	5.50	3.54	3.00	3.00	5.50	8.00	8.00
		Tofacitinib 10 mg BID	3	2.00	1.73	0.00	0.00	3.00	3.00	3.00
		Placebo	4	7.75	2.63	5.00	5.50	8.00	10.00	10.00
	Month 3	Tofacitinib 5 mg BID	137	2.68	2.75	0.00	0.00	2.00	4.00	10.00
		Tofacitinib 10 mg BID	129	2.81	2.89	0.00	0.00	2.00	4.00	10.00
		Placebo	76	3.38	2.84	0.00	0.00	3.50	5.50	10.00
		Adalimumab 40 mg SC q2w	139	3.09	2.81	0.00	0.00	3.00	5.00	10.00
	Month 6	Tofacitinib 5 mg BID	125	2.31	2.51	0.00	0.00	2.00	4.00	10.00
		Tofacitinib 10 mg BID	125	2.39	2.84	0.00	0.00	2.00	3.00	10.00
		Placebo	35	2.17	2.64	0.00	0.00	1.00	4.00	10.00
		Placebo→5 mg	22	2.09	2.54	0.00	0.00	1.00	3.00	8.00
		Placebo→10 mg	14	2.64	3.25	0.00	0.00	1.50	4.00	10.00
		Adalimumab 40 mg SC q2w	127	2.66	2.54	0.00	0.00	2.00	5.00	10.00
	Month 9	Tofacitinib 5 mg BID	3	5.67	5.13	0.00	0.00	7.00	10.00	10.00
		Tofacitinib 10 mg BID	4	3.25	4.72	0.00	0.00	1.50	6.50	10.00
		Adalimumab 40 mg SC q2w	4	2.75	1.89	0.00	1.50	3.50	4.00	4.00
	Month 12	Tofacitinib 5 mg BID	101	2.18	2.65	0.00	0.00	1.00	4.00	10.00
		Tofacitinib 10 mg BID	101	1.92	2.50	0.00	0.00	1.00	3.00	10.00
		Placebo→5 mg	32	2.69	2.66	0.00	0.00	2.00	4.50	10.00
		Placebo→10 mg	30	2.23	3.02	0.00	0.00	1.00	3.00	10.00
		Adalimumab 40 mg SC q2w	107	1.93	2.45	0.00	0.00	1.00	3.00	10.00

Table 115. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Work Performance in Past 3 Months on Days Bothered

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 116. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Unable to Complete Chores in Past 3 Months due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Unable to complete chores in past 3 months due to RA	Baseline	Tofacitinib 5 mg BID	201	1.41	0.49	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.46	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo	105	1.53	0.50	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	198	1.41	0.49	1.00	1.00	1.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 10 mg BID	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Placebo	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	1.00	-	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	182	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	182	1.71	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo	99	1.59	0.50	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	189	1.66	0.47	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	171	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	178	1.74	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo	45	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	27	1.74	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.75	0.44	1.00	1.50	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	175	1.67	0.47	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.40	0.55	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	1.50	0.55	1.00	1.00	1.50	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	146	1.81	0.40	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	150	1.75	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	47	1.79	0.41	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.84	0.37	1.00	2.00	2.00	2.00	2.00

Table 116. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Unable to Complete Chores in Past 3 Months due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	154	1.73	0.45	1.00	1.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 117. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Chores Carried out by Housekeeper due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Chores carried out by housekeeper due to RA	Baseline	Tofacitinib 5 mg BID	201	1.89	0.32	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.90	0.29	1.00	2.00	2.00	2.00	2.00
		Placebo	106	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.91	0.29	1.00	2.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	3	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo	6	1.83	0.41	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	184	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	183	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo	99	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.94	0.24	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	172	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo	45	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	28	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	180	1.96	0.19	1.00	2.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.80	0.45	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	6	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	148	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.97	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.95	0.23	1.00	2.00	2.00	2.00	2.00

Table 117. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Chores Carried out by Housekeeper due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	1.93	0.25	1.00	2.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 118. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hours per day Chores Done by Housekeeper

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Hours per day chores done by housekeeping	Baseline	Tofacitinib 5 mg BID	22	5.23	4.60	2.00	3.00	4.00	6.00	24.00
		Tofacitinib 10 mg BID	19	5.53	5.36	1.00	2.00	4.00	8.00	24.00
		Placebo	7	8.00	7.55	2.00	3.00	6.00	10.00	24.00
		Adalimumab 40 mg SC q2w	18	3.89	2.37	1.00	2.00	3.50	5.00	9.00
	Month 1	Placebo	1	4.00	-	4.00	4.00	4.00	4.00	4.00
	Month 3	Tofacitinib 5 mg BID	17	4.00	2.12	1.00	3.00	4.00	5.00	9.00
		Tofacitinib 10 mg BID	11	5.73	2.61	2.00	4.00	6.00	8.00	10.00
		Placebo	7	5.00	2.00	2.00	4.00	5.00	7.00	8.00
		Adalimumab 40 mg SC q2w	12	4.17	1.99	2.00	3.00	4.00	4.50	8.00
	Month 6	Tofacitinib 5 mg BID	11	3.36	2.58	1.00	1.00	3.00	5.00	8.00
		Tofacitinib 10 mg BID	10	5.40	2.50	2.00	3.00	5.00	8.00	9.00
		Placebo	3	5.33	1.53	4.00	4.00	5.00	7.00	7.00
		Placebo→10 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	7	6.29	7.95	1.00	2.00	4.00	5.00	24.00
	Month 9	Tofacitinib 5 mg BID	1	5	-	5.00	5.00	5.00	5.00	5.00
	Month 12	Tofacitinib 5 mg BID	8	4.63	3.16	1.00	2.00	4.00	7.00	10.00
		Tofacitinib 10 mg BID	4	4.75	0.96	4.00	4.00	4.50	5.50	6.00
		Placebo→5 mg	1	3.00	-	3.00	3.00	3.00	3.00	3.00
		Placebo→10 mg	2	6.00	1.41	5.00	5.00	6.00	7.00	7.00
		Adalimumab 40 mg SC q2w	10	4.10	2.08	2.00	2.00	4.00	5.00	8.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA =rheumatoid arthritis; SC = subcutaneous.

Table 119. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of days Chores Done by Housekeeper

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of days chores done by housekeeper	Baseline	Tofacitinib 5 mg BID	23	15.57	25.73	1.00	3.00	5.00	12.00	90.00
		Tofacitinib 10 mg BID	19	14.95	27.24	1.00	2.00	5.00	10.00	90.00
		Placebo	6	38.83	41.44	1.00	6.00	23.00	90.00	90.00
		Adalimumab 40 mg SC q2w	18	6.94	6.86	1.00	2.00	5.00	10.00	30.00
	Month 1	Placebo	1	3.00	-	3.00	3.00	3.00	3.00	3.00
	Month 3	Tofacitinib 5 mg BID	17	12.59	23.15	1.00	1.00	4.00	12.00	90.00
		Tofacitinib 10 mg BID	11	6.00	8.63	1.00	2.00	2.00	7.00	30.00
		Placebo	7	8.00	12.54	1.00	1.00	4.00	7.00	36.00
		Adalimumab 40 mg SC q2w	12	10.50	16.08	1.00	2.50	6.50	10.00	60.00
	Month 6	Tofacitinib 5 mg BID	11	7.73	8.25	1.00	3.00	5.00	12.00	30.00
		Tofacitinib 10 mg BID	10	15.80	22.73	1.00	2.00	3.50	15.00	60.00
		Placebo	3	44.00	42.57	6.00	6.00	36.00	90.00	90.00
		Placebo→10 mg	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Adalimumab 40 mg SC q2w	7	7.29	3.82	1.00	5.00	8.00	10.00	12.00
	Month 9	Tofacitinib 5 mg BID	1	6.00	-	6.00	6.00	6.00	6.00	6.00
	Month 12	Tofacitinib 5 mg BID	9	4.44	3.40	1.00	2.00	4.00	6.00	12.00
		Tofacitinib 10 mg BID	4	7.75	5.06	2.00	3.50	8.50	12.00	12.00
		Placebo→5 mg	1	90.00	-	90.00	90.00	90.00	90.00	90.00
		Placebo→10 mg	2	24.00	16.97	12.00	12.00	24.00	36.00	36.00
		Adalimumab 40 mg SC q2w	10	4.90	3.78	1.00	2.00	3.00	8.00	12.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 120. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Chores Carried out by Family/Friends due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Chores carried out by family/friends due to RA	Baseline	Tofacitinib 5 mg BID	200	1.50	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.48	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo	106	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	201	1.51	0.50	1.00	1.00	2.00	2.00	2.00
	Month 1	Tofacitinib 5 mg BID	2	1.5	0.71	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 10 mg BID	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Placebo	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	1	2.00	-	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	183	1.67	0.47	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	183	1.74	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo	99	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	190	1.68	0.47	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	172	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	180	1.74	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo	46	1.67	0.47	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	28	1.82	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	20	1.80	0.41	1.00	2.00	2.00	2.00	2.00
		Adalimumab 40 mg SC q2w	180	1.71	0.45	1.00	1.00	2.00	2.00	2.00
	Month 9	Tofacitinib 5 mg BID	5	1.40	0.55	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
		Placebo	6	1.67	0.52	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	145	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	151	1.80	0.40	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	38	1.71	0.46	1.00	1.00	2.00	2.00	2.00

Table 120. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Chores Carried out by Family/Friends due to Rheumatoid Arthritis

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
		Adalimumab 40 mg SC q2w	160	1.71	0.45	1.00	1.00	2.00	2.00	2.00

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 121. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hours per Day Chores Done by Family/Friends

