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

PROTOCOL NO.: A3921044

PROTOCOL TITLE: Phase 3 Randomized, Double-Blind, 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: One hundred and ten (110) centers took part in the study and enrolled subjects: 3 centers in Australia, 7 centers in Brazil, 4 centers in Bulgaria, 7 centers in Canada, 4 centers in Colombia, 6 centers in the Czech Republic, 1 center in Greece, 8 centers in India, 15 centers in Japan, 8 centers in the Republic of Korea, 2 centers in Mexico, 2 centers in Poland, 6 centers in Taiwan, 5 centers in the Ukraine, and 32 centers in the United States.

Study Initiation Date, Primary Completion and Final Completion Dates:

Study Initiation Date: 31 March 2009

Primary Completion Date: 01 April 2011

Final Completion Date: 10 February 2012

Phase of Development: Phase 3

Study Objectives:

Primary Objectives:

- To compare the efficacy of CP-690,550 (tofacitinib) in doses of 5 mg twice daily (BID) and 10 mg 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, as measured by American College of Rheumatology (ACR) definition for calculating improvement in RA calculated as a $\geq 20\%$ improvement in tender and swollen joint counts and $\geq 20\%$ improvement in 3 of the 5 remaining ACR core set measures (ACR20) response rates at Month 6.
- To compare evidence of preservation of joint structure after administration of tofacitinib in doses of 5 mg BID or 10 mg BID versus placebo in subjects with active RA on a stable background of methotrexate, as measured by changes from Baseline using a validated method, such as the van der Heijde modified Sharp score.

- To compare physical function status of subjects after administration of tofacitinib in doses of 5 mg BID or 10 mg BID 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 methotrexate.
- To compare the rate of achieving Disease Activity Score (DAS28)-4 Erythrocyte Sedimentation Rate (ESR) <2.6 after administration of tofacitinib in doses of 5 mg BID or 10 mg BID versus placebo at Month 6 in subjects with active RA on a stable background of methotrexate.
- To evaluate the safety and tolerability of tofacitinib in doses of 5 mg BID and 10 mg BID versus placebo in subjects with active RA on a stable background of methotrexate.

Secondary Objectives:

- To compare the efficacy of tofacitinib in doses of 5 mg BID and 10 mg BID versus placebo for the treatment of signs and symptoms of RA in subjects with active RA on a stable background of methotrexate, as measured by ACR20 response rates at Months 1 and 3, and ACR definition for calculating improvement in RA calculated as a $\geq 50\%$ improvement in tender and swollen joint counts and $\geq 50\%$ improvement in 3 of the 5 remaining ACR core set measures (ACR50), ACR definition for calculating improvement in RA calculated as a $\geq 70\%$ improvement in tender and swollen joint counts and $\geq 70\%$ improvement in 3 of the 5 remaining ACR core set measures (ACR70) and DAS28 response rates at Months 1, 3, and 6.
- To compare the durability of ACR20, ACR50, and ACR70 and DAS28 response rates.
- To compare the incidence of DAS28 <2.6 and DAS28 ≤ 3.2 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.

METHODS

Study Design: This was a Phase 3, randomized, 2-year, double-blind, placebo-controlled, parallel group study. Subjects were randomized in a 4:4:1:1 ratio to 1 of the following 4 parallel treatment sequences (Table 1).

Table 1. Treatment Sequences

Treatment Sequence	Study Drug Administered Per Period		Sequence Names
	Double-Blind Placebo-Controlled Period ^a	Double-Blind Active-Extension Period ^b	
Sequence 1	Tofacitinib 5 mg BID	Tofacitinib 5 mg BID	Tofacitinib 5 mg
Sequence 2	Tofacitinib 10 mg BID	Tofacitinib 10 mg BID	Tofacitinib 10 mg
Sequence 3	Placebo	Tofacitinib 5 mg BID	Placebo → Tofacitinib 5 mg
Sequence 4	Placebo	Tofacitinib 10 mg BID	Placebo → Tofacitinib 10 mg

BID = twice daily

- a. Duration of 3 to 6 months; response was assessed at Month 3, and nonresponsive subjects were advanced to the double-blind active-extension period in a blinded manner by the automated web/telephone randomization system supplied by the Sponsor.
- b. All subjects entered this period by Month 6.

At the Month 3 visit, the tender/painful joint counts and swollen joint counts for each subject were calculated and compared to Baseline values. If there was not at least a 20% improvement in both the tender/painful and swollen joint counts as reported in the study database, the subject was considered a non-responder. That subject was then advanced in a blinded fashion to the “Double-Blind Active Extension Period”. At the end of Month 6, all subjects were automatically advanced to the “Double-Blind Active Extension Period.” The subjects randomized to sequences that began with active treatment with tofacitinib (Treatment Sequence 1 or Treatment Sequence 2) remained on those active treatments after advancement. Subjects randomized to Treatment Sequence 3 or Treatment Sequence 4 began receiving tofacitinib after advancement. The timing of activities has been summarized in Table 2.

Table 2. Schedule of Activities

		Screening ^a	V 1	V 2	V 3	V 4	V 5	V 6	V 7	V 8	V 9	V 10	
			Baseline Day 0	1 Mo	3 Mo	6 Mo	9 Mo	12 Mo	15 Mo	18 Mo	21 Mo	24 Mo/EOS	
Informed consent, RA activity, medical history ^b		X											
Concomitant medications		X	X	X	X	X	X	X	X	X	X	X	
Complete physical examination		X	X					X				X	
Targeted physical examination ^c			X	X	X	X			X	X	X		
Vital signs, temperature		X	X	X	X	X	X	X	X	X	X	X	
QuantiFERON-Gold or PPD, radiograph of chest		X											
12-lead electrocardiogram		X						X				X	
Radiograph of hands & feet ^d			X		X ^c	X		X				X	
Blood/Urine	Rheumatoid factor, anti-CCP	X	X									X	
	Hematology ^f , chemistry panel ^g	X	X	X	X	X	X	X	X	X	X	X	
	Lipid profile (fasting) ^h	X	X	X	X	X	X	X		X		X	
	CBC with differential & chemistry labs ⁱ		As appropriate for standard of care										
	Urine/urine pregnancy test (HCG) ^j	X	X	X	X	X	X	X	X	X	X	X	X
	Stool examination for parasites (Brazil only)	X											
	Molecular profiling sampling (pharmacogenomic) ^k		X	X	X	X			X		X		X
	HIV serology, HBsAg, HCV Ab	X											
ACR/ DAS	C-reactive protein	X	X	X	X	X	X	X	X	X	X	X	
	Erythrocyte sedimentation rate ^l	X	X	X	X	X	X	X	X	X	X	X	
	Tender/painful joint count, swollen joint count	X	X	X	X	X	X	X	X	X	X	X	
	Patient Assessment of Arthritis Pain		X	X	X	X	X	X	X	X	X	X	
	Patient Global Assessment of Arthritis		X	X	X	X	X	X	X	X	X	X	
	Physician Global Assessment of Arthritis		X	X	X	X	X	X	X	X	X	X	
	Health Assessment Questionnaire – Disability Index		X	X	X	X	X	X	X	X	X	X	X
SF-36 (Version 2, acute)			X	X	X	X	X	X	X	X	X	X	
MOS Sleep Scale/FACIT- Fatigue Scale			X	X	X	X		X		X		X	
EuroQol EQ-5D, Work Limitations Questionnaire			X		X	X		X		X		X	
RA Healthcare Resource Utilization Questionnaire			X		X	X		X		X		X	
Randomization			X										
Drug dispensing			X		X	X	X	X	X	X	X		
Drug accountability					X	X	X	X	X	X	X	X	
Adverse event reporting			X	X	X	X	X	X	X	X	X	X	
Review entry criteria for open-label follow-up studies (in Japan only)												X	

Table 2. Schedule of Activities

ACR = American College of Rheumatology; CBC = complete blood count; CCP = cyclic citrullinated peptide; DAS = disease activity score; EOS = end of study; EuroQol EQ-5D = European Quality of Life 5-dimension scale; FACIT = Functional Assessment of Chronic Illness Therapy; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; HBsAg = hepatitis B surface antigen; HCV Ab = hepatitis C virus antibody; HCG = human chorionic gonadotropin; LDL = low-density lipoprotein; mo = month; MOS = Medical Outcomes Study; PPD = purified protein derivative; RA = rheumatoid arthritis; RBC = red blood cell; SF-36 = Short Form-36; V = visit; WBC = white blood cell.

- a. Screening visit occurred within 1 month prior to the Baseline visit.
- b. Medical history included smoking status, average weekly alcohol consumption, family history of premature coronary heart disease.
- c. Targeted physical exam consisted of weight, examination of heart, lungs, and lower extremities for peripheral edema, abdomen and lymph nodes.
- d. Hand and foot radiographs were read and scored centrally.
- e. Only non-responders who were identified at Month 3 had hand and feet radiographs taken.
- f. Hematology included RBC, WBC with differential, hemoglobin, hematocrit, and platelet count.
- g. Chemistry panel included blood urea nitrogen, creatinine, glucose, calcium, sodium, potassium, bicarbonate, chloride, total protein, total bilirubin, direct bilirubin, indirect bilirubin, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, gamma-glutamyl transferase, albumin, creatine kinase. In Japan, serum β -D-glucan and KL-6 were also obtained at Screening.
- h. Lipid profile included fasting total cholesterol, LDL, HDL, and triglycerides; apolipoprotein A1 and B and other lipoprotein tests potentially including particle size measurements were obtained at Baseline and Months 3, 6, 9, 12, 18, and 24.
- i. Chemistry laboratories as appropriate for standard of care in subjects receiving methotrexate; might have included creatinine, albumin and liver tests.
- j. Urinalysis included specific gravity, pH, protein, glucose, ketones, blood, and leukocyte esterase. Urine pregnancy testing (β -HCG) was required only for women who were of childbearing potential; might have been repeated more frequently if required by local practices, if a menstrual cycle was missed, or if potential pregnancy was otherwise suspected.
- k. Only at sites participating in the molecular profiling (pharmacogenomics) research component.
- l. At sites where local laboratory had the capability of reporting results only to the central laboratory.

Number of Subjects (Planned and Analyzed): It was planned to enrol a total of 750 subjects in a 4:4:1:1 ratio to 1 of the following 4 parallel treatment sequences: tofacitinib 5 mg BID; tofacitinib 10 mg BID; placebo→tofacitinib 5 mg BID; or placebo→tofacitinib 10 mg BID. Eight hundred subjects were randomized to treatment: 321 to tofacitinib 5 mg BID, 319 to tofacitinib 10 mg BID, 81 to placebo→tofacitinib 5 mg BID; and 79 to placebo→tofacitinib 10 mg BID; all randomized subjects except 3 subjects in the tofacitinib 10 mg BID group received at least 1 dose of study medication.

Diagnosis and Main Criteria for Inclusion: The study included males and females of non-childbearing potential of 18 years of age and above with moderate to severe RA on a stable dose of methotrexate. Pregnant subjects and those suffering with severe acute or chronic medical conditions, including serious infections or clinically significant laboratory abnormalities were excluded from the study.

Study Treatment: The Sponsor provided tofacitinib in 5 mg tablets and placebo tablets, which were similar in appearance to tofacitinib. Two active tablets/dose were taken by subjects receiving tofacitinib 10 mg; 1 active and 1 placebo tablet were taken by subjects receiving tofacitinib 5 mg, and 2 placebo tablets were taken by subjects receiving placebo. Study drug was allowed to be taken with or without food, other than on study visit days where fasting was required. Study drug was to be self-administered by the subject. Subjects were instructed to take their study drug BID. It was suggested that study drug doses be administered approximately 12 hours apart. Background methotrexate could be administered either orally or parenterally in a dose and frequency consistent with the requirements of the inclusion criteria.

Efficacy Endpoints:

Primary Efficacy Endpoints: The study had 4 primary efficacy endpoints:

- Signs and symptoms as measured by ACR20 at Month 6;
- Structure preservation as measured by the modified Total Sharp Score (mTSS) change from Baseline at Month 6;
- Physical function as measured by the HAQ-DI change from Baseline at Month 3;
- Incidence of DAS28-4(ESR) <2.6 at Month 6.

Secondary Efficacy Endpoints: Secondary endpoints included the following, analyzed at all time points where collected.

- ACR20 Responder rate at times other than Month 6;
- ACR50 Responder rate;
- ACR70 Responder rate;

- Actual and change from Baseline of the 7 individual components (tender joint count, swollen joint count, Patient Assessment of Arthritis Pain (visual analog scale [VAS]), Physician Global Assessment of Arthritis, Patient Global Assessment of Arthritis, C-Reactive Protein [CRP] and HAQ-DI) of the ACR criteria variables (separate analyses);
- Actual mTSS at Months 6, 12 and 24 and change from Baseline in mTSS at Months 12 and 24;
- Actual and change from Baseline of 2 individual components of mTSS (erosion and joint space narrowing [JSN] scores) at Months 6, 12 and 24 (separate analyses);
- Rate of subjects with no progression in mTSS (≤ 0.5 unit change) at Months 6, 12, and 24 (separate analyses for each month);
- Rate of subjects with no progression in mean erosion score (≤ 0.5 unit change) at Months 6, 12, and 24 (separate analyses for each month);
- Actual and change from Baseline in DAS28-3(CRP) and DAS28-4(ESR), that is, separate endpoints, analyzed separately;
- Incidences of DAS28-3(CRP) ≤ 3.2 , and DAS28-4(ESR) ≤ 3.2 (separate endpoints, analyzed separately);
- Rates of DAS28-4(ESR) < 2.6 at time points other than Month 6;
- Rates of DAS28-3(CRP) < 2.6 ;
- DAS28 response rates (no improvement versus improvement [good or moderate improvement]) based on DAS28-3(CRP) and DAS28-4(ESR) (separate endpoints, analyzed separately). DAS28 response rates are more commonly known as European League Against Rheumatism (EULAR) response rates (the 3 categories of EULAR response are no response, good response, and moderate response);
- Rates of ACR70 Response for at least 6 months;
- Durability of ACR (ACR20, ACR50, and ACR70) and DAS28 (DAS28-3[CRP] < 2.6 and DAS28-4[ESR] < 2.6) response rates. Durability was measured as:
 - The proportion of subjects who first achieved the response at each post-baseline visit (eg, at Month 1) and, of these, the proportion of subjects that continued to sustain a response for the following consecutive visits (eg, Month 3 to Month 12, and Month 3 to Month 24).
- Patient Reported Outcomes (PROs):

- Actual and change from Baseline in the Short Form-36 (SF-36) 8 domain scores and 2 component scores (separate analyses);
- Actual and change from Baseline in Work Limitations Questionnaire (WLQ) domain scores and the Work Loss Index (separate analyses);
- Actual and change from Baseline in the European Quality of Life 5-dimension scale (EuroQol EQ-5D);
- RA Healthcare Resource Utilization (RA-HCRU) Questionnaire;
- Actual and change from Baseline in the Medical Outcomes Study (MOS)-Sleep Scale (MOS-SS) subscales;
- Actual and change from Baseline in the Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Scale;
- 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 (0.3)”, “HAQ-DI (0.5)”, “HAQ-DI (0.8),” respectively;
- Rate of advancement to active treatment at Month 3;
- Rate of erroneous advancement to active treatment at Month 3.

Safety Evaluations: Safety was assessed by the reporting of adverse events (AEs), physical examinations, electrocardiograms, vital signs, chest x-rays, tuberculosis testing, and clinical laboratory evaluations in all subjects who received at least 1 dose of study drug. Investigators and Sponsor clinicians reviewed individual subject data throughout the conduct of the study to ensure the subjects' well-being.

Statistical Methods:

Analysis Sets: 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) or placebo; this was the primary analysis set. Subjects must have had at least 1 post-baseline measurement (including safety data) in order to be included in any of the analyses that used the FAS dataset.

FAS subjects who had a protocol deviation thought to affect the efficacy analysis were excluded from the Per Protocol efficacy analysis.

The Safety Analysis Set was defined as those subjects who received at least 1 dose of the study drug (tofacitinib) or placebo.

Analysis of Primary Endpoints: In order to preserve Type I error, each endpoint was assessed sequentially using a gate-keeping (step-down) approach where statistical significance could be claimed for a given endpoint only if the prior endpoint in the sequence

met the requirement for significance. Additionally, as there were 2 doses within each endpoint, this step-down approach was also applied, ie, the high dose (10 mg BID) at a given endpoint could achieve significance only if the high dose at the prior endpoint was significant; the low dose (5 mg BID) at a given endpoint could achieve significance only if both the high dose at the same endpoint and the low dose at the prior endpoint were significant.

After last observation carried forward (LOCF) imputation was applied, missing values due to a subject dropping from the study for any reason (eg, lack of efficacy or AE) were handled by setting the ACR value (ACR20, ACR50, and ACR70) to nonresponsive from that visit onward (ie, baseline observation carried forward, BOCF). This also meant that if a subject withdrew at a visit but had responsive ACR values at that visit, the ACR value was still set to nonresponsive. Note that this method, BOCF, also went by the name non-responder imputation.

Also, if a subject was advanced at Month 3 by the system to the next dose in the sequence to which the subject was randomized, that subject's ACR value was set to nonresponsive on or after Month 3. This is known as an "advancement penalty," and this was done for analyses that showed comparisons to placebo (that is, analyses that included only up to Month 6).

For continuous variables such as change from Baseline in HAQ-DI where measurements were taken at each visit, a longitudinal mixed-effect linear model was used; this model imputed any missing data due to a subject dropping from the study.

For mTSS, subjects who were advanced at Month 3 had their Month 6 measurement calculated using a linear extrapolation from the X-rays taken at Baseline and Month 3. For Month 12, comparisons to placebo were done by linearly extrapolating a Month 12 value based on Baseline and Month 6. All Sharp Score-related variables were imputed using this method.

For ACR20 and incidence of DAS28-4(ESR) <2.6 at Month 6, the normal approximation for the difference in binomial variables was used.

For the change from Baseline in the HAQ-DI at Month 3, a mixed-effect model with repeated measures as treatment effect model was used. The Baseline value was a covariate; fixed effects included treatment, visit, and treatment by visit interaction, with subjects as a random effect and structured covariance matrix.

For change from Baseline in mTSS, an analysis of variance model was used. The same approach was used for change from Baseline in erosion scores and JSN scores. Binary variables (rates of subjects with no progression in mTSS and rates of subjects with no progression in mean erosion score) were analyzed using normal approximation to the binomial.

Analyses of Secondary Endpoints: Secondary analyses included the normal approximation for the difference in binomial proportions for the ACR variables (ACR20, ACR50, and ACR70) done in separate analyses. The incidence of DAS28 <3.2 and DAS28 <2.6 responses (good or moderate improvement) and clinically meaningful decrease in HAQ-DI

(at least 0.22 improvement) were analyzed by considering the proportion of subjects responding to each endpoint and using the same normal approximation to the difference in binomial proportions as the analyses of ACR variables.

For the change from Baseline in the HAQ-DI at Month 6, the same mixed-effect model that tested Month 3 was used; subjects who were non-responders (in all sequences) at Month 3 had their values set to missing.

The other 6 components of the ACR criteria, DAS28 scores, the 8 domains and 2 component scores of the SF-36, the MOS-SS subscales, the EuroQoL EQ-5D, the 4 domain scores and the Work Loss Index of the WLQ, and the FACIT Fatigue scale were each analyzed in the same way as the HAQ-DI.

The data from the RA Healthcare Resources Utilization (RA-HCRU) Questionnaire were listed and descriptive statistics were generated.

All the safety data were summarized descriptively through appropriate data tabulations, descriptive statistics, and graphical presentations. AEs were displayed for the period of time from Baseline to Month 3 (ie, AEs that occurred up to Month 3), from Months 3 to 6, and from post Month 6 to the end of the treatment period (Month 24). Serious AE (SAE) presentations were derived from a combination of data contained within the clinical study database and the corporate safety database.

RESULTS

Subject Disposition and Demography: Table 3 summarizes subject disposition by treatment sequence. Eight hundred subjects were randomized to treatment, and 797 received at least 1 dose of study medication. Three subjects in the tofacitinib 10 mg sequence were randomized but not treated. Overall, 539 (67.6%) subjects completed 2 years of treatment and 257 (32.2%) subjects discontinued the study. Demographic characteristics are presented by treatment sequence in Table 4.

Table 3. Subject Disposition and Evaluation Groups by Treatment Sequence

Number (%) of Subjects	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo → Tofacitinib 5 mg BID	Placebo → Tofacitinib 10 mg BID
Screened: 1291				
Assigned to study treatment	321	319	81	79
Treated	321	316	81	79
Completed	212 (66.0)	220 (69.0)	55 (67.9)	52 (65.8)
Ongoing ^a	0	1 (0.3)	0	0
Discontinued	109 (34.0)	95 (29.8)	26 (32.1)	27 (34.2)
Subject died	4 (1.2)	1 (0.3)	1 (1.2)	0
Related to study drug	47 (14.6)	44 (13.9)	13 (16.0)	12 (15.2)
Adverse event	36 (11.2)	37 (11.7)	8 (9.9)	10 (12.7)
Lack of efficacy	10 (3.1)	7 (2.2)	3 (3.7)	1 (1.3)
Study terminated by Sponsor ^b	1 (0.3)	0	2 (2.5)	1 (1.3)
Not related to study drug	58 (18.1)	50 (15.8)	12 (14.8)	15 (19.0)
Adverse event	19 (5.9)	10 (3.2)	1 (1.2)	3 (3.8)
Lost to follow-up	6 (1.9)	4 (1.3)	0	3 (3.8)
Protocol violation	9 (2.8)	8 (2.5)	4 (4.9)	1 (1.3)
Pregnancy	1 (0.3)	1 (0.3)	0	0
Site closure ^c	1 (0.3)	0	0	1 (1.3)
Subject no longer willing to participate in study	15 (4.7)	20 (6.3)	4 (4.9)	5 (6.3)
Other	1 (0.3) ^d	1 (0.3) ^e	0	2 (2.5) ^f
Other: subject moving	4 (1.2)	1 (0.3)	0	0
Other: subject planning extended travel	1 (0.3)	0	1 (1.2)	0
Other: Sponsor request	0	3 (0.9)	0	0
Other: met laboratory criteria	1 (0.3)	2 (0.6)	2 (2.5)	0
Analyzed for efficacy				
Full analysis set ^g	316 (98.4)	309 (96.9)	79 (97.5)	77 (97.5)
Per protocol analysis set	299 (93.1)	286 (89.7)	75 (92.6)	76 (96.2)
Analyzed for safety				
Adverse events	321 (100.0)	316 (99.1)	81 (100.0)	78 (98.7)
Laboratory data	318 (99.1)	315 (98.7)	81 (100.0)	78 (98.7)

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; DMARD = disease-modifying antirheumatic drug; GCP = Good Clinical Practice;

TB = *Mycobacterium tuberculosis*.

- One site closed due to GCP noncompliance and study documentation for this subject was not returned.
- These are subjects from site closed due to GCP noncompliance.
- These subjects were discontinued because the site closed and the Sponsor was not able to transfer them to another study site.
- Subject was withdrawn because the subject's father had TB and the Investigator feared for the subject's safety.
- Subject could not be reached for a period of time and was not willing to return to the site.
- Subject was withdrawn with permission from the Sponsor due to stopping background DMARD in anticipation of entering follow-up study. Another subject was withdrawn due to increased risk of significant infection.
- Subjects from 2 study sites were excluded from the full analysis set due to GCP violations.

Table 4. Demographic Characteristics by Treatment Sequence

Demographic Characteristic Parameter	Tofacitinib 5 mg BID	Tofacitinib 10 mg BID	Placebo → Tofacitinib 5 mg BID	Placebo → Tofacitinib 10 mg BID
	N=321	N=316	N=81	N=79
Age (years), n (%):				
18-44	54 (16.8)	78 (24.7)	16 (19.8)	23 (29.1)
45-64	220 (68.5)	195 (61.7)	55 (67.9)	47 (59.5)
≥65	47 (14.6)	43 (13.6)	10 (12.3)	9 (11.4)
Mean (SD)	53.7 (11.6)	52.0 (11.4)	53.2 (11.5)	52.1 (11.8)
Range	20-82	18-81	22-81	21-76
Gender				
Male	52	44	16	7
Female	269	272	65	72

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; N = number of subjects; n = number of subjects meeting pre-specified criteria;

SD = standard deviation.

Efficacy Results:

Primary Endpoints:

ACR20 Response Rate at Month 6 (1-Year Analysis): Both tofacitinib doses demonstrated statistically significant (p-value <0.0001 for both doses) and clinically meaningful reductions in signs and symptoms of RA compared with placebo as measured by the ACR20 at Month 6 (Table 5).

Table 5. Normal Approximation to ACR20 Response Rates at Month 6 (FAS, NRI, Differences From Placebo, 1-Year Analysis)

Treatment	N	n	%	Difference From Placebo			p-Value
				Difference of %s	95% CI for Difference		
					Lower	Upper	
Tofacitinib 5 mg BID	309	159	51.46	26.13	17.28	34.97	<0.0001
Tofacitinib 10 mg BID	309	191	61.81	36.48	27.73	45.23	<0.0001
Placebo	154	39	25.32				

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 = non-responder imputation.

Changes From Baseline in HAQ-DI at Month 3 (1-Year Analysis): Both tofacitinib doses demonstrated clinically meaningful improvements in physical function compared to placebo as measured by the HAQ-DI at Month 3 (Table 6).

Table 6. Summary of LS Mean Changes From Baseline in HAQ-DI at Month 3 (FAS, Differences From Placebo, 1-Year Analysis)

Treatment	N	LS Mean	Differences From Placebo			p-Value
			LS Mean Difference	95% CI for Difference Lower	Upper	
Tofacitinib 5 mg BID	294	-0.40	-0.25	-0.34	-0.16	<0.0001
Tofacitinib 10 mg BID	300	-0.54	-0.40	-0.49	-0.31	<0.0001
Placebo	146	-0.15				

Nominal p-values are presented for information; however, due to the predefined step-down procedure, significance at the 5% level can only be claimed for the tofacitinib 10 mg BID group compared to placebo. BID = twice daily; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire - Disability Index; LS = least squares; N = number of subjects.

Changes From Baseline in mTSS at Month 6 (1-Year Analysis): The tofacitinib 10 mg group demonstrated statistically significant structural preservation compared with placebo as measured by the mTSS at Month 6 (p-value=0.0376; Table 7).

Table 7. Summary of LS Mean Changes From Baseline in mTSS at Month 6 (FAS, LEP, Differences From Placebo, 1-Year Analysis)

Treatment	N	LS Mean	Differences From Placebo			p-Value
			LS Mean Difference	95% CI for Difference Lower	Upper	
Tofacitinib 5 mg BID	277	0.12	-0.34	-0.73	0.04	0.0792
Tofacitinib 10 mg BID	290	0.06	-0.40	-0.79	-0.02	0.0376
Placebo	139	0.47				

mTSS scored according to Sharp/van der Heijde method.
 If subjects did not have any valid post-baseline radiographs, they were not included in this summary. BID = twice daily; CI = confidence interval; FAS = full analysis set; LS = least squares; LEP = linear extrapolation; mTSS = modified Total Sharp Scores; N = number of subjects.

Rates of Subjects Achieving DAS28-4(ESR) <2.6 at Month 6 (1-Year Analysis): Both tofacitinib doses demonstrated clinically meaningful reductions in signs and symptoms of RA compared to placebo as measured by DAS28-4(ESR) <2.6 response rates at Month 6 (Table 8).

Table 8. Summary (%) of Subjects Achieving DAS28-4(ESR) <2.6 at Month 6 (FAS, NRI, Comparisons to Placebo, 1-Year Analysis)

Treatment	N	n	%	Comparison to Placebo			
				Difference	95% CI for Difference		p-Value
					Lower	Upper	
Tofacitinib 5 mg BID	265	19	7.17	5.61	1.85	9.38	0.0034
Tofacitinib 10 mg BID	257	41	15.95	14.40	9.44	19.36	<0.0001
Placebo	129	2	1.55				

Nominal p-values are presented for information; however, due to the predefined step-down procedure, significance at the 5% level can only be claimed for the tofacitinib 10 mg BID group compared to placebo. 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 = non-responder imputation.

Secondary Endpoints:

- ACR20 Response Rates at Time Points Other Than Month 6: All 4 treatment sequences had noticeable, clinically significant response rates at Month 12 that were maintained through Month 24. ACR20 response rates are summarized in Table 9 and Table 10.

Table 9. Normal Approximation to ACR20 Response Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
								Lower	Upper		
Month 1 (NRI)	Tofacitinib 5 mg BID	309	128	41.42	2.80	25.08	4.09	6.12	17.05	33.11	<0.0001
	Tofacitinib 10 mg BID	309	161	52.10	2.84	35.76	4.12	8.67	27.67	43.84	<0.0001
	Placebo	153	25	16.34	2.98						
Month 3 (NRI)	Tofacitinib 5 mg BID	309	174	56.31	2.82	29.03	4.56	6.36	20.09	37.98	<0.0001
	Tofacitinib 10 mg BID	309	205	66.34	2.68	39.07	4.48	8.71	30.28	47.85	<0.0001
	Placebo	154	42	27.27	3.58						

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 failure 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.

ACR20 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis; calculated as a $\geq 20\%$ improvement in tender and swollen joint counts and $\geq 20\%$ 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 pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 10. Normal Approximation to ACR20 Response Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	128	41.42	2.80	14.78	35.93	46.91	<0.0001
	Tofacitinib 10 mg BID	309	161	52.10	2.84	18.33	46.53	57.67	<0.0001
	Placebo→5 mg	79	15	18.99	4.41	4.30	10.33	27.63	<0.0001
	Placebo→10 mg	74	10	13.51	3.97	3.40	5.72	21.30	0.0006
Month 3 (NRI)	Tofacitinib 5 mg BID	309	174	56.31	2.82	19.95	50.78	61.84	<0.0001
	Tofacitinib 10 mg BID	309	205	66.34	2.68	24.67	61.07	71.61	<0.0001
	Placebo→5 mg	79	23	29.11	5.11	5.69	19.09	39.13	<0.0001
	Placebo→10 mg	75	19	25.33	5.02	5.04	15.49	35.17	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	309	159	51.46	2.84	18.09	45.88	57.02	<0.0001
	Tofacitinib 10 mg BID	309	191	61.81	2.76	22.36	56.39	67.22	<0.0001
	Placebo→5 mg	79	21	26.58	4.97	5.34	16.84	36.32	<0.0001
	Placebo→10 mg	75	18	24.00	4.93	4.86	14.33	33.66	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	309	148	47.90	2.84	16.85	42.32	53.46	<0.0001
	Tofacitinib 10 mg BID	309	193	62.46	2.75	22.67	57.06	67.85	<0.0001
	Placebo→5 mg	79	26	32.91	5.28	6.22	22.54	43.27	<0.0001
	Placebo→10 mg	75	22	29.33	5.25	5.57	19.02	39.63	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	309	150	48.54	2.84	17.07	42.97	54.11	<0.0001
	Tofacitinib 10 mg BID	309	171	55.34	2.82	19.56	49.79	60.88	<0.0001
	Placebo→5 mg	79	24	30.38	5.17	5.87	20.23	40.52	<0.0001
	Placebo→10 mg	75	25	33.33	5.44	6.12	22.66	44.00	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	309	147	47.57	2.84	16.74	42.00	53.14	<0.0001
	Tofacitinib 10 mg BID	309	172	55.66	2.82	19.69	50.12	61.20	<0.0001
	Placebo→5 mg	79	23	29.11	5.11	5.69	19.09	39.13	<0.0001
	Placebo→10 mg	75	25	33.33	5.44	6.12	22.66	44.00	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	309	139	44.98	2.83	15.89	39.43	50.53	<0.0001
	Tofacitinib 10 mg BID	309	159	51.46	2.84	18.09	45.88	57.02	<0.0001
	Placebo→5 mg	79	21	26.58	4.97	5.34	16.84	36.32	<0.0001
	Placebo→10 mg	75	25	33.33	5.44	6.12	22.66	44.00	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	309	124	40.13	2.78	14.39	34.66	45.59	<0.0001
	Tofacitinib 10 mg BID	309	157	50.81	2.84	17.86	45.23	56.38	<0.0001
	Placebo→5 mg	79	18	22.78	4.71	4.82	13.53	32.03	<0.0001
	Placebo→10 mg	75	23	30.67	5.32	5.75	20.23	41.10	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	309	127	41.10	2.79	14.68	35.61	46.58	<0.0001
	Tofacitinib 10 mg BID	309	153	49.51	2.84	17.40	43.93	55.08	<0.0001
	Placebo→5 mg	79	20	25.32	4.89	5.17	15.72	34.90	<0.0001
	Placebo→10 mg	75	23	30.67	5.32	5.75	20.23	41.10	<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 failure 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.

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 pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- ACR50 Response Rate at All Time Points: All 4 treatment sequences had noticeable, clinically significant response rates at Month 12 that were maintained through Month 24. ACR50 response rates are summarized in Table 11 and Table 12.

Table 11. Normal Approximation to ACR50 Response Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	52	16.83	2.12	15.52	2.31	6.69	10.97	20.06	<0.0001
	Tofacitinib 10 mg BID	309	57	18.45	2.20	17.13	2.38	7.17	12.45	21.82	<0.0001
	Placebo	153	2	1.31	0.91						
Month 3 (NRI)	Tofacitinib 5 mg BID	309	89	28.80	2.57	21.01	3.36	6.24	14.42	27.59	<0.0001
	Tofacitinib 10 mg BID	309	112	36.25	2.73	28.45	3.48	8.16	21.62	35.28	<0.0001
	Placebo	154	12	7.79	2.15						
Month 6 (NRI)	Tofacitinib 5 mg BID	309	100	32.36	2.66	23.92	3.47	6.87	17.10	30.73	<0.0001
	Tofacitinib 10 mg BID	309	135	43.69	2.82	35.24	3.60	9.78	28.18	42.30	<0.0001
	Placebo	154	13	8.44	2.24						

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 failure 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.

ACR50 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis; calculated as a $\geq 50\%$ improvement in tender and swollen joint counts and $\geq 50\%$ 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 pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 12. Normal Approximation to ACR50 Response Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	52	16.83	2.12	7.90	12.65	20.99	<0.0001
	Tofacitinib 10 mg BID	309	57	18.45	2.20	8.36	14.12	22.77	<0.0001
	Placebo→5 mg	79	1	1.27	1.25	1.00	-1.19	3.73	0.3142
	Placebo→10 mg	74	1	1.35	1.34	1.00	-1.27	3.98	0.3140
Month 3 (NRI)	Tofacitinib 5 mg BID	309	89	28.80	2.57	11.18	23.75	33.85	<0.0001
	Tofacitinib 10 mg BID	309	112	36.25	2.73	13.25	30.88	41.60	<0.0001
	Placebo→5 mg	79	7	8.86	3.19	2.77	2.59	15.12	0.0055
	Placebo→10 mg	75	5	6.67	2.88	2.31	1.02	12.31	0.0206
Month 6 (NRI)	Tofacitinib 5 mg BID	309	100	32.36	2.66	12.15	27.14	37.57	<0.0001
	Tofacitinib 10 mg BID	309	135	43.69	2.82	15.48	38.15	49.21	<0.0001
	Placebo→5 mg	79	10	12.66	3.74	3.38	5.32	19.99	0.0007
	Placebo→10 mg	75	3	4.00	2.26	1.76	-0.43	8.43	0.0770
Month 9 (NRI)	Tofacitinib 5 mg BID	309	101	32.69	2.66	12.24	27.45	37.91	<0.0001
	Tofacitinib 10 mg BID	309	136	44.01	2.82	15.58	38.47	49.54	<0.0001
	Placebo→5 mg	79	18	22.78	4.71	4.82	13.53	32.03	<0.0001
	Placebo→10 mg	75	15	20.00	4.61	4.33	10.94	29.05	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	309	100	32.36	2.66	12.15	27.14	37.57	<0.0001
	Tofacitinib 10 mg BID	309	122	39.48	2.78	14.19	34.03	44.93	<0.0001
	Placebo→5 mg	79	17	21.52	4.62	4.65	12.45	30.58	<0.0001
	Placebo→10 mg	75	12	16.00	4.23	3.77	7.70	24.29	0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	309	99	32.04	2.65	12.06	26.83	37.24	<0.0001
	Tofacitinib 10 mg BID	309	121	39.16	2.77	14.10	33.71	44.60	<0.0001
	Placebo→5 mg	79	17	21.52	4.62	4.65	12.45	30.58	<0.0001
	Placebo→10 mg	75	20	26.67	5.10	5.22	16.65	36.67	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	309	96	31.07	2.63	11.80	25.90	36.22	<0.0001
	Tofacitinib 10 mg BID	309	125	40.45	2.79	14.48	34.98	45.92	<0.0001
	Placebo→5 mg	79	14	17.72	4.29	4.12	9.30	26.14	<0.0001
	Placebo→10 mg	75	17	22.67	4.83	4.68	13.19	32.14	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	309	85	27.51	2.54	10.82	22.52	32.48	<0.0001
	Tofacitinib 10 mg BID	309	121	39.16	2.77	14.10	33.71	44.60	<0.0001
	Placebo→5 mg	79	13	16.46	4.17	3.94	8.27	24.63	<0.0001
	Placebo→10 mg	75	17	22.67	4.83	4.68	13.19	32.14	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	309	89	28.80	2.57	11.18	23.75	33.85	<0.0001
	Tofacitinib 10 mg BID	309	123	39.81	2.78	14.29	34.34	45.26	<0.0001
	Placebo→5 mg	79	16	20.25	4.52	4.47	11.39	29.11	<0.0001
	Placebo→10 mg	75	13	17.33	4.37	3.96	8.76	25.90	<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 failure 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.

ACR50 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis; calculated as a ≥50% improvement in tender and swollen joint counts and ≥50% 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 pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- ACR70 Response Rates at All Time Points: All 4 treatment sequences had noticeable, clinically significant response rates at Month 12 that were maintained through Month 24. ACR70 response rates are summarized in Table 13 and Table 14.

Table 13. Normal Approximation to ACR70 Response Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					
						Difference	SE of Difference	Z	95% CI for Difference		p-Value
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	12	3.88	1.09	3.88	1.09	3.53	1.72	6.03	0.0004
	Tofacitinib 10 mg BID	309	11	3.56	1.05	3.55	1.05	3.37	1.49	5.62	0.0007
	Placebo	153	0	0.0							
Month 3 (NRI)	Tofacitinib 5 mg BID	309	33	10.68	1.75	8.08	2.17	3.71	3.81	12.34	0.0002
	Tofacitinib 10 mg BID	309	53	17.15	2.14	14.55	2.49	5.82	9.65	19.45	<0.0001
	Placebo	154	4	2.60	1.28						
Month 6 (NRI)	Tofacitinib 5 mg BID	309	45	14.56	2.00	13.26	2.20	6.01	8.94	17.58	<0.0001
	Tofacitinib 10 mg BID	309	69	22.33	2.36	21.03	2.53	8.28	16.05	26.00	<0.0001
	Placebo	154	2	1.30	0.91						

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 failure 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.

ACR70 = American College of Rheumatology’s (ACR) definition for calculating improvement in rheumatoid arthritis; calculated as a ≥70% improvement in tender and swollen joint counts and ≥70% 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 pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 14. Normal Approximation to ACR70 Response Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	12	3.88	1.09	3.53	1.72	6.03	0.0004
	Tofacitinib 10 mg BID	309	11	3.56	1.05	3.37	1.49	5.62	0.0007
	Placebo→5 mg	79	0	0.00					
	Placebo→10 mg	74	0	0.00					
Month 3 (NRI)	Tofacitinib 5 mg BID	309	33	10.68	1.75	6.07	7.23	14.12	<0.0001
	Tofacitinib 10 mg BID	309	53	17.15	2.14	7.99	12.94	21.35	<0.0001
	Placebo→5 mg	79	3	3.80	2.15	1.76	-0.41	8.01	0.0774
	Placebo→10 mg	75	1	1.33	1.32	1.00	-1.26	3.92	0.3140
Month 6 (NRI)	Tofacitinib 5 mg BID	309	45	14.56	2.00	7.25	10.63	18.49	<0.0001
	Tofacitinib 10 mg BID	309	69	22.33	2.36	9.42	17.68	26.97	<0.0001
	Placebo→5 mg	79	2	2.53	1.76	1.43	-0.93	5.99	0.1520
	Placebo→10 mg	75	0	0.00					
Month 9 (NRI)	Tofacitinib 5 mg BID	309	56	18.12	2.19	8.27	13.82	22.41	<0.0001
	Tofacitinib 10 mg BID	309	88	28.48	2.56	11.09	23.44	33.51	<0.0001
	Placebo→5 mg	79	7	8.86	3.19	2.77	2.59	15.12	0.0055
	Placebo→10 mg	75	9	12.00	3.75	3.19	4.64	19.35	0.0013
Month 12 (NRI)	Tofacitinib 5 mg BID	309	58	18.77	2.22	8.44	14.41	23.12	<0.0001
	Tofacitinib 10 mg BID	309	82	26.54	2.51	10.56	21.61	31.46	<0.0001
	Placebo→5 mg	79	8	10.13	3.39	2.98	3.47	16.77	0.0028
	Placebo→10 mg	75	9	12.00	3.75	3.19	4.64	19.35	0.0013
Month 15 (NRI)	Tofacitinib 5 mg BID	309	61	19.74	2.26	8.71	15.30	24.17	<0.0001
	Tofacitinib 10 mg BID	309	76	24.60	2.44	10.03	19.79	29.39	<0.0001
	Placebo→5 mg	79	8	10.13	3.39	2.98	3.47	16.77	0.0028
	Placebo→10 mg	75	11	14.67	4.08	3.59	6.66	22.67	0.0003
Month 18 (NRI)	Tofacitinib 5 mg BID	309	51	16.50	2.11	7.81	12.36	20.64	<0.0001
	Tofacitinib 10 mg BID	309	82	26.54	2.51	10.56	21.61	31.46	<0.0001
	Placebo→5 mg	79	11	13.92	3.89	3.57	6.28	21.55	0.0003
	Placebo→10 mg	75	11	14.67	4.08	3.59	6.66	22.67	0.0003
Month 21 (NRI)	Tofacitinib 5 mg BID	309	50	16.18	2.09	7.72	12.07	20.28	<0.0001
	Tofacitinib 10 mg BID	309	72	23.30	2.40	9.68	18.58	28.01	<0.0001
	Placebo→5 mg	79	6	7.59	2.98	2.54	1.75	13.43	0.0108
	Placebo→10 mg	75	13	17.33	4.37	3.96	8.76	25.90	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	309	53	17.15	2.14	7.99	12.94	21.35	<0.0001
	Tofacitinib 10 mg BID	309	79	25.57	2.48	10.30	20.70	30.43	<0.0001
	Placebo→5 mg	79	8	10.13	3.39	2.98	3.47	16.77	0.0028
	Placebo→10 mg	75	10	13.33	3.92	3.39	5.63	21.02	0.0006

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 failure 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.

ACR70 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis, calculated as a ≥70% improvement in tender and swollen joint counts and ≥70% 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 pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- Rates of Subjects With ACR70 Response Sustained at Least 6 Months: By Month 24, the tofacitinib 10 mg and the placebo→tofacitinib 10 mg sequences had the highest proportion of subjects (25.89% and 19.48%, respectively) with ACR70 response sustained at least 6 months; the proportion of subjects in the tofacitinib 5 mg and placebo→tofacitinib 5 mg sequences were 16.46% and 18.99%, respectively (Table 15).

Table 15. Number (%) of Subjects With ACR70 Response Sustained at Least 6 Months Through Month 24 (FAS, No Imputation, Comparisons Within Sequence)

Treatment Sequence	N	n (%)	Exact 95% CI for %
Tofacitinib 5 mg BID	316	52 (16.46)	12.54, 21.01
Tofacitinib 10 mg BID	309	80 (25.89)	21.10, 31.15
Placebo→Tofacitinib 5 mg BID	79	15 (18.99)	11.03, 29.38
Placebo→Tofacitinib 10 mg BID	77	15 (19.48)	11.33, 30.09

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

ACR70 = American College of Rheumatology’s (ACR) definition for calculating improvement in rheumatoid arthritis, calculated as a $\geq 70\%$ improvement in tender and swollen joint counts and $\geq 70\%$ 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 pre-specified criteria.

- Actual mTSS at Months 6, 12 and 24 and change From Baseline in mTSS at Months 12 and 24: For these analyses, the Month 12 and Month 24 values for the placebo group (including subjects in both placebo→tofacitinib sequences) were extrapolated via linear extrapolation (LEP) from the Month 6 values. Subjects randomized to Treatment Sequence 3 or 4 were advanced to tofacitinib at Month 3 or Month 6. After advancement, all subjects were on tofacitinib. Data beyond advancement were extrapolated. The mean changes from Baseline in tofacitinib (5 mg and 10 mg) demonstrated inhibition of progression for mTSS. The mTSS results are summarized in Table 16, Table 17, Table 18 and Table 19.

Table 16. Descriptive Statistics of Modified Total Sharp Scores per Visit at Baseline, Months 6 and 12 Within Sequence Comparisons, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline (LEP)	Tofacitinib 5 mg BID	287	33.8	50.23	0.0	3.00	13.50	39.00	324.50
	Tofacitinib 10 mg BID	298	38.8	55.01	0.0	3.00	13.25	50.00	317.00
Month 6 (LEP)	Placebo→Tofacitinib 5 mg BID	71	36.6	44.02	0.0	4.50	17.50	47.50	185.00
	Placebo→Tofacitinib 10 mg BID	68	32.6	42.20	0.0	3.00	15.50	51.50	208.00
	Tofacitinib 5 mg BID	278	34.2	50.51	0.0	3.50	15.25	39.93	324.50
	Tofacitinib 10 mg BID	291	38.9	54.71	0.0	3.00	13.50	50.50	317.00
Month 12 (LEP)	Placebo→Tofacitinib 5 mg BID	71	36.9	43.88	0.0	5.00	18.00	47.50	185.00
	Placebo→Tofacitinib 10 mg BID	68	33.0	42.58	0.0	3.25	15.75	53.50	208.00
	Tofacitinib 5 mg BID	287	34.2	50.52	0.0	3.50	14.50	40.00	324.50
	Tofacitinib 10 mg BID	298	38.9	55.03	0.0	3.00	13.50	51.00	317.00
Month 24 (LEP)	Placebo→Tofacitinib 5 mg BID	71	37.2	43.80	0.0	4.63	25.00	49.39	185.00
	Placebo→Tofacitinib 10 mg BID	68	33.3	43.01	0.0	3.50	15.75	53.75	208.00

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 17. Descriptive Statistics of Change From Baseline Modified Total Sharp Scores per Visit at Months 12 and 24 Within Sequence Comparisons, 2-Year Analysis (FAS, Imputation using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 12 (LEP)	Tofacitinib 5 mg BID	287	0.45	2.83	-20.22	0.00	0.00	0.00	21.69
	Tofacitinib 10 mg BID	298	0.10	3.47	-42.00	0.00	0.00	0.00	16.70
	Placebo→Tofacitinib 5 mg BID	71	0.59	3.18	-7.16	0.00	0.00	0.98	15.82
	Placebo→Tofacitinib 10 mg BID	68	0.65	3.55	-10.59	0.00	0.00	0.00	17.61
Month 24 (LEP)	Tofacitinib 5 mg BID	287	0.87	5.10	-26.50	0.00	0.00	0.50	43.67
	Tofacitinib 10 mg BID	298	0.36	5.36	-41.50	0.00	0.00	0.00	33.63
	Placebo→Tofacitinib 5 mg BID	71	1.18	6.40	-14.42	0.00	0.00	1.98	31.87
	Placebo→Tofacitinib 10 mg BID	68	1.31	7.15	-21.32	0.00	0.00	0.00	35.46

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 18. Descriptive Statistics of Modified Total Sharp Scores per Visit at Baseline, Months 6 and 12 Comparisons to Placebo, 2-Year Analysis (FAS, Imputation using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline (LEP)	Tofacitinib 5 mg BID	287	33.8	50.23	0.0	3.00	13.50	39.00	324.50
	Tofacitinib 10 mg BID	298	38.8	55.01	0.0	3.00	13.25	50.00	317.00
	Placebo	139	34.7	43.03	0.0	3.50	17.00	50.00	208.00
Month 6 (LEP)	Tofacitinib 5 mg BID	278	34.2	50.51	0.0	3.50	15.25	39.93	324.50
	Tofacitinib 10 mg BID	291	38.9	54.71	0.0	3.00	13.50	50.50	317.00
	Placebo	139	35.0	43.14	0.0	3.50	17.50	53.00	208.00
Month 12 (LEP)	Tofacitinib 5 mg BID	287	34.2	50.52	0.0	3.50	14.50	40.00	324.50
	Tofacitinib 10 mg BID	298	38.9	55.03	0.0	3.00	13.50	51.00	317.00
	Placebo	139	35.3	43.30	0.0	4.00	17.50	53.00	208.00

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 19. Descriptive Statistics of Change From Baseline Modified Total Sharp Scores at Month 12 Comparison to Placebo, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 12 (LEP)	Tofacitinib 5 mg BID	287	0.45	2.83	-20.22	0.00	0.00	0.00	21.69
	Tofacitinib 10 mg BID	298	0.10	3.47	-42.00	0.00	0.00	0.00	16.70
	Placebo	139	0.62	3.35	-10.59	0.00	0.00	0.00	17.61

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Rate of Subjects With no Progression in mTSS (≤ 0.5 Unit Change) at Months 6, 12, and 24: The tofacitinib 5 mg and 10 mg groups had similar rates of subjects with no progression in mTSS (FAS, LEP) from Baseline at Months 6, 12 and 24 (Table 20).

Table 20. Normal Approximation to Rates (%) of Subjects With No Progression in Modified Total Sharp Scores at Months 12 and 24 (FAS, LEP)

Time Point/ Treatment	N	n	%	Difference From Placebo			p-Value
				Difference in %	95% CI for Difference Lower	Upper	
Month 6							
Tofacitinib 5 mg BID	278	235	84.53	1.79	-5.78	9.38	0.6421
Tofacitinib 10 mg BID	291	251	86.25	3.52	-3.90	10.94	0.3527
Placebo	139	115	82.73				
Month 12							
Tofacitinib 5 mg BID	287	237	82.58	3.44	-4.61	11.49	0.4023
Tofacitinib 10 mg BID	298	248	83.22	4.08	-3.89	12.06	0.3155
Placebo	139	110	79.14				
Month 24							
Tofacitinib 5 mg BID	287	229	79.79	0.65	-7.54	8.85	0.8757
Tofacitinib 10 mg BID	298	244	81.88	2.74	-5.30	10.78	0.5041
Placebo	139	110	79.14				

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

mTSS (Sharp/van der Heijde method) was used.

No progression in mTSS defined as change from Baseline ≤ 0.5 units.

BID = twice daily; CI = confidence interval, FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria.

- Actual and Change From Baseline of 2 Individual Components of mTSS (Erosion and JSN scores) at Months 6, 12 and 24: Treatment with tofacitinib (5 mg or 10 mg) resulted in less progression from Baseline in JSN compared to placebo extrapolated at Months 6, 12 and 24. The mean changes from Baseline in tofacitinib (5 mg and 10 mg) demonstrated inhibition of progression for JSN. Rates of progression in mean erosion scores at Months 12 and 24 were similar for the tofacitinib 5 mg and extrapolated placebo groups, with modest improvement from Baseline in the tofacitinib 10 mg group. The tofacitinib 5 mg and 10 mg groups had similar rates of subjects with no progression in mean erosion scores (FAS, LEP) from Baseline at Months 12 and 24. The results for Erosion and JSN scores have been summarized in Table 21, Table 22, Table 23, Table 24, Table 25, Table 26, Table 27 and Table 28.

Table 21. Descriptive Statistics of Erosion Scores per Visit at Months 6, 12 and 24 Within Sequence Comparisons, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	15.66	26.20	0.00	1.50	5.05	17.00	181.00
	Tofacitinib 10 mg BID	291	18.36	27.72	0.00	1.50	6.50	23.50	174.50
	Placebo→Tofacitinib 5 mg BID	71	14.51	18.03	0.00	2.00	6.00	20.00	92.50
Month 12 (LEP)	Placebo→Tofacitinib 10 mg BID	68	15.27	20.93	0.00	2.00	5.25	25.22	104.00
	Tofacitinib 5 mg BID	287	15.66	26.19	0.00	1.00	5.00	16.51	181.00
	Tofacitinib 10 mg BID	298	18.36	27.83	0.00	1.50	6.00	23.50	174.50
Month 24 (LEP)	Placebo→Tofacitinib 5 mg BID	71	14.55	18.03	0.00	2.00	6.02	20.38	92.50
	Placebo→Tofacitinib 10 mg BID	68	15.44	21.32	0.00	2.00	5.50	24.29	104.00
	Tofacitinib 5 mg BID	287	15.88	26.40	0.00	1.00	5.00	17.38	181.00
Month 24 (LEP)	Tofacitinib 10 mg BID	298	18.35	27.84	0.00	1.50	6.00	23.50	174.50
	Placebo→Tofacitinib 5 mg BID	71	14.62	18.06	0.00	2.00	7.06	22.30	92.50
	Placebo→Tofacitinib 10 mg BID	68	15.79	22.25	0.00	1.50	6.00	22.92	104.00

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 22. Descriptive Statistics of Change from Baseline Erosion Scores per Visit at Months 6, 12 and 24 Within Sequence Comparisons, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	0.10	1.08	-10.39	0.00	0.00	0.00	6.69
	Tofacitinib 10 mg BID	291	0.01	0.85	-8.13	0.00	0.00	0.00	4.00
	Placebo→Tofacitinib 5 mg BID	71	0.04	0.46	-2.10	0.00	0.00	0.00	1.13
	Placebo→Tofacitinib 10 mg BID	68	0.17	1.09	-3.26	0.00	0.00	0.00	5.44
Month 12 (LEP)	Tofacitinib 5 mg BID	287	0.24	1.72	-12.50	0.00	0.00	0.00	13.01
	Tofacitinib 10 mg BID	298	0.00	1.37	-15.82	0.00	0.00	0.00	7.42
	Placebo→Tofacitinib 5 mg BID	71	0.07	0.91	-4.09	0.00	0.00	0.00	2.20
	Placebo→Tofacitinib 10 mg BID	68	0.34	2.14	-6.35	0.00	0.00	0.00	10.59
Month 24 (LEP)	Tofacitinib 5 mg BID	287	0.45	2.99	-12.50	0.00	0.00	0.00	26.20
	Tofacitinib 10 mg BID	298	-0.02	2.47	-31.50	0.00	0.00	0.00	14.95
	Placebo→Tofacitinib 5 mg BID	71	0.15	1.83	-8.24	0.00	0.00	0.00	4.42
	Placebo→Tofacitinib 10 mg BID	68	0.69	4.30	-12.79	0.00	0.00	0.00	21.32

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 23. Descriptive Statistics of Erosion Scores per Visit at Months 6 and 12 Comparisons to Placebo, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	15.66	26.20	0.00	1.50	5.05	17.00	181.00
	Tofacitinib 10 mg BID	291	18.36	27.72	0.00	1.50	6.50	23.50	174.50
	Placebo	139	14.88	19.44	0.00	2.00	5.50	21.13	104.00
Month 12 (LEP)	Tofacitinib 5 mg BID	287	15.66	26.19	0.00	1.00	5.00	16.51	181.00
	Tofacitinib 10 mg BID	298	18.36	27.83	0.00	1.50	6.00	23.50	174.50
	Placebo	139	14.98	19.64	0.00	2.00	6.01	22.20	104.00

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 24. Descriptive Statistics of Change From Baseline Erosion Scores per Visit at Months 6 and 12 Comparisons to Placebo, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	0.10	1.08	-10.39	0.00	0.00	0.00	6.69
	Tofacitinib 10 mg BID	291	0.01	0.85	-8.13	0.00	0.00	0.00	4.00
	Placebo	139	0.10	0.83	-3.26	0.00	0.00	0.00	5.44
Month 12 (LEP)	Tofacitinib 5 mg BID	287	0.24	1.72	-12.50	0.00	0.00	0.00	13.01
	Tofacitinib 10 mg BID	298	0.00	1.37	-15.82	0.00	0.00	0.00	7.42
	Placebo	139	0.20	1.63	-6.35	0.00	0.00	0.00	10.59

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 25. Descriptive Statistics of Joint Space Narrowing per Visit at Months 6, 12 and 24 Within Sequence Comparisons, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	18.52	25.87	0.00	1.00	7.00	25.08	143.50
	Tofacitinib 10 mg BID	291	20.51	28.34	0.00	1.00	6.50	31.00	142.50
	Placebo→Tofacitinib 5 mg BID	71	22.40	28.18	0.00	0.50	12.50	28.50	106.00
Month 12 (LEP)	Placebo→Tofacitinib 10 mg BID	68	17.69	22.67	0.00	0.75	8.00	31.75	104.00
	Tofacitinib 5 mg BID	287	18.57	25.91	0.00	1.00	7.00	25.50	143.50
	Tofacitinib 10 mg BID	298	20.54	28.56	0.00	0.50	6.68	31.00	142.50
Month 24 (LEP)	Placebo→Tofacitinib 5 mg BID	71	22.65	28.16	0.00	0.50	12.50	28.95	106.00
	Placebo→Tofacitinib 10 mg BID	68	17.85	22.79	0.00	0.75	7.78	31.75	104.00
	Tofacitinib 5 mg BID	287	18.82	26.03	0.00	1.00	7.00	26.50	143.50
Month 24 (LEP)	Tofacitinib 10 mg BID	298	20.84	28.69	0.00	0.50	7.00	31.50	142.50
	Placebo→Tofacitinib 5 mg BID	71	23.17	28.35	0.00	0.50	12.50	33.50	106.00
	Placebo→Tofacitinib 10 mg BID	68	18.18	23.20	0.00	0.62	7.48	33.00	104.00

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 26. Descriptive Statistics of Change From Baseline Joint Space Narrowing per Visit at Months 6, 12 and 24 Within Sequence Comparisons, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	0.16	1.05	-5.50	0.00	0.00	0.00	6.50
	Tofacitinib 10 mg BID	291	0.02	2.78	-43.00	0.00	0.00	0.00	8.50
	Placebo→Tofacitinib 5 mg BID	71	0.26	1.50	-3.50	0.00	0.00	0.00	8.00
Month 12 (LEP)	Placebo→Tofacitinib 10 mg BID	68	0.16	1.10	-2.18	0.00	0.00	0.00	6.03
	Tofacitinib 5 mg BID	287	0.24	1.59	-5.93	0.00	0.00	0.00	11.74
	Tofacitinib 10 mg BID	298	0.11	3.14	-45.00	0.00	0.00	0.00	13.85
Month 24 (LEP)	Placebo→Tofacitinib 5 mg BID	71	0.51	2.95	-7.16	0.00	0.00	0.00	15.82
	Placebo→Tofacitinib 10 mg BID	68	0.32	2.16	-4.24	0.00	0.00	0.00	11.74
	Tofacitinib 5 mg BID	287	0.48	3.01	-11.89	0.00	0.00	0.00	23.64
Month 24 (LEP)	Tofacitinib 10 mg BID	298	0.41	4.25	-45.00	0.00	0.00	0.00	27.88
	Placebo→Tofacitinib 5 mg BID	71	1.03	5.93	-14.42	0.00	0.00	0.00	31.87
	Placebo→Tofacitinib 10 mg BID	68	0.64	4.34	-8.53	0.00	0.00	0.00	23.64

If subjects did not have any valid post-baseline radiographs, they are not included in this summary. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 27. Descriptive Statistics of Joint Space Narrowing per Visit at Months 6 and 12 Comparisons to Placebo, 2-Year Analysis (FAS, Imputation Using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	18.52	25.87	0.00	1.00	7.00	25.08	143.50
	Tofacitinib 10 mg BID	291	20.51	28.34	0.00	1.00	6.50	31.00	142.50
	Placebo	139	20.10	25.65	0.00	0.50	9.51	31.50	106.00
Month 12 (LEP)	Tofacitinib 5 mg BID	287	18.57	25.91	0.00	1.00	7.00	25.50	143.50
	Tofacitinib 10 mg BID	298	20.54	28.56	0.00	0.50	6.68	31.00	142.50
	Placebo	139	20.31	25.69	0.00	0.50	9.50	31.50	106.00

If subjects did not have any valid post-baseline radiographs, they are not included in this summary.

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FAS = Full Analysis Set; Min = minimum; Max = maximum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 28. Descriptive Statistics of Change From Baseline Joint Space Narrowing per Visit at Months 6 and 12 Comparisons to Placebo, 2-Year Analysis (FAS, Imputation using Linear Extrapolation)

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 6 (LEP)	Tofacitinib 5 mg BID	278	0.16	1.05	-5.50	0.00	0.00	0.00	6.50
	Tofacitinib 10 mg BID	291	0.02	2.78	-43.00	0.00	0.00	0.00	8.50
	Placebo	139	0.21	1.31	-3.50	0.00	0.00	0.00	8.00
Month 12 (LEP)	Tofacitinib 5 mg BID	287	0.24	1.59	-5.93	0.00	0.00	0.00	11.74
	Tofacitinib 10 mg BID	298	0.11	3.14	-45.00	0.00	0.00	0.00	13.85
	Placebo	139	0.42	2.58	-7.16	0.00	0.00	0.00	15.82

If subjects did not have any valid post-baseline radiographs, they are not included in this summary.

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FAS = full analysis set; Max = maximum; Min = minimum; LEP = linear extrapolation; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- HAQ-DI:
 - HAQ-DI Actual Values and Change From Baseline: Noticeable decreases (improvements) from Baseline in mean HAQ-DI scores were seen in all 4 treatment sequences by Month 12; the scores plateaued around Month 12 and remained stable through Month 24. The results are summarized in Table 29, Table 30, Table 31 and Table 32.

Table 29. Descriptive Statistics of HAQ-DI per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	1.41	0.68	0.00	0.88	1.38	2.00	3.00
	Tofacitinib 10 mg BID	309	1.40	0.66	0.00	0.88	1.38	1.88	2.88
	Placebo	156	1.31	0.68	0.00	0.81	1.38	1.88	2.88
Month 1	Tofacitinib 5 mg BID	309	1.16	0.67	0.00	0.63	1.13	1.63	2.88
	Tofacitinib 10 mg BID	308	1.02	0.65	0.00	0.50	1.00	1.44	3.00
	Placebo	153	1.25	0.67	0.00	0.75	1.38	1.75	2.75
Month 3	Tofacitinib 5 mg BID	295	1.00	0.65	0.00	0.50	1.00	1.38	2.88
	Tofacitinib 10 mg BID	300	0.84	0.65	0.00	0.25	0.88	1.25	3.00
	Placebo	146	1.19	0.69	0.00	0.63	1.19	1.75	2.88
Month 6	Tofacitinib 5 mg BID	282	0.94	0.62	0.00	0.38	0.88	1.38	3.00
	Tofacitinib 10 mg BID	284	0.79	0.64	0.00	0.25	0.75	1.25	3.00
	Placebo	62	1.09	0.62	0.00	0.75	1.06	1.63	2.50
	Placebo→5 mg	40	1.10	0.77	0.00	0.56	1.00	1.75	2.63
	Placebo→10 mg	37	0.78	0.65	0.00	0.13	0.75	1.25	1.88

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; HAQ-DI = Health Assessment Questionnaire-Disability Index; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 30. Descriptive Statistics of HAQ-DI per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	1.41	0.68	0.00	0.88	1.38	2.00	3.00
	Tofacitinib 10 mg BID	309	1.40	0.66	0.00	0.88	1.38	1.88	2.88
Month 1	Placebo→Tofacitinib 5 mg BID	79	1.40	0.62	0.00	1.00	1.50	1.88	2.88
	Placebo→Tofacitinib 10 mg BID	77	1.23	0.73	0.00	0.63	1.25	1.75	2.88
	Tofacitinib 5 mg BID	309	1.16	0.67	0.00	0.63	1.13	1.63	2.88
	Tofacitinib 10 mg BID	308	1.02	0.65	0.00	0.50	1.00	1.44	3.00
Month 3	Placebo→Tofacitinib 5 mg BID	79	1.32	0.68	0.00	0.75	1.38	1.75	2.75
	Placebo→Tofacitinib 10 mg BID	74	1.18	0.66	0.00	0.63	1.25	1.75	2.50
	Tofacitinib 5 mg BID	295	1.00	0.65	0.00	0.50	1.00	1.38	2.88
	Tofacitinib 10 mg BID	300	0.84	0.65	0.00	0.25	0.88	1.25	3.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	1.30	0.71	0.00	0.75	1.25	1.88	2.88
	Placebo→Tofacitinib 10 mg BID	71	1.06	0.64	0.00	0.50	1.13	1.63	2.38
	Tofacitinib 5 mg BID	282	0.94	0.62	0.00	0.38	0.88	1.38	3.00
	Tofacitinib 10 mg BID	284	0.79	0.64	0.00	0.25	0.75	1.25	3.00
Month 9	Placebo→Tofacitinib 5 mg BID	71	1.08	0.68	0.00	0.63	1.00	1.63	2.63
	Placebo→Tofacitinib 10 mg BID	68	0.94	0.69	0.00	0.19	1.00	1.56	2.38
	Tofacitinib 5 mg BID	266	0.91	0.65	0.00	0.38	0.88	1.38	2.75
	Tofacitinib 10 mg BID	279	0.75	0.64	0.00	0.25	0.63	1.13	3.00
Month 12	Placebo→Tofacitinib 5 mg BID	68	0.94	0.66	0.00	0.38	0.88	1.38	2.50
	Placebo→Tofacitinib 10 mg BID	63	0.74	0.67	0.00	0.00	0.75	1.25	2.13
	Tofacitinib 5 mg BID	252	0.90	0.65	0.00	0.25	0.88	1.38	2.75
	Tofacitinib 10 mg BID	265	0.76	0.68	0.00	0.13	0.63	1.13	3.00
Month 15	Placebo→Tofacitinib 5 mg BID	67	0.84	0.66	0.00	0.25	0.88	1.25	2.13
	Placebo→Tofacitinib 10 mg BID	63	0.74	0.68	0.00	0.13	0.38	1.38	2.13
	Tofacitinib 5 mg BID	242	0.89	0.62	0.00	0.38	0.88	1.38	2.63
	Tofacitinib 10 mg BID	254	0.74	0.67	0.00	0.13	0.63	1.13	3.00
Month 18	Placebo→Tofacitinib 5 mg BID	62	0.80	0.66	0.00	0.25	0.63	1.13	2.63
	Placebo→Tofacitinib 10 mg BID	60	0.65	0.60	0.00	0.00	0.44	1.13	2.13
	Tofacitinib 5 mg BID	235	0.88	0.66	0.00	0.25	0.88	1.38	2.75
	Tofacitinib 10 mg BID	244	0.72	0.67	0.00	0.13	0.56	1.13	2.75
Month 21	Placebo→Tofacitinib 5 mg BID	59	0.76	0.59	0.00	0.25	0.75	1.13	2.13
	Placebo→Tofacitinib 10 mg BID	55	0.61	0.55	0.00	0.00	0.50	1.00	2.00
	Tofacitinib 5 mg BID	220	0.82	0.64	0.00	0.25	0.75	1.25	2.75
	Tofacitinib 10 mg BID	230	0.72	0.67	0.00	0.13	0.63	1.25	2.75
Month 24	Placebo→Tofacitinib 5 mg BID	57	0.76	0.63	0.00	0.25	0.75	1.13	2.50
	Placebo→Tofacitinib 10 mg BID	53	0.67	0.62	0.00	0.13	0.38	1.25	2.00
	Tofacitinib 5 mg BID	211	0.82	0.63	0.00	0.25	0.75	1.25	2.38
	Tofacitinib 10 mg BID	218	0.71	0.68	0.00	0.13	0.50	1.25	2.88
	Placebo→Tofacitinib 5 mg BID	54	0.75	0.66	0.00	0.13	0.69	1.25	2.50
	Placebo→Tofacitinib 10 mg BID	52	0.60	0.64	0.00	0.00	0.31	1.25	2.13

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; HAQ-DI = Health Assessment Questionnaire-Disability Index; FAS = full analysis set; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 31. Descriptive Statistics of Change From Baseline of HAQ-DI per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	308	-0.3	0.45	-2.1	-0.50	-0.13	0.00	1.00
	Tofacitinib 10 mg BID	308	-0.4	0.48	-1.9	-0.63	-0.25	0.00	2.13
	Placebo	153	-0.1	0.38	-1.5	-0.25	0.00	0.13	1.00
Month 3	Tofacitinib 5 mg BID	294	-0.4	0.58	-2.3	-0.75	-0.38	0.00	1.88
	Tofacitinib 10 mg BID	300	-0.6	0.53	-2.1	-0.88	-0.50	-0.13	1.13
	Placebo	146	-0.1	0.48	-1.4	-0.38	-0.13	0.13	1.25
Month 6	Tofacitinib 5 mg BID	281	-0.5	0.55	-2.8	-0.75	-0.38	-0.13	1.00
	Tofacitinib 10 mg BID	284	-0.6	0.58	-2.5	-1.00	-0.63	-0.25	1.38
	Placebo	62	-0.2	0.47	-1.4	-0.63	-0.13	0.00	0.88
	Placebo→5 mg	40	-0.4	0.48	-1.5	-0.75	-0.38	0.00	0.50
	Placebo→10 mg	37	-0.3	0.76	-2.8	-0.63	-0.25	0.13	1.13

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; HAQ-DI = Health Assessment Questionnaire-Disability Index; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 32. Descriptive Statistics of Change From Baseline of HAQ-DI per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	308	-0.3	0.45	-2.1	-0.50	-0.13	0.00	1.00
	Tofacitinib 10 mg BID	308	-0.4	0.48	-1.9	-0.63	-0.25	0.00	2.13
	Placebo→Tofacitinib 5 mg BID	79	-0.1	0.36	-1.3	-0.38	-0.13	0.25	0.75
	Placebo→Tofacitinib 10 mg BID	74	-0.0	0.40	-1.5	-0.25	0.00	0.13	1.00
Month 3	Tofacitinib 5 mg BID	294	-0.4	0.58	-2.3	-0.75	-0.38	0.00	1.88
	Tofacitinib 10 mg BID	300	-0.6	0.53	-2.1	-0.88	-0.50	-0.13	1.13
	Placebo→Tofacitinib 5 mg BID	75	-0.1	0.50	-1.4	-0.38	-0.13	0.25	1.25
	Placebo→Tofacitinib 10 mg BID	71	-0.1	0.46	-1.4	-0.38	-0.13	0.13	1.00
Month 6	Tofacitinib 5 mg BID	281	-0.5	0.55	-2.8	-0.75	-0.38	-0.13	1.00
	Tofacitinib 10 mg BID	284	-0.6	0.58	-2.5	-1.00	-0.63	-0.25	1.38
	Placebo→Tofacitinib 5 mg BID	71	-0.4	0.47	-1.5	-0.75	-0.25	0.00	0.88
	Placebo→Tofacitinib 10 mg BID	68	-0.3	0.64	-2.8	-0.56	-0.13	0.13	1.13
Month 9	Tofacitinib 5 mg BID	265	-0.5	0.57	-2.9	-0.75	-0.38	-0.13	0.63
	Tofacitinib 10 mg BID	279	-0.7	0.59	-2.3	-1.13	-0.63	-0.25	0.88
	Placebo→Tofacitinib 5 mg BID	68	-0.5	0.50	-1.6	-0.88	-0.50	-0.13	0.50
	Placebo→Tofacitinib 10 mg BID	63	-0.5	0.73	-2.8	-0.88	-0.25	-0.13	1.38
Month 12	Tofacitinib 5 mg BID	251	-0.5	0.58	-3.0	-0.75	-0.50	-0.13	0.88
	Tofacitinib 10 mg BID	265	-0.6	0.62	-2.4	-1.13	-0.63	-0.25	1.13
	Placebo→Tofacitinib 5 mg BID	67	-0.6	0.52	-1.9	-1.00	-0.63	-0.13	0.25
	Placebo→Tofacitinib 10 mg BID	63	-0.5	0.77	-2.8	-0.88	-0.38	0.00	1.38
Month 15	Tofacitinib 5 mg BID	241	-0.5	0.56	-2.9	-0.88	-0.50	-0.13	1.00
	Tofacitinib 10 mg BID	254	-0.7	0.61	-2.3	-1.13	-0.63	-0.25	0.75
	Placebo→Tofacitinib 5 mg BID	62	-0.6	0.60	-1.9	-1.00	-0.50	-0.13	1.25
	Placebo→Tofacitinib 10 mg BID	60	-0.6	0.67	-2.1	-1.00	-0.56	-0.13	1.50
Month 18	Tofacitinib 5 mg BID	234	-0.5	0.58	-2.9	-0.88	-0.38	-0.13	0.88
	Tofacitinib 10 mg BID	244	-0.7	0.64	-2.4	-1.13	-0.63	-0.25	1.13
	Placebo→Tofacitinib 5 mg BID	59	-0.6	0.53	-2.0	-1.00	-0.50	-0.13	0.38
	Placebo→Tofacitinib 10 mg BID	55	-0.6	0.61	-2.0	-1.00	-0.63	-0.13	1.38
Month 21	Tofacitinib 5 mg BID	219	-0.6	0.59	-2.8	-1.00	-0.50	-0.13	0.88
	Tofacitinib 10 mg BID	230	-0.7	0.62	-2.4	-1.13	-0.63	-0.25	1.38
	Placebo→Tofacitinib 5 mg BID	57	-0.6	0.53	-2.0	-1.00	-0.63	-0.25	0.75
	Placebo→Tofacitinib 10 mg BID	53	-0.5	0.65	-2.3	-0.88	-0.50	-0.13	1.75
Month 24	Tofacitinib 5 mg BID	210	-0.5	0.61	-2.5	-1.00	-0.50	-0.13	1.50
	Tofacitinib 10 mg BID	218	-0.7	0.62	-2.3	-1.13	-0.69	-0.25	1.75
	Placebo→Tofacitinib 5 mg BID	54	-0.6	0.61	-2.0	-1.13	-0.63	-0.25	0.75
	Placebo→Tofacitinib 10 mg BID	52	-0.6	0.59	-2.5	-0.88	-0.50	-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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; HAQ-DI = Health Assessment Questionnaire-Disability Index; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Rates of At Least 0.22 Units Improvement in HAQ-DI: The results are summarized in Table 33 and Table 34.

Table 33. Normal Approximation to Rates of at Least 0.22 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	308	151	49.03	2.84	18.96	4.67	4.05	9.79	28.12	<0.0001
	Tofacitinib 10 mg BID	308	180	58.44	2.80	28.37	4.65	6.10	19.26	37.49	<0.0001
	Placebo	153	46	30.07	3.70						
Month 3 (NRI)	Tofacitinib 5 mg BID	308	141	45.78	2.83	21.10	4.48	4.70	12.31	29.89	<0.0001
	Tofacitinib 10 mg BID	308	182	59.09	2.80	34.41	4.46	7.71	25.66	43.16	<0.0001
	Placebo	154	38	24.68	3.47						
Month 6 (NRI)	Tofacitinib 5 mg BID	308	146	47.40	2.84	28.57	4.24	6.73	20.25	36.89	<0.0001
	Tofacitinib 10 mg BID	308	186	60.39	2.78	41.55	4.20	9.88	33.31	49.80	<0.0001
	Placebo	154	29	18.83	3.15						

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 failure 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; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 34. Normal Approximation to Rates of at Least 0.22 Improvement in HAQ-DI per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	308	151	49.03	2.84	17.21	43.44	54.60	<0.0001
	Tofacitinib 10 mg BID	308	180	58.44	2.80	20.81	52.93	63.94	<0.0001
	Placebo→5 mg	79	27	34.18	5.33	6.40	23.71	44.63	<0.0001
	Placebo→10 mg	74	19	25.68	5.07	5.05	15.72	35.62	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	308	141	45.78	2.83	16.12	40.21	51.34	<0.0001
	Tofacitinib 10 mg BID	308	182	59.09	2.80	21.09	53.59	64.58	<0.0001
	Placebo→5 mg	79	21	26.58	4.97	5.34	16.84	36.32	<0.0001
	Placebo→10 mg	75	17	22.67	4.83	4.68	13.19	32.14	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	308	146	47.40	2.84	16.66	41.82	52.97	<0.0001
	Tofacitinib 10 mg BID	308	186	60.39	2.78	21.66	54.92	65.85	<0.0001
	Placebo→5 mg	79	19	24.05	4.80	5.00	14.62	33.47	<0.0001
	Placebo→10 mg	75	10	13.33	3.92	3.39	5.63	21.02	0.0006
Month 9 (NRI)	Tofacitinib 5 mg BID	308	134	43.51	2.82	15.4	37.96	49.04	<0.0001
	Tofacitinib 10 mg BID	308	181	58.77	2.80	20.95	53.26	64.26	<0.0001
	Placebo→5 mg	79	23	29.11	5.11	5.69	19.09	39.13	<0.0001
	Placebo→10 mg	75	19	25.33	5.02	5.04	15.49	35.17	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	308	136	44.16	2.82	15.60	38.61	49.70	<0.0001
	Tofacitinib 10 mg BID	308	169	54.87	2.83	19.35	49.31	60.42	<0.0001
	Placebo→5 mg	79	22	27.85	5.04	5.52	17.96	37.73	<0.0001
	Placebo→10 mg	75	20	26.67	5.10	5.22	16.65	36.67	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	308	126	40.91	2.80	14.6	35.41	46.40	<0.0001
	Tofacitinib 10 mg BID	308	162	52.60	2.84	18.48	47.02	58.17	<0.0001
	Placebo→5 mg	79	22	27.85	5.04	5.52	17.96	37.73	<0.0001
	Placebo→10 mg	75	21	28.00	5.18	5.40	17.83	38.16	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	308	129	41.88	2.81	14.89	36.37	47.39	<0.0001
	Tofacitinib 10 mg BID	308	158	51.30	2.84	18.01	45.71	56.88	<0.0001
	Placebo→5 mg	79	18	22.78	4.71	4.82	13.53	32.03	<0.0001
	Placebo→10 mg	75	23	30.67	5.32	5.75	20.23	41.10	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	308	121	39.29	2.78	14.11	33.83	44.74	<0.0001
	Tofacitinib 10 mg BID	308	153	49.68	2.84	17.43	44.09	55.25	<0.0001
	Placebo→5 mg	79	19	24.05	4.80	5.00	14.62	33.47	<0.0001
	Placebo→10 mg	75	20	26.67	5.10	5.22	16.65	36.67	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	308	113	36.69	2.74	13.35	31.30	42.07	<0.0001
	Tofacitinib 10 mg BID	308	149	48.38	2.84	16.98	42.79	53.95	<0.0001
	Placebo→5 mg	79	19	24.05	4.80	5.00	14.62	33.47	<0.0001
	Placebo→10 mg	75	20	26.67	5.10	5.22	16.65	36.67	<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 failure 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; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- Rates of At Least 0.3 Units Improvement in HAQ-DI: The results are summarized in Table 35 and Table 36.

Table 35. Normal Approximation to Rates of at Least 0.3 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	308	116	37.66	2.76	16.09	4.32	3.72	7.62	24.56	0.0001
	Tofacitinib 10 mg BID	308	152	49.35	2.84	27.78	4.37	6.34	19.19	36.36	<0.0001
	Placebo	153	33	21.57	3.32						
Month 3 (NRI)	Tofacitinib 5 mg BID	308	126	40.91	2.80	19.48	4.33	4.49	10.98	27.97	<0.0001
	Tofacitinib 10 mg BID	308	160	51.95	2.84	30.51	4.36	6.99	21.96	39.07	<0.0001
	Placebo	154	33	21.43	3.30						
Month 6 (NRI)	Tofacitinib 5 mg BID	308	131	42.53	2.81	28.89	3.94	7.32	21.15	36.63	<0.0001
	Tofacitinib 10 mg BID	308	167	54.22	2.83	40.58	3.96	10.24	32.81	48.35	<0.0001
	Placebo	154	21	13.64	2.76						

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 failure 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; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 36. Normal Approximation to Rates of at Least 0.3 Improvement in HAQ-DI per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	308	116	37.66	2.76	13.64	32.25	43.07	<0.0001
	Tofacitinib 10 mg BID	308	152	49.35	2.84	17.32	43.76	54.93	<0.0001
	Placebo→5 mg	79	21	26.58	4.97	5.34	16.84	36.32	<0.0001
	Placebo→10 mg	74	12	16.22	4.28	3.78	7.81	24.61	0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	308	126	40.91	2.80	14.60	35.41	46.40	<0.0001
	Tofacitinib 10 mg BID	308	160	51.95	2.84	18.24	46.36	57.52	<0.0001
	Placebo→5 mg	79	19	24.05	4.80	5.00	14.62	33.47	<0.0001
	Placebo→10 mg	75	14	18.67	4.49	4.14	9.84	27.48	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	308	131	42.53	2.81	15.09	37.01	48.05	<0.0001
	Tofacitinib 10 mg BID	308	167	54.22	2.83	19.09	48.65	59.78	<0.0001
	Placebo→5 mg	79	12	15.19	4.03	3.76	7.27	23.10	0.0001
	Placebo→10 mg	75	9	12.00	3.75	3.19	4.64	19.35	0.0013
Month 9 (NRI)	Tofacitinib 5 mg BID	308	121	39.29	2.78	14.11	33.83	44.74	<0.0001
	Tofacitinib 10 mg BID	308	161	52.27	2.84	18.36	46.69	57.85	<0.0001
	Placebo→5 mg	79	19	24.05	4.80	5.00	14.62	33.47	<0.0001
	Placebo→10 mg	75	17	22.67	4.83	4.68	13.19	32.14	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	308	117	37.99	2.76	13.73	32.56	43.40	<0.0001
	Tofacitinib 10 mg BID	308	146	47.40	2.84	16.66	41.82	52.97	<0.0001
	Placebo→5 mg	79	20	25.32	4.89	5.17	15.72	34.90	<0.0001
	Placebo→10 mg	75	18	24.00	4.93	4.86	14.33	33.66	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	308	112	36.36	2.74	13.26	30.99	41.73	<0.0001
	Tofacitinib 10 mg BID	308	140	45.45	2.83	16.02	39.89	51.01	<0.0001
	Placebo→5 mg	79	20	25.32	4.89	5.17	15.72	34.90	<0.0001
	Placebo→10 mg	75	19	25.33	5.02	5.04	15.49	35.17	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	308	113	36.69	2.74	13.35	31.30	42.07	<0.0001
	Tofacitinib 10 mg BID	308	143	46.43	2.84	16.33	40.85	51.99	<0.0001
	Placebo→5 mg	79	15	18.99	4.41	4.30	10.33	27.63	<0.0001
	Placebo→10 mg	75	22	29.33	5.25	5.57	19.02	39.63	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	308	107	34.74	2.71	12.80	29.42	40.05	<0.0001
	Tofacitinib 10 mg BID	308	141	45.78	2.83	16.12	40.21	51.34	<0.0001
	Placebo→5 mg	79	16	20.25	4.52	4.47	11.39	29.11	<0.0001
	Placebo→10 mg	75	18	24.00	4.93	4.86	14.33	33.66	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	308	102	33.12	2.68	12.34	27.86	38.37	<0.0001
	Tofacitinib 10 mg BID	308	132	42.86	2.81	15.19	37.33	48.38	<0.0001
	Placebo→5 mg	79	15	18.99	4.41	4.30	10.33	27.63	<0.0001
	Placebo→10 mg	75	17	22.67	4.83	4.68	13.19	32.14	<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 failure 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; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- Rates of At Least 0.5 Units Improvement in HAQ-DI: The results are summarized in Table 37 and Table 38.

Table 37. Normal Approximation to Rates of at Least 0.5 Improvement in HAQ-DI per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	308	88	28.57	2.57	18.11	3.57	5.07	11.11	25.11	<0.0001
	Tofacitinib 10 mg BID	308	124	40.26	2.79	29.80	3.73	7.98	22.48	37.11	<0.0001
	Placebo	153	16	10.46	2.47						
Month 3 (NRI)	Tofacitinib 5 mg BID	308	106	34.42	2.70	16.88	4.08	4.12	8.86	24.89	<0.0001
	Tofacitinib 10 mg BID	308	140	45.45	2.83	27.92	4.17	6.68	19.73	36.10	<0.0001
	Placebo	154	27	17.53	3.06						
Month 6 (NRI)	Tofacitinib 5 mg BID	308	107	34.74	2.71	23.70	3.70	6.39	16.43	30.96	<0.0001
	Tofacitinib 10 mg BID	308	147	47.73	2.84	36.68	3.80	9.64	29.23	44.14	<0.0001
	Placebo	154	17	11.04	2.52						

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 failure 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; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 38. Normal Approximation to Rates of at Least 0.5 Improvement in HAQ-DI per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	308	88	28.57	2.57	11.09	23.52	33.61	<0.0001
	Tofacitinib 10 mg BID	308	124	40.26	2.79	14.4	34.78	45.73	<0.0001
	Placebo→5 mg	79	7	8.86	3.19	2.77	2.59	15.12	0.0055
	Placebo→10 mg	74	9	12.16	3.79	3.20	4.71	19.60	0.0013
Month 3 (NRI)	Tofacitinib 5 mg BID	308	106	34.42	2.70	12.71	29.1	39.72	<0.0001
	Tofacitinib 10 mg BID	308	140	45.45	2.83	16.02	39.89	51.01	<0.0001
	Placebo→5 mg	79	17	21.52	4.62	4.65	12.45	30.58	<0.0001
	Placebo→10 mg	75	10	13.33	3.92	3.39	5.63	21.02	0.0006
Month 6 (NRI)	Tofacitinib 5 mg BID	308	107	34.74	2.71	12.80	29.42	40.05	<0.0001
	Tofacitinib 10 mg BID	308	147	47.73	2.84	16.76	42.14	53.30	<0.0001
	Placebo→5 mg	79	10	12.66	3.74	3.38	5.32	19.99	0.0007
	Placebo→10 mg	75	7	9.33	3.35	2.77	2.74	15.91	0.0054
Month 9 (NRI)	Tofacitinib 5 mg BID	308	99	32.14	2.66	12.07	26.92	37.35	<0.0001
	Tofacitinib 10 mg BID	308	149	48.38	2.84	16.98	42.79	53.95	<0.0001
	Placebo→5 mg	79	18	22.78	4.71	4.82	13.53	32.03	<0.0001
	Placebo→10 mg	75	14	18.67	4.49	4.14	9.84	27.48	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	308	100	32.47	2.66	12.16	27.23	37.69	<0.0001
	Tofacitinib 10 mg BID	308	134	43.51	2.82	15.40	37.96	49.04	<0.0001
	Placebo→5 mg	79	20	25.32	4.89	5.17	15.72	34.90	<0.0001
	Placebo→10 mg	75	15	20.00	4.61	4.33	10.94	29.05	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	308	97	31.49	2.64	11.89	26.30	36.68	<0.0001
	Tofacitinib 10 mg BID	308	126	40.91	2.80	14.60	35.41	46.40	<0.0001
	Placebo→5 mg	79	17	21.52	4.62	4.65	12.45	30.58	<0.0001
	Placebo→10 mg	75	19	25.33	5.02	5.04	15.49	35.17	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	308	86	27.92	2.55	10.92	22.91	32.93	<0.0001
	Tofacitinib 10 mg BID	308	130	42.21	2.81	14.99	36.69	47.72	<0.0001
	Placebo→5 mg	79	13	16.46	4.17	3.94	8.27	24.63	<0.0001
	Placebo→10 mg	75	20	26.67	5.10	5.22	16.65	36.67	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	308	91	29.55	2.59	11.36	24.45	34.64	<0.0001
	Tofacitinib 10 mg BID	308	128	41.56	2.80	14.79	36.05	47.06	<0.0001
	Placebo→5 mg	79	15	18.99	4.41	4.30	10.33	27.63	<0.0001
	Placebo→10 mg	75	16	21.33	4.73	4.50	12.06	30.60	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	308	88	28.57	2.57	11.09	23.52	33.61	<0.0001
	Tofacitinib 10 mg BID	308	117	37.99	2.76	13.73	32.56	43.40	<0.0001
	Placebo→5 mg	79	15	18.99	4.41	4.30	10.33	27.63	<0.0001
	Placebo→10 mg	75	14	18.67	4.49	4.14	9.84	27.48	<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 failure 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; CI = confidence interval; FAS = full analysis set; HAQ-DI = Health Assessment Questionnaire-Disability Index; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- Rates of At Least 0.8 Units Improvement in HAQ-DI: The analyses of rates of subjects with at least 0.8 units improvement in HAQ-DI from Baseline were not performed.
- Incidences of DAS28-4(ESR) <2.6 at Time Points Other Than Month 6: All 4 treatment sequences had similar, clinically meaningful decreases from Baseline (improvements) compared to Baseline and maintained through Month 24. Table 39 presents the proportions of subjects with active joints (ie, tender or swollen) who achieved DAS28-4(ESR) <2.6 per visit for Months 1 through 24 (comparisons within sequence). The proportion of subjects in the tofacitinib 5 mg sequence with DAS28-4(ESR) <2.6 and 0 active joints ranged from 47.2% to 62.1%. The proportion of subjects in the tofacitinib 10 mg sequence with DAS28-4(ESR) <2.6 and 0 active joints ranged from 50.0% to 73.2%. Table 40 summarizes subjects with DAS28-4(ESR) active joints (FAS, no imputation) at Months 1 and 3 (comparisons to placebo).

Table 39. Number (%) of Subjects With Active Joints per Visit Who Achieved DAS28-4(ESR) <2.6 Months 1 Through 24 (FAS, No Imputation, Comparisons Within Sequence)

Visit	Treatment	N	Active Joints (Tender or Swollen)			
			0 Joints n (%)	1 Joint n (%)	2 Joint n (%)	≥3 Joints n (%)
Month 1	Tofacitinib 5 mg BID	4	1 (25.0)	0	1 (25.0)	2 (50.0)
	Tofacitinib 10 mg BID	8	1 (12.5)	1 (12.5)	0	6 (75.0)
	Placebo→Tofacitinib 5 mg BID	0	0	0	0	0
	Placebo→Tofacitinib 10 mg BID	0	0	0	0	0
Month 3	Tofacitinib 5 mg BID	14	7 (50.0)	1 (7.1)	4 (28.6)	2 (14.3)
	Tofacitinib 10 mg BID	29	6 (20.7)	6 (20.7)	4 (13.8)	13 (44.8)
	Placebo→Tofacitinib 5 mg BID	1	1 (100)	0	0	0
	Placebo→Tofacitinib 10 mg BID	1	0	0	0	1 (100)
Month 9	Tofacitinib 5 mg BID	30	13 (43.3)	3 (10.0)	5 (16.7)	9 (30.0)
	Tofacitinib 10 mg BID	39	16 (41.0)	9 (23.1)	6 (15.4)	8 (20.5)
	Placebo→Tofacitinib 5 mg BID	6	3 (50.0)	1 (16.7)	0	2 (33.3)
	Placebo→Tofacitinib 10 mg BID	8	2 (25.0)	3 (37.5)	1 (12.5)	2 (25.0)
Month 12	Tofacitinib 5 mg BID	28	15 (53.6)	5 (17.9)	4 (14.3)	4 (14.3)
	Tofacitinib 10 mg BID	41	30 (73.2)	1 (2.4)	4 (9.8)	6 (14.6)
	Placebo→Tofacitinib 5 mg BID	7	4 (57.1)	3 (42.9)	0	0
	Placebo→Tofacitinib 10 mg BID	14	4 (28.6)	3 (21.4)	2 (14.3)	5 (35.7)
Month 15	Tofacitinib 5 mg BID	29	18 (62.1)	1 (3.4)	1 (3.4)	9 (31.0)
	Tofacitinib 10 mg BID	44	22 (50.0)	9 (20.5)	5 (11.4)	8 (18.2)
	Placebo→Tofacitinib 5 mg BID	3	3 (100)	0	0	0
	Placebo→Tofacitinib 10 mg BID	9	2 (22.2)	2 (22.2)	0	5 (55.6)
Month 18	Tofacitinib 5 mg BID	32	16 (50.0)	4 (12.5)	5 (15.6)	7 (21.9)
	Tofacitinib 10 mg BID	39	26 (66.7)	1 (2.6)	5 (12.8)	7 (17.9)
	Placebo→Tofacitinib 5 mg BID	6	5 (83.3)	0	1 (16.7)	0
	Placebo→Tofacitinib 10 mg BID	7	3 (42.9)	1 (14.3)	1 (14.3)	2 (28.6)
Month 21	Tofacitinib 5 mg BID	36	17 (47.2)	7 (19.4)	6 (16.7)	6 (16.7)
	Tofacitinib 10 mg BID	36	22 (61.1)	6 (16.7)	2 (5.6)	6 (16.7)
	Placebo→Tofacitinib 5 mg BID	7	3 (42.9)	2 (28.6)	1 (14.3)	1 (14.3)
	Placebo→Tofacitinib 10 mg BID	9	5 (55.6)	1 (11.1)	2 (22.2)	1 (11.1)
Month 24	Tofacitinib 5 mg BID	30	16 (53.3)	2 (6.7)	5 (16.7)	7 (23.3)
	Tofacitinib 10 mg BID	37	25 (67.6)	5 (13.5)	4 (10.8)	3 (8.1)
	Placebo→Tofacitinib 5 mg BID	5	4 (80.0)	0	0	1 (20.0)
	Placebo→Tofacitinib 10 mg BID	10	6 (60.0)	2 (20.0)	1 (10.0)	1 (10.0)

At each month, N is the number of subjects with DAS <2.6.

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 advanced 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 meeting pre-specified criteria; N = number of subjects. (14.2.13.26)

Table 40. Number (%) of Subjects with DAS28-4(ESR) Active Joints at Months 1 and 3 (FAS, No Imputation), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	Active Joints (Tender or Swollen)			
			0 Joints n (%)	1 Joint n (%)	2 Joint n (%)	≥3 Joints n (%)
Month 1	Tofacitinib 5 mg BID	4	1 (25.0)	0	1 (25.0)	2 (50.0)
	Tofacitinib 10 mg BID	8	1 (12.5)	1 (12.5)	0	6 (75.0)
	Placebo→Tofacitinib 5 mg BID	0	0	0	0	0
	Placebo→Tofacitinib 10 mg BID	0	0	0	0	0
Month 3	Tofacitinib 5 mg BID	14	7 (50.0)	1 (7.1)	4 (28.6)	2 (14.3)
	Tofacitinib 10 mg BID	29	6 (20.7)	6 (20.7)	4 (13.8)	13 (44.8)
	Placebo→Tofacitinib 5 mg BID	2	1 (50.0)	0	0	1 (50.0)
	Placebo→Tofacitinib 10 mg BID	0	0	0	0	0

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 advanced 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 meeting pre-specified criteria; N = number of subjects.

Table 41. Normal Approximation to DAS28-4(ESR) <2.6 Rates per Visit (FAS, No Imputation), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1	Tofacitinib 5 mg BID	258	4	1.55	0.76	1.55	0.76	2.01	0.04	3.05	0.0438
	Tofacitinib 10 mg BID	250	8	3.20	1.11	3.20	1.11	2.87	1.01	5.38	0.0040
	Placebo	127	0	0.00	1.45						
Month 3	Tofacitinib 5 mg BID	250	14	5.60	2.03	3.96	1.85	2.13	0.32	7.59	0.0326
	Tofacitinib 10 mg BID	249	29	11.65	1.14	10.00	2.33	4.28	5.42	14.58	<0.0001
	Placebo	122	2	1.64	1.76						
Month 6	Tofacitinib 5 mg BID	237	19	8.02	2.48	2.79	2.72	1.02	-2.53	8.13	0.3038
	Tofacitinib 10 mg BID	236	42	17.80	2.07	12.57	3.24	3.88	6.22	18.93	0.0001
	Placebo	115	6	5.22	0.76						

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; CI = confidence interval; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; SE = standard error.

Table 42. Normal Approximation to DAS 28-4(ESR) <2.6 Rates per Visit (FAS, No Imputation), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1	Tofacitinib 5 mg BID	258	4	1.55	0.76	2.01	0.04	3.05	0.0438
	Tofacitinib 10 mg BID	250	8	3.20	1.11	2.87	1.01	5.38	0.0040
	Placebo→5 mg	65	0	0.00					
	Placebo→10 mg	62	0	0.00					
Month 3	Tofacitinib 5 mg BID	250	14	5.60	1.45	3.85	2.74	8.45	0.0001
	Tofacitinib 10 mg BID	249	29	11.65	2.03	5.72	7.66	15.63	<0.0001
	Placebo→5 mg	61	1	1.64	1.62	1.00	-1.54	4.82	0.3133
	Placebo→10 mg	61	1	1.64	1.62	1.00	-1.54	4.82	0.3133
Month 6	Tofacitinib 5 mg BID	237	19	8.02	1.76	4.54	4.55	11.47	<0.0001
	Tofacitinib 10 mg BID	236	42	17.80	2.48	7.14	12.91	22.67	<0.0001
	Placebo→5 mg	58	2	3.45	2.39	1.43	1.24	8.14	0.1500
	Placebo→10 mg	57	4	7.02	3.38	2.07	0.38	13.64	0.0380
Month 9	Tofacitinib 5 mg BID	227	30	13.22	2.24	5.87	8.81	17.62	<0.0001
	Tofacitinib 10 mg BID	230	39	16.96	2.47	6.85	12.10	21.80	<0.0001
	Placebo→5 mg	55	6	10.91	4.20	2.59	2.66	19.14	0.0094
	Placebo→10 mg	54	8	14.81	4.83	3.06	5.33	24.29	0.0021
Month 12	Tofacitinib 5 mg BID	218	28	12.84	2.26	5.66	8.40	17.28	<0.0001
	Tofacitinib 10 mg BID	221	41	18.55	2.61	7.09	13.42	23.67	<0.0001
	Placebo→5 mg	54	7	12.96	4.57	2.83	4.00	21.92	0.0045
	Placebo→10 mg	54	14	25.93	5.96	4.34	14.23	37.61	<0.0001
Month 15	Tofacitinib 5 mg BID	208	29	13.94	2.40	5.80	9.23	18.64	<0.0001
	Tofacitinib 10 mg BID	209	44	21.05	2.81	7.46	15.52	26.57	<0.0001
	Placebo→5 mg	49	3	6.12	3.42	1.78	-0.59	12.83	0.0738
	Placebo→10 mg	51	9	17.65	5.33	3.30	7.18	28.10	0.0009
Month 18	Tofacitinib 5 mg BID	203	32	15.76	2.55	6.16	10.75	20.77	<0.0001
	Tofacitinib 10 mg BID	201	39	19.40	2.78	6.95	13.93	24.87	<0.0001
	Placebo→5 mg	45	6	13.33	5.06	2.63	3.40	23.26	0.0085
	Placebo→10 mg	46	7	15.22	5.29	2.87	4.83	25.59	0.0040
Month 21	Tofacitinib 5 mg BID	189	36	19.05	2.85	6.66	13.44	24.64	<0.0001
	Tofacitinib 10 mg BID	192	36	18.75	2.81	6.65	13.22	24.27	<0.0001
	Placebo→5 mg	43	7	16.28	5.62	2.89	5.24	27.31	0.0038
	Placebo→10 mg	44	9	20.45	6.08	3.36	8.53	32.37	0.0007
Month 24	Tofacitinib 5 mg BID	179	30	16.76	2.79	6.00	11.28	22.23	<0.0001
	Tofacitinib 10 mg BID	179	37	20.67	3.02	6.82	14.73	26.60	<0.0001
	Placebo→5 mg	41	5	12.20	5.11	2.38	2.17	22.21	0.0170
	Placebo→10 mg	44	10	22.73	6.31	3.59	10.34	35.11	0.0003

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; CI = confidence interval; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; SE = standard error.

- **Incidences of DAS28-3(CRP) <2.6:** All 4 treatment sequences had similar, clinically meaningful decreases (improvements) from Baseline in DAS28-3(CRP) by Month 12 that were maintained through Month 24. Table 43 and Table 44 presents the rates of subjects achieving DAS28-3(CRP) <2.6 through Month 24 (FAS, comparisons within sequence).

Table 43. Normal Approximation to DAS28-3(CRP) <2.6 Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	35	11.33	1.80	9.35	2.12	4.39	5.18	13.52	<0.0001
	Tofacitinib 10 mg BID	308	28	9.09	1.63	7.11	1.98	3.57	3.21	11.01	0.0003
	Placebo	152	3	1.97	1.12						
Month 3 (NRI)	Tofacitinib 5 mg BID	309	63	20.39	2.29	15.19	2.90	5.22	9.49	20.89	<0.0001
	Tofacitinib 10 mg BID	308	83	26.95	2.52	21.75	3.09	7.02	15.68	27.82	<0.0001
	Placebo	154	8	5.19	1.78						
Month 6 (NRI)	Tofacitinib 5 mg BID	309	71	22.98	2.39	17.78	2.98	5.95	11.92	23.63	<0.0001
	Tofacitinib 10 mg BID	308	112	36.36	2.74	31.16	3.27	9.52	24.75	37.58	<0.0001
	Placebo	154	8	5.19	1.78						

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 failure 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; CI = confidence interval; CRP = C-reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 44. Normal Approximation to DAS28-3(CRP) <2.6 Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	35	11.33	1.80	6.28	7.79	14.86	<0.0001
	Tofacitinib 10 mg BID	308	28	9.09	1.63	5.54	5.88	12.30	<0.0001
	Placebo→5 mg	78	2	2.56	1.78	1.43	-0.94	6.07	0.1519
	Placebo→10 mg	74	1	1.35	1.34	1.00	-1.27	3.98	0.3140
Month 3 (NRI)	Tofacitinib 5 mg BID	309	63	20.39	2.29	8.89	15.89	24.88	<0.0001
	Tofacitinib 10 mg BID	308	83	26.95	2.52	10.65	21.99	31.90	<0.0001
	Placebo→5 mg	79	7	8.86	3.19	2.77	2.59	15.12	0.0055
	Placebo→10 mg	75	1	1.33	1.32	1.00	-1.26	3.92	0.3140
Month 6 (NRI)	Tofacitinib 5 mg BID	309	71	22.98	2.39	9.60	18.28	27.66	<0.0001
	Tofacitinib 10 mg BID	308	112	36.36	2.74	13.26	30.99	41.73	<0.0001
	Placebo→5 mg	79	6	7.59	2.98	2.54	1.75	13.43	0.0108
	Placebo→10 mg	75	2	2.67	1.86	1.43	-0.97	6.31	0.1517
Month 9 (NRI)	Tofacitinib 5 mg BID	309	83	26.86	2.52	10.65	21.91	31.80	<0.0001
	Tofacitinib 10 mg BID	308	118	38.31	2.77	13.83	32.88	43.74	<0.0001
	Placebo→5 mg	79	17	21.52	4.62	4.65	12.45	30.58	<0.0001
	Placebo→10 mg	75	11	14.67	4.08	3.59	6.66	22.67	0.0003
Month 12 (NRI)	Tofacitinib 5 mg BID	309	89	28.80	2.57	11.18	23.75	33.85	<0.0001
	Tofacitinib 10 mg BID	308	119	38.64	2.77	13.92	33.19	44.07	<0.0001
	Placebo→5 mg	79	14	17.72	4.29	4.12	9.30	26.14	<0.0001
	Placebo→10 mg	75	14	18.67	4.49	4.14	9.84	27.48	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	309	94	30.42	2.61	11.62	25.29	35.55	<0.0001
	Tofacitinib 10 mg BID	308	117	37.99	2.76	13.73	32.56	43.40	<0.0001
	Placebo→5 mg	79	12	15.19	4.03	3.76	7.27	23.10	0.0001
	Placebo→10 mg	75	16	21.33	4.73	4.50	12.06	30.60	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	309	90	29.13	2.58	11.26	24.06	34.19	<0.0001
	Tofacitinib 10 mg BID	308	111	36.04	2.73	13.17	30.67	41.40	<0.0001
	Placebo→5 mg	79	12	15.19	4.03	3.76	7.27	23.10	0.0001
	Placebo→10 mg	75	16	21.33	4.73	4.50	12.06	30.60	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	309	81	26.21	2.50	10.47	21.30	31.11	<0.0001
	Tofacitinib 10 mg BID	308	110	35.71	2.73	13.08	30.36	41.06	<0.0001
	Placebo→5 mg	79	11	13.92	3.89	3.57	6.28	21.55	0.0003
	Placebo→10 mg	75	16	21.33	4.73	4.50	12.06	30.60	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	309	78	25.24	2.47	10.21	20.39	30.08	<0.0001
	Tofacitinib 10 mg BID	308	107	34.74	2.71	12.80	29.42	40.05	<0.0001
	Placebo→5 mg	79	9	11.39	3.57	3.18	4.38	18.39	0.0014
	Placebo→10 mg	75	15	20	4.61	4.33	10.94	29.05	<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 failure 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; CI = confidence interval; FAS = full analysis set; CRP = C-reactive protein; DAS = Disease Activity Score; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- DAS28 Response Rates (No Improvement versus Improvement [Moderate improvement or Good improvement]), Based on DAS28-3(CRP): Table 45 and Table 46 presents the rates of DAS28-3(CRP) response (good or moderate improvement) through Month 24 (FAS, comparisons to placebo and comparisons within sequence). All 4 treatment sequences had similar, clinically meaningful response rates compared to Baseline by Month 12 that were maintained through Month 24.
- DAS28 Response Rates (No Improvement versus Improvement [Moderate improvement or Good improvement]), Based on DAS28-4(ESR): Table 47 and Table 48 present the rates of DAS28-3(CRP) response (good or moderate improvement) through Month 24 (FAS, comparisons within sequence). All 4 treatment sequences had similar, clinically meaningful response rates compared to Baseline by Month 12 that were maintained through Month 24.

Table 45 Normal Approximation to DAS28-4(CRP) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1(NRI)	Tofacitinib 5 mg BID	309	197	63.75	2.73	36.78	4.52	8.13	27.91	45.64	<0.0001
	Tofacitinib 10 mg BID	308	231	75.00	2.46	48.02	4.36	11.00	39.47	56.58	<0.0001
	Placebo	152	41	26.97	3.59						
Month 3(NRI)	Tofacitinib 5 mg BID	309	194	62.78	2.74	32.91	4.60	7.15	23.89	41.92	<0.0001
	Tofacitinib 10 mg BID	308	224	72.73	2.53	42.85	4.47	9.57	34.08	51.63	<0.0001
	Placebo	154	46	29.87	3.68						
Month 6(NRI)	Tofacitinib 5 mg BID	309	189	61.17	2.77	32.59	4.57	7.12	23.62	41.56	<0.0001
	Tofacitinib 10 mg BID	308	217	70.45	2.59	41.88	4.47	9.36	33.11	50.65	<0.0001
	Placebo	154	44	28.57	3.64						

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 failure 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; CI = confidence interval; CRP = C-Reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 46. Normal Approximation to DAS28-3(CRP) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRINAP), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRINAP)	Tofacitinib 5 mg BID	309	197	63.75	2.73	23.31	58.39	69.11	<0.0001
	Tofacitinib 10 mg BID	308	231	75.00	2.46	30.39	70.16	79.83	<0.0001
	Placebo→5 mg	78	20	25.64	4.94	5.18	15.95	35.33	<0.0001
	Placebo→10 mg	74	21	28.38	5.24	5.41	18.10	38.65	<0.0001
Month 3 (NRINAP)	Tofacitinib 5 mg BID	309	231	74.76	2.47	30.25	69.91	79.60	<0.0001
	Tofacitinib 10 mg BID	308	248	80.52	2.25	35.68	76.09	84.94	<0.0001
	Placebo→5 mg	79	35	44.30	5.58	7.92	33.34	55.25	<0.0001
	Placebo→10 mg	75	28	37.33	5.58	6.68	26.38	48.28	<0.0001
Month 6 (NRINAP)	Tofacitinib 5 mg BID	309	242	78.32	2.34	33.40	73.72	82.91	<0.0001
	Tofacitinib 10 mg BID	308	257	83.44	2.11	39.39	79.29	87.59	<0.0001
	Placebo→5 mg	79	57	72.15	5.04	14.30	62.26	82.03	<0.0001
	Placebo→10 mg	75	52	69.33	5.32	13.02	58.89	79.76	<0.0001
Month 9 (NRINAP)	Tofacitinib 5 mg BID	309	230	74.43	2.48	29.99	69.56	79.29	<0.0001
	Tofacitinib 10 mg BID	308	253	82.14	2.18	37.64	77.86	86.42	<0.0001
	Placebo→5 mg	79	63	79.75	4.52	17.63	70.88	88.60	<0.0001
	Placebo→10 mg	75	57	76.00	4.93	15.41	66.33	85.66	<0.0001
Month 12 (NRINAP)	Tofacitinib 5 mg BID	309	222	71.84	2.55	28.07	66.82	76.85	<0.0001
	Tofacitinib 10 mg BID	308	238	77.27	2.38	32.36	72.59	81.95	<0.0001
	Placebo→5 mg	79	58	73.42	4.97	14.77	63.67	83.15	<0.0001
	Placebo→10 mg	75	57	76.00	4.93	15.41	66.33	85.66	<0.0001
Month 15 (NRINAP)	Tofacitinib 5 mg BID	309	218	70.55	2.59	27.2	65.46	75.63	<0.0001
	Tofacitinib 10 mg BID	308	232	75.32	2.45	30.66	70.50	80.13	<0.0001
	Placebo→5 mg	79	57	72.15	5.04	14.30	62.26	82.03	<0.0001
	Placebo→10 mg	75	56	74.67	5.02	14.86	64.82	84.50	<0.0001
Month 18 (NRINAP)	Tofacitinib 5 mg BID	309	209	67.64	2.66	25.41	62.42	72.85	<0.0001
	Tofacitinib 10 mg BID	308	214	69.48	2.62	26.48	64.33	74.62	<0.0001
	Placebo→5 mg	79	56	70.89	5.11	13.86	60.86	80.90	<0.0001
	Placebo→10 mg	75	52	69.33	5.32	13.02	58.89	79.76	<0.0001
Month 21 (NRINAP)	Tofacitinib 5 mg BID	309	192	62.14	2.75	22.51	56.72	67.54	<0.0001
	Tofacitinib 10 mg BID	308	212	68.83	2.63	26.08	63.65	74.00	<0.0001
	Placebo→5 mg	79	52	65.82	5.33	12.33	55.36	76.28	<0.0001
	Placebo→10 mg	75	48	64.00	5.54	11.54	53.13	74.86	<0.0001
Month 24 (NRINAP)	Tofacitinib 5 mg BID	309	192	62.14	2.75	22.51	56.72	67.54	<0.0001
	Tofacitinib 10 mg BID	308	206	66.88	2.68	24.94	61.62	72.13	<0.0001
	Placebo→5 mg	79	53	67.09	5.28	12.69	56.72	77.45	<0.0001
	Placebo→10 mg	75	49	65.33	5.49	11.88	54.56	76.10	<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 failure 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; CI = confidence interval; CRP = C-Reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRINAP = non-responder imputation no advancement penalty; SE = standard error.

Table 47. Normal Approximation to DAS28-4(ESR) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1(NRI)	Tofacitinib 5 mg BID	258	139	53.88	3.10	23.16	5.13	4.51	13.09	33.23	<0.0001
	Tofacitinib 10 mg BID	248	168	67.74	2.96	37.03	5.05	7.32	27.12	46.94	<0.0001
	Placebo	127	39	30.71	4.09						
Month 3(NRI)	Tofacitinib 5 mg BID	265	158	59.62	3.01	34.04	4.88	6.97	24.47	43.61	<0.0001
	Tofacitinib 10 mg BID	255	178	69.80	2.87	44.22	4.79	9.21	34.81	53.62	<0.0001
	Placebo	129	33	25.58	3.84						
Month 6(NRI)	Tofacitinib 5 mg BID	265	152	57.36	3.03	31.00	4.92	6.29	21.34	40.65	<0.0001
	Tofacitinib 10 mg BID	255	175	68.63	2.90	42.27	4.84	8.72	32.77	51.77	<0.0001
	Placebo	129	34	26.36	3.87						

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 failure 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; CI = confidence interval; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 48. Normal Approximation to DAS28-4(ESR) Response (Good or Moderate Improvement) Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	258	139	53.88	3.10	17.35	47.79	59.95	<0.0001
	Tofacitinib 10 mg BID	248	168	67.74	2.96	22.82	61.92	73.55	<0.0001
	Placebo→5 mg	65	17	26.15	5.45	4.79	15.46	36.83	<0.0001
	Placebo→10 mg	62	22	35.48	6.07	5.83	23.57	47.39	<0.0001
Month 3 (NRI)	Tofacitinib 5 mg BID	265	158	59.62	3.01	19.78	53.71	65.53	<0.0001
	Tofacitinib 10 mg BID	255	178	69.80	2.87	24.27	64.16	75.43	<0.0001
	Placebo→5 mg	65	17	26.15	5.45	4.79	15.46	36.83	<0.0001
	Placebo→10 mg	64	16	25.00	5.41	4.61	14.39	35.60	<0.0001
Month 6 (NRI)	Tofacitinib 5 mg BID	265	152	57.36	3.03	18.88	51.40	63.31	<0.0001
	Tofacitinib 10 mg BID	255	175	68.63	2.90	23.61	62.93	74.32	<0.0001
	Placebo→5 mg	65	18	27.69	5.55	4.98	16.81	38.57	<0.0001
	Placebo→10 mg	64	16	25.00	5.41	4.61	14.39	35.60	<0.0001
Month 9 (NRI)	Tofacitinib 5 mg BID	265	151	56.98	3.04	18.73	51.02	62.94	<0.0001
	Tofacitinib 10 mg BID	255	169	66.27	2.96	22.38	60.47	72.07	<0.0001
	Placebo→5 mg	65	19	29.23	5.64	5.18	18.17	40.28	<0.0001
	Placebo→10 mg	64	21	32.81	5.86	5.59	21.30	44.31	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	265	147	55.47	3.05	18.16	49.48	61.45	<0.0001
	Tofacitinib 10 mg BID	255	157	61.57	3.04	20.21	55.59	67.53	<0.0001
	Placebo→5 mg	65	17	26.15	5.45	4.79	15.46	36.83	<0.0001
	Placebo→10 mg	64	21	32.81	5.86	5.59	21.30	44.31	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	265	140	52.83	3.06	17.22	46.81	58.84	<0.0001
	Tofacitinib 10 mg BID	255	153	60.00	3.06	19.55	53.98	66.01	<0.0001
	Placebo→5 mg	65	16	24.62	5.34	4.60	14.14	35.08	<0.0001
	Placebo→10 mg	64	23	35.94	5.99	5.99	24.18	47.69	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	265	143	53.96	3.06	17.62	47.96	59.96	<0.0001
	Tofacitinib 10 mg BID	255	146	57.25	3.09	18.48	51.18	63.32	<0.0001
	Placebo→5 mg	65	15	23.08	5.22	4.41	12.83	33.31	<0.0001
	Placebo→10 mg	64	22	34.38	5.93	5.78	22.73	46.01	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	265	127	47.92	3.06	15.61	41.9	53.93	<0.0001
	Tofacitinib 10 mg BID	255	141	55.29	3.11	17.75	49.19	61.39	<0.0001
	Placebo→5 mg	64	22	34.38	5.93	5.78	22.73	46.01	<0.0001
	Placebo→10 mg	265	127	47.92	3.06	15.61	41.90	53.93	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	255	133	52.16	3.12	16.67	46.02	58.28	<0.0001
	Tofacitinib 10 mg BID	65	14	21.54	5.09	4.22	11.54	31.53	<0.0001
	Placebo→5 mg	64	22	34.38	5.93	5.78	22.73	46.01	<0.0001
	Placebo→10 mg	64	22	34.38	5.93	5.78	22.73	46.01	<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 failure 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; CI = confidence interval; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- **DAS28-3(CRP) and DAS28-4(ESR): Actual Values and Change From Baseline:**
 DAS28-3(CRP) results are summarized in Table 49, Table 50, Table 53 and Table 54.
 DAS28-4(ESR) results are summarized in Table 51, Table 52, Table 55 and Table 56. All 4 treatment sequences had similar, clinically meaningful response rates compared to Baseline by Month 12 that were maintained through Month 24.

Table 49. Descriptive Statistics of DAS28-3(CRP) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	5.22	0.88	2.86	4.62	5.23	5.85	7.55
	Tofacitinib 10 mg BID	309	5.20	0.88	2.92	4.61	5.12	5.79	7.93
	Placebo	156	5.16	0.87	3.22	4.54	5.09	5.90	7.17
Month 1	Tofacitinib 5 mg BID	309	4.04	1.14	1.22	3.25	3.93	4.91	6.92
	Tofacitinib 10 mg BID	308	3.84	1.09	1.22	3.05	3.72	4.59	6.79
	Placebo	152	4.73	1.10	2.00	4.06	4.63	5.52	7.46
Month 3	Tofacitinib 5 mg BID	294	3.62	1.13	1.26	2.74	3.51	4.41	7.22
	Tofacitinib 10 mg BID	299	3.29	1.14	1.22	2.51	3.23	4.02	6.50
	Placebo	145	4.54	1.18	1.26	3.73	4.54	5.31	7.05
Month 6	Tofacitinib 5 mg BID	282	3.33	1.12	1.22	2.58	3.2	4.07	6.66
	Tofacitinib 10 mg BID	284	2.96	1.09	1.22	2.12	2.88	3.66	6.04
	Placebo	62	3.79	1.06	1.57	3.14	3.60	4.47	6.90
	Placebo→5 mg	40	3.56	1.02	1.53	2.87	3.40	4.46	6.17
	Placebo→10 mg	37	3.34	1.21	1.22	2.41	3.29	4.11	6.25

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 50. Descriptive Statistics of DAS28-3(CRP) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	5.22	0.88	2.86	4.62	5.23	5.85	7.55
	Tofacitinib 10 mg BID	309	5.2	0.88	2.92	4.61	5.12	5.79	7.93
	Placebo→Tofacitinib 5 mg BID	79	5.14	0.89	3.27	4.42	5.09	5.91	6.70
Month 1	Placebo→Tofacitinib 10 mg BID	77	5.18	0.86	3.22	4.60	5.08	5.75	7.17
	Tofacitinib 5 mg BID	309	4.04	1.14	1.22	3.25	3.93	4.91	6.92
	Tofacitinib 10 mg BID	308	3.84	1.09	1.22	3.05	3.72	4.59	6.79
Month 3	Placebo→Tofacitinib 5 mg BID	78	4.75	1.22	2.13	4.05	4.69	5.72	7.04
	Placebo→Tofacitinib 10 mg BID	74	4.71	0.96	2.00	4.13	4.51	5.48	7.46
	Tofacitinib 5 mg BID	294	3.62	1.13	1.26	2.74	3.51	4.41	7.22
Month 6	Tofacitinib 10 mg BID	299	3.29	1.14	1.22	2.51	3.23	4.02	6.50
	Placebo→Tofacitinib 5 mg BID	75	4.53	1.30	1.26	3.68	4.60	5.37	7.05
	Placebo→Tofacitinib 10 mg BID	70	4.54	1.04	2.52	3.73	4.51	5.23	6.80
Month 9	Tofacitinib 5 mg BID	282	3.33	1.12	1.22	2.58	3.2	4.07	6.66
	Tofacitinib 10 mg BID	284	2.96	1.09	1.22	2.12	2.88	3.66	6.04
	Placebo→Tofacitinib 5 mg BID	71	3.56	1.08	1.53	2.86	3.48	4.37	6.90
Month 12	Placebo→Tofacitinib 10 mg BID	68	3.65	1.13	1.22	2.91	3.55	4.43	6.25
	Tofacitinib 5 mg BID	265	3.11	1.17	1.22	2.15	2.95	3.93	7.01
	Tofacitinib 10 mg BID	279	2.88	1.2	1.22	1.94	2.70	3.66	6.29
Month 15	Placebo→Tofacitinib 5 mg BID	68	2.98	1.11	1.24	2.20	2.83	3.64	6.72
	Placebo→Tofacitinib 10 mg BID	63	3.03	1.06	1.22	2.30	2.85	3.77	5.08
	Tofacitinib 5 mg BID	252	3.06	1.23	1.22	2.09	2.97	3.94	7.04
Month 18	Tofacitinib 10 mg BID	263	2.74	1.14	1.22	1.80	2.60	3.46	6.06
	Placebo→Tofacitinib 5 mg BID	67	3.05	1.17	1.23	2.17	2.69	3.89	6.31
	Placebo→Tofacitinib 10 mg BID	63	2.91	1.05	1.22	2.13	2.99	3.86	5.56
Month 21	Tofacitinib 5 mg BID	243	2.98	1.13	1.22	2.13	2.88	3.75	6.72
	Tofacitinib 10 mg BID	253	2.78	1.16	1.22	1.88	2.54	3.54	6.54
	Placebo→Tofacitinib 5 mg BID	61	2.86	1.06	1.23	2.09	2.76	3.49	5.50
Month 24	Placebo→Tofacitinib 10 mg BID	60	2.81	1.04	1.22	1.86	2.90	3.48	5.36
	Tofacitinib 5 mg BID	234	2.90	1.11	1.22	2.03	2.77	3.70	6.03
	Tofacitinib 10 mg BID	244	2.75	1.17	1.22	1.81	2.53	3.38	6.50
Month 27	Placebo→Tofacitinib 5 mg BID	59	2.77	1.01	1.22	2.09	2.66	3.60	4.86
	Placebo→Tofacitinib 10 mg BID	55	2.70	0.93	1.22	1.86	2.75	3.41	5.40
	Tofacitinib 5 mg BID	219	2.89	1.18	1.22	1.96	2.71	3.59	6.22
Month 30	Tofacitinib 10 mg BID	231	2.69	1.14	1.22	1.75	2.55	3.44	6.35
	Placebo→Tofacitinib 5 mg BID	56	2.81	1.11	1.22	1.91	2.82	3.54	5.27
	Placebo→Tofacitinib 10 mg BID	53	2.75	1.12	1.22	1.71	2.69	3.65	5.04
Month 33	Tofacitinib 5 mg BID	209	2.93	1.14	1.22	2.04	2.81	3.67	5.96
	Tofacitinib 10 mg BID	216	2.62	1.13	1.22	1.65	2.37	3.41	5.75
	Placebo→Tofacitinib 5 mg BID	54	2.61	0.94	1.22	1.90	2.63	3.27	5.20
Month 36	Placebo→Tofacitinib 10 mg BID	52	2.58	1.09	1.22	1.59	2.4	3.44	5.21

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 advanced 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; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 51. Descriptive Statistics of DAS28-4(ESR) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	6.33	0.97	3.12	5.61	6.31	7.04	8.81
	Tofacitinib 10 mg BID	306	6.25	0.99	3.17	5.61	6.23	6.89	8.81
	Placebo	154	6.27	1.01	3.94	5.59	6.26	6.94	8.78
Month 1	Tofacitinib 5 mg BID	258	5.12	1.32	1.64	4.24	5.10	6.03	8.79
	Tofacitinib 10 mg BID	250	4.84	1.28	1.28	3.92	4.88	5.67	7.67
	Placebo	127	5.83	1.17	3.08	5.03	5.68	6.81	8.29
Month 3	Tofacitinib 5 mg BID	250	4.58	1.29	1.67	3.71	4.54	5.53	7.66
	Tofacitinib 10 mg BID	249	4.18	1.34	1.36	3.17	4.15	5.11	7.51
	Placebo	122	5.57	1.23	2.26	4.89	5.59	6.50	8.46
Month 6	Tofacitinib 5 mg BID	237	4.34	1.25	1.48	3.46	4.22	5.25	7.51
	Tofacitinib 10 mg BID	236	3.90	1.31	1.20	2.88	3.88	4.75	7.38
	Placebo	49	4.81	1.21	1.90	3.99	4.81	5.86	7.41
	Placebo→5 mg	35	4.65	1.32	1.93	3.58	4.58	5.25	7.80
	Placebo→10 mg	31	4.19	1.42	2.14	3.24	3.79	5.15	8.38

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 52. Descriptive Statistics of DAS28-4(ESR) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	6.33	0.97	3.12	5.61	6.31	7.04	8.81
	Tofacitinib 10 mg BID	306	6.25	0.99	3.17	5.61	6.23	6.89	8.81
	Placebo→Tofacitinib 5 mg BID	78	6.25	0.96	4.32	5.57	6.33	6.84	8.18
Month 1	Placebo→Tofacitinib 10 mg BID	76	6.29	1.07	3.94	5.62	6.15	7.05	8.78
	Tofacitinib 5 mg BID	258	5.12	1.32	1.64	4.24	5.10	6.03	8.79
	Tofacitinib 10 mg BID	250	4.84	1.28	1.28	3.92	4.88	5.67	7.67
Month 3	Placebo→Tofacitinib 5 mg BID	65	5.93	1.34	3.1	4.95	5.88	7.10	8.29
	Placebo→Tofacitinib 10 mg BID	62	5.73	0.96	3.08	5.09	5.61	6.49	7.57
	Tofacitinib 5 mg BID	250	4.58	1.29	1.67	3.71	4.54	5.53	7.66
Month 6	Tofacitinib 10 mg BID	249	4.18	1.34	1.36	3.17	4.15	5.11	7.51
	Placebo→Tofacitinib 5 mg BID	61	5.70	1.24	2.37	4.92	5.72	6.62	7.94
	Placebo→Tofacitinib 10 mg BID	61	5.43	1.20	2.26	4.84	5.44	6.12	8.46
Month 9	Tofacitinib 5 mg BID	237	4.34	1.25	1.48	3.46	4.22	5.25	7.51
	Tofacitinib 10 mg BID	236	3.90	1.31	1.20	2.88	3.88	4.75	7.38
	Placebo→Tofacitinib 5 mg BID	58	4.60	1.31	1.90	3.62	4.51	5.34	7.80
Month 12	Placebo→Tofacitinib 10 mg BID	57	4.59	1.33	2.14	3.50	4.8	5.42	8.38
	Tofacitinib 5 mg BID	227	4.12	1.26	1.58	3.22	4.11	4.88	7.33
	Tofacitinib 10 mg BID	230	3.84	1.35	0.56	2.83	3.67	4.73	7.12
Month 15	Placebo→Tofacitinib 5 mg BID	55	4.04	1.34	0.90	2.90	3.90	5.00	7.06
	Placebo→Tofacitinib 10 mg BID	54	3.87	1.30	1.19	2.97	3.57	4.96	6.76
	Tofacitinib 5 mg BID	218	4.08	1.32	1.40	3.07	4.02	4.98	8.12
Month 18	Tofacitinib 10 mg BID	221	3.78	1.33	0.39	2.76	3.67	4.65	7.25
	Placebo→Tofacitinib 5 mg BID	54	4.20	1.41	1.85	3.18	3.74	5.24	7.19
	Placebo→Tofacitinib 10 mg BID	54	3.84	1.35	0.54	2.59	4.09	4.80	6.39
Month 21	Tofacitinib 5 mg BID	208	3.99	1.28	1.32	3.08	3.91	4.9	7.68
	Tofacitinib 10 mg BID	209	3.85	1.34	0.72	2.86	3.74	4.65	7.44
	Placebo→Tofacitinib 5 mg BID	49	3.95	1.12	1.55	3.13	3.9	4.43	6.83
Month 24	Placebo→Tofacitinib 10 mg BID	51	3.75	1.25	1.18	2.97	3.79	4.43	6.55
	Tofacitinib 5 mg BID	203	3.91	1.26	1.46	2.97	3.84	4.73	7.40
	Tofacitinib 10 mg BID	201	3.77	1.35	0.04	2.88	3.63	4.65	7.43
Month 27	Placebo→Tofacitinib 5 mg BID	45	3.74	1.13	1.48	2.94	3.56	4.49	6.18
	Placebo→Tofacitinib 10 mg BID	46	3.59	1.14	1.37	2.77	3.67	4.49	6.81
	Tofacitinib 5 mg BID	189	3.87	1.32	1.14	2.89	3.80	4.81	7.28
Month 30	Tofacitinib 10 mg BID	192	3.73	1.31	0.1	2.78	3.50	4.65	6.88
	Placebo→Tofacitinib 5 mg BID	43	3.85	1.15	1.54	2.87	3.77	4.68	6.25
	Placebo→Tofacitinib 10 mg BID	44	3.77	1.38	0.57	2.91	4.00	4.55	6.36
Month 33	Tofacitinib 5 mg BID	179	3.9	1.33	0.06	2.92	3.81	4.83	7.00
	Tofacitinib 10 mg BID	179	3.67	1.31	0.38	2.73	3.45	4.64	7.07
	Placebo→Tofacitinib 5 mg BID	41	3.76	1.21	1.53	3.02	3.58	4.47	6.26
Month 36	Placebo→Tofacitinib 10 mg BID	44	3.59	1.11	1.37	2.63	3.65	4.26	5.92

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 advanced 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; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 53. Descriptive Statistics of Change From Baseline of DAS28-3(CRP) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-1.2	0.97	-4.0	-1.72	-1.18	-0.54	1.28
	Tofacitinib 10 mg BID	308	-1.4	0.92	-4.2	-1.90	-1.33	-0.76	0.94
	Placebo	152	-0.4	0.79	-2.5	-0.87	-0.30	0.11	1.24
Month 3	Tofacitinib 5 mg BID	294	-1.6	1.18	-5.2	-2.37	-1.60	-0.77	1.86
	Tofacitinib 10 mg BID	299	-1.9	1.08	-5.5	-2.68	-1.90	-1.10	0.79
	Placebo	145	-0.6	1.05	-3.3	-1.20	-0.49	0.09	1.79
Month 6	Tofacitinib 5 mg BID	282	-1.9	1.14	-5.1	-2.63	-1.74	-1.11	1.15
	Tofacitinib 10 mg BID	284	-2.2	1.13	-5.4	-3.07	-2.16	-1.52	1.33
	Placebo	62	-1.4	1.13	-3.9	-2.17	-1.34	-0.52	1.01
	Placebo→5 mg	40	-1.6	0.95	-4.1	-2.21	-1.53	-1.16	0.52
	Placebo→10 mg	37	-1.9	1.01	-4.0	-2.61	-2.05	-0.93	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; CRP = C-reactive protein; DAS = Disease Activity Score; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 54. Descriptive Statistics of Change From Baseline of DAS28-3(CRP) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-1.2	0.97	-4.0	-1.72	-1.18	-0.54	1.28
	Tofacitinib 10 mg BID	308	-1.4	0.92	-4.2	-1.90	-1.33	-0.76	0.94
	Placebo→Tofacitinib 5 mg BID	78	-0.4	0.86	-2.5	-0.83	-0.29	0.19	1.24
	Placebo→Tofacitinib 10 mg BID	74	-0.4	0.71	-2.1	-0.97	-0.31	0.05	1.17
Month 3	Tofacitinib 5 mg BID	294	-1.6	1.18	-5.2	-2.37	-1.60	-0.77	1.86
	Tofacitinib 10 mg BID	299	-1.9	1.08	-5.5	-2.68	-1.90	-1.10	0.79
	Placebo→Tofacitinib 5 mg BID	75	-0.6	1.09	-3.3	-1.31	-0.53	0.21	1.79
	Placebo→Tofacitinib 10 mg BID	70	-0.6	1.00	-3.1	-1.09	-0.49	0.02	1.60
Month 6	Tofacitinib 5 mg BID	282	-1.9	1.14	-5.1	-2.63	-1.74	-1.11	1.15
	Tofacitinib 10 mg BID	284	-2.2	1.13	-5.4	-3.07	-2.16	-1.52	1.33
	Placebo→Tofacitinib 5 mg BID	71	-1.6	1.07	-4.1	-2.26	-1.58	-0.99	1.01
	Placebo→Tofacitinib 10 mg BID	68	-1.5	1.06	-4.0	-2.37	-1.37	-0.88	0.91
Month 9	Tofacitinib 5 mg BID	265	-2.1	1.21	-5.3	-2.99	-2.09	-1.30	0.93
	Tofacitinib 10 mg BID	279	-2.3	1.17	-5.0	-3.12	-2.38	-1.50	0.56
	Placebo→Tofacitinib 5 mg BID	68	-2.2	1.16	-4.6	-3.08	-1.94	-1.18	0.83
	Placebo→Tofacitinib 10 mg BID	63	-2.1	1.12	-4.9	-2.92	-2.14	-1.22	0.54
Month 12	Tofacitinib 5 mg BID	252	-2.2	1.23	-5.5	-3.05	-2.17	-1.28	1.28
	Tofacitinib 10 mg BID	263	-2.5	1.14	-5.0	-3.25	-2.48	-1.64	0.57
	Placebo→Tofacitinib 5 mg BID	67	-2.1	1.06	-4.6	-2.88	-2.01	-1.23	0.15
	Placebo→Tofacitinib 10 mg BID	63	-2.2	1.01	-4.3	-2.96	-2.11	-1.46	-0.45
Month 15	Tofacitinib 5 mg BID	243	-2.3	1.23	-5.6	-3.08	-2.20	-1.40	1.14
	Tofacitinib 10 mg BID	253	-2.4	1.18	-5.8	-3.26	-2.48	-1.61	1.21
	Placebo→Tofacitinib 5 mg BID	61	-2.2	1.14	-5.3	-2.94	-2.16	-1.44	0.36
	Placebo→Tofacitinib 10 mg BID	60	-2.3	1.11	-4.5	-3.05	-2.44	-1.60	0.39
Month 18	Tofacitinib 5 mg BID	234	-2.4	1.25	-5.1	-3.23	-2.31	-1.51	1.25
	Tofacitinib 10 mg BID	244	-2.4	1.26	-5.2	-3.31	-2.55	-1.54	0.97
	Placebo→Tofacitinib 5 mg BID	59	-2.3	1.12	-4.8	-3.08	-2.24	-1.59	1.21
	Placebo→Tofacitinib 10 mg BID	55	-2.4	1.03	-4.8	-3.15	-2.35	-1.52	0.16
Month 21	Tofacitinib 5 mg BID	219	-2.4	1.30	-6.2	-3.29	-2.35	-1.40	0.91
	Tofacitinib 10 mg BID	231	-2.5	1.25	-5.5	-3.36	-2.60	-1.66	0.83
	Placebo→Tofacitinib 5 mg BID	56	-2.3	1.09	-4.7	-3.04	-2.28	-1.47	1.72
	Placebo→Tofacitinib 10 mg BID	53	-2.3	1.24	-4.3	-3.38	-2.40	-1.46	0.38
Month 24	Tofacitinib 5 mg BID	209	-2.3	1.25	-5.6	-3.09	-2.32	-1.37	0.56
	Tofacitinib 10 mg BID	216	-2.6	1.23	-5.1	-3.40	-2.56	-1.77	0.94
	Placebo→Tofacitinib 5 mg BID	54	-2.4	0.87	-4.6	-3.17	-2.32	-1.80	-0.13
	Placebo→Tofacitinib 10 mg BID	52	-2.5	1.12	-4.3	-3.30	-2.52	-1.76	0.10

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 advanced 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; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 55. Descriptive Statistics of Change From Baseline of DAS28-4(ESR) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	258	-1.3	1.06	-4.2	-1.88	-1.11	-0.50	1.31
	Tofacitinib 10 mg BID	248	-1.5	0.99	-4.8	-2.05	-1.40	-0.83	1.05
	Placebo	127	-0.5	0.83	-2.8	-1.09	-0.48	0.09	1.28
Month 3	Tofacitinib 5 mg BID	250	-1.8	1.20	-5.2	-2.59	-1.67	-0.93	1.19
	Tofacitinib 10 mg BID	247	-2.1	1.18	-5.3	-2.93	-2.13	-1.29	0.84
	Placebo	122	-0.8	1.08	-3.7	-1.44	-0.62	-0.14	1.80
Month 6	Tofacitinib 5 mg BID	237	-2.0	1.21	-5.5	-2.83	-2.01	-1.19	1.35
	Tofacitinib 10 mg BID	234	-2.4	1.25	-6.5	-3.24	-2.39	-1.56	1.02
	Placebo	49	-1.6	1.23	-5.7	-2.28	-1.68	-0.87	0.84
	Placebo→5 mg	35	-1.8	1.10	-4.0	-2.40	-1.50	-1.16	0.66
	Placebo→10 mg	31	-2.0	1.12	-3.9	-2.89	-2.02	-1.09	0.02

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 56. Descriptive Statistics of Change From Baseline of DAS28-4(ESR) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	258	-1.3	1.06	-4.2	-1.88	-1.11	-0.5	1.31
	Tofacitinib 10 mg BID	248	-1.5	0.99	-4.8	-2.05	-1.4	-0.83	1.05
	Placebo→Tofacitinib 5 mg BID	65	-0.5	0.85	-2.6	-1.01	-0.30	0.11	1.28
	Placebo→Tofacitinib 10 mg BID	62	-0.6	0.81	-2.8	-1.10	-0.59	0.01	0.92
Month 3	Tofacitinib 5 mg BID	250	-1.8	1.20	-5.2	-2.59	-1.67	-0.93	1.19
	Tofacitinib 10 mg BID	247	-2.1	1.18	-5.3	-2.93	-2.13	-1.29	0.84
	Placebo→Tofacitinib 5 mg BID	61	-0.7	1.04	-3.3	-1.46	-0.64	0.10	1.21
	Placebo→Tofacitinib 10 mg BID	61	-0.9	1.11	-3.7	-1.41	-0.57	-0.28	1.80
Month 6	Tofacitinib 5 mg BID	237	-2.0	1.21	-5.5	-2.83	-2.01	-1.19	1.35
	Tofacitinib 10 mg BID	234	-2.4	1.25	-6.5	-3.24	-2.39	-1.56	1.02
	Placebo→Tofacitinib 5 mg BID	58	-1.8	1.20	-5.7	-2.53	-1.77	-1.21	0.82
	Placebo→Tofacitinib 10 mg BID	57	-1.7	1.13	-3.9	-2.40	-1.53	-1.01	0.84
Month 9	Tofacitinib 5 mg BID	227	-2.2	1.25	-5.4	-3.10	-2.2	-1.28	1.02
	Tofacitinib 10 mg BID	228	-2.5	1.28	-5.7	-3.39	-2.52	-1.65	0.71
	Placebo→Tofacitinib 5 mg BID	55	-2.4	1.25	-4.8	-3.25	-2.59	-1.45	0.47
	Placebo→Tofacitinib 10 mg BID	54	-2.4	1.24	-5.4	-3.08	-2.32	-1.48	0.55
Month 1 2	Tofacitinib 5 mg BID	218	-2.3	1.33	-5.6	-3.21	-2.32	-1.40	1.32
	Tofacitinib 10 mg BID	220	-2.5	1.29	-6.1	-3.48	-2.54	-1.57	0.66
	Placebo→Tofacitinib 5 mg BID	54	-2.2	1.22	-5.0	-3.05	-2.49	-1.30	0.07
	Placebo→Tofacitinib 10 mg BID	54	-2.4	1.21	-5.3	-3.24	-2.45	-1.41	0.05
Month 1 5	Tofacitinib 5 mg BID	208	-2.4	1.32	-6.1	-3.26	-2.39	-1.54	0.88
	Tofacitinib 10 mg BID	208	-2.5	1.32	-5.9	-3.39	-2.54	-1.56	1.20
	Placebo→Tofacitinib 5 mg BID	49	-2.4	1.07	-4.9	-2.99	-2.35	-1.83	0.25
	Placebo→Tofacitinib 10 mg BID	51	-2.5	1.27	-5.3	-3.39	-2.61	-1.55	0.60
Month 1 8	Tofacitinib 5 mg BID	203	-2.5	1.34	-6.1	-3.33	-2.46	-1.62	0.96
	Tofacitinib 10 mg BID	200	-2.5	1.36	-7.6	-3.45	-2.49	-1.63	1.07
	Placebo→Tofacitinib 5 mg BID	45	-2.6	1.03	-5.5	-3.41	-2.42	-1.83	-0.64
	Placebo→Tofacitinib 10 mg BID	46	-2.5	1.11	-5.1	-3.36	-2.47	-1.60	-0.31
Month 2 1	Tofacitinib 5 mg BID	189	-2.6	1.35	-6.5	-3.50	-2.56	-1.62	1.10
	Tofacitinib 10 mg BID	191	-2.6	1.35	-5.8	-3.44	-2.55	-1.67	0.89
	Placebo→Tofacitinib 5 mg BID	43	-2.5	1.15	-5.5	-3.20	-2.33	-1.82	-0.15
	Placebo→Tofacitinib 10 mg BID	44	-2.3	1.33	-4.9	-3.52	-2.29	-1.31	0.29
Month 2 4	Tofacitinib 5 mg BID	179	-2.5	1.37	-6.2	-3.34	-2.42	-1.49	0.44
	Tofacitinib 10 mg BID	178	-2.7	1.30	-5.9	-3.48	-2.55	-1.83	0.77
	Placebo→Tofacitinib 5 mg BID	41	-2.6	1.04	-5.0	-3.30	-2.41	-1.97	-0.41
	Placebo→Tofacitinib 10 mg BID	44	-2.5	1.17	-5.1	-3.48	-2.45	-1.73	-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 advanced 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; Min = minimum; Max = maximum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Incidences of DAS28-3(CRP) ≤3.2, and DAS28-4(ESR) ≤3.2: The results are summarized in Table 57, Table 58, Table 59 and Table 60.