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Hours per day chores done by family/friends	Baseline	Tofacitinib 5 mg BID	101	4.24	4.75	1.00	2.00	3.00	5.00	24.00
		Tofacitinib 10 mg BID	102	3.31	2.76	0.00	2.00	2.00	4.00	15.00
		Placebo	39	4.21	4.71	1.00	2.00	3.00	4.00	24.00
		Adalimumab 40 mg SC q2w	95	2.82	1.79	1.00	1.00	3.00	3.00	8.00
	Month 1	Tofacitinib 5 mg BID	1	1.00	-	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	1	2.00	-	2.00	2.00	2.00	2.00	2.00
		Placebo	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	59	3.46	3.67	1.00	2.00	2.00	4.00	24.00
		Tofacitinib 10 mg BID	46	3.28	2.60	1.00	2.00	2.00	4.00	12.00
		Placebo	34	3.41	2.72	0.00	2.00	3.00	4.00	12.00
		Adalimumab 40 mg SC q2w	59	3.68	3.72	1.00	2.00	3.00	4.00	24.00
	Month 6	Tofacitinib 5 mg BID	47	3.30	2.69	0.00	2.00	3.00	4.00	15.00
		Tofacitinib 10 mg BID	45	2.91	2.00	1.00	2.00	2.00	3.00	8.00
		Placebo	13	3.69	2.32	1.00	2.00	4.00	4.00	10.00
		Placebo→5 mg	5	2.00	0.71	1.00	2.00	2.00	2.00	3.00
		Placebo→10 mg	4	2.75	0.50	2.00	2.50	3.00	3.00	3.00
		Adalimumab 40 mg SC q2w	51	3.33	3.55	1.00	2.00	2.00	4.00	24.00
	Month 9	Tofacitinib 5 mg BID	3	4.00	3.61	1.00	1.00	3.00	8.00	8.00
		Tofacitinib 10 mg BID	1	3.00	-	3.00	3.00	3.00	3.00	3.00
		Adalimumab 40 mg SC q2w	2	3.00	1.41	2.00	2.00	3.00	4.00	4.00
	Month 12	Tofacitinib 5 mg BID	34	2.65	1.95	0.00	1.00	2.00	3.00	8.00
		Tofacitinib 10 mg BID	30	4.00	4.11	1.00	2.00	2.00	4.00	20.00
		Placebo→5 mg	8	2.88	2.17	1.00	2.00	2.00	3.00	8.00
		Placebo→10 mg	10	2.70	2.26	1.00	1.00	2.00	4.00	8.00
		Adalimumab 40 mg SC q2w	44	2.55	1.81	1.00	1.50	2.00	3.00	10.00

Table 121. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Hours per Day Chores Done by Family/Friends

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or Tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Table 122. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of days Chores Done by Family/Friends

Scale	Visit	Treatment	N	Mean	Standard Deviation	Minimum	Q1	Q2	Q3	Maximum
Number of days chores done by family/friends	Baseline	Tofacitinib 5 mg BID	101	24.06	29.27	1.00	5.00	10.00	30.00	90.00
		Tofacitinib 10 mg BID	102	26.57	31.02	1.00	4.00	12.00	40.00	90.00
		Placebo	39	26.95	32.87	1.00	4.00	12.00	30.00	90.00
		Adalimumab 40 mg SC q2w	97	29.80	32.91	1.00	5.00	10.00	45.00	90.00
	Month 1	Tofacitinib 5 mg BID	1	80.00	-	80.00	80.00	80.00	80.00	80.00
		Tofacitinib 10 mg BID	1	90.00	-	90.00	90.00	90.00	90.00	90.00
		Placebo	2	27.50	17.68	15.00	15.00	27.50	40.00	40.00
	Month 3	Tofacitinib 5 mg BID	60	24.10	32.38	1.00	5.00	10.00	20.00	90.00
		Tofacitinib 10 mg BID	47	18.32	24.03	1.00	4.00	7.00	25.00	90.00
		Placebo	34	24.97	31.72	2.00	5.00	10.00	30.00	90.00
		Adalimumab 40 mg SC q2w	58	25.41	30.46	1.00	5.00	10.00	36.00	90.00
	Month 6	Tofacitinib 5 mg BID	46	13.59	16.95	1.00	4.00	8.00	15.00	90.00
		Tofacitinib 10 mg BID	46	29.09	35.16	0.00	3.00	7.00	56.00	92.00
		Placebo	15	35.53	39.39	1.00	3.00	12.00	90.00	90.00
		Placebo→5 mg	5	41.20	42.43	5.00	12.00	14.00	85.00	90.00
		Placebo→10 mg	4	8.75	2.50	6.00	7.00	8.50	10.50	12.00
		Adalimumab 40 mg SC q2w	50	22.64	29.51	1.00	4.00	9.50	20.00	90.00
	Month 9	Tofacitinib 5 mg BID	3	33.33	49.12	3.00	3.00	7.00	90.00	90.00
		Tofacitinib 10 mg BID	1	90.00	-	90.00	90.00	90.00	90.00	90.00
		Adalimumab 40 mg SC q2w	2	33.50	37.48	7.00	7.00	33.50	60.00	60.00
	Month 12	Tofacitinib 5 mg BID	35	22.06	27.84	2.00	6.00	10.00	30.00	91.00
		Tofacitinib 10 mg BID	30	13.13	12.28	1.00	5.00	8.50	24.00	50.00
		Placebo→5 mg	8	51.88	40.91	7.00	14.00	55.00	90.00	90.00
		Placebo→10 mg	10	28.40	33.88	1.00	7.00	11.00	30.00	90.00
		Adalimumab 40 mg SC q2w	45	23.49	28.68	1.00	5.00	8.00	30.00	90.00

Table 122. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Tofacitinib Versus Controls – Number of days Chores Done by Family/Friends

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5 mg BID or placebo→10 mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; N = number of subjects; q2w = every 2 weeks; RA = rheumatoid arthritis; SC = subcutaneous.

Rate of Advancement at Month 3:

At Month 3, 28/56 (50.0%) subjects in the placebo → tofacitinib 5 mg sequence and 21/52 (40.4%) subjects in the placebo → tofacitinib 10 mg sequence were advanced from placebo to active drug.

Rate of Erroneous Advancement at Month 3:

Some subjects in the placebo → tofacitinib 5 or 10 mg sequences were erroneously advanced from placebo to active study drug at Month 3. One subject in the placebo → tofacitinib 5 mg sequence should have been advanced (in a blinded fashion) to active treatment at Month 3 but was not. Four subjects in the placebo → tofacitinib 10 mg sequence should have been advanced (in a blinded fashion) to active treatment at Month 3 but were not, and 5 subjects did not have joint counts at Month 3 to determine advancement.

Safety Results:

Adverse Events: Table 123, Table 124 and Table 125 respectively present all causalities treatment-emergent adverse events (TEAEs) by system organ from Baseline to Month 3, from Month 3 to Month 6, and post Month 6 respectively.

Table 126, Table 127, and Table 128 present treatment-related TEAEs from Baseline to Month 3, from Month 3 to Month 6, and post Month 6 respectively.

Serious Adverse Events: Table 129, Table 130, Table 131 present treatment-emergent SAEs from Baseline to Month 3, from Month 3 to Month 6, and post Month 6 respectively. Table 132 presents SAEs by relationship to study treatment.

Table 123. Treatment-Emergent Non-Serious Adverse Events, up to Month 3 For Events Having a Frequency Rate Greater Than or Equal to 2

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**204**	**201**	**108**	**204**
With Adverse Events	**51 (25.0)**	**44 (21.9)**	**18 (16.7)**	**50 (24.5)**
Number (%) of subjects with adverse event by:				
System organ class and MedDRA (v13.1) preferred term				
Gastrointestinal disorders	13 (6.4)	7 (3.5)	4 (3.7)	8 (3.9)
Abdominal pain upper	4 (2.0)	2 (1.0)	1 (0.9)	3 (1.5)
Diarrhoea	5 (2.5)	2 (1.0)	0.00	2 (1.0)
Dyspepsia	4 (2.0)	3 (1.5)	2 (1.9)	3 (1.5)
Vomiting	4 (2.0)	0.00	1 (0.9)	0
General disorders and administration site conditions	3 (1.5)	4 (2.0)	3 (2.8)	3 (1.5)
Oedema peripheral	3 (1.5)	4 (2.0)	3 (2.8)	3 (1.5)
Infections and infestations	22 (10.8)	21 (10.4)	2 (1.9)	23 (11.3)
Bronchitis	2 (1.0)	3 (1.5)	1 (0.9)	4 (2.0)
Herpes zoster	0	5 (2.5)	0	0
Nasopharyngitis	8 (3.9)	4 (2.0)	0	7 (3.4)
Upper respiratory tract infection	9 (4.4)	7 (3.5)	1 (0.9)	7 (3.4)
Urinary tract infection	5 (2.5)	2 (1.0)	0	7 (3.4)
Investigations	4 (2.0)	6 (3.0)	1 (0.9)	2 (1.0)
Alanine aminotransferase increased	3 (1.5)	4 (2.0)	0	1 (0.5)
Blood creatine phosphokinase increased	1 (0.5)	4 (2.0)	1 (0.9)	1 (0.5)
Musculoskeletal and connective tissue disorders	6 (2.9)	1 (0.5)	3 (2.8)	5 (2.5)
Arthralgia	2 (1.0)	1 (0.5)	1 (0.9)	4 (2.0)
Rheumatoid arthritis	4 (2.0)	0.00	2 (1.9)	1 (0.5)
Nervous system disorders	8 (3.9)	6 (3.0)	2 (1.9)	5 (2.5)
Headache	8 (3.9)	6 (3.0)	2 (1.9)	5 (2.5)

Table 123. Treatment-Emergent Non-Serious Adverse Events, up to Month 3 For Events Having a Frequency Rate Greater Than or Equal to 2

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**204**	**201**	**108**	**204**
With Adverse Events	**51 (25.0)**	**44 (21.9)**	**18 (16.7)**	**50 (24.5)**
Respiratory, thoracic and mediastinal disorders	0	2 (1.0)	3 (2.8)	4 (2.0)
Cough	0	2 (1.0)	3 (2.8)	4 (2.0)
Skin and subcutaneous tissue disorders	1 (0.5)	3 (1.5)	1 (0.9)	4 (2.0)
Rash	1 (0.5)	3 (1.5)	1 (0.9)	4 (2.0)
Vascular disorders	2 (1.0)	5 (2.5)	2 (1.9)	0
Hypertension	2 (1.0)	5 (2.5)	2 (1.9)	0

Subjects were only counted once per treatment for each row.
MedDRA (v13.1) coding dictionary applied.
Tofacitinib 5 mg BID tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; Placebo→tofacitinib 5 mg BID or Placebo→tofacitinib 10 mg BID subjects received Placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of the subjects in specific category; q2w = every 2 weeks; v = version.