Table 57. Normal Approximation to DAS28-3(CRP) ≤ 3.2 Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	73	23.62	2.41	17.04	3.14	5.42	10.88	23.20	<0.0001
	Tofacitinib 10 mg BID	308	97	31.49	2.64	24.91	3.32	7.49	18.39	31.42	<0.0001
	Placebo	152	10	6.58	2.01						
Month 3 (NRI)	Tofacitinib 5 mg BID	309	109	35.28	2.71	23.58	3.75	6.28	16.22	30.94	<0.0001
	Tofacitinib 10 mg BID	308	137	44.48	2.83	32.79	3.83	8.54	25.27	40.31	<0.0001
	Placebo	154	18	11.69	2.58						
Month 6 (NRI)	Tofacitinib 5 mg BID	309	117	37.86	2.75	27.47	3.69	7.43	20.23	34.71	<0.0001
	Tofacitinib 10 mg BID	308	157	50.97	2.84	40.58	3.76	10.78	33.20	47.95	<0.0001
	Placebo	154	16	10.39	2.45						

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 failure 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; CI = confidence interval; CRP = C-reactive protein; DAS = Disease Activity Score; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 58. Normal Approximation to DAS28-3(CRP) ≤ 3.2 Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI for Difference		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	309	73	23.62	2.41	9.77	18.88	28.36	<0.0001
	Tofacitinib 10 mg BID	308	97	31.49	2.64	11.89	26.3	36.68	<0.0001
	Placebo→5 mg	78	7	8.97	3.23	2.77	2.63	15.31	0.0055
	Placebo→10 mg	74	3	4.05	2.29	1.76	-0.43	8.54	0.0770
Month 3 (NRI)	Tofacitinib 5 mg BID	309	109	35.28	2.71	12.97	29.94	40.6	<0.0001
	Tofacitinib 10 mg BID	308	137	44.48	2.83	15.70	38.93	50.03	<0.0001
	Placebo→5 mg	79	12	15.19	4.03	3.76	7.27	23.10	0.0001
	Placebo→10 mg	75	6	8.00	3.13	2.55	1.86	14.13	0.0106
Month 6 (NRI)	Tofacitinib 5 mg BID	309	117	37.86	2.75	13.72	32.45	43.27	<0.0001
	Tofacitinib 10 mg BID	308	157	50.97	2.84	17.89	45.39	56.55	<0.0001
	Placebo→5 mg	79	10	12.66	3.74	3.38	5.32	19.99	0.0007
	Placebo→10 mg	75	6	8.00	3.13	2.55	1.86	14.13	0.0106
Month 9 (NRI)	Tofacitinib 5 mg BID	309	119	38.51	2.76	13.91	33.08	43.93	<0.0001
	Tofacitinib 10 mg BID	308	161	52.27	2.84	18.36	46.69	57.85	<0.0001
	Placebo→5 mg	79	20	25.32	4.89	5.17	15.72	34.90	<0.0001
	Placebo→10 mg	75	18	24.00	4.93	4.86	14.33	33.66	<0.0001
Month 12 (NRI)	Tofacitinib 5 mg BID	309	124	40.13	2.78	14.39	34.66	45.59	<0.0001
	Tofacitinib 10 mg BID	308	155	50.32	2.84	17.66	44.74	55.90	<0.0001
	Placebo→5 mg	79	18	22.78	4.71	4.82	13.53	32.03	<0.0001
	Placebo→10 mg	75	18	24.00	4.93	4.86	14.33	33.66	<0.0001
Month 15 (NRI)	Tofacitinib 5 mg BID	309	122	39.48	2.78	14.19	34.03	44.93	<0.0001
	Tofacitinib 10 mg BID	308	143	46.43	2.84	16.33	40.85	51.99	<0.0001
	Placebo→5 mg	79	19	24.05	4.80	5.00	14.62	33.47	<0.0001
	Placebo→10 mg	75	20	26.67	5.10	5.22	16.65	36.67	<0.0001
Month 18 (NRI)	Tofacitinib 5 mg BID	309	119	38.51	2.76	13.91	33.08	43.93	<0.0001
	Tofacitinib 10 mg BID	308	149	48.38	2.84	16.98	42.79	53.95	<0.0001
	Placebo→5 mg	79	18	22.78	4.71	4.82	13.53	32.03	<0.0001
	Placebo→10 mg	75	22	29.33	5.25	5.57	19.02	39.63	<0.0001
Month 21 (NRI)	Tofacitinib 5 mg BID	309	108	34.95	2.71	12.88	29.63	40.26	<0.0001
	Tofacitinib 10 mg BID	308	134	43.51	2.82	15.40	37.96	49.04	<0.0001
	Placebo→5 mg	79	17	21.52	4.62	4.65	12.45	30.58	<0.0001
	Placebo→10 mg	75	19	25.33	5.02	5.04	15.49	35.17	<0.0001
Month 24 (NRI)	Tofacitinib 5 mg BID	309	108	34.95	2.71	12.88	29.63	40.26	<0.0001
	Tofacitinib 10 mg BID	308	131	42.53	2.81	15.09	37.01	48.05	<0.0001
	Placebo→5 mg	79	20	25.32	4.89	5.17	15.72	34.90	<0.0001
	Placebo→10 mg	75	19	25.33	5.02	5.04	15.49	35.17	<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 failure 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; CI = confidence interval; FAS = full analysis set; CRP = C-reactive protein; DAS = Disease Activity Score; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 59. Normal Approximation to DAS28-4(ESR) ≤ 3.2 Rates per Visit (FAS, NRI), Comparisons to Placebo, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	258	18	6.98	1.58	3.82	2.21	1.72	-0.51	8.17	0.0843
	Tofacitinib 10 mg BID	250	26	10.40	1.93	7.25	2.47	2.92	2.39	12.10	0.0034
	Placebo	127	4	3.15	1.54						
Month 3 (NRI)	Tofacitinib 5 mg BID	265	37	13.96	2.12	10.08	2.72	3.70	4.74	15.42	0.0002
	Tofacitinib 10 mg BID	257	64	24.90	2.69	21.02	3.18	6.59	14.77	27.27	<0.0001
	Placebo	129	5	3.88	1.69						
Month 6 (NRI)	Tofacitinib 5 mg BID	265	38	14.34	2.15	11.23	2.63	4.25	6.06	16.41	<0.0001
	Tofacitinib 10 mg BID	257	73	28.40	2.81	25.30	3.20	7.90	19.03	31.57	<0.0001
	Placebo	129	4	3.10	1.52						

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 failure 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; CI = confidence interval; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

Table 60. Normal Approximation to DAS28-4(ESR) \leq 3.2 Rates per Visit (FAS, NRI), Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment	N	n	Response Rate	SE	Z	95% CI		p-Value
							Lower	Upper	
Month 1 (NRI)	Tofacitinib 5 mg BID	258	18	6.98	1.58	4.39	3.86	10.08	<0.0001
	Tofacitinib 10 mg BID	250	26	10.40	1.93	5.38	6.61	14.18	<0.0001
	Placebo→5 mg	65	3	4.62	2.60	1.77	-0.48	9.71	0.0761
	Placebo→10 mg	62	1	1.61	1.59	1.00	-1.52	4.74	0.3133
Month 3 (NRI)	Tofacitinib 5 mg BID	265	37	13.96	2.12	6.55	9.78	18.13	<0.0001
	Tofacitinib 10 mg BID	257	64	24.90	2.69	9.23	19.61	30.18	<0.0001
	Placebo→5 mg	65	3	4.62	2.60	1.77	-0.48	9.71	0.0761
	Placebo→10 mg	64	2	3.13	2.17	1.43	-1.13	7.38	0.1507
Month 6 (NRI)	Tofacitinib 5 mg BID	265	38	14.34	2.15	6.66	10.11	18.55	<0.0001
	Tofacitinib 10 mg BID	257	73	28.40	2.81	10.09	22.89	33.91	<0.0001
	Placebo→5 mg	65	3	4.62	2.60	1.77	-0.48	9.71	0.0761
	Placebo→10 mg	64	1	1.56	1.55	1.00	-1.47	4.60	0.3134
Month 9 (NRI)	Tofacitinib 5 mg BID	265	50	18.87	2.40	7.85	14.15	23.57	<0.0001
	Tofacitinib 10 mg BID	257	86	33.46	2.94	11.36	27.69	39.23	<0.0001
	Placebo→5 mg	65	7	10.77	3.84	2.80	3.23	18.30	0.005
	Placebo→10 mg	64	8	12.50	4.13	3.02	4.39	20.60	0.0024
Month 1 2 (NRI)	Tofacitinib 5 mg BID	265	56	21.13	2.50	8.42	16.21	26.04	<0.0001
	Tofacitinib 10 mg BID	257	70	27.24	2.77	9.80	21.79	32.68	<0.0001
	Placebo→5 mg	65	6	9.23	3.59	2.57	2.19	16.26	0.0101
	Placebo→10 mg	64	11	17.19	4.71	3.64	7.94	26.43	0.0002
Month 1 5 (NRI)	Tofacitinib 5 mg BID	265	56	21.13	2.50	8.42	16.21	26.04	<0.0001
	Tofacitinib 10 mg BID	257	62	24.12	2.66	9.03	18.89	29.35	<0.0001
	Placebo→5 mg	65	6	9.23	3.59	2.57	2.19	16.26	0.0101
	Placebo→10 mg	64	9	14.06	4.34	3.23	5.54	22.57	0.0012
Month 1 8 (NRI)	Tofacitinib 5 mg BID	265	62	23.40	2.60	8.99	18.29	28.49	<0.0001
	Tofacitinib 10 mg BID	257	65	25.29	2.71	9.32	19.97	30.60	<0.0001
	Placebo→5 mg	65	6	9.23	3.59	2.57	2.19	16.26	0.0101
	Placebo→10 mg	64	11	17.19	4.71	3.64	7.94	26.43	0.0002
Month 2 1 (NRI)	Tofacitinib 5 mg BID	265	54	20.38	2.47	8.23	15.52	25.22	<0.0001
	Tofacitinib 10 mg BID	257	71	27.63	2.78	9.90	22.15	33.09	<0.0001
	Placebo→5 mg	65	5	7.69	3.30	2.32	1.21	14.17	0.0199
	Placebo→10 mg	64	9	14.06	4.34	3.23	5.54	22.57	0.0012
Month 2 4 (NRI)	Tofacitinib 5 mg BID	265	54	20.38	2.47	8.23	15.52	25.22	<0.0001
	Tofacitinib 10 mg BID	257	70	27.24	2.77	9.80	21.79	32.68	<0.0001
	Placebo→5 mg	65	4	6.15	2.98	2.06	0.31	11.99	0.0389
	Placebo→10 mg	64	8	12.50	4.13	3.02	4.39	20.60	0.0024

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 failure 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; CI = confidence interval; FAS = full analysis set; DAS = Disease Activity Score; ESR = erythrocyte sedimentation rate; N = number of subjects; n = number of subjects meeting pre-specified criteria; NRI = non-responder imputation; SE = standard error.

- Durability of ACR20 response: The rate of subjects with ACR20 response at 9 consecutive visits was 13.3% for the tofacitinib 5 mg sequence and 24.6% for the tofacitinib 10 mg sequence. The rate of ACR20 response at 2 or more consecutive visits through Month 24 was 74.4% (235/316) for the tofacitinib 5 mg sequence and 83.2% (257/309) for the tofacitinib 10 mg sequence (Table 61).

Once advanced to tofacitinib, the placebo→tofacitinib sequences had patterns of ACR20 response similar to the pattern shown by the tofacitinib sequences at the start of the study. The overall response rate at 2 or more consecutive visits was 74.7% (59/79) for the placebo→tofacitinib 5 mg sequence and 68.8% (53/77) for the placebo→tofacitinib 10 mg sequence.

- Durability of ACR50 response: The rates of subjects with ACR50 response at 9 consecutive visits were similar in the tofacitinib 5 mg and 10 mg sequences. The rates of subjects with ACR50 response at 2 or more consecutive visits through Month 24 was 49.7% (157/316) in the tofacitinib 5 mg sequence and 61.8% (191/309) in the tofacitinib 10 mg sequence (Table 62). Once advanced to tofacitinib, the placebo→tofacitinib sequences had patterns of ACR50 response similar to the pattern shown by the tofacitinib sequences at the start of the study. The overall response rate at 2 or more consecutive visits was 53.2% (42/79) for the placebo→tofacitinib 5 mg sequence and 49.4% (38/77) for the placebo→tofacitinib 10 mg sequence.
- Durability of ACR70 response: The percentage of subjects with ACR70 response at 2 or more consecutive visits through Month 24 was 23.7% (75/316) in the tofacitinib 5 mg sequence and 35.9% (111/309) in the tofacitinib 10 mg sequence (Table 63). The overall response rate at 2 or more consecutive visits was 33.8% (26/77) for the placebo→tofacitinib 10 mg sequence and 29.1% (23/79) for the placebo→tofacitinib 5 mg sequence.

Table 61. Rates (%) of Subjects With Consecutive Visits With ACR20 Response Through Month 24 (FAS, No Imputation, Comparisons Within Sequence)

Treatment	N	Most Consecutive Visits With Response							
		2 n (%)	3 n (%)	4 n (%)	5 n (%)	6 n (%)	7 n (%)	8 n (%)	9 n (%)
Tofacitinib 5 mg BID	316	38 (12.0)	25 (7.9)	36 (11.4)	21 (6.6)	28 (8.9)	22 (7.0)	23 (7.3)	42 (13.3)
Tofacitinib 10 mg BID	309	27 (8.7)	22 (7.1)	32 (10.4)	23 (7.4)	24 (7.8)	24 (7.8)	29 (9.4)	76 (24.6)
Placebo→Tofacitinib 5 mg BID	79	7 (8.9)	6 (7.6)	5 (6.3)	3 (3.8)	12 (15.2)	17 (21.5)	7 (8.9)	2 (2.5)
Placebo→Tofacitinib 10 mg BID	77	7 (9.1)	4 (5.2)	7 (9.1)	6 (7.8)	4 (5.2)	15 (19.5)	7 (9.1)	3 (3.9)

N refers to the number in each sequence at Baseline, with percent = $100 \times (n/N)$.

Any subjects not counted here had ACR20 response at 0 or 1 visit through Month 24.

A subject was represented only once in each row.

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

ACR20 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis, calculated as a $\geq 20\%$ improvement in tender and swollen joint counts and $\geq 20\%$ improvement in 3 of the 5 remaining ACR core set measures; BID = twice daily; FAS = full analysis set; N = number of subjects; n = number of subjects meeting prespecified criteria.

Table 62. Rates (%) of Subjects With Consecutive Visits With ACR50 Response Through Month 24 (FAS, No Imputation, Comparisons Within Sequence)

Treatment	N	Most Consecutive Visits With Response							
		2 n (%)	3 n (%)	4 n (%)	5 n (%)	6 n (%)	7 n (%)	8 n (%)	9 n (%)
Tofacitinib 5 mg BID	316	44 (13.9)	25 (7.9)	22 (7.0)	19 (6.0)	9 (2.8)	11 (3.5)	11 (3.5)	16 (5.1)
Tofacitinib 10 mg BID	309	42 (13.6)	27 (8.7)	34 (11.0)	13 (4.2)	13 (4.2)	17 (5.5)	24 (7.8)	21 (6.8)
Placebo→Tofacitinib 5 mg BID	79	6 (7.6)	12 (15.2)	6 (7.6)	3 (3.8)	10 (12.7)	5 (6.3)	0	0
Placebo→Tofacitinib 10 mg BID	77	8 (10.4)	5 (6.5)	8 (10.4)	4 (5.2)	7 (9.1)	4 (5.2)	2 (2.6)	0

N refers to the number in each sequence at Baseline, with percent = $100 \times (n/N)$.

Any subjects not counted here had ACR50 response at 0 or 1 visit through Month 24.

A subject is represented only once in each row.

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

ACR50 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis, calculated as a $\geq 50\%$ improvement in tender and swollen joint counts and $\geq 50\%$ improvement in 3 of the 5 remaining ACR core set measures; BID = twice daily; FAS = full analysis set; N = number of subjects; n = number of subjects meeting pre-specified criteria.

Table 63. Rates (%) of Subjects With Consecutive Visits With ACR70 Response Through Month 24 (FAS, No Imputation, Comparisons Within Sequence)

Treatment	N	Most Consecutive Visits With Response							
		2 n (%)	3 n (%)	4 n (%)	5 n (%)	6 n (%)	7 n (%)	8 n (%)	9 n (%)
Tofacitinib 5 mg BID	316	23 (7.3)	16 (5.1)	11 (3.5)	3 (<1.0)	5 (1.6)	6 (1.9)	9 (2.8)	2 (<1.0)
Tofacitinib 10 mg BID	309	31 (10.0)	17 (5.5)	20 (6.5)	11 (3.6)	5 (1.6)	10 (3.2)	14 (4.5)	3 (<1.0)
Placebo→Tofacitinib 5 mg BID	79	8 (10.1)	4 (5.1)	2 (2.5)	3 (3.8)	4 (5.1)	2 (2.5)	0	0
Placebo→Tofacitinib 10 mg BID	77	11 (14.3)	4 (5.2)	4 (5.2)	2 (2.6)	4 (5.2)	1 (1.3)	0	0

N refers to the number in each sequence at Baseline, with percent = $100 \times (n/N)$.

Any subjects not counted here had ACR70 response at 0 or 1 visit through Month 24.

A subject was represented only once in each row.

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

ACR70 = American College of Rheumatology's (ACR) definition for calculating improvement in rheumatoid arthritis, calculated as a $\geq 70\%$ improvement in tender and swollen joint counts and $\geq 70\%$ improvement in 3 of the 5 remaining ACR core set measures; BID = twice daily, FAS = full analysis set; N = number of subjects, n = number of subjects meeting prespecified criteria.

- Durability of DAS Responses:
 - Durability of DAS28-3(CRP) <2.6 response: The percentage of subjects with DAS28-3(CRP) <2.6 response at 2 or more consecutive visits through Month 24 was 43.0% (136/316) in the tofacitinib 5 mg sequence and 54.4% (168/309) in the tofacitinib 10 mg sequence (Table 64). The overall rate of DAS28-3(CRP) <2.6 at 2 or more consecutive visits was 40.5% (32/79) for the placebo→tofacitinib 5 mg sequence and 39.0% (30/77) for the placebo→ tofacitinib 10 mg sequence.
 - Durability of DAS28-4(ESR) <2.6 response: The percentage of subjects with DAS28-4(ESR) <2.6 response at 2 or more consecutive visits through Month 24 was 12.3% (39/316) for the tofacitinib 5 mg sequence (Table 65) and 18.8% (58/309) for the tofacitinib 10 mg sequence. The overall rate of DAS28-4(ESR) <2.6 response at 2 or more consecutive visits was 8.9% (7/79) for the placebo→tofacitinib 5 mg sequence and 14.3% (11/77) for the placebo→ tofacitinib 10 mg sequence.

Table 64. Rates (%) of Subjects With Consecutive Visits With DAS28-3(CRP) <2.6 Response Through Month 24 (FAS, No Imputation, Comparisons Within Sequence)

Treatment	N	Most Consecutive Visits With Response							
		2 n (%)	3 n (%)	4 n (%)	5 n (%)	6 n (%)	7 n (%)	8 n (%)	9 n (%)
Tofacitinib 5 mg BID	316	37 (11.7)	26 (8.2)	19 (6.0)	14 (4.4)	12 (3.8)	12 (3.8)	11 (3.5)	5 (1.6)
Tofacitinib 10 mg BID	309	36 (11.7)	25 (8.1)	27 (8.7)	13 (4.2)	16 (5.2)	20 (6.5)	25 (8.1)	6 (1.9)
Placebo→Tofacitinib 5 mg BID	79	7 (8.9)	3 (3.8)	5 (6.3)	4 (5.1)	7 (8.9)	4 (5.1)	2 (2.5)	0
Placebo→Tofacitinib 10 mg BID	77	5 (6.5)	6 (7.8)	3 (3.9)	2 (2.6)	10 (13.0)	4 (5.2)	0	0

N refers to the number in each sequence at Baseline, with percent = 100×(n/N).

Any subjects not counted here had DAS28-3(CRP) <2.6 response at 0 or 1 visit through Month 24.

A subject is represented only once in each row.

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 advanced 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.

Table 65. Rates (%) of Subjects With Consecutive Visits With DAS28-4(ESR) <2.6 Response Through Month 24 (FAS, No Imputation, Comparisons Within Sequence)

Treatment	N	Most Consecutive Visits With Response							
		2 n (%)	3 n (%)	4 n (%)	5 n (%)	6 n (%)	7 n (%)	8 n (%)	9 n (%)
Tofacitinib 5 mg BID	316	11 (3.5)	10 (3.2)	9 (2.8)	3 (<1.0)	2 (<1.0)	0	4 (1.3)	0
Tofacitinib 10 mg BID	309	20 (6.5)	11 (3.6)	7 (2.3)	5 (1.6)	2 (<1.0)	6 (1.9)	5 (1.6)	2 (<1.0)
Placebo→Tofacitinib 5 mg BID	79	2 (2.5)	4 (5.1)	1 (1.3)	0	0	0	0	0
Placebo→Tofacitinib 10 mg BID	77	4 (5.2)	1 (1.3)	0	3 (3.9)	3 (3.9)	0	0	0

N refers to the number in each sequence at Baseline, with percent = 100×(n/N).

Any subjects not counted here had DAS28-4(ESR) <2.6 response at 0 or 1 visit through Month 24.

A subject is represented only once in each row.

Tofacitinib 5 mg BID or tofacitinib 10 mg BID subjects received this dose from Day 1; placebo subject 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 advanced 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 pre-specified criteria.

- ACR Response Components and Patient Reported Outcomes
 - Patient Global Assessment of Arthritis: All 4 treatment sequences had similar, clinically meaningful decreases from Baseline in pain from Months 12 through 24. The results are presented in Table 66, Table 67, Table 68 and Table 69.

Table 66. Descriptive Statistics of Patient Global Assessment (mm) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	58.03	23.61	0.00	43.00	59.00	76.00	100
	Tofacitinib 10 mg BID	308	56.45	22.96	0.00	43.50	56.00	75.00	100
	Placebo	156	54.12	22.88	5.00	41.50	51.50	70.50	98
Month 1	Tofacitinib 5 mg BID	309	41.26	23.69	0.00	22.00	43.00	61.00	97.00
	Tofacitinib 10 mg BID	308	34.95	21.43	0.00	18.00	33.00	50.76	94.00
	Placebo	153	48.30	24.47	1.00	31.00	49.00	65.00	100.00
Month 3	Tofacitinib 5 mg BID	295	35.07	22.68	0.00	15.00	35.00	50.00	99.00
	Tofacitinib 10 mg BID	300	29.11	20.54	0.00	11.00	25.50	43.50	94.00
	Placebo	146	46.96	24.09	0.00	29.00	49.00	60.00	100.00
Month 6	Tofacitinib 5 mg BID	281	33.50	22.34	0.00	14.00	30.00	51.00	98.00
	Tofacitinib 10 mg BID	284	28.80	22.34	0.00	10.00	24.00	45.00	100.00
	Placebo	62	38.87	23.17	3.00	20.00	38.00	52.00	100.00
	Placebo→5 mg	40	35.05	23.44	1.00	14.50	32.00	53.00	99.00
	Placebo→10 mg	36	30.50	24.49	1.00	9.00	24.00	51.50	96.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 67. Descriptive Statistics of Patient Global Assessment (mm) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	58.03	23.61	0.00	43.00	59.00	76.00	100.00
	Tofacitinib 10 mg BID	308	56.45	22.96	0.00	43.50	56.00	75.00	100.00
	Placebo→Tofacitinib 5 mg BID	79	54.60	20.10	11.00	42.00	53.00	69.00	96.00
	Placebo→Tofacitinib 10 mg BID	77	53.62	25.54	5.00	36.00	51.00	73.00	98.00
Month 1	Tofacitinib 5 mg BID	309	41.26	23.69	0.00	22.00	43.00	61.00	97.00
	Tofacitinib 10 mg BID	308	34.95	21.43	0.00	18.00	33.00	50.76	94.00
	Placebo→Tofacitinib 5 mg BID	79	50.61	25.74	5.00	30.00	53.00	69.00	100.00
	Placebo→Tofacitinib 10 mg BID	74	45.84	22.96	1.00	31.00	48.00	62.00	97.00
Month 3	Tofacitinib 5 mg BID	295	35.07	22.68	0.00	15.00	35.00	50.00	99.00
	Tofacitinib 10 mg BID	300	29.11	20.54	0.00	11.00	25.50	43.50	94.00
	Placebo→Tofacitinib 5 mg BID	75	50.80	24.41	5.00	33.00	52.00	68.00	98.00
	Placebo→Tofacitinib 10 mg BID	71	42.91	23.22	0.00	25.00	45.00	57.00	100.00
Month 6	Tofacitinib 5 mg BID	281	33.50	22.34	0.00	14.00	30.00	51.00	98.00
	Tofacitinib 10 mg BID	284	28.80	22.34	0.00	10.00	24.00	45.00	100.00
	Placebo→Tofacitinib 5 mg BID	71	37.55	24.38	1.00	17.00	36.00	54.00	99.00
	Placebo→Tofacitinib 10 mg BID	67	33.49	22.90	1.00	16.00	29.00	51.00	100.00
Month 9	Tofacitinib 5 mg BID	266	31.30	22.13	0.00	13.00	29.00	46.00	97.00
	Tofacitinib 10 mg BID	279	28.15	22.48	0.00	9.00	23.00	43.00	96.00
	Placebo→Tofacitinib 5 mg BID	68	31.43	23.39	0.00	14.50	23.50	47.00	92.00
	Placebo→Tofacitinib 10 mg BID	63	27.41	23.22	1.00	8.00	21.00	45.00	94.00
Month 12	Tofacitinib 5 mg BID	252	31.65	22.59	0.00	12.00	28.00	48.00	98.00
	Tofacitinib 10 mg BID	265	29.12	24.06	0.00	9.00	22.00	47.00	99.00
	Placebo→Tofacitinib 5 mg BID	67	29.6	23.15	0.00	12.00	21.00	46.00	85.00
	Placebo→Tofacitinib 10 mg BID	63	28.11	24.09	1.00	7.00	22.00	42.00	100.00
Month 15	Tofacitinib 5 mg BID	242	32.13	22.63	0.00	13.00	28.50	49.00	100.00
	Tofacitinib 10 mg BID	254	27.68	23.13	0.00	10.00	20.50	44.00	97.00
	Placebo→Tofacitinib 5 mg BID	62	29.15	23.97	1.00	10.00	23.00	42.00	97.00
	Placebo→Tofacitinib 10 mg BID	60	26.28	20.84	2.00	10.00	22.50	39.00	86.00
Month 18	Tofacitinib 5 mg BID	235	32.23	23.70	0.00	11.00	29.00	49.00	97.00
	Tofacitinib 10 mg BID	244	26.79	23.20	0.00	8.00	20.00	41.50	98.00
	Placebo→Tofacitinib 5 mg BID	59	30.08	23.17	0.00	8.00	23.00	52.00	87.00
	Placebo→Tofacitinib 10 mg BID	55	26.51	21.52	0.00	8.00	20.00	44.00	89.00
Month 21	Tofacitinib 5 mg BID	220	31.42	22.89	0.00	10.00	30.00	47.00	96.00
	Tofacitinib 10 mg BID	231	28.52	23.57	0.00	7.00	23.00	44.00	98.00
	Placebo→Tofacitinib 5 mg BID	57	29.60	21.84	0.00	14.00	25.00	43.00	89.00
	Placebo→Tofacitinib 10 mg BID	53	29.45	24.88	1.00	10.00	22.00	46.00	95.00
Month 24	Tofacitinib 5 mg BID	210	30.34	23.39	0.00	10.00	24.00	49.00	94.00
	Tofacitinib 10 mg BID	218	26.05	22.99	0.00	7.00	20.00	40.00	90.00
	Placebo→Tofacitinib 5 mg BID	54	31.69	23.63	1.00	9.00	30.50	49.00	89.00
	Placebo→Tofacitinib 10 mg BID	52	25.12	20.96	1.00	6.00	19.50	40.00	73.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 68. Descriptive Statistics of Change From Baseline of Patient Global Assessment (mm) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-16.7	25.79	-94.0	-31.00	-15.00	0.00	63.00
	Tofacitinib 10 mg BID	307	-21.6	24.49	-91.0	-37.66	-20.00	-4.00	50.00
	Placebo	153	-5.4	20.52	-91.0	-19.00	-4.00	4.00	54.00
Month 3	Tofacitinib 5 mg BID	295	-22.8	27.00	-92.0	-42.00	-23.00	-4.00	50.00
	Tofacitinib 10 mg BID	299	-27.4	26.88	-96.0	-45.00	-25.05	-10.00	69.00
	Placebo	146	-6.3	24.64	-89.0	-20.00	-5.00	6.00	72.00
Month 6	Tofacitinib 5 mg BID	281	-24.0	27.88	-90.0	-43.00	-23.00	-4.00	54.00
	Tofacitinib 10 mg BID	283	-28.3	28.44	-100.0	-47.00	-29.00	-8.00	89.00
	Placebo	62	-14.0	22.95	-69.0	-26.00	-15.50	-1.00	56.00
	Placebo→5 mg	40	-21.0	30.89	-92.0	-36.00	-22.50	0.07	73.00
	Placebo→10 mg	36	-21.7	30.76	-86.0	-38.50	-18.00	-5.00	48.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 69. Descriptive Statistics of Change From Baseline of Patient Global Assessment (mm) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-16.7	25.79	-94.0	-31.00	-15.00	0.00	63.00
	Tofacitinib 10 mg BID	307	-21.6	24.49	-91.0	-37.66	-20.00	-4.00	50.00
Month 3	Placebo→Tofacitinib 5 mg BID	79	-4.0	21.35	-51.0	-19.00	-5.00	11.00	54.00
	Placebo→Tofacitinib 10 mg BID	74	-6.9	19.62	-91.0	-20.00	-2.50	4.00	26.00
	Tofacitinib 5 mg BID	295	-22.8	27.00	-92.0	-42.00	-23.00	-4.00	50.00
	Tofacitinib 10 mg BID	299	-27.4	26.88	-96.0	-45.00	-25.05	-10.00	69.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	-4.4	26.4	-89.0	-20.00	-1.00	10.00	72.00
	Placebo→Tofacitinib 10 mg BID	71	-8.3	22.65	-66.0	-21.00	-9.00	2.00	61.00
	Tofacitinib 5 mg BID	281	-24.0	27.88	-90.0	-43.00	-23.00	-4.00	54.00
	Tofacitinib 10 mg BID	283	-28.3	28.44	100.0	-47.00	-29.00	-8.00	89.00
Month 9	Placebo→Tofacitinib 5 mg BID	71	-18.2	28.00	-92.0	-35.00	-21.00	1.00	73.00
	Placebo→Tofacitinib 10 mg BID	67	-17.9	27.35	-86.0	-31.00	-16.00	-5.00	56.00
	Tofacitinib 5 mg BID	266	-25.9	28.75	-98.0	-47.00	-26.50	-6.00	51.00
	Tofacitinib 10 mg BID	278	-29.3	29.42	-98.0	-50.00	-27.00	-10.00	76.00
Month 12	Placebo→Tofacitinib 5 mg BID	68	-24.2	28.73	-91.0	-40.00	-26.50	-6.50	64.00
	Placebo→Tofacitinib 10 mg BID	63	-23.4	26.94	-86.0	-43.00	-19.00	-5.00	49.00
	Tofacitinib 5 mg BID	252	-25.5	29.47	-95.0	-45.00	-25.00	-5.00	61.00
	Tofacitinib 10 mg BID	264	-27.9	28.82	-99.0	-48.00	-27.00	-9.00	56.00
Month 15	Placebo→Tofacitinib 5 mg BID	67	-26.0	26.03	-82.0	-40.26	-27.00	-8.00	53.00
	Placebo→Tofacitinib 10 mg BID	63	-22.7	26.28	-86.0	-39.00	-18.00	-5.00	35.00
	Tofacitinib 5 mg BID	242	-25.9	28.7	-99.0	-46.00	-26.00	-4.00	44.00
	Tofacitinib 10 mg BID	253	-29.1	29.49	-94.0	-51.00	-29.00	-10.00	62.00
Month 18	Placebo→Tofacitinib 5 mg BID	62	-25.0	28.08	-75.0	-41.00	-27.00	-10.00	53.00
	Placebo→Tofacitinib 10 mg BID	60	-24.3	26.05	-85.0	-39.50	-19.50	-5.70	18.00
	Tofacitinib 5 mg BID	235	-25.5	28.23	-98.0	-47.00	-25.00	-4.00	50.00
	Tofacitinib 10 mg BID	243	-29.3	28.46	-94.0	-50.00	-28.00	-9.00	51.00
Month 21	Placebo→Tofacitinib 5 mg BID	59	-23.9	29.05	-75.0	-44.00	-24.00	-5.00	61.00
	Placebo→Tofacitinib 10 mg BID	55	-21.9	24.01	-80.0	-36.00	-14.00	-6.00	42.00
	Tofacitinib 5 mg BID	220	-26.0	28.76	-90.0	-45.50	-26.00	-7.00	42.00
	Tofacitinib 10 mg BID	230	-28.4	29.11	-94.0	-46.00	-27.00	-9.00	63.00
Month 24	Placebo→Tofacitinib 5 mg BID	57	-24.1	28.27	-69.0	-41.00	-27.00	-6.00	51.00
	Placebo→Tofacitinib 10 mg BID	53	-18.3	22.26	-80.0	-29.00	-18.00	-5.00	24.00
	Tofacitinib 5 mg BID	210	-26.0	28.65	-97.0	-46.00	-28.00	-5.00	50.00
	Tofacitinib 10 mg BID	217	-31.0	27.61	-97.0	-50.00	-29.00	-12.00	38.00
Month 24	Placebo→Tofacitinib 5 mg BID	54	-21.7	26.84	-65.0	-38.00	-22.00	-4.00	63.00
	Placebo→Tofacitinib 10 mg BID	52	-22.4	22.27	-75.0	-36.00	-18.00	-7.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **Tender-Joint Counts:** All 4 treatment sequences had clinically meaningful decreases from Baseline in tender joint counts by Month 12 that were similar and stable from Months 12 through 24. The results are presented in Table 70, Table 71, Table 72 and Table 73.

Table 70. Descriptive Statistics of Tender-Joint Counts per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	24.1	14.01	6.0	13.00	21.00	32.00	68.00
	Tofacitinib 10 mg BID	309	23.0	14.52	6.0	12.00	18.00	30.00	68.00
	Placebo	156	22.9	13.14	6.0	12.00	20.50	30.00	68.00
Month 1	Tofacitinib 5 mg BID	309	16.5	13.52	0.0	6.00	13.00	22.00	68.00
	Tofacitinib 10 mg BID	309	14.4	14.09	0.0	4.00	10.00	19.00	68.00
	Placebo	153	19.2	14.06	0.0	9.00	15.00	26.00	63.00
Month 3	Tofacitinib 5 mg BID	294	12.7	13.71	0.0	3.00	8.00	18.00	66.00
	Tofacitinib 10 mg BID	300	10.2	12.43	0.0	2.00	6.00	14.00	66.00
	Placebo	146	17.8	14.37	0.0	7.00	14.00	25.00	67.00
Month 6	Tofacitinib 5 mg BID	282	10.8	12.83	0.0	2.00	6.00	14.00	68.00
	Tofacitinib 10 mg BID	284	8.4	11.23	0.0	1.00	4.00	11.00	63.00
	Placebo	62	8.7	8.14	0.0	2.00	7.50	12.00	48.00
	Placebo→5 mg	40	14.4	16.66	0.0	3.00	8.00	18.50	67.00
	Placebo→10 mg	37	12.3	14.45	0.0	2.00	7.00	19.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 71. Descriptive Statistics of Tender-Joint Counts per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	24.1	14.01	6.0	13.00	21.00	32.00	68.00
	Tofacitinib 10 mg BID	309	23.0	14.52	6.0	12.00	18.00	30.00	68.00
Month 1	Placebo→Tofacitinib 5 mg BID	79	23.3	13.48	6.0	12.00	22.00	33.00	68.00
	Placebo→Tofacitinib 10 mg BID	77	22.6	12.87	6.0	12.00	20.00	30.00	58.00
	Tofacitinib 5 mg BID	309	16.5	13.52	0.0	6.00	13.00	22.00	68.00
	Tofacitinib 10 mg BID	309	14.4	14.09	0.0	4.00	10.00	19.00	68.00
Month 3	Placebo→Tofacitinib 5 mg BID	79	20.9	15.88	0.0	9.00	17.00	31.00	63.00
	Placebo→Tofacitinib 10 mg BID	74	17.4	11.66	0.0	10.00	14.00	23.00	60.00
	Tofacitinib 5 mg BID	294	12.7	13.71	0.0	3.00	8.00	18.00	66.00
	Tofacitinib 10 mg BID	300	10.2	12.43	0.0	2.00	6.00	14.00	66.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	17.9	13.62	0.0	8.00	15.00	26.00	62.00
	Placebo→Tofacitinib 10 mg BID	71	17.7	15.22	0.0	7.00	13.00	25.00	67.00
	Tofacitinib 5 mg BID	282	10.8	12.83	0.0	2.00	6.00	14.00	68.00
	Tofacitinib 10 mg BID	284	8.4	11.23	0.0	1.00	4.00	11.00	63.00
Month 9	Placebo→Tofacitinib 5 mg BID	71	11.4	13.63	0.0	3.00	7.00	16.00	67.00
	Placebo→Tofacitinib 10 mg BID	68	11.1	12.35	0.0	2.00	7.50	16.00	63.00
	Tofacitinib 5 mg BID	266	9.5	12.33	0.0	2.00	5.00	12.00	61.00
	Tofacitinib 10 mg BID	279	8.0	12.31	0.0	1.00	3.00	9.00	67.00
Month 12	Placebo→Tofacitinib 5 mg BID	68	8.4	12.50	0.0	1.00	3.50	8.50	63.00
	Placebo→Tofacitinib 10 mg BID	63	8.9	12.45	0.0	1.00	6.00	14.00	65.00
	Tofacitinib 5 mg BID	252	8.4	10.43	0.0	1.00	4.00	12.00	57.00
	Tofacitinib 10 mg BID	265	7.1	11.02	0.0	0.00	3.00	9.00	66.00
Month 15	Placebo→Tofacitinib 5 mg BID	67	8.6	10.92	0.0	2.00	4.00	12.00	55.00
	Placebo→Tofacitinib 10 mg BID	63	8.3	9.22	0.0	1.00	5.00	14.00	40.00
	Tofacitinib 5 mg BID	243	7.9	11.16	0.0	1.00	4.00	9.00	63.00
	Tofacitinib 10 mg BID	254	7.1	11.37	0.0	0.00	3.00	8.00	68.00
Month 18	Placebo→Tofacitinib 5 mg BID	62	6.2	8.62	0.0	1.00	2.50	8.00	50.00
	Placebo→Tofacitinib 10 mg BID	60	7.4	10.30	0.0	0.00	4.00	9.50	52.00
	Tofacitinib 5 mg BID	235	7.5	10.54	0.0	1.00	4.00	10.00	68.00
	Tofacitinib 10 mg BID	244	6.7	10.93	0.0	0.00	2.00	8.00	60.00
Month 21	Placebo→Tofacitinib 5 mg BID	59	5.5	7.74	0.0	1.00	3.00	7.00	41.00
	Placebo→Tofacitinib 10 mg BID	55	5.9	8.50	0.0	0.00	2.00	8.00	48.00
	Tofacitinib 5 mg BID	220	7.0	9.81	0.0	1.00	3.00	9.00	58.00
	Tofacitinib 10 mg BID	232	6.0	10.25	0.0	0.00	2.00	8.00	60.00
Month 24	Placebo→Tofacitinib 5 mg BID	57	6.6	8.67	0.0	1.00	3.00	8.00	41.00
	Placebo→Tofacitinib 10 mg BID	53	6.1	8.61	0.0	0.00	3.00	8.00	36.00
	Tofacitinib 5 mg BID	211	8.2	11.97	0.0	1.00	4.00	10.00	66.00
	Tofacitinib 10 mg BID	218	5.6	10.21	0.0	0.00	2.00	6.00	62.00
Month 24	Placebo→Tofacitinib 5 mg BID	54	5.8	8.13	0.0	1.00	3.00	7.0	34.00
	Placebo→Tofacitinib 10 mg BID	52	6.2	9.54	0.0	0.00	2.00	6.50	36.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 72. Descriptive Statistics of Change From Baseline of Tender-Joint Counts per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-7.6	10.80	-57.0	-12.00	-6.00	-2.00	26.00
	Tofacitinib 10 mg BID	309	-8.6	10.80	-54.0	-12.00	-7.00	-3.00	24.00
	Placebo	153	-3.7	9.54	-43.0	-8.00	-3.00	1.00	19.00
Month 3	Tofacitinib 5 mg BID	294	-11.4	12.78	-61.0	-17.00	-10.00	-4.00	26.00
	Tofacitinib 10 mg BID	300	-12.8	11.34	-56.0	-19.00	-11.00	-6.00	30.00
	Placebo	146	-5.3	10.87	-48.0	-11.00	-5.00	1.00	24.00
Month 6	Tofacitinib 5 mg BID	282	-13.2	12.33	-60.0	-20.00	-11.00	-6.00	38.00
	Tofacitinib 10 mg BID	284	-14.5	12.79	-57.0	-19.00	-12.00	-7.00	24.00
	Placebo	62	-13.3	11.74	-68.0	-18.00	-11.00	-5.00	2.00
	Placebo→5 mg	40	-9.2	12.73	-38.0	-17.00	-8.50	-3.50	33.00
	Placebo→10 mg	37	-12.0	12.77	-42.0	-16.00	-11.00	-6.00	18.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 73. Descriptive Statistics of Change From Baseline of Tender-Joint Counts per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-7.6	10.80	-57.0	-12.00	-6.00	-2.00	26.00
	Tofacitinib 10 mg BID	309	-8.6	10.80	-54.0	-12.00	-7.00	-3.00	24.00
	Placebo→Tofacitinib 5 mg BID	79	-2.4	9.17	-28.0	-7.00	-2.00	2.00	19.00
	Placebo→Tofacitinib 10 mg BID	74	-5.0	9.80	-43.0	-9.00	-3.50	1.00	12.00
Month 3	Tofacitinib 5 mg BID	294	-11.4	12.78	-61.0	-17.00	-10.00	-4.00	26.00
	Tofacitinib 10 mg BID	300	-12.8	11.34	-56.0	-19.00	-11.00	-6.00	30.00
	Placebo→Tofacitinib 5 mg BID	75	-5.4	11.66	-48.0	-12.00	-4.00	1.00	17.00
	Placebo→Tofacitinib 10 mg BID	71	-5.1	10.04	-29.0	-10.00	-6.00	1.00	24.00
Month 6	Tofacitinib 5 mg BID	282	-13.2	12.33	-60.0	-20.00	-11.00	-6.00	38.00
	Tofacitinib 10 mg BID	284	-14.5	12.79	-57.0	-19.00	-12.00	-7.00	24.00
	Placebo→Tofacitinib 5 mg BID	71	-11.8	13.77	-68.0	-18.00	-10.00	-4.00	33.00
	Placebo→Tofacitinib 10 mg BID	68	-11.7	10.74	-42.0	-15.00	-11.00	-5.50	18.00
Month 9	Tofacitinib 5 mg BID	266	-14.1	12.89	-60.0	-20.00	-12.00	-6.00	35.00
	Tofacitinib 10 mg BID	279	-15.0	12.77	-62.0	-19.00	-13.00	-8.00	26.00
	Placebo→Tofacitinib 5 mg BID	68	-14.6	10.91	-43.0	-23.00	-12.00	-6.00	5.00
	Placebo→Tofacitinib 10 mg BID	63	-13.8	12.92	-46.0	-17.00	-12.00	-8.00	39.00
Month 12	Tofacitinib 5 mg BID	252	-15.4	11.97	-60.0	-21.00	-13.00	-7.00	17.00
	Tofacitinib 10 mg BID	265	-15.7	12.29	-64.0	-19.00	-13.00	-8.00	12.00
	Placebo→Tofacitinib 5 mg BID	67	-14.5	11.52	-46.0	-21.00	-12.00	-7.00	17.00
	Placebo→Tofacitinib 10 mg BID	63	-14.4	10.48	-40.0	-19.00	-12.00	-8.00	9.00
Month 15	Tofacitinib 5 mg BID	243	-16.0	12.79	-60.0	-22.00	-14.00	-9.00	28.00
	Tofacitinib 10 mg BID	254	-15.9	12.99	-64.0	-20.00	-14.00	-8.00	16.00
	Placebo→Tofacitinib 5 mg BID	62	-16.2	13.99	-66.0	-24.00	-13.50	-7.00	15.00
	Placebo→Tofacitinib 10 mg BID	60	-15.3	11.65	-47.0	-21.00	-13.50	-9.00	14.00
Month 18	Tofacitinib 5 mg BID	235	-16.4	12.74	-60.0	-23.00	-14.00	-8.00	33.00
	Tofacitinib 10 mg BID	244	-15.9	13.11	-66.0	-21.00	-14.00	-8.00	15.00
	Placebo→Tofacitinib 5 mg BID	59	-15.9	11.79	-50.0	-22.00	-13.00	-7.00	10.00
	Placebo→Tofacitinib 10 mg BID	55	-15.4	12.32	-50.0	-19.00	-15.00	-9.00	22.00
Month 21	Tofacitinib 5 mg BID	220	-17.1	13.12	-60.0	-24.00	-15.00	-8.00	19.00
	Tofacitinib 10 mg BID	232	-16.5	13.49	-66.0	-22.00	-14.50	-8.00	36.00
	Placebo→Tofacitinib 5 mg BID	57	-15.2	12.21	-49.0	-22.00	-13.00	-8.00	22.00
	Placebo→Tofacitinib 10 mg BID	53	-15.4	9.87	-44.0	-18.00	-15.00	-9.00	9.00
Month 24	Tofacitinib 5 mg BID	211	-15.6	13.93	-60.0	-22.00	-14.00	-8.00	39.00
	Tofacitinib 10 mg BID	218	-16.8	13.45	-65.0	-22.00	-15.00	-9.00	25.00
	Placebo→Tofacitinib 5 mg BID	54	-15.5	10.98	-47.0	-22.00	-13.00	-8.00	3.00
	Placebo→Tofacitinib 10 mg BID	52	-15.5	11.58	-57.0	-20.00	-15.00	-9.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **Swollen Joint Counts:** All 4 treatment sequences had clinically meaningful decreases from Baseline in swollen joint counts by Month 12 that were maintained from Month 12 through Month 24. The results are presented in Table 74, Table 75, Table 76 and Table 77.

Table 74. Descriptive Statistics of Swollen-Joint Counts per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	14.1	8.21	6.0	8.00	12.00	17.00	58.00
	Tofacitinib 10 mg BID	309	14.4	7.71	6.0	9.00	12.00	18.00	47.00
	Placebo	156	14.2	8.38	6.0	8.00	12.00	18.00	55.00
Month 1	Tofacitinib 5 mg BID	309	8.5	7.62	0.0	3.00	7.00	11.00	48.00
	Tofacitinib 10 mg BID	309	9.0	8.70	0.0	3.00	7.00	12.00	66.00
	Placebo	153	11.3	8.91	0.0	5.00	9.00	16.00	41.00
Month 3	Tofacitinib 5 mg BID	294	5.9	8.01	0.0	1.00	4.00	8.00	62.00
	Tofacitinib 10 mg BID	300	5.6	6.71	0.0	1.00	4.00	8.00	60.00
	Placebo	146	10.3	9.35	0.0	3.00	8.00	14.00	54.00
Month 6	Tofacitinib 5 mg BID	282	4.8	6.28	0.0	0.00	3.00	7.00	51.00
	Tofacitinib 10 mg BID	284	3.9	5.04	0.0	0.00	2.00	6.00	33.00
	Placebo	62	5.0	4.63	0.0	2.00	3.50	7.00	26.00
	Placebo→5 mg	40	6.1	7.27	0.0	1.50	2.50	7.50	25.00
	Placebo→10 mg	37	6.6	8.61	0.0	1.00	4.00	8.00	42.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 75. Descriptive Statistics of Swollen-Joint Counts per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	14.1	8.21	6.0	8.00	12.00	17.00	58.00
	Tofacitinib 10 mg BID	309	14.4	7.71	6.0	9.00	12.00	18.00	47.00
Month 1	Placebo→Tofacitinib 5 mg BID	79	14.0	7.90	6.0	8.00	12.00	19.00	45.00
	Placebo→Tofacitinib 10 mg BID	77	14.5	8.89	6.0	8.00	12.00	17.00	55.00
	Tofacitinib 5 mg BID	309	8.5	7.62	0.0	3.00	7.00	11.00	48.00
	Tofacitinib 10 mg BID	309	9.0	8.70	0.0	3.00	7.00	12.00	66.00
Month 3	Placebo→Tofacitinib 5 mg BID	79	11.4	9.20	1.0	4.00	9.00	16.00	41.00
	Placebo→Tofacitinib 10 mg BID	74	11.2	8.66	0.0	6.00	9.00	16.00	37.00
	Tofacitinib 5 mg BID	294	5.9	8.01	0.0	1.00	4.00	8.00	62.00
	Tofacitinib 10 mg BID	300	5.6	6.71	0.0	1.00	4.00	8.00	60.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	9.5	7.68	0.0	3.00	8.00	15.00	36.00
	Placebo→Tofacitinib 10 mg BID	71	11.1	10.84	0.0	4.00	8.00	14.00	54.00
	Tofacitinib 5 mg BID	282	4.8	6.28	0.0	0.00	3.00	7.00	51.00
	Tofacitinib 10 mg BID	284	3.9	5.04	0.0	0.00	2.00	6.00	33.00
Month 9	Placebo→Tofacitinib 5 mg BID	71	5.2	6.20	0.0	1.00	3.00	7.00	25.00
	Placebo→Tofacitinib 10 mg BID	68	6.3	7.09	0.0	2.00	5.00	8.00	42.00
	Tofacitinib 5 mg BID	266	3.8	5.72	0.0	0.00	2.00	5.00	37.00
	Tofacitinib 10 mg BID	279	3.6	5.01	0.0	0.00	2.00	5.00	31.00
Month 12	Placebo→Tofacitinib 5 mg BID	68	3.4	5.00	0.0	0.00	1.00	5.00	26.00
	Placebo→Tofacitinib 10 mg BID	63	4.6	6.45	0.0	0.00	3.00	6.00	38.00
	Tofacitinib 5 mg BID	252	3.5	5.71	0.0	0.00	2.00	5.00	49.00
	Tofacitinib 10 mg BID	265	3.0	4.50	0.0	0.00	1.00	4.00	28.00
Month 15	Placebo→Tofacitinib 5 mg BID	67	3.7	5.07	0.0	0.00	1.00	5.00	25.00
	Placebo→Tofacitinib 10 mg BID	63	5.1	8.22	0.0	0.00	2.00	6.00	44.00
	Tofacitinib 5 mg BID	243	3.4	5.31	0.0	0.00	2.00	4.00	36.00
	Tofacitinib 10 mg BID	254	2.9	4.67	0.0	0.00	1.00	4.00	34.00
Month 18	Placebo→Tofacitinib 5 mg BID	62	2.7	3.14	0.0	0.00	2.00	4.00	14.00
	Placebo→Tofacitinib 10 mg BID	60	4.2	7.99	0.0	0.00	2.00	5.00	43.00
	Tofacitinib 5 mg BID	235	3.1	5.05	0.0	0.00	1.00	5.00	37.00
	Tofacitinib 10 mg BID	244	3.1	4.84	0.0	0.00	1.00	4.00	29.00
Month 21	Placebo→Tofacitinib 5 mg BID	59	2.8	3.61	0.0	0.00	2.00	5.00	17.00
	Placebo→Tofacitinib 10 mg BID	55	3.0	6.51	0.0	0.00	1.00	3.00	42.00
	Tofacitinib 5 mg BID	220	3.2	4.88	0.0	0.00	1.00	5.00	34.00
	Tofacitinib 10 mg BID	232	3.1	4.43	0.0	0.00	1.00	4.50	26.00
Month 24	Placebo→Tofacitinib 5 mg BID	57	3.1	4.93	0.0	0.00	1.00	4.00	26.00
	Placebo→Tofacitinib 10 mg BID	53	3.9	7.35	0.0	0.00	1.00	4.00	34.00
	Tofacitinib 5 mg BID	211	2.8	4.11	0.0	0.00	1.00	4.00	23.00
	Tofacitinib 10 mg BID	218	2.4	4.31	0.0	0.00	1.00	3.00	29.00
Month 24	Placebo→Tofacitinib 5 mg BID	54	2.1	3.03	0.0	0.00	1.00	3.00	15.00
	Placebo→Tofacitinib 10 mg BID	52	3.4	7.00	0.0	0.00	1.00	3.00	35.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 76. Descriptive Statistics of Change From Baseline of Swollen-Joint Counts per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-5.7	6.92	-32.0	-9.00	-5.00	-2.00	30.00
	Tofacitinib 10 mg BID	309	-5.4	7.82	-40.0	-8.00	-5.00	-2.00	52.00
	Placebo	153	-2.9	7.15	-33.0	-6.00	-3.00	0.00	30.00
Month 3	Tofacitinib 5 mg BID	294	-8.2	8.41	-40.0	-11.00	-7.00	-5.00	45.00
	Tofacitinib 10 mg BID	300	-8.7	7.78	-41.0	-12.00	-8.00	-5.00	47.00
	Placebo	146	-3.9	6.84	-28.0	-8.00	-4.00	0.00	24.00
Month 6	Tofacitinib 5 mg BID	282	-9.4	7.73	-46.0	-13.00	-8.00	-5.00	9.00
	Tofacitinib 10 mg BID	284	-10.5	6.75	-37.0	-14.00	-9.00	-6.00	10.00
	Placebo	62	-8.5	6.67	-37.0	-10.00	-7.00	-5.00	2.00
	Placebo→5 mg	40	-7.4	7.22	-24.0	-11.50	-7.00	-4.00	14.00
	Placebo→10 mg	37	-9.3	8.13	-40.0	-13.00	-8.00	-4.00	5.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 77. Descriptive Statistics of Change From Baseline of Swollen-Joint Counts per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-5.7	6.92	-32.0	-9.00	-5.00	-2.00	30.00
	Tofacitinib 10 mg BID	309	-5.4	7.82	-40.0	-8.00	-5.00	-2.00	52.00
	Placebo→Tofacitinib 5 mg BID	79	-2.6	7.43	-26.0	-6.00	-3.00	0.00	30.00
	Placebo→Tofacitinib 10 mg BID	74	-3.3	6.86	-33.0	-6.00	-3.00	0.00	18.00
Month 3	Tofacitinib 5 mg BID	294	-8.2	8.41	-40.0	-11.00	-7.00	-5.00	45.00
	Tofacitinib 10 mg BID	300	-8.7	7.78	-41.0	-12.00	-8.00	-5.00	47.00
	Placebo→Tofacitinib 5 mg BID	75	-4.3	7.17	-28.0	-8.00	-4.00	0.00	17.00
	Placebo→Tofacitinib 10 mg BID	71	-3.5	6.49	-20.0	-7.00	-4.00	0.00	24.00
Month 6	Tofacitinib 5 mg BID	282	-9.4	7.73	-46.0	-13.00	-8.00	-5.00	9.00
	Tofacitinib 10 mg BID	284	-10.5	6.75	-37.0	-14.00	-9.00	-6.00	10.00
	Placebo→Tofacitinib 5 mg BID	71	-8.6	7.63	-37.0	-12.00	-7.00	-5.00	14.00
	Placebo→Tofacitinib 10 mg BID	68	-8.1	6.82	-40.0	-11.00	-7.00	-4.00	5.00
Month 9	Tofacitinib 5 mg BID	266	-10.3	7.89	-47.0	-13.00	-9.00	-6.00	21.00
	Tofacitinib 10 mg BID	279	-10.8	7.30	-43.0	-14.00	-9.00	-6.00	12.00
	Placebo→Tofacitinib 5 mg BID	68	-10.5	7.01	-44.0	-14.00	-9.00	-6.00	1.00
	Placebo→Tofacitinib 10 mg BID	63	-9.8	7.51	-46.0	-14.00	-10.00	-6.00	7.00
Month 12	Tofacitinib 5 mg BID	252	-10.5	7.92	-48.0	-13.50	-9.00	-6.00	20.00
	Tofacitinib 10 mg BID	265	-11.2	7.15	-43.0	-14.00	-10.00	-7.00	7.00
	Placebo→Tofacitinib 5 mg BID	67	-10.4	7.27	-44.0	-14.00	-10.00	-6.00	9.00
	Placebo→Tofacitinib 10 mg BID	63	-9.3	6.18	-30.0	-13.00	-9.00	-6.00	8.00
Month 15	Tofacitinib 5 mg BID	243	-10.4	8.41	-48.0	-13.00	-9.00	-6.00	25.00
	Tofacitinib 10 mg BID	254	-11.4	7.90	-43.0	-14.00	-10.00	-7.00	15.00
	Placebo→Tofacitinib 5 mg BID	62	-11.1	7.08	-38.0	-15.00	-8.50	-6.00	-2.00
	Placebo→Tofacitinib 10 mg BID	60	-10.1	8.44	-49.0	-14.00	-9.50	-6.00	22.00
Month 18	Tofacitinib 5 mg BID	235	-10.7	8.26	-48.0	-13.00	-9.00	-6.00	24.00
	Tofacitinib 10 mg BID	244	-11.2	8.00	-39.0	-14.00	-10.00	-7.00	10.00
	Placebo→Tofacitinib 5 mg BID	59	-10.9	7.75	-41.0	-14.00	-9.00	-6.00	11.00
	Placebo→Tofacitinib 10 mg BID	55	-10.2	5.50	-27.0	-14.00	-9.00	-6.00	4.00
Month 21	Tofacitinib 5 mg BID	220	-10.6	8.78	-48.0	-13.00	-9.00	-6.00	24.00
	Tofacitinib 10 mg BID	232	-11.3	7.65	-41.0	-15.00	-10.00	-6.00	14.00
	Placebo→Tofacitinib 5 mg BID	57	-10.8	9.17	-44.0	-15.00	-9.00	-6.00	20.00
	Placebo→Tofacitinib 10 mg BID	53	-9.2	6.62	-24.0	-13.00	-9.00	-6.00	9.00
Month 24	Tofacitinib 5 mg BID	211	-10.9	8.22	-48.0	-13.00	-9.00	-6.00	10.00
	Tofacitinib 10 mg BID	218	-11.8	7.80	-41.0	-16.00	-10.00	-7.00	21.00
	Placebo→Tofacitinib 5 mg BID	54	-11.5	7.83	-44.0	-14.00	-9.50	-6.00	1.00
	Placebo→Tofacitinib 10 mg BID	52	-9.9	6.38	-24.0	-13.50	-10.00	-6.50	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **Physician Global Assessment of Arthritis:** All 4 treatment sequences had similar, clinically meaningful decreases from Baseline in Physician Global Assessment of Arthritis from Months 12 through 24. The results are presented in Table 78, Table 79, Table 80 and Table 81.

Table 78. Descriptive Statistics of Physician Global Assessment (mm) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	59.44	15.87	6.00	49.00	59.00	71.00	97.00
	Tofacitinib 10 mg BID	309	58.42	17.08	12.00	49.00	58.00	69.00	100.00
	Placebo	156	55.90	17.39	14.00	44.00	55.00	70.00	95.00
Month 1	Tofacitinib 5 mg BID	309	37.97	18.58	0.00	24.00	37.00	52.00	84.00
	Tofacitinib 10 mg BID	308	35.19	19.29	0.00	21.00	33.00	49.50	92.00
	Placebo	152	45.50	19.57	3.00	31.00	45.00	56.50	98.00
Month 3	Tofacitinib 5 mg BID	294	30.12	18.61	1.00	14.00	27.00	42.00	88.00
	Tofacitinib 10 mg BID	300	24.47	17.51	1.00	11.00	21.00	36.00	88.00
	Placebo	146	43.29	22.25	2.00	25.00	43.00	59.00	100.00
Month 6	Tofacitinib 5 mg BID	282	25.52	18.63	0.00	10.00	21.00	36.00	80.00
	Tofacitinib 10 mg BID	283	20.34	15.68	0.00	8.00	18.00	28.00	71.00
	Placebo	61	26.61	17.73	4.00	15.00	22.00	36.00	84.00
	Placebo→5 mg	40	24.70	18.56	2.00	11.00	19.50	35.50	70.00
	Placebo→10 mg	37	28.30	21.24	1.00	15.00	23.00	36.00	81.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 79. Descriptive Statistics of Physician Global Assessment (mm) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	59.44	15.87	6.00	49.00	59.00	71.00	97.00
	Tofacitinib 10 mg BID	309	58.42	17.08	12.00	49.00	58.00	69.00	100.0
Month 1	Placebo→Tofacitinib 5 mg BID	79	55.36	18.36	14.00	43.00	56.00	70.00	94.00
	Placebo→Tofacitinib 10 mg BID	77	56.46	16.43	21.00	46.00	54.00	70.00	95.00
	Tofacitinib 5 mg BID	309	37.97	18.58	0.00	24.00	37.00	52.00	84.00
	Tofacitinib 10 mg BID	308	35.19	19.29	0.00	21.00	33.00	49.50	92.00
Month 3	Placebo→Tofacitinib 5 mg BID	79	46.54	19.93	3.00	31.00	47.00	59.00	96.00
	Placebo→Tofacitinib 10 mg BID	73	44.37	19.24	7.00	31.00	44.00	56.00	98.00
	Tofacitinib 5 mg BID	294	30.12	18.61	1.00	14.00	27.00	42.00	88.00
	Tofacitinib 10 mg BID	300	24.47	17.51	1.00	11.00	21.00	36.00	88.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	44.12	24.07	4.00	24.00	42.00	60.00	100.0
	Placebo→Tofacitinib 10 mg BID	71	42.41	20.29	2.00	28.00	44.00	59.00	84.00
	Tofacitinib 5 mg BID	282	25.52	18.63	0.00	10.00	21.00	36.00	80.00
	Tofacitinib 10 mg BID	283	20.34	15.68	0.00	8.00	18.00	28.00	71.00
Month 9	Placebo→Tofacitinib 5 mg BID	70	25.22	17.80	2.00	13.00	21.03	34.00	78.00
	Placebo→Tofacitinib 10 mg BID	68	27.84	19.95	1.00	14.00	22.00	38.00	84.00
	Tofacitinib 5 mg BID	265	21.61	16.15	0.00	9.00	19.00	29.00	80.00
	Tofacitinib 10 mg BID	279	19.00	15.94	0.00	7.00	15.00	27.00	96.00
Month 12	Placebo→Tofacitinib 5 mg BID	68	20.02	17.70	0.00	8.21	14.50	24.00	80.00
	Placebo→Tofacitinib 10 mg BID	62	19.29	15.53	0.00	7.00	16.50	26.00	69.00
	Tofacitinib 5 mg BID	252	20.33	15.72	0.00	8.00	16.00	29.00	78.00
	Tofacitinib 10 mg BID	265	17.97	15.08	0.00	7.00	15.00	24.00	84.00
Month 15	Placebo→Tofacitinib 5 mg BID	67	20.42	16.63	0.00	8.00	16.00	33.00	66.00
	Placebo→Tofacitinib 10 mg BID	63	18.79	15.42	0.00	7.00	15.00	27.00	77.00
	Tofacitinib 5 mg BID	242	20.81	15.11	0.00	9.00	18.00	30.00	70.00
	Tofacitinib 10 mg BID	254	16.72	13.72	0.00	5.00	13.00	25.00	60.00
Month 18	Placebo→Tofacitinib 5 mg BID	62	17.77	15.40	0.00	6.00	12.00	23.00	66.00
	Placebo→Tofacitinib 10 mg BID	60	18.78	13.15	0.00	8.00	15.00	25.00	60.00
	Tofacitinib 5 mg BID	235	20.17	15.18	0.00	8.00	17.00	30.00	88.00
	Tofacitinib 10 mg BID	244	17.99	15.64	0.00	6.00	13.50	25.00	69.00
Month 21	Placebo→Tofacitinib 5 mg BID	59	15.90	14.48	0.00	5.00	12.00	22.00	61.00
	Placebo→Tofacitinib 10 mg BID	55	17.06	13.49	0.00	7.00	13.00	26.00	69.00
	Tofacitinib 5 mg BID	220	18.38	14.81	0.00	7.00	14.00	27.00	68.00
	Tofacitinib 10 mg BID	232	17.38	16.40	0.00	4.00	12.00	26.00	79.00
Month 24	Placebo→Tofacitinib 5 mg BID	57	19.68	17.72	0.00	7.00	15.00	26.00	77.00
	Placebo→Tofacitinib 10 mg BID	53	15.25	11.82	0.00	5.00	13.00	24.00	48.00
	Tofacitinib 5 mg BID	209	17.45	14.24	0.00	6.00	14.00	26.00	66.00
	Tofacitinib 10 mg BID	218	14.49	13.81	0.00	4.00	10.00	20.00	68.00
Month 24	Placebo→Tofacitinib 5 mg BID	54	15.04	12.97	0.00	5.00	11.00	23.00	53.00
	Placebo→Tofacitinib 10 mg BID	52	13.36	11.96	0.00	3.50	9.50	20.50	52.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 80. Descriptive Statistics of Change From Baseline of Physician Global Assessment (mm) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-21.7	18.34	-78.0	-34.00	-20.00	-9.00	19.00
	Tofacitinib 10 mg BID	308	-23.2	20.05	-86.0	-36.00	-22.00	-10.00	38.00
	Placebo	152	-9.9	18.18	-79.0	-20.00	-10.00	3.00	31.00
Month 3	Tofacitinib 5 mg BID	294	-29.7	20.95	-84.0	-44.00	-30.00	-15.00	23.00
	Tofacitinib 10 mg BID	300	-33.9	21.52	-92.0	-48.00	-34.00	-20.00	46.00
	Placebo	146	-12.0	23.64	-79.0	-26.00	-11.50	2.00	50.00
Month 6	Tofacitinib 5 mg BID	282	-34.2	20.00	-86.0	-47.00	-35.00	-21.00	29.00
	Tofacitinib 10 mg BID	283	-38.2	20.54	-100.0	-53.00	-39.00	-26.00	21.00
	Placebo	61	-27.9	20.88	-74.0	-40.00	-26.00	-12.00	24.00
	Placebo→5 mg	40	-31.2	17.58	-79.0	-36.50	-31.00	-19.50	8.00
	Placebo→10 mg	37	-27.6	24.24	-63.0	-46.00	-33.00	-11.00	25.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 81. Descriptive Statistics of Change From Baseline of Physician Global Assessment (mm) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-21.7	18.34	-78.0	-34.00	-20.00	-9.00	19.00
	Tofacitinib 10 mg BID	308	-23.2	20.05	-86.0	-36.00	-22.00	-10.00	38.00
Month 3	Placebo→Tofacitinib 5 mg BID	79	-8.8	17.82	-79.0	-17.00	-10.00	4.00	31.00
	Placebo→Tofacitinib 10 mg BID	73	-11.1	18.60	-66.0	-24.00	-10.00	3.00	22.00
	Tofacitinib 5 mg BID	294	-29.7	20.95	-84.0	-44.00	-30.00	-15.00	23.00
	Tofacitinib 10 mg BID	300	-33.9	21.52	-92.0	-48.00	-34.00	-20.00	46.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	-11.6	26.93	-79.0	-27.00	-12.00	8.00	47.00
	Placebo→Tofacitinib 10 mg BID	71	-12.4	19.78	-58.0	-26.00	-10.00	0.00	50.00
	Tofacitinib 5 mg BID	282	-34.2	20.00	-86.0	-47.00	-35.00	-21.00	29.00
	Tofacitinib 10 mg BID	283	-38.2	20.54	-100.0	-53.00	-39.00	-26.00	21.00
Month 9	Placebo→Tofacitinib 5 mg BID	70	-30.6	19.42	-79.0	-37.00	-29.00	-19.00	24.00
	Placebo→Tofacitinib 10 mg BID	68	-26.9	22.27	-74.0	-43.00	-26.50	-9.00	25.00
	Tofacitinib 5 mg BID	265	-37.6	18.36	-85.0	-49.00	-38.00	-25.00	16.00
	Tofacitinib 10 mg BID	279	-39.5	20.33	-92.0	-52.00	-39.00	-26.00	43.00
Month 12	Placebo→Tofacitinib 5 mg BID	68	-35.9	19.51	-89.0	-47.00	-35.00	-23.50	2.00
	Placebo→Tofacitinib 10 mg BID	62	-35.5	19.79	-83.0	-48.00	-37.77	-25.00	5.00
	Tofacitinib 5 mg BID	252	-38.8	19.59	-88.0	-52.00	-40.00	-27.00	38.00
	Tofacitinib 10 mg BID	265	-40.1	18.87	-94.0	-52.00	-40.00	-29.00	14.00
Month 15	Placebo→Tofacitinib 5 mg BID	67	-35.5	20.24	-91.0	-47.00	-37.00	-23.00	16.00
	Placebo→Tofacitinib 10 mg BID	63	-35.9	19.45	-71.0	-49.00	-38.00	-25.00	9.00
	Tofacitinib 5 mg BID	242	-38.5	19.14	-84.0	-50.00	-39.50	-28.00	30.00
	Tofacitinib 10 mg BID	254	-41.4	19.28	-100.0	-55.00	-41.50	-29.00	14.00
Month 18	Placebo→Tofacitinib 5 mg BID	62	-37.1	20.96	-90.0	-45.00	-37.50	-25.00	11.00
	Placebo→Tofacitinib 10 mg BID	60	-35.8	18.15	-86.0	-46.00	-37.50	-25.00	-1.00
	Tofacitinib 5 mg BID	235	-39.3	20.02	-86.0	-53.00	-39.00	-28.00	39.00
	Tofacitinib 10 mg BID	244	-40.0	20.50	-100.0	-53.50	-42.00	-27.50	22.00
Month 21	Placebo→Tofacitinib 5 mg BID	59	-37.8	18.97	-90.0	-46.00	-36.00	-25.00	9.00
	Placebo→Tofacitinib 10 mg BID	55	-36.6	19.67	-84.0	-49.00	-38.00	-24.00	8.00
	Tofacitinib 5 mg BID	220	-41.5	19.88	-91.0	-53.00	-40.50	-31.00	28.00
	Tofacitinib 10 mg BID	232	-40.7	20.36	-100.0	-53.00	-42.00	-29.00	18.00
Month 24	Placebo→Tofacitinib 5 mg BID	57	-33.9	22.84	-90.0	-46.00	-36.00	-22.00	57.00
	Placebo→Tofacitinib 10 mg BID	53	-38.5	16.25	-86.0	-46.00	-41.00	-28.00	-10.00
	Tofacitinib 5 mg BID	209	-42.5	18.71	-89.00	-54.00	-42.00	-30.00	14.00
	Tofacitinib 10 mg BID	218	-43.4	19.00	-100.00	-56.00	-43.50	-32.00	17.00
Month 24	Placebo→Tofacitinib 5 mg BID	54	-38.1	20.26	-90.00	-49.00	-39.00	-23.00	9.00
	Placebo→Tofacitinib 10 mg BID	52	-40.4	18.70	-84.00	-51.00	-43.50	-29.50	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **Patient Assessment of Arthritis Pain:** Subjects assessed the severity of their arthritis pain using a 100 mm visual analog scale (VAS) placing a mark on the scale between 0 (no pain) and 100 (most severe pain), which corresponds to the magnitude of their pain. All 4 treatment sequences had similar, clinically meaningful decreases from Baseline in pain from Months 12 through 24. The results are summarized in Table 82, Table 83, Table 84 and Table 85.

Table 82. Descriptive Statistics of Pain VAS (mm) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	58.39	23.08	0.00	43.00	60.00	75.00	100.00
	Tofacitinib 10 mg BID	309	57.62	24.10	2.00	43.00	59.00	76.00	100.00
	Placebo	156	54.94	23.98	3.00	37.00	54.00	72.50	98.00
Month 1	Tofacitinib 5 mg BID	309	41.61	24.08	0.00	22.00	42.00	60.00	98.00
	Tofacitinib 10 mg BID	308	33.91	22.30	0.00	15.00	31.00	49.50	94.00
	Placebo	153	49.23	24.51	5.00	29.00	49.00	68.00	100.00
Month 3	Tofacitinib 5 mg BID	295	34.47	23.49	0.00	13.00	32.00	51.00	98.00
	Tofacitinib 10 mg BID	300	29.24	21.96	0.00	9.50	25.00	43.50	96.00
	Placebo	146	46.96	24.02	0.00	28.00	48.50	64.00	100.00
Month 6	Tofacitinib 5 mg BID	282	32.76	22.93	0.00	14.00	29.00	49.00	97.00
	Tofacitinib 10 mg BID	284	28.91	22.44	0.00	10.00	24.00	44.00	98.00
	Placebo	62	36.76	22.14	3.00	19.00	34.50	52.00	96.00
	Placebo→5 mg	40	34.48	25.43	0.00	13.00	28.00	49.00	100.00
	Placebo→10 mg	36	29.06	24.66	2.00	6.50	23.00	48.00	96.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; VAS = visual analog scale.

Table 83. Descriptive Statistics of Pain VAS (mm) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	58.39	23.08	0.00	43.00	60.00	75.00	100.00
	Tofacitinib 10 mg BID	309	57.62	24.10	2.00	43.00	59.00	76.00	100.00
	Placebo→Tofacitinib 5 mg BID	79	57.93	21.26	8.00	45.00	57.00	73.00	98.00
	Placebo→Tofacitinib 10 mg BID	77	51.88	26.27	3.00	30.00	53.00	72.00	97.00
Month 1	Tofacitinib 5 mg BID	309	41.61	24.08	0.00	22.00	42.00	60.00	98.00
	Tofacitinib 10 mg BID	308	33.91	22.30	0.00	15.00	31.00	49.50	94.00
	Placebo→Tofacitinib 5 mg BID	79	51.46	25.75	5.00	27.00	55.00	72.00	97.00
	Placebo→Tofacitinib 10 mg BID	74	46.84	23.04	5.00	32.00	47.50	64.00	100.00
Month 3	Tofacitinib 5 mg BID	295	34.47	23.49	0.00	13.00	32.00	51.00	98.00
	Tofacitinib 10 mg BID	300	29.24	21.96	0.00	9.50	25.00	43.50	96.00
	Placebo→Tofacitinib 5 mg BID	75	50.67	25.34	0.00	29.00	49.00	69.00	98.00
	Placebo→Tofacitinib 10 mg BID	71	43.05	22.05	0.00	26.00	47.00	58.00	100.00
Month 6	Tofacitinib 5 mg BID	282	32.76	22.93	0.00	14.00	29.00	49.00	97.00
	Tofacitinib 10 mg BID	284	28.91	22.44	0.00	10.00	24.00	44.00	98.00
	Placebo→Tofacitinib 5 mg BID	71	35.75	25.50	0.00	14.00	30.00	50.00	100.00
	Placebo→Tofacitinib 10 mg BID	67	32.33	21.96	2.00	10.00	30.00	51.00	96.00
Month 9	Tofacitinib 5 mg BID	266	31.60	23.08	0.00	13.00	28.00	47.00	98.00
	Tofacitinib 10 mg BID	279	27.28	23.17	0.00	9.00	21.00	42.00	96.00
	Placebo→Tofacitinib 5 mg BID	68	31.78	23.43	0.00	14.50	25.50	49.00	96.00
	Placebo→Tofacitinib 10 mg BID	63	27.54	23.12	1.00	9.00	19.00	46.00	95.00
Month 12	Tofacitinib 5 mg BID	252	30.42	23.03	0.00	10.00	27.00	44.50	97.00
	Tofacitinib 10 mg BID	265	27.45	24.56	0.00	7.00	18.00	46.00	100.00
	Placebo→Tofacitinib 5 mg BID	67	27.99	23.55	0.00	9.00	20.00	45.00	87.00
	Placebo→Tofacitinib 10 mg BID	63	29.41	26.22	1.00	8.00	21.00	41.00	100.00
Month 15	Tofacitinib 5 mg BID	241	31.34	22.92	0.00	12.00	28.00	45.00	96.00
	Tofacitinib 10 mg BID	254	27.20	23.41	0.00	9.00	20.00	41.00	98.00
	Placebo→Tofacitinib 5 mg BID	62	27.55	22.91	0.00	8.00	22.00	41.00	94.00
	Placebo→Tofacitinib 10 mg BID	60	23.62	20.46	1.00	6.50	19.00	32.00	87.00
Month 18	Tofacitinib 5 mg BID	235	30.81	22.96	0.00	11.00	27.00	47.00	97.00
	Tofacitinib 10 mg BID	244	27.21	23.20	0.00	7.00	21.00	43.00	97.00
	Placebo→Tofacitinib 5 mg BID	59	28.29	22.55	0.00	9.00	22.00	49.00	86.00
	Placebo→Tofacitinib 10 mg BID	55	27.24	21.75	0.00	6.00	25.00	42.00	79.00
Month 21	Tofacitinib 5 mg BID	219	28.82	22.77	0.00	9.00	25.00	43.00	94.00
	Tofacitinib 10 mg BID	231	26.23	23.01	0.00	7.00	20.00	39.00	98.00
	Placebo→Tofacitinib 5 mg BID	57	29.25	22.95	0.00	10.00	21.00	44.00	89.00
	Placebo→Tofacitinib 10 mg BID	53	26.60	23.47	2.00	8.00	20.00	41.00	94.00
Month 24	Tofacitinib 5 mg BID	210	28.49	22.78	0.00	9.00	22.50	45.00	96.00
	Tofacitinib 10 mg BID	218	24.88	22.48	0.00	6.00	18.00	35.00	94.00
	Placebo→Tofacitinib 5 mg BID	54	30.41	23.93	2.00	10.00	22.00	44.00	94.00
	Placebo→Tofacitinib 10 mg BID	52	24.35	21.65	0.00	5.50	18.50	38.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; VAS = visual analog scale.

Table 84. Descriptive Statistics of Change From Baseline of Pain VAS (mm) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-16.8	24.96	-92.0	-31.00	-13.00	0.00	63.00
	Tofacitinib 10 mg BID	308	-23.7	24.12	-92.0	-37.09	-22.00	-6.50	43.00
	Placebo	153	-5.5	20.48	-84.0	-16.00	-3.00	5.00	49.00
Month 3	Tofacitinib 5 mg BID	295	-23.9	27.86	-88.0	-45.00	-21.00	-5.00	69.00
	Tofacitinib 10 mg BID	300	-28.3	26.29	-91.0	-44.50	-28.00	-9.00	48.00
	Placebo	146	-7.4	25.42	-89.0	-22.00	-5.50	4.00	64.00
Month 6	Tofacitinib 5 mg BID	282	-25.3	26.77	-89.0	-45.00	-25.00	-6.00	43.00
	Tofacitinib 10 mg BID	284	-29.4	28.36	-91.0	-49.00	-30.00	-7.50	64.00
	Placebo	62	-17.8	24.49	-86.0	-34.00	-14.50	-3.00	35.00
	Placebo→5 mg	40	-23.6	27.94	-91.0	-41.50	-23.00	-4.52	26.00
	Placebo→10 mg	36	-21.2	30.08	-87.0	-37.00	-16.00	-5.50	51.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; VAS = visual analog scale.

Table 85. Descriptive Statistics of Change From Baseline of Pain VAS (mm) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-16.8	24.96	-92.0	-31.00	-13.00	0.00	63.00
	Tofacitinib 10 mg BID	308	-23.7	24.12	-92.0	-37.09	-22.00	-6.50	43.00
	Placebo→Tofacitinib 5 mg BID	79	-6.5	21.09	-82.0	-18.00	-3.04	4.00	49.00
	Placebo→Tofacitinib 10 mg BID	74	-4.6	19.90	-84.0	-15.00	-2.50	5.00	38.00
Month 3	Tofacitinib 5 mg BID	295	-23.9	27.86	-88.0	-45.00	-21.00	-5.00	69.00
	Tofacitinib 10 mg BID	300	-28.3	26.29	-91.0	-44.50	-28.00	-9.00	48.00
	Placebo→Tofacitinib 5 mg BID	75	-7.6	26.42	-89.0	-22.00	-4.00	10.00	61.00
	Placebo→Tofacitinib 10 mg BID	71	-7.2	24.52	-64.0	-23.00	-7.00	2.00	64.00
Month 6	Tofacitinib 5 mg BID	282	-25.3	26.77	-89.0	-45.00	-25.00	-6.00	43.00
	Tofacitinib 10 mg BID	284	-29.4	28.36	-91.0	-49.00	-30.00	-7.50	64.00
	Placebo→Tofacitinib 5 mg BID	71	-22.8	26.40	-91.0	-41.00	-22.00	-4.00	26.00
	Placebo→Tofacitinib 10 mg BID	67	-17.7	27.49	-87.0	-35.00	-14.00	1.00	51.00
Month 9	Tofacitinib 5 mg BID	266	-26.1	28.54	-93.0	-48.00	-27.00	-4.00	45.00
	Tofacitinib 10 mg BID	279	-31.3	29.10	-97.0	-52.00	-30.00	-9.00	44.00
	Placebo→Tofacitinib 5 mg BID	68	-26.5	24.88	-72.0	-42.00	-24.73	-9.50	33.00
	Placebo→Tofacitinib 10 mg BID	63	-22.9	25.98	-88.0	-42.00	-20.00	-7.00	55.00
Month 12	Tofacitinib 5 mg BID	252	-27.5	29.63	-98.0	-48.00	-26.50	-8.00	91.00
	Tofacitinib 10 mg BID	265	-30.6	29.65	-97.0	-53.00	-31.00	-8.00	53.00
	Placebo→Tofacitinib 5 mg BID	67	-30.3	24.63	-87.0	-48.00	-29.00	-11.00	16.00
	Placebo→Tofacitinib 10 mg BID	63	-21.0	29.97	-88.0	-44.00	-20.00	-6.00	58.00
Month 15	Tofacitinib 5 mg BID	241	-27.0	27.75	-97.0	-47.00	-25.00	-9.00	50.00
	Tofacitinib 10 mg BID	254	-30.6	28.42	-98.0	-51.00	-28.50	-11.00	52.00
	Placebo→Tofacitinib 5 mg BID	62	-29.8	25.06	-86.0	-49.00	-29.50	-10.00	30.00
	Placebo→Tofacitinib 10 mg BID	60	-26.7	26.30	-90.0	-43.50	-21.00	-8.50	23.00
Month 18	Tofacitinib 5 mg BID	235	-27.2	28.39	-99.0	-48.00	-26.00	-6.00	40.00
	Tofacitinib 10 mg BID	244	-30.1	30.13	-98.0	-50.50	-29.00	-6.00	45.00
	Placebo→Tofacitinib 5 mg BID	59	-28.9	24.17	-85.0	-43.00	-29.00	-12.00	23.00
	Placebo→Tofacitinib 10 mg BID	55	-20.4	26.30	-72.0	-38.00	-18.00	-4.00	67.00
Month 21	Tofacitinib 5 mg BID	219	-28.8	27.59	-98.0	-50.00	-26.00	-12.00	37.00
	Tofacitinib 10 mg BID	231	-31.3	28.56	-97.0	-51.56	-30.00	-10.00	50.00
	Placebo→Tofacitinib 5 mg BID	57	-28.2	28.08	-85.0	-47.00	-30.00	-8.04	36.00
	Placebo→Tofacitinib 10 mg BID	53	-20.4	24.03	-78.0	-36.00	-21.00	-6.00	34.00
Month 24	Tofacitinib 5 mg BID	210	-28.4	28.62	-97.0	-50.00	-24.00	-9.00	55.00
	Tofacitinib 10 mg BID	218	-32.6	27.01	-97.0	-51.00	-32.50	-12.00	32.00
	Placebo→Tofacitinib 5 mg BID	54	-27.4	26.08	-73.0	-46.00	-27.53	-14.00	61.00
	Placebo→Tofacitinib 10 mg BID	52	-21.8	26.94	-80.0	-37.50	-19.21	-6.00	60.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; VAS = visual analog scale.

- **C-Reactive Protein (CRP):** All 4 treatment sequences had similar, clinically meaningful decreases from Baseline in CRP by Month 12 that were maintained through Month 24. The results are summarized in Table 86, Table 87, Table 88 and Table 89.

Table 86. Descriptive Statistics of C-Reactive Protein (mg/L) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	15.5	19.07	0.2	4.05	8.19	20.85	174.00
	Tofacitinib 10 mg BID	309	17.0	26.93	0.2	4.15	8.08	21.10	360.00
	Placebo	156	13.7	14.83	0.2	4.29	8.73	18.6	94.50
Month 1	Tofacitinib 5 mg BID	309	5.4	11.02	0.2	0.76	2.11	6.14	145.00
	Tofacitinib 10 mg BID	308	4.7	11.23	0.2	0.51	1.36	4.11	113.00
	Placebo	152	13.3	14.75	0.2	4.54	8.02	17.40	82.80
Month 3	Tofacitinib 5 mg BID	296	6.9	17.36	0.2	0.88	2.60	6.15	190.00
	Tofacitinib 10 mg BID	299	4.4	8.67	0.2	0.57	1.62	4.49	88.80
	Placebo	145	14.6	18.78	0.2	3.52	8.16	16.70	129.00
Month 6	Tofacitinib 5 mg BID	282	5.7	11.83	0.2	0.83	2.18	5.78	125.00
	Tofacitinib 10 mg BID	284	4.1	8.18	0.2	0.47	1.48	4.31	64.00
	Placebo	63	15.6	25.85	0.2	2.98	8.33	16.10	174.00
	Placebo→5 mg	40	3.0	4.64	0.2	0.57	1.48	3.51	23.90
	Placebo→10 mg	37	5.7	13.80	0.2	0.36	1.33	7.24	84.40

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 87. Descriptive Statistics of C-Reactive Protein (mg/L) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	316	15.5	19.07	0.2	4.05	8.19	20.85	174.00
	Tofacitinib 10 mg BID	309	17.0	26.93	0.2	4.15	8.08	21.10	360.00
	Placebo→Tofacitinib 5 mg BID	79	12.2	14.54	0.2	3.40	8.63	15.90	94.50
	Placebo→Tofacitinib 10 mg BID	77	15.3	15.05	0.4	4.69	8.74	23.50	77.50
Month 1	Tofacitinib 5 mg BID	309	5.4	11.02	0.2	0.76	2.11	6.14	145.00
	Tofacitinib 10 mg BID	308	4.7	11.23	0.2	0.51	1.36	4.11	113.00
	Placebo→Tofacitinib 5 mg BID	78	13.1	14.45	0.2	4.76	7.94	17.00	71.80
	Placebo→Tofacitinib 10 mg BID	74	13.5	15.16	0.3	4.16	8.07	17.50	82.80
Month 3	Tofacitinib 5 mg BID	296	6.9	17.36	0.2	0.88	2.60	6.15	190.00
	Tofacitinib 10 mg BID	299	4.4	8.67	0.2	0.57	1.62	4.49	88.80
	Placebo→Tofacitinib 5 mg BID	75	15.0	18.57	0.2	3.46	7.87	19.30	88.70
	Placebo→Tofacitinib 10 mg BID	70	14.2	19.14	0.2	3.62	8.41	16.30	129.00
Month 6	Tofacitinib 5 mg BID	282	5.7	11.83	0.2	0.83	2.18	5.78	125.00
	Tofacitinib 10 mg BID	284	4.1	8.18	0.2	0.47	1.48	4.31	64.00
	Placebo→Tofacitinib 5 mg BID	71	9.1	22.15	0.2	0.80	2.71	8.98	174.00
	Placebo→Tofacitinib 10 mg BID	69	9.7	16.86	0.2	0.70	5.20	9.28	101.10
Month 9	Tofacitinib 5 mg BID	266	4.9	8.38	0.2	0.54	2.05	5.44	85.60
	Tofacitinib 10 mg BID	279	4.5	8.97	0.2	0.43	1.57	4.36	85.30
	Placebo→Tofacitinib 5 mg BID	68	5.3	14.49	0.2	0.55	1.71	4.73	117.00
	Placebo→Tofacitinib 10 mg BID	63	4.3	7.13	0.2	0.61	1.54	5.25	48.50
Month 12	Tofacitinib 5 mg BID	252	5.9	12.58	0.2	0.60	2.35	6.36	137.00
	Tofacitinib 10 mg BID	263	5.1	14.08	0.2	0.57	1.37	3.58	155.00
	Placebo→Tofacitinib 5 mg BID	67	3.8	6.66	0.2	0.41	1.41	4.05	36.40
	Placebo→Tofacitinib 10 mg BID	63	2.6	3.31	0.2	0.34	0.77	4.46	13.60
Month 15	Tofacitinib 5 mg BID	242	4.9	6.79	0.2	0.67	2.24	6.68	37.50
	Tofacitinib 10 mg BID	253	5.1	12.23	0.2	0.40	1.37	4.90	122.00
	Placebo→Tofacitinib 5 mg BID	61	4.6	8.07	0.2	0.38	1.79	5.94	46.50
	Placebo→Tofacitinib 10 mg BID	60	4.1	5.40	0.2	0.54	1.66	5.66	26.80
Month 18	Tofacitinib 5 mg BID	234	5.5	11.16	0.2	0.79	2.37	5.94	124.00
	Tofacitinib 10 mg BID	245	5.7	12.46	0.2	0.55	1.60	5.48	88.80
	Placebo→Tofacitinib 5 mg BID	59	5.6	11.90	0.2	0.44	1.48	6.93	79.00
	Placebo→Tofacitinib 10 mg BID	55	4.0	5.47	0.2	0.69	2.09	5.12	24.40
Month 21	Tofacitinib 5 mg BID	219	4.9	7.89	0.2	0.57	1.89	6.17	61.50
	Tofacitinib 10 mg BID	232	5.3	11.88	0.2	0.50	1.54	4.88	100.00
	Placebo→Tofacitinib 5 mg BID	56	4.0	6.13	0.2	0.52	1.23	4.17	27.90
	Placebo→Tofacitinib 10 mg BID	53	4.3	5.78	0.2	0.59	1.26	7.70	27.80
Month 24	Tofacitinib 5 mg BID	209	5.3	10.12	0.2	0.61	1.99	5.49	79.60
	Tofacitinib 10 mg BID	216	5.2	11.29	0.2	0.44	1.66	4.70	108.20
	Placebo→Tofacitinib 5 mg BID	54	3.3	6.68	0.2	0.41	1.23	4.09	38.60
	Placebo→Tofacitinib 10 mg BID	52	3.1	3.88	0.2	0.58	1.32	5.13	19.90

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 88. Descriptive Statistics of Change From Baseline of C-Reactive Protein (mg/L) per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-10.3	18.66	-165.8	-15.83	-5.17	-1.00	102.20
	Tofacitinib 10 mg BID	308	-12.3	26.00	-319.8	-16.70	-5.45	-2.01	104.94
	Placebo	152	0.4	12.69	-90.6	-2.88	0.00	3.65	59.40
Month 3	Tofacitinib 5 mg BID	296	-8.9	25.46	-167.2	-15.99	-4.68	-0.36	183.41
	Tofacitinib 10 mg BID	299	-12.8	26.31	-343.5	-17.42	-5.54	-1.52	25.10
	Placebo	145	1.5	17.46	-53.7	-4.40	0.09	4.15	122.63
Month 6	Tofacitinib 5 mg BID	282	-9.6	21.36	-166.5	-15.02	-4.76	-0.60	84.10
	Tofacitinib 10 mg BID	284	-13.5	27.21	-351.6	-18.54	-5.87	-1.98	55.98
	Placebo	63	1.1	27.98	-65.8	-7.67	-1.01	4.36	156.50
	Placebo→5 mg	40	-8.1	12.05	-58.0	-12.65	-6.86	-1.58	19.68
	Placebo→10 mg	37	-8.4	18.86	-50.2	-18.52	-5.37	-0.96	69.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 89. Descriptive Statistics of Change From Baseline of C-Reactive Protein (mg/L) per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	309	-10.3	18.66	-165.8	-15.83	-5.17	-1.00	102.20
	Tofacitinib 10 mg BID	308	-12.3	26.00	-319.8	-16.70	-5.45	-2.01	104.94
	Placebo→Tofacitinib 5 mg BID	78	0.8	14.85	-90.6	-2.16	0.49	4.76	59.40
	Placebo→Tofacitinib 10 mg BID	74	-0.1	9.98	-26.6	-4.10	-0.23	2.25	53.50
Month 3	Tofacitinib 5 mg BID	296	-8.9	25.46	-167.2	-15.99	-4.68	-0.36	183.41
	Tofacitinib 10 mg BID	299	-12.8	26.31	-343.5	-17.42	-5.54	-1.52	25.10
	Placebo→Tofacitinib 5 mg BID	75	2.6	15.99	-53.7	-3.14	0.20	5.49	58.50
	Placebo→Tofacitinib 10 mg BID	70	0.3	18.96	-32.4	-5.46	-0.07	2.10	122.63
Month 6	Tofacitinib 5 mg BID	282	-9.6	21.36	-166.5	-15.02	-4.76	-0.60	84.10
	Tofacitinib 10 mg BID	284	-13.5	27.21	-351.6	-18.54	-5.87	-1.98	55.98
	Placebo→Tofacitinib 5 mg BID	71	-3.7	25.16	-65.8	-11.40	-3.45	0.44	156.50
	Placebo→Tofacitinib 10 mg BID	69	-4.4	19.44	-50.2	-9.57	-2.95	1.56	92.79
Month 9	Tofacitinib 5 mg BID	266	-10.8	19.95	-171.8	-15.30	-4.95	-0.88	44.70
	Tofacitinib 10 mg BID	279	-13.1	26.15	-318.4	-17.76	-5.71	-1.66	34.50
	Placebo→Tofacitinib 5 mg BID	68	-7.7	20.04	-82.3	-13.71	-5.25	-0.98	99.50
	Placebo→Tofacitinib 10 mg BID	63	-9.9	12.30	-41.0	-17.29	-6.20	-0.61	12.68
Month 12	Tofacitinib 5 mg BID	252	-9.9	22.53	-163.1	-15.97	-5.23	-0.59	134.30
	Tofacitinib 10 mg BID	263	-12.9	30.20	-351.7	-16.70	-5.99	-1.95	134.60
	Placebo→Tofacitinib 5 mg BID	67	-9.2	13.72	-93.4	-12.36	-6.28	-1.65	11.38
	Placebo→Tofacitinib 10 mg BID	63	-11.7	12.79	-46.0	-18.85	-6.55	-2.01	7.54
Month 15	Tofacitinib 5 mg BID	242	-10.9	19.42	-173.5	-15.10	-5.63	-0.55	18.60
	Tofacitinib 10 mg BID	253	-12.8	27.79	-321.4	-15.81	-5.65	-1.38	77.08
	Placebo→Tofacitinib 5 mg BID	61	-8.7	16.02	-94.0	-12.87	-5.89	-0.88	44.68
	Placebo→Tofacitinib 10 mg BID	60	-9.8	13.83	-43.6	-15.76	-6.17	-1.6	19.57
Month 18	Tofacitinib 5 mg BID	234	-10.3	22.15	-170.8	-15.01	-5.00	-0.68	115.45
	Tofacitinib 10 mg BID	245	-12.0	29.09	-327.5	-17.53	-4.70	-1.51	76.32
	Placebo→Tofacitinib 5 mg BID	59	-7.5	15.16	-93.3	-13.70	-4.81	-0.69	27.53
	Placebo→Tofacitinib 10 mg BID	55	-9.7	12.86	-42.9	-20.00	-5.92	-0.63	12.63
Month 21	Tofacitinib 5 mg BID	219	-11.2	21.34	-173.4	-16.23	-5.58	-0.81	45.20
	Tofacitinib 10 mg BID	232	-11.4	20.98	-100.5	-17.58	-5.25	-1.40	65.90
	Placebo→Tofacitinib 5 mg BID	56	-9.2	14.97	-91.3	-14.26	-5.99	-1.03	14.43
	Placebo→Tofacitinib 10 mg BID	53	-9.2	13.44	-48.3	-13.40	-5.41	-0.61	16.43
Month 24	Tofacitinib 5 mg BID	209	-10.2	18.31	-108.8	-15.98	-5.34	-0.57	45.20
	Tofacitinib 10 mg BID	216	-11.8	21.48	-108.5	-16.65	-5.38	-1.12	70.36
	Placebo→Tofacitinib 5 mg BID	54	-8.5	7.93	-28.6	-13.72	-5.91	-1.71	2.27
	Placebo→Tofacitinib 10 mg BID	52	-10.2	11.98	-41.9	-15.07	-5.98	-1.76	2.67

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Patient Reported Outcomes:
 - SF-36 Health Survey (Version 2, Acute): All 4 treatment sequences had similar, clinically meaningful increases (improvements) from Baseline in SF-36 domain scores by Month 12 which remained stable through Month 24.
 - Physical Functioning Score: The results are presented in Table 90, Table 91, Table 92 and Table 93.

Table 90. Descriptive Statistics of SF-36 Physical Functioning per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	32.16	9.98	16.18	24.37	30.51	40.74	55.07
	Tofacitinib 10 mg BID	309	32.61	9.86	16.18	24.37	30.51	38.69	55.07
	Placebo	156	33.50	10.70	16.18	24.37	32.55	40.74	57.11
Month 1	Tofacitinib 5 mg BID	308	34.61	9.96	16.18	26.41	32.55	42.79	57.11
	Tofacitinib 10 mg BID	308	36.72	10.01	16.18	28.46	36.65	44.83	57.11
	Placebo	153	35.27	10.48	16.18	26.41	34.60	42.79	57.11
Month 3	Tofacitinib 5 mg BID	295	36.40	10.51	16.18	28.46	36.65	44.83	57.11
	Tofacitinib 10 mg BID	300	39.34	10.66	18.23	30.51	40.74	48.93	57.11
	Placebo	146	35.39	10.66	16.18	26.41	34.60	44.83	57.11
Month 6	Tofacitinib 5 mg BID	282	37.37	10.51	16.18	28.46	36.65	44.83	57.11
	Tofacitinib 10 mg BID	283	39.81	10.70	16.18	30.51	40.74	48.93	57.11
	Placebo	62	37.60	8.70	18.23	32.55	38.69	42.79	57.11
	Placebo→5 mg	40	36.54	11.43	16.18	28.46	35.62	46.88	57.11
	Placebo→10 mg	37	39.30	12.87	16.18	28.46	42.79	50.97	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 91. Descriptive Statistics of SF-36 Physical Functioning per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	32.16	9.98	16.18	24.37	30.51	40.74	55.07
	Tofacitinib 10 mg BID	309	32.61	9.86	16.18	24.37	30.51	38.69	55.07
Month 1	Placebo→Tofacitinib 5 mg BID	79	31.93	10.11	16.18	24.37	30.51	38.69	57.11
	Placebo→Tofacitinib 10 mg BID	77	35.11	11.11	16.18	26.41	32.55	44.83	57.11
	Tofacitinib 5 mg BID	308	34.61	9.96	16.18	26.41	32.55	42.79	57.11
	Tofacitinib 10 mg BID	308	36.72	10.01	16.18	28.46	36.65	44.83	57.11
Month 3	Placebo→Tofacitinib 5 mg BID	79	33.62	10.27	16.18	26.41	32.55	40.74	57.11
	Placebo→Tofacitinib 10 mg BID	74	37.03	10.49	16.18	28.46	36.65	44.83	57.11
	Tofacitinib 5 mg BID	295	36.40	10.51	16.18	28.46	36.65	44.83	57.11
	Tofacitinib 10 mg BID	300	39.34	10.66	18.23	30.51	40.74	48.93	57.11
Month 6	Placebo→Tofacitinib 5 mg BID	75	33.21	10.01	16.18	26.41	32.55	42.79	57.11
	Placebo→Tofacitinib 10 mg BID	71	37.68	10.91	20.27	26.41	38.69	46.88	57.11
	Tofacitinib 5 mg BID	282	37.37	10.51	16.18	28.46	36.65	44.83	57.11
	Tofacitinib 10 mg BID	283	39.81	10.70	16.18	30.51	40.74	48.93	57.11
Month 9	Placebo→Tofacitinib 5 mg BID	71	36.68	9.98	16.18	30.51	36.65	42.79	57.11
	Placebo→Tofacitinib 10 mg BID	68	38.87	11.38	16.18	28.46	38.69	48.93	57.11
	Tofacitinib 5 mg BID	265	37.94	10.36	16.18	30.51	36.65	46.88	57.11
	Tofacitinib 10 mg BID	279	40.61	10.71	16.18	32.55	42.79	48.93	57.11
Month 12	Placebo→Tofacitinib 5 mg BID	68	38.51	10.56	16.18	29.48	38.69	47.90	57.11
	Placebo→Tofacitinib 10 mg BID	63	41.29	11.80	18.23	30.51	44.83	53.02	57.11
	Tofacitinib 5 mg BID	252	38.49	10.86	16.18	30.51	38.69	46.88	57.11
	Tofacitinib 10 mg BID	265	40.01	11.03	16.18	30.51	42.79	48.93	57.11
Month 15	Placebo→Tofacitinib 5 mg BID	67	39.43	10.51	16.18	32.55	36.65	48.93	55.07
	Placebo→Tofacitinib 10 mg BID	63	42.27	11.02	18.23	32.55	44.83	53.02	57.11
	Tofacitinib 5 mg BID	242	38.48	10.64	16.18	30.51	38.69	46.88	57.11
	Tofacitinib 10 mg BID	254	40.66	11.15	16.18	32.55	42.79	48.93	57.11
Month 18	Placebo→Tofacitinib 5 mg BID	62	40.61	10.52	16.18	34.60	40.74	48.93	57.11
	Placebo→Tofacitinib 10 mg BID	60	41.80	11.15	18.23	34.60	42.79	50.97	57.11
	Tofacitinib 5 mg BID	235	38.63	10.93	16.18	30.51	38.69	46.88	57.11
	Tofacitinib 10 mg BID	244	40.56	11.40	16.18	32.55	42.79	48.93	57.11
Month 21	Placebo→Tofacitinib 5 mg BID	59	40.74	10.17	18.23	32.55	40.74	48.93	57.11
	Placebo→Tofacitinib 10 mg BID	55	41.56	10.20	18.23	34.60	40.74	50.97	57.11
	Tofacitinib 5 mg BID	220	38.84	10.62	16.18	30.51	38.69	46.88	57.11
	Tofacitinib 10 mg BID	231	40.39	11.07	16.18	32.55	40.74	48.93	57.11
Month 24	Placebo→Tofacitinib 5 mg BID	57	40.92	9.81	16.18	34.60	40.74	48.93	57.11
	Placebo→Tofacitinib 10 mg BID	53	41.74	10.60	16.18	32.55	42.79	50.97	57.11
	Tofacitinib 5 mg BID	211	39.38	10.63	16.18	30.51	38.69	48.93	57.11
	Tofacitinib 10 mg BID	218	40.75	11.60	16.18	30.51	41.76	50.97	57.11
	Placebo→Tofacitinib 5 mg BID	54	40.44	10.77	16.18	32.55	40.74	46.88	57.11
	Placebo→Tofacitinib 10 mg BID	52	43.14	9.72	20.27	36.65	44.83	52.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 92. Descriptive Statistics of Change From Baseline of SF-36 Physical Functioning per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	2.58	7.50	-18.42	-2.05	2.05	6.14	30.70
	Tofacitinib 10 mg BID	308	4.08	7.70	-16.37	0.00	2.05	8.19	32.74
	Placebo	153	1.51	7.16	-26.60	-2.05	2.05	6.14	32.74
Month 3	Tofacitinib 5 mg BID	294	4.24	8.85	-26.60	-2.05	4.09	10.23	26.60
	Tofacitinib 10 mg BID	300	6.78	8.80	-28.65	2.05	6.14	12.28	32.74
	Placebo	146	1.67	8.32	-22.51	-4.09	2.05	6.14	34.79
Month 6	Tofacitinib 5 mg BID	281	5.11	9.15	-30.70	0.00	4.09	10.23	30.70
	Tofacitinib 10 mg BID	283	7.30	9.32	-24.56	0.00	8.19	12.28	36.84
	Placebo	62	4.52	7.42	-18.42	0.00	4.09	8.19	24.56
	Placebo→5 mg	40	4.81	9.34	-16.37	-2.05	5.12	11.26	24.56
	Placebo→10 mg	37	2.65	10.85	-22.51	-2.05	2.05	8.19	30.70

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 93. Descriptive Statistics of Change From Baseline of SF-36 Physical Functioning per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	2.58	7.50	-18.42	-2.05	2.05	6.14	30.70
	Tofacitinib 10 mg BID	308	4.08	7.70	-16.37	0.00	2.05	8.19	32.74
Month 3	Placebo→Tofacitinib 5 mg BID	79	1.68	7.03	-22.51	-2.05	2.05	6.14	14.33
	Placebo→Tofacitinib 10 mg BID	74	1.33	7.34	-26.60	-2.05	0.00	6.14	32.74
	Tofacitinib 5 mg BID	294	4.24	8.85	-26.60	-2.05	4.09	10.23	26.60
	Tofacitinib 10 mg BID	300	6.78	8.80	-28.65	2.05	6.14	12.28	32.74
Month 6	Placebo→Tofacitinib 5 mg BID	75	1.45	8.53	-22.51	-4.09	2.05	8.19	20.47
	Placebo→Tofacitinib 10 mg BID	71	1.90	8.14	-18.42	-4.09	2.05	6.14	34.79
	Tofacitinib 5 mg BID	281	5.11	9.15	-30.7	0.00	4.09	10.23	30.70
	Tofacitinib 10 mg BID	283	7.30	9.32	-24.56	0.0	8.19	12.28	36.84
Month 9	Placebo→Tofacitinib 5 mg BID	71	5.13	8.23	-16.37	0.00	4.09	10.23	24.56
	Placebo→Tofacitinib 10 mg BID	68	3.04	9.63	-22.51	-2.05	3.07	8.19	30.70
	Tofacitinib 5 mg BID	264	5.29	10.02	-28.65	0.00	6.14	10.23	30.70
	Tofacitinib 10 mg BID	279	8.15	9.12	-18.42	2.05	8.19	14.33	36.84
Month 12	Placebo→Tofacitinib 5 mg BID	68	6.74	9.15	-22.51	2.05	6.14	12.28	34.79
	Placebo→Tofacitinib 10 mg BID	63	4.78	10.17	-24.56	-2.05	4.09	12.28	34.79
	Tofacitinib 5 mg BID	251	5.93	10.18	-38.88	0.00	4.09	12.28	38.88
	Tofacitinib 10 mg BID	265	7.41	9.27	-14.33	2.05	6.14	12.28	34.79
Month 15	Placebo→Tofacitinib 5 mg BID	67	7.70	8.27	-6.14	2.05	6.14	12.28	36.84
	Placebo→Tofacitinib 10 mg BID	63	5.75	10.84	-26.60	0.00	4.09	12.28	34.79
	Tofacitinib 5 mg BID	241	5.93	10.84	-38.88	0.00	6.14	12.28	38.88
	Tofacitinib 10 mg BID	254	7.93	9.75	-18.42	2.05	8.19	14.33	36.84
Month 18	Placebo→Tofacitinib 5 mg BID	62	8.19	9.30	-14.33	0.00	8.19	16.37	40.93
	Placebo→Tofacitinib 10 mg BID	60	5.73	10.20	-26.60	0.0	6.14	12.28	24.56
	Tofacitinib 5 mg BID	234	6.03	10.35	-38.88	0.0	6.14	12.28	36.84
	Tofacitinib 10 mg BID	244	7.89	9.72	-18.42	0.00	8.19	14.33	36.84
Month 21	Placebo→Tofacitinib 5 mg BID	59	8.22	9.04	-12.28	2.05	8.19	14.33	36.84
	Placebo→Tofacitinib 10 mg BID	55	5.47	8.67	-20.47	0.00	4.09	10.23	26.60
	Tofacitinib 5 mg BID	219	6.14	10.53	-38.88	0.00	6.14	12.28	40.93
	Tofacitinib 10 mg BID	231	7.90	9.74	-30.7	2.05	8.19	14.33	36.84
Month 24	Placebo→Tofacitinib 5 mg BID	57	8.55	9.28	-14.33	2.05	8.19	14.33	32.74
	Placebo→Tofacitinib 10 mg BID	53	5.48	9.04	-18.42	-2.05	6.14	12.28	24.56
	Tofacitinib 5 mg BID	210	6.52	10.20	-34.79	0.00	6.14	12.28	40.93
	Tofacitinib 10 mg BID	218	8.25	9.91	-24.56	2.05	8.19	14.33	36.84
Month 24	Placebo→Tofacitinib 5 mg BID	54	7.66	8.91	-14.33	2.05	8.19	12.28	26.60
	Placebo→Tofacitinib 10 mg BID	52	6.69	8.78	-20.47	2.05	6.14	12.28	24.56

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- Role Physical Score: The results are presented in Table 94, Table 95, Table 96 and Table 97.

Table 94. Descriptive Statistics of SF-36 Role Physical Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	34.61	9.40	18.45	27.99	35.15	39.92	56.62
	Tofacitinib 10 mg BID	309	35.41	9.73	18.45	27.99	35.15	39.92	56.62
	Placebo	156	36.69	10.54	18.45	27.99	37.53	43.50	56.62
Month 1	Tofacitinib 5 mg BID	307	39.21	10.04	18.45	32.76	37.53	47.08	56.62
	Tofacitinib 10 mg BID	308	41.02	9.81	18.45	35.15	39.92	49.47	56.62
	Placebo	153	38.30	10.24	18.45	30.38	37.53	47.08	56.62
Month 3	Tofacitinib 5 mg BID	295	39.83	10.11	18.45	32.76	39.92	47.08	56.62
	Tofacitinib 10 mg BID	300	42.82	9.98	18.45	37.53	44.69	51.85	56.62
	Placebo	146	38.37	10.65	18.45	30.38	37.53	47.08	56.62
Month 6	Tofacitinib 5 mg BID	281	41.51	10.14	18.45	35.15	42.31	49.47	56.62
	Tofacitinib 10 mg BID	283	43.46	9.52	18.45	37.53	44.69	51.85	56.62
	Placebo	62	41.38	8.78	23.22	35.15	39.92	47.08	56.62
	Placebo→5 mg	40	39.50	9.77	20.83	30.38	37.53	47.08	56.62
	Placebo→10 mg	37	43.60	10.75	18.45	35.15	47.08	51.85	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 95. Descriptive Statistics of SF-36 Physical Functioning per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	34.61	9.40	18.45	27.99	35.15	39.92	56.62
	Tofacitinib 10 mg BID	309	35.41	9.73	18.45	27.99	35.15	39.92	56.62
Month 1	Placebo→Tofacitinib 5 mg BID	79	35.33	9.69	18.45	27.99	35.15	42.31	56.62
	Placebo→Tofacitinib 10 mg BID	77	38.09	11.22	18.45	30.38	37.53	44.69	56.62
	Tofacitinib 5 mg BID	307	39.21	10.04	18.45	32.76	37.53	47.08	56.62
	Tofacitinib 10 mg BID	308	41.02	9.81	18.45	35.15	39.92	49.47	56.62
Month 3	Placebo→Tofacitinib 5 mg BID	79	37.02	9.98	18.45	27.99	37.53	44.69	56.62
	Placebo→Tofacitinib 10 mg BID	74	39.66	10.41	18.45	32.76	37.53	47.08	56.62
	Tofacitinib 5 mg BID	295	39.83	10.11	18.45	32.76	39.92	47.08	56.62
	Tofacitinib 10 mg BID	300	42.82	9.98	18.45	37.53	44.69	51.85	56.62
Month 6	Placebo→Tofacitinib 5 mg BID	75	36.10	10.66	18.45	27.99	37.53	44.69	56.62
	Placebo→Tofacitinib 10 mg BID	71	40.76	10.18	18.45	32.76	42.31	47.08	56.62
	Tofacitinib 5 mg BID	281	41.51	10.14	18.45	35.15	42.31	49.47	56.62
	Tofacitinib 10 mg BID	283	43.46	9.52	18.45	37.53	44.69	51.85	56.62
Month 9	Placebo→Tofacitinib 5 mg BID	71	40.09	9.03	20.83	32.76	37.53	47.08	56.62
	Placebo→Tofacitinib 10 mg BID	68	42.83	10.18	18.45	35.15	44.69	49.47	56.62
	Tofacitinib 5 mg BID	264	41.47	10.32	18.45	35.15	39.92	49.47	56.62
	Tofacitinib 10 mg BID	279	43.92	9.86	18.45	37.53	44.69	51.85	56.62
Month 12	Placebo→Tofacitinib 5 mg BID	68	41.71	9.75	20.83	36.34	39.92	49.47	56.62
	Placebo→Tofacitinib 10 mg BID	63	44.96	10.21	18.45	37.53	47.08	54.24	56.62
	Tofacitinib 5 mg BID	252	41.44	10.21	18.45	35.15	41.11	49.47	56.62
	Tofacitinib 10 mg BID	264	43.57	9.94	18.45	37.53	44.69	54.24	56.62
Month 15	Placebo→Tofacitinib 5 mg BID	67	42.31	10.62	18.45	35.15	44.69	49.47	56.62
	Placebo→Tofacitinib 10 mg BID	63	45.15	10.12	18.45	37.53	47.08	54.24	56.62
	Tofacitinib 5 mg BID	241	41.32	10.02	18.45	35.15	39.92	49.47	56.62
	Tofacitinib 10 mg BID	253	43.97	10.09	18.45	37.53	44.69	54.24	56.62
Month 18	Placebo→Tofacitinib 5 mg BID	62	42.77	9.56	18.45	37.53	43.5	49.47	56.62
	Placebo→Tofacitinib 10 mg BID	60	44.53	9.96	20.83	37.53	44.69	54.24	56.62
	Tofacitinib 5 mg BID	234	41.68	9.93	18.45	35.15	39.92	49.47	56.62
	Tofacitinib 10 mg BID	244	43.71	9.96	18.45	37.53	44.69	51.85	56.62
Month 21	Placebo→Tofacitinib 5 mg BID	59	42.83	9.45	20.83	37.53	42.31	51.85	56.62
	Placebo→Tofacitinib 10 mg BID	55	45.82	8.52	25.60	37.53	47.08	54.24	56.62
	Tofacitinib 5 mg BID	219	42.01	9.47	18.45	35.15	42.31	49.47	56.62
	Tofacitinib 10 mg BID	231	42.96	10.08	18.45	37.53	44.69	51.85	56.62
Month 24	Placebo→Tofacitinib 5 mg BID	57	42.56	10.27	25.60	35.15	42.31	54.24	56.62
	Placebo→Tofacitinib 10 mg BID	53	44.65	8.95	20.83	37.53	44.69	51.85	56.62
	Tofacitinib 5 mg BID	210	41.94	9.82	18.45	35.15	39.92	49.47	56.62
	Tofacitinib 10 mg BID	218	43.72	9.95	18.45	37.53	44.69	51.85	56.62
	Placebo→Tofacitinib 5 mg BID	54	42.88	9.30	18.45	37.53	43.5	49.47	56.62
	Placebo→Tofacitinib 10 mg BID	52	44.42	9.42	20.83	37.53	43.5	51.85	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 96. Descriptive Statistics of Change From Baseline of SF-36 Role Physical Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	4.66	9.34	-28.63	0.00	4.77	9.54	33.41
	Tofacitinib 10 mg BID	308	5.59	9.12	-21.48	0.00	4.77	9.54	35.79
	Placebo	153	1.39	8.19	-31.02	-2.39	0.00	7.16	33.41
Month 3	Tofacitinib 5 mg BID	294	5.36	9.33	-31.02	0.00	4.77	11.93	35.79
	Tofacitinib 10 mg BID	300	7.44	9.57	-16.70	0.00	7.16	14.32	35.79
	Placebo	146	1.45	9.15	-31.02	-2.39	0.00	7.16	28.63
Month 6	Tofacitinib 5 mg BID	280	6.85	10.20	-26.25	0.00	7.16	11.93	38.18
	Tofacitinib 10 mg BID	283	7.90	10.34	-21.48	0.00	7.16	14.32	38.18
	Placebo	62	3.85	9.86	-16.70	0.00	3.58	7.16	38.18
	Placebo→5 mg	40	5.55	9.70	-7.16	0.00	2.39	10.74	28.63
	Placebo→10 mg	37	5.29	9.89	-19.09	0.00	4.77	9.54	28.63

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 97. Descriptive Statistics of Change From Baseline of SF-36 Role Physical Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	4.66	9.34	-28.63	0.00	4.77	9.54	33.41
	Tofacitinib 10 mg BID	308	5.59	9.12	-21.48	0.00	4.77	9.54	35.79
	Placebo→Tofacitinib 5 mg BID	79	1.69	8.29	-16.70	-4.77	0.00	7.16	33.41
	Placebo→Tofacitinib 10 mg BID	74	1.06	8.12	-31.02	0.00	0.00	4.77	21.48
Month 3	Tofacitinib 5 mg BID	294	5.36	9.33	-31.02	0.00	4.77	11.93	35.79
	Tofacitinib 10 mg BID	300	7.44	9.57	-16.70	0.00	7.16	14.32	35.79
	Placebo→Tofacitinib 5 mg BID	75	0.89	9.02	-26.25	-4.77	0.00	7.16	21.48
	Placebo→Tofacitinib 10 mg BID	71	2.05	9.31	-31.02	0.00	0.00	7.16	28.63
Month 6	Tofacitinib 5 mg BID	280	6.85	10.20	-26.25	0.00	7.16	11.93	38.18
	Tofacitinib 10 mg BID	283	7.90	10.34	-21.48	0.00	7.16	14.32	38.18
	Placebo→Tofacitinib 5 mg BID	71	5.21	10.02	-16.70	0.00	2.39	9.54	38.18
	Placebo→Tofacitinib 10 mg BID	68	4.21	9.57	-19.09	0.00	4.77	9.54	28.63
Month 9	Tofacitinib 5 mg BID	263	6.60	10.86	-33.41	0.00	7.16	14.32	38.18
	Tofacitinib 10 mg BID	279	8.60	10.18	-16.70	0.00	7.16	14.32	38.18
	Placebo→Tofacitinib 5 mg BID	68	6.42	7.92	-4.77	0.00	4.77	11.93	26.25
	Placebo→Tofacitinib 10 mg BID	63	6.14	9.63	-23.86	0.00	4.77	11.93	28.63
Month 12	Tofacitinib 5 mg BID	251	6.77	10.16	-23.86	0.00	7.16	14.32	38.18
	Tofacitinib 10 mg BID	264	8.18	10.18	-16.70	0.00	7.16	16.70	38.18
	Placebo→Tofacitinib 5 mg BID	67	7.12	8.26	-9.54	0.00	7.16	11.93	28.63
	Placebo→Tofacitinib 10 mg BID	63	6.33	10.86	-23.86	0.00	4.77	14.32	28.63
Month 15	Tofacitinib 5 mg BID	240	6.61	10.35	-21.48	0.00	7.16	14.32	35.79
	Tofacitinib 10 mg BID	253	8.56	10.60	-28.63	0.00	7.16	16.70	35.79
	Placebo→Tofacitinib 5 mg BID	62	6.70	9.42	-16.70	0.00	4.77	11.93	28.63
	Placebo→Tofacitinib 10 mg BID	60	5.89	10.15	-23.86	0.00	7.16	13.12	31.02
Month 18	Tofacitinib 5 mg BID	233	6.82	10.32	-23.86	0.00	7.16	14.32	33.41
	Tofacitinib 10 mg BID	244	8.29	10.17	-19.09	0.00	7.16	14.32	35.79
	Placebo→Tofacitinib 5 mg BID	59	6.59	9.12	-16.70	0.00	4.77	11.93	33.41
	Placebo→Tofacitinib 10 mg BID	55	7.25	8.90	-21.48	0.00	7.16	14.32	21.48
Month 21	Tofacitinib 5 mg BID	218	7.37	9.97	-21.48	0.00	7.16	14.32	38.18
	Tofacitinib 10 mg BID	231	7.82	10.38	-19.09	0.00	7.16	14.32	35.79
	Placebo→Tofacitinib 5 mg BID	57	6.28	9.70	-11.93	0.00	4.77	11.93	38.18
	Placebo→Tofacitinib 10 mg BID	53	5.67	10.91	-19.09	0.00	4.77	14.32	33.41
Month 24	Tofacitinib 5 mg BID	209	7.12	10.43	-31.02	0.00	7.16	14.32	38.18
	Tofacitinib 10 mg BID	218	8.56	10.71	-28.63	2.39	7.16	14.32	38.18
	Placebo→Tofacitinib 5 mg BID	54	6.36	8.53	-7.16	0.00	5.97	11.93	31.02
	Placebo→Tofacitinib 10 mg BID	52	5.55	9.53	-16.7	-1.19	4.77	13.12	28.63

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **Social Functioning Score:** The results are presented in Table 98, Table 99, Table 100 and Table 101.

Table 98. Descriptive Statistics of SF-36 Social Functioning Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	37.16	11.05	13.38	29.52	34.89	45.65	56.40
	Tofacitinib 10 mg BID	309	39.17	11.42	13.38	29.52	40.27	45.65	56.40
	Placebo	156	39.37	11.54	13.38	29.52	40.27	48.34	56.40
Month 1	Tofacitinib 5 mg BID	308	41.74	10.46	18.76	34.89	40.27	51.03	56.40
	Tofacitinib 10 mg BID	308	43.54	10.06	13.38	34.89	45.65	51.03	56.40
	Placebo	153	41.01	11.57	13.38	34.89	40.27	51.03	56.40
Month 3	Tofacitinib 5 mg BID	295	42.73	10.60	13.38	34.89	45.65	51.03	56.40
	Tofacitinib 10 mg BID	300	44.50	10.27	13.38	34.89	45.65	56.40	56.40
	Placebo	146	40.86	11.23	13.38	34.89	40.27	51.03	56.40
Month 6	Tofacitinib 5 mg BID	282	43.09	10.45	13.38	34.89	45.65	51.03	56.40
	Tofacitinib 10 mg BID	284	44.91	10.53	13.38	40.27	45.65	56.40	56.40
	Placebo	62	42.79	9.48	18.76	34.89	40.27	51.03	56.40
	Placebo→5 mg	40	41.88	10.42	24.14	34.89	40.27	51.03	56.40
	Placebo→10 mg	37	45.79	10.94	24.14	34.89	51.03	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 99. Descriptive Statistics of SF-36 Social Functioning Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	37.16	11.05	13.38	29.52	34.89	45.65	56.40
	Tofacitinib 10 mg BID	309	39.17	11.42	13.38	29.52	40.27	45.65	56.40
	Placebo→Tofacitinib 5 mg BID	79	38.91	10.98	13.38	29.52	40.27	45.65	56.40
	Placebo→Tofacitinib 10 mg BID	77	39.85	12.14	13.38	29.52	40.27	51.03	56.40
Month 1	Tofacitinib 5 mg BID	308	41.74	10.46	18.76	34.89	40.27	51.03	56.40
	Tofacitinib 10 mg BID	308	43.54	10.06	13.38	34.89	45.65	51.03	56.40
	Placebo→Tofacitinib 5 mg BID	79	40.41	12.09	13.38	34.89	40.27	51.03	56.40
	Placebo→Tofacitinib 10 mg BID	74	41.65	11.05	18.76	34.89	40.27	51.03	56.40
Month 3	Tofacitinib 5 mg BID	295	42.73	10.60	13.38	34.89	45.65	51.03	56.40
	Tofacitinib 10 mg BID	300	44.50	10.27	13.38	34.89	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	75	38.69	10.60	13.38	29.52	34.89	45.65	56.40
	Placebo→Tofacitinib 10 mg BID	71	43.15	11.49	18.76	34.89	45.65	56.40	56.40
Month 6	Tofacitinib 5 mg BID	282	43.09	10.45	13.38	34.89	45.65	51.03	56.40
	Tofacitinib 10 mg BID	284	44.91	10.53	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	71	42.09	10.04	24.14	34.89	40.27	51.03	56.40
	Placebo→Tofacitinib 10 mg BID	68	44.62	10.27	18.76	34.89	45.65	56.40	56.40
Month 9	Tofacitinib 5 mg BID	265	44.13	10.12	13.38	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	279	45.17	10.67	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	68	43.91	10.03	18.76	34.89	42.96	56.40	56.40
	Placebo→Tofacitinib 10 mg BID	63	45.90	11.40	18.76	34.89	51.03	56.40	56.40
Month 12	Tofacitinib 5 mg BID	252	43.54	10.57	13.38	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	265	45.18	10.54	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	67	44.28	10.48	13.38	34.89	45.65	56.40	56.40
	Placebo→Tofacitinib 10 mg BID	63	47.18	10.29	18.76	40.27	51.03	56.40	56.40
Month 15	Tofacitinib 5 mg BID	242	43.58	10.28	13.38	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	254	45.37	10.89	13.38	34.89	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	62	44.43	9.71	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 10 mg BID	60	45.83	10.80	13.38	34.89	45.65	56.40	56.40
Month 18	Tofacitinib 5 mg BID	235	43.25	10.52	13.38	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	244	45.82	10.04	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	59	44.28	10.41	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 10 mg BID	55	46.23	10.64	18.76	40.27	45.65	56.40	56.40
Month 21	Tofacitinib 5 mg BID	220	43.94	10.22	18.76	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	231	45.90	10.49	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	57	46.40	9.98	13.38	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 10 mg BID	53	47.27	10.47	13.38	40.27	51.03	56.40	56.40
Month 24	Tofacitinib 5 mg BID	211	44.40	10.27	18.76	34.89	45.65	56.40	56.40
	Tofacitinib 10 mg BID	218	45.89	10.40	18.76	40.27	45.65	56.40	56.40
	Placebo→Tofacitinib 5 mg BID	54	43.76	9.86	18.76	34.89	45.65	51.03	56.40
	Placebo→Tofacitinib 10 mg BID	52	47.30	10.24	18.76	40.27	51.03	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 100. Descriptive Statistics of Change From Baseline of SF-36 Social Functioning Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	4.57	10.28	-26.89	0.00	5.38	10.76	37.64
	Tofacitinib 10 mg BID	308	4.35	10.34	-32.27	0.00	5.38	10.76	32.27
	Placebo	153	1.48	9.66	-26.89	-5.38	0.00	5.38	26.89
Month 3	Tofacitinib 5 mg BID	294	5.45	10.97	-32.27	0.00	5.38	10.76	43.02
	Tofacitinib 10 mg BID	300	5.38	10.46	-32.27	0.00	5.38	10.76	32.27
	Placebo	146	1.25	10.09	-26.89	-5.38	0.00	5.38	26.89
Month 6	Tofacitinib 5 mg BID	281	5.78	11.14	-32.27	0.00	5.38	10.76	37.64
	Tofacitinib 10 mg BID	284	5.89	11.68	-32.27	0.00	5.38	16.13	37.64
	Placebo	62	4.08	9.52	-16.13	-5.38	5.38	10.76	32.27
	Placebo→5 mg	40	4.17	10.58	-16.13	0.00	2.69	10.76	32.27
	Placebo→10 mg	37	4.07	11.44	-16.13	0.00	5.38	10.76	26.89

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 101. Descriptive Statistics of Change From Baseline of SF-36 Social Functioning Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	4.57	10.28	-26.89	0.00	5.38	10.76	37.64
	Tofacitinib 10 mg BID	308	4.35	10.34	-32.27	0.00	5.38	10.76	32.27
Month 3	Placebo→Tofacitinib 5 mg BID	79	1.50	10.19	-26.89	-5.38	0.00	5.38	26.89
	Placebo→Tofacitinib 10 mg BID	74	1.45	9.13	-26.89	0.00	0.00	5.38	21.51
	Tofacitinib 5 mg BID	294	5.45	10.97	-32.27	0.00	5.38	10.76	43.02
	Tofacitinib 10 mg BID	300	5.38	10.46	-32.27	0.00	5.38	10.76	32.27
Month 6	Placebo→Tofacitinib 5 mg BID	75	0.07	10.29	-26.89	-5.38	0.00	5.38	26.89
	Placebo→Tofacitinib 10 mg BID	71	2.50	9.78	-26.89	0.00	0.00	10.76	21.51
	Tofacitinib 5 mg BID	281	5.78	11.14	-32.27	0.00	5.38	10.76	37.64
	Tofacitinib 10 mg BID	284	5.89	11.68	-32.27	0.00	5.38	16.13	37.64
Month 9	Placebo→Tofacitinib 5 mg BID	71	4.09	10.26	-16.13	-5.38	5.38	10.76	32.27
	Placebo→Tofacitinib 10 mg BID	68	4.11	10.39	-16.13	0.00	5.38	10.76	32.27
	Tofacitinib 5 mg BID	264	6.50	11.81	-26.89	0.00	5.38	16.13	43.02
	Tofacitinib 10 mg BID	279	6.13	11.13	-26.89	0.00	5.38	16.13	37.64
Month 12	Placebo→Tofacitinib 5 mg BID	68	5.69	9.33	-16.13	0.00	5.38	10.76	26.89
	Placebo→Tofacitinib 10 mg BID	63	4.61	10.57	-21.51	0.00	0.00	10.76	32.27
	Tofacitinib 5 mg BID	251	5.93	11.90	-32.27	0.00	5.38	16.13	37.64
	Tofacitinib 10 mg BID	265	6.13	11.50	-26.89	0.00	5.38	16.13	37.64
Month 15	Placebo→Tofacitinib 5 mg BID	67	6.26	10.90	-16.13	0.00	5.38	10.76	32.27
	Placebo→Tofacitinib 10 mg BID	63	5.89	11.86	-26.89	0.00	0.00	10.76	32.27
	Tofacitinib 5 mg BID	241	6.31	11.05	-26.89	0.00	5.38	16.13	37.64
	Tofacitinib 10 mg BID	254	5.97	11.38	-43.02	0.00	5.38	16.13	37.64
Month 18	Placebo→Tofacitinib 5 mg BID	62	6.24	10.41	-16.13	0.00	5.38	10.76	32.27
	Placebo→Tofacitinib 10 mg BID	60	4.66	9.87	-26.89	0.00	5.38	10.76	32.27
	Tofacitinib 5 mg BID	234	5.81	11.80	-26.89	0.00	5.38	16.13	43.02
	Tofacitinib 10 mg BID	244	6.33	11.21	-21.51	0.00	5.38	13.44	37.64
Month 21	Placebo→Tofacitinib 5 mg BID	59	5.92	9.40	-10.76	0.00	5.38	10.76	32.27
	Placebo→Tofacitinib 10 mg BID	55	4.30	11.40	-26.89	0.00	0.00	10.76	26.89
	Tofacitinib 5 mg BID	219	6.43	12.29	-26.89	0.00	5.38	16.13	43.02
	Tofacitinib 10 mg BID	231	6.66	10.99	-21.51	0.00	5.38	16.13	37.64
Month 24	Placebo→Tofacitinib 5 mg BID	57	8.21	8.81	-10.76	0.00	5.38	10.76	32.27
	Placebo→Tofacitinib 10 mg BID	53	4.97	12.60	-32.27	-5.38	0.00	16.13	37.64
	Tofacitinib 5 mg BID	210	6.53	11.63	-26.89	0.00	5.38	16.13	32.27
	Tofacitinib 10 mg BID	218	6.51	10.68	-21.51	0.00	5.38	16.13	37.64
Month 24	Placebo→Tofacitinib 5 mg BID	54	5.58	8.92	-10.76	0.00	5.38	10.76	26.89
	Placebo→Tofacitinib 10 mg BID	52	5.07	10.78	-16.13	0.00	5.38	10.76	26.89

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **Bodily Pain Score:** The results are presented in Table 102, Table 103, Table 104 and Table 105.