Table 124. Treatment-Emergent Non-Serious Adverse Events, Month 3 to Month 6 For Events Having a Frequency Rate Greater Than or Equal to 2

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**232**	**222**	**59**	**204**
With Adverse Events	**18 (7.8)**	**8 (3.6)**	**3 (5.1)**	**18 (8.8)**
Number (%) of subjects with adverse event by: System organ class and MedDRA (v13.1) preferred term				
Infections and infestations	11 (4.7)	4 (1.8)	1 (1.7)	13 (6.4)
Nasopharyngitis	5 (2.2)	2 (0.9)	1 (1.7)	3 (1.5)
Pharyngitis	1 (0.4)	1 (0.5)	0	4 (2.0)
Urinary tract infection	5 (2.2)	1 (0.5)	0.00	6 (2.9)
Injury, poisoning and procedural complications	4 (1.7)	2 (0.9)	2 (3.4)	1 (0.5)
Fall	4 (1.7)	2 (0.9)	2 (3.4)	1 (0.5)
Musculoskeletal and connective tissue disorders	3 (1.3)	2 (0.9)	0	5 (2.5)
Back pain	3 (1.3)	2 (0.9)	0	5 (2.5)

Subjects were only counted once per treatment for each row.
MedDRA (v13.1) coding dictionary applied.
Tofacitinib 5 mg BID tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; Placebo→tofacitinib 5 mg BID or Placebo→tofacitinib 10 mg BID subjects received Placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of the subjects in specific category; q2w = every 2 week; v = version.

Table 125. Treatment-Emergent Non-Serious Adverse Events, Post Month 6 For Events Having a Frequency Rate Greater Than or Equal to 2

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**260**	**253**	**204**
With Adverse Events	**36 (13.8)**	**44 (17.4)**	**24 (11.8)**
Number (%) of subjects with adverse event by:			
System organ class and MedDRA (v13.1) preferred term			
Gastrointestinal disorders	1 (0.4)	7 (2.8)	0
Abdominal pain upper	1 (0.4)	7 (2.8)	0
Infections and infestations	26 (10.0)	27 (10.7)	21 (10.3)
Bronchitis	7 (2.7)	10 (4.0)	4 (2.0)
Herpes zoster	3 (1.2)	6 (2.4)	4 (2.0)
Nasopharyngitis	8 (3.1)	3 (1.2)	5 (2.5)
Upper respiratory tract infection	9 (3.5)	6 (2.4)	4 (2.0)
Urinary tract infection	2 (0.8)	4 (1.6)	5 (2.5)
Investigations	3 (1.2)	5 (2.0)	1 (0.5)
Alanine aminotransferase increased	3 (1.2)	5 (2.0)	1 (0.5)
Musculoskeletal and connective tissue disorders	0	7 (2.8)	1 (0.5)
Arthralgia	0	7 (2.8)	1 (0.5)
Vascular disorder	7 (2.7)	3 (1.2)	2 (1.0)
Hypertension	7 (2.7)	3 (1.2)	2 (1.0)

Subjects were only counted once per treatment for each row.
MedDRA (v13.1) coding dictionary applied.
Tofacitinib 5 mg BID tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; Placebo→tofacitinib 5 mg BID or Placebo→tofacitinib 10 mg BID subjects received Placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of the subjects in specific category; q2w = every 2 week; v = version.

Table 126. Most Frequent Treatment-Emergent AEs by System Organ Class (≥5% of Subjects in Any Treatment Group) and Preferred Term (≥2% of Subjects in Any Treatment Group) Baseline to Month 3 (Treatment-Related)

System Organ Class[a] Preferred Term, n (%)[a]	Tofacitinib BID		Placebo	Adalimumab 40 mg SC q2W
	5 mg	10 mg		
Number of subjects evaluated	204	201	108	204
Gastrointestinal disorders	18 (8.8)	16 (8.0)	6 (5.6)	11 (5.4)
Abdominal pain upper	4 (2.0)	2 (1.0)	1 (0.9)	2 (1.0)
Diarrhea	4 (2.0)	1 (0.5)	0	1 (0.5)
Infections and infestations	19 (9.3)	22 (10.9)	3 (2.8)	16 (7.8)
Herpes zoster	0	4 (2.0)	0	0
Nasopharyngitis	1 (0.5)	4 (2.0)	0	3 (1.5)
Upper respiratory tract infection	4 (2.0)	4 (2.0)	0	3 (1.5)

AEs and SAEs are not separated out.

If the same subject in a given treatment had >1 occurrence in the same preferred term event category, only the most severe occurrence was taken. Subjecst were counted only once per treatment in each row. For the TESS algorithm any missing severities were imputed as severe unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded. In this case, the reported severity was summarized. Missing Baseline severities were imputed as mild.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of subjects meeting prespecified criteria; q2W = every 2 weeks; SC = subcutaneous; TESS = treatment-emergent signs and symptoms.

a. MedDRA (version 13.1) coding dictionary applied.

Table 127. Most Frequent Treatment-Emergent AEs by System Organ Class (≥5% of Subjects in Any Treatment Sequence) and Preferred Term (≥2% of Subjects in Any Treatment Sequence) Month 3 to Month 6 (Treatment-Related)

System Organ Class[a] Preferred Term, n (%)[a]	Tofacitinib BID 5 mg	Tofacitinib BID 10 mg	Placebo → Tofacitinib 5 mg BID	Placebo → Tofacitinib BID 10 mg	Placebo	Adalimumab 40 mg SC q2W
Number of subjects evaluated	204	201	28	21	59	204
Infections and infestations	16 (7.8)	11 (5.5)	0	1 (4.8)	2 (3.4)	16 (7.8)
Influenza	0	1 (0.5)	0	1 (4.8)	0	0
Urinary tract infection	4 (2.0)	0	0	1 (4.8)	0	3 (1.5)
Investigations	5 (2.5)	6 (3.0)	3 (10.7)	0	0	3 (1.5)
Gamma-glutamyltransferase increased	0	0	1 (3.6)	0	0	0
Weight increased	2 (1.0)	0	2 (7.1)	0	0	0
Respiratory , thoracic and mediastinal disorders	2 (1.0)	2 (1.0)	2 (7.1)	1 (4.8)	1 (1.7)	0
Cough	2 (1.0)	0	0	1 (4.8)	1 (1.7)	0
Dysphonia	0	0	1 (3.6)	0	0	0
Dyspnea exertional	0	1 (0.5)	1 (3.6)	0	0	0

AEs and SAEs are not separated out.
If the same subject in a given treatment had >1 occurrence in the same preferred term event category, only the most severe occurrence was taken.
Subjects were counted only once per treatment in each row. For the TESS algorithm any missing severities were imputed as severe unless the subject experienced another occurrence of the same event in a given treatment for which severity was recorded. In this case, the reported severity was summarized.
Missing baseline severities were imputed as mild.
Included data up to 999 days after last dose of study drug.
AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of subjects meeting prespecified criteria; q2W = every 2 weeks; SC = subcutaneous; TESS = treatment-emergent signs and symptoms.
a. MedDRA (version 13.1) coding dictionary applied.

Table 128. Most Frequent Treatment-Emergent AEs by System Organ Class (≥5% of Subjects in Any Treatment Sequence and Preferred Term (≥2% of Subjects in Any Treatment Sequence) Post Month 6 (Treatment-Related)

System Organ Class[a]	Tofacitinib BID		Placebo → Tofacitinib BID		Adalimumab 40 mg SC q2W
Preferred Term, n (%)[a]	5 mg	10 mg	5 mg	10 mg	
Number of subjects evaluated	204	201	56	52	204
Infections and infestations	20 (9.8)	23 (11.4)	2 (3.6)	3 (5.8)	14 (6.9)
Bronchitis	1 (0.5)	4 (2.0)	1 (1.8)	2 (3.8)	1 (0.5)
Herpes zoster	3 (1.5)	5 (2.5)	0	0	2 (1.0)
Upper respiratory tract infection	5 (2.5)	2 (1.0)	0	0	1 (0.5)
Investigations	6 (2.9)	5 (2.5)	1 (1.8)	5 (9.6)	2 (1.0)
Alanine aminotransferase increased	2 (1.0)	1 (0.5)	0	3 (5.8)	1 (0.5)
Aspartate aminotransferase increased	1 (0.5)	1 (0.5)	0	3 (5.8)	0

AEs and SAEs are not separated out.
AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of subjects meeting prespecified criteria; q2W = every 2 weeks; SC = subcutaneous.
a. MedDRA (version 13.1) coding dictionary applied.

Table 129. Treatment-Emergent Serious Adverse Events, up to Month 3

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**204**	**201**	**108**	**204**
With Adverse Events	**12 (5.9)**	**10 (5.0)**	**2 (1.9)**	**5 (2.5)**
Number (%) of subjects with adverse event by:				
System organ class and MedDRA (v13.1) preferred term				
Cardiac disorders	0	1 (0.5)	1 (0.9)	2 (1.0)
Acute myocardial infarction	0	0	0	1 (0.5)
Atrioventricular block complete	0	0	1 (0.9)	0
Cardiac arrest	0	0	0	1 (0.5)
Myocardial infarction	0	1 (0.5)	0	0
Ear and labyrinth disorders	0	1 (0.5)	0	0
Vertigo	0	1 (0.5)	0	0
Gastrointestinal disorders	0	2 (1.0)	1 (0.9)	0
Anal polyp	0	1 (0.5)	0	0
Diverticular perforation	0	1 (0.5)	0	0
Salivary gland calculus	0	0	1 (0.9)	0
General disorders and administration site conditions	1 (0.5)	0	0	0
Impaired healing	1 (0.5)	0	0	0
Hepatobiliary disorders	2 (1.0)	0	0	1 (0.5)
Cholecystitis	1 (0.5)	0	0	0
Cholecystitis acute	0	0	0	1 (0.5)
Cholelithiasis	1 (0.5)	0	0	0
Infections and infestations	2 (1.0)	4 (2.0)	1 (0.9)	0
Arthritis bacterial	0	1 (0.5)	0	0
Cellulitis	2 (1.0)	1 (0.5)	0	0
Herpes zoster	0	1 (0.5)	0	0
Labyrinthitis	0	1 (0.5)	0	0
Osteomyelitis	1 (0.5)	0	0	0
Sialoadenitis	0	0	1 (0.9)	0