Table 102. Descriptive Statistics of SF-36 Bodily Pain Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	34.01	7.52	19.23	28.40	36.31	36.73	60.88
	Tofacitinib 10 mg BID	309	34.64	7.89	19.23	28.40	36.31	40.47	60.88
	Placebo	156	35.57	8.05	19.23	28.40	36.31	40.47	60.88
Month 1	Tofacitinib 5 mg BID	308	39.75	8.08	19.23	36.31	36.73	45.06	60.88
	Tofacitinib 10 mg BID	308	42.02	8.41	19.23	36.31	40.89	49.22	60.88
	Placebo	153	37.31	8.93	19.23	28.40	36.31	44.64	60.88
Month 3	Tofacitinib 5 mg BID	295	41.30	9.23	19.23	36.31	40.89	49.22	60.88
	Tofacitinib 10 mg BID	300	44.43	9.02	19.23	36.31	45.06	50.05	60.88
	Placebo	146	38.17	9.16	19.23	32.14	36.31	45.06	60.88
Month 6	Tofacitinib 5 mg BID	282	41.95	8.78	19.23	36.31	40.89	49.22	60.88
	Tofacitinib 10 mg BID	284	44.21	9.38	19.23	36.31	45.06	50.05	60.88
	Placebo	62	40.70	8.06	23.40	36.31	40.47	45.06	60.88
	Placebo→5 mg	40	41.48	8.61	28.40	36.31	40.89	49.22	60.88
	Placebo→10 mg	37	46.10	10.27	32.14	36.31	45.06	54.22	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 103. Descriptive Statistics of SF-36 Bodily Pain Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	34.01	7.52	19.23	28.40	36.31	36.73	60.88
	Tofacitinib 10 mg BID	309	34.64	7.89	19.23	28.40	36.31	40.47	60.88
Month 1	Placebo→Tofacitinib 5 mg BID	79	34.67	7.20	19.23	28.40	36.31	40.47	60.88
	Placebo→Tofacitinib 10 mg BID	77	36.50	8.80	19.23	32.14	36.31	40.89	60.88
	Tofacitinib 5 mg BID	308	39.75	8.08	19.23	36.31	36.73	45.06	60.88
	Tofacitinib 10 mg BID	308	42.02	8.41	19.23	36.31	40.89	49.22	60.88
Month 3	Placebo→Tofacitinib 5 mg BID	79	36.49	8.57	19.23	28.40	36.31	40.89	60.88
	Placebo→Tofacitinib 10 mg BID	74	38.19	9.27	19.23	31.73	36.31	45.06	60.88
	Tofacitinib 5 mg BID	295	41.30	9.23	19.23	36.31	40.89	49.22	60.88
	Tofacitinib 10 mg BID	300	44.43	9.02	19.23	36.31	45.06	50.05	60.88
Month 6	Placebo→Tofacitinib 5 mg BID	75	37.01	9.34	19.23	32.14	36.31	45.06	60.88
	Placebo→Tofacitinib 10 mg BID	71	39.40	8.86	23.40	32.56	37.56	45.06	60.88
	Tofacitinib 5 mg BID	282	41.95	8.78	19.23	36.31	40.89	49.22	60.88
	Tofacitinib 10 mg BID	284	44.21	9.38	19.23	36.31	45.06	50.05	60.88
Month 9	Placebo→Tofacitinib 5 mg BID	71	40.80	8.53	23.40	32.56	40.89	45.89	60.88
	Placebo→Tofacitinib 10 mg BID	68	44.00	9.40	32.14	36.31	42.97	50.05	60.88
	Tofacitinib 5 mg BID	265	42.26	8.90	19.23	36.31	40.89	49.22	60.88
	Tofacitinib 10 mg BID	279	44.13	9.46	19.23	36.31	45.06	50.05	60.88
Month 12	Placebo→Tofacitinib 5 mg BID	68	44.00	8.57	23.40	36.31	45.06	50.05	60.88
	Placebo→Tofacitinib 10 mg BID	63	47.17	9.99	28.40	36.31	49.22	54.22	60.88
	Tofacitinib 5 mg BID	252	42.91	8.90	19.23	36.31	40.89	50.05	60.88
	Tofacitinib 10 mg BID	265	44.18	9.59	19.23	36.31	45.06	50.05	60.88
Month 15	Placebo→Tofacitinib 5 mg BID	67	43.60	8.21	23.40	36.31	45.06	50.05	60.88
	Placebo→Tofacitinib 10 mg BID	63	45.78	9.89	28.40	40.47	45.06	54.22	60.88
	Tofacitinib 5 mg BID	242	42.37	8.71	23.40	36.31	40.89	49.22	60.88
	Tofacitinib 10 mg BID	254	45.33	9.77	19.23	36.31	45.06	54.22	60.88
Month 18	Placebo→Tofacitinib 5 mg BID	62	44.40	8.42	27.98	40.47	45.06	50.05	60.88
	Placebo→Tofacitinib 10 mg BID	60	45.72	8.56	28.40	38.39	45.06	52.14	60.88
	Tofacitinib 5 mg BID	235	42.61	8.92	19.23	36.31	40.89	50.05	60.88
	Tofacitinib 10 mg BID	244	44.46	9.63	19.23	36.31	45.06	50.05	60.88
Month 21	Placebo→Tofacitinib 5 mg BID	59	44.82	8.24	28.40	36.31	45.06	50.05	60.88
	Placebo→Tofacitinib 10 mg BID	55	46.21	9.17	28.40	40.47	45.06	54.22	60.88
	Tofacitinib 5 mg BID	220	43.12	9.40	23.40	36.31	44.64	50.05	60.88
	Tofacitinib 10 mg BID	231	44.93	10.20	19.23	36.31	45.06	54.22	60.88
Month 24	Placebo→Tofacitinib 5 mg BID	57	44.08	8.49	28.40	36.31	45.06	50.05	60.88
	Placebo→Tofacitinib 10 mg BID	53	46.27	10.63	19.23	36.31	45.06	54.22	60.88
	Tofacitinib 5 mg BID	211	42.87	9.20	23.40	36.31	40.89	50.05	60.88
	Tofacitinib 10 mg BID	218	45.17	9.88	19.23	36.31	45.06	54.22	60.88
	Placebo→Tofacitinib 5 mg BID	54	44.17	8.91	24.23	40.47	45.06	50.05	60.88
	Placebo→Tofacitinib 10 mg BID	52	45.48	10.04	19.23	36.31	45.06	54.22	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 104. Descriptive Statistics of Change From Baseline of SF-36 Bodily Pain Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	5.75	7.22	-16.24	0.00	4.58	9.16	29.99
	Tofacitinib 10 mg BID	308	7.38	8.53	-12.50	0.00	7.91	12.91	34.99
	Placebo	153	1.63	6.31	-12.08	-4.17	0.00	4.58	24.57
Month 3	Tofacitinib 5 mg BID	294	7.38	8.86	-17.49	0.00	7.91	13.33	34.99
	Tofacitinib 10 mg BID	300	9.86	9.56	-21.66	4.17	9.16	17.29	37.49
	Placebo	146	2.32	8.02	-21.24	0.00	0.00	7.91	25.82
Month 6	Tofacitinib 5 mg BID	281	7.89	9.01	-13.33	0.00	7.91	12.91	34.99
	Tofacitinib 10 mg BID	284	9.75	10.26	-20.41	4.17	8.75	16.66	36.65
	Placebo	62	4.46	8.68	-14.99	0.00	4.17	12.50	24.57
	Placebo→5 mg	40	8.64	9.35	-8.33	3.75	4.58	16.66	30.82
	Placebo→10 mg	37	8.77	10.36	-12.91	0.00	8.75	15.83	41.65

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 105. Descriptive Statistics of Change From Baseline of SF-36 Bodily Pain Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	5.75	7.22	-16.24	0.00	4.58	9.16	29.99
	Tofacitinib 10 mg BID	308	7.38	8.53	-12.50	0.00	7.91	12.91	34.99
	Placebo→Tofacitinib 5 mg BID	79	1.82	6.54	-8.75	-4.17	0.00	4.58	24.57
	Placebo→Tofacitinib 10 mg BID	74	1.42	6.09	-12.08	0.00	0.00	4.58	13.74
Month 3	Tofacitinib 5 mg BID	294	7.38	8.86	-17.49	0.00	7.91	13.33	34.99
	Tofacitinib 10 mg BID	300	9.86	9.56	-21.66	4.17	9.16	17.29	37.49
	Placebo→Tofacitinib 5 mg BID	75	2.27	8.55	-21.24	-0.42	0.00	7.91	25.82
	Placebo→Tofacitinib 10 mg BID	71	2.38	7.47	-16.66	0.00	0.00	7.91	20.41
Month 6	Tofacitinib 5 mg BID	281	7.89	9.01	-13.33	0.00	7.91	12.91	34.99
	Tofacitinib 10 mg BID	284	9.75	10.26	-20.41	4.17	8.75	16.66	36.65
	Placebo→Tofacitinib 5 mg BID	71	6.34	9.93	-14.99	0.00	4.58	12.91	30.82
	Placebo→Tofacitinib 10 mg BID	68	7.31	9.11	-12.91	0.00	7.91	12.91	41.65
Month 9	Tofacitinib 5 mg BID	264	8.06	9.54	-17.91	0.62	7.91	13.74	34.99
	Tofacitinib 10 mg BID	279	9.72	10.32	-24.57	3.75	8.75	17.08	36.65
	Placebo→Tofacitinib 5 mg BID	68	9.38	10.25	-13.33	3.75	8.75	16.87	32.49
	Placebo→Tofacitinib 10 mg BID	63	10.33	8.55	-7.91	4.17	10.83	16.24	41.65
Month 12	Tofacitinib 5 mg BID	251	8.64	8.99	-16.24	3.75	8.33	13.74	34.99
	Tofacitinib 10 mg BID	265	9.72	10.16	-17.49	3.75	8.75	17.08	34.99
	Placebo→Tofacitinib 5 mg BID	67	9.14	8.14	-12.91	3.75	9.16	13.74	28.32
	Placebo→Tofacitinib 10 mg BID	63	8.94	9.46	-12.50	3.75	9.16	15.83	25.82
Month 15	Tofacitinib 5 mg BID	241	8.28	8.60	-16.66	3.75	7.91	13.74	36.65
	Tofacitinib 10 mg BID	254	10.75	10.47	-20.83	4.17	9.37	17.91	41.65
	Placebo→Tofacitinib 5 mg BID	62	9.59	9.42	-15.83	3.75	8.75	16.66	28.32
	Placebo→Tofacitinib 10 mg BID	60	9.09	7.55	-4.17	4.17	8.75	13.54	25.82
Month 18	Tofacitinib 5 mg BID	234	8.42	9.50	-17.08	0.00	8.12	13.74	32.49
	Tofacitinib 10 mg BID	244	9.83	10.95	-37.49	1.67	9.16	17.08	41.65
	Placebo→Tofacitinib 5 mg BID	59	9.88	9.05	-9.58	4.17	9.16	13.74	32.49
	Placebo→Tofacitinib 10 mg BID	55	8.63	8.35	-9.58	4.17	8.33	15.83	24.57
Month 21	Tofacitinib 5 mg BID	219	8.94	9.29	-12.08	0.00	8.75	15.83	34.99
	Tofacitinib 10 mg BID	231	10.43	11.11	-17.49	3.75	8.75	17.91	41.65
	Placebo→Tofacitinib 5 mg BID	57	9.34	9.66	-13.74	4.17	8.75	16.66	32.49
	Placebo→Tofacitinib 10 mg BID	53	8.58	9.49	-17.08	3.75	7.91	13.33	41.65
Month 24	Tofacitinib 5 mg BID	210	8.38	9.56	-16.66	0.00	8.33	13.74	34.99
	Tofacitinib 10 mg BID	218	10.61	10.29	-12.91	4.17	9.16	17.91	41.65
	Placebo→Tofacitinib 5 mg BID	54	9.37	9.81	-12.08	3.75	9.16	13.74	32.49
	Placebo→Tofacitinib 10 mg BID	52	7.77	8.17	-17.49	3.75	9.16	13.12	24.57

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **Mental Health Score:** The results are presented in Table 106, Table 107, Table 108 and Table 109.

Table 106. Descriptive Statistics of SF-36 Mental Health Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	39.94	11.30	10.79	32.96	38.50	49.58	63.43
	Tofacitinib 10 mg BID	309	40.45	11.15	8.02	32.96	38.50	49.58	63.43
	Placebo	156	42.03	11.28	13.56	35.73	42.65	50.96	63.43
Month 1	Tofacitinib 5 mg BID	308	43.70	11.76	10.79	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	308	44.88	10.82	8.02	38.50	44.04	52.35	63.43
	Placebo	153	42.70	11.98	13.56	35.73	44.04	52.35	63.43
Month 3	Tofacitinib 5 mg BID	295	43.84	11.82	10.79	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	300	45.52	10.50	13.56	38.50	46.81	52.35	63.43
	Placebo	146	42.80	11.47	13.56	35.73	42.65	52.35	63.43
Month 6	Tofacitinib 5 mg BID	282	44.59	11.68	8.02	35.73	44.04	55.12	63.43
	Tofacitinib 10 mg BID	284	45.63	11.35	10.79	38.50	46.81	55.12	63.43
	Placebo	62	43.37	8.46	19.10	35.73	44.04	49.58	60.66
	Placebo→5 mg	40	42.31	10.99	19.10	35.73	42.65	49.58	63.43
	Placebo→10 mg	37	47.63	12.14	19.10	38.50	52.35	57.89	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 107. Descriptive Statistics of SF-36 Mental Health Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	39.94	11.30	10.79	32.96	38.50	49.58	63.43
	Tofacitinib 10 mg BID	309	40.45	11.15	8.02	32.96	38.50	49.58	63.43
	Placebo→Tofacitinib 5 mg BID	79	40.81	10.35	19.10	32.96	41.27	46.81	63.43
	Placebo→Tofacitinib 10 mg BID	77	43.28	12.10	13.56	35.73	44.04	52.35	63.43
Month 1	Tofacitinib 5 mg BID	308	43.70	11.76	10.79	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	308	44.88	10.82	8.02	38.50	44.04	52.35	63.43
	Placebo→Tofacitinib 5 mg BID	79	41.38	11.42	13.56	32.96	41.27	52.35	63.43
	Placebo→Tofacitinib 10 mg BID	74	44.11	12.48	16.33	35.73	44.04	55.12	63.43
Month 3	Tofacitinib 5 mg BID	295	43.84	11.82	10.79	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	300	45.52	10.50	13.56	38.50	46.81	52.35	63.43
	Placebo→Tofacitinib 5 mg BID	75	41.05	11.16	13.56	35.73	41.27	49.58	60.66
	Placebo→Tofacitinib 10 mg BID	71	44.66	11.57	13.56	35.73	46.81	55.12	63.43
Month 6	Tofacitinib 5 mg BID	282	44.59	11.68	8.02	35.73	44.04	55.12	63.43
	Tofacitinib 10 mg BID	284	45.63	11.35	10.79	38.50	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	71	42.36	9.73	19.10	35.73	41.27	49.58	63.43
	Placebo→Tofacitinib 10 mg BID	68	46.12	10.86	19.10	38.50	46.81	55.12	63.43
Month 9	Tofacitinib 5 mg BID	265	44.88	11.39	8.02	38.50	46.81	52.35	63.43
	Tofacitinib 10 mg BID	279	45.02	11.74	8.02	35.73	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	68	44.65	11.33	10.79	35.73	44.04	55.12	63.43
	Placebo→Tofacitinib 10 mg BID	63	48.35	11.68	13.56	41.27	49.58	57.89	63.43
Month 12	Tofacitinib 5 mg BID	252	44.81	10.83	13.56	35.73	46.81	52.35	63.43
	Tofacitinib 10 mg BID	265	45.07	11.22	8.02	38.50	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	67	44.66	12.07	8.02	35.73	44.04	55.12	63.43
	Placebo→Tofacitinib 10 mg BID	63	46.81	11.48	13.56	38.50	49.58	57.89	63.43
Month 15	Tofacitinib 5 mg BID	242	44.28	11.04	8.02	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	254	45.47	11.34	8.02	35.73	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	62	43.99	11.88	8.02	35.73	44.04	55.12	63.43
	Placebo→Tofacitinib 10 mg BID	60	46.53	9.81	24.64	39.88	46.81	55.12	63.43
Month 18	Tofacitinib 5 mg BID	235	43.84	11.06	10.79	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	244	45.34	10.97	10.79	38.50	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	59	45.31	12.24	8.02	35.73	46.81	55.12	63.43
	Placebo→Tofacitinib 10 mg BID	55	47.97	9.87	21.87	38.50	49.58	57.89	63.43
Month 21	Tofacitinib 5 mg BID	220	44.13	11.25	8.02	35.73	44.04	52.35	63.43
	Tofacitinib 10 mg BID	231	46.32	10.26	19.10	38.50	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	57	45.59	11.55	8.02	38.50	46.81	55.12	63.43
	Placebo→Tofacitinib 10 mg BID	53	46.60	10.66	19.10	41.27	49.58	55.12	63.43
Month 24	Tofacitinib 5 mg BID	211	44.72	11.32	8.02	35.73	46.81	55.12	63.43
	Tofacitinib 10 mg BID	218	45.91	10.99	13.56	38.50	46.81	55.12	63.43
	Placebo→Tofacitinib 5 mg BID	54	44.29	12.03	10.79	35.73	44.04	52.35	63.43
	Placebo→Tofacitinib 10 mg BID	52	48.30	10.98	13.56	41.27	49.58	57.89	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 108. Descriptive Statistics of Change From Baseline of SF-36 Mental Health Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	3.77	8.85	-24.93	-2.77	2.77	8.31	30.48
	Tofacitinib 10 mg BID	308	4.40	9.70	-27.70	-2.77	2.77	11.08	38.79
	Placebo	153	0.57	8.59	-33.25	-5.54	0.00	5.54	30.48
Month 3	Tofacitinib 5 mg BID	294	3.78	10.85	-36.02	-2.77	2.77	11.08	47.10
	Tofacitinib 10 mg BID	300	5.13	10.81	-27.70	-2.77	5.54	11.08	38.79
	Placebo	146	0.59	9.76	-24.93	-5.54	0.00	5.54	24.93
Month 6	Tofacitinib 5 mg BID	281	4.64	11.39	-24.93	-2.77	2.77	11.08	44.33
	Tofacitinib 10 mg BID	284	5.06	10.62	-38.79	-2.77	5.54	11.08	41.56
	Placebo	62	1.03	10.15	-33.25	-2.77	2.77	8.31	33.25
	Placebo→5 mg	40	4.16	10.99	-16.62	-2.77	4.16	11.08	30.48
	Placebo→10 mg	37	3.07	10.98	-19.39	-2.77	0.00	5.54	30.48

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 109. Descriptive Statistics of Change From Baseline of SF-36 Mental Health Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	3.77	8.85	-24.93	-2.77	2.77	8.31	30.48
	Tofacitinib 10 mg BID	308	4.40	9.70	-27.70	-2.77	2.77	11.08	38.79
	Placebo→Tofacitinib 5 mg BID	79	0.57	9.48	-24.93	-5.54	0.00	8.31	24.93
	Placebo→Tofacitinib 10 mg BID	74	0.56	7.59	-33.25	-2.77	0.00	2.77	30.48
Month 3	Tofacitinib 5 mg BID	294	3.78	10.85	-36.02	-2.77	2.77	11.08	47.1
	Tofacitinib 10 mg BID	300	5.13	10.81	-27.7	-2.77	5.54	11.08	38.79
	Placebo→Tofacitinib 5 mg BID	75	0.66	9.97	-24.93	-5.54	0.00	5.54	22.16
	Placebo→Tofacitinib 10 mg BID	71	0.51	9.61	-24.93	-2.77	0.00	5.54	24.93
Month 6	Tofacitinib 5 mg BID	281	4.64	11.39	-24.93	-2.77	2.77	11.08	44.33
	Tofacitinib 10 mg BID	284	5.06	10.62	-38.79	-2.77	5.54	11.08	41.56
	Placebo→Tofacitinib 5 mg BID	71	2.19	10.13	-22.16	-2.77	2.77	8.31	30.48
	Placebo→Tofacitinib 10 mg BID	68	2.77	11.20	-33.25	-2.77	2.77	6.93	33.25
Month 9	Tofacitinib 5 mg BID	264	4.48	11.92	-44.33	-2.77	2.77	11.08	49.87
	Tofacitinib 10 mg BID	279	4.43	10.97	-24.93	-2.77	2.77	11.08	52.64
	Placebo→Tofacitinib 5 mg BID	68	4.60	10.04	-13.85	0.00	2.77	8.31	33.25
	Placebo→Tofacitinib 10 mg BID	63	4.44	11.74	-19.39	-2.77	2.77	8.31	33.25
Month 12	Tofacitinib 5 mg BID	251	4.43	11.51	-30.48	-2.77	2.77	11.08	49.87
	Tofacitinib 10 mg BID	265	4.50	10.75	-24.93	-2.77	2.77	11.08	52.64
	Placebo→Tofacitinib 5 mg BID	67	4.96	10.64	-19.39	-2.77	2.77	11.08	38.79
	Placebo→Tofacitinib 10 mg BID	63	2.90	10.30	-30.48	-2.77	2.77	8.31	24.93
Month 15	Tofacitinib 5 mg BID	241	4.02	10.84	-27.70	-2.77	2.77	11.08	36.02
	Tofacitinib 10 mg BID	254	4.74	11.76	-36.02	-2.77	4.16	11.08	55.41
	Placebo→Tofacitinib 5 mg BID	62	4.51	10.55	-16.62	-2.77	2.77	8.31	36.02
	Placebo→Tofacitinib 10 mg BID	60	2.72	8.39	-22.16	-1.39	2.77	8.31	22.16
Month 18	Tofacitinib 5 mg BID	234	3.42	11.03	-36.02	-2.77	2.77	11.08	47.10
	Tofacitinib 10 mg BID	244	4.55	11.48	-33.25	-2.77	5.54	11.08	49.87
	Placebo→Tofacitinib 5 mg BID	59	5.73	9.54	-16.62	0.00	5.54	11.08	30.48
	Placebo→Tofacitinib 10 mg BID	55	3.27	7.54	-11.08	-2.77	2.77	8.31	19.39
Month 21	Tofacitinib 5 mg BID	219	3.96	11.02	-30.48	-2.77	2.77	11.08	49.87
	Tofacitinib 10 mg BID	231	5.70	10.66	-22.16	0.00	5.54	11.08	49.87
	Placebo→Tofacitinib 5 mg BID	57	5.98	11.10	-16.62	0.00	5.54	8.31	44.33
	Placebo→Tofacitinib 10 mg BID	53	1.83	8.84	-19.39	-2.77	2.77	8.31	22.16
Month 24	Tofacitinib 5 mg BID	210	4.22	11.34	-27.7	-2.77	2.77	11.08	41.56
	Tofacitinib 10 mg BID	218	5.22	10.92	-24.93	-2.77	5.54	11.08	55.41
	Placebo→Tofacitinib 5 mg BID	54	5.18	11.16	-24.93	0.00	4.16	11.08	38.79
	Placebo→Tofacitinib 10 mg BID	52	3.41	7.53	-16.62	0.00	2.77	8.31	19.39

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- Role Emotional Score: The results are presented in Table 110, Table 111, Table 112 and Table 113.

Table 110. Descriptive Statistics of SF-36 Role Emotional Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	35.64	12.67	10.25	25.39	32.96	44.32	55.68
	Tofacitinib 10 mg BID	309	36.25	13.37	10.25	25.39	32.96	48.11	55.68
	Placebo	156	37.43	13.82	10.25	29.18	36.75	48.11	55.68
Month 1	Tofacitinib 5 mg BID	307	39.06	12.34	10.25	32.96	40.54	48.11	55.68
	Tofacitinib 10 mg BID	308	41.13	12.03	10.25	32.96	40.54	51.89	55.68
	Placebo	153	38.53	12.47	10.25	29.18	36.75	51.89	55.68
Month 3	Tofacitinib 5 mg BID	295	39.52	12.64	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	300	43.12	11.97	10.25	32.96	44.32	55.68	55.68
	Placebo	146	38.20	13.46	10.25	29.18	36.75	51.89	55.68
Month 6	Tofacitinib 5 mg BID	281	40.68	12.43	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	283	42.82	11.55	10.25	32.96	44.32	55.68	55.68
	Placebo	62	41.88	10.80	17.82	32.96	40.54	55.68	55.68
	Placebo→5 mg	40	39.21	11.29	17.82	32.96	38.64	46.21	55.68
	Placebo→10 mg	37	43.20	12.46	14.03	36.75	44.32	55.68	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 111. Descriptive Statistics of SF-36 Role Emotional Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	35.64	12.67	10.25	25.39	32.96	44.32	55.68
	Tofacitinib 10 mg BID	309	36.25	13.37	10.25	25.39	32.96	48.11	55.68
	Placebo→Tofacitinib 5 mg BID	79	36.27	13.80	10.25	25.39	36.75	48.11	55.68
	Placebo→Tofacitinib 10 mg BID	77	38.62	13.82	10.25	29.18	40.54	51.89	55.68
Month 1	Tofacitinib 5 mg BID	307	39.06	12.34	10.25	32.96	40.54	48.11	55.68
	Tofacitinib 10 mg BID	308	41.13	12.03	10.25	32.96	40.54	51.89	55.68
	Placebo→Tofacitinib 5 mg BID	79	37.04	11.91	10.25	29.18	32.96	44.32	55.68
	Placebo→Tofacitinib 10 mg BID	74	40.13	12.93	10.25	32.96	40.54	51.89	55.68
Month 3	Tofacitinib 5 mg BID	295	39.52	12.64	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	300	43.12	11.97	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	75	35.84	13.62	10.25	25.39	36.75	44.32	55.68
	Placebo→Tofacitinib 10 mg BID	71	40.70	12.92	10.25	29.18	40.54	55.68	55.68
Month 6	Tofacitinib 5 mg BID	281	40.68	12.43	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	283	42.82	11.55	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	71	40.00	10.64	17.82	32.96	40.54	48.11	55.68
	Placebo→Tofacitinib 10 mg BID	68	42.99	12.07	14.03	32.96	44.32	55.68	55.68
Month 9	Tofacitinib 5 mg BID	264	41.71	12.56	10.25	32.96	44.32	55.68	55.68
	Tofacitinib 10 mg BID	279	43.01	11.70	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	68	42.15	11.24	10.25	32.96	44.32	53.79	55.68
	Placebo→Tofacitinib 10 mg BID	63	45.28	11.54	10.25	32.96	48.11	55.68	55.68
Month 12	Tofacitinib 5 mg BID	252	41.15	12.74	10.25	32.96	44.32	55.68	55.68
	Tofacitinib 10 mg BID	264	42.80	11.44	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	67	41.27	12.59	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 10 mg BID	63	44.38	12.34	10.25	36.75	48.11	55.68	55.68
Month 15	Tofacitinib 5 mg BID	241	40.33	12.15	10.25	32.96	40.54	51.89	55.68
	Tofacitinib 10 mg BID	254	43.20	11.18	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	62	41.51	11.51	14.03	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 10 mg BID	60	43.94	12.23	10.25	32.96	48.11	55.68	55.68
Month 18	Tofacitinib 5 mg BID	234	40.91	11.93	10.25	32.96	44.32	51.89	55.68
	Tofacitinib 10 mg BID	244	42.63	11.95	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	59	42.27	11.75	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 10 mg BID	55	44.11	11.73	14.03	32.96	44.32	55.68	55.68
Month 21	Tofacitinib 5 mg BID	219	41.92	11.14	10.25	32.96	44.32	51.89	55.68
	Tofacitinib 10 mg BID	231	42.76	11.32	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	57	41.86	12.26	17.82	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 10 mg BID	53	44.32	11.62	10.25	36.75	48.11	55.68	55.68
Month 24	Tofacitinib 5 mg BID	210	41.76	11.63	10.25	32.96	44.32	55.68	55.68
	Tofacitinib 10 mg BID	218	43.73	11.33	10.25	32.96	44.32	55.68	55.68
	Placebo→Tofacitinib 5 mg BID	54	40.68	11.95	10.25	32.96	40.54	55.68	55.68
	Placebo→Tofacitinib 10 mg BID	52	45.41	10.66	21.61	36.75	46.21	55.68	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 112. Descriptive Statistics of Change From Baseline of SF-36 Role Emotional Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	3.48	12.54	-34.07	-3.79	0	11.36	45.43
	Tofacitinib 10 mg BID	308	4.83	12.18	-22.71	0.00	3.79	11.36	45.43
	Placebo	153	0.87	11.80	-30.29	-3.79	0.00	7.57	45.43
Month 3	Tofacitinib 5 mg BID	294	3.94	12.34	-37.86	-3.79	3.79	11.36	45.43
	Tofacitinib 10 mg BID	300	6.97	13.16	-30.29	0.00	3.79	15.14	45.43
	Placebo	146	0.65	12.77	-37.86	-7.57	0.00	7.57	41.64
Month 6	Tofacitinib 5 mg BID	280	4.85	13.70	-34.07	-3.79	3.79	11.36	45.43
	Tofacitinib 10 mg BID	283	6.64	13.66	-37.86	0.00	3.79	15.14	45.43
	Placebo	62	4.52	12.69	-34.07	0.00	3.79	7.57	45.43
	Placebo→5 mg	40	4.83	10.25	-11.36	-1.89	1.89	11.36	34.07
	Placebo→10 mg	37	3.38	12.61	-30.29	0.00	0.00	7.57	41.64

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 113. Descriptive Statistics of Change From Baseline of SF-36 Role Emotional Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	3.48	12.54	-34.07	-3.79	0.00	11.36	45.43
	Tofacitinib 10 mg BID	308	4.83	12.18	-22.71	0.00	3.79	11.36	45.43
	Placebo→Tofacitinib 5 mg BID	79	0.77	12.07	-30.29	-3.79	0.00	7.57	45.43
	Placebo→Tofacitinib 10 mg BID	74	0.97	11.59	-30.29	-3.79	0.00	7.57	37.86
Month 3	Tofacitinib 5 mg BID	294	3.94	12.34	-37.86	-3.79	3.79	11.36	45.43
	Tofacitinib 10 mg BID	300	6.97	13.16	-30.29	0.00	3.79	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	75	-0.05	13.47	-37.86	-7.57	0.00	7.57	41.64
	Placebo→Tofacitinib 10 mg BID	71	1.39	12.04	-30.29	-3.79	0.00	7.57	37.86
Month 6	Tofacitinib 5 mg BID	280	4.85	13.7	-34.07	-3.79	3.79	11.36	45.43
	Tofacitinib 10 mg BID	283	6.64	13.66	-37.86	0.00	3.79	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	71	4.64	11.31	-15.14	0.00	3.79	11.36	45.43
	Placebo→Tofacitinib 10 mg BID	68	3.95	12.66	-34.07	0.00	0.00	7.57	41.64
Month 9	Tofacitinib 5 mg BID	263	5.31	14.3	-37.86	0.00	3.79	15.14	45.43
	Tofacitinib 10 mg BID	279	7.14	13.38	-26.50	0.00	7.57	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	68	6.46	11.24	-22.71	0.00	7.57	11.36	45.43
	Placebo→Tofacitinib 10 mg BID	63	5.83	10.46	-18.93	0.00	3.79	11.36	37.86
Month 12	Tofacitinib 5 mg BID	251	5.11	13.39	-30.29	0.00	3.79	15.14	45.43
	Tofacitinib 10 mg BID	264	6.84	13.23	-22.71	0.00	7.57	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	67	5.82	10.47	-18.93	0.00	3.79	15.14	26.50
	Placebo→Tofacitinib 10 mg BID	63	4.93	14.31	-41.64	0.00	3.79	15.14	37.86
Month 15	Tofacitinib 5 mg BID	240	4.13	13.70	-41.64	-3.79	3.79	11.36	45.43
	Tofacitinib 10 mg BID	254	7.18	13.55	-34.07	0.00	7.57	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	62	4.88	12.81	-22.71	-3.79	3.79	11.36	34.07
	Placebo→Tofacitinib 10 mg BID	60	4.54	12.33	-34.07	-1.89	1.89	11.36	45.43
Month 18	Tofacitinib 5 mg BID	233	4.55	13.17	-41.64	-3.79	3.79	11.36	45.43
	Tofacitinib 10 mg BID	244	6.52	14.13	-30.29	0.00	3.79	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	59	5.45	10.69	-22.71	0.00	3.79	11.36	41.64
	Placebo→Tofacitinib 10 mg BID	55	4.27	12.45	-30.29	0.00	3.79	11.36	37.86
Month 21	Tofacitinib 5 mg BID	218	5.87	12.85	-30.29	0.00	3.79	11.36	45.43
	Tofacitinib 10 mg BID	231	7.10	13.39	-34.07	0.00	7.57	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	57	5.11	10.74	-15.14	-3.79	3.79	11.36	45.43
	Placebo→Tofacitinib 10 mg BID	53	4.43	14.94	-34.07	-3.79	3.79	11.36	37.86
Month 24	Tofacitinib 5 mg BID	209	5.34	14.03	-37.86	0.00	3.79	15.14	45.43
	Tofacitinib 10 mg BID	218	7.94	14.00	-26.50	0.00	7.57	15.14	45.43
	Placebo→Tofacitinib 5 mg BID	54	3.86	11.07	-18.93	-3.79	3.79	11.36	37.86
	Placebo→Tofacitinib 10 mg BID	52	5.61	10.88	-18.93	0.00	3.79	11.36	34.07

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **Vitality Score:** The results are presented in Table 114, Table 115, Table 116 and Table 117.

Table 114. Descriptive Statistics of SF-36 Vitality Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	40.62	9.90	22.02	33.99	39.98	45.97	69.92
	Tofacitinib 10 mg BID	309	42.53	9.67	22.02	36.99	42.97	48.96	69.92
	Placebo	156	42.97	9.95	22.02	35.49	42.97	48.96	69.92
Month 1	Tofacitinib 5 mg BID	308	45.33	10.33	22.02	36.99	45.97	51.95	69.92
	Tofacitinib 10 mg BID	308	46.84	9.77	22.02	39.98	45.97	51.95	69.92
	Placebo	153	43.82	10.40	22.02	36.99	42.97	51.95	69.92
Month 3	Tofacitinib 5 mg BID	295	46.72	10.31	22.02	39.98	45.97	51.95	69.92
	Tofacitinib 10 mg BID	300	48.60	9.52	22.02	42.97	48.96	54.95	69.92
	Placebo	146	44.24	10.15	22.02	36.99	45.97	51.95	69.92
Month 6	Tofacitinib 5 mg BID	282	46.67	10.02	22.02	39.98	45.97	54.95	69.92
	Tofacitinib 10 mg BID	284	48.51	9.43	22.02	42.97	48.96	54.95	69.92
	Placebo	62	46.31	9.14	25.01	39.98	45.97	51.95	69.92
	Placebo→5 mg	40	45.22	9.98	28.01	36.99	45.97	51.95	66.92
	Placebo→10 mg	37	50.58	10.41	33.99	42.97	48.96	57.94	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 115. Descriptive Statistics of SF-36 Vitality Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	40.62	9.90	22.02	33.99	39.98	45.97	69.92
	Tofacitinib 10 mg BID	309	42.53	9.67	22.02	36.99	42.97	48.96	69.92
	Placebo→Tofacitinib 5 mg BID	79	41.65	9.54	22.02	33.99	42.97	48.96	69.92
	Placebo→Tofacitinib 10 mg BID	77	44.33	10.24	25.01	36.99	45.97	48.96	69.92
Month 1	Tofacitinib 5 mg BID	308	45.33	10.33	22.02	36.99	45.97	51.95	69.92
	Tofacitinib 10 mg BID	308	46.84	9.77	22.02	39.98	45.97	51.95	69.92
	Placebo→Tofacitinib 5 mg BID	79	43.01	9.53	22.02	36.99	42.97	48.96	63.93
	Placebo→Tofacitinib 10 mg BID	74	44.67	11.26	22.02	36.99	42.97	51.95	69.92
Month 3	Tofacitinib 5 mg BID	295	46.72	10.31	22.02	39.98	45.97	51.95	69.92
	Tofacitinib 10 mg BID	300	48.60	9.52	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	75	42.65	9.65	22.02	36.99	42.97	48.96	60.93
	Placebo→Tofacitinib 10 mg BID	71	45.93	10.45	25.01	36.99	45.97	54.95	69.92
Month 6	Tofacitinib 5 mg BID	282	46.67	10.02	22.02	39.98	45.97	54.95	69.92
	Tofacitinib 10 mg BID	284	48.51	9.43	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	71	45.59	9.15	28.01	39.98	45.97	51.95	66.92
	Placebo→Tofacitinib 10 mg BID	68	48.74	10.44	25.01	39.98	48.96	54.95	69.92
Month 9	Tofacitinib 5 mg BID	265	47.40	10.38	22.02	39.98	48.96	54.95	69.92
	Tofacitinib 10 mg BID	279	47.94	9.79	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	68	46.32	10.06	22.02	39.98	45.97	51.95	69.92
	Placebo→Tofacitinib 10 mg BID	63	50.10	9.83	28.01	42.97	48.96	57.94	69.92
Month 12	Tofacitinib 5 mg BID	252	47.58	10.16	22.02	39.98	48.96	54.95	69.92
	Tofacitinib 10 mg BID	265	48.12	9.96	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	67	47.08	11.04	22.02	39.98	48.96	54.95	69.92
	Placebo→Tofacitinib 10 mg BID	63	49.20	10.33	22.02	42.97	48.96	57.94	69.92
Month 15	Tofacitinib 5 mg BID	242	47.02	9.94	22.02	39.98	45.97	54.95	69.92
	Tofacitinib 10 mg BID	254	48.49	9.91	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	62	47.42	10.41	22.02	42.97	47.46	54.95	69.92
	Placebo→Tofacitinib 10 mg BID	60	49.46	10.46	22.02	42.97	51.95	57.94	69.92
Month 18	Tofacitinib 5 mg BID	235	46.87	10.77	22.02	39.98	45.97	54.95	69.92
	Tofacitinib 10 mg BID	244	48.24	9.98	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	59	47.24	10.07	22.02	42.97	48.96	51.95	69.92
	Placebo→Tofacitinib 10 mg BID	55	49.83	9.19	22.02	42.97	51.95	57.94	63.93
Month 21	Tofacitinib 5 mg BID	220	47.00	10.23	22.02	39.98	45.97	54.95	69.92
	Tofacitinib 10 mg BID	231	48.77	9.37	22.02	42.97	48.96	54.95	69.92
	Placebo→Tofacitinib 5 mg BID	57	47.44	10.19	25.01	39.98	48.96	54.95	66.92
	Placebo→Tofacitinib 10 mg BID	53	48.68	10.26	22.02	42.97	48.96	54.95	69.92
Month 24	Tofacitinib 5 mg BID	211	47.67	10.00	22.02	39.98	45.97	54.95	69.92
	Tofacitinib 10 mg BID	218	48.82	9.67	22.02	42.97	48.96	57.94	69.92
	Placebo→Tofacitinib 5 mg BID	54	46.97	9.85	25.01	39.98	45.97	51.95	69.92
	Placebo→Tofacitinib 10 mg BID	52	50.05	10.27	22.02	45.97	51.95	56.44	66.92

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 116. Descriptive Statistics of Change From Baseline of SF-36 Vitality Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	4.87	8.30	-14.97	0.00	2.99	8.98	32.93
	Tofacitinib 10 mg BID	308	4.29	8.92	-23.95	0.00	2.99	8.98	38.92
	Placebo	153	0.72	8.01	-26.94	-2.99	0.00	5.99	23.95
Month 3	Tofacitinib 5 mg BID	294	6.23	9.59	-23.95	0.00	5.99	11.97	38.92
	Tofacitinib 10 mg BID	300	6.04	10.12	-23.95	0.00	5.99	11.97	38.92
	Placebo	146	0.90	7.96	-20.95	-2.99	0.00	5.99	17.96
Month 6	Tofacitinib 5 mg BID	281	6.23	9.75	-20.95	0.00	5.99	11.97	35.92
	Tofacitinib 10 mg BID	284	6.11	10.37	-29.94	0.00	5.99	11.97	47.90
	Placebo	62	2.56	8.46	-23.95	0.00	2.99	8.98	20.95
	Placebo→5 mg	40	5.69	9.84	-17.96	0.00	5.99	11.97	29.94
	Placebo→10 mg	37	5.83	9.60	-17.96	0.00	5.99	11.97	23.95

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 117. Descriptive Statistics of Change From Baseline of SF-36 Vitality Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	4.87	8.30	-14.97	0.00	2.99	8.98	32.93
	Tofacitinib 10 mg BID	308	4.29	8.92	-23.95	0.00	2.99	8.98	38.92
Month 3	Placebo→Tofacitinib 5 mg BID	79	1.36	8.65	-26.94	-2.99	0.00	5.99	23.95
	Placebo→Tofacitinib 10 mg BID	74	0.04	7.26	-23.95	-2.99	0.00	5.99	17.96
	Tofacitinib 5 mg BID	294	6.23	9.59	-23.95	0.00	5.99	11.97	38.92
	Tofacitinib 10 mg BID	300	6.04	10.12	-23.95	0.00	5.99	11.97	38.92
Month 6	Placebo→Tofacitinib 5 mg BID	75	1.00	8.51	-20.95	-5.99	0.00	5.99	17.96
	Placebo→Tofacitinib 10 mg BID	71	0.80	7.38	-14.97	-2.99	0.00	5.99	17.96
	Tofacitinib 5 mg BID	281	6.23	9.75	-20.95	0.00	5.99	11.97	35.92
	Tofacitinib 10 mg BID	284	6.11	10.37	-29.94	0.00	5.99	11.97	47.90
Month 9	Placebo→Tofacitinib 5 mg BID	71	4.38	9.40	-23.95	0.00	5.99	8.98	29.94
	Placebo→Tofacitinib 10 mg BID	68	4.27	9.17	-17.96	0.00	2.99	11.97	23.95
	Tofacitinib 5 mg BID	264	6.68	10.68	-29.94	0.00	5.99	13.47	41.91
	Tofacitinib 10 mg BID	279	5.60	10.28	-23.95	0.00	5.99	11.97	35.92
Month 12	Placebo→Tofacitinib 5 mg BID	68	5.24	10.49	-20.95	0.00	5.99	8.98	38.92
	Placebo→Tofacitinib 10 mg BID	63	5.27	9.18	-14.97	0.00	5.99	11.97	26.94
	Tofacitinib 5 mg BID	251	6.88	10.37	-35.92	0.00	5.99	14.97	38.92
	Tofacitinib 10 mg BID	265	5.84	9.59	-17.96	0.00	5.99	11.97	38.92
Month 15	Placebo→Tofacitinib 5 mg BID	67	6.21	10.62	-23.95	0.00	5.99	11.97	38.92
	Placebo→Tofacitinib 10 mg BID	63	4.37	10.16	-20.95	0.00	5.99	8.98	26.94
	Tofacitinib 5 mg BID	241	6.38	9.71	-23.95	0.00	5.99	11.97	32.93
	Tofacitinib 10 mg BID	254	5.98	10.50	-20.95	0.00	5.99	11.97	44.90
Month 18	Placebo→Tofacitinib 5 mg BID	62	6.18	10.27	-14.97	0.00	5.99	14.97	35.92
	Placebo→Tofacitinib 10 mg BID	60	5.04	9.85	-23.95	0.00	5.99	11.97	26.94
	Tofacitinib 5 mg BID	234	6.14	10.48	-26.94	0.00	5.99	11.97	38.92
	Tofacitinib 10 mg BID	244	5.73	10.75	-23.95	0.00	2.99	11.97	41.91
Month 21	Placebo→Tofacitinib 5 mg BID	59	6.04	9.57	-17.96	0.00	5.99	11.97	29.94
	Placebo→Tofacitinib 10 mg BID	55	4.84	9.48	-20.95	0.00	5.99	11.97	23.95
	Tofacitinib 5 mg BID	219	6.33	9.71	-20.95	0.00	5.99	11.97	41.91
	Tofacitinib 10 mg BID	231	6.47	10.47	-20.95	0.00	5.99	11.97	47.90
Month 24	Placebo→Tofacitinib 5 mg BID	57	6.25	9.21	-14.97	2.99	5.99	11.97	38.92
	Placebo→Tofacitinib 10 mg BID	53	3.50	8.42	-23.95	0.00	2.99	8.98	20.95
	Tofacitinib 5 mg BID	210	6.51	10.03	-23.95	0.00	5.99	14.97	32.93
	Tofacitinib 10 mg BID	218	6.47	10.40	-20.95	0.00	5.99	11.97	47.90
Month 24	Placebo→Tofacitinib 5 mg BID	54	5.99	10.29	-26.94	0.00	5.99	11.97	32.93
	Placebo→Tofacitinib 10 mg BID	52	4.89	8.73	-17.96	0.00	5.99	11.97	26.94

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- General Health Perception Score: The results are presented in Table 118, Table 119, Table 120 and Table 121.

Table 118. Descriptive Statistics of SF-36 General Health Perception Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	35.16	9.07	16.75	28.49	35.54	41.18	62.31
	Tofacitinib 10 mg BID	309	36.03	8.79	16.75	30.84	35.54	41.18	59.97
	Placebo	156	36.82	8.11	16.75	33.19	37.89	41.18	59.97
Month 1	Tofacitinib 5 mg BID	308	38.49	9.28	16.75	32.49	37.89	45.40	63.72
	Tofacitinib 10 mg BID	308	39.91	9.00	16.75	33.19	40.24	45.87	63.72
	Placebo	153	37.70	8.85	19.10	30.84	36.48	43.53	59.97
Month 3	Tofacitinib 5 mg BID	294	39.76	9.31	16.75	33.19	38.83	45.87	63.72
	Tofacitinib 10 mg BID	300	41.20	8.84	16.75	35.54	41.18	45.87	63.72
	Placebo	146	38.24	8.79	19.10	33.19	38.83	43.53	59.97
Month 6	Tofacitinib 5 mg BID	282	40.42	9.12	16.75	33.19	41.18	45.87	63.72
	Tofacitinib 10 mg BID	284	41.81	9.24	16.75	36.48	42.59	48.22	63.72
	Placebo	62	39.90	7.03	23.80	35.54	39.53	43.53	62.31
	Placebo→5 mg	40	38.57	9.94	21.45	30.84	37.89	43.53	63.72
	Placebo→10 mg	37	42.46	10.53	16.75	35.54	42.59	50.57	59.97

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 119. Descriptive Statistics of SF-36 General Health Perception Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	35.16	9.07	16.75	28.49	35.54	41.18	62.31
	Tofacitinib 10 mg BID	309	36.03	8.79	16.75	30.84	35.54	41.18	59.97
Month 1	Placebo→Tofacitinib 5 mg BID	79	35.39	8.42	16.75	30.84	35.54	41.18	55.27
	Placebo→Tofacitinib 10 mg BID	77	38.29	7.56	21.45	33.19	37.89	42.59	59.97
	Tofacitinib 5 mg BID	308	38.49	9.28	16.75	32.49	37.89	45.40	63.72
	Tofacitinib 10 mg BID	308	39.91	9.00	16.75	33.19	40.24	45.87	63.72
Month 3	Placebo→Tofacitinib 5 mg BID	79	37.43	9.06	21.45	30.84	37.89	43.53	59.97
	Placebo→Tofacitinib 10 mg BID	74	37.98	8.67	19.10	33.19	36.48	43.53	59.97
	Tofacitinib 5 mg BID	294	39.76	9.31	16.75	33.19	38.83	45.87	63.72
	Tofacitinib 10 mg BID	300	41.20	8.84	16.75	35.54	41.18	45.87	63.72
Month 6	Placebo→Tofacitinib 5 mg BID	75	37.02	9.15	19.10	30.84	37.89	43.53	57.62
	Placebo→Tofacitinib 10 mg BID	71	39.53	8.26	21.45	35.54	40.24	44.93	59.97
	Tofacitinib 5 mg BID	282	40.42	9.12	16.75	33.19	41.18	45.87	63.72
	Tofacitinib 10 mg BID	284	41.81	9.24	16.75	36.48	42.59	48.22	63.72
Month 9	Placebo→Tofacitinib 5 mg BID	71	39.24	8.38	21.45	33.19	37.89	43.53	63.72
	Placebo→Tofacitinib 10 mg BID	68	41.20	9.55	16.75	35.54	41.18	47.75	62.31
	Tofacitinib 5 mg BID	265	40.56	9.18	16.75	34.13	40.24	45.87	63.72
	Tofacitinib 10 mg BID	279	42.03	9.56	16.75	35.54	41.18	48.22	63.72
Month 12	Placebo→Tofacitinib 5 mg BID	68	40.78	8.70	23.80	34.13	40.71	45.87	63.72
	Placebo→Tofacitinib 10 mg BID	63	43.98	9.96	21.45	35.54	43.53	52.92	63.72
	Tofacitinib 5 mg BID	252	40.37	9.29	16.75	33.19	40.24	45.87	63.72
	Tofacitinib 10 mg BID	265	41.65	9.38	16.75	35.54	42.59	48.22	63.72
Month 15	Placebo→Tofacitinib 5 mg BID	67	40.48	9.38	19.10	34.13	40.24	48.22	61.38
	Placebo→Tofacitinib 10 mg BID	63	43.83	9.53	21.45	36.48	43.53	50.57	63.72
	Tofacitinib 5 mg BID	242	40.04	8.93	19.10	33.19	40.24	45.87	63.72
	Tofacitinib 10 mg BID	254	41.21	8.85	19.10	35.54	41.18	48.22	63.72
Month 18	Placebo→Tofacitinib 5 mg BID	61	42.47	9.75	16.75	36.48	41.18	48.22	63.72
	Placebo→Tofacitinib 10 mg BID	60	42.85	8.30	23.80	37.89	42.35	48.93	62.31
	Tofacitinib 5 mg BID	235	39.91	9.90	16.75	33.19	40.24	48.22	63.72
	Tofacitinib 10 mg BID	244	41.43	9.54	16.75	35.54	41.18	48.22	63.72
Month 21	Placebo→Tofacitinib 5 mg BID	59	41.04	8.90	21.45	33.19	41.18	45.87	63.72
	Placebo→Tofacitinib 10 mg BID	55	43.19	9.54	21.45	36.48	41.18	51.98	62.31
	Tofacitinib 5 mg BID	220	40.39	9.28	19.10	33.19	40.24	45.87	63.72
	Tofacitinib 10 mg BID	231	41.31	9.07	16.75	35.54	41.18	47.28	63.72
Month 24	Placebo→Tofacitinib 5 mg BID	57	42.82	9.03	23.80	35.54	43.53	48.22	63.72
	Placebo→Tofacitinib 10 mg BID	53	42.29	9.83	19.10	37.89	41.18	48.22	62.31
	Tofacitinib 5 mg BID	210	40.46	9.32	16.75	33.19	40.24	45.87	63.72
	Tofacitinib 10 mg BID	218	41.29	9.24	16.75	35.54	41.18	45.87	63.72
	Placebo→Tofacitinib 5 mg BID	54	40.34	9.70	23.80	33.19	40.24	45.87	63.72
	Placebo→Tofacitinib 10 mg BID	52	42.41	9.68	19.10	35.54	41.18	49.40	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 120. Descriptive Statistics of Change From Baseline of SF-36 General Health Perception Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	3.43	6.88	-16.44	0.00	2.35	7.05	25.83
	Tofacitinib 10 mg BID	308	3.85	6.70	-15.03	0.00	3.29	7.99	38.52
	Placebo	153	0.73	6.70	-23.49	-2.35	0.00	4.70	17.38
Month 3	Tofacitinib 5 mg BID	293	4.81	7.61	-18.79	0.00	4.70	9.39	31.47
	Tofacitinib 10 mg BID	300	5.18	7.51	-14.09	0.00	4.70	10.33	27.24
	Placebo	146	1.17	7.53	-21.14	-2.35	0.47	5.64	31.47
Month 6	Tofacitinib 5 mg BID	281	5.32	8.06	-16.44	0.00	4.70	9.39	33.82
	Tofacitinib 10 mg BID	284	6.09	8.16	-16.44	0.94	4.70	11.74	26.77
	Placebo	62	3.21	5.94	-7.99	0.00	1.64	7.05	17.38
	Placebo→5 mg	40	4.76	8.35	-9.39	0.00	3.29	8.92	36.17
	Placebo→10 mg	37	2.25	7.08	-14.09	0.00	2.35	5.64	19.73

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 121. Descriptive Statistics of Change From Baseline of SF-36 General Health Perception Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	307	3.43	6.88	-16.44	0.00	2.35	7.05	25.83
	Tofacitinib 10 mg BID	308	3.85	6.70	-15.03	0.00	3.29	7.99	38.52
Month 3	Placebo→Tofacitinib 5 mg BID	79	2.04	6.86	-14.09	-2.35	2.35	7.05	17.38
	Placebo→Tofacitinib 10 mg BID	74	-0.67	6.27	-23.49	-3.29	0.00	3.29	14.09
	Tofacitinib 5 mg BID	293	4.81	7.61	-18.79	0.00	4.70	9.39	31.47
	Tofacitinib 10 mg BID	300	5.18	7.51	-14.09	0.00	4.70	10.33	27.24
Month 6	Placebo→Tofacitinib 5 mg BID	75	1.60	8.31	-21.14	-4.70	1.41	7.05	31.47
	Placebo→Tofacitinib 10 mg BID	71	0.71	6.63	-21.14	-2.35	0.00	4.70	14.09
	Tofacitinib 5 mg BID	281	5.32	8.06	-16.44	0.00	4.70	9.39	33.82
	Tofacitinib 10 mg BID	284	6.09	8.16	-16.44	0.94	4.70	11.74	26.77
Month 9	Placebo→Tofacitinib 5 mg BID	71	4.28	7.39	-9.39	0.00	3.29	9.39	36.17
	Placebo→Tofacitinib 10 mg BID	68	2.48	6.54	-14.09	-2.35	2.35	5.64	19.73
	Tofacitinib 5 mg BID	264	5.12	8.11	-14.09	0.00	4.70	10.33	45.56
	Tofacitinib 10 mg BID	279	6.30	9.18	-23.49	0.00	5.64	11.74	38.52
Month 12	Placebo→Tofacitinib 5 mg BID	68	5.73	6.92	-9.39	1.64	5.17	9.39	31.47
	Placebo→Tofacitinib 10 mg BID	63	5.21	7.22	-11.74	0.00	4.70	9.39	21.14
	Tofacitinib 5 mg BID	251	4.88	8.81	-25.83	-1.41	4.70	9.39	43.21
	Tofacitinib 10 mg BID	265	5.75	8.46	-17.38	0.00	4.70	11.74	36.17
Month 15	Placebo→Tofacitinib 5 mg BID	67	5.50	7.75	-11.74	0.00	5.64	10.33	31.47
	Placebo→Tofacitinib 10 mg BID	63	5.06	7.81	-11.74	0.00	4.70	10.80	21.14
	Tofacitinib 5 mg BID	241	4.56	8.11	-18.79	0.00	3.29	9.39	33.82
	Tofacitinib 10 mg BID	254	5.37	8.27	-14.09	0.00	4.70	10.33	36.17
Month 18	Placebo→Tofacitinib 5 mg BID	61	6.93	8.41	-11.74	0.00	7.05	13.15	38.52
	Placebo→Tofacitinib 10 mg BID	60	4.27	6.15	-9.39	0.00	3.29	7.05	19.73
	Tofacitinib 5 mg BID	234	4.3	8.36	-16.44	-0.94	3.29	9.39	31.47
	Tofacitinib 10 mg BID	244	5.67	9.1	-19.73	0.00	5.17	10.33	35.23
Month 21	Placebo→Tofacitinib 5 mg BID	59	5.72	7.65	-10.33	0.94	4.70	9.39	38.52
	Placebo→Tofacitinib 10 mg BID	55	4.64	7.94	-14.09	0.00	3.29	9.39	19.73
	Tofacitinib 5 mg BID	219	4.72	8.11	-15.03	0.00	3.76	10.33	38.52
	Tofacitinib 10 mg BID	231	5.55	8.47	-17.38	0.00	4.70	11.74	36.17
Month 24	Placebo→Tofacitinib 5 mg BID	57	7.57	7.46	-4.70	2.35	7.99	11.74	38.52
	Placebo→Tofacitinib 10 mg BID	53	3.69	7.77	-18.79	0.00	3.29	7.05	24.43
	Tofacitinib 5 mg BID	209	4.48	8.16	-17.38	-0.94	4.70	9.39	26.77
	Tofacitinib 10 mg BID	218	5.43	8.86	-17.38	0.00	4.70	11.74	30.53
Month 24	Placebo→Tofacitinib 5 mg BID	54	5.54	7.68	-7.99	0.00	5.64	9.39	38.52
	Placebo→Tofacitinib 10 mg BID	52	3.69	7.87	-14.09	0.00	2.35	8.69	24.43

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **Mental Component Score:** The results are presented in Table 122, Table 123, Table 124 and Table 125.

Table 122. Descriptive Statistics of SF-36 Mental Component Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	41.01	11.54	12.35	32.37	40.26	49.04	66.56
	Tofacitinib 10 mg BID	309	42.24	11.52	9.87	33.59	41.01	51.66	67.76
	Placebo	156	43.21	11.90	14.86	34.18	43.10	53.03	67.18
Month 1	Tofacitinib 5 mg BID	307	44.91	11.73	10.92	36.87	45.24	54.26	73.59
	Tofacitinib 10 mg BID	308	46.28	10.70	11.05	38.49	47.22	54.78	65.96
	Placebo	153	43.86	11.90	14.78	34.61	43.37	54.13	64.76
Month 3	Tofacitinib 5 mg BID	294	45.22	11.69	12.42	36.79	45.85	54.20	72.87
	Tofacitinib 10 mg BID	300	47.05	10.27	20.41	39.68	47.47	55.86	65.52
	Placebo	146	43.70	11.68	15.38	35.8	43.76	53.47	66.49
Month 6	Tofacitinib 5 mg BID	281	45.53	11.65	9.35	37.48	45.84	54.62	67.85
	Tofacitinib 10 mg BID	283	46.86	10.85	12.08	40.41	48.20	55.66	66.50
	Placebo	62	45.42	9.35	26.17	39.37	46.05	51.61	64.29
	Placebo→5 mg	40	43.67	11.22	17.30	35.58	43.92	52.52	67.77
	Placebo→10 mg	37	48.65	10.76	25.02	42.81	51.04	57.43	61.61

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 123. Descriptive Statistics of SF-36 Mental Component Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	41.01	11.54	12.35	32.37	40.26	49.04	66.56
	Tofacitinib 10 mg BID	309	42.24	11.52	9.87	33.59	41.01	51.66	67.76
	Placebo→Tofacitinib 5 mg BID	79	42.32	11.46	18.22	33.49	42.42	52.14	67.18
	Placebo→Tofacitinib 10 mg BID	77	44.13	12.35	14.86	35.06	44.74	54.13	66.31
Month 1	Tofacitinib 5 mg BID	307	44.91	11.73	10.92	36.87	45.24	54.26	73.59
	Tofacitinib 10 mg BID	308	46.28	10.70	11.05	38.49	47.22	54.78	65.96
	Placebo→Tofacitinib 5 mg BID	79	42.84	11.48	16.59	34.36	41.39	52.56	64.13
	Placebo→Tofacitinib 10 mg BID	74	44.95	12.31	14.78	34.76	45.54	54.83	64.76
Month 3	Tofacitinib 5 mg BID	294	45.22	11.69	12.42	36.79	45.85	54.26	72.87
	Tofacitinib 10 mg BID	300	47.05	10.27	20.41	39.68	47.47	55.86	65.52
	Placebo→Tofacitinib 5 mg BID	75	41.78	11.68	17.09	33.28	41.78	50.55	66.49
	Placebo→Tofacitinib 10 mg BID	71	45.74	11.42	15.38	37.23	44.68	55.88	64.75
Month 6	Tofacitinib 5 mg BID	281	45.53	11.65	9.35	37.48	45.84	54.62	67.85
	Tofacitinib 10 mg BID	283	46.86	10.85	12.08	40.41	48.20	55.66	66.50
	Placebo→Tofacitinib 5 mg BID	71	44.14	10.19	17.30	36.19	43.24	51.96	67.77
	Placebo→Tofacitinib 10 mg BID	68	47.49	10.40	25.02	42.01	48.87	56.68	61.69
Month 9	Tofacitinib 5 mg BID	264	46.45	11.57	12.76	38.15	46.68	55.13	71.05
	Tofacitinib 10 mg BID	279	46.37	11.14	10.96	39.45	47.09	55.41	67.02
	Placebo→Tofacitinib 5 mg BID	68	45.88	10.99	16.89	39.47	43.97	54.21	68.68
	Placebo→Tofacitinib 10 mg BID	63	49.07	10.98	15.15	40.45	50.93	57.29	64.74
Month 12	Tofacitinib 5 mg BID	252	45.87	11.24	13.41	37.72	46.56	54.99	72.26
	Tofacitinib 10 mg BID	264	46.49	10.61	10.22	39.39	46.78	55.71	69.79
	Placebo→Tofacitinib 5 mg BID	67	45.55	12.12	8.33	38.38	44.04	54.16	69.68
	Placebo→Tofacitinib 10 mg BID	63	47.95	10.79	15.85	40.67	50.25	55.91	62.52
Month 15	Tofacitinib 5 mg BID	241	45.20	11.06	10.72	37.65	45.43	53.83	70.37
	Tofacitinib 10 mg BID	253	46.80	10.67	7.17	39.68	48.06	55.90	64.58
	Placebo→Tofacitinib 5 mg BID	61	45.19	11.64	13.59	38.61	45.10	54.14	70.11
	Placebo→Tofacitinib 10 mg BID	60	47.53	11.06	22.72	39.58	49.64	56.95	66.77
Month 18	Tofacitinib 5 mg BID	234	45.03	11.09	11.20	37.3	45.10	54.02	69.29
	Tofacitinib 10 mg BID	244	46.62	10.55	17.49	39.01	47.83	55.92	64.63
	Placebo→Tofacitinib 5 mg BID	59	45.83	12.33	7.86	39.00	46.04	55.24	69.65
	Placebo→Tofacitinib 10 mg BID	55	48.34	10.88	20.95	38.72	49.25	58.58	65.64
Month 21	Tofacitinib 5 mg BID	219	45.66	10.87	10.30	37.81	45.80	54.61	69.29
	Tofacitinib 10 mg BID	231	47.39	10.08	15.84	39.10	48.35	56.28	65.13
	Placebo→Tofacitinib 5 mg BID	57	46.45	11.19	14.14	39.20	46.77	55.16	67.74
	Placebo→Tofacitinib 10 mg BID	53	47.88	10.75	15.46	40.90	50.05	55.60	63.38
Month 24	Tofacitinib 5 mg BID	209	46.11	11.40	12.79	36.96	46.23	55.11	70.76
	Tofacitinib 10 mg BID	218	47.42	10.75	11.62	40.32	48.04	56.65	68.46
	Placebo→Tofacitinib 5 mg BID	54	44.58	11.94	12.88	36.29	42.67	55.38	65.30
	Placebo→Tofacitinib 10 mg BID	52	49.30	10.47	18.67	42.87	51.30	58.15	62.62

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 124. Descriptive Statistics of Change From Baseline of SF-36 Mental Component Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	3.94	9.47	-27.82	-1.46	2.95	8.82	33.55
	Tofacitinib 10 mg BID	308	4.01	10.05	-24.98	-2.25	2.89	9.20	38.57
	Placebo	153	0.53	8.92	-36.45	-3.97	0.47	4.96	25.74
Month 3	Tofacitinib 5 mg BID	293	4.07	10.83	-37.40	-2.43	3.22	10.37	43.26
	Tofacitinib 10 mg BID	300	4.87	10.76	-26.25	-2.32	4.28	11.60	41.84
	Placebo	146	0.31	9.88	-34.17	-6.21	0.61	6.02	26.34
Month 6	Tofacitinib 5 mg BID	280	4.48	11.40	-30.46	-2.98	2.98	11.02	38.97
	Tofacitinib 10 mg BID	283	4.56	11.05	-37.23	-2.50	3.35	12.21	40.53
	Placebo	62	2.16	10.06	-26.39	-3.03	2.31	8.85	35.70
	Placebo→5 mg	40	3.87	9.51	-13.51	-1.58	3.91	8.69	34.45
	Placebo→10 mg	37	3.27	10.42	-22.49	-2.17	1.9	6.95	26.88

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 125. Descriptive Statistics of Change From Baseline of SF-36 Mental Component Score per Visit, Comparisons Within Sequence, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	3.94	9.47	-27.82	-1.46	2.95	8.82	33.55
	Tofacitinib 10 mg BID	308	4.01	10.05	-24.98	-2.25	2.89	9.20	38.57
Month 3	Placebo→Tofacitinib 5 mg BID	79	0.53	9.82	-22.28	-6.24	0.39	5.90	25.74
	Placebo→Tofacitinib 10 mg BID	74	0.53	7.92	-36.45	-2.43	0.81	3.81	17.94
	Tofacitinib 5 mg BID	293	4.07	10.83	-37.40	-2.43	3.22	10.37	43.26
	Tofacitinib 10 mg BID	300	4.87	10.76	-26.25	-2.32	4.28	11.60	41.84
Month 6	Placebo→Tofacitinib 5 mg BID	75	-0.13	10.43	-34.17	-7.40	-0.06	6.27	26.34
	Placebo→Tofacitinib 10 mg BID	71	0.78	9.32	-21.59	-5.70	0.91	6.02	21.17
	Tofacitinib 5 mg BID	280	4.48	11.40	-30.46	-2.98	2.98	11.02	38.97
	Tofacitinib 10 mg BID	283	4.56	11.05	-37.23	-2.50	3.35	12.21	40.53
Month 9	Placebo→Tofacitinib 5 mg BID	71	2.70	9.15	-16.30	-3.78	2.98	8.84	34.45
	Placebo→Tofacitinib 10 mg BID	68	3.20	10.79	-26.39	-1.97	2.75	7.61	35.70
	Tofacitinib 5 mg BID	263	4.91	12.07	-37.12	-2.60	4.04	11.90	48.15
	Tofacitinib 10 mg BID	279	4.23	11.09	-25.74	-2.76	4.51	10.61	46.04
Month 12	Placebo→Tofacitinib 5 mg BID	68	4.46	9.26	-12.72	-0.19	3.26	8.23	29.73
	Placebo→Tofacitinib 10 mg BID	63	4.23	10.65	-15.39	-2.49	3.12	10.60	35.89
	Tofacitinib 5 mg BID	251	4.47	11.65	-33.45	-2.45	3.27	11.46	44.43
	Tofacitinib 10 mg BID	264	4.31	10.69	-24.86	-2.61	4.16	10.87	35.78
Month 15	Placebo→Tofacitinib 5 mg BID	67	4.46	10.43	-19.51	-1.68	3.22	10.31	32.95
	Placebo→Tofacitinib 10 mg BID	63	3.11	10.97	-36.55	-2.99	3.48	8.68	31.14
	Tofacitinib 5 mg BID	240	3.89	10.96	-32.63	-3.05	3.36	11.44	37.01
	Tofacitinib 10 mg BID	253	4.54	11.77	-33.45	-2.76	4.37	11.44	48.46
Month 18	Placebo→Tofacitinib 5 mg BID	61	3.65	10.34	-21.21	-2.22	2.47	7.24	30.38
	Placebo→Tofacitinib 10 mg BID	60	2.74	9.64	-24.78	-1.54	3.38	8.21	26.63
	Tofacitinib 5 mg BID	233	3.54	11.29	-29.70	-2.92	2.28	10.19	46.08
	Tofacitinib 10 mg BID	244	4.21	11.66	-31.50	-2.08	3.09	10.70	44.99
Month 21	Placebo→Tofacitinib 5 mg BID	59	4.41	9.16	-18.96	0.59	4.00	9.77	24.99
	Placebo→Tofacitinib 10 mg BID	55	2.68	9.13	-22.35	-2.57	4.04	9.45	19.91
	Tofacitinib 5 mg BID	218	4.42	10.84	-22.24	-1.92	4.43	11.67	42.60
	Tofacitinib 10 mg BID	231	5.28	10.96	-21.04	-1.12	3.83	11.87	44.13
Month 24	Placebo→Tofacitinib 5 mg BID	57	5.03	9.27	-12.67	0.41	3.57	9.26	40.00
	Placebo→Tofacitinib 10 mg BID	53	2.12	10.87	-32.04	-3.02	2.78	9.17	21.02
	Tofacitinib 5 mg BID	208	4.36	12.07	-35.97	-3.23	4.07	11.66	35.43
	Tofacitinib 10 mg BID	218	5.18	11.28	-27.02	-1.65	3.87	12.14	46.80
Month 24	Placebo→Tofacitinib 5 mg BID	54	3.55	10.74	-27.04	-2.20	3.49	10.68	38.00
	Placebo→Tofacitinib 10 mg BID	52	3.57	8.61	-19.44	-2.17	3.07	9.59	19.92

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **Physical Component Score:** The results are presented in Table 126, Table 127, Table 128 and Table 129.

Table 126. Descriptive Statistics of SF-36 Physical Component Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	33.05	7.94	13.35	27.23	32.95	38.64	55.71
	Tofacitinib 10 mg BID	309	33.75	7.77	14.49	28.44	33.51	38.98	54.06
	Placebo	156	34.51	8.03	19.23	28.11	33.35	40.69	54.49
Month 1	Tofacitinib 5 mg BID	307	36.99	8.24	15.79	31.34	36.60	42.19	60.06
	Tofacitinib 10 mg BID	308	38.96	8.07	15.31	33.25	38.98	44.49	58.76
	Placebo	153	36.25	8.24	16.00	29.89	35.37	41.73	59.82
Month 3	Tofacitinib 5 mg BID	294	38.65	8.62	9.18	33.09	38.78	44.67	60.86
	Tofacitinib 10 mg BID	300	41.30	8.49	20.96	34.58	41.81	47.91	59.88
	Placebo	146	36.79	8.39	20.10	29.90	36.84	42.73	57.85
Month 6	Tofacitinib 5 mg BID	281	39.70	8.40	19.84	33.39	39.04	45.21	62.06
	Tofacitinib 10 mg BID	283	41.82	8.55	15.37	35.88	41.82	47.80	60.56
	Placebo	62	39.21	6.99	25.71	33.60	39.02	44.28	60.62
	Placebo→5 mg	40	38.75	9.08	24.90	31.18	37.76	44.32	58.61
	Placebo→10 mg	37	41.97	10.50	23.34	32.64	42.09	51.46	59.98

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 127. Descriptive Statistics of SF-36 Physical Component Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	33.05	7.94	13.35	27.23	32.95	38.64	55.71
	Tofacitinib 10 mg BID	309	33.75	7.77	14.49	28.44	33.51	38.98	54.06
	Placebo→Tofacitinib 5 mg BID	79	33.18	7.60	19.23	26.52	33.03	38.25	54.49
Month 1	Placebo→Tofacitinib 10 mg BID	77	35.87	8.27	22.45	28.75	35.66	42.04	54.29
	Tofacitinib 5 mg BID	307	36.99	8.24	15.79	31.34	36.60	42.19	60.06
	Tofacitinib 10 mg BID	308	38.96	8.07	15.31	33.25	38.98	44.49	58.76
Month 3	Placebo→Tofacitinib 5 mg BID	79	35.33	8.14	16.00	28.69	34.72	41.11	59.82
	Placebo→Tofacitinib 10 mg BID	74	37.23	8.28	22.74	29.98	36.53	42.36	55.82
	Tofacitinib 5 mg BID	294	38.65	8.62	9.18	33.09	38.78	44.67	60.86
Month 6	Tofacitinib 10 mg BID	300	41.30	8.49	20.96	34.58	41.81	47.91	59.88
	Placebo→Tofacitinib 5 mg BID	75	35.21	8.33	20.10	28.18	34.76	41.49	53.06
	Placebo→Tofacitinib 10 mg BID	71	38.45	8.18	21.94	32.63	39.42	44.01	57.85
Month 9	Tofacitinib 5 mg BID	281	39.70	8.40	19.84	33.39	39.04	45.21	62.06
	Tofacitinib 10 mg BID	283	41.82	8.55	15.37	35.88	41.82	47.80	60.56
	Placebo→Tofacitinib 5 mg BID	71	38.80	7.90	24.90	32.75	37.85	44.42	58.61
Month 12	Placebo→Tofacitinib 10 mg BID	68	40.87	9.37	23.34	33.36	41.12	48.48	60.62
	Tofacitinib 5 mg BID	264	39.82	8.38	16.71	34.27	38.90	46.04	61.60
	Tofacitinib 10 mg BID	279	42.45	8.75	19.97	36.01	42.80	49.29	65.40
Month 15	Placebo→Tofacitinib 5 mg BID	68	40.64	8.48	17.58	33.98	40.30	47.85	59.30
	Placebo→Tofacitinib 10 mg BID	63	43.44	10.11	26.24	35.24	45.05	51.16	60.01
	Tofacitinib 5 mg BID	252	40.28	8.63	21.19	34.20	39.93	46.42	62.79
Month 18	Tofacitinib 10 mg BID	264	42.01	8.81	21.74	35.27	42.49	48.98	61.49
	Placebo→Tofacitinib 5 mg BID	67	41.22	8.29	20.08	34.04	41.69	47.33	57.11
	Placebo→Tofacitinib 10 mg BID	63	43.92	9.20	22.62	36.54	44.58	51.11	59.92
Month 21	Tofacitinib 5 mg BID	241	40.28	8.34	18.10	33.83	39.86	45.89	64.72
	Tofacitinib 10 mg BID	253	42.50	9.02	19.25	35.20	43.39	49.83	61.63
	Placebo→Tofacitinib 5 mg BID	61	42.94	7.89	27.95	37.07	42.42	49.18	58.54
Month 24	Placebo→Tofacitinib 10 mg BID	60	43.40	8.91	23.66	36.74	43.64	51.22	60.27
	Tofacitinib 5 mg BID	234	40.51	8.95	19.53	34.45	40.72	46.94	60.57
	Tofacitinib 10 mg BID	244	42.32	9.12	18.45	35.16	42.68	49.72	61.14
Month 27	Placebo→Tofacitinib 5 mg BID	59	42.16	7.62	24.99	35.31	41.61	47.74	58.69
	Placebo→Tofacitinib 10 mg BID	55	43.65	8.01	25.52	37.89	42.27	50.81	58.52
	Tofacitinib 5 mg BID	219	40.72	8.75	20.05	34.72	39.98	47.04	58.25
Month 30	Tofacitinib 10 mg BID	231	41.87	9.34	16.74	35.98	42.38	48.88	59.94
	Placebo→Tofacitinib 5 mg BID	57	42.36	7.71	27.62	36.46	42.54	46.87	57.28
	Placebo→Tofacitinib 10 mg BID	53	43.33	9.29	25.29	36.76	41.74	50.74	58.46
Month 33	Tofacitinib 5 mg BID	209	40.81	8.86	13.00	35.04	40.61	47.69	58.50
	Tofacitinib 10 mg BID	218	42.27	9.49	14.96	35.50	42.97	49.85	61.77
	Placebo→Tofacitinib 5 mg BID	54	42.19	8.44	25.32	35.03	42.17	49.00	58.69
	Placebo→Tofacitinib 10 mg BID	52	43.08	8.65	25.34	36.28	44.31	49.76	59.83

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 128. Descriptive Statistics of Change From Baseline of SF-36 Physical Component Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	3.99	6.41	-20.62	0.15	3.78	7.40	30.11
	Tofacitinib 10 mg BID	308	5.19	6.81	-14.44	0.42	4.22	9.06	32.58
	Placebo	153	1.55	5.54	-17.22	-1.66	1.62	4.95	18.72
Month 3	Tofacitinib 5 mg BID	293	5.78	7.18	-13.01	0.95	5.33	9.93	31.00
	Tofacitinib 10 mg BID	300	7.57	7.53	-10.05	1.84	7.47	12.93	34.10
	Placebo	146	2.01	6.68	-27.07	-1.60	1.70	4.95	23.64
Month 6	Tofacitinib 5 mg BID	280	6.59	7.53	-12.97	1.80	6.39	11.55	29.98
	Tofacitinib 10 mg BID	283	8.21	8.55	-19.44	3.20	7.63	13.57	36.09
	Placebo	62	4.44	6.36	-10.58	-0.42	4.37	9.69	17.06
	Placebo→5 mg	40	6.21	7.71	-6.20	-0.79	6.83	10.01	23.21
	Placebo→10 mg	37	5.14	8.45	-9.93	-1.42	5.04	9.58	24.07

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

Table 129. Descriptive Statistics of Change From Baseline of SF-36 Physical Component Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	306	3.99	6.41	-20.62	0.15	3.78	7.40	30.11
	Tofacitinib 10 mg BID	308	5.19	6.81	-14.44	0.42	4.22	9.06	32.58
Month 3	Placebo→Tofacitinib 5 mg BID	79	2.15	5.79	-10.74	-1.49	2.57	5.02	18.72
	Placebo→Tofacitinib 10 mg BID	74	0.90	5.21	-17.22	-1.67	0.89	4.92	13.97
	Tofacitinib 5 mg BID	293	5.78	7.18	-13.01	0.95	5.33	9.93	31.00
	Tofacitinib 10 mg BID	300	7.57	7.53	-10.05	1.84	7.47	12.93	34.10
Month 6	Placebo→Tofacitinib 5 mg BID	75	1.94	7.15	-27.07	-2.14	1.78	6.18	19.51
	Placebo→Tofacitinib 10 mg BID	71	2.09	6.18	-13.51	-1.60	1.62	4.47	23.64
	Tofacitinib 5 mg BID	280	6.59	7.53	-12.97	1.80	6.39	11.55	29.98
	Tofacitinib 10 mg BID	283	8.21	8.55	-19.44	3.20	7.63	13.57	36.09
Month 9	Placebo→Tofacitinib 5 mg BID	71	5.81	7.09	-6.55	-0.42	6.57	10.32	23.21
	Placebo→Tofacitinib 10 mg BID	68	4.43	7.57	-10.58	-1.43	3.25	9.49	24.07
	Tofacitinib 5 mg BID	263	6.54	8.25	-11.25	1.72	6.34	11.67	30.37
	Tofacitinib 10 mg BID	279	8.90	8.78	-14.22	2.96	8.33	14.63	38.11
Month 12	Placebo→Tofacitinib 5 mg BID	68	7.37	7.40	-9.26	2.24	7.51	13.08	20.58
	Placebo→Tofacitinib 10 mg BID	63	6.78	8.14	-14.47	0.92	6.61	13.49	22.98
	Tofacitinib 5 mg BID	251	7.04	8.13	-23.05	1.97	6.26	11.79	31.95
	Tofacitinib 10 mg BID	264	8.32	7.91	-9.23	2.44	7.88	13.71	29.54
Month 15	Placebo→Tofacitinib 5 mg BID	67	7.96	5.97	-9.04	3.95	7.53	12.65	22.13
	Placebo→Tofacitinib 10 mg BID	63	7.26	8.45	-11.58	1.44	6.56	12.76	26.25
	Tofacitinib 5 mg BID	240	7.06	8.14	-22.21	2.01	7.12	12.08	29.25
	Tofacitinib 10 mg BID	253	8.74	8.44	-13.57	3.24	8.08	14.66	33.19
Month 18	Placebo→Tofacitinib 5 mg BID	61	8.89	7.52	-7.22	2.32	8.61	14.22	27.78
	Placebo→Tofacitinib 10 mg BID	60	7.08	7.75	-12.76	2.70	5.81	12.63	25.25
	Tofacitinib 5 mg BID	233	7.20	8.58	-22.82	1.54	6.18	12.01	35.22
	Tofacitinib 10 mg BID	244	8.66	8.61	-17.72	3.04	8.71	14.22	33.03
Month 21	Placebo→Tofacitinib 5 mg BID	59	8.18	7.10	-7.84	2.23	9.13	13.81	23.34
	Placebo→Tofacitinib 10 mg BID	55	7.33	7.16	-5.17	0.50	7.34	14.14	22.45
	Tofacitinib 5 mg BID	218	7.32	7.98	-22.85	1.86	6.74	13.03	30.35
	Tofacitinib 10 mg BID	231	8.31	8.78	-19.88	2.25	7.69	13.67	30.68
Month 24	Placebo→Tofacitinib 5 mg BID	57	8.50	7.39	-6.57	2.79	8.66	14.24	24.51
	Placebo→Tofacitinib 10 mg BID	53	6.77	7.76	-7.85	-0.09	7.28	10.81	21.48
	Tofacitinib 5 mg BID	208	7.30	8.06	-19.59	1.60	6.73	12.29	28.91
	Tofacitinib 10 mg BID	218	8.69	8.86	-26.59	2.82	7.71	14.47	30.24
Month 24	Placebo→Tofacitinib 5 mg BID	54	8.09	7.33	-8.75	2.71	7.66	13.71	20.39
	Placebo→Tofacitinib 10 mg BID	52	6.45	6.93	-8.54	1.21	7.29	11.61	19.58

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation; SF-36 = short form 36.

- **MOS Sleep Scale (MOS-SS):** In all 4 treatment sequences, improvements from Baseline in the MOS-SS subscale scores were generally stable from Months 12 through 24; the Sleep Problems Index II (9-item scale) was used for this analysis. The proportions of subjects in all 4 treatment sequences achieving optimal sleep on the MOS-SS Optimal Sleep subscale were stable from Months 12 through 24; the placebo→tofacitinib 10 mg group had the lowest response rates throughout the study. The results are presented in Table 130, Table 131, Table 132 and Table 133.

Table 130. Descriptive Statistics of Medical Outcome Study (MOS) Overall Sleep Problem Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	314	40.19	20.12	0.00	25.00	39.17	53.89	95.56
	Tofacitinib 10 mg BID	309	39.70	19.48	0.00	24.44	37.78	54.44	93.33
	Placebo	156	37.30	18.32	0.00	24.44	36.11	50.56	82.22
Month 1	Tofacitinib 5 mg BID	307	34.74	20.68	0.00	18.33	31.67	47.22	100.00
	Tofacitinib 10 mg BID	307	33.90	18.55	0.00	18.89	31.67	45.56	86.67
	Placebo	151	35.80	19.12	0.00	22.22	33.89	46.67	86.67
Month 3	Tofacitinib 5 mg BID	295	34.67	20.37	0.00	20.00	32.22	46.67	95.56
	Tofacitinib 10 mg BID	300	34.10	19.56	0.00	17.78	31.67	47.22	90.56
	Placebo	146	35.45	18.16	4.44	22.22	32.78	47.78	88.89
Month 6	Tofacitinib 5 mg BID	281	32.95	19.01	0.00	17.78	31.11	45.56	88.89
	Tofacitinib 10 mg BID	284	32.62	18.57	0.00	18.33	29.44	42.78	91.11
	Placebo	62	32.40	13.97	0.00	22.78	31.11	40.56	62.22
	Placebo→5 mg	40	36.31	18.96	0.00	21.39	36.39	47.50	80.00
	Placebo→10 mg	37	27.03	19.22	4.44	11.11	25.00	35.56	82.22

Overall sleep problem score is an index measure that assesses sleep disturbance constructed from 9 items on the MOS. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 131. Descriptive Statistics of Medical Outcome Study (MOS) Overall Sleep Problem Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	314	40.19	20.12	0.00	25.00	39.17	53.89	95.56
	Tofacitinib 10 mg BID	309	39.70	19.48	0.00	24.44	37.78	54.44	93.33
Month 1	Placebo→Tofacitinib 5 mg BID	79	38.06	17.89	4.44	22.22	37.22	51.67	80.00
	Placebo→Tofacitinib 10 mg BID	77	36.52	18.83	0.00	24.44	35.56	42.78	82.22
	Tofacitinib 5 mg BID	307	34.74	20.68	0.00	18.33	31.67	47.22	100.00
	Tofacitinib 10 mg BID	307	33.90	18.55	0.00	18.89	31.67	45.56	86.67
Month 3	Placebo→Tofacitinib 5 mg BID	77	37.78	17.89	8.89	22.78	36.11	53.33	75.56
	Placebo→Tofacitinib 10 mg BID	74	33.74	20.24	0.00	22.22	31.11	42.78	86.67
	Tofacitinib 5 mg BID	295	34.67	20.37	0.00	20.00	32.22	46.67	95.56
	Tofacitinib 10 mg BID	300	34.10	19.56	0.00	17.78	31.67	47.22	90.56
Month 6	Placebo→Tofacitinib 5 mg BID	75	38.09	17.71	4.44	24.44	37.22	49.44	72.22
	Placebo→Tofacitinib 10 mg BID	71	32.66	18.34	4.44	18.33	29.44	45.00	88.89
	Tofacitinib 5 mg BID	281	32.95	19.01	0.00	17.78	31.11	45.56	88.89
	Tofacitinib 10 mg BID	284	32.62	18.57	0.00	18.33	29.44	42.78	91.11
Month 12	Placebo→Tofacitinib 5 mg BID	71	34.41	17.29	0.00	20.56	35.56	47.22	80.00
	Placebo→Tofacitinib 10 mg BID	68	29.68	16.92	0.00	20.00	29.17	37.22	82.22
	Tofacitinib 5 mg BID	248	32.40	18.25	0.00	18.33	31.11	43.06	86.11
	Tofacitinib 10 mg BID	264	32.68	19.05	0.00	18.33	29.44	44.44	86.67
Month 18	Placebo→Tofacitinib 5 mg BID	67	30.92	17.24	2.22	20.00	29.44	40.56	86.67
	Placebo→Tofacitinib 10 mg BID	63	28.34	17.87	2.22	13.89	25.00	38.33	80.00
	Tofacitinib 5 mg BID	234	32.33	18.58	0.00	18.33	29.17	45.56	86.11
	Tofacitinib 10 mg BID	243	33.08	17.97	0.00	20.00	29.44	44.44	80.00
Month 24	Placebo→Tofacitinib 5 mg BID	59	32.29	18.81	0.00	20.00	28.89	45.56	82.22
	Placebo→Tofacitinib 10 mg BID	55	29.14	16.16	0.00	17.78	27.78	40.56	82.22
	Tofacitinib 5 mg BID	211	32.35	18.68	0.00	18.33	29.44	45.56	84.44
	Tofacitinib 10 mg BID	217	32.62	18.51	0.00	20.56	29.44	42.78	91.67
Month 24	Placebo→Tofacitinib 5 mg BID	54	32.16	17.32	4.44	17.78	31.11	47.22	72.78
	Placebo→Tofacitinib 10 mg BID	52	28.11	14.96	2.22	14.44	28.06	39.44	72.22

Overall sleep problem score is an index measure that assesses sleep disturbance constructed from 9 items on the MOS. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 132. Descriptive Statistics of Change From Baseline of Medical Outcome Study (MOS) Overall Sleep Problem Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	305	-5.6	13.10	-45.0	-12.78	-4.44	2.22	33.33
	Tofacitinib 10 mg BID	307	-5.9	14.69	-61.1	-13.33	-4.44	2.22	35.00
	Placebo	151	-1.4	12.86	-33.3	-9.44	0.00	4.44	53.33
Month 3	Tofacitinib 5 mg BID	293	-5.8	15.30	-61.7	-15.00	-5.00	2.22	51.11
	Tofacitinib 10 mg BID	300	-5.7	15.33	-52.2	-14.17	-5.00	2.78	42.78
	Placebo	146	-1.8	15.94	-57.2	-11.11	-2.22	6.67	43.33
Month 6	Tofacitinib 5 mg BID	279	-7.2	15.46	-70.6	-15.56	-6.11	2.78	34.44
	Tofacitinib 10 mg BID	284	-7.2	17.10	-61.1	-16.11	-5.00	3.89	47.78
	Placebo	62	-5.6	14.92	-52.2	-11.11	-3.33	4.44	32.78
	Placebo→5 mg	40	-2.4	13.46	-34.4	-10.00	-3.61	6.11	28.33
	Placebo→10 mg	37	-8.4	17.28	-42.2	-20.00	-6.67	1.67	31.11

Overall sleep problem score is an index measure that assesses sleep disturbance constructed from 9 items on the MOS. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 133. Descriptive Statistics of Change From Baseline of Medical Outcome Study (MOS) Overall Sleep Problem Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	305	-5.6	13.10	-45.0	-12.78	-4.44	2.22	33.33
	Tofacitinib 10 mg BID	307	-5.9	14.69	-61.1	-13.33	-4.44	2.22	35.00
Month 3	Placebo→Tofacitinib 5 mg BID	77	-0.5	14.30	-33.3	-8.89	0.00	6.11	53.33
	Placebo→Tofacitinib 10 mg BID	74	-2.4	11.18	-32.8	-9.44	0.00	3.89	25.00
	Tofacitinib 5 mg BID	293	-5.8	15.30	-61.7	-15.00	-5.00	2.22	51.11
	Tofacitinib 10 mg BID	300	-5.7	15.33	-52.2	-14.17	-5.00	2.78	42.78
Month 6	Placebo→Tofacitinib 5 mg BID	75	-0.3	15.00	-31.1	-11.11	0.00	9.44	43.33
	Placebo→Tofacitinib 10 mg BID	71	-3.3	16.83	-57.2	-12.22	-4.44	6.67	40.00
	Tofacitinib 5 mg BID	279	-7.2	15.46	-70.6	-15.56	-6.11	2.78	34.44
	Tofacitinib 10 mg BID	284	-7.2	17.10	-61.1	-16.11	-5.00	3.89	47.78
Month 12	Placebo→Tofacitinib 5 mg BID	71	-4.0	15.18	-52.2	-10.00	-2.78	6.67	28.33
	Placebo→Tofacitinib 10 mg BID	68	-6.9	15.29	-42.2	-15.56	-6.39	1.67	32.78
	Tofacitinib 5 mg BID	247	-7.2	16.61	-62.2	-17.78	-5.00	2.22	51.11
	Tofacitinib 10 mg BID	264	-7.5	15.68	-77.8	-17.78	-6.67	2.78	27.78
Month 18	Placebo→Tofacitinib 5 mg BID	67	-7.6	16.46	-50.0	-16.11	-5.56	2.22	36.67
	Placebo→Tofacitinib 10 mg BID	63	-7.1	12.45	-37.8	-13.33	-7.22	-2.22	31.67
	Tofacitinib 5 mg BID	233	-6.6	17.21	-57.8	-16.11	-4.44	3.33	44.44
	Tofacitinib 10 mg BID	243	-7.4	15.69	-52.2	-16.67	-7.22	2.22	46.67
Month 24	Placebo→Tofacitinib 5 mg BID	59	-4.5	14.10	-35.6	-13.89	-3.89	6.67	32.22
	Placebo→Tofacitinib 10 mg BID	55	-5.6	14.79	-39.4	-13.89	-6.67	0.56	31.67
	Tofacitinib 5 mg BID	210	-6.2	17.58	-63.3	-17.78	-5.00	2.22	57.78
	Tofacitinib 10 mg BID	217	-8.4	16.95	-82.2	-19.44	-6.67	4.44	38.89
Month 24	Placebo→Tofacitinib 5 mg BID	54	-5.1	16.62	-52.2	-16.11	-5.00	4.44	41.67
	Placebo→Tofacitinib 10 mg BID	52	-6.2	13.15	-32.8	-15.28	-5.00	0.00	28.89

Overall sleep problem score is an index measure that assesses sleep disturbance constructed from 9 items on the MOS. 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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **FACIT Fatigue Scale:** All 4 treatment sequences had clinically meaningful improvements from Baseline in the FACIT Fatigue Scale beginning at Month 12; improvements from Months 12 through 24 were stable and similar for all 4 treatment sequences. The results are presented in Table 134, Table 135, Table 136 and Table 137.

Table 134. Descriptive Statistics of FACIT - Fatigue Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	28.59	10.62	2.00	21.00	29.00	36.00	52.00
	Tofacitinib 10 mg BID	307	29.49	10.62	1.00	22.00	30.00	37.00	52.00
	Placebo	155	31.07	11.06	3.00	24.00	32.00	39.00	51.00
Month 1	Tofacitinib 5 mg BID	309	33.13	10.47	4.00	27.00	34.00	41.00	51.00
	Tofacitinib 10 mg BID	306	34.31	10.19	7.00	28.00	35.50	42.00	51.00
	Placebo	150	31.52	10.63	7.00	25.00	32.00	40.00	51.00
Month 3	Tofacitinib 5 mg BID	295	34.19	10.29	1.00	28.00	35.00	42.00	52.00
	Tofacitinib 10 mg BID	300	36.14	9.53	5.00	30.00	37.00	44.00	52.00
	Placebo	146	31.51	11.10	4.00	25.00	33.00	39.00	51.00
Month 6	Tofacitinib 5 mg BID	282	34.41	9.93	3.00	29.00	35.00	42.00	52.00
	Tofacitinib 10 mg BID	283	36.49	9.78	6.00	30.00	37.00	45.00	52.00
	Placebo	61	33.69	9.06	10.00	29.00	35.00	39.00	49.00
	Placebo→5 mg	40	31.70	10.66	6.00	24.00	33.50	40.00	52.00
	Placebo→10 mg	37	37.54	10.04	11.00	31.00	40.00	45.00	51.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FACIT = Functional Assessment of Chronic Illness Therapy; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 135. Descriptive Statistics of FACIT - Fatigue Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	315	28.59	10.62	2.00	21.00	29.00	36.00	52.00
	Tofacitinib 10 mg BID	307	29.49	10.62	1.00	22.00	30.00	37.00	52.00
Month 1	Placebo→Tofacitinib 5 mg BID	79	30.42	11.57	3.00	24.00	32.00	39.00	51.00
	Placebo→Tofacitinib 10 mg BID	76	31.75	10.54	6.00	24.50	33.00	39.50	50.00
	Tofacitinib 5 mg BID	309	33.13	10.47	4.00	27.00	34.00	41.00	51.00
	Tofacitinib 10 mg BID	306	34.31	10.19	7.00	28.00	35.50	42.00	51.00
Month 3	Placebo→Tofacitinib 5 mg BID	77	29.94	10.75	7.00	22.00	31.00	39.00	50.00
	Placebo→Tofacitinib 10 mg BID	73	33.19	10.31	10.00	28.00	33.00	41.00	51.00
	Tofacitinib 5 mg BID	295	34.19	10.29	1.00	28.00	35.00	42.00	52.00
	Tofacitinib 10 mg BID	300	36.14	9.53	5.00	30.00	37.00	44.00	52.00
Month 6	Placebo→Tofacitinib 5 mg BID	75	29.83	10.88	4.00	24.00	32.00	37.00	49.00
	Placebo→Tofacitinib 10 mg BID	71	33.29	11.14	8.00	26.00	36.00	41.00	51.00
	Tofacitinib 5 mg BID	282	34.41	9.93	3.00	29.00	35.00	42.00	52.00
	Tofacitinib 10 mg BID	283	36.49	9.78	6.00	30.00	37.00	45.00	52.00
Month 12	Placebo→Tofacitinib 5 mg BID	71	32.58	10.31	6.00	25.00	34.00	41.00	52.00
	Placebo→Tofacitinib 10 mg BID	67	35.81	9.42	10.00	31.00	35.00	44.00	51.00
	Tofacitinib 5 mg BID	251	35.10	10.00	7.00	29.00	36.00	43.00	52.00
	Tofacitinib 10 mg BID	265	35.88	10.04	2.00	29.00	37.00	44.00	52.00
Month 18	Placebo→Tofacitinib 5 mg BID	67	35.58	10.65	11.00	29.00	35.00	46.00	51.00
	Placebo→Tofacitinib 10 mg BID	62	37.29	9.98	13.00	31.00	37.50	47.00	51.00
	Tofacitinib 5 mg BID	234	35.66	9.72	7.00	29.00	36.00	43.00	52.00
	Tofacitinib 10 mg BID	244	36.58	10.21	8.00	30.00	38.00	45.00	52.00
Month 24	Placebo→Tofacitinib 5 mg BID	58	36.47	9.74	7.00	31.00	37.00	44.00	51.00
	Placebo→Tofacitinib 10 mg BID	55	38.64	8.14	20.00	32.00	38.00	46.00	52.00
	Tofacitinib 5 mg BID	209	35.59	9.92	6.00	29.00	36.00	43.00	52.00
	Tofacitinib 10 mg BID	216	36.75	10.24	7.00	30.00	38.00	45.50	52.00
Month 24	Placebo→Tofacitinib 5 mg BID	54	35.67	10.63	8.00	28.00	35.00	45.00	51.00
	Placebo→Tofacitinib 10 mg BID	52	38.48	9.42	13.00	32.00	39.50	47.00	50.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID.

BID = twice daily; FACIT = Functional Assessment of Chronic Illness Therapy; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 136. Descriptive Statistics of Change From Baseline of FACIT - Fatigue Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	308	4.54	7.99	-16.00	0.00	4.00	9.00	30.00
	Tofacitinib 10 mg BID	304	4.70	8.61	-24.00	-0.50	4.00	9.00	44.00
	Placebo	149	0.42	7.77	-29.00	-4.00	0.00	5.00	27.00
Month 3	Tofacitinib 5 mg BID	294	5.71	9.41	-33.00	0.00	5.50	11.00	35.00
	Tofacitinib 10 mg BID	298	6.51	8.94	-18.00	1.00	5.00	11.00	43.00
	Placebo	145	0.02	7.88	-29.00	-3.00	0.00	5.00	20.00
Month 6	Tofacitinib 5 mg BID	281	5.90	9.98	-19.00	-1.00	5.00	12.00	35.00
	Tofacitinib 10 mg BID	282	6.95	10.32	-41.00	1.00	6.00	14.00	42.00
	Placebo	60	2.27	7.24	-20.00	-1.00	2.00	7.00	16.00
	Placebo→5 mg	40	3.20	10.39	-15.00	-2.00	1.00	6.50	35.00
	Placebo→10 mg	37	4.57	10.54	-21.00	0.00	3.00	12.00	34.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FACIT = Functional Assessment of Chronic Illness Therapy; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 137. Descriptive Statistics of Change From Baseline of FACIT - Fatigue Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 1	Tofacitinib 5 mg BID	308	4.54	7.99	-16.00	0.00	4.00	9.00	30.00
	Tofacitinib 10 mg BID	304	4.70	8.61	-24.00	-0.50	4.00	9.00	44.00
	Placebo→Tofacitinib 5 mg BID	77	-0.61	7.74	-22.00	-6.00	0.00	4.00	18.00
	Placebo→Tofacitinib 10 mg BID	72	1.51	7.70	-29.00	-2.00	1.00	7.00	27.00
Month 3	Tofacitinib 5 mg BID	294	5.71	9.41	-33.00	0.00	5.50	11.00	35.00
	Tofacitinib 10 mg BID	298	6.51	8.94	-18.00	1.00	5.00	11.00	43.00
	Placebo→Tofacitinib 5 mg BID	75	-0.64	7.56	-25.00	-5.00	0.00	5.00	20.00
	Placebo→Tofacitinib 10 mg BID	70	0.72	8.21	-29.00	-2.00	1.00	6.00	16.00
Month 6	Tofacitinib 5 mg BID	281	5.90	9.98	-19.00	-1.00	5.00	12.00	35.00
	Tofacitinib 10 mg BID	282	6.95	10.32	-41.00	1.00	6.00	14.00	42.00
	Placebo→Tofacitinib 5 mg BID	71	2.25	9.14	-17.00	-2.00	2.00	6.00	35.00
	Placebo→Tofacitinib 10 mg BID	66	4.14	9.17	-21.00	0.00	3.00	11.00	34.00
Month 12	Tofacitinib 5 mg BID	250	6.22	10.23	-30.00	0.00	6.00	13.00	41.00
	Tofacitinib 10 mg BID	264	6.33	9.10	-17.00	0.00	5.00	11.00	39.00
	Placebo→Tofacitinib 5 mg BID	67	5.36	10.11	-23.00	-1.00	4.00	12.00	35.00
	Placebo→Tofacitinib 10 mg BID	61	5.08	10.66	-20.00	1.00	5.00	13.00	31.00
Month 18	Tofacitinib 5 mg BID	233	6.59	10.21	-20.00	0.00	5.00	14.00	38.00
	Tofacitinib 10 mg BID	243	7.02	10.41	-23.00	0.00	6.00	14.00	43.00
	Placebo→Tofacitinib 5 mg BID	58	5.03	9.38	-10.00	-1.00	4.00	10.00	32.00
	Placebo→Tofacitinib 10 mg BID	54	6.56	7.83	-16.00	3.00	6.00	13.00	23.00
Month 24	Tofacitinib 5 mg BID	208	6.12	10.07	-13.00	-1.50	6.00	14.00	35.00
	Tofacitinib 10 mg BID	215	7.18	9.35	-19.00	1.00	6.00	14.00	43.00
	Placebo→Tofacitinib 5 mg BID	54	4.96	10.05	-18.00	-1.00	3.00	10.00	35.00
	Placebo→Tofacitinib 10 mg BID	51	5.98	9.27	-20.00	2.00	4.00	14.00	28.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; FACIT = Functional Assessment of Chronic Illness Therapy; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **EuroQoL EQ-5D Health State Profile – Utility Score:** All 4 treatment sequences had clinically meaningful improvements from Baseline in the EuroQoL EQ-5D Health State Profile (utility score) beginning at Month 12; improvements from Months 12 through 24 were stable and similar for all 4 treatment sequences. The results are presented in Table 138, Table 139, Table 140 and Table 141.

Table 138. Descriptive Statistics of EuroQol EQ-5D Health State Profile-Utility Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	313	0.43	0.31	-0.59	0.09	0.52	0.66	1.00
	Tofacitinib 10 mg BID	309	0.47	0.30	-0.48	0.26	0.59	0.69	1.00
	Placebo	153	0.47	0.30	-0.35	0.16	0.59	0.69	1.00
Month 3	Tofacitinib 5 mg BID	261	0.60	0.27	-0.59	0.52	0.62	0.75	1.00
	Tofacitinib 10 mg BID	262	0.67	0.22	-0.35	0.59	0.69	0.80	1.00
	Placebo	125	0.52	0.30	-0.48	0.52	0.59	0.73	1.00
Month 6	Tofacitinib 5 mg BID	282	0.62	0.25	-0.59	0.52	0.66	0.74	1.00
	Tofacitinib 10 mg BID	284	0.70	0.23	-0.43	0.59	0.69	0.80	1.00
	Placebo	62	0.59	0.24	-0.18	0.52	0.62	0.73	1.00
	Placebo→5 mg	40	0.59	0.26	-0.18	0.52	0.59	0.76	1.00
	Placebo→10 mg	37	0.68	0.29	-0.04	0.52	0.73	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; EuroQol EQ-5D = European Quality of Life 5-dimension scale; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 139. Descriptive Statistics of EuroQol EQ-5D Health State Profile-Utility Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	313	0.43	0.31	-0.59	0.09	0.52	0.66	1.00
	Tofacitinib 10 mg BID	309	0.47	0.30	-0.48	0.26	0.59	0.69	1.00
	Placebo→Tofacitinib 5 mg BID	79	0.43	0.30	-0.35	0.12	0.52	0.66	0.81
Month 3	Placebo→Tofacitinib 10 mg BID	74	0.51	0.29	-0.07	0.52	0.59	0.73	1.00
	Tofacitinib 5 mg BID	261	0.60	0.27	-0.59	0.52	0.62	0.75	1.00
	Tofacitinib 10 mg BID	262	0.67	0.22	-0.35	0.59	0.69	0.80	1.00
Month 6	Placebo→Tofacitinib 5 mg BID	67	0.49	0.31	-0.24	0.52	0.59	0.69	1.00
	Placebo→Tofacitinib 10 mg BID	58	0.56	0.29	-0.48	0.52	0.60	0.73	1.00
	Tofacitinib 5 mg BID	282	0.62	0.25	-0.59	0.52	0.66	0.74	1.00
Month 12	Tofacitinib 10 mg BID	284	0.70	0.23	-0.43	0.59	0.69	0.80	1.00
	Placebo→Tofacitinib 5 mg BID	71	0.60	0.24	-0.18	0.52	0.62	0.73	1.00
	Placebo→Tofacitinib 10 mg BID	68	0.64	0.28	-0.18	0.52	0.65	0.80	1.00
Month 18	Tofacitinib 5 mg BID	252	0.65	0.25	-0.59	0.52	0.69	0.80	1.00
	Tofacitinib 10 mg BID	265	0.69	0.26	-0.59	0.59	0.73	0.80	1.00
	Placebo→Tofacitinib 5 mg BID	67	0.63	0.30	-0.32	0.52	0.69	0.80	1.00
Month 24	Placebo→Tofacitinib 10 mg BID	63	0.74	0.22	-0.24	0.59	0.73	1.00	1.00
	Tofacitinib 5 mg BID	235	0.64	0.26	-0.18	0.52	0.69	0.80	1.00
	Tofacitinib 10 mg BID	244	0.70	0.25	-0.43	0.59	0.73	0.81	1.00
Month 24	Placebo→Tofacitinib 5 mg BID	59	0.68	0.21	-0.24	0.59	0.69	0.80	1.00
	Placebo→Tofacitinib 10 mg BID	55	0.71	0.27	-0.04	0.62	0.73	1.00	1.00
	Tofacitinib 5 mg BID	209	0.66	0.24	-0.35	0.59	0.69	0.80	1.00
Month 24	Tofacitinib 10 mg BID	218	0.71	0.25	-0.59	0.59	0.73	0.85	1.00
	Placebo→Tofacitinib 5 mg BID	54	0.67	0.23	-0.18	0.62	0.69	0.80	1.00
Month 24	Placebo→Tofacitinib 10 mg BID	52	0.75	0.22	0.02	0.62	0.76	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; EuroQol EQ-5D = European Quality of Life 5-dimension scale; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 140. Descriptive Statistics of Change From Baseline of EuroQol EQ-5D Health State Profile-Utility Score per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	260	0.2	0.31	-0.8	0.00	0.10	0.36	1.02
	Tofacitinib 10 mg BID	262	0.2	0.28	-0.6	0.00	0.11	0.31	0.95
	Placebo	124	0.0	0.33	-1.2	-0.07	0.00	0.10	0.93
Month 6	Tofacitinib 5 mg BID	281	0.2	0.33	-0.7	0.00	0.10	0.48	1.08
	Tofacitinib 10 mg BID	284	0.2	0.30	-0.6	0.02	0.17	0.41	1.24
	Placebo	62	0.1	0.27	-0.8	-0.02	0.07	0.21	0.87
Month 6	Placebo→5 mg	40	0.2	0.34	-0.5	0.00	0.07	0.43	0.95
	Placebo→10 mg	35	0.2	0.37	-0.7	0.00	0.16	0.43	0.95

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; EuroQol EQ-5D = European Quality of Life 5-dimension scale; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 141. Descriptive Statistics of Change From Baseline of EuroQol EQ-5D Health State Profile-Utility Score per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	260	0.2	0.31	-0.8	0.00	0.10	0.36	1.02
	Tofacitinib 10 mg BID	262	0.2	0.28	-0.6	0.00	0.11	0.31	0.95
	Placebo→Tofacitinib 5 mg BID	67	0.0	0.34	-0.7	-0.07	0.00	0.12	0.93
Month 6	Placebo→Tofacitinib 10 mg BID	57	0.0	0.33	-1.2	-0.04	0.00	0.10	0.60
	Tofacitinib 5 mg BID	281	0.2	0.33	-0.7	0.00	0.10	0.48	1.08
	Tofacitinib 10 mg BID	284	0.2	0.30	-0.6	0.02	0.17	0.41	1.24
Month 12	Placebo→Tofacitinib 5 mg BID	71	0.2	0.31	-0.5	0.00	0.07	0.38	0.95
	Placebo→Tofacitinib 10 mg BID	66	0.1	0.33	-0.8	-0.03	0.07	0.27	0.95
	Tofacitinib 5 mg BID	251	0.2	0.34	-0.7	0.00	0.11	0.48	1.35
Month 18	Tofacitinib 10 mg BID	265	0.2	0.31	-0.8	0.00	0.17	0.41	1.48
	Placebo→Tofacitinib 5 mg BID	67	0.2	0.30	-0.4	0.00	0.11	0.46	1.02
	Placebo→Tofacitinib 10 mg BID	61	0.2	0.30	-0.3	0.00	0.18	0.38	0.95
Month 24	Tofacitinib 5 mg BID	234	0.2	0.34	-0.7	0.00	0.14	0.34	1.35
	Tofacitinib 10 mg BID	244	0.2	0.32	-0.7	0.04	0.17	0.41	1.35
	Placebo→Tofacitinib 5 mg BID	59	0.2	0.27	-0.3	0.00	0.14	0.43	0.81
Month 24	Placebo→Tofacitinib 10 mg BID	54	0.2	0.33	-0.8	0.00	0.17	0.28	0.80
	Tofacitinib 5 mg BID	208	0.2	0.33	-0.9	0.00	0.15	0.44	0.95
	Tofacitinib 10 mg BID	218	0.3	0.32	-0.7	0.04	0.18	0.42	1.20
Month 24	Placebo→Tofacitinib 5 mg BID	54	0.2	0.30	-0.4	0.03	0.18	0.38	0.95
	Placebo→Tofacitinib 10 mg BID	51	0.2	0.23	-0.2	0.00	0.16	0.28	0.80

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; EuroQol EQ-5D = European Quality of Life 5-dimension scale; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **Work Limitations Questionnaire (WLQ):** All 4 treatment sequences had clinically meaningful decreases (improvements) in the Time Management Scale beginning at Month 18 that were maintained through Month 24. Changes from Baseline in the other WLQ subscales (Physical Demands, Mental/Interpersonal Demands, Output Demands, and Work Loss Index) were generally small and variable.
 - **Time Management Scale:** The results are presented in Table 142, Table 143, Table 144 and Table 145.

Table 142. Descriptive Statistics of Work Limitation Questionnaire: Time Management Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	147	49.74	25.59	0.00	30.00	50.00	68.75	100.00
	Tofacitinib 10 mg BID	146	41.93	26.90	0.00	20.00	40.00	60.00	100.00
	Placebo	81	44.02	28.39	0.00	25.00	45.00	60.00	100.00
Month 3	Tofacitinib 5 mg BID	107	45.18	31.06	0.00	20.00	40.00	75.00	100.00
	Tofacitinib 10 mg BID	116	35.87	33.78	0.00	2.50	25.00	65.00	100.00
	Placebo	52	41.11	27.36	0.00	22.50	40.00	60.00	100.00
Month 6	Tofacitinib 5 mg BID	97	37.90	30.57	0.00	15.00	30.00	55.00	100.00
	Tofacitinib 10 mg BID	116	34.33	33.47	0.00	5.00	25.00	60.00	100.00
	Placebo	19	40.53	32.70	0.00	10.00	40.00	65.00	100.00
	Placebo→5 mg	16	43.98	32.27	0.00	25.00	37.50	67.50	100.00
	Placebo→10 mg	23	31.79	32.29	0.00	0.00	25.00	65.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 143. Descriptive Statistics of Work Limitation Questionnaire: Time Management Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	147	49.74	25.59	0.00	30.00	50.00	68.75	100.00
	Tofacitinib 10 mg BID	146	41.93	26.90	0.00	20.00	40.00	60.00	100.00
Month 3	Placebo→Tofacitinib 5 mg BID	40	42.96	25.27	0.00	25.00	45.00	60.00	100.00
	Placebo→Tofacitinib 10 mg BID	41	45.06	31.41	0.00	20.00	45.00	65.00	100.00
	Tofacitinib 5 mg BID	107	45.18	31.06	0.00	20.00	40.00	75.00	100.00
	Tofacitinib 10 mg BID	116	35.87	33.78	0.00	2.50	25.00	65.00	100.00
Month 6	Placebo→Tofacitinib 5 mg BID	25	45.27	24.33	5.00	25.00	45.00	65.00	85.00
	Placebo→Tofacitinib 10 mg BID	27	37.27	29.84	0.00	10.00	30.00	60.00	100.00
	Tofacitinib 5 mg BID	97	37.90	30.57	0.00	15.00	30.00	55.00	100.00
	Tofacitinib 10 mg BID	116	34.33	33.47	0.00	5.00	25.00	60.00	100.00
Month 12	Placebo→Tofacitinib 5 mg BID	24	43.28	31.62	0.00	25.00	37.50	65.00	100.00
	Placebo→Tofacitinib 10 mg BID	34	34.30	32.69	0.00	0.00	27.50	65.00	100.00
	Tofacitinib 5 mg BID	92	35.82	31.75	0.00	10.00	25.00	65.83	100.00
	Tofacitinib 10 mg BID	108	31.30	31.68	0.00	0.00	22.50	50.00	100.00
Month 18	Placebo→Tofacitinib 5 mg BID	22	43.69	32.76	0.00	15.00	40.00	70.00	100.00
	Placebo→Tofacitinib 10 mg BID	32	37.58	36.88	0.00	5.00	22.50	58.13	100.00
	Tofacitinib 5 mg BID	87	36.78	32.22	0.00	5.00	30.00	60.00	100.00
	Tofacitinib 10 mg BID	95	29.92	32.56	0.00	0.00	20.00	45.00	100.00
Month 24	Placebo→Tofacitinib 5 mg BID	20	28.25	30.49	0.00	0.00	27.50	37.50	95.00
	Placebo→Tofacitinib 10 mg BID	26	23.75	28.99	0.00	0.00	11.25	40.00	95.00
	Tofacitinib 5 mg BID	80	34.59	31.43	0.00	5.00	25.00	55.00	100.00
	Tofacitinib 10 mg BID	82	23.45	28.95	0.00	0.00	10.00	40.00	100.00
Month 24	Placebo→Tofacitinib 5 mg BID	18	36.67	34.81	0.00	10.00	27.50	55.00	100.00
	Placebo→Tofacitinib 10 mg BID	29	30.86	32.46	0.00	0.00	20.00	55.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 144. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Time Management Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	98	-2.80	31.33	-85.00	-20.00	-5.00	10.00	100.00
	Tofacitinib 10 mg BID	101	-5.07	31.94	-90.00	-20.00	-5.00	5.00	80.00
	Placebo	49	-1.55	19.87	-50.00	-10.00	0.00	8.75	62.50
Month 6	Tofacitinib 5 mg BID	91	-9.51	31.51	-85.00	-30.00	-10.00	5.00	100.00
	Tofacitinib 10 mg BID	97	-8.67	32.58	-95.00	-25.00	-10.00	6.25	80.00
	Placebo	19	1.71	29.78	-50.00	-15.00	0.00	10.00	75.00
	Placebo→5 mg	15	-1.92	26.44	-52.50	-25.00	0.00	12.50	58.75
	Placebo→10 mg	19	-13.95	34.87	-95.00	-35.00	-10.00	0.00	43.75

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 145. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Time Management Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	98	-2.80	31.33	-85.00	-20.00	-5.00	10.00	100.00
	Tofacitinib 10 mg BID	101	-5.07	31.94	-90.00	-20.00	-5.00	5.00	80.00
	Placebo→Tofacitinib 5 mg BID	23	2.52	18.45	-30.00	-10.00	0.00	11.67	62.50
	Placebo→Tofacitinib 10 mg BID	26	-5.14	20.73	-50.00	-15.00	-1.88	5.00	50.00
Month 6	Tofacitinib 5 mg BID	91	-9.51	31.51	-85.00	-30.00	-10.00	5.00	100.00
	Tofacitinib 10 mg BID	97	-8.67	32.58	-95.00	-25.00	-10.00	6.25	80.00
	Placebo→Tofacitinib 5 mg BID	23	-0.92	23.04	-52.50	-15.00	0.00	12.50	58.75
	Placebo→Tofacitinib 10 mg BID	30	-8.00	36.12	-95.00	-25.00	-1.25	5.00	75.00
Month 1 2	Tofacitinib 5 mg BID	79	-12.65	33.73	-85.00	-30.00	-10.00	5.00	65.00
	Tofacitinib 10 mg BID	90	-10.61	32.77	-100.00	-30.00	-10.00	5.00	80.00
	Placebo→Tofacitinib 5 mg BID	21	-4.94	18.50	-30.00	-20.00	-12.50	5.00	40.00
	Placebo→Tofacitinib 10 mg BID	28	-6.92	41.92	-80.00	-37.50	-7.50	5.00	100.00
Month 1 8	Tofacitinib 5 mg BID	77	-14.50	34.42	-90.00	-35.00	-15.00	10.00	60.00
	Tofacitinib 10 mg BID	77	-9.47	32.56	-90.00	-30.00	-5.00	0.00	95.00
	Placebo→Tofacitinib 5 mg BID	19	-18.03	20.04	-75.00	-30.00	-15.00	-5.00	10.00
	Placebo→Tofacitinib 10 mg BID	23	-16.90	33.96	-80.00	-40.00	-20.00	0.00	57.50
Month 2 4	Tofacitinib 5 mg BID	65	-14.54	39.68	-100.00	-40.00	-15.00	5.00	85.00
	Tofacitinib 10 mg BID	67	-18.31	27.50	-90.00	-35.00	-15.00	0.00	35.00
	Placebo→Tofacitinib 5 mg BID	16	-9.53	30.17	-75.00	-20.00	-13.75	0.00	70.00
	Placebo→Tofacitinib 10 mg BID	26	-9.23	40.47	-80.00	-40.00	-6.25	10.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Physical Demands Scale: The results are presented in Table 146, Table 147, Table 148 and Table 149.

Table 146. Descriptive Statistics of Work Limitation Questionnaire: Physical Demands Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	149	50.17	24.18	0.00	33.33	50.00	66.67	100.00
	Tofacitinib 10 mg BID	152	50.11	24.19	0.00	31.67	50.00	66.67	100.00
	Placebo	86	49.96	26.67	0.00	30.00	50.00	70.00	100.00
Month 3	Tofacitinib 5 mg BID	106	47.11	29.37	0.00	20.83	50.00	70.83	100.00
	Tofacitinib 10 mg BID	124	44.06	32.26	0.00	12.50	45.83	70.00	100.00
	Placebo	55	46.02	25.36	0.00	29.17	50.00	70.83	87.50
Month 6	Tofacitinib 5 mg BID	104	48.00	29.47	0.00	25.00	47.92	70.83	100.00
	Tofacitinib 10 mg BID	116	43.01	34.57	0.00	11.25	33.33	75.00	100.00
	Placebo	19	43.90	31.26	0.00	12.50	45.83	58.33	100.00
	Placebo→5 mg	16	49.79	29.09	0.00	25.00	54.17	75.00	95.00
	Placebo→10 mg	23	41.83	37.43	0.00	6.25	29.17	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 147. Descriptive Statistics of Work Limitation Questionnaire: Physical Demands Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	149	50.17	24.18	0.00	33.33	50.00	66.67	100.00
	Tofacitinib 10 mg BID	152	50.11	24.19	0.00	31.67	50.00	66.67	100.00
	Placebo→Tofacitinib 5 mg BID	42	51.57	25.27	0.00	35.00	50.00	66.67	100.00
	Placebo→Tofacitinib 10 mg BID	44	48.43	28.14	0.00	27.08	50.00	70.42	100.00
Month 3	Tofacitinib 5 mg BID	106	47.11	29.37	0.00	20.83	50.00	70.83	100.00
	Tofacitinib 10 mg BID	124	44.06	32.26	0.00	12.5	45.83	70.00	100.00
	Placebo→Tofacitinib 5 mg BID	27	46.68	21.44	5.00	30.00	45.83	66.67	79.17
	Placebo→Tofacitinib 10 mg BID	28	45.37	29.02	0.00	16.67	50.00	70.83	87.50
Month 6	Tofacitinib 5 mg BID	104	48.00	29.47	0.00	25.00	47.92	70.83	100.00
	Tofacitinib 10 mg BID	116	43.01	34.57	0.00	11.25	33.33	75.00	100.00
	Placebo→Tofacitinib 5 mg BID	24	46.77	28.48	0.00	18.75	50.00	66.67	95.00
	Placebo→Tofacitinib 10 mg BID	34	43.25	36.05	0.00	8.33	33.33	75.00	100.00
Month 1 2	Tofacitinib 5 mg BID	91	45.64	33.67	0.00	16.67	41.67	75.00	100.00
	Tofacitinib 10 mg BID	110	45.48	33.18	0.00	16.67	42.71	75.00	100.00
	Placebo→Tofacitinib 5 mg BID	22	47.01	32.96	0.00	18.75	47.92	75.00	100.00
	Placebo→Tofacitinib 10 mg BID	33	41.10	35.89	0.00	8.33	35.00	62.50	100.00
Month 1 8	Tofacitinib 5 mg BID	88	45.91	31.66	0.00	19.38	45.83	68.75	100.00
	Tofacitinib 10 mg BID	93	48.57	34.84	0.00	15.00	50.00	75.00	100.00
	Placebo→Tofacitinib 5 mg BID	20	47.25	32.44	0.00	24.58	47.92	70.83	100.00
	Placebo→Tofacitinib 10 mg BID	26	49.33	38.15	0.00	4.17	47.92	87.50	100.00
Month 2 4	Tofacitinib 5 mg BID	83	50.24	31.90	0.00	20.83	50.00	79.17	100.00
	Tofacitinib 10 mg BID	83	44.15	35.98	0.00	8.33	45.00	79.17	100.00
	Placebo→Tofacitinib 5 mg BID	17	41.67	32.48	0.00	12.50	35.00	75.00	100.00
	Placebo→Tofacitinib 10 mg BID	29	41.87	35.95	0.00	8.33	41.67	62.50	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 148. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Physical Demands Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	96	-2.02	28.09	-79.17	-16.67	0.00	14.17	71.67
	Tofacitinib 10 mg BID	109	-6.57	33.89	-95.83	-25.00	-1.25	12.50	87.50
	Placebo	53	-0.86	28.04	-87.50	-15.00	0.00	12.50	67.50
Month 6	Tofacitinib 5 mg BID	96	-2.40	32.89	-75.00	-22.92	0.00	12.50	100.00
	Tofacitinib 10 mg BID	101	-5.76	38.53	-91.67	-33.33	-5.83	20.00	89.58
	Placebo	19	-4.74	34.76	-87.50	-18.75	-4.17	10.42	62.50
	Placebo→5 mg	15	-2.17	40.12	-65.83	-29.17	-6.67	8.33	95.00
	Placebo→10 mg	20	-4.71	37.79	-66.67	-27.08	-4.17	5.21	80.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 149. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Physical Demands Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	96	-2.02	28.09	-79.17	-16.67	0.00	14.17	71.67
	Tofacitinib 10 mg BID	109	-6.57	33.89	-95.83	-25.00	-1.25	12.5	87.50
	Placebo→Tofacitinib 5 mg BID	25	-2.15	23.69	-52.08	-15.00	-4.17	8.33	43.75
	Placebo→Tofacitinib 10 mg BID	28	0.28	31.82	-87.50	-15.83	2.08	20.83	67.50
Month 6	Tofacitinib 5 mg BID	96	-2.40	32.89	-75.00	-22.92	0.00	12.50	100.00
	Tofacitinib 10 mg BID	101	-5.76	38.53	-91.67	-33.33	-5.83	20.00	89.58
	Placebo→Tofacitinib 5 mg BID	23	-4.13	33.70	-65.83	-25.00	-8.33	8.33	95.00
	Placebo→Tofacitinib 10 mg BID	31	-3.92	39.38	-87.50	-29.17	-4.17	10.42	80.00
Month 12	Tofacitinib 5 mg BID	79	-7.39	36.12	-91.67	-31.25	-5.00	12.50	100.00
	Tofacitinib 10 mg BID	91	-3.06	34.84	-91.67	-25.00	-4.17	16.67	83.33
	Placebo→Tofacitinib 5 mg BID	21	-2.70	32.37	-70.83	-20.83	0.00	10.42	53.33
	Placebo→Tofacitinib 10 mg BID	29	-6.47	37.32	-87.50	-19.17	-8.33	5.00	80.00
Month 18	Tofacitinib 5 mg BID	78	-5.35	32.49	-75.00	-25.00	-8.33	12.50	91.67
	Tofacitinib 10 mg BID	76	2.33	36.68	-95.83	-20.83	-4.17	25.00	95.83
	Placebo→Tofacitinib 5 mg BID	19	0.90	34.50	-70.83	-25.00	4.17	29.17	58.33
	Placebo→Tofacitinib 10 mg BID	23	0.13	39.63	-83.33	-29.17	0.00	25.00	70.83
Month 24	Tofacitinib 5 mg BID	67	-4.41	33.35	-75.00	-29.17	-5.00	12.50	80.00
	Tofacitinib 10 mg BID	70	-1.99	38.38	-91.67	-25.00	-8.33	29.17	95.83
	Placebo→Tofacitinib 5 mg BID	16	-0.55	31.79	-50.00	-27.50	-2.08	22.92	58.33
	Placebo→Tofacitinib 10 mg BID	26	-7.80	37.54	-79.17	-40.00	-6.04	12.50	80.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Mental/Interpersonal Demands Scale: The results are presented in Table 150, Table 151, Table 152, and Table 153.

**Table 150. Descriptive Statistics of Work Limitation Questionnaire:
 Mental/Interpersonal Demands Scale per Visit, Comparisons to Placebo,
 2-Year Analysis**

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	151	33.91	25.41	0.00	13.89	28.13	50.00	97.22
	Tofacitinib 10 mg BID	151	29.28	24.47	0.00	8.33	25.00	47.22	100.00
	Placebo	86	33.13	27.93	0.00	6.25	27.78	50.00	100.00
Month 3	Tofacitinib 5 mg BID	111	27.92	27.18	0.00	5.56	21.88	41.67	100.00
	Tofacitinib 10 mg BID	124	23.52	27.09	0.00	0.00	13.19	36.11	100.00
	Placebo	55	34.24	27.87	0.00	13.89	25.00	55.56	94.44
Month 6	Tofacitinib 5 mg BID	103	25.30	29.75	0.00	2.78	13.89	36.11	100.00
	Tofacitinib 10 mg BID	117	21.95	28.40	0.00	0.00	11.11	25.00	100.00
	Placebo	18	32.43	30.69	0.00	5.56	31.94	41.67	100.00
	Placebo→5 mg	17	34.19	31.75	0.00	5.56	28.13	50.00	97.22
	Placebo→10 mg	23	24.73	30.85	0.00	0.00	11.11	44.44	97.22

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 151. Descriptive Statistics of Work Limitation Questionnaire: Mental/Interpersonal Demands Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	151	33.91	25.41	0.00	13.89	28.13	50.00	97.22
	Tofacitinib 10 mg BID	151	29.28	24.47	0.00	8.33	25.00	47.22	100.00
	Placebo→Tofacitinib 5 mg BID	43	35.90	30.30	0.00	8.33	27.78	63.89	100.00
Month 3	Placebo→Tofacitinib 10 mg BID	43	30.36	25.41	0.00	5.56	30.56	50.00	91.67
	Tofacitinib 5 mg BID	111	27.92	27.18	0.00	5.56	21.88	41.67	100.00
	Tofacitinib 10 mg BID	124	23.52	27.09	0.00	0.00	13.19	36.11	100.00
	Placebo→Tofacitinib 5 mg BID	27	42.18	29.03	0.00	22.22	37.50	63.89	94.44
Month 6	Placebo→Tofacitinib 10 mg BID	28	26.57	24.86	0.00	2.78	19.44	41.67	83.33
	Tofacitinib 5 mg BID	103	25.30	29.75	0.00	2.78	13.89	36.11	100.00
	Tofacitinib 10 mg BID	117	21.95	28.40	0.00	0.00	11.11	25.00	100.00
	Placebo→Tofacitinib 5 mg BID	25	37.38	33.92	0.00	5.56	33.33	55.56	100.00
Month 1	Placebo→Tofacitinib 10 mg BID	33	24.22	27.41	0.00	0.00	16.67	36.11	97.22
	Tofacitinib 5 mg BID	93	21.24	25.05	0.00	2.78	12.50	25.00	100.00
	Tofacitinib 10 mg BID	115	20.42	25.99	0.00	0.00	8.33	27.78	100.00
	Placebo→Tofacitinib 5 mg BID	23	39.29	35.39	0.00	0.00	27.78	72.22	100.00
Month 2	Placebo→Tofacitinib 10 mg BID	33	27.70	33.57	0.00	0.00	8.33	52.78	100.00
	Tofacitinib 5 mg BID	88	27.35	30.73	0.00	3.13	16.67	40.28	100.00
	Tofacitinib 10 mg BID	97	19.27	26.33	0.00	0.00	8.33	25.00	100.00
	Placebo→Tofacitinib 5 mg BID	20	33.45	34.19	0.00	1.39	26.39	62.50	97.22
Month 1	Placebo→Tofacitinib 10 mg BID	26	16.28	21.74	0.00	0.00	1.39	30.56	66.67
	Tofacitinib 5 mg BID	82	27.08	29.15	0.00	0.00	17.26	47.22	100.00
	Tofacitinib 10 mg BID	84	18.81	26.64	0.00	0.00	5.56	23.61	100.00
	Placebo→Tofacitinib 5 mg BID	18	32.34	36.20	0.00	2.78	23.61	50.00	100.00
Month 2	Placebo→Tofacitinib 10 mg BID	29	21.39	27.97	0.00	0.00	9.38	38.89	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 152. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Mental/Interpersonal Demands Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	103	-2.02	24.99	-66.67	-13.89	-2.78	5.56	100.00
	Tofacitinib 10 mg BID	108	-2.99	27.94	-77.78	-13.89	-2.78	5.56	94.44
	Placebo	54	1.77	15.50	-44.44	-2.78	0.00	8.33	43.75
Month 6	Tofacitinib 5 mg BID	95	-2.75	25.97	-69.44	-15.18	-2.78	5.56	100.00
	Tofacitinib 10 mg BID	99	-5.61	30.09	-100.00	-19.44	-5.56	2.78	97.22
	Placebo	18	-0.96	20.67	-50.00	-5.56	0.00	13.89	25.00
	Placebo→5 mg	16	-2.93	23.43	-50.00	-20.83	0.00	13.89	30.56
	Placebo→10 mg	20	-2.83	27.31	-44.44	-11.11	-2.48	0.00	97.22

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 153. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Mental/Interpersonal Demands Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	103	-2.02	24.99	-66.67	-13.89	-2.78	5.56	100.00
	Tofacitinib 10 mg BID	108	-2.99	27.94	-77.78	-13.89	-2.78	5.56	94.44
	Placebo→Tofacitinib 5 mg BID	26	1.64	17.27	-44.44	-5.56	0.00	9.72	43.75
Month 6	Placebo→Tofacitinib 10 mg BID	28	1.90	13.97	-36.11	-2.78	0.00	6.94	33.33
	Tofacitinib 5 mg BID	95	-2.75	25.97	-69.44	-15.18	-2.78	5.56	100.00
	Tofacitinib 10 mg BID	99	-5.61	30.09	-100	-19.44	-5.56	2.78	97.22
Month 12	Placebo→Tofacitinib 5 mg BID	24	-0.35	21.65	-50.00	-12.50	0.00	18.06	30.56
	Placebo→Tofacitinib 10 mg BID	30	-3.75	25.45	-50.00	-13.89	-0.87	2.78	97.22
	Tofacitinib 5 mg BID	80	-6.54	22.49	-66.67	-16.32	-5.56	0.00	100.00
Month 18	Tofacitinib 10 mg BID	96	-7.38	27.92	-77.78	-19.44	-5.56	0.00	97.22
	Placebo→Tofacitinib 5 mg BID	22	-1.00	23.90	-44.44	-8.33	-2.78	8.33	68.25
	Placebo→Tofacitinib 10 mg BID	29	0.85	29.50	-55.56	-8.33	0.00	8.33	100.00
Month 24	Tofacitinib 5 mg BID	79	-1.41	27.99	-66.67	-16.67	-2.78	6.25	100.00
	Tofacitinib 10 mg BID	80	-6.20	25.78	-77.78	-17.71	-5.56	2.95	100.00
	Placebo→Tofacitinib 5 mg BID	19	-7.77	22.29	-83.33	-22.22	0.00	2.78	19.44
Month 24	Placebo→Tofacitinib 10 mg BID	23	-7.17	19.97	-55.56	-16.67	0.00	0.00	30.56
	Tofacitinib 5 mg BID	67	-1.97	22.85	-58.33	-16.67	-2.78	6.25	71.88
	Tofacitinib 10 mg BID	71	-5.88	30.37	-77.78	-22.22	-5.56	2.78	100.00
Month 24	Placebo→Tofacitinib 5 mg BID	17	-15.27	25.22	-83.33	-25.00	-8.33	-2.78	22.22
	Placebo→Tofacitinib 10 mg BID	26	-2.18	22.27	-50.00	-5.56	0.00	5.56	44.44

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- **Output Demands Scale:** The results are presented in Table 154, Table 155, Table 156 and Table 157.

Table 154. Descriptive Statistics of Work Limitation Questionnaire: Output Demands Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	149	38.81	26.66	0.00	20.00	37.50	60.00	100.00
	Tofacitinib 10 mg BID	147	36.85	25.95	0.00	15.00	30.00	55.00	100.00
	Placebo	83	40.57	29.38	0.00	15.00	40.00	60.00	100.00
Month 3	Tofacitinib 5 mg BID	108	32.71	27.67	0.00	10.00	25.00	50.00	100.00
	Tofacitinib 10 mg BID	119	25.48	28.69	0.00	0.00	18.75	45.00	100.00
	Placebo	54	39.23	28.44	0.00	15.00	32.50	65.00	95.00
Month 6	Tofacitinib 5 mg BID	101	29.43	29.61	0.00	5.00	20.00	50.00	100.00
	Tofacitinib 10 mg BID	117	24.26	29.30	0.00	0.00	15.00	35.00	100.00
	Placebo	18	35.56	26.78	0.00	10.00	35.00	55.00	95.00
	Placebo→5 mg	16	46.88	32.55	0.00	15.00	50.00	75.00	95.00
Month 6	Placebo→10 mg	22	27.73	31.08	0.00	0.00	20.00	45.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 155. Descriptive Statistics of Work Limitation Questionnaire: Output Demands Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	149	38.81	26.66	0.00	20.00	37.50	60.00	100.00
	Tofacitinib 10 mg BID	147	36.85	25.95	0.00	15.00	30.00	55.00	100.00
	Placebo→Tofacitinib 5 mg BID	42	42.83	28.36	0.00	20.00	38.75	60.00	100.00
	Placebo→Tofacitinib 10 mg BID	41	38.25	30.57	0.00	8.33	40.00	60.00	100.00
Month 3	Tofacitinib 5 mg BID	108	32.71	27.67	0.00	10.00	25.00	50.00	100.00
	Tofacitinib 10 mg BID	119	25.48	28.69	0.00	0.00	18.75	45.00	100.00
	Placebo→Tofacitinib 5 mg BID	26	47.31	26.92	5.00	25.00	42.50	70.00	95.00
	Placebo→Tofacitinib 10 mg BID	28	31.73	28.21	0.00	9.17	25.00	55.00	85.00
Month 6	Tofacitinib 5 mg BID	101	29.43	29.61	0.00	5.00	20.00	50.00	100.00
	Tofacitinib 10 mg BID	117	24.26	29.30	0.00	0.00	15.00	35.00	100.00
	Placebo→Tofacitinib 5 mg BID	24	45.83	30.99	0.00	17.50	47.50	72.50	95.00
	Placebo→Tofacitinib 10 mg BID	32	28.13	28.62	0.00	0.00	22.50	47.50	95.00
Month 12	Tofacitinib 5 mg BID	93	23.71	26.59	0.00	0.00	20.00	30.00	100.00
	Tofacitinib 10 mg BID	107	21.18	26.52	0.00	0.00	10.00	35.00	100.00
	Placebo→Tofacitinib 5 mg BID	23	37.12	34.59	0.00	0.00	25.00	60.00	100.00
	Placebo→Tofacitinib 10 mg BID	31	33.67	34.78	0.00	0.00	25.00	65.00	100.00
Month 18	Tofacitinib 5 mg BID	86	28.28	31.84	0.00	0.00	20.00	37.50	100.00
	Tofacitinib 10 mg BID	93	22.67	27.99	0.00	0.00	15.00	35.00	100.00
	Placebo→Tofacitinib 5 mg BID	20	31.00	32.99	0.00	0.00	25.00	52.50	100.00
	Placebo→Tofacitinib 10 mg BID	25	16.20	21.32	0.00	0.00	5.00	30.00	80.00
Month 24	Tofacitinib 5 mg BID	82	29.19	30.21	0.00	0.00	25.00	50.00	100.00
	Tofacitinib 10 mg BID	81	20.01	28.46	0.00	0.00	5.00	25.00	100.00
	Placebo→Tofacitinib 5 mg BID	18	38.06	37.11	0.00	5.00	25.00	70.00	100.00
	Placebo→Tofacitinib 10 mg BID	29	26.55	31.49	0.00	0.00	10.00	45.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 156. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Output Demands Scale per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	98	-5.37	27.94	-75.00	-15.00	0.00	5.00	100.00
	Tofacitinib 10 mg BID	104	-8.64	29.06	-75.00	-25.00	-7.50	5.00	80.00
	Placebo	53	-0.53	16.69	-55.00	-10.00	0.00	5.00	45.00
Month 6	Tofacitinib 5 mg BID	93	-5.46	30.40	-75.00	-20.00	-5.00	10.00	100.00
	Tofacitinib 10 mg BID	99	-9.75	30.97	-95.00	-30.00	-10.00	0.00	90.00
	Placebo	18	-3.61	21.41	-45.00	-10.00	0.00	10.00	40.00
	Placebo→5 mg	15	3.67	25.04	-40.00	-20.00	5.00	20.00	58.33
	Placebo→10 mg	18	-9.07	35.28	-80.00	-15.00	-5.00	0.00	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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 157. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Output Demands Scale per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	98	-5.37	27.94	-75.00	-15.00	0.00	5.00	100.00
	Tofacitinib 10 mg BID	104	-8.64	29.06	-75.00	-25.00	-7.50	5.00	80.00
	Placebo→Tofacitinib 5 mg BID	25	1.08	14.92	-25.00	-10.00	0.00	10.00	33.33
Month 6	Placebo→Tofacitinib 10 mg BID	28	-1.96	18.27	-55.00	-10.00	0.00	5.00	45.00
	Tofacitinib 5 mg BID	93	-5.46	30.40	-75.00	-20.00	-5.00	10.00	100.00
	Tofacitinib 10 mg BID	99	-9.75	30.97	-95.00	-30.00	-10.00	0.00	90.00
Month 12	Placebo→Tofacitinib 5 mg BID	23	1.74	21.78	-40.00	-15.00	0.00	15.00	58.33
	Placebo→Tofacitinib 10 mg BID	28	-7.62	31.93	-80.00	-22.50	-5.00	2.50	85.00
	Tofacitinib 5 mg BID	80	-12.24	26.97	-75.00	-27.50	-10.00	0.00	100.00
Month 18	Tofacitinib 10 mg BID	92	-11.33	28.75	-75.00	-30.00	-10.00	0.00	100.00
	Placebo→Tofacitinib 5 mg BID	22	-10.44	18.87	-50.00	-20.00	-10.00	0.00	30.00
	Placebo→Tofacitinib 10 mg BID	26	-0.13	32.31	-70.00	-10.00	0.00	5.00	100.00
Month 24	Tofacitinib 5 mg BID	77	-9.22	24.70	-80.00	-20.00	-5.00	5.00	55.00
	Tofacitinib 10 mg BID	75	-10.14	27.05	-71.25	-25.00	-10.00	0.00	85.00
	Placebo→Tofacitinib 5 mg BID	19	-17.81	30.20	-100.00	-33.33	-10.00	5.00	10.00
Month 24	Placebo→Tofacitinib 10 mg BID	21	-17.14	26.25	-80.00	-30.00	-5.00	0.00	20.00
	Tofacitinib 5 mg BID	69	-6.56	26.75	-75.00	-25.00	-5.00	5.00	65.00
	Tofacitinib 10 mg BID	67	-13.06	31.37	-75.00	-31.67	-15.00	0.00	85.00
Month 24	Placebo→Tofacitinib 5 mg BID	17	-14.31	24.91	-75.00	-20.00	-5.00	0.00	15.00
	Placebo→Tofacitinib 10 mg BID	25	-2.73	24.22	-50.00	-10.00	0.00	10.00	40.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Work Loss Index: The results are presented in Table 158, Table 159, Table 160 and Table 161.