Table 129. Treatment-Emergent Serious Adverse Events, up to Month 3

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**204**	**201**	**108**	**204**
With Adverse Events	**12 (5.9)**	**10 (5.0)**	**2 (1.9)**	**5 (2.5)**
Tooth abscess	1 (0.5)	0	0	0
Urinary tract infection	0	1 (0.5)	0	0
Injury, poisoning and procedural complications	1 (0.5)	1 (0.5)	0	1 (0.5)
Fall	0	1 (0.5)	0	0
Femur fracture	0	1 (0.5)	0.00	1 (0.5)
Humerus fracture	1 (0.5)	0	0	0
Metabolism and nutrition disorders	1 (0.5)	0	0	0
Diabetes mellitus	1 (0.5)	0	0	0
Musculoskeletal and connective tissue disorders	1 (0.5)	1 (0.5)	0	0
Spinal column stenosis	0	1 (0.5)	0	0
Tendon disorder	1 (0.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (1.0)	1 (0.5)	0	0
Hair follicle tumour benign	1 (0.5)	0	0	0
Metastatic renal cell carcinoma	1 (0.5)	0	0	0
Ovarian germ cell teratoma benign	0	1 (0.5)	0	0
Nervous system disorders	0	0	1 (0.9)	0
Dysarthria	0	0	1 (0.9)	0
Renal and urinary disorders	0	0	0	1 (0.5)
IgA nephropathy	0	0	0	1 (0.5)
Respiratory, thoracic and mediastinal disorders	2 (1.0)	0	0	1 (0.5)
Chronic obstructive pulmonary disease	1 (0.5)	0	0	0
Hydrothorax	0	0	0	1 (0.5)
Pleuritic pain	1 (0.5)	0	0	0
Skin and subcutaneous tissue disorders	1 (0.5)	0	0	0
Prurigo	1 (0.5)	0	0	0

Table 129. Treatment-Emergent Serious Adverse Events, up to Month 3

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**204**	**201**	**108**	**204**
With Adverse Events	**12 (5.9)**	**10 (5.0)**	**2 (1.9)**	**5 (2.5)**
Vascular disorders	0	2 (1.0)	0	0
Hypertension	0	1 (0.5)	0	0
Venous thrombosis limb	0	1 (0.5)	0	0

Subjects were only counted once per treatment for each row.
Included data up to 999 days after last dose of study drug.
MedDRA (v13.1) coding dictionary applied.
Tofacitinib 5 mg BID tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; Placebo→tofacitinib 5 mg BID or Placebo→tofacitinib 10 mg BID subjects received Placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of the subjects in specific category; q2w = every 2 weeks; v = version.

Table 130. Treatment-Emergent Serious Adverse Events, Month 3 to 6

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**232**	**222**	**59**	**204**
With Adverse Events	**10 (4.3)**	**7 (3.2)**	**2 (3.4)**	**6 (2.9)**
Number (%) of subjects with adverse event by:				
System organ class and MedDRA (v13.1) preferred term				
Cardiac disorders	1 (0.4)	0	0	1 (0.5)
Myocardial infarction	1 (0.4)	0	0.00	0
Myocardial ischaemia	0	0	0	1 (0.5)
Eye disorders	0	1 (0.5)	0	0
Retinal detachment	0	1 (0.5)	0	0
Gastrointestinal disorders	0	1 (0.5)	0	1 (0.5)
Haematemesis	0	0.00	0	1 (0.5)
Haematochezia	0	0.00	0	1 (0.5)
Peptic ulcer haemorrhage	0	1 (0.5)	0	0
General disorders and administration site conditions	0	1 (0.5)	0	0
Pyrexia	0	1 (0.5)	0	0
Infections and infestations	3 (1.3)	1 (0.5)	0	3 (1.5)
Breast abscess	0	0	0	1 (0.5)
Cellulitis	1 (0.4)	0	0	1 (0.5)
Clostridial infection	0	1 (0.5)	0	0
Erysipelas	0	0	0	1 (0.5)
Gallbladder empyema	0	0	0	1 (0.5)
Gastroenteritis	1 (0.4)	0	0	0
Localised infection	1 (0.4)	0	0	0
Septic shock	1 (0.4)	0	0	0
Injury, poisoning and procedural complications	3 (1.3)	1 (0.5)	0	0
Fibula fracture	1 (0.4)	0	0	0
Humerus fracture	1 (0.4)	0	0	0

Table 130. Treatment-Emergent Serious Adverse Events, Month 3 to 6

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**232**	**222**	**59**	**204**
With Adverse Events	**10 (4.3)**	**7 (3.2)**	**2 (3.4)**	**6 (2.9)**
Scapula fracture	1 (0.4)	0	0	0
Tendon rupture	0	1 (0.5)	0	0
Tibia fracture	2 (0.9)	0	0	0
Musculoskeletal and connective tissue disorders	0	1 (0.5)	0	1 (0.5)
Rheumatoid arthritis	0	1 (0.5)	0	0
Spondylolisthesis	0	0	0	1 (0.5)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	1 (0.4)	2 (0.9)	0	1 (0.5)
Benign salivary gland neoplasm	1 (0.4)	0	0	0
Cervix carcinoma	0	1 (0.5)	0	0
Cholesteatoma	0	1 (0.5)	0	0
Myelodysplastic syndrome	0	0	0	1 (0.5)
Nervous system disorders	0	0	1 (1.7)	0
Ischaemic stroke	0	0	1 (1.7)	0
Reproductive system and breast disorders	2 (0.9)	0	1 (1.7)	0
Cervix disorder	1 (0.4)	0	0	0
Ovarian cyst	0	0	1 (1.7)	0
Ovarian torsion	1 (0.4)	0	0	0

Subjects were only counted once per treatment for each row.
Included data up to 999 days after last dose of study drug.
MedDRA (v13.1) coding dictionary applied.
Tofacitinib 5 mg BID tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; Placebo→tofacitinib 5 mg BID or Placebo→tofacitinib 10 mg BID subjects received Placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of the subjects in specific category; q2w = every 2 weeks; v = version.

Table 131. Treatment-Emergent Serious Adverse Events, Post Month 6

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**260**	**253**	**204**
With Adverse Events	**11 (4.2)**	**10 (4.0)**	**7 (3.4)**
Number (%) of subjects with adverse event by: System organ class and MedDRA (v13.1) preferred term			
Cardiac disorders	0	1 (0.4)	1 (0.5)
Cardiac failure congestive	0	1 (0.4)	0
Myocardial infarction	0	0	1 (0.5)
Endocrine disorders	1 (0.4)	0	0
Autoimmune thyroiditis	1 (0.4)	0	0
Gastrointestinal disorders	0	1 (0.4)	1 (0.5)
Abdominal hernia	0	0	1 (0.5)
Ileus	0	1 (0.4)	0
General disorders and administration site conditions	0	0	1 (0.5)
Chest pain	0	0	1 (0.5)
Hepatobiliary disorders	0	1 (0.4)	0
Cholelithiasis	0	1 (0.4)	0
Infections and infestations	4 (1.5)	3 (1.2)	0
Herpes zoster	1 (0.4)	0	0
Lung abscess	1 (0.4)	0	0
Pneumonia	1 (0.4)	1 (0.4)	0
Pulmonary tuberculosis	0	2 (0.8)	0
Salpingo-oophoritis	1 (0.4)	0	0
Injury, poisoning and procedural complications	3 (1.2)	1 (0.4)	1 (0.5)
Femur fracture	1 (0.4)	0	0
Fibula fracture	0	1 (0.4)	0
Joint dislocation	0	0	1 (0.5)
Lower limb fracture	1 (0.4)	0	0
Tendon rupture	1 (0.4)	0	0

Table 131. Treatment-Emergent Serious Adverse Events, Post Month 6

For Events Having a Frequency Rate Greater Than or Equal to 0

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Adalimumab 40 mg Subcutaneous q2W
	n (%)	n (%)	n (%)
Evaluable for Adverse Events	**260**	**253**	**204**
With Adverse Events	**11 (4.2)**	**10 (4.0)**	**7 (3.4)**
Musculoskeletal and connective tissue disorders	0	0	2 (1.0)
Bursitis	0	0	1 (0.5)
Rheumatoid arthritis	0	0	1 (0.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.4)	1 (0.4)	1 (0.5)
Neuroma	0	1 (0.4)	0
Non-small cell lung cancer	1 (0.4)	0	1 (0.5)
Nervous system disorders	0	1 (0.4)	0
Headache	0	1 (0.4)	0
Renal and urinary disorders	0	1 (0.4)	0
Renal failure acute	0	1 (0.4)	0
Reproductive system and breast disorders	1 (0.4)	0	0
Metrorrhagia	1 (0.4)	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.4)	1 (0.4)	0
Interstitial lung disease	0	1 (0.4)	0
Pulmonary sarcoidosis	1 (0.4)	0	0
Surgical and medical procedures	0	1 (0.4)	0
Cholecystectomy	0	1 (0.4)	0

Subjects were only counted once per treatment for each row.
Included data up to 999 days after last dose of study drug.
MedDRA (v13.1) coding dictionary applied.
Tofacitinib 5 mg BID tofacitinib 10 mg BID subjects received this dose from Day 1; Placebo subjects received this dose from Day 1 to either Month 3 or Month 6; Placebo→tofacitinib 5 mg BID or Placebo→tofacitinib 10 mg BID subjects received Placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; n = number of the subjects in specific category; q2w = every 2 weeks; v = version.