Table 158. Descriptive Statistics of Work Limitation Questionnaire: Work Loss Index per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	155	11.13	5.71	0.00	6.70	11.10	15.60	25.50
	Tofacitinib 10 mg BID	157	9.98	5.66	0.00	5.50	9.70	13.70	24.60
	Placebo	87	10.99	6.78	0.00	5.50	10.40	15.80	25.40
Month 3	Tofacitinib 5 mg BID	111	9.77	6.29	0.00	5.30	8.50	13.40	25.80
	Tofacitinib 10 mg BID	127	7.86	6.44	0.00	3.30	6.20	11.60	25.20
	Placebo	55	10.89	6.4	0.00	5.50	10.00	15.00	23.20
Month 6	Tofacitinib 5 mg BID	105	8.78	6.75	0.00	3.90	6.80	11.70	26.40
	Tofacitinib 10 mg BID	123	7.47	6.57	0.00	3.40	5.50	9.60	25.60
	Placebo	19	10.05	6.54	0.00	4.40	10.60	14.10	25.60
	Placebo→5 mg	17	11.63	7.14	1.00	6.00	9.90	16.50	23.80
	Placebo→10 mg	23	8.22	7.14	0.00	2.40	6.50	11.90	22.00

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 159. Descriptive Statistics of Work Limitation Questionnaire: Work Loss Index per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Baseline	Tofacitinib 5 mg BID	155	11.13	5.71	0.00	6.70	11.10	15.60	25.50
	Tofacitinib 10 mg BID	157	9.98	5.66	0.00	5.50	9.70	13.70	24.60
	Placebo→Tofacitinib 5 mg BID	43	11.61	6.72	1.20	6.10	10.00	18.60	25.00
Month 3	Placebo→Tofacitinib 10 mg BID	44	10.38	6.86	0.00	4.35	10.80	15.20	25.40
	Tofacitinib 5 mg BID	111	9.77	6.29	0.00	5.30	8.50	13.40	25.80
	Tofacitinib 10 mg BID	127	7.86	6.44	0.00	3.30	6.20	11.60	25.20
Month 6	Placebo→Tofacitinib 5 mg BID	27	12.56	6.06	2.50	7.20	12.90	16.80	23.20
	Placebo→Tofacitinib 10 mg BID	28	9.28	6.40	0.00	4.75	8.50	12.90	22.30
	Tofacitinib 5 mg BID	105	8.78	6.75	0.00	3.90	6.80	11.70	26.40
Month 12	Tofacitinib 10 mg BID	123	7.47	6.57	0.00	3.40	5.50	9.60	25.60
	Placebo→Tofacitinib 5 mg BID	25	11.87	7.19	1.00	6.00	11.60	16.50	25.60
	Placebo→Tofacitinib 10 mg BID	34	8.26	6.51	0.00	3.60	7.25	11.90	22.00
Month 18	Tofacitinib 5 mg BID	94	7.78	5.94	0.00	3.80	6.55	9.50	25.00
	Tofacitinib 10 mg BID	118	6.86	6.00	0.00	2.60	5.20	9.40	26.50
	Placebo→Tofacitinib 5 mg BID	23	11.33	7.64	0.00	3.70	9.30	18.90	25.00
Month 24	Placebo→Tofacitinib 10 mg BID	33	9.24	7.91	0.20	3.60	5.70	16.40	25.00
	Tofacitinib 5 mg BID	90	8.76	6.94	0.00	3.60	6.60	11.40	26.20
	Tofacitinib 10 mg BID	99	7.09	6.14	0.00	3.50	5.10	9.90	25.00
Month 24	Placebo→Tofacitinib 5 mg BID	20	9.56	7.31	0.00	3.70	8.80	14.75	24.50
	Placebo→Tofacitinib 10 mg BID	26	6.13	5.42	0.00	2.40	4.40	9.50	18.90
	Tofacitinib 5 mg BID	85	8.83	6.93	0.00	3.80	6.80	12.90	28.40
Month 24	Tofacitinib 10 mg BID	84	6.52	6.41	0.00	2.05	4.70	8.50	24.50
	Placebo→Tofacitinib 5 mg BID	19	9.77	8.14	0.00	2.30	8.70	16.10	25.00
	Placebo→Tofacitinib 10 mg BID	29	7.86	6.97	0.60	1.90	4.80	12.60	24.80

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 160. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Work Loss Index per Visit, Comparisons to Placebo, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	104	-0.86	5.94	-13.40	-4.35	-0.65	1.45	22.60
	Tofacitinib 10 mg BID	113	-1.81	6.11	-19.00	-4.10	-2.20	0.90	17.90
	Placebo	54	-0.10	3.32	-9.00	-1.70	-0.10	1.60	8.70
Month 6	Tofacitinib 5 mg BID	98	-1.42	6.40	-14.90	-5.60	-1.05	1.60	22.60
	Tofacitinib 10 mg BID	107	-2.21	6.82	-24.20	-6.10	-2.50	0.70	20.60
	Placebo	19	-0.62	4.34	-9.60	-2.90	0.00	3.00	6.70
Month 6	Placebo→5 mg	16	-0.64	4.73	-6.30	-4.95	-0.85	2.45	8.60
	Placebo→10 mg	20	-1.31	7.84	-19.10	-3.25	-0.10	1.20	17.50

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

Table 161. Descriptive Statistics of Change From Baseline of Work Limitation Questionnaire: Work Loss Index per Visit, Within Sequence Comparisons, 2-Year Analysis

Visit	Treatment Sequence	N	Mean	SD	Min	Q1	Q2	Q3	Max
Month 3	Tofacitinib 5 mg BID	104	-0.86	5.94	-13.4	-4.35	-0.65	1.45	22.60
	Tofacitinib 10 mg BID	113	-1.81	6.11	-19.00	-4.10	-2.20	0.90	17.90
	Placebo→Tofacitinib 5 mg BID	26	0.05	3.37	-5.00	-1.70	-0.40	0.70	8.70
Month 6	Placebo→Tofacitinib 10 mg BID	28	-0.24	3.33	-9.00	-1.80	0.00	2.00	5.10
	Tofacitinib 5 mg BID	98	-1.42	6.40	-14.90	-5.60	-1.05	1.60	22.60
	Tofacitinib 10 mg BID	107	-2.21	6.82	-24.20	-6.10	-2.50	0.70	20.60
Month 12	Placebo→Tofacitinib 5 mg BID	24	-0.41	4.32	-7.00	-4.25	0.20	2.80	8.60
	Placebo→Tofacitinib 10 mg BID	31	-1.24	6.85	-19.10	-3.50	0.00	1.20	17.50
	Tofacitinib 5 mg BID	82	-2.70	5.66	-16.10	-6.10	-1.85	-0.30	20.20
Month 18	Tofacitinib 10 mg BID	101	-2.69	6.27	-20.40	-5.60	-2.40	0.00	21.50
	Placebo→Tofacitinib 5 mg BID	22	-1.61	3.60	-9.80	-2.40	-0.80	0.00	7.20
	Placebo→Tofacitinib 10 mg BID	29	-0.12	7.85	-16.10	-3.60	-0.10	2.50	25.00
Month 24	Tofacitinib 5 mg BID	80	-2.12	5.61	-16.80	-4.65	-1.60	0.55	13.20
	Tofacitinib 10 mg BID	82	-2.15	6.07	-19.00	-5.30	-2.05	0.70	20.60
	Placebo→Tofacitinib 5 mg BID	19	-3.46	5.58	-18.80	-7.20	-1.80	0.60	2.70
Month 24	Placebo→Tofacitinib 10 mg BID	23	-3.19	4.89	-11.70	-9.10	-2.60	0.60	4.30
	Tofacitinib 5 mg BID	70	-1.70	5.18	-13.00	-5.10	-2.40	0.80	14.60
	Tofacitinib 10 mg BID	72	-2.71	6.48	-20.40	-6.20	-2.90	-0.20	18.20
	Placebo→Tofacitinib 5 mg BID	17	-3.82	5.99	-20.60	-4.80	-2.30	0.00	2.10
	Placebo→Tofacitinib 10 mg BID	26	-1.21	5.47	-11.90	-2.90	-0.35	1.30	8.40

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 advanced to either tofacitinib 5 mg BID or tofacitinib 10 mg BID. BID = twice daily; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; SD = standard deviation.

- Rate of Advancement at Month 3: Summary statistics were not provided for the rate of advancement at Month 3.
- Rate of Erroneous Advancement at Month 3: Summary statistics were not provided for the rate of erroneous advancement at Month 3.
- Rate of not Progressing in mTSS: Inhibition of progression between Month 12 and Month 24 for subjects treated with tofacitinib can also be seen in the rates of nonprogression in mTSS and rates of subjects with no new erosions from Month 12 to Month 24. The results are presented in Table 162.

Table 162. Normal Approximation of “Not Progressing” in Modified Sharp Scores per Visit at Months 6, 12 and 24, 2-Year Analysis (FAS, Imputation using Linear Extrapolation)

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 6 (LEP)	Tofacitinib 5 mg BID	278	235	84.53	2.16	1.79	3.87	0.46	-5.78	9.38	0.6421
	Tofacitinib 10 mg BID	291	251	86.25	2.01	3.52	3.78	0.92	-3.90	10.94	0.3527
	Placebo	139	115	82.73	3.20						
Month 12 (LEP)	Tofacitinib 5 mg BID	287	237	82.58	2.23	3.44	4.10	0.83	-4.61	11.49	0.4023
	Tofacitinib 10 mg BID	298	248	83.22	2.16	4.08	4.06	1	-3.89	12.06	0.3155
	Placebo	139	110	79.14	3.44						
Month 24 (LEP)	Tofacitinib 5 mg BID	287	229	79.79	2.37	0.65	4.18	0.15	-7.54	8.85	0.8757
	Tofacitinib 10 mg BID	298	244	81.88	2.23	2.74	4.10	0.66	-5.30	10.78	0.5041
	Placebo	139	110	79.14	3.44						

If subjects did not have any valid post-baseline radiographs, they are not included in this summary.

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; CI = confidence interval; FAS = full analysis set; LEP = linear extrapolation; N = number of subjects; n = number of subjects meeting pre-specified criteria; SE = standard error.

- Rate of no New Erosions in Erosion Score: Inhibition of progression between Month 12 and Month 24 for subjects treated with tofacitinib can also be seen in the rates of nonprogression in mTSS and rates of subjects with no new erosions from Month 12 to Month 24. Results are presented in Table 163.

Table 163. Normal Approximation of “No New Erosion” in Erosion Scores per Visit at Months 6, 12 and 24, 2-Year Analysis (FAS, Imputation using Linear Extrapolation)

Visit	Treatment	N	n	Response Rate	SE	Difference From Placebo					p-Value
						Difference	SE of Difference	Z	95% CI for Difference		
									Lower	Upper	
Month 6 (LEP)	Tofacitinib 5 mg BID	278	253	91.01	1.71	-0.35	2.93	-0.12	-6.11	5.39	0.9024
	Tofacitinib 10 mg BID	291	276	94.85	1.29	3.47	2.71	1.28	-1.83	8.79	0.1996
	Placebo	139	127	91.37	2.38						
Month 12 (LEP)	Tofacitinib 5 mg BID	287	258	89.90	1.77	2.12	3.29	0.64	-4.34	8.59	0.5194
	Tofacitinib 10 mg BID	298	277	92.95	1.48	5.18	3.14	1.64	-0.99	11.35	0.0998
	Placebo	139	122	87.77	2.77						
Month 24 (LEP)	Tofacitinib 5 mg BID	287	249	86.76	2.00	-1.01	3.42	-0.29	-7.72	5.70	0.7679
	Tofacitinib 10 mg BID	298	268	89.93	1.74	2.16	3.28	0.65	-4.26	8.59	0.5096
	Placebo	139	122	87.77	2.77						

If subjects did not have any valid post-baseline radiographs, they are not included in this summary.

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; CI = confidence interval; FAS = full analysis set; LEP = linear extrapolation; N = number of subjects; n = number of subjects meeting pre-specified criteria; SE = standard error.

- RA Healthcare Resource Utilization (RA-HCRU) Questionnaire: Results are presented in Table 164, Table 165 Table 166 and Table 167.

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Seen any doctor/healthcare professional in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.14	0.34	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	305	1.15	0.36	1.00	1.00	1.00	1.00	2.00
		Placebo	154	1.16	0.36	1.00	1.00	1.00	1.00	2.00
	Month 3	Tofacitinib 5 mg BID	259	1.31	0.46	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.31	0.46	1.00	1.00	1.00	2.00	2.00
		Placebo	121	1.28	0.45	1.00	1.00	1.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	281	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	284	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Placebo	61	1.31	0.47	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	39	1.23	0.43	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	37	1.32	0.47	1.00	1.00	1.00	2.00	2.00
	Total visits to doctor/healthcare professional in past 3 months	Baseline	Tofacitinib 5 mg BID	273	3.78	4.24	0.00	2.00	3.00	4.00
Tofacitinib 10 mg BID			262	4.00	5.07	1.00	2.00	3.00	4.00	62.00
Placebo			132	4.80	5.61	1.00	2.00	3.00	5.00	32.00
Month 3		Tofacitinib 5 mg BID	181	2.85	1.79	1.00	2.00	2.00	3.00	12.00
		Tofacitinib 10 mg BID	181	3.08	2.76	1.00	1.00	2.00	3.00	20.00
		Placebo	89	3.27	3.73	1.00	1.00	3.00	4.00	25.00
Month 6		Tofacitinib 5 mg BID	225	3.00	2.89	1.00	1.00	2.00	4.00	25.00
		Tofacitinib 10 mg BID	224	2.71	2.28	1.00	1.00	2.00	4.00	13.00
		Placebo	43	4.51	6.05	1.00	1.00	3.00	4.00	32.00
		Placebo→5 mg	31	4.65	4.71	1.00	2.00	3.00	5.00	20.00
		Placebo→10 mg	25	2.68	2.10	1.00	1.00	2.00	4.00	7.00
RA related		Baseline	Tofacitinib 5 mg BID	271	1.16	0.70	0.00	1.00	1.00	1.00
	Tofacitinib 10 mg BID		262	1.20	0.80	0.00	1.00	1.00	1.00	7.00
	Placebo		131	1.25	0.67	0.00	1.00	1.00	1.00	4.00
	Month 3	Tofacitinib 5 mg BID	181	0.92	0.63	0.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	180	0.79	0.54	0.00	0.00	1.00	1.00	3.00
		Placebo	89	0.87	0.61	0.00	1.00	1.00	1.00	4.00
	Month 6	Tofacitinib 5 mg BID	224	0.87	0.56	0.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	223	0.86	0.56	0.00	1.00	1.00	1.00	4.00
		Placebo	43	0.91	0.61	0.00	1.00	1.00	1.00	3.00
		Placebo→5 mg	30	1.00	0.59	0.00	1.00	1.00	1.00	3.00
		Placebo→10 mg	25	1.00	0.50	0.00	1.00	1.00	1.00	2.00

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Treated in a hospital emergency room in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	306	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo	155	1.94	0.23	1.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	259	1.95	0.23	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Placebo	121	1.97	0.18	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	282	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Placebo	61	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	40	1.98	0.16	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	37	1.97	0.16	1.00	2.00	2.00	2.00	2.00
	Number of visits to hospital ER in past 3 months	Baseline	Tofacitinib 5 mg BID	19	1.42	0.77	1.00	1.00	1.00	2.00
Tofacitinib 10 mg BID			11	1.73	1.27	1.00	1.00	1.00	2.00	5.00
Placebo			9	1.22	0.67	1.00	1.00	1.00	1.00	3.00
Month 3		Tofacitinib 5 mg BID	14	1.29	0.61	1.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	11	1.45	0.93	1.00	1.00	1.00	2.00	4.00
		Placebo	4	1.00	0.00	1.00	1.00	1.00	1.00	1.00
Month 6		Tofacitinib 5 mg BID	15	1.27	0.59	1.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	12	1.33	0.49	1.00	1.00	1.00	2.00	2.00
		Placebo	4	2.25	2.50	1.00	1.00	1.00	3.50	6.00
		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
Admitted for overnight stay		Baseline	Tofacitinib 5 mg BID	22	0.27	0.63	0.00	0.00	0.00	0.00
	Tofacitinib 10 mg BID		12	0.25	0.45	0.00	0.00	0.00	0.50	1.00
	Placebo		9	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 3	Tofacitinib 5 mg BID	14	0.64	0.84	0.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	12	0.08	0.29	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
	Month 6	Tofacitinib 5 mg BID	17	0.12	0.33	0.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	12	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo	4	1.00	1.15	0.00	0.00	1.00	2.00	2.00
		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
	ER visit RA related	Baseline	Tofacitinib 5 mg BID	23	0.74	0.81	0.00	0.00	1.00	1.00

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 3	Tofacitinib 10 mg BID	12	0.83	1.34	0.00	0.00	0.00	1.00	4.00	
		Placebo	9	0.56	0.73	0.00	0.00	0.00	1.00	2.00	
		Tofacitinib 5 mg BID	14	0.29	0.73	0.00	0.00	0.00	0.00	2.00	
	Month 6	Tofacitinib 10 mg BID	13	0.15	0.55	0.00	0.00	0.00	0.00	2.00	
		Placebo	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 5 mg BID	16	0.25	0.58	0.00	0.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	12	0.33	0.78	0.00	0.00	0.00	0.00	2.00	
		Placebo	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	1	0.00		0.00	0.00	0.00	0.00	0.00
	Hospitalized in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.94	0.23	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	306	1.94	0.24	1.00	2.00	2.00	2.00	2.00
Placebo			155	1.97	0.18	1.00	2.00	2.00	2.00	2.00	
Month 3		Tofacitinib 5 mg BID	259	1.97	0.18	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	1.98	0.12	1.00	2.00	2.00	2.00	2.00	
		Placebo	121	1.99	0.09	1.00	2.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	282	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Placebo	61	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	40	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	37	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Number of visits hospitalized in past 3 months		Baseline	Tofacitinib 5 mg BID	18	1.17	0.51	1.00	1.00	1.00	1.00	3.00
	Tofacitinib 10 mg BID		18	1.17	0.38	1.00	1.00	1.00	1.00	2.00	
	Placebo		5	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
	Month 3	Tofacitinib 5 mg BID	9	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Tofacitinib 10 mg BID	4	1.25	0.50	1.00	1.00	1.00	1.50	2.00	
		Placebo	1	2.00		2.00	2.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Tofacitinib 10 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Placebo	4	1.25	0.50	1.00	1.00	1.00	1.50	2.00	
	Hospitalized length of stay	Baseline	Tofacitinib 5 mg BID	18	10.94	9.12	1.00	5.00	7.00	15.00	30.00
			Tofacitinib 10 mg BID	18	20.22	19.70	1.00	5.00	15.50	28.00	70.00
			Placebo	5	22.20	15.37	3.00	14.00	22.00	28.00	44.00
Month 3		Tofacitinib 5 mg BID	9	5.67	4.95	1.00	2.00	5.00	7.00	17.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 6	Tofacitinib 10 mg BID	4	16.25	26.51	2.00	2.50	3.50	30.00	56.00	
		Placebo	1	32.00		32.00	32.00	32.00	32.00	32.00	
		Tofacitinib 5 mg BID	3	12.67	9.07	6.00	6.00	9.00	23.00	23.00	
		Tofacitinib 10 mg BID	3	8.33	6.66	1.00	1.00	10.00	14.00	14.00	
		Placebo	4	9.25	2.50	6.00	7.50	9.50	11.00	12.00	
Hospitalized RA related	Baseline	Tofacitinib 5 mg BID	18	1.11	0.58	0.00	1.00	1.00	1.00	2.00	
		Tofacitinib 10 mg BID	19	1.32	1.34	0.00	0.00	1.00	2.00	4.00	
		Placebo	5	1.40	0.55	1.00	1.00	1.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	9	0.11	0.33	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo	1	0.00		0.00	0.00	0.00	0.00	0.00	
	Month 6	Tofacitinib 5 mg BID	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00	
		Tofacitinib 10 mg BID	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00	
		Placebo	4	0.50	1.00	0.00	0.00	0.00	1.00	2.00	
	Had any outpatient surgeries in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.97	0.16	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	305	1.96	0.20	1.00	2.00	2.00	2.00	2.00
			Placebo	155	1.97	0.18	1.00	2.00	2.00	2.00	2.00
Month 3		Tofacitinib 5 mg BID	259	1.97	0.17	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	1.98	0.12	1.00	2.00	2.00	2.00	2.00	
		Placebo	121	1.99	0.09	1.00	2.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	282	1.96	0.20	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Placebo	61	1.95	0.22	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	40	1.93	0.27	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	37	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
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	13	1.85	2.76	1.00	1.00	1.00	1.00	11.00	
		Placebo	5	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
	Month 3	Tofacitinib 5 mg BID	8	1.25	0.46	1.00	1.00	1.00	1.50	2.00	
		Tofacitinib 10 mg BID	5	1.20	0.45	1.00	1.00	1.00	1.00	2.00	
		Placebo	1	1.00		1.00	1.00	1.00	1.00	1.00	
	Month 6	Tofacitinib 5 mg BID	12	1.33	0.89	1.00	1.00	1.00	1.00	4.00	
		Tofacitinib 10 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Placebo	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
Outpatient surgery RA related	Baseline	Placebo→5 mg	3	1.33	0.58	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 5 mg BID	8	0.38	0.52	0.00	0.00	0.00	1.00	1.00	
		Tofacitinib 10 mg BID	14	0.43	0.85	0.00	0.00	0.00	0.00	2.00	
	Month 3	Placebo	5	0.40	0.55	0.00	0.00	0.00	1.00	1.00	
		Tofacitinib 5 mg BID	8	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	
	Month 6	Placebo	1	0.00		0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 5 mg BID	12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 10 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Had any non-study diagnostic tests in past 3 months	Baseline	Placebo	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Placebo→5 mg	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Tofacitinib 5 mg BID	315	1.82	0.39	1.00	2.00	2.00	2.00	2.00
Month 3		Tofacitinib 10 mg BID	306	1.83	0.37	1.00	2.00	2.00	2.00	2.00	
		Placebo	155	1.85	0.36	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	259	1.86	0.35	1.00	2.00	2.00	2.00	2.00	
Month 6		Tofacitinib 10 mg BID	260	1.83	0.37	1.00	2.00	2.00	2.00	2.00	
		Placebo	121	1.88	0.32	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	281	1.79	0.41	1.00	2.00	2.00	2.00	2.00	
Placebo→5 mg		Tofacitinib 10 mg BID	283	1.84	0.36	1.00	2.00	2.00	2.00	2.00	
		Placebo	61	1.82	0.39	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	40	1.88	0.33	1.00	2.00	2.00	2.00	2.00	
Number of non-study diagnostic tests	Baseline	Placebo->10 mg	37	1.86	0.35	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	56	1.80	1.18	1.00	1.00	1.00	2.00	7.00	
		Tofacitinib 10 mg BID	51	1.67	1.16	1.00	1.00	1.00	2.00	7.00	
	Month 3	Placebo	22	1.73	1.12	1.00	1.00	1.00	2.00	4.00	
		Tofacitinib 5 mg BID	32	1.41	0.71	1.00	1.00	1.00	2.00	3.00	
		Tofacitinib 10 mg BID	43	1.56	1.35	1.00	1.00	1.00	2.00	7.00	
	Month 6	Placebo	13	1.46	0.97	1.00	1.00	1.00	1.00	4.00	
		Tofacitinib 5 mg BID	58	1.78	1.83	1.00	1.00	1.00	2.00	12.00	
		Tofacitinib 10 mg BID	41	1.73	1.40	1.00	1.00	1.00	2.00	7.00	
	Placebo→10 mg	Placebo	11	2.00	1.00	1.00	1.00	2.00	3.00	4.00	
		Placebo→5 mg	5	1.40	0.55	1.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	5	2.00	1.41	1.00	1.00	1.00	3.00	4.00	
Diagnostic tests RA	Baseline	Tofacitinib 5 mg BID	57	0.74	1.09	0.00	0.00	0.00	1.00	5.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 3	Tofacitinib 10 mg BID	53	0.77	1.19	0.00	0.00	0.00	1.00	5.00	
		Placebo	23	0.83	1.15	0.00	0.00	1.00	1.00	4.00	
	Month 6	Tofacitinib 5 mg BID	37	0.14	0.35	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	44	0.07	0.25	0.00	0.00	0.00	0.00	1.00	
		Placebo	14	0.14	0.36	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	60	0.25	0.68	0.00	0.00	0.00	0.00	3.00	
		Tofacitinib 10 mg BID	44	0.25	0.69	0.00	0.00	0.00	0.00	3.00	
		Placebo	11	0.09	0.30	0.00	0.00	0.00	0.00	1.00	
			Placebo→5 mg	5	0.20	0.45	0.00	0.00	0.00	0.00	1.00
			Placebo→10 mg	5	0.20	0.45	0.00	0.00	0.00	0.00	1.00
	Subject in a nursing home in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.99	0.10	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	306	1.99	0.10	1.00	2.00	2.00	2.00	2.00
Placebo			155	1.99	0.11	1.00	2.00	2.00	2.00	2.00	
Month 3		Tofacitinib 5 mg BID	259	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	2.00	0.06	1.00	2.00	2.00	2.00	2.00	
		Placebo	121	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	282	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo	61	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	40	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	37	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Number of days in nursing home in past 3 months	Baseline	Tofacitinib 5 mg BID	3	14.33	12.10	5.00	5.00	10.00	28.00	28.00	
		Tofacitinib 10 mg BID	3	17.67	3.51	14.00	14.00	18.00	21.00	21.00	
		Placebo	2	15.50	7.78	10.00	10.00	15.50	21.00	21.00	
	Month 3	Tofacitinib 10 mg BID	1	28.00		28.00	28.00	28.00	28.00	28.00	
	Month 6	Tofacitinib 5 mg BID	3	24.00	3.61	21.00	21.00	23.00	28.00	28.00	
Used home healthcare services in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.97	0.16	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	306	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Placebo	154	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	257	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	2.00	0.06	1.00	2.00	2.00	2.00	2.00	
		Placebo	121	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	281	1.98	0.13	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	283	1.99	0.08	1.00	2.00	2.00	2.00	2.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
		Placebo	61	1.98	0.13	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	40	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	37	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Home healthcare services hours per day	Baseline	Tofacitinib 5 mg BID	6	1.50	0.84	1.00	1.00	1.00	2.00	3.00	
		Tofacitinib 10 mg BID	2	3.00	1.41	2.00	2.00	3.00	4.00	4.00	
		Placebo	3	1.33	0.58	1.00	1.00	1.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	5	1.20	0.45	1.00	1.00	1.00	1.00	2.00	
		Tofacitinib 10 mg BID	1	4.00		4.00	4.00	4.00	4.00	4.00	
	Month 6	Tofacitinib 5 mg BID	5	2.20	2.17	1.00	1.00	1.00	2.00	6.00	
		Tofacitinib 10 mg BID	2	3.00	2.83	1.00	1.00	3.00	5.00	5.00	
			Placebo	1	1.00		1.00	1.00	1.00	1.00	
	Home healthcare services RA related	Baseline	Tofacitinib 5 mg BID	8	1.00	0.76	0.00	0.50	1.00	1.50	2.00
Tofacitinib 10 mg BID			4	1.50	1.00	0.00	1.00	2.00	2.00	2.00	
Placebo			3	0.67	1.15	0.00	0.00	0.00	2.00	2.00	
Month 3		Tofacitinib 5 mg BID	5	0.80	0.84	0.00	0.00	1.00	1.00	2.00	
		Tofacitinib 10 mg BID	1	3.00		3.00	3.00	3.00	3.00	3.00	
Month 6		Tofacitinib 5 mg BID	5	1.20	0.84	0.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	2	1.50	2.12	0.00	0.00	1.50	3.00	3.00	
			Placebo	1	0.00		0.00	0.00	0.00	0.00	
Required aids/devices for daily functioning in past 3 months		Baseline	Tofacitinib 5 mg BID	315	1.87	0.34	1.00	2.00	2.00	2.00	2.00
	Tofacitinib 10 mg BID		306	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
	Placebo		155	1.90	0.30	1.00	2.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	259	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
	Month 6	Placebo	121	1.89	0.31	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	282	1.90	0.30	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	1.94	0.24	1.00	2.00	2.00	2.00	2.00	
			Placebo	61	1.97	0.18	1.00	2.00	2.00	2.00	2.00
			Placebo→5 mg	40	1.90	0.30	1.00	2.00	2.00	2.00	2.00
			Placebo->10 mg	37	1.97	0.16	1.00	2.00	2.00	2.00	2.00
	Aids or devices used days	Baseline	Tofacitinib 5 mg BID	41	109.63	108.88	1.00	14.00	90.00	180.00	540.00
Tofacitinib 10 mg BID			25	74.08	66.11	3.00	12.00	90.00	90.00	180.00	
Placebo			14	102.21	75.87	1.00	20.00	90.00	180.00	180.00	
Month 3		Tofacitinib 5 mg BID	23	107.22	102.77	1.00	10.00	90.00	180.00	360.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 6	Tofacitinib 10 mg BID	22	73.59	65.16	3.00	8.00	90.00	90.00	186.00	
		Placebo	13	85.00	57.64	1.00	60.00	90.00	102.00	180.00	
		Tofacitinib 5 mg BID	27	93.44	104.39	1.00	10.00	56.00	180.00	360.00	
		Tofacitinib 10 mg BID	17	87.12	61.54	3.00	32.00	90.00	90.00	210.00	
		Placebo	2	110.00	98.99	40.00	40.00	110.00	180.00	180.00	
		Placebo→5 mg	4	74.50	79.35	4.00	14.00	57.00	135.00	180.00	
		Placebo→10 mg	1	90.00		90.00	90.00	90.00	90.00	90.00	
Aids or devices RA related	Baseline	Tofacitinib 5 mg BID	42	1.93	1.24	1.00	1.00	2.00	2.00	6.00	
		Tofacitinib 10 mg BID	29	1.59	1.02	0.00	1.00	1.00	2.00	5.00	
		Placebo	14	1.64	0.50	1.00	1.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	23	1.78	1.04	0.00	1.00	2.00	2.00	4.00	
		Tofacitinib 10 mg BID	24	1.29	0.75	0.00	1.00	1.00	1.50	4.00	
		Placebo	14	1.21	0.70	0.00	1.00	1.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	28	1.36	1.06	0.00	1.00	1.00	2.00	4.00	
		Tofacitinib 10 mg BID	18	1.56	1.20	0.00	1.00	1.00	2.00	5.00	
		Placebo	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	4	1.25	0.96	0.00	0.50	1.50	2.00	2.00	
		Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00	
	Seen any non-medical practitioners in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.97	0.18	1.00	2.00	2.00	2.00	2.00
Tofacitinib 10 mg BID			306	1.94	0.23	1.00	2.00	2.00	2.00	2.00	
Placebo			155	1.95	0.21	1.00	2.00	2.00	2.00	2.00	
Month 3		Tofacitinib 5 mg BID	259	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	1.97	0.17	1.00	2.00	2.00	2.00	2.00	
		Placebo	121	1.98	0.16	1.00	2.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	282	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	1.97	0.17	1.00	2.00	2.00	2.00	2.00	
		Placebo	61	1.97	0.18	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	40	1.95	0.22	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	37	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Non-medical practitioner visits		Baseline	Tofacitinib 5 mg BID	10	12.50	12.29	1.00	3.00	9.00	20.00	40.00
	Tofacitinib 10 mg BID		17	10.88	13.09	1.00	3.00	5.00	20.00	40.00	
	Placebo		7	12.57	13.23	1.00	1.00	10.00	30.00	32.00	
	Month 3	Tofacitinib 5 mg BID	4	7.50	11.03	1.00	1.50	2.50	13.50	24.00	
		Tofacitinib 10 mg BID	8	3.63	1.51	2.00	2.50	3.00	5.00	6.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 6	Placebo	3	22.33	11.24	10.00	10.00	25.00	32.00	32.00	
		Tofacitinib 5 mg BID	6	15.00	17.34	2.00	4.00	8.00	20.00	48.00	
		Tofacitinib 10 mg BID	8	6.13	4.55	2.00	2.00	4.50	11.00	12.00	
		Placebo	2	25.00	7.07	20.00	20.00	25.00	30.00	30.00	
		Placebo→5 mg	2	13.00	9.90	6.00	6.00	13.00	20.00	20.00	
Non-medical practitioner RA related	Baseline	Tofacitinib 5 mg BID	11	1.00	0.77	0.00	0.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	18	1.00	0.84	0.00	0.00	1.00	2.00	2.00	
		Placebo	7	1.57	1.27	0.00	1.00	1.00	2.00	4.00	
	Month 3	Tofacitinib 5 mg BID	4	0.50	1.00	0.00	0.00	0.00	1.00	2.00	
		Tofacitinib 10 mg BID	8	0.38	0.52	0.00	0.00	0.00	1.00	1.00	
		Placebo	3	0.67	0.58	0.00	0.00	1.00	1.00	1.00	
	Month 6	Tofacitinib 5 mg BID	6	1.50	1.52	0.00	0.00	1.50	2.00	4.00	
		Tofacitinib 10 mg BID	8	0.25	0.46	0.00	0.00	0.00	0.50	1.00	
		Placebo	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	2	1.00	1.41	0.00	0.00	1.00	2.00	2.00	
	Are you currently employed	Baseline	Tofacitinib 5 mg BID	314	1.65	0.48	1.00	1.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	306	1.60	0.49	1.00	1.00	2.00	2.00	2.00
			Placebo	155	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Month 3	Tofacitinib 5 mg BID	259	1.63	0.48	1.00	1.00	2.00	2.00	2.00
Tofacitinib 10 mg BID			260	1.57	0.50	1.00	1.00	2.00	2.00	2.00	
Placebo			121	1.60	0.49	1.00	1.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	282	1.65	0.48	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	1.59	0.49	1.00	1.00	2.00	2.00	2.00	
		Placebo	61	1.70	0.46	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	40	1.65	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	37	1.43	0.50	1.00	1.00	1.00	2.00	2.00	
Hours of work per day		Baseline	Tofacitinib 5 mg BID	108	8.01	4.05	1.00	6.50	8.00	8.00	40.00
			Tofacitinib 10 mg BID	121	8.22	4.41	1.00	7.00	8.00	8.00	40.00
			Placebo	59	8.12	5.25	2.00	6.00	8.00	8.00	40.00
	Month 3	Tofacitinib 5 mg BID	97	7.71	4.83	2.00	6.00	8.00	8.00	50.00	
		Tofacitinib 10 mg BID	113	8.25	3.60	2.00	7.00	8.00	9.00	40.00	
		Placebo	48	7.42	2.47	1.00	6.00	8.00	8.00	16.00	
	Month 6	Tofacitinib 5 mg BID	98	8.15	4.15	2.00	7.00	8.00	8.00	40.00	
		Tofacitinib 10 mg BID	117	7.90	1.85	2.00	8.00	8.00	8.00	15.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
Days of work per week	Baseline	Placebo	18	7.56	3.05	1.00	6.00	8.00	9.00	16.00	
		Placebo→5 mg	14	7.36	1.82	3.00	7.00	8.00	8.00	9.00	
		Placebo→10 mg	21	7.52	1.54	4.00	7.00	8.00	8.00	10.00	
	Month 3	Tofacitinib 5 mg BID	Tofacitinib 5 mg BID	109	5.01	1.14	1.00	5.00	5.00	6.00	8.00
			Tofacitinib 10 mg BID	121	5.14	0.92	1.00	5.00	5.00	5.00	8.00
			Placebo	59	4.93	1.39	1.00	5.00	5.00	5.00	8.00
		Tofacitinib 10 mg BID	Tofacitinib 5 mg BID	97	5.03	1.03	1.00	5.00	5.00	6.00	7.00
			Tofacitinib 10 mg BID	113	5.25	0.92	2.00	5.00	5.00	6.00	8.00
			Placebo	48	4.88	1.21	1.00	5.00	5.00	5.00	7.00
		Month 6	Tofacitinib 5 mg BID	98	5.02	1.16	1.00	5.00	5.00	6.00	7.00
			Tofacitinib 10 mg BID	117	5.29	0.78	3.00	5.00	5.00	6.00	7.00
			Placebo	18	4.94	1.00	2.00	5.00	5.00	6.00	6.00
Month 6	Placebo→5 mg	14	5.00	0.88	3.00	5.00	5.00	6.00	6.00		
	Placebo→10 mg	21	4.90	1.30	2.00	5.00	5.00	5.00	7.00		
Feel well enough to work if job were available	Baseline	Tofacitinib 5 mg BID	182	1.87	0.33	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	89	1.82	0.39	1.00	2.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	147	1.78	0.41	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	140	1.73	0.45	1.00	1.00	2.00	2.00	2.00	
		Placebo	68	1.82	0.38	1.00	2.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	175	1.77	0.42	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	153	1.73	0.44	1.00	1.00	2.00	2.00	2.00	
		Placebo	38	1.79	0.41	1.00	2.00	2.00	2.00	2.00	
	Month 6	Placebo→5 mg	24	1.88	0.34	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	16	1.69	0.48	1.00	1.00	2.00	2.00	2.00	
Unable to work due to RA	Baseline	Tofacitinib 5 mg BID	185	1.37	0.48	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	169	1.37	0.48	1.00	1.00	1.00	2.00	2.00	
		Placebo	88	1.33	0.47	1.00	1.00	1.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	148	1.44	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	139	1.50	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo	67	1.39	0.49	1.00	1.00	1.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	176	1.47	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	154	1.56	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo	40	1.43	0.50	1.00	1.00	1.00	2.00	2.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
Lost job or retired early due to RA	Baseline	Placebo→5 mg	24	1.21	0.41	1.00	1.00	1.00	1.00	2.00	
		Placebo→10 mg	16	1.38	0.50	1.00	1.00	1.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	184	1.61	0.49	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	169	1.61	0.49	1.00	1.00	2.00	2.00	2.00	
		Placebo	86	1.67	0.47	1.00	1.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	148	1.64	0.48	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	139	1.63	0.49	1.00	1.00	2.00	2.00	2.00	
		Placebo	67	1.57	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	172	1.69	0.46	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	157	1.63	0.48	1.00	1.00	2.00	2.00	2.00	
	Work disabled due to RA	Baseline	Placebo	38	1.79	0.41	1.00	2.00	2.00	2.00	2.00
			Placebo→5 mg	24	1.42	0.50	1.00	1.00	1.00	2.00	2.00
			Placebo→10 mg	16	1.81	0.40	1.00	2.00	2.00	2.00	2.00
		Month 3	Tofacitinib 5 mg BID	186	1.52	0.50	1.00	1.00	2.00	2.00	2.00
Tofacitinib 10 mg BID			168	1.61	0.49	1.00	1.00	2.00	2.00	2.00	
Placebo	88		1.53	0.50	1.00	1.00	2.00	2.00	2.00		
Month 6	Tofacitinib 5 mg BID	150	1.53	0.50	1.00	1.00	2.00	2.00	2.00		
	Tofacitinib 10 mg BID	140	1.64	0.48	1.00	1.00	2.00	2.00	2.00		
	Placebo	68	1.57	0.50	1.00	1.00	2.00	2.00	2.00		
	Tofacitinib 5 mg BID	173	1.52	0.50	1.00	1.00	2.00	2.00	2.00		
	Tofacitinib 10 mg BID	153	1.66	0.48	1.00	1.00	2.00	2.00	2.00		
I am retired	Baseline	Placebo	38	1.66	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	24	1.46	0.51	1.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	16	1.56	0.51	1.00	1.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	193	1.51	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	171	1.51	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo	92	1.52	0.50	1.00	1.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	150	1.51	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	142	1.42	0.50	1.00	1.00	1.00	2.00	2.00	
		Placebo	70	1.63	0.49	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	177	1.50	0.50	1.00	1.00	1.00	2.00	2.00	
Month 6	Tofacitinib 10 mg BID	156	1.49	0.50	1.00	1.00	1.00	2.00	2.00		
	Placebo	41	1.61	0.49	1.00	1.00	2.00	2.00	2.00		
	Placebo→5 mg	26	1.42	0.50	1.00	1.00	1.00	2.00	2.00		

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
Sick leave in past 3 months from work due to RA	Baseline	Placebo→10 mg	17	1.65	0.49	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	236	1.83	0.38	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	236	1.81	0.39	1.00	2.00	2.00	2.00	2.00	
	Month 3	Placebo	123	1.76	0.43	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	175	1.89	0.31	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	200	1.93	0.26	1.00	2.00	2.00	2.00	2.00	
	Month 6	Placebo	89	1.82	0.39	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	194	1.92	0.27	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	216	1.95	0.22	1.00	2.00	2.00	2.00	2.00	
		Placebo	37	1.89	0.31	1.00	2.00	2.00	2.00	2.00	
	Number of days on sick leave due to RA	Baseline	Placebo→5 mg	32	1.91	0.30	1.00	2.00	2.00	2.00	2.00
			Placebo→10 mg	33	1.88	0.33	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 5 mg BID	41	13.17	21.61	1.00	3.00	5.00	10.00	90.00
Month 3		Tofacitinib 10 mg BID	44	16.84	27.67	1.00	2.50	5.00	11.00	90.00	
		Placebo	29	15.45	25.69	1.00	2.00	4.00	11.00	90.00	
	Tofacitinib 5 mg BID	19	12.16	20.51	1.00	1.00	5.00	15.00	90.00		
Month 6	Tofacitinib 10 mg BID	15	8.20	19.95	1.00	2.00	3.00	5.00	80.00		
	Placebo	16	11.13	21.56	1.00	3.00	4.50	9.00	90.00		
	Tofacitinib 5 mg BID	15	14.93	24.05	1.00	3.00	6.00	14.00	90.00		
	Tofacitinib 10 mg BID	11	14.18	25.86	1.00	1.00	5.00	14.00	90.00		
Performed part time work in past 3 months due to RA	Baseline	Placebo	4	24.25	43.84	2.00	2.00	2.50	46.50	90.00	
		Placebo→5 mg	3	3.00	1.00	2.00	2.00	3.00	4.00	4.00	
		Placebo→10 mg	4	2.25	0.96	1.00	1.50	2.50	3.00	3.00	
	Month 3	Tofacitinib 5 mg BID	235	1.87	0.34	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	236	1.87	0.33	1.00	2.00	2.00	2.00	2.00	
Placebo		121	1.90	0.30	1.00	2.00	2.00	2.00	2.00		
Month 6	Tofacitinib 5 mg BID	176	1.91	0.29	1.00	2.00	2.00	2.00	2.00		
	Tofacitinib 10 mg BID	196	1.94	0.24	1.00	2.00	2.00	2.00	2.00		
	Placebo	89	1.87	0.34	1.00	2.00	2.00	2.00	2.00		
	Tofacitinib 5 mg BID	192	1.96	0.20	1.00	2.00	2.00	2.00	2.00		
Month 6	Tofacitinib 10 mg BID	215	1.94	0.23	1.00	2.00	2.00	2.00	2.00		
	Placebo	37	1.92	0.28	1.00	2.00	2.00	2.00	2.00		
	Placebo→5 mg	32	1.91	0.30	1.00	2.00	2.00	2.00	2.00		
Month 6	Placebo→10 mg	33	1.91	0.29	1.00	2.00	2.00	2.00	2.00		

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Number of days performed part time due to RA	Baseline	Tofacitinib 5 mg BID	30	9.07	12.62	0.00	2.00	4.50	10.00	60.00
		Tofacitinib 10 mg BID	29	12.07	16.50	1.00	2.00	3.00	20.00	70.00
		Placebo	12	26.92	32.20	2.00	5.00	12.00	39.00	90.00
	Month 3	Tofacitinib 5 mg BID	16	9.44	11.51	1.00	3.00	5.50	11.50	45.00
		Tofacitinib 10 mg BID	12	9.42	13.17	1.00	3.00	4.50	10.50	48.00
		Placebo	12	15.67	26.60	2.00	3.00	5.00	9.00	89.00
	Month 6	Tofacitinib 5 mg BID	8	11.88	14.99	2.00	2.50	4.00	17.50	45.00
		Tofacitinib 10 mg BID	12	11.33	11.44	0.00	2.00	6.50	22.00	30.00
		Placebo	3	4.33	1.15	3.00	3.00	5.00	5.00	5.00
		Placebo→5 mg	3	42.33	44.84	1.00	1.00	36.00	90.00	90.00
		Placebo→10 mg	3	2.00	1.00	1.00	1.00	2.00	3.00	3.00
	Average hours of missed work per day due to RA	Baseline	Tofacitinib 5 mg BID	30	7.03	9.98	0.00	2.00	4.00	6.00
Tofacitinib 10 mg BID			30	5.33	4.47	1.00	3.00	4.00	6.00	20.00
Placebo			12	4.33	6.29	0.00	2.00	3.00	3.50	24.00
Month 3		Tofacitinib 5 mg BID	16	9.94	16.85	1.00	2.00	3.00	5.50	64.00
		Tofacitinib 10 mg BID	12	3.17	2.92	0.00	0.00	4.00	4.00	10.00
		Placebo	12	5.42	6.16	1.00	2.50	3.50	5.50	24.00
Month 6		Tofacitinib 5 mg BID	8	2.38	1.60	0.00	1.50	2.00	3.50	5.00
		Tofacitinib 10 mg BID	12	2.50	1.62	0.00	1.50	2.50	4.00	5.00
		Placebo	3	1.00	1.73	0.00	0.00	0.00	3.00	3.00
		Placebo→5 mg	3	3.33	1.15	2.00	2.00	4.00	4.00	4.00
		Placebo→10 mg	3	3.67	0.58	3.00	3.00	4.00	4.00	4.00
Performed paid work in past 3 months while bothered by RA		Baseline	Tofacitinib 5 mg BID	235	1.60	0.49	1.00	1.00	2.00	2.00
	Tofacitinib 10 mg BID		235	1.62	0.49	1.00	1.00	2.00	2.00	2.00
	Placebo		122	1.61	0.49	1.00	1.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	174	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	197	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo	88	1.69	0.46	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	192	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	216	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo	37	1.65	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	31	1.68	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	33	1.76	0.44	1.00	2.00	2.00	2.00	2.00
	Number of days	Baseline	Tofacitinib 5 mg BID	92	29.13	30.81	1.00	6.00	12.00	56.00

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 3	Tofacitinib 10 mg BID	88	31.59	30.12	1.00	7.00	20.00	60.00	90.00	
		Placebo	48	31.90	31.61	1.00	5.00	20.00	54.00	90.00	
	Month 6	Tofacitinib 5 mg BID	52	20.60	27.99	2.00	5.00	8.50	20.00	90.00	
		Tofacitinib 10 mg BID	48	17.42	21.52	2.00	5.00	7.00	20.00	90.00	
		Placebo	27	34.59	33.58	1.00	3.00	20.00	65.00	90.00	
		Tofacitinib 5 mg BID	46	18.87	25.75	2.00	5.00	8.00	20.00	98.00	
		Tofacitinib 10 mg BID	52	18.67	19.85	1.00	5.00	10.00	30.00	90.00	
		Placebo	13	12.85	15.66	1.00	3.00	10.00	10.00	60.00	
			Placebo→5 mg	10	31.20	26.23	2.00	10.00	31.00	45.00	90.00
			Placebo→10 mg	8	14.25	25.87	2.00	4.00	5.00	8.00	78.00
	Work performance in past 3 months on days bothered	Baseline	Tofacitinib 5 mg BID	204	5.29	3.09	0.00	3.00	5.00	8.00	10.00
			Tofacitinib 10 mg BID	202	4.88	3.03	0.00	3.00	5.00	7.00	10.00
Placebo			104	4.68	3.03	0.00	2.50	5.00	7.00	10.00	
Month 3		Tofacitinib 5 mg BID	151	3.81	3.11	0.00	1.00	3.00	6.00	10.00	
		Tofacitinib 10 mg BID	176	3.11	2.67	0.00	1.00	3.00	5.00	10.00	
		Placebo	81	4.40	2.87	0.00	2.00	4.00	7.00	10.00	
Month 6		Tofacitinib 5 mg BID	159	3.70	3.17	0.00	1.00	3.00	6.00	10.00	
		Tofacitinib 10 mg BID	185	2.99	2.94	0.00	0.00	2.00	5.00	10.00	
		Placebo	29	3.41	2.85	0.00	1.00	3.00	5.00	10.00	
		Placebo→5 mg	30	4.13	3.15	0.00	2.00	3.50	6.00	10.00	
		Placebo→10 mg	31	2.90	2.81	0.00	0.00	3.00	5.00	10.00	
Unable to complete chores in past 3 months due to RA	Baseline	Tofacitinib 5 mg BID	312	1.38	0.48	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	302	1.43	0.50	1.00	1.00	1.00	2.00	2.00	
		Placebo	152	1.43	0.50	1.00	1.00	1.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	257	1.60	0.49	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	256	1.70	0.46	1.00	1.00	2.00	2.00	2.00	
		Placebo	121	1.52	0.50	1.00	1.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	280	1.63	0.48	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	283	1.80	0.40	1.00	2.00	2.00	2.00	2.00	
		Placebo	61	1.64	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	40	1.50	0.51	1.00	1.00	1.50	2.00	2.00	
		Placebo→10 mg	37	1.57	0.50	1.00	1.00	2.00	2.00	2.00	
Chores carried out by	Baseline	Tofacitinib 5 mg BID	315	1.83	0.37	1.00	2.00	2.00	2.00	2.00	

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max		
	Month 3	Tofacitinib 10 mg BID	305	1.85	0.36	1.00	2.00	2.00	2.00	2.00		
		Placebo	155	1.90	0.30	1.00	2.00	2.00	2.00	2.00		
	Month 6	Tofacitinib 5 mg BID	257	1.90	0.30	1.00	2.00	2.00	2.00	2.00		
		Tofacitinib 10 mg BID	259	1.92	0.27	1.00	2.00	2.00	2.00	2.00		
		Placebo	121	1.90	0.30	1.00	2.00	2.00	2.00	2.00		
		Tofacitinib 5 mg BID	280	1.89	0.31	1.00	2.00	2.00	2.00	2.00		
		Tofacitinib 10 mg BID	284	1.92	0.28	1.00	2.00	2.00	2.00	2.00		
		Placebo	61	1.90	0.30	1.00	2.00	2.00	2.00	2.00		
		Baseline	Placebo→5 mg	40	1.85	0.36	1.00	2.00	2.00	2.00	2.00	
			Placebo→10 mg	37	1.92	0.28	1.00	2.00	2.00	2.00	2.00	
		Hours per day chores done by housekeeper	Baseline	Tofacitinib 5 mg BID	51	4.27	2.19	1.00	2.00	4.00	6.00	10.00
				Tofacitinib 10 mg BID	44	4.98	2.76	1.00	2.50	4.00	8.00	12.00
Placebo	14			4.21	2.22	1.00	2.00	4.00	6.00	8.00		
Month 3	Tofacitinib 5 mg BID		25	4.84	4.59	1.00	3.00	4.00	6.00	24.00		
	Tofacitinib 10 mg BID		21	4.48	2.18	2.00	2.00	4.00	6.00	8.00		
	Placebo		12	4.83	2.62	2.00	3.50	4.00	6.00	11.00		
Month 6	Tofacitinib 5 mg BID		30	4.97	3.00	1.00	3.00	4.00	8.00	12.00		
	Tofacitinib 10 mg BID		23	4.87	2.32	1.00	4.00	4.00	8.00	8.00		
	Placebo		6	2.67	1.21	1.00	2.00	2.50	4.00	4.00		
	Placebo→5 mg		6	4.83	2.71	2.00	2.00	4.50	8.00	8.00		
	Baseline		Placebo->10 mg	3	4.33	3.21	2.00	2.00	3.00	8.00	8.00	
	Number of days chores done by housekeeper	Baseline	Tofacitinib 5 mg BID	50	19.06	23.91	1.00	4.00	10.00	24.00	90.00	
			Tofacitinib 10 mg BID	44	20.89	33.69	1.00	3.00	7.00	26.00	180.00	
Placebo			15	17.87	18.71	2.00	4.00	10.00	30.00	60.00		
Month 3		Tofacitinib 5 mg BID	25	17.00	20.88	1.00	3.00	7.00	30.00	90.00		
		Tofacitinib 10 mg BID	21	6.05	5.65	1.00	2.00	3.00	9.00	24.00		
		Placebo	12	21.75	32.56	1.00	2.00	9.00	20.00	90.00		
Month 6		Tofacitinib 5 mg BID	30	15.90	22.43	1.00	4.00	8.50	15.00	90.00		
		Tofacitinib 10 mg BID	24	18.08	26.29	1.00	3.00	6.00	24.50	90.00		
		Placebo	6	44.00	40.99	4.00	10.00	35.00	90.00	90.00		
		Placebo→5 mg	6	6.17	5.91	1.00	2.00	3.50	12.00	15.00		
		Baseline	Placebo→10 mg	3	12.67	15.04	3.00	3.00	5.00	30.00	30.00	
Chores carried out by	Baseline	Tofacitinib 5 mg BID	315	1.49	0.50	1.00	1.00	1.00	2.00	2.00		

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 3	Tofacitinib 10 mg BID	305	1.50	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo	155	1.53	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	257	1.67	0.47	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	259	1.73	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo	121	1.53	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	40	1.53	0.51	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	280	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo	61	1.75	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	40	1.53	0.51	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	37	1.68	0.47	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	37	1.68	0.47	1.00	1.00	2.00	2.00	2.00
Hours per day chores done by family/friends	Baseline	Tofacitinib 5 mg BID	158	3.95	4.33	0.00	2.00	3.00	4.00	24.00
		Tofacitinib 10 mg BID	152	3.66	3.87	1.00	2.00	3.00	4.00	30.00
		Placebo	71	3.49	4.16	1.00	2.00	2.00	4.00	24.00
	Month 3	Tofacitinib 5 mg BID	83	4.31	9.29	1.00	1.00	2.00	4.00	81.00
		Tofacitinib 10 mg BID	70	3.64	4.73	0.00	1.00	2.00	4.00	35.00
		Placebo	56	4.04	4.45	1.00	2.00	3.00	5.00	24.00
	Month 6	Tofacitinib 5 mg BID	82	3.15	2.40	1.00	2.00	2.00	4.00	12.00
		Tofacitinib 10 mg BID	67	3.25	4.09	1.00	1.00	2.00	4.00	24.00
		Placebo	15	2.93	1.79	1.00	2.00	3.00	4.00	8.00
		Placebo→5 mg	18	3.28	2.22	1.00	2.00	2.00	4.00	8.00
		Placebo→10 mg	12	3.42	3.34	1.00	1.50	2.00	4.00	12.00
		Placebo→10 mg	12	3.42	3.34	1.00	1.50	2.00	4.00	12.00
No of days chores done by family/friends	Baseline	Tofacitinib 5 mg BID	158	36.28	34.40	1.00	7.00	18.50	70.00	90.00
		Tofacitinib 10 mg BID	152	30.39	34.00	0.00	5.00	15.00	45.00	180.00
		Placebo	73	37.11	34.99	2.00	10.00	20.00	90.00	90.00
	Month 3	Tofacitinib 5 mg BID	84	31.37	34.32	1.00	5.00	10.00	60.00	90.00
		Tofacitinib 10 mg BID	70	21.46	29.48	1.00	3.00	10.00	20.00	90.00
		Placebo	57	27.53	33.51	1.00	3.00	10.00	30.00	90.00
	Month 6	Tofacitinib 5 mg BID	84	29.67	33.34	1.00	5.00	10.00	55.00	90.00
		Tofacitinib 10 mg BID	66	29.65	33.02	1.00	4.00	10.00	50.00	90.00
		Placebo	15	34.87	40.65	2.00	3.00	10.00	90.00	90.00
		Placebo→5 mg	18	36.61	36.65	2.00	6.00	15.00	90.00	90.00
		Placebo→10 mg	12	14.33	24.67	1.00	3.00	6.00	15.00	90.00
		Placebo→10 mg	12	14.33	24.67	1.00	3.00	6.00	15.00	90.00

Table 164. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Tofacitinib 5mg BID or tofacitinib 10mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo →5mg BID or placebo →10mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5mg BID or tofacitinib 10 mg BID.										
BID = twice daily; ER = emergency room; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; RA = rheumatoid arthritis; RA-HCRU = RA Healthcare Resource Utilization Questionnaire; St Dev = standard deviation.										

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Seen any doctor/healthcare professional in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.14	0.34	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	305	1.15	0.36	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	79	1.14	0.35	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	75	1.17	0.38	1.00	1.00	1.00	1.00	2.00
	Month 3	Tofacitinib 5 mg BID	259	1.31	0.46	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.31	0.46	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	64	1.20	0.41	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	57	1.37	0.49	1.00	1.00	1.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	281	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	284	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	69	1.28	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo→10 mg	68	1.31	0.47	1.00	1.00	1.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	251	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	265	1.18	0.39	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	67	1.16	0.37	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	63	1.17	0.38	1.00	1.00	1.00	1.00	2.00
	Month 18	Tofacitinib 5 mg BID	235	1.18	0.38	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	243	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	59	1.14	0.35	1.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	55	1.27	0.45	1.00	1.00	1.00	2.00	2.00
	Month 24	Tofacitinib 5 mg BID	209	1.20	0.40	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	218	1.21	0.41	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	54	1.28	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo→10 mg	52	1.29	0.46	1.00	1.00	1.00	2.00	2.00
Total visits to doctor/healthcare professional in past 3 months	Baseline	Tofacitinib 5 mg BID	273	3.78	4.24	0.00	2.00	3.00	4.00	35.00
		Tofacitinib 10 mg BID	262	4.00	5.07	1.00	2.00	3.00	4.00	62.00
		Placebo→5 mg	69	5.57	6.29	1.00	2.00	4.00	6.00	32.00
		Placebo→10 mg	63	3.97	4.67	1.00	2.00	3.00	4.00	27.00
	Month 3	Tofacitinib 5 mg BID	181	2.85	1.79	1.00	2.00	2.00	3.00	12.00
		Tofacitinib 10 mg BID	181	3.08	2.76	1.00	1.00	2.00	3.00	20.00
		Placebo→5 mg	51	3.33	3.80	1.00	1.00	2.00	4.00	25.00
		Placebo→10 mg	38	3.18	3.69	1.00	1.00	3.00	3.00	23.00
	Month 6	Tofacitinib 5 mg BID	225	3.00	2.89	1.00	1.00	2.00	4.00	25.00
		Tofacitinib 10 mg BID	224	2.71	2.28	1.00	1.00	2.00	4.00	13.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→5 mg	51	5.25	6.42	1.00	2.00	3.00	6.00	32.00	
		Placebo→10 mg	48	2.85	1.94	1.00	1.00	3.00	4.00	8.00	
		Tofacitinib 5 mg BID	198	2.71	2.74	1.00	1.00	2.00	3.00	22.00	
		Tofacitinib 10 mg BID	221	2.43	2.26	0.00	1.00	2.00	3.00	15.00	
	Month 18	Placebo→5 mg	56	3.27	4.02	1.00	1.00	2.00	4.00	25.00	
		Placebo→10 mg	52	2.81	3.91	1.00	1.00	2.00	3.00	27.00	
		Tofacitinib 5 mg BID	194	2.58	3.27	1.00	1.00	2.00	3.00	35.00	
		Tofacitinib 10 mg BID	197	3.22	4.37	0.00	1.00	2.00	3.00	43.00	
	Month 24	Placebo→5 mg	51	4.02	5.67	1.00	1.00	2.00	5.00	36.00	
		Placebo→10 mg	40	1.98	1.23	1.00	1.00	2.00	2.00	7.00	
		Tofacitinib 5 mg BID	167	2.29	1.54	1.00	1.00	2.00	3.00	8.00	
		Tofacitinib 10 mg BID	173	2.69	3.72	1.00	1.00	2.00	3.00	32.00	
	RA related	Baseline	Placebo→5 mg	39	3.28	5.14	1.00	1.00	2.00	3.00	33.00
			Placebo→10 mg	38	1.97	1.20	1.00	1.00	2.00	2.00	6.00
			Tofacitinib 5 mg BID	271	1.16	0.70	0.00	1.00	1.00	1.00	5.00
			Tofacitinib 10 mg BID	262	1.20	0.80	0.00	1.00	1.00	1.00	7.00
Month 3		Placebo→5 mg	69	1.33	0.72	0.00	1.00	1.00	2.00	3.00	
		Placebo→10 mg	62	1.16	0.61	0.00	1.00	1.00	1.00	4.00	
		Tofacitinib 5 mg BID	181	0.92	0.63	0.00	1.00	1.00	1.00	3.00	
		Tofacitinib 10 mg BID	180	0.79	0.54	0.00	0.00	1.00	1.00	3.00	
Month 6		Placebo→5 mg	51	0.84	0.67	0.00	0.00	1.00	1.00	4.00	
		Placebo→10 mg	38	0.89	0.51	0.00	1.00	1.00	1.00	2.00	
		Tofacitinib 5 mg BID	224	0.87	0.56	0.00	1.00	1.00	1.00	3.00	
		Tofacitinib 10 mg BID	223	0.86	0.56	0.00	1.00	1.00	1.00	4.00	
Month 12		Placebo→5 mg	50	0.96	0.57	0.00	1.00	1.00	1.00	3.00	
		Placebo→10 mg	48	0.96	0.58	0.00	1.00	1.00	1.00	3.00	
		Tofacitinib 5 mg BID	198	0.92	0.52	0.00	1.00	1.00	1.00	3.00	
		Tofacitinib 10 mg BID	220	0.89	0.43	0.00	1.00	1.00	1.00	2.00	
Month 18	Placebo→5 mg	56	0.93	0.60	0.00	1.00	1.00	1.00	3.00		
	Placebo→10 mg	52	0.88	0.47	0.00	1.00	1.00	1.00	2.00		
	Tofacitinib 5 mg BID	195	0.92	0.51	0.00	1.00	1.00	1.00	4.00		
	Tofacitinib 10 mg BID	197	0.86	0.49	0.00	1.00	1.00	1.00	3.00		
		Placebo→5 mg	51	0.90	0.54	0.00	1.00	1.00	1.00	2.00	
		Placebo→10 mg	40	0.95	0.39	0.00	1.00	1.00	1.00	2.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Treated in a hospital emergency room in past 3 months	Month 24	Tofacitinib 5 mg BID	167	0.93	0.46	0.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	173	0.90	0.48	0.00	1.00	1.00	1.00	3.00
		Placebo→5 mg	38	1.05	0.46	0.00	1.00	1.00	1.00	2.00
		Placebo→10 mg	38	0.95	0.32	0.00	1.00	1.00	1.00	2.00
	Baseline	Tofacitinib 5 mg BID	315	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	306	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	79	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	76	1.96	0.20	1.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	259	1.95	0.23	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	64	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	57	1.96	0.19	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	282	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	70	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	68	1.96	0.21	1.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	251	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	265	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	67	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	63	1.95	0.21	1.00	2.00	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	235	1.95	0.21	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	243	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	59	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	55	2.00	0.00	2.00	2.00	2.00	2.00	2.00
Month 24	Tofacitinib 5 mg BID	209	1.96	0.20	1.00	2.00	2.00	2.00	2.00	
	Tofacitinib 10 mg BID	218	1.97	0.18	1.00	2.00	2.00	2.00	2.00	
	Placebo→5 mg	54	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
	Placebo→10 mg	52	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
Number of visits to hospital ER in past 3 months	Baseline	Tofacitinib 5 mg BID	19	1.42	0.77	1.00	1.00	1.00	2.00	3.00
		Tofacitinib 10 mg BID	11	1.73	1.27	1.00	1.00	1.00	2.00	5.00
		Placebo→5 mg	6	1.33	0.82	1.00	1.00	1.00	1.00	3.00
		Placebo→10 mg	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	14	1.29	0.61	1.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	11	1.45	0.93	1.00	1.00	1.00	2.00	4.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 6	Placebo→5 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Placebo→10 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Tofacitinib 5 mg BID	15	1.27	0.59	1.00	1.00	1.00	1.00	3.00	
		Tofacitinib 10 mg BID	12	1.33	0.49	1.00	1.00	1.00	2.00	2.00	
		Placebo→5 mg	3	2.67	2.89	1.00	1.00	1.00	6.00	6.00	
	Month 12	Placebo→10 mg	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Tofacitinib 5 mg BID	18	1.61	1.58	1.00	1.00	1.00	1.00	7.00	
		Tofacitinib 10 mg BID	11	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Placebo→5 mg	4	1.25	0.50	1.00	1.00	1.00	1.50	2.00	
		Placebo→10 mg	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
	Month 18	Tofacitinib 5 mg BID	11	1.73	1.35	1.00	1.00	1.00	3.00	5.00	
		Tofacitinib 10 mg BID	18	1.17	0.51	1.00	1.00	1.00	1.00	3.00	
		Placebo→5 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
	Month 24	Tofacitinib 5 mg BID	9	1.89	2.32	1.00	1.00	1.00	1.00	8.00	
		Tofacitinib 10 mg BID	6	1.00	0.00	1.00	1.00	1.00	1.00	1.00	
		Placebo→5 mg	1	2.00		2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00	
	Admitted for overnight stay	Baseline	Tofacitinib 5 mg BID	22	0.27	0.63	0.00	0.00	0.00	0.00	2.00
			Tofacitinib 10 mg BID	12	0.25	0.45	0.00	0.00	0.00	0.50	1.00
			Placebo→5 mg	6	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Placebo→10 mg			3	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
Month 3		Tofacitinib 5 mg BID	14	0.64	0.84	0.00	0.00	0.00	1.00	2.00	
		Tofacitinib 10 mg BID	12	0.08	0.29	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	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	
Month 6		Tofacitinib 5 mg BID	17	0.12	0.33	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo→5 mg	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00	
		Placebo→10 mg	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00	
Month 12		Tofacitinib 5 mg BID	18	0.17	0.38	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	11	0.18	0.40	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	4	0.25	0.50	0.00	0.00	0.00	0.50	1.00	
		Placebo→10 mg	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00	
Month 18		Tofacitinib 5 mg BID	12	0.00	0.00	0.00	0.00	0.00	0.00	0.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 24	Tofacitinib 10 mg BID	18	0.28	0.57	0.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 5 mg BID	9	0.22	0.44	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	8	0.38	0.74	0.00	0.00	0.00	0.50	2.00	
		Placebo→5 mg	1	0.00		0.00	0.00	0.00	0.00	0.00	
ER visit RA related	Baseline	Tofacitinib 5 mg BID	23	0.74	0.81	0.00	0.00	1.00	1.00	2.00	
		Tofacitinib 10 mg BID	12	0.83	1.34	0.00	0.00	0.00	1.00	4.00	
		Placebo→5 mg	6	0.67	0.82	0.00	0.00	0.50	1.00	2.00	
	Month 3	Placebo→10 mg	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00	
		Tofacitinib 5 mg BID	14	0.29	0.73	0.00	0.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	13	0.15	0.55	0.00	0.00	0.00	0.00	2.00	
	Month 6	Placebo→5 mg	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	
		Tofacitinib 5 mg BID	16	0.25	0.58	0.00	0.00	0.00	0.00	2.00	
	Month 12	Tofacitinib 10 mg BID	12	0.33	0.78	0.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo→10 mg	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00	
	Month 18	Tofacitinib 5 mg BID	18	0.11	0.32	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	11	0.09	0.30	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	4	0.25	0.50	0.00	0.00	0.00	0.50	1.00	
	Month 24	Placebo→10 mg	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 5 mg BID	12	0.25	0.62	0.00	0.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	18	0.17	0.51	0.00	0.00	0.00	0.00	2.00	
		Month 24	Placebo→5 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Tofacitinib 5 mg BID	9	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Tofacitinib 10 mg BID	8	0.50	0.93	0.00	0.00	0.00	1.00	2.00
		Month 24	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
	Hospitalized in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.94	0.23	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	306	1.94	0.24	1.00	2.00	2.00	2.00	2.00
			Placebo→5 mg	79	1.99	0.11	1.00	2.00	2.00	2.00	2.00
			Placebo→10 mg	76	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Month 3	Tofacitinib 5 mg BID	259	1.97	0.18	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	260	1.98	0.12	1.00	2.00	2.00	2.00	2.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	64	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	57	1.98	0.13	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	282	1.99	0.10	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.99	0.10	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	70	1.99	0.12	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	68	1.96	0.21	1.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	251	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	265	1.98	0.12	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	67	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	63	1.98	0.13	1.00	2.00	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	235	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	243	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	59	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	55	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 24	Tofacitinib 5 mg BID	209	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	218	1.99	0.12	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	54	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	52	2.00	0.00	2.00	2.00	2.00	2.00	2.00
Number of visits hospitalized in past 3 months	Baseline	Tofacitinib 5 mg BID	18	1.17	0.51	1.00	1.00	1.00	1.00	3.00
		Tofacitinib 10 mg BID	18	1.17	0.38	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
		Placebo→10 mg	4	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	9	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	4	1.25	0.50	1.00	1.00	1.00	1.50	2.00
	Month 6	Placebo→10 mg	1	2.00		2.00	2.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	3	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
	Month 12	Placebo→10 mg	3	1.33	0.58	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 5 mg BID	8	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	4	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→5 mg	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
	Month 18	Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
		Tofacitinib 5 mg BID	5	1.00	0.00	1.00	1.00	1.00	1.00	1.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 24	Tofacitinib 10 mg BID	9	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Tofacitinib 5 mg BID	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→5 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
Hospitalized length of stay	Baseline	Tofacitinib 5 mg BID	18	10.94	9.12	1.00	5.00	7.00	15.00	30.00
		Tofacitinib 10 mg BID	18	20.22	19.70	1.00	5.00	15.50	28.00	70.00
		Placebo→5 mg	1	44.00		44.00	44.00	44.00	44.00	44.00
		Placebo→10 mg	4	16.75	10.81	3.00	8.50	18.00	25.00	28.00
	Month 3	Tofacitinib 5 mg BID	9	5.67	4.95	1.00	2.00	5.00	7.00	17.00
		Tofacitinib 10 mg BID	4	16.25	26.51	2.00	2.50	3.50	30.00	56.00
		Placebo→10 mg	1	32.00		32.00	32.00	32.00	32.00	32.00
	Month 6	Tofacitinib 5 mg BID	3	12.67	9.07	6.00	6.00	9.00	23.00	23.00
		Tofacitinib 10 mg BID	3	8.33	6.66	1.00	1.00	10.00	14.00	14.00
		Placebo→5 mg	1	6.00		6.00	6.00	6.00	6.00	6.00
	Month 12	Placebo→10 mg	3	10.33	1.53	9.00	9.00	10.00	12.00	12.00
		Tofacitinib 5 mg BID	8	10.13	6.58	2.00	4.50	9.50	15.50	20.00
		Tofacitinib 10 mg BID	4	7.00	5.35	1.00	2.50	7.50	11.50	12.00
		Placebo→5 mg	2	2.50	2.12	1.00	1.00	2.50	4.00	4.00
	Month 18	Placebo→10 mg	1	3.00		3.00	3.00	3.00	3.00	3.00
		Tofacitinib 5 mg BID	5	10.40	5.73	6.00	6.00	10.00	10.00	20.00
	Month 24	Tofacitinib 10 mg BID	10	7.00	3.83	0.00	4.00	8.00	10.00	12.00
		Tofacitinib 5 mg BID	6	11.33	16.23	2.00	2.00	6.00	8.00	44.00
		Tofacitinib 10 mg BID	3	14.67	10.26	6.00	6.00	12.00	26.00	26.00
	Hospitalized RA related	Baseline	Placebo→5 mg	2	19.50	23.33	3.00	3.00	19.50	36.00
Tofacitinib 5 mg BID			18	1.11	0.58	0.00	1.00	1.00	1.00	2.00
Tofacitinib 10 mg BID			19	1.32	1.34	0.00	0.00	1.00	2.00	4.00
Placebo→10 mg			1	1.00		1.00	1.00	1.00	1.00	1.00
Month 3		Placebo→5 mg	4	1.50	0.58	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 5 mg BID	9	0.11	0.33	0.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	4	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Month 6		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
		Tofacitinib 5 mg BID	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
Placebo→5 mg	1	0.00		0.00	0.00	0.00	0.00	0.00		

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00	
		Tofacitinib 5 mg BID	8	0.50	0.76	0.00	0.00	0.00	1.00	2.00	
		Tofacitinib 10 mg BID	4	0.50	0.58	0.00	0.00	0.50	1.00	1.00	
	Month 18	Placebo→5 mg	2	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	
		Tofacitinib 5 mg BID	5	0.40	0.89	0.00	0.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Month 24	Tofacitinib 5 mg BID	6	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	
	Had any outpatient surgeries in past 3 months	Baseline	Placebo→5 mg	2	1.00	1.41	0.00	0.00	1.00	2.00	2.00
			Tofacitinib 5 mg BID	315	1.97	0.16	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	305	1.96	0.20	1.00	2.00	2.00	2.00	2.00
			Placebo→10 mg	79	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Month 3	Placebo→5 mg	76	1.97	0.16	1.00	2.00	2.00	2.00	2.00
Placebo→10 mg			76	1.97	0.16	1.00	2.00	2.00	2.00	2.00	
Tofacitinib 5 mg BID			259	1.97	0.17	1.00	2.00	2.00	2.00	2.00	
Tofacitinib 10 mg BID			260	1.98	0.12	1.00	2.00	2.00	2.00	2.00	
Month 6		Placebo→5 mg	64	1.98	0.13	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	57	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	282	1.96	0.20	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
Month 12		Placebo→5 mg	70	1.91	0.28	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	68	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	251	1.95	0.22	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	265	1.98	0.12	1.00	2.00	2.00	2.00	2.00	
Month 18		Placebo→5 mg	67	1.99	0.12	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	63	1.98	0.13	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	235	1.97	0.16	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	243	1.96	0.20	1.00	2.00	2.00	2.00	2.00	
Month 24		Placebo→5 mg	59	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	55	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	209	1.95	0.21	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	218	1.95	0.22	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	54	1.96	0.19	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	52	1.98	0.14	1.00	2.00	2.00	2.00	2.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
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	13	1.85	2.76	1.00	1.00	1.00	1.00	11.00
		Placebo→5 mg	3	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→10 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	8	1.25	0.46	1.00	1.00	1.00	1.50	2.00
		Tofacitinib 10 mg BID	5	1.20	0.45	1.00	1.00	1.00	1.00	2.00
		Placebo→5 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	12	1.33	0.89	1.00	1.00	1.00	1.00	4.00
		Tofacitinib 10 mg BID	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo→5 mg	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
	Month 12	Tofacitinib 5 mg BID	13	2.31	2.39	1.00	1.00	1.00	2.00	8.00
		Tofacitinib 10 mg BID	4	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
	Month 18	Placebo→10 mg	1	2.00		2.00	2.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	10	1.20	0.42	1.00	1.00	1.00	1.00	2.00
	Month 24	Tofacitinib 5 mg BID	9	1.22	0.44	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	11	1.45	1.21	1.00	1.00	1.00	1.00	5.00
		Placebo→5 mg	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
			Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00
Outpatient surgery RA related	Baseline	Tofacitinib 5 mg BID	8	0.38	0.52	0.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	14	0.43	0.85	0.00	0.00	0.00	0.00	2.00
		Placebo→5 mg	3	0.33	0.58	0.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
	Month 3	Tofacitinib 5 mg BID	8	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
	Month 6	Tofacitinib 5 mg BID	12	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	6	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 12	Tofacitinib 5 mg BID	13	0.46	0.66	0.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	4	0.25	0.50	0.00	0.00	0.00	0.50	1.00
		Placebo→5 mg	1	2.00		2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 18	Tofacitinib 5 mg BID	6	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 10 mg BID	11	0.09	0.30	0.00	0.00	0.00	0.00	1.00	
	Month 24	Tofacitinib 5 mg BID	10	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 10 mg BID	12	0.17	0.58	0.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	2	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		
Had any non-study diagnostic tests in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.82	0.39	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	306	1.83	0.37	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	79	1.80	0.40	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	76	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	259	1.86	0.35	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	1.83	0.37	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	64	1.86	0.35	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	57	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	281	1.79	0.41	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	283	1.84	0.36	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	70	1.89	0.32	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	68	1.81	0.40	1.00	2.00	2.00	2.00	2.00	
	Month 12	Tofacitinib 5 mg BID	251	1.79	0.41	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	265	1.81	0.39	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	67	1.87	0.34	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	63	1.86	0.35	1.00	2.00	2.00	2.00	2.00	
	Month 18	Tofacitinib 5 mg BID	235	1.86	0.35	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	243	1.81	0.40	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	59	1.76	0.43	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	55	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
	Month 24	Tofacitinib 5 mg BID	209	1.80	0.40	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	218	1.84	0.36	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	54	1.81	0.39	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	52	1.88	0.32	1.00	2.00	2.00	2.00	2.00	
	Number of	Baseline	Tofacitinib 5 mg BID	56	1.80	1.18	1.00	1.00	1.00	2.00	7.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 3	Tofacitinib 10 mg BID	51	1.67	1.16	1.00	1.00	1.00	2.00	7.00	
		Placebo→5 mg	16	1.69	1.08	1.00	1.00	1.00	2.00	4.00	
		Placebo→10 mg	6	1.83	1.33	1.00	1.00	1.00	3.00	4.00	
		Tofacitinib 5 mg BID	32	1.41	0.71	1.00	1.00	1.00	2.00	3.00	
		Tofacitinib 10 mg BID	43	1.56	1.35	1.00	1.00	1.00	2.00	7.00	
		Placebo→5 mg	9	1.11	0.33	1.00	1.00	1.00	1.00	2.00	
	Month 6	Placebo→10 mg	4	2.25	1.50	1.00	1.00	2.00	3.50	4.00	
		Tofacitinib 5 mg BID	58	1.78	1.83	1.00	1.00	1.00	2.00	12.00	
		Tofacitinib 10 mg BID	41	1.73	1.40	1.00	1.00	1.00	2.00	7.00	
		Placebo→5 mg	8	1.50	0.53	1.00	1.00	1.50	2.00	2.00	
	Month 12	Placebo→10 mg	13	2.08	1.19	1.00	1.00	2.00	3.00	4.00	
		Tofacitinib 5 mg BID	50	1.98	1.49	1.00	1.00	1.00	2.00	7.00	
		Tofacitinib 10 mg BID	47	1.55	1.14	1.00	1.00	1.00	2.00	6.00	
	Month 18	Placebo→5 mg	9	2.00	1.00	1.00	1.00	2.00	2.00	4.00	
		Placebo→10 mg	9	1.78	0.83	1.00	1.00	2.00	2.00	3.00	
		Tofacitinib 5 mg BID	35	1.60	1.06	1.00	1.00	1.00	2.00	6.00	
		Tofacitinib 10 mg BID	47	1.96	2.26	1.00	1.00	1.00	2.00	15.00	
	Month 24	Placebo→5 mg	14	1.50	1.09	1.00	1.00	1.00	2.00	5.00	
		Placebo→10 mg	5	1.40	0.89	1.00	1.00	1.00	1.00	3.00	
		Tofacitinib 5 mg BID	40	1.65	0.86	1.00	1.00	1.50	2.00	5.00	
		Tofacitinib 10 mg BID	33	1.58	1.23	1.00	1.00	1.00	2.00	6.00	
		Placebo→5 mg	10	2.10	1.91	1.00	1.00	1.00	3.00	7.00	
	Diagnostic tests RA related	Baseline	Placebo→10 mg	6	1.17	0.41	1.00	1.00	1.00	1.00	2.00
			Tofacitinib 5 mg BID	57	0.74	1.09	0.00	0.00	0.00	1.00	5.00
			Tofacitinib 10 mg BID	53	0.77	1.19	0.00	0.00	0.00	1.00	5.00
		Month 3	Placebo→5 mg	16	0.81	1.05	0.00	0.00	1.00	1.00	4.00
			Placebo→10 mg	7	0.86	1.46	0.00	0.00	0.00	1.00	4.00
			Tofacitinib 5 mg BID	37	0.14	0.35	0.00	0.00	0.00	0.00	1.00
Tofacitinib 10 mg BID			44	0.07	0.25	0.00	0.00	0.00	0.00	1.00	
Month 6		Placebo→5 mg	9	0.22	0.44	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	5	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Tofacitinib 5 mg BID	60	0.25	0.68	0.00	0.00	0.00	0.00	3.00	
	Tofacitinib 10 mg BID	44	0.25	0.69	0.00	0.00	0.00	0.00	3.00		
	Placebo→5 mg	8	0.13	0.35	0.00	0.00	0.00	0.00	1.00		

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	13	0.15	0.38	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	52	0.27	0.56	0.00	0.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	50	0.24	0.48	0.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	9	0.22	0.67	0.00	0.00	0.00	0.00	2.00	
	Month 18	Placebo→10 mg	10	0.10	0.32	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	35	0.20	0.41	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	47	0.06	0.32	0.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	14	0.21	0.43	0.00	0.00	0.00	0.00	1.00	
	Month 24	Placebo→10 mg	5	0.20	0.45	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	41	0.20	0.46	0.00	0.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	35	0.11	0.40	0.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	10	0.30	0.48	0.00	0.00	0.00	1.00	1.00	
	Subject in a nursing home in past 3 months	Baseline	Placebo→10 mg	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
			Tofacitinib 5 mg BID	315	1.99	0.10	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	306	1.99	0.10	1.00	2.00	2.00	2.00	2.00
			Placebo→5 mg	79	1.99	0.11	1.00	2.00	2.00	2.00	2.00
Month 3		Placebo→10 mg	76	1.99	0.11	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	259	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	2.00	0.06	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	64	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Month 6		Placebo→10 mg	57	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	282	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	284	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	70	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Month 12		Placebo→10 mg	68	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	251	1.99	0.09	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	265	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	67	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Month 18		Placebo→10 mg	63	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	235	1.99	0.09	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	243	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	59	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Month 24		Placebo→10 mg	55	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	209	2.00	0.00	2.00	2.00	2.00	2.00	2.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
		Tofacitinib 10 mg BID	218	2.00	0.07	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	54	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	52	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
Number of days in nursing home in past 3 months	Baseline	Tofacitinib 5 mg BID	3	14.33	12.10	5.00	5.00	10.00	28.00	28.00	
		Tofacitinib 10 mg BID	3	17.67	3.51	14.00	14.00	18.00	21.00	21.00	
		Placebo→5 mg	1	10.00		10.00	10.00	10.00	10.00	10.00	
			Placebo→10 mg	1	21.00		21.00	21.00	21.00	21.00	21.00
	Month 3	Tofacitinib 10 mg BID	1	28.00		28.00	28.00	28.00	28.00	28.00	
	Month 6	Tofacitinib 5 mg BID	3	24.00	3.61	21.00	21.00	23.00	28.00	28.00	
	Month 12	Tofacitinib 5 mg BID	2	11.50	2.12	10.00	10.00	11.50	13.00	13.00	
	Month 18	Tofacitinib 5 mg BID	2	17.50	4.95	14.00	14.00	17.50	21.00	21.00	
	Month 24	Tofacitinib 10 mg BID	1	16.00		16.00	16.00	16.00	16.00	16.00	
Used home healthcare services in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.97	0.16	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	306	1.99	0.10	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	78	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	76	1.96	0.20	1.00	2.00	2.00	2.00	2.00	
	Month 3	Tofacitinib 5 mg BID	257	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	260	2.00	0.06	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	64	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	57	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
	Month 6	Tofacitinib 5 mg BID	281	1.98	0.13	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	283	1.99	0.08	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	70	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	68	1.99	0.12	1.00	2.00	2.00	2.00	2.00	
	Month 12	Tofacitinib 5 mg BID	250	1.99	0.09	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	264	2.00	0.06	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	67	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	63	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
	Month 18	Tofacitinib 5 mg BID	234	2.00	0.07	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	242	2.00	0.06	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	59	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	55	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
	Month 24	Tofacitinib 5 mg BID	210	2.00	0.07	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	218	2.00	0.07	1.00	2.00	2.00	2.00	2.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	54	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	52	2.00	0.00	2.00	2.00	2.00	2.00	2.00
Home healthcare services hours per day	Baseline	Tofacitinib 5 mg BID	6	1.50	0.84	1.00	1.00	1.00	2.00	3.00
		Tofacitinib 10 mg BID	2	3.00	1.41	2.00	2.00	3.00	4.00	4.00
		Placebo→10 mg	3	1.33	0.58	1.00	1.00	1.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	5	1.20	0.45	1.00	1.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	1	4.00		4.00	4.00	4.00	4.00	4.00
	Month 6	Tofacitinib 5 mg BID	5	2.20	2.17	1.00	1.00	1.00	2.00	6.00
		Tofacitinib 10 mg BID	2	3.00	2.83	1.00	1.00	3.00	5.00	5.00
		Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	2	20.50	27.58	1.00	1.00	20.50	40.00	40.00
		Tofacitinib 10 mg BID	1	4.00		4.00	4.00	4.00	4.00	4.00
	Month 18	Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	1	6.00		6.00	6.00	6.00	6.00	6.00
	Month 24	Tofacitinib 5 mg BID	1	4.00		4.00	4.00	4.00	4.00	4.00
		Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
Home healthcare services RA related	Baseline	Tofacitinib 5 mg BID	8	1.00	0.76	0.00	0.50	1.00	1.50	2.00
		Tofacitinib 10 mg BID	4	1.50	1.00	0.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	5	0.80	0.84	0.00	0.00	1.00	1.00	2.00
		Tofacitinib 10 mg BID	1	3.00		3.00	3.00	3.00	3.00	3.00
	Month 6	Tofacitinib 5 mg BID	5	1.20	0.84	0.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	2	1.50	2.12	0.00	0.00	1.50	3.00	3.00
		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 12	Tofacitinib 5 mg BID	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Tofacitinib 10 mg BID	1	3.00		3.00	3.00	3.00	3.00	3.00
	Month 18	Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	1	6.00		6.00	6.00	6.00	6.00	6.00
	Month 24	Tofacitinib 5 mg BID	1	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
Required	Baseline	Tofacitinib 5 mg BID	315	1.87	0.34	1.00	2.00	2.00	2.00	2.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	306	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	79	1.87	0.33	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	76	1.93	0.25	1.00	2.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	259	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	64	1.86	0.35	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	57	1.93	0.26	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	282	1.90	0.30	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	70	1.93	0.26	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	68	1.97	0.17	1.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	251	1.90	0.31	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	265	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	67	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	63	1.98	0.13	1.00	2.00	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	235	1.92	0.27	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	243	1.93	0.25	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	59	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	55	1.98	0.13	1.00	2.00	2.00	2.00	2.00
	Month 24	Tofacitinib 5 mg BID	209	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	218	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	54	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	52	2.00	0.00	2.00	2.00	2.00	2.00	2.00
Aids or devices used days	Baseline	Tofacitinib 5 mg BID	41	109.63	108.88	1.00	14.00	90.00	180.00	540.00
		Tofacitinib 10 mg BID	25	74.08	66.11	3.00	12.00	90.00	90.00	180.00
		Placebo→5 mg	10	105.60	82.17	1.00	20.00	135.00	180.00	180.00
		Placebo→10 mg	4	93.75	67.50	15.00	52.50	90.00	135.00	180.00
	Month 3	Tofacitinib 5 mg BID	23	107.22	102.77	1.00	10.00	90.00	180.00	360.00
		Tofacitinib 10 mg BID	22	73.59	65.16	3.00	8.00	90.00	90.00	186.00
		Placebo→5 mg	9	98.11	55.42	1.00	90.00	90.00	102.00	180.00
		Placebo→10 mg	4	55.50	58.51	3.00	6.00	49.50	105.00	120.00
	Month 6	Tofacitinib 5 mg BID	27	93.44	104.39	1.00	10.00	56.00	180.00	360.00
		Tofacitinib 10 mg BID	17	87.12	61.54	3.00	32.00	90.00	90.00	210.00
		Placebo→5 mg	5	67.60	70.43	4.00	24.00	40.00	90.00	180.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	2	135.00	63.64	90.00	90.00	135.00	180.00	180.00	
		Tofacitinib 5 mg BID	25	85.68	95.83	4.00	14.00	90.00	100.00	450.00	
		Tofacitinib 10 mg BID	14	138.21	110.42	4.00	90.00	90.00	180.00	372.00	
	Month 18	Placebo→5 mg	4	100.50	57.63	42.00	66.00	90.00	135.00	180.00	
		Placebo→10 mg	1	180.00		180.00	180.00	180.00	180.00	180.00	
		Tofacitinib 5 mg BID	19	85.68	83.58	11.00	24.00	90.00	90.00	384.00	
		Tofacitinib 10 mg BID	16	150.94	114.72	7.00	90.00	101.00	180.00	408.00	
		Placebo→5 mg	2	90.00	0.00	90.00	90.00	90.00	90.00	90.00	
		Placebo→10 mg	1	5.00		5.00	5.00	5.00	5.00	5.00	
	Month 24	Tofacitinib 5 mg BID	13	99.15	174.83	4.00	14.00	30.00	90.00	660.00	
		Tofacitinib 10 mg BID	12	106.25	53.67	28.00	87.00	90.00	140.00	204.00	
		Placebo→5 mg	2	18.50	16.26	7.00	7.00	18.50	30.00	30.00	
	Aids or devices RA related	Baseline	Tofacitinib 5 mg BID	42	1.93	1.24	1.00	1.00	2.00	2.00	6.00
			Tofacitinib 10 mg BID	29	1.59	1.02	0.00	1.00	1.00	2.00	5.00
			Placebo→5 mg	10	1.70	0.48	1.00	1.00	2.00	2.00	2.00
Placebo→10 mg			4	1.50	0.58	1.00	1.00	1.50	2.00	2.00	
Month 3		Tofacitinib 5 mg BID	23	1.78	1.04	0.00	1.00	2.00	2.00	4.00	
		Tofacitinib 10 mg BID	24	1.29	0.75	0.00	1.00	1.00	1.50	4.00	
		Placebo→5 mg	10	1.20	0.79	0.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	4	1.25	0.50	1.00	1.00	1.00	1.50	2.00	
Month 6		Tofacitinib 5 mg BID	28	1.36	1.06	0.00	1.00	1.00	2.00	4.00	
		Tofacitinib 10 mg BID	18	1.56	1.20	0.00	1.00	1.00	2.00	5.00	
		Placebo→5 mg	5	1.40	0.89	0.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00	
Month 12		Tofacitinib 5 mg BID	26	1.62	1.06	0.00	1.00	1.50	2.00	5.00	
		Tofacitinib 10 mg BID	16	1.94	1.69	0.00	1.00	1.00	2.50	6.00	
		Placebo→5 mg	4	1.00	0.82	0.00	0.50	1.00	1.50	2.00	
		Placebo→10 mg	1	2.00		2.00	2.00	2.00	2.00	2.00	
Month 18		Tofacitinib 5 mg BID	19	1.32	1.38	0.00	1.00	1.00	2.00	6.00	
		Tofacitinib 10 mg BID	16	2.00	1.97	0.00	1.00	1.00	3.00	6.00	
		Placebo→5 mg	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00	
		Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00	
Month 24		Tofacitinib 5 mg BID	13	1.85	1.99	0.00	1.00	2.00	2.00	8.00	
		Tofacitinib 10 mg BID	13	1.77	1.54	0.00	1.00	1.00	3.00	4.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	3	0.67	0.58	0.00	0.00	1.00	1.00	1.00
Seen any non-medical practitioners in past 3 months	Baseline	Tofacitinib 5 mg BID	315	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	306	1.94	0.23	1.00	2.00	2.00	2.00	2.00
	Month 3	Placebo→5 mg	79	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	76	1.95	0.22	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	259	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	64	1.97	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	57	1.98	0.13	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	282	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	70	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	68	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	251	1.98	0.13	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	265	1.98	0.15	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	67	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	63	1.98	0.13	1.00	2.00	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	235	1.99	0.09	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	243	1.97	0.17	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	59	1.98	0.13	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	55	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 24	Tofacitinib 5 mg BID	209	2.00	0.07	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	218	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	54	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	52	2.00	0.00	2.00	2.00	2.00	2.00	2.00
Non-medical practitioner visits	Baseline	Tofacitinib 5 mg BID	10	12.50	12.29	1.00	3.00	9.00	20.00	40.00
		Tofacitinib 10 mg BID	17	10.88	13.09	1.00	3.00	5.00	20.00	40.00
	Month 3	Placebo→5 mg	3	17.00	11.27	10.00	10.00	11.00	30.00	30.00
		Placebo→10 mg	4	9.25	15.20	1.00	1.00	2.00	17.50	32.00
		Tofacitinib 5 mg BID	4	7.50	11.03	1.00	1.50	2.50	13.50	24.00
		Tofacitinib 10 mg BID	8	3.63	1.51	2.00	2.50	3.00	5.00	6.00
		Placebo→5 mg	2	17.50	10.61	10.00	10.00	17.50	25.00	25.00
		Placebo→10 mg	1	32.00		32.00	32.00	32.00	32.00	32.00
	Month 6	Tofacitinib 5 mg BID	6	15.00	17.34	2.00	4.00	8.00	20.00	48.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	8	6.13	4.55	2.00	2.00	4.50	11.00	12.00
		Placebo→5 mg	4	19.00	9.87	6.00	13.00	20.00	25.00	30.00
	Month 12	Tofacitinib 5 mg BID	4	12.00	5.89	6.00	8.00	11.00	16.00	20.00
		Tofacitinib 10 mg BID	6	9.83	15.03	1.00	2.00	4.00	8.00	40.00
		Placebo→5 mg	4	10.00	7.12	4.00	5.00	8.00	15.00	20.00
		Placebo→10 mg	1	9.00		9.00	9.00	9.00	9.00	9.00
	Month 18	Tofacitinib 5 mg BID	2	9.00	1.41	8.00	8.00	9.00	10.00	10.00
		Tofacitinib 10 mg BID	7	14.57	22.01	3.00	3.00	8.00	10.00	64.00
		Placebo→5 mg	1	5.00		5.00	5.00	5.00	5.00	5.00
	Month 24	Tofacitinib 5 mg BID	1	10.00		10.00	10.00	10.00	10.00	10.00
		Tofacitinib 10 mg BID	9	15.11	22.31	2.00	2.00	8.00	15.00	72.00
Non-medical practitioner RA related	Baseline	Tofacitinib 5 mg BID	11	1.00	0.77	0.00	0.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	18	1.00	0.84	0.00	0.00	1.00	2.00	2.00
		Placebo→5 mg	3	1.67	0.58	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	4	1.50	1.73	0.00	0.50	1.00	2.50	4.00
	Month 3	Tofacitinib 5 mg BID	4	0.50	1.00	0.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	8	0.38	0.52	0.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	2	1.00	0.00	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
	Month 6	Tofacitinib 5 mg BID	6	1.50	1.52	0.00	0.00	1.50	2.00	4.00
		Tofacitinib 10 mg BID	8	0.25	0.46	0.00	0.00	0.00	0.50	1.00
		Placebo→5 mg	5	1.40	0.89	0.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	4	1.25	0.96	0.00	0.50	1.50	2.00	2.00
		Tofacitinib 10 mg BID	6	0.17	0.41	0.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	4	0.75	0.96	0.00	0.00	0.50	1.50	2.00
		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 18	Tofacitinib 5 mg BID	2	1.50	0.71	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 10 mg BID	7	0.43	0.79	0.00	0.00	0.00	1.00	2.00
		Placebo→5 mg	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
	Month 24	Tofacitinib 5 mg BID	1	2.00		2.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	10	0.80	1.32	0.00	0.00	0.00	1.00	4.00
Are you currently	Baseline	Tofacitinib 5 mg BID	314	1.65	0.48	1.00	1.00	2.00	2.00	2.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 3	Tofacitinib 10 mg BID	306	1.60	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	79	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	76	1.58	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	259	1.63	0.48	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	260	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	64	1.64	0.48	1.00	1.00	2.00	2.00	2.00
	Month 6	Placebo→10 mg	57	1.56	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	282	1.65	0.48	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.59	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	70	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	68	1.53	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	251	1.62	0.49	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 10 mg BID	265	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	67	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	63	1.51	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	235	1.63	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	243	1.60	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	59	1.66	0.48	1.00	1.00	2.00	2.00	2.00
	Month 18	Placebo→10 mg	55	1.53	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	209	1.61	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	218	1.61	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	54	1.69	0.47	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	52	1.46	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 5 mg BID	108	8.01	4.05	1.00	6.50	8.00	8.00	40.00
Hours of work per day	Baseline	Tofacitinib 10 mg BID	121	8.22	4.41	1.00	7.00	8.00	8.00	40.00
		Placebo→5 mg	27	6.89	1.99	2.00	6.00	8.00	8.00	9.00
		Placebo→10 mg	32	9.16	6.77	2.00	6.50	8.00	8.00	40.00
		Tofacitinib 5 mg BID	97	7.71	4.83	2.00	6.00	8.00	8.00	50.00
	Month 3	Tofacitinib 10 mg BID	113	8.25	3.60	2.00	7.00	8.00	9.00	40.00
		Placebo→5 mg	23	7.22	2.00	2.00	6.00	8.00	8.00	10.00
		Placebo→10 mg	25	7.60	2.86	1.00	6.00	8.00	8.00	16.00
		Tofacitinib 5 mg BID	98	8.15	4.15	2.00	7.00	8.00	8.00	40.00
	Month 6	Tofacitinib 10 mg BID	117	7.90	1.85	2.00	8.00	8.00	8.00	15.00
		Placebo→5 mg	21	7.14	1.96	3.00	6.00	8.00	8.00	9.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	32	7.72	2.33	1.00	7.50	8.00	8.00	16.00	
		Tofacitinib 5 mg BID	95	7.78	3.81	2.00	7.00	8.00	8.00	40.00	
		Tofacitinib 10 mg BID	114	7.92	1.88	4.00	7.00	8.00	8.00	15.00	
	Month 18	Placebo→5 mg	23	7.48	2.02	3.00	6.00	8.00	9.00	10.00	
		Placebo→10 mg	31	8.03	2.09	5.00	7.00	8.00	8.00	16.00	
		Tofacitinib 5 mg BID	89	7.63	1.94	3.00	7.00	8.00	8.00	14.00	
		Tofacitinib 10 mg BID	97	8.32	4.23	4.00	8.00	8.00	8.00	40.00	
		Placebo→5 mg	20	7.20	1.54	4.00	6.00	8.00	8.00	9.00	
		Placebo→10 mg	26	8.00	2.26	4.00	7.00	8.00	8.00	16.00	
	Month 24	Tofacitinib 5 mg BID	81	7.33	2.13	3.00	6.00	8.00	8.00	14.00	
		Tofacitinib 10 mg BID	85	7.55	1.84	0.00	7.00	8.00	8.00	12.00	
		Placebo→5 mg	17	7.71	1.45	5.00	7.00	8.00	9.00	10.00	
		Placebo→10 mg	28	7.75	2.27	3.00	8.00	8.00	8.00	16.00	
	Days of work per week	Baseline	Tofacitinib 5 mg BID	109	5.01	1.14	1.00	5.00	5.00	6.00	8.00
			Tofacitinib 10 mg BID	121	5.14	0.92	1.00	5.00	5.00	5.00	8.00
Placebo→5 mg			27	5.04	1.13	1.00	5.00	5.00	6.00	7.00	
Month 3		Placebo→10 mg	32	4.84	1.59	1.00	4.50	5.00	5.00	8.00	
		Tofacitinib 5 mg BID	97	5.03	1.03	1.00	5.00	5.00	6.00	7.00	
		Tofacitinib 10 mg BID	113	5.25	0.92	2.00	5.00	5.00	6.00	8.00	
Month 6		Placebo→5 mg	23	5.04	1.15	2.00	5.00	5.00	6.00	7.00	
		Placebo→10 mg	25	4.72	1.28	1.00	5.00	5.00	5.00	7.00	
		Tofacitinib 5 mg BID	98	5.02	1.16	1.00	5.00	5.00	6.00	7.00	
Month 12		Tofacitinib 10 mg BID	117	5.29	0.78	3.00	5.00	5.00	6.00	7.00	
		Placebo→5 mg	21	5.00	1.05	2.00	5.00	5.00	6.00	6.00	
		Placebo→10 mg	32	4.91	1.12	2.00	5.00	5.00	5.00	7.00	
Month 18		Tofacitinib 5 mg BID	94	5.01	1.15	1.00	5.00	5.00	6.00	7.00	
		Tofacitinib 10 mg BID	114	5.20	0.75	2.00	5.00	5.00	6.00	7.00	
		Placebo→5 mg	23	4.65	1.15	2.00	4.00	5.00	5.00	6.00	
Month 24		Placebo→10 mg	31	4.87	1.26	2.00	5.00	5.00	5.00	7.00	
		Tofacitinib 5 mg BID	88	5.00	1.13	1.00	5.00	5.00	6.00	7.00	
		Tofacitinib 10 mg BID	97	5.21	0.79	2.00	5.00	5.00	5.00	8.00	
		Month 18	Placebo→5 mg	20	5.00	0.92	3.00	5.00	5.00	6.00	6.00
			Placebo→10 mg	26	5.35	1.13	2.00	5.00	5.00	6.00	7.00
			Tofacitinib 5 mg BID	81	5.05	1.18	1.00	5.00	5.00	6.00	7.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Feel well enough to work if job were available	Baseline	Tofacitinib 10 mg BID	85	5.07	0.84	0.00	5.00	5.00	5.00	7.00
		Placebo→5 mg	17	4.94	0.97	2.00	5.00	5.00	5.00	6.00
		Placebo→10 mg	28	5.25	1.11	2.00	5.00	5.00	5.50	8.00
	Month 3	Tofacitinib 5 mg BID	182	1.87	0.33	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→5 mg	49	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	40	1.80	0.41	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	147	1.78	0.41	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	140	1.73	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	37	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	31	1.81	0.40	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	175	1.77	0.42	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 10 mg BID	153	1.73	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	44	1.84	0.37	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	34	1.74	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	152	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	142	1.65	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	41	1.80	0.40	1.00	2.00	2.00	2.00	2.00
	Month 12	Placebo→10 mg	29	1.62	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	139	1.73	0.44	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	138	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	36	1.67	0.48	1.00	1.00	2.00	2.00	2.00
	Month 18	Placebo→10 mg	28	1.50	0.51	1.00	1.00	1.50	2.00	2.00
		Tofacitinib 5 mg BID	121	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	127	1.69	0.47	1.00	1.00	2.00	2.00	2.00
	Month 24	Placebo→5 mg	34	1.74	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	22	1.73	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	185	1.37	0.48	1.00	1.00	1.00	2.00	2.00
Tofacitinib 10 mg BID		169	1.37	0.48	1.00	1.00	1.00	2.00	2.00	
Unable to work due to RA	Baseline	Placebo→5 mg	48	1.27	0.45	1.00	1.00	1.00	2.00	2.00
		Placebo→10 mg	40	1.40	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 5 mg BID	148	1.44	0.50	1.00	1.00	1.00	2.00	2.00
	Month 3	Tofacitinib 10 mg BID	139	1.50	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	36	1.36	0.49	1.00	1.00	1.00	2.00	2.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 6	Placebo→10 mg	31	1.42	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 5 mg BID	176	1.47	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	154	1.56	0.50	1.00	1.00	2.00	2.00	2.00	
	Month 12	Placebo→5 mg	45	1.29	0.46	1.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	35	1.43	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 5 mg BID	151	1.50	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	142	1.54	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	41	1.49	0.51	1.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	29	1.66	0.48	1.00	1.00	2.00	2.00	2.00	
	Month 18	Tofacitinib 5 mg BID	139	1.48	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	138	1.58	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	36	1.47	0.51	1.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	27	1.59	0.50	1.00	1.00	2.00	2.00	2.00	
	Month 24	Tofacitinib 5 mg BID	121	1.48	0.50	1.00	1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	127	1.57	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	33	1.52	0.51	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	22	1.50	0.51	1.00	1.00	1.50	2.00	2.00	
	Lost job or retired early due to RA	Baseline	Tofacitinib 5 mg BID	184	1.61	0.49	1.00	1.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	169	1.61	0.49	1.00	1.00	2.00	2.00	2.00
			Placebo→5 mg	47	1.57	0.50	1.00	1.00	2.00	2.00	2.00
			Placebo→10 mg	39	1.79	0.41	1.00	2.00	2.00	2.00	2.00
		Month 3	Tofacitinib 5 mg BID	148	1.64	0.48	1.00	1.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	139	1.63	0.49	1.00	1.00	2.00	2.00	2.00
			Placebo→5 mg	36	1.47	0.51	1.00	1.00	1.00	2.00	2.00
Placebo→10 mg			31	1.68	0.48	1.00	1.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	172	1.69	0.46	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	157	1.63	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	44	1.57	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	34	1.82	0.39	1.00	2.00	2.00	2.00	2.00	
Month 12		Tofacitinib 5 mg BID	152	1.73	0.45	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	144	1.69	0.47	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	41	1.68	0.47	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	29	1.83	0.38	1.00	2.00	2.00	2.00	2.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 18	Tofacitinib 5 mg BID	139	1.73	0.45	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	140	1.64	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	36	1.64	0.49	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	27	1.81	0.40	1.00	2.00	2.00	2.00	2.00	
	Month 24	Tofacitinib 5 mg BID	121	1.70	0.46	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	129	1.64	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	34	1.62	0.49	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	22	1.73	0.46	1.00	1.00	2.00	2.00	2.00	
	Work disabled due to RA	Baseline	Tofacitinib 5 mg BID	186	1.52	0.50	1.00	1.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	168	1.61	0.49	1.00	1.00	2.00	2.00	2.00
			Placebo→5 mg	48	1.44	0.50	1.00	1.00	1.00	2.00	2.00
			Placebo→10 mg	40	1.65	0.48	1.00	1.00	2.00	2.00	2.00
Month 3		Tofacitinib 5 mg BID	150	1.53	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	140	1.64	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	37	1.46	0.51	1.00	1.00	1.00	2.00	2.00	
		Placebo→10 mg	31	1.71	0.46	1.00	1.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	173	1.52	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	153	1.66	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	44	1.52	0.51	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	34	1.65	0.49	1.00	1.00	2.00	2.00	2.00	
Month 12		Tofacitinib 5 mg BID	152	1.61	0.49	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	144	1.67	0.47	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	42	1.57	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	30	1.77	0.43	1.00	2.00	2.00	2.00	2.00	
Month 18		Tofacitinib 5 mg BID	139	1.65	0.48	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	139	1.66	0.47	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	36	1.67	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	27	1.78	0.42	1.00	2.00	2.00	2.00	2.00	
Month 24		Tofacitinib 5 mg BID	121	1.55	0.50	1.00	1.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	126	1.65	0.48	1.00	1.00	2.00	2.00	2.00	
		Placebo→5 mg	34	1.56	0.50	1.00	1.00	2.00	2.00	2.00	
		Placebo→10 mg	22	1.64	0.49	1.00	1.00	2.00	2.00	2.00	
I am retired	Baseline	Tofacitinib 5 mg BID	193	1.51	0.50	1.00	1.00	2.00	2.00	2.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 3	Tofacitinib 10 mg BID	171	1.51	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	50	1.48	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo→10 mg	42	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	150	1.51	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	142	1.42	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	39	1.54	0.51	1.00	1.00	2.00	2.00	2.00
	Month 6	Placebo→10 mg	31	1.74	0.44	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	177	1.50	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	156	1.49	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	48	1.52	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	36	1.61	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	155	1.50	0.50	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 10 mg BID	141	1.43	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	42	1.52	0.51	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	30	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	143	1.49	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	141	1.43	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	38	1.50	0.51	1.00	1.00	1.50	2.00	2.00
	Month 18	Placebo→10 mg	27	1.56	0.51	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	124	1.44	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	129	1.41	0.49	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	35	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	22	1.45	0.51	1.00	1.00	1.00	2.00	2.00
		Sick leave in past 3 months from work due to RA	Baseline	Tofacitinib 5 mg BID	236	1.83	0.38	1.00	2.00	2.00
Tofacitinib 10 mg BID	236			1.81	0.39	1.00	2.00	2.00	2.00	2.00
Placebo→5 mg	63			1.76	0.43	1.00	2.00	2.00	2.00	2.00
Placebo→10 mg	60			1.77	0.43	1.00	2.00	2.00	2.00	2.00
Month 3	Tofacitinib 5 mg BID		175	1.89	0.31	1.00	2.00	2.00	2.00	2.00
	Tofacitinib 10 mg BID		200	1.93	0.26	1.00	2.00	2.00	2.00	2.00
	Placebo→5 mg		47	1.77	0.43	1.00	2.00	2.00	2.00	2.00
	Placebo→10 mg		42	1.88	0.33	1.00	2.00	2.00	2.00	2.00
Month 6	Tofacitinib 5 mg BID		194	1.92	0.27	1.00	2.00	2.00	2.00	2.00
	Tofacitinib 10 mg BID		216	1.95	0.22	1.00	2.00	2.00	2.00	2.00
	Placebo→5 mg		49	1.90	0.31	1.00	2.00	2.00	2.00	2.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	53	1.89	0.32	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	169	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	200	1.93	0.26	1.00	2.00	2.00	2.00	2.00	
	Month 18	Placebo→5 mg	46	1.98	0.15	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	48	1.90	0.31	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	160	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	176	1.94	0.23	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	38	1.97	0.16	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	43	1.93	0.26	1.00	2.00	2.00	2.00	2.00	
	Month 24	Tofacitinib 5 mg BID	138	1.95	0.22	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	153	1.97	0.18	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	31	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	40	1.90	0.30	1.00	2.00	2.00	2.00	2.00	
	Number of days on sick leave due to RA	Baseline	Tofacitinib 5 mg BID	41	13.17	21.61	1.00	3.00	5.00	10.00	90.00
			Tofacitinib 10 mg BID	44	16.84	27.67	1.00	2.50	5.00	11.00	90.00
			Placebo→5 mg	15	19.07	32.55	1.00	1.00	3.00	20.00	90.00
Month 3		Placebo→10 mg	14	11.57	15.80	1.00	3.00	5.50	11.00	60.00	
		Tofacitinib 5 mg BID	19	12.16	20.51	1.00	1.00	5.00	15.00	90.00	
		Tofacitinib 10 mg BID	15	8.20	19.95	1.00	2.00	3.00	5.00	80.00	
		Placebo→5 mg	11	14.00	25.76	1.00	3.00	5.00	10.00	90.00	
Month 6		Placebo→10 mg	5	4.80	3.27	2.00	3.00	3.00	6.00	10.00	
		Tofacitinib 5 mg BID	15	14.93	24.05	1.00	3.00	6.00	14.00	90.00	
		Tofacitinib 10 mg BID	11	14.18	25.86	1.00	1.00	5.00	14.00	90.00	
Month 12		Placebo→5 mg	5	20.20	39.03	2.00	2.00	3.00	4.00	90.00	
		Placebo→10 mg	6	2.33	0.82	1.00	2.00	2.50	3.00	3.00	
		Tofacitinib 5 mg BID	11	32.27	39.24	2.00	2.00	5.00	90.00	92.00	
		Tofacitinib 10 mg BID	15	5.13	4.42	1.00	2.00	3.00	7.00	15.00	
Month 18		Placebo→5 mg	1	1.00		1.00	1.00	1.00	1.00	1.00	
		Placebo→10 mg	5	5.60	4.51	2.00	2.00	5.00	6.00	13.00	
		Tofacitinib 5 mg BID	11	17.09	26.34	1.00	2.00	7.00	21.00	91.00	
		Tofacitinib 10 mg BID	10	11.70	12.63	1.00	3.00	4.00	20.00	35.00	
Month 24		Placebo→5 mg	1	3.00		3.00	3.00	3.00	3.00	3.00	
		Placebo→10 mg	3	31.67	50.52	2.00	2.00	3.00	90.00	90.00	
		Tofacitinib 5 mg BID	7	17.57	32.06	2.00	3.00	6.00	9.00	90.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	5	14.20	25.63	1.00	3.00	3.00	4.00	60.00
		Placebo→10 mg	4	6.75	6.29	1.00	1.50	6.00	12.00	14.00
Performed part time work in past 3 months due to RA	Baseline	Tofacitinib 5 mg BID	235	1.87	0.34	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	236	1.87	0.33	1.00	2.00	2.00	2.00	2.00
	Month 3	Placebo→5 mg	61	1.90	0.30	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	60	1.90	0.30	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	176	1.91	0.29	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	196	1.94	0.24	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	47	1.85	0.36	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	42	1.88	0.33	1.00	2.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	192	1.96	0.20	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	215	1.94	0.23	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	49	1.92	0.28	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	53	1.91	0.30	1.00	2.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	168	1.99	0.11	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	199	1.96	0.18	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	46	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	48	1.94	0.24	1.00	2.00	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	159	1.98	0.14	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	174	1.95	0.21	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	37	1.92	0.28	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	43	2.00	0.00	2.00	2.00	2.00	2.00	2.00
	Month 24	Tofacitinib 5 mg BID	138	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	153	1.96	0.19	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	31	1.94	0.25	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	40	1.95	0.22	1.00	2.00	2.00	2.00	2.00
Number of days performed part time work due to RA	Baseline	Tofacitinib 5 mg BID	30	9.07	12.62	0.00	2.00	4.50	10.00	60.00
		Tofacitinib 10 mg BID	29	12.07	16.50	1.00	2.00	3.00	20.00	70.00
		Placebo→5 mg	6	28.17	34.61	2.00	4.00	12.50	48.00	90.00
		Placebo→10 mg	6	25.67	32.85	4.00	6.00	12.00	30.00	90.00
	Month 3	Tofacitinib 5 mg BID	16	9.44	11.51	1.00	3.00	5.50	11.50	45.00
		Tofacitinib 10 mg BID	12	9.42	13.17	1.00	3.00	4.50	10.50	48.00
		Placebo→5 mg	7	24.00	33.15	2.00	5.00	7.00	50.00	89.00
		Placebo→10 mg	5	4.00	2.45	2.00	2.00	4.00	4.00	8.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 6	Tofacitinib 5 mg BID	8	11.88	14.99	2.00	2.50	4.00	17.50	45.00	
		Tofacitinib 10 mg BID	12	11.33	11.44	0.00	2.00	6.50	22.00	30.00	
		Placebo→5 mg	4	33.00	41.09	1.00	3.00	20.50	63.00	90.00	
		Placebo→10 mg	5	2.80	1.48	1.00	2.00	3.00	3.00	5.00	
	Month 12	Tofacitinib 5 mg BID	3	16.33	17.90	1.00	1.00	12.00	36.00	36.00	
		Tofacitinib 10 mg BID	7	15.57	21.19	1.00	2.00	6.00	25.00	60.00	
		Placebo→10 mg	3	31.67	51.39	1.00	1.00	3.00	91.00	91.00	
	Month 18	Tofacitinib 5 mg BID	2	2.50	2.12	1.00	1.00	2.50	4.00	4.00	
		Tofacitinib 10 mg BID	8	9.00	3.59	5.00	7.00	7.50	11.50	15.00	
		Placebo→5 mg	3	3.33	2.08	1.00	1.00	4.00	5.00	5.00	
	Month 24	Tofacitinib 5 mg BID	4	28.00	41.71	2.00	3.50	10.00	52.50	90.00	
		Tofacitinib 10 mg BID	6	17.50	30.85	1.00	3.00	4.50	12.00	80.00	
		Placebo→5 mg	2	32.50	38.89	5.00	5.00	32.50	60.00	60.00	
		Placebo→10 mg	2	3.00	0.00	3.00	3.00	3.00	3.00	3.00	
	Average hours of missed work per day due to RA	Baseline	Tofacitinib 5 mg BID	30	7.03	9.98	0.00	2.00	4.00	6.00	40.00
			Tofacitinib 10 mg BID	30	5.33	4.47	1.00	3.00	4.00	6.00	20.00
Placebo→5 mg			6	2.00	1.26	0.00	2.00	2.00	2.00	4.00	
Placebo→10 mg			6	6.67	8.50	3.00	3.00	3.00	4.00	24.00	
Month 3		Tofacitinib 5 mg BID	16	9.94	16.85	1.00	2.00	3.00	5.50	64.00	
		Tofacitinib 10 mg BID	12	3.17	2.92	0.00	0.00	4.00	4.00	10.00	
		Placebo→5 mg	7	6.57	8.02	1.00	2.00	3.00	8.00	24.00	
		Placebo→10 mg	5	3.80	1.48	2.00	3.00	4.00	4.00	6.00	
Month 6		Tofacitinib 5 mg BID	8	2.38	1.60	0.00	1.50	2.00	3.50	5.00	
		Tofacitinib 10 mg BID	12	2.50	1.62	0.00	1.50	2.50	4.00	5.00	
		Placebo→5 mg	4	2.50	1.91	0.00	1.00	3.00	4.00	4.00	
		Placebo→10 mg	5	2.80	1.64	0.00	3.00	3.00	4.00	4.00	
Month 12		Tofacitinib 5 mg BID	3	1.33	1.15	0.00	0.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	7	8.71	12.42	0.00	2.00	5.00	8.00	36.00	
		Placebo→10 mg	3	2.67	1.53	1.00	1.00	3.00	4.00	4.00	
Month 18		Tofacitinib 5 mg BID	2	3.50	2.12	2.00	2.00	3.50	5.00	5.00	
		Tofacitinib 10 mg BID	8	7.00	13.48	0.00	1.00	2.00	5.00	40.00	
		Placebo→5 mg	3	2.00	2.00	0.00	0.00	2.00	4.00	4.00	
Month 24		Tofacitinib 5 mg BID	4	24.00	44.00	2.00	2.00	2.00	46.00	90.00	
		Tofacitinib 10 mg BID	6	4.33	3.56	1.00	1.00	3.50	8.00	9.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Placebo→10 mg	2	3.50	0.71	3.00	3.00	3.50	4.00	4.00
Performed paid work in past 3 months while bothered by RA	Baseline	Tofacitinib 5 mg BID	235	1.60	0.49	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	235	1.62	0.49	1.00	1.00	2.00	2.00	2.00
	Month 3	Placebo→5 mg	62	1.66	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	60	1.57	0.50	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 5 mg BID	174	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	197	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	47	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	41	1.66	0.48	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	192	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	216	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	48	1.67	0.48	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	53	1.72	0.45	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	169	1.78	0.42	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	200	1.81	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	46	1.78	0.42	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	48	1.75	0.44	1.00	1.50	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	159	1.79	0.41	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	173	1.79	0.41	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	37	1.73	0.45	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	43	1.84	0.37	1.00	2.00	2.00	2.00	2.00
	Month 24	Tofacitinib 5 mg BID	137	1.72	0.45	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	154	1.83	0.38	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	31	1.74	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	40	1.80	0.41	1.00	2.00	2.00	2.00	2.00
Number of days performed paid work while bothered by RA	Baseline	Tofacitinib 5 mg BID	92	29.13	30.81	1.00	6.00	12.00	56.00	90.00
		Tofacitinib 10 mg BID	88	31.59	30.12	1.00	7.00	20.00	60.00	90.00
		Placebo→5 mg	21	31.71	29.67	1.00	9.00	20.00	48.00	90.00
		Placebo→10 mg	27	32.04	33.59	2.00	5.00	18.00	60.00	90.00
	Month 3	Tofacitinib 5 mg BID	52	20.60	27.99	2.00	5.00	8.50	20.00	90.00
		Tofacitinib 10 mg BID	48	17.42	21.52	2.00	5.00	7.00	20.00	90.00
		Placebo→5 mg	13	44.54	34.15	1.00	15.00	30.00	72.00	90.00
		Placebo→10 mg	14	25.36	31.43	3.00	3.00	10.00	30.00	90.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 6	Tofacitinib 5 mg BID	46	18.87	25.75	2.00	5.00	8.00	20.00	98.00
		Tofacitinib 10 mg BID	52	18.67	19.85	1.00	5.00	10.00	30.00	90.00
		Placebo→5 mg	16	23.69	23.00	2.00	10.00	15.00	36.00	90.00
		Placebo→10 mg	15	14.27	22.93	1.00	3.00	5.00	10.00	78.00
	Month 12	Tofacitinib 5 mg BID	38	20.89	24.78	2.00	4.00	9.50	30.00	90.00
		Tofacitinib 10 mg BID	38	18.58	24.28	1.00	5.00	8.00	20.00	90.00
		Placebo→5 mg	10	23.80	28.35	1.00	3.00	5.50	48.00	75.00
		Placebo→10 mg	12	28.17	35.51	2.00	4.50	10.00	51.00	90.00
	Month 18	Tofacitinib 5 mg BID	33	20.61	28.45	2.00	5.00	8.00	20.00	90.00
		Tofacitinib 10 mg BID	36	18.08	26.13	1.00	3.00	6.50	18.50	90.00
		Placebo→5 mg	10	20.40	30.42	2.00	3.00	4.50	25.00	90.00
		Placebo→10 mg	7	8.43	8.30	2.00	3.00	5.00	10.00	26.00
	Month 24	Tofacitinib 5 mg BID	37	20.41	27.02	1.00	3.00	6.00	30.00	90.00
		Tofacitinib 10 mg BID	25	32.04	34.18	2.00	5.00	14.00	40.00	90.00
		Placebo→5 mg	7	11.00	17.40	2.00	3.00	4.00	10.00	50.00
		Placebo→10 mg	8	15.63	30.32	1.00	2.50	4.50	10.00	90.00
Work performance in past 3 months on days bothered	Baseline	Tofacitinib 5 mg BID	204	5.29	3.09	0.00	3.00	5.00	8.00	10.00
		Tofacitinib 10 mg BID	202	4.88	3.03	0.00	3.00	5.00	7.00	10.00
		Placebo→5 mg	52	4.88	2.90	0.00	3.00	5.00	7.00	10.00
		Placebo→10 mg	52	4.48	3.17	0.00	1.50	5.00	7.00	10.00
	Month 3	Tofacitinib 5 mg BID	151	3.81	3.11	0.00	1.00	3.00	6.00	10.00
		Tofacitinib 10 mg BID	176	3.11	2.67	0.00	1.00	3.00	5.00	10.00
		Placebo→5 mg	42	4.79	3.00	0.00	3.00	4.00	7.00	10.00
		Placebo→10 mg	39	3.97	2.70	0.00	2.00	4.00	7.00	8.00
	Month 6	Tofacitinib 5 mg BID	159	3.70	3.17	0.00	1.00	3.00	6.00	10.00
		Tofacitinib 10 mg BID	185	2.99	2.94	0.00	0.00	2.00	5.00	10.00
		Placebo→5 mg	44	3.93	3.05	0.00	1.00	3.00	6.00	10.00
		Placebo→10 mg	46	3.04	2.82	0.00	0.00	3.00	5.00	10.00
	Month 12	Tofacitinib 5 mg BID	145	3.17	3.13	0.00	0.00	2.00	5.00	10.00
		Tofacitinib 10 mg BID	164	2.65	2.80	0.00	0.00	2.00	4.00	10.00
		Placebo→5 mg	39	2.51	2.54	0.00	0.00	2.00	4.00	10.00
		Placebo→10 mg	44	2.66	2.72	0.00	0.00	2.00	4.50	10.00
	Month 18	Tofacitinib 5 mg BID	130	2.92	3.05	0.00	0.00	2.00	5.00	10.00
		Tofacitinib 10 mg BID	143	2.71	2.71	0.00	0.00	2.00	4.00	10.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max		
	Month 24	Placebo→5 mg	35	2.71	2.73	0.00	1.00	2.00	4.00	10.00		
		Placebo→10 mg	35	2.57	2.60	0.00	0.00	2.00	4.00	9.00		
		Tofacitinib 5 mg BID	116	3.22	3.07	0.00	1.00	2.50	5.00	10.00		
		Tofacitinib 10 mg BID	127	2.64	2.64	0.00	1.00	2.00	4.00	10.00		
		Placebo→5 mg	30	1.97	2.39	0.00	0.00	1.00	3.00	10.00		
			Placebo→10 mg	38	2.18	2.52	0.00	0.00	1.00	5.00	7.00	
	Unable to complete chores in past 3 months due to RA	Baseline	Tofacitinib 5 mg BID	312	1.38	0.48	1.00	1.00	1.00	2.00	2.00	
			Tofacitinib 10 mg BID	302	1.43	0.50	1.00	1.00	1.00	2.00	2.00	
				Placebo→5 mg	78	1.44	0.50	1.00	1.00	1.00	2.00	2.00
				Placebo→10 mg	74	1.43	0.50	1.00	1.00	1.00	2.00	2.00
Month 3		Tofacitinib 5 mg BID	257	1.60	0.49	1.00	1.00	2.00	2.00	2.00		
		Tofacitinib 10 mg BID	256	1.70	0.46	1.00	1.00	2.00	2.00	2.00		
			Placebo→5 mg	64	1.47	0.50	1.00	1.00	1.00	2.00	2.00	
			Placebo→10 mg	57	1.58	0.50	1.00	1.00	2.00	2.00	2.00	
Month 6		Tofacitinib 5 mg BID	280	1.63	0.48	1.00	1.00	2.00	2.00	2.00		
		Tofacitinib 10 mg BID	283	1.80	0.40	1.00	2.00	2.00	2.00	2.00		
			Placebo→5 mg	70	1.54	0.50	1.00	1.00	2.00	2.00	2.00	
			Placebo→10 mg	68	1.62	0.49	1.00	1.00	2.00	2.00	2.00	
Month 12		Tofacitinib 5 mg BID	247	1.66	0.48	1.00	1.00	2.00	2.00	2.00		
		Tofacitinib 10 mg BID	265	1.78	0.42	1.00	2.00	2.00	2.00	2.00		
			Placebo→5 mg	67	1.82	0.39	1.00	2.00	2.00	2.00	2.00	
			Placebo→10 mg	63	1.75	0.44	1.00	1.00	2.00	2.00	2.00	
Month 18		Tofacitinib 5 mg BID	233	1.73	0.45	1.00	1.00	2.00	2.00	2.00		
		Tofacitinib 10 mg BID	242	1.81	0.40	1.00	2.00	2.00	2.00	2.00		
			Placebo→5 mg	59	1.75	0.44	1.00	1.00	2.00	2.00	2.00	
			Placebo→10 mg	55	1.71	0.46	1.00	1.00	2.00	2.00	2.00	
Month 24	Tofacitinib 5 mg BID	210	1.70	0.46	1.00	1.00	2.00	2.00	2.00			
	Tofacitinib 10 mg BID	217	1.76	0.42	1.00	2.00	2.00	2.00	2.00			
		Placebo→5 mg	54	1.69	0.47	1.00	1.00	2.00	2.00	2.00		
		Placebo→10 mg	52	1.83	0.38	1.00	2.00	2.00	2.00	2.00		
Chores carried out	Baseline	Tofacitinib 5 mg BID	315	1.83	0.37	1.00	2.00	2.00	2.00	2.00		

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 3	Tofacitinib 10 mg BID	305	1.85	0.36	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	79	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	76	1.89	0.31	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 5 mg BID	257	1.90	0.30	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	259	1.92	0.27	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	64	1.89	0.31	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	57	1.91	0.29	1.00	2.00	2.00	2.00	2.00	
		Month 6	Tofacitinib 5 mg BID	280	1.89	0.31	1.00	2.00	2.00	2.00	2.00
			Tofacitinib 10 mg BID	284	1.92	0.28	1.00	2.00	2.00	2.00	2.00
			Placebo→5 mg	70	1.89	0.32	1.00	2.00	2.00	2.00	2.00
			Placebo→10 mg	68	1.90	0.31	1.00	2.00	2.00	2.00	2.00
		Month 12	Tofacitinib 5 mg BID	250	1.92	0.27	1.00	2.00	2.00	2.00	2.00
	Tofacitinib 10 mg BID		264	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
	Placebo→5 mg		67	1.94	0.24	1.00	2.00	2.00	2.00	2.00	
	Placebo→10 mg		63	2.00	0.00	2.00	2.00	2.00	2.00	2.00	
	Month 18	Tofacitinib 5 mg BID	235	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	243	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	59	1.97	0.18	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	55	1.96	0.19	1.00	2.00	2.00	2.00	2.00	
	Month 24	Tofacitinib 5 mg BID	210	1.93	0.25	1.00	2.00	2.00	2.00	2.00	
		Tofacitinib 10 mg BID	218	1.92	0.27	1.00	2.00	2.00	2.00	2.00	
		Placebo→5 mg	54	1.94	0.23	1.00	2.00	2.00	2.00	2.00	
		Placebo→10 mg	52	1.98	0.14	1.00	2.00	2.00	2.00	2.00	
	Hours per day chores done by housekeeper	Baseline	Tofacitinib 5 mg BID	51	4.27	2.19	1.00	2.00	4.00	6.00	10.00
Tofacitinib 10 mg BID			44	4.98	2.76	1.00	2.50	4.00	8.00	12.00	
Placebo→5 mg			7	4.00	2.38	1.00	2.00	4.00	6.00	8.00	
Placebo→10 mg			7	4.43	2.23	2.00	2.00	4.00	7.00	7.00	
Month 3		Tofacitinib 5 mg BID	25	4.84	4.59	1.00	3.00	4.00	6.00	24.00	
		Tofacitinib 10 mg BID	21	4.48	2.18	2.00	2.00	4.00	6.00	8.00	
		Placebo→5 mg	7	4.57	2.15	2.00	3.00	4.00	7.00	8.00	
		Placebo→10 mg	5	5.20	3.42	2.00	4.00	4.00	5.00	11.00	
Month 6		Tofacitinib 5 mg BID	30	4.97	3.00	1.00	3.00	4.00	8.00	12.00	
		Tofacitinib 10 mg BID	23	4.87	2.32	1.00	4.00	4.00	8.00	8.00	
		Placebo→5 mg	8	4.13	2.70	1.00	2.00	3.50	6.50	8.00	

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	7	3.57	2.15	2.00	2.00	3.00	4.00	8.00	
		Tofacitinib 5 mg BID	17	4.47	2.27	1.00	3.00	4.00	6.00	8.00	
		Tofacitinib 10 mg BID	17	4.53	1.70	2.00	3.00	4.00	6.00	8.00	
	Month 18	Placebo→5 mg	4	5.25	3.40	1.00	2.50	6.00	8.00	8.00	
		Tofacitinib 5 mg BID	16	5.25	2.49	1.00	3.00	5.00	7.50	10.00	
		Tofacitinib 10 mg BID	16	5.69	3.40	1.00	3.50	4.50	8.00	15.00	
	Month 24	Placebo→5 mg	2	8.00	0.00	8.00	8.00	8.00	8.00	8.00	
		Placebo→10 mg	2	4.00	1.41	3.00	3.00	4.00	5.00	5.00	
		Tofacitinib 5 mg BID	14	5.00	2.22	1.00	4.00	5.00	6.00	8.00	
		Tofacitinib 10 mg BID	17	4.53	3.28	1.00	2.00	4.00	8.00	12.00	
		Placebo→5 mg	3	7.00	1.73	5.00	5.00	8.00	8.00	8.00	
			Placebo→10 mg	1	3.00		3.00	3.00	3.00	3.00	3.00
	Number of days chores done by housekeeper	Baseline	Tofacitinib 5 mg BID	50	19.06	23.91	1.00	4.00	10.00	24.00	90.00
			Tofacitinib 10 mg BID	44	20.89	33.69	1.00	3.00	7.00	26.00	180.00
			Placebo→5 mg	7	18.86	19.36	2.00	4.00	10.00	45.00	48.00
		Month 3	Placebo→10 mg	8	17.00	19.41	2.00	5.00	11.00	21.00	60.00
Tofacitinib 5 mg BID			25	17.00	20.88	1.00	3.00	7.00	30.00	90.00	
Tofacitinib 10 mg BID			21	6.05	5.65	1.00	2.00	3.00	9.00	24.00	
Month 6		Placebo→5 mg	7	19.29	31.92	1.00	2.00	8.00	20.00	90.00	
		Placebo→10 mg	5	25.20	36.89	2.00	4.00	10.00	20.00	90.00	
		Tofacitinib 5 mg BID	30	15.90	22.43	1.00	4.00	8.50	15.00	90.00	
Month 12		Tofacitinib 10 mg BID	24	18.08	26.29	1.00	3.00	6.00	24.50	90.00	
		Placebo→5 mg	8	17.13	29.90	1.00	2.00	7.50	13.50	90.00	
		Placebo→10 mg	7	28.86	33.96	3.00	4.00	10.00	60.00	90.00	
Month 18		Tofacitinib 5 mg BID	18	14.06	20.23	1.00	4.00	8.50	13.00	90.00	
		Tofacitinib 10 mg BID	18	10.11	11.20	1.00	4.00	6.00	10.00	40.00	
		Placebo→5 mg	4	24.50	43.68	1.00	2.00	3.50	47.00	90.00	
Month 24		Tofacitinib 5 mg BID	16	21.44	28.50	1.00	4.00	9.00	25.00	90.00	
		Tofacitinib 10 mg BID	16	15.25	21.74	3.00	4.00	6.50	18.00	90.00	
		Placebo→5 mg	2	4.50	2.12	3.00	3.00	4.50	6.00	6.00	
		Month 24	Placebo→10 mg	2	8.00	9.90	1.00	1.00	8.00	15.00	15.00
			Tofacitinib 5 mg BID	14	21.79	25.17	2.00	5.00	17.00	24.00	90.00
			Tofacitinib 10 mg BID	17	19.24	28.46	1.00	3.00	4.00	12.00	90.00
			Placebo→5 mg	3	2.67	0.58	2.00	2.00	3.00	3.00	3.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
Chores carried out by family/friends due to RA	Baseline	Tofacitinib 5 mg BID	315	1.49	0.50	1.00	1.00	1.00	2.00	2.00
		Tofacitinib 10 mg BID	305	1.50	0.50	1.00	1.00	1.00	2.00	2.00
		Placebo→5 mg	79	1.51	0.50	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	76	1.55	0.50	1.00	1.00	2.00	2.00	2.00
	Month 3	Tofacitinib 5 mg BID	257	1.67	0.47	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	259	1.73	0.44	1.00	1.00	2.00	2.00	2.00
		Placebo→5 mg	64	1.50	0.50	1.00	1.00	1.50	2.00	2.00
		Placebo→10 mg	57	1.56	0.50	1.00	1.00	2.00	2.00	2.00
	Month 6	Tofacitinib 5 mg BID	280	1.70	0.46	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	284	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	70	1.63	0.49	1.00	1.00	2.00	2.00	2.00
		Placebo→10 mg	68	1.71	0.46	1.00	1.00	2.00	2.00	2.00
	Month 12	Tofacitinib 5 mg BID	250	1.75	0.44	1.00	1.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	264	1.79	0.41	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	67	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	63	1.79	0.41	1.00	2.00	2.00	2.00	2.00
	Month 18	Tofacitinib 5 mg BID	235	1.76	0.43	1.00	2.00	2.00	2.00	2.00
		Tofacitinib 10 mg BID	243	1.82	0.39	1.00	2.00	2.00	2.00	2.00
		Placebo→5 mg	59	1.78	0.42	1.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	55	1.78	0.42	1.00	2.00	2.00	2.00	2.00
Month 24	Tofacitinib 5 mg BID	210	1.77	0.42	1.00	2.00	2.00	2.00	2.00	
	Tofacitinib 10 mg BID	218	1.77	0.42	1.00	2.00	2.00	2.00	2.00	
	Placebo→5 mg	54	1.80	0.41	1.00	2.00	2.00	2.00	2.00	
	Placebo→10 mg	52	1.87	0.34	1.00	2.00	2.00	2.00	2.00	
Hours per day chores done by family/friends	Baseline	Tofacitinib 5 mg BID	158	3.95	4.33	0.00	2.00	3.00	4.00	24.00
		Tofacitinib 10 mg BID	152	3.66	3.87	1.00	2.00	3.00	4.00	30.00
		Placebo→5 mg	38	4.24	5.39	1.00	2.00	3.00	4.00	24.00
		Placebo→10 mg	33	2.64	1.69	1.00	1.00	2.00	4.00	8.00
	Month 3	Tofacitinib 5 mg BID	83	4.31	9.29	1.00	1.00	2.00	4.00	81.00
		Tofacitinib 10 mg BID	70	3.64	4.73	0.00	1.00	2.00	4.00	35.00
		Placebo→5 mg	31	4.77	5.66	1.00	2.00	3.00	5.00	24.00
		Placebo→10 mg	25	3.12	1.94	1.00	2.00	2.00	5.00	8.00
	Month 6	Tofacitinib 5 mg BID	82	3.15	2.40	1.00	2.00	2.00	4.00	12.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	67	3.25	4.09	1.00	1.00	2.00	4.00	24.00
		Placebo→5 mg	25	3.08	2.00	1.00	2.00	2.00	4.00	8.00
		Placebo→10 mg	20	3.35	2.87	1.00	2.00	2.00	4.00	12.00
	Month 12	Tofacitinib 5 mg BID	62	3.31	2.36	1.00	2.00	3.00	4.00	12.00
		Tofacitinib 10 mg BID	56	3.20	2.16	1.00	2.00	2.50	4.00	10.00
		Placebo→5 mg	16	3.75	2.38	2.00	2.00	3.00	4.00	10.00
		Placebo→10 mg	13	2.31	0.95	1.00	2.00	2.00	3.00	4.00
	Month 18	Tofacitinib 5 mg