Table 132. Subjects with Serious Adverse Events

Subject ID	Age/Sex	MedDRA Preferred Term (Day of Onset)	Outcome	Causality	Action Taken with Respect to Study Drug
Randomized not treated					
1[a]	61/F	Hypertension (-16)	Recovered/Resolved	Related	N/A
		Hyperglycemia (-16)	Recovered/Resolved	Related	N/A
2	UNK	Rheumatoid Arthritis (NA)	Recovered/Resolved	N/A	N/A
3	55/F	Head injury (-29)	Recovered/Resolved	N/A	N/A
		Concussion (-29)	Recovered/Resolved	N/A	N/A
4	40/F	Cervical dysplasia (-7)	Recovered/Resolved	Related	N/A
5	UNK	Cerebrovascular accident (N/A)	Recovering/resolving	N/A	N/A
Tofacitinib 5 mg BID					
6	74/F	Cholelithiasis (26)	Recovered/Resolved	Unrelated	Temporarily withdrawn
7	46/F	Prurigo (3)	Recovered/Resolved	Related	Permanently withdrawn
8	58/F	Humerus fracture (102)	Recovered/Resolved	Unrelated	Post-therapy
9	62/F	Diabetes mellitus (51)	Recovered/Resolved	Unrelated	Dose not changed
10	66/F	Localized infection (128)	Recovered/Resolved	Unrelated	Temporarily withdrawn
11	64/M	Osteomyelitis (64)	Recovered/Resolved	Related	Permanently withdrawn
		Abscess jaw (64)	Recovered/Resolved	Related	Permanently withdrawn
		Cellulitis (64)	Recovered/Resolved	Related	Permanently withdrawn
12	31/F	Ovarian torsion (138)	Recovered/Resolved	Unrelated	Temporarily withdrawn
13	51/M	Hair follicle tumor benign (N/A)	Recovered/Resolved	Unrelated	Permanently withdrawn
		Impaired healing (124)	Recovered/Resolved	Unrelated	Permanently withdrawn
14	42/F	Cholecystitis infective (7)	Recovered/Resolved	Unrelated	Temporarily withdrawn
15	53/F	Pneumonia (247)	Recovered/Resolved	Unrelated	Temporarily withdrawn
16	29/F	Salpingo-oophoritis (250)	Recovered/Resolved	Unrelated	Permanently withdrawn
17	52/F	Tendon disorder (15)	Recovered/Resolved	Unrelated	Temporarily withdrawn
18	63/F	Tendon rupture (211)	Recovered/Resolved	Unrelated	Temporarily withdrawn
19	42/F	Cervix disorder (162)	Recovered/Resolved	Unrelated	Temporarily withdrawn
20	31/M	Lower limb fracture (228)	Recovered/Resolved	Unrelated	Temporarily withdrawn
21	63/F	Humerus fracture (103)	Recovered/Resolved	Unrelated	Dose not changed
22	44/F	Pleuritic pain (11)	Recovered/Resolved	Unrelated	Temporarily withdrawn
23	71/M	Chronic obstructive pulmonary disease (85)	Recovered/Resolved	Unrelated	Dose not changed
		Femur fracture (270)	Recovered/Resolved	Unrelated	Temporarily withdrawn
24	45/F	Autoimmune thyroiditis (234)	Recovered/Resolved	Unrelated	Temporarily withdrawn
25	54/F	Pneumonia (385)	Fatal	Related	Not applicable

Table 132. Subjects with Serious Adverse Events

Subject ID	Age/Sex	MedDRA Preferred Term (Day of Onset)	Outcome	Causality	Action Taken with Respect to Study Drug
26	51/M	Gastroenteritis (118)	Recovered/Resolved	Related	Temporarily withdrawn
27	61/F	Acute myocardial infarction (137)	Recovered/Resolved	Unrelated	Permanently withdrawn
28	57/F	Salivary gland neoplasm (114)	Recovered/Resolved	Unrelated	Dose not changed
29	70/F	*Herpes zoster* (280)	Recovered/Resolved	Related	Permanently withdrawn
30	55/F	Non-small cell lung cancer (171)	Not recovered/Not resolved	Related	Permanently withdrawn
31	52/F	Tibia fracture (116)	Recovered/Resolved	Unrelated	Temporarily withdrawn
32	55/F	Lung abscess (284)	Recovered/Resolved	Related	Permanently withdrawn
33	53/F	Metrorrhagia (325)	Recovered/Resolved	Related	Dose not changed
34	63/F	Metastatic renal cell carcinoma (85)	Not recovered/Not resolved	Related	Permanently withdrawn
35	51/F	Cellulitis (18)	Recovered/Resolved	Related	Permanently withdrawn
36	58/F	Multiple fractures (147)	Recovered/Resolved	Unrelated	Temporarily withdrawn
37	77/F	Septic shock (206)	Recovered/Resolved	Related	Permanently withdrawn
Tofactinib 10 mg BID					
38	40/F	Anal polyp (73)	Recovered/Resolved	Unrelated	Temporarily withdrawn
39	67/M	Peptic ulcer hemorrhage (158)	Recovered/Resolved	Related	Temporarily withdrawn
40	63/M	Pulmonary tuberculosis (305)	Recovering/Resolving	Related	N/A
41	55/F	Spinal column stenosis (53)	Recovered/Resolved	Unrelated	Permanently withdrawn
		Herpes zoster (63)	Recovered/Resolved	Related	Permanently withdrawn
42	53/F	Fibula fracture (345)	Recovering/Resolving	Unrelated	Temporarily withdrawn
43	66/F	Diverticular perforation (63)	Recovered/Resolved	Related	Permanenly withdrawn
44	46/M	Rheumatoid arthritis (147)	Recovered/Resolved	Unrelated	Dose not changed
45	59/F	Femur fracture (32)	Recovered/Resolved	Unrelated	Temporarily withdrawn
46	56/M	Cholesteatoma (124)	Recovered/ Resolved	Unrelated	Temporarily withdrawn
47	45/F	Ovarian germ cell teratoma benign (11)	Recovered/Resolved	Unrelated	Dose not changed
48	49/F	Tendon rupture (160)	Recovered/Resolved	Unrelated	Temporarily withdrawn
49	67/M	Pyrexia (125)	Recovered/Resolved	Related	Temporarily withdrawn
		Clostridial infection (147)	Recovered/Resolved	Unrelated	Temporarily withdrawn
50	57/M	Retinal detachment (120)	Recovered/Resolved	Unrelated	Temporarily withdrawn
51	47/F	Venous thrombosis (90)	Recovered/Resolved	Unrelated	Permanently withdrawn
52	72/F	Cellulitis (12)	Recovered/Resolved	Unrelated	Dose not changed
		Urinary tract infection (103)	Recovered/Resolved	Related	Permanently withdrawn
53	63/M	Labyrinthitis (87)	Not recovered/Not resolved	Related	Permanently withdrawn
		Vertigo (87)	Not recovered/Not resolved	Related	Permanently withdrawn

Table 132. Subjects with Serious Adverse Events

Subject ID	Age/Sex	MedDRA Preferred Term (Day of Onset)	Outcome	Causality	Action Taken with Respect to Study Drug
54	44/M	Pneumonia (313)	Recovered/Resolved	Unrelated	Temporarily withdrawn
55	50/F	Cervix carcinoma (150)	Not recovered/Not resolved	Unrelated	Permanently withdrawn
56	65/F	Myocardial infarction (72)	Recovered/Resolved	Related	Permanently withdrawn
		Arthritis bacterial (87)	Recovered/Resolved	Related	Permanently withdrawn
57	51/F	Renal failure acute (247)	Recovered/Resolved	Unrelated	Permanently withdrawn
58	67/F	Headache (290)	Recovered/Resolved	Related	Permanently withdrawn
		Pulmonary tuberculosis (290)	Not recovered/Not resolved	Related	Permanently withdrawn
59	70/F	Cardiac failure congestive (230)	Recovered/Resolved	Unrelated	Permanenly withdrawn
Placebo → Tofactinib 5mg					
60 (on placebo)	64/F	Salivary gland calculus (84)	Recovered/Resolved	Unrelated	Temporarily withdrawn
		Dysarthria (84)	Recovered/Resolved	Unrelated	Temporarily withdrawn
		Sialoadenitis (84)	Recovered/Resolved	Unrelated	Temporarily withdrawn
61 (on placebo)	62/F	Ischemic stroke (151)	Recovered/Resolved	Unrelated	Temporarily withdrawn
62 (advanced to 5 mg BID)	67/F	Pulmonary sarcoidosis (315)	Recovered/Resolved	Unrelated	Temporarily withdrawn
Placebo → Tofactinib 10mg					
63 (on placebo)	57/F	Atrioventricular block complete (2)	Recovered/Resolved	Unrelated	Permanently withdrawn
64 (on placebo)	49/F	Ovarian cyst (134)	Recovered/Resolved	Unrelated	Dose not changed
65	71/M	Ileus (300)	Recovered/Resolved	Unrelated	Permanently withdrawn
66 (on placebo)	60/M	Liver disorder (8)	Recovered/Resolved	Related	Permanently withdrawn
67 (advanced to 10 mg BID)	64/F	Neuroma (168)	Recovered/Resolved	Unrelated	Temporarily withdrawn
68 (advanced to 10 mg BID)	51/F	Interstitial lung disease (253)	Recovering/Resolving	Related	Permanently withdrawn
69 (advanced to 10 mg BID)	66/M	Cholelithiasis (277)	Recovered/Resolved	Unrelated	Temporarily withdrawn
Adalimumab 40 mg SC q2w					
70	44/F	Cholecystitis acute (54)	Recovered/Resolved	Unrelated	Temporarily withdrawn
71	58/F	Hematemesis (209)	Recovered/Resolved	Unrelated	Permanently withdrawn
		Melaena (208)	Recovered/Resolved	Unrelated	Permanently withdrawn
72	46/M	Drug exposure during pregnancy (276)	Unknown	Related	N/A
73	75/F	Breast cellulitis (179)	Recovered/Resolved	Related	Permanently withdrawn
		Breast abscess (179)	Recovered/Resolved	Related	Permanently withdrawn

Table 132. Subjects with Serious Adverse Events

Subject ID	Age/Sex	MedDRA Preferred Term (Day of Onset)	Outcome	Causality	Action Taken with Respect to Study Drug
74	62/F	Femur fracture (79)	Recovered/Resolved	Unrelated	Temporarily withdrawn
		IGA nephropathy (102)	Recovered/Resolved	Related	Permanently withdrawn
75	74/M	Acute myocardial infarction (57)	Recovered/Resolved	Related	Permanently withdrawn
76	71/F	Bursitis (263)	Recovered/Resolved	Related	Not applicable
77	65/M	Erysipelas (192)	Recovered/Resolved	Related	Permanently withdrawn
78	45/F	Spondylolisthesis (184)	Recovered/Resolved	Unrelated	Permanently withdrawn
79	64/M	Myocardial infarction (382)	Recovered/Resolved	Unrelated	Dose not changed
80	62/F	Chest pain (200)	Recovered/Resolved	Unrelated	Dose not changed
81	55/F	Myocardial ischaemia (101)	Recovered/Resolved	Unrelated	Temporarily withdrawn
82	58/M	Hydrothorax (72)	Recovered/Resolved	Unrelated	Dose not changed
83	60/F	Joint dislocation (210)	Recovered/Resolved	Unrelated	Dose not changed
84	35/F	Gallbladder emphysema (173)	Recovered/Resolved	Related	Permanenly withdrawn
85	64/F	Bone marrow failure (297)	Unknown	Related	Unknown
86	53/F	Rheumatoid Arthritis (338)	Recovered/Resolved	Unrelated	Permanently withdrawn
87	66/F	Abdominal hernia (300)	Recovered/Resolved	Unrelated	Temporarily withdrawn
88	62/M	Non-small cell lung cancer (253)	Recovering/Resolving	Related	Permanently withdrawn
89	68/M	Cardiac arrest (72)	Fatal	Unrelated	Permanently withdrawn

The events in this table were cumulative through 06 August 2010. Age was age (in years) at Screening.
MedDRA (version 13.1) coding dictionary applied.
BID = twice daily, F = female, M = male, MedDRA = Medical Dictionary for Regulatory Activities, N/A = not applicable or not available; q = every;
SC = subcutaneous; UNK = unknown.
a. Hypertension started study day 9; the dose arm for this patient and this event was tofacitinib 5 mg.

Deaths: There were 2 deaths reported during this study. One death occurred in a subject treated with adalimumab 40 mg who experienced a cardiac arrest. The other death was due to apical pneumonia, in a subject treated with tofacitinib 5 mg; worsening respiratory insufficiency due to the pneumonia was associated with multisystem failure leading to death 35 days post therapy.

Temporary Discontinuations and Dose Reductions Due to Adverse Events: AEs leading to temporary discontinuation or dose reduction in ≥1% (by preferred term) of subjects in any treatment sequence are presented in Table 133.

Table 133. Summary of AEs Leading to Temporary Discontinuation or Dose Reduction in ≥1% of Subjects in Any Treatment Sequence

MedDRA System Organ Class Preferred Term	Tofacitinib BID		Placebo→Tofacitinib		Adalimumab	Total
	5 mg	10 mg	5 mg	10 mg	40 mg SC q2W	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Months 0-3						
Infections and infestations						
Lower respiratory tract infection	2 (1.0)	0	0	0	0	2
Respiratory, thoracic and mediastinal disorders						
Pleuritic pain	2 (1.0)	0	0	0	0	2
Months 3-6						
Injury poisoning, and procedural complications						
Tibia fracture	2 (1.0)	0	0	0	0	2
Tendon rupture	0	2 (1.0)	0	0	0	2
Nervous system disorders						
Ischemic stroke	0	1 (1.7)	0	0	0	1
Post 6-months						
Cardiac disorders						
Palpitations	0	0	0	1 (1.9)	0	1
Hepatobilliary disorders						
Cholelithiasis	0	0	0	1 (1.9)	0	1
Infections and infestations						
Bronchitis	1 (0.5)	2 (1.0)	0	1 (1.9)	0	4
Diverticulitis	0	0	0	1 (1.9)	0	1
Herpes zoster	1 (0.5)	4 (2.0)	0	0	1 (0.5)	6
Pneumonia	1 (0.5)	2 (1.0)	0	0	0	3
Sinusitis	0	0	1 (1.8)	0	0	1
Injury, poisoning and procedural complications						
Spinal compression fracture	0	0	0	1 (1.9)	0	1
Neoplasms benign, malignant and unspecified (including cysts and polyps)						
Neuroma	0	0	0	1 (1.9)	0	1
Respiratory, thoracic and mediastinal disorders						
Pulmonary sarcoidosis	0	0	1 (1.8)	0	0	1
Surgical and medical procedures						
Cholecystecomy	0	0	0	1 (1.9)	0	1

MedDRA (version 13.1) coding dictionary applied.
AE = adverse events; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities, n = number of subjects meeting prespecified criteria, q2w = every 2 weeks; SC = subcutaneous.

Permanent Discontinuations due to Adverse Events: Permanent discontinuations due to treatment-emergent AEs are presented in Table 134.

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
Tofacitinib 5 mg BID						
1	Injury, poisoning and procedural complications	Ankle fracture	Active	212/304	Moderate/resolved (29 Oct 2010)	Other illness - osteoporosis secondary steroids
2	Skin and subcutaneous tissue disorders	Prurigo[b]	Active	11/22	Severe/resolved (29 Mar 2010)	Study drug
3	Blood and lymphatic system disorders	Lymphadenitis	Active	57[>183]	Mild/still present	Other illness - history of lymphadenitis
4	Investigations	Hepatic enzyme increased	Active	176/261	Moderate/resolved (01 Jun 2010)	Study drug
5	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic renal cell carcinoma[b]	Active	85/[>127]	Severe/still present	Study drug
6	Infections and infestations	Septic shock[b]	Active	206/213	Severe/resolved (02 Jul 2010)	Study drug
7	Infections and infestations	Cellulitis[b]	Active	64/[>150]	Severe/still present	Study drug
		Osteomyelitis[b]	Active	64/[>150]	Severe/ still present	Study drug
		Tooth abscess[b]	Active	64/[>150]	Severe/ still present	Study drug
8	Investigations	Weight increased	Active	110/[>133]	Moderate/still present	Study drug
9	Investigations	Neutrophil count decreased	Active	1/92	Mild/resolved (17 Mar 2010)	Study drug
10	Infections and infestations	Cellulitis[b]	Active	22/34	Severe/resolved (29 Sep 2009)	Study drug
		Cellulitis	Active	35/64	Moderate/resolved (29 Oct 2009)	Study drug
11	Skin and subcutaneous tissue disorders	Blister	Active	265/297	Mild/resolved (25 Sep 2010)	Study drug
		Rash vesicular	Active	147/313	Mild/resolved (11 Oct 2010)	Study drug
		Skin lesion	Active	265/297	Mild/resolved (25 Sep 2010)	Study drug

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
12	Neoplasms, benign, malignant and unspecified	Hair follicle tumor benign[b]	Active	1/121	Mild/resolved (08 Jun 2010)	Other illness
13	Gastrointestinal disorders	Gastrointestinal pain	Active	43/43	Severe/resolved (03 Mar 2010)	Study Drug
14	Infections and infestations	Salpingo-oophoritis[b]	Active	250/261	Severe/resolved (20 Apr 2010)	Other illness
15	Gastrointestinal disorders	Abdominal pain upper	Active	126/168	Severe/resolved (26 Jan 2010)	Study drug
		Dyspepsia	Active	126/168	Severe/resolved (26 Jan 2010)	Study drug
		Nausea	Active	126/168	Severe/resolved (26 Jan 2010)	Study drug
16	Nervous system disorders	Dizziness	Active	8/35	Moderate/resolved (28 Jul 2009)	Study drug
17	Infections and infestations	Bronchopneumonia	Active	25/46	Moderate/resolved (12 Mar 2010)	Study drug
18	Gastrointestinal disorders	Abdominal pain upper	Active	5/18	Moderate/resolved (14 Mar 2010)	Study drug
		Dyspepsia	Active	5/18	Moderate/resolved 14 Mar 2010)	Study drug
	Nervous system disorders	Headache	Active	5/18	Mild/resolved (14 Mar 2010)	Study drug
19	Blood and lymphatic system disorders	Anemia	Active	34/[>99]	Mild/still present	Study drug
20	Cardiac disorders	Myocardial infarction[b]	Active	137/146	Severe/resolved (28 Mar 2010)	Other illness-uncontrolled hypertension
21	Infections and infestations	*Herpes zoster*[b]	Active	280/307	Moderate/resolved (07 Dec 2010)	Study drug
22	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-small cell lung cancer[b]	Active	211/[>226]	Severe/still present	Study drug

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
23	Infections and infestations	Lung abscess[b]	Active	284/[>291]	Moderate/still present	Study drug
24	Investigations	Blood creatinine increased	Active	65/156	Mild/resolved (06 Jul 2010)	Study drug
Tofacitinib 10 mg BID						
25	Gastrointestinal disorders	Nausea	Active	124/169	Moderate/resolved (08 Feb 2010)	Backround study drug- not willing to continue in study
26	Metabolism and nutrition disorders	Hyperglycemia	Active	-14/36	Moderate/resolved (28 Oct 2010)	Other - possible low insulin levels
	Vascular disorders	Hypertension[b]	Active	9/21	Moderate/resolved (13 Oct 2010)	Other - anxious
27	Investigations	Blood creatinine increased	Active	179/253	Moderate/resolved (28 May 2010)	Study drug
28	Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	Active	194/300	Severe/resolved (15 Sep 2010)	Other – worsening of previous condition
29	Infections and infestations	*Herpes zoster*	Active	35/85	Severe/resolved (03 Mar 2010)	Study drug
30	Investigations	Blood pressure increased	Active	135/>171	Severe/still present	Other illness-uncontrolled hypertension
31	Infections and infestations	*Herpes zoster*[b]	Active	63/71	Moderate/resolved (27 Oct 2009)	Study drug
	Musculoskeletal and connective tissue disorders	Spinal column stenosis[b]	Active	53/134	Severe/resolved (29 Dec 2009)	Other
32	Ear and labyrinth disorders	Vertigo	Active	5/14	Moderate/resolved (31 Aug 2009)	Study drug
33	Gastrointestinal disorders	Abdominal pain upper	Active	128/146	Moderate/resolved (08 Feb 2010)	Study drug
34	Gastrointestinal disorders	Diverticular perforation[b]	Active	63/78	Severe/resolved (25 Jan 2010)	Study drug

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
35	Gastrointestinal disorders	Nausea	Active	194/338	Mild/resolved (06 Oct 2010)	Study drug
	General disorders and administration site conditions	General physical health deterioration	Active	194/338	Mild/resolved (06 Oct 2010)	Study drug
	Respiratory thoracic and mediastinal disorders	Dyspnea	Active	194/338	Moderate/resolved (06 Oct 2010)	Study drug
36	Infections and infestations	Clostridial infection[b]	Active	147/155	Mild/resolved (09 June 2010)	Other - nosocomial infection during hospitalization of infectious disease
37	Vascular disorders	Venous thrombosis limb[b]	Active	90/96	Severe/resolved (07 May 2010)	Concomitant treatment - mirelle hormonal contraceptive
38	Infections and infestations	Urinary tract infection[b]	Active	103/110	Severe/resolved (11 May 2010)	Study drug
		Diverticulitis	Active	103/110	Mild/resolved (11 May 2010)	Study drug
		Herpes zoster	Active	95/[>175]	Moderate/still present	Other illness - unknown
	Metabolism and nutrition disorders	Dehydration	Active	103/103	Moderate/resolved (04 May 2010)	Study drug
39	Ear and labyrinth disorders	Vertigo[b]	Active	87/[>197]	Moderate/still present	Study drug
	Infections and infestations	Labyrinthitis[b]	Active	87/[>197]	Moderate/still present	Study drug
40	Reproductive system and breast disorders	Cervical dysplasia	Active	-5/111	Moderate/resolved (11 Jan 2010)	Other-unknown
41	Investigations	Alanine aminotransferase increased	Active	169/340	Mild/resolved (31 Jan 2011)	Study drug

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
		Aspartate aminotransferase increased	Active	169/194	Mild/resolved (07 Sep 2010)	Study drug
42	Neoplasms, benign, malignant and unspecified (including cysts and polyps)	Cervix carcinoma[b]	Active	135/>150	Severe/still present	Other illness - neoplasm
43	Investigations	Hepatic enzyme increased	Active	169/[>217]	Moderate/still present	Study drug
44	Cardiac disorders	Cardiac failure congestive	Active	72/122	Moderate/resolved (11 Mar 2010)	Study drug
		Myocardial infarction[b]	Active	72/122	Severe/resolved (11 Mar 2010)	Study drug
45	Renal and urinary disorders	Nephrolithiasis	Active	247/333	Moderate/resolved (03 Sep 2010)	Other illness diabetic neuropathy
		Acute renal insufficiency[b]	Active	247/333	Severe/resolved (03 Sep 2010)	Other illness - diabetes mellitus type 2
46	Infections and infestations	Pulmonary tuberculosis[b]	Active	290/[>290]	Severe/still present	Study drug
	Nervous system disorders	Headache[b]	Active	290/292	Severe/resolved (05 Dec 2010)	Study drug
47	Investigations	Alanine aminotransferase increased	Active	169/248	Mild/resolved (09 Oct 2010)	Study drug
		Aspartate aminotransferase increased	Active	169/248	Mild/resolved (09 Oct 2010)	Study drug
48	Infections and infestations	*Herpes zoster*	Active	22/58	Moderate/resolved (30 Mar 2010)	Study drug

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
Placebo						
49	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	Active	34/[>85]	Moderate/still present	Study drug
50	Cardiac disorders	Atrioventricular block complete[b]	Active	2/9	Severe/resolved (11 Dec 2009)	Other - unknown
51	Gastrointestinal disorders	Dyspepsia	Active	1/8	Moderate/resolved (17 Feb 2010)	Study drug
52	Investigations	Liver function test abnormal	Active	-13/6	Mild/Resolved (16 Mar 2010)	Concomitant treatment - nidrazid
Placebo →Tofacitinib 5 mg BID						
53	Investigations	Gamma-glutamyltransferase increased	Active	169/240	Moderate/resolved (25 Mar 2010)	Study drug
Placebo →Tofacitinib 10 mg BID						
54	General disorders and administration site conditions	Pyrexia	Active	251/[>287]	Moderate/still present	Study drug
	Respiratory thoracic and mediastinal disorders	Interstitial lung disease[b]	Active	253/[>287]	Moderate/still present	Study drug
55	Gastrointestinal disorders	Ileus[b]	Active	300/322	Severe/resolved (24 Aug 2010)	Other – obstruction caused by abdominal adhesions

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
Adalimumab 40 mg SC q2w						
56	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome[b]	Active	208/[>257]	Severe/still present	Study drug
	Gastrointestinal disorders	Hematamesis	Active	209/209	Moderate/resolved (08 Jun 2010)	Other - blood dyscrasia
		Hematochezia	Active	208/257	Moderate/resolved (26 Jul 2010)	Other - blood dyscrasia
57	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	Active	39/80	Severe/resolved (09 Apr 2010)	Disease under study
58	Psychiatric disorders	Anxiety	Active	16/19	Moderate/resolved (11 Aug 2009)	Study drug
59	Skin and subcutaneous tissue disorders	Rash	Active	61/76	Mild/resolved (06 Apr 2010)	Study drug
60	Infections and infestations	Breast abscess[b]	Active	179/203	Severe/resolved (17 May 2010)	Study drug
		Cellulitis[b]	Active	179/203	Severe/resolved (17 May 2010)	Study drug
61	Renal and urinary disorders	Iga nephropathy[b]	Active	102/141	Severe/resolved (18 Dec 2009)	Study drug
62	Cardiac disorders	Acute myocardial infarction[b]	Active	57/85	Severe/resolved (29 Oct 2009)	Study drug
63	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-small cell lung cancer[b]	Active	253/[>279]	Moderate/still present	Study drug
64	Blood and lymphatic system disorders	Leukopenia	Active	171/381	Moderate/resolved (13 Oct 2010)	Study drug
65	Infections and infestations	Erysipelas[b]	Active	192/246	Mild/resolved (24 May 2010)	Study drug

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
66	Musculoskeletal and connective tissue disorders	Spondylolisthesis[b]	Active	184/315	Severe/resolved (10 Aug 2010)	Other-illness aggravated back pain
67	Blood and lymphatic system disorders	Leukopenia	Active	171/381	Moderate/resolved (13 Oct 2010)	Study drug
68	Investigations	Hepatic enzyme increased	Active	169/[>330]	Severe/still present	Study drug
69	Skin and subcutaneous tissue disorders	Pruritus	Active	113/[>127]	Mild/still present	Study drug
		Rash generalized	Active	113/[>127]	Mild/still present	Study drug
70	Gastrointestinal disorders	Diarrhea	Active	32/62	Mild/resolved (22 Mar 2010)	Study drug
71	Infections and infestations	Gallbladder empyema[b]	Active	172/182	Severe/resolved (11 May 2010)	Study drug
	Nervous system disorders	Carpal tunnel syndrome	Active	32/[>92]	Moderate/still present	Other-numbness bilateral wrist
72	Gastrointestinal disorders	Dyspepsia	Active	28/34	Moderate/resolved (19 Jan 2010)	Study drug
73	Skin and subcutaneous tissue disorders	Rash	Active	13/20	Moderate/resolved (02 Mar 2010)	Study drug
74	Musculoskeletal and connective tissue disorders	Tenosynovitis	Active	230/274	Moderate/resolved (09 Jun 2010)	Disease under study
		Worsening of RA	Active	230/[>246]	Moderate/ still present	Disease under study
	Infections and infestations	*Herpes zoster* infection eurological	Active	139/267	Moderate/resolved (15 Nov 2010)	Background study drug
75	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	Active	337/358	Moderate/resolved (27 Jan 2011)	Background study drug-exacerbation of RA onset was 7 days after background methotrexate discontinuation

Table 134. Permanent Discontinuations due to Treatment-Emergent Adverse Events

Serial No.	System Organ Class	MedDRA Preferred Term	Treatment Phase	Study Start Day[a]/ Study Stop Day[a]	Severity/Outcome	Causality
76	General disorders and administration site conditions	Fatigue	Active	214/218	Mild/resolved (30 Sep 2010)	Study drug

All events were treatment-emergent. Values in brackets were imputed from incomplete dates and time.
MedDRA (version 13.1) coding dictionary applied.
BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; q2w = every 2 weeks; No. = number; RA = rheumatoid arthritis; SC = subcutaneous.
a. Duration of adverse event; day relative to start of study treatment. First day of treatment = Day 1.
b. Serious adverse event, according to Investigator assessment.

Infections: The greatest number of subjects with serious infections reported at any visit up to the Month 6 visit was 3/201 subjects (1.5%) in the tofacitinib 10 mg treatment sequence, reported at Month 3 (Table 135). There were 20 serious infections in 19 subjects: 1 localized infection, 2 cases of cellulitis, 1 case of infective cholecystitis, 2 cases of pneumonia, 1 case of gastroenteritis, and 1 case of *Herpes zoster*. In subjects in the tofacitinib 5 mg BID treatment arm; there was 1 case of cellulitis, 2 cases of pulmonary tuberculosis, 1 case of pneumonia, 1 case of *Herpes zoster*, 1 case of clostridium infection, and 1 case of urinary tract infection. In subjects in the tofacitinib 10 mg BID treatment arm, there was 1 case of cellulitis and 1 case of breast abscess in 1 subject. In the adalimumab treatment arm, there was 1 case of cholecystitis.

Table 135. Number (%) of Subjects With Serious Infection at Each Visit Through Month 12; Comparisons Within Sequence

Time of Visit	Tofacitinib BID		Placebo→Tofacitinib BID		Adalimumab 40 mg SC q2W
	5 mg (N=204)	10 mg (N=201)	5 mg (N=56)	10 mg (N=52)	(N=204)
			n (%)		
Baseline	0	0	0	0	0
Month 1	1 (0.5)	1 (0.5)	0	0	0
Month 3	2 (1.0)	3 (1.5)	1 (1.8)[a]	0	0
Month 6	2 (1.0)	1 (0.5)	0	0	2 (1.0)
Month 9	2 (1.0)	2 (1.0)	0	1 (1.9)	1 (0.5)
Month 12	0	1 (0.5)	0	0	0

Subjects were counted only once per visit based on the start day of the treated infection.
BID = twice daily; N = number of subjects; n = number of subjects meeting prespecified criteria; q2w = every 2 weeks; SC = subcutaneous.
a. Event occurred while on placebo.

A treated infection was any infection that required antimicrobial therapy by any route of administration or any surgical intervention (eg, incision and drainage). The highest percentages of subjects with treated infection were in the tofacitinib 5 mg and 10 mg sequences at Month 3 (11.8% and 11.9%, respectively) and the placebo → tofacitinib 10 mg sequence at Month 9 (13.5%).

Laboratory Values: In general, more subjects who received tofacitinib 10 mg had creatine kinase (CK) elevations compared to subjects who had received tofacitinib 5 mg, and more subjects who received 5 or 10 mg tofacitinib had CK elevations compared to placebo and adalimumab.

Mean hemoglobin values remained relatively stable at each visit through Month 12. Tofacitinib 5 mg showed an increase in mean hemoglobin levels compared to placebo with the greatest increase in hemoglobin levels from Baseline to Month 6 in adalimumab. The changes from Baseline in hemoglobin through Month 12 were similar among treatment sequences.

After an initial dose-dependent decrease, neutrophil counts remained relatively stable through Month 12, although small decreases were observed in all treatment sequences. In addition, subjects taking adalimumab showed an initial decrease in neutrophil counts.

In general, a higher proportion of subjects in the adalimumab and tofacitinib treatment sequences had mild, moderate, and severe neutropenia than subjects in the placebo → tofacitinib treatment sequences, and a slightly higher proportion of subjects in the tofacitinib 10 mg treatment sequence had neutropenia than subjects in the tofacitinib 5 mg treatment sequence.

Mean changes from Baseline in platelet values were similar across all the treatment sequences. Overall, platelet values fell in parallel with decreases in RA disease activity.

A greater proportion of subjects who received tofacitinib 10 mg had aspartate aminotransferase (AST) values ≥1x the upper limit of normal (ULN) through Month 3 than those who received tofacitinib 5 mg, adalimumab, or placebo. However, a greater proportion of subjects who received tofacitinib 5 mg had alanine aminotransferase (ALT) values ≥1xULN through Month 3 than those who received tofacitinib 10 mg, adalimumab, or placebo. The proportions of subjects experiencing AST, ALT, and bilirubin abnormalities that were ≥2xULN or ≥3xULN were low and similar across all treatment sequences. In general, the percentage of subjects with ALT or AST values ≥1xULN Months 3 to 6 was higher in the tofacitinib 5 mg and 10 mg treatment sequences followed by the placebo → tofacitinib treatment sequences. Post Month 6, the percentage of subjects with total bilirubin ≥1xULN was highest in the placebo → tofacitinib 10 mg sequence (4.8%), followed by the adalimumab sequence (4.5%). The percentage of subjects with AST and ALT values ≥1xULN and ≥2xULN post Month 6 was highest in the tofacitinib 10 mg treatment sequence compared to the other treatment sequences.

A small increase in mean AST concentrations from Baseline at Month 3, Month 6, and Month 12 was noted for all treatment sequences, with the exception of the adalimumab sequence. At Month 6, a small increase in mean ALT concentrations was noted for both tofacitinib treatment sequences that continued through Month 12.

The mean changes from Baseline in bilirubin through Month 6 were minimal in all treatments with adalimumab showing the greatest changes at all time points. No subjects had an ALT or AST >3x ULN and a total bilirubin >2x ULN (potential Hy's law). One subject had an ALT >3x ULN and a total bilirubin of >1x ULN but <2x ULN; this subject received tofacitinib 10 mg BID and experienced the AE of ALT increased; during the course of the study ALT, AST, and bilirubin increased from Baseline; the Investigator assessed the causality as related to fatty liver.

At Month 6, LS mean changes from Baseline in serum creatinine were small in magnitude across the treatment sequences. At Month 6, changes were greatest for the tofacitinib 10 mg treatment sequence. At Month 12, mean changes from Baseline were greatest for the placebo → tofacitinib 10 mg treatment sequence, followed by the tofacitinib 10 mg sequence.

At Month 6, the tofacitinib 5 mg and 10 mg treatments had similar and greater increases in percent high-density lipoprotein (HDL) from Baseline compared to the placebo sequences and adalimumab. From Month 6 to Month 12, all treatment sequences had greater changes in

percent HDL compared to Baseline with the greatest changes in the placebo → tofacitinib BID 5 mg sequence followed by the tofacitinib 10 mg treatment.

Increases in mean low density lipoprotein (LDL) occurred at Month 1 for the tofacitinib 5 and 10 mg sequences and were sustained at Month 6. LDL concentrations appeared to increase with tofacitinib in a dose-dependent manner. Mean LDL levels for placebo and adalimumab remained stable through Month 6.

There was no significant difference among sequences in change from Baseline in triglyceride concentrations except between tofacitinib 10 mg and adalimumab at Month 6 (p= 0.0286).

Increases in mean total cholesterol occurred by Month 1 for tofacitinib 5 and 10 mg and were generally sustained at Month 6. Total cholesterol percentage changes were significantly greater for the tofacitinib sequences and adalimumab at all time points compared to placebo except for adalimumab versus placebo at Month 6 (p=0.2283). Total cholesterol percentage changes were significantly greater for the tofacitinib sequences at all time points compared to adalimumab.

A higher proportion of subjects who had a baseline LDL of <100 mg/dL exhibited a maximum increase in LDL from Baseline to Month 3 of ≥130 mg/dL in the tofacitinib 10 mg group (13/201, 6.47%) and tofacitinib 5 mg group (8/204, 3.92%) compared to placebo (1/108, 0.93%) or adalimumab subjects (2/204, 0.98%). Similar shift patterns from Baseline were observed with other LDL categories, and from Month 3 to Month 6 and post Month 6.

Electrocardiograms data were not summarized in the report.

Minimal changes were noted in the ratios of apolipoprotein A-I and B-100 from Baseline to Month 12, and no substantial differences between treatment sequences were noted.

The highest proportion of subjects meeting the criteria for any single hemoglobin value <8.0 g/dL or a value that dropped ≥2 g/dL below Baseline up to Month 3 occurred in the 2 tofacitinib dose groups. The highest proportion of subjects meeting the criteria for any single hemoglobin value <8.0 g/dL or a value that dropped ≥2 g/dL below Baseline from Month 3 to 6, occurred in the placebo → tofacitinib 10 mg sequence. For the post Month 6 time period, the placebo → tofacitinib 10 mg treatment sequence also had the highest proportion of subjects meeting these criteria.

All treatment sequences exhibited a slight increase in mean systolic blood pressure (BP) through Month 6 with the exception of adalimumab, which showed a decrease at Month 6. At Month 12, both placebo → tofacitinib treatment sequences exhibited decreases in mean systolic BP compared to Baseline though these decreases were not statistically significant. Overall, changes in diastolic BP were slight and variable.

The proportion of subjects meeting the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure criteria for Stage 1 or 2 hypertension remained relatively stable throughout the 12 months of therapy with no consistent changes across sequences.

By Month 12, there were increases in weight for subjects in all treatment sequences, with the greatest increases in subjects treated with tofacitinib 10 mg, and the least increases in subjects who received adalimumab.

Conclusions:

- Treatment with tofacitinib (5 and 10 mg BID) was efficacious compared to placebo, with statistically significant differences from placebo, in reducing the signs and symptoms of RA, and in increasing the physical functioning of subjects with RA, as measured by the 3 co-primary endpoints: ACR20 response rate at Month 6, HAQ-DI response rate at Month 3, and subjects achieving DAS28-4(ESR) <2.6 at Month 6.

- Treatment with tofacitinib (5 and 10 mg BID) and adalimumab was efficacious compared to placebo in improving secondary endpoints of signs and symptoms of RA as measured by the ACR20, ACR50, ACR70, HAQ-DI, DAS28-3(CRP), and DAS28-4(ESR) through Month 6.

- Subjects treated with tofacitinib (5 or 10 mg BID) generally showed numerically greater response rates and improvements from Baseline on all primary and secondary efficacy outcomes compared to those treated with adalimumab.

- Subjects who received placebo for 3 to 6 months and then advanced to tofacitinib treatment (5 or 10 mg BID) showed improvement in all efficacy measures (ACR20, ACR50, ACR70, HAQ-DI, DAS28-3[CRP], and DAS28-4[ESR]).

- In general, treatment with tofacitinib (5 or 10 mg BID) resulted in improvements compared to placebo through Month 6 in self-reported measures of sleep (MOS-SS) and health status (SF-36), with similar improvements observed for adalimumab.

- Treatment with tofacitinib (5 or 10 mg BID) and adalimumab resulted in statistically significant improvements from Baseline in the FACIT Fatigue Scale at Month 3 and Month 6 compared to placebo.

- Both tofacitinib doses resulted in statistically significant improvements in the utility score for the EuroQoL EQ-5D Questionnaire compared to placebo at Month 3 and Month 6; changes for subjects taking adalimumab did not reach statistical significance.

- Both tofacitinib doses resulted in statistically significant improvements compared to placebo and adalimumab on the WLQ subscales with greater improvements over time observed for subjects taking tofacitinib 10 mg.

- Rapid onset of efficacy (within 1 month, first postbaseline assessment) was observed and sustained in the tofacitinib 5 and 10 mg BID sequences through Month 12.

- The most frequently reported AEs were those coding to the Medical Dictionary of Regulatory Activites system organ class of infections and infestations, gastrointestinal disorders, investigations, and musculoskeletal and connective tissue disorders with

similar occurrences between active treatment arms and greater incidences as compared to placebo.

- There were 2 deaths during the study. One death occurred in a subject treated with adalimumab 40 mg who experienced a cardiac arrest. The other death was due to apical pneumonia, in a subject treated with tofacitinib 5 mg; worsening respiratory insufficiency due to the pneumonia was associated with multisystem failure leading to death 35 days post therapy.

- Over the course of the study, SAEs were reported in 33 subjects in the tofacitinib 5 mg BID group, 27 subjects in the tofacitinib 10 mg BID group, 18 subjects in the adalimumab group and 4 subjects experienced SAEs while on placebo.

- Serious infections were reported in 7 subjects in the tofacitinib 5 mg BID group, 9 subjects in the tofacitinib 10 mg BID group, 3 subjects in the adalimumab group and 1 subject while on placebo over the course of the study.

- There were more discontinuations due to AEs in the active treatment sequences (tofacitinib 5 and 10 mg BID, and adalimumab) compared to discontinuations due to AEs in the placebo sequences.

- Changes in laboratory parameters observed for tofacitinib 5 and 10 mg BID relative to placebo were consistent with expectations, including small increases in creatinine levels, and increases in mean HDL, LDL, and total cholesterol not seen in the adalimumab treatment arm.

- Neutrophil count reductions were observed over the first 3 months and were stable thereafter for both tofacitinib doses and adalimumab.

- In comparison to placebo, subjects treated with tofacitinib 5 mg showed a slight increase in mean hemoglobin levels at Month 6, with a greater increase in subjects treated with adalimumab. Subjects treated with tofacitinib 10 mg exhibited mean hemoglobin levels slightly lower than placebo at Month 6 and Month 12.

- Transaminase elevations ≥1xULN were more common with tofacitinib than with adalimumab or placebo; elevations ≥3xULN were uncommon.

- The safety profile of tofacitinib (5 and 10 mg BID) was similar to that seen in previous studies with tofacitinib with no new safety signals observed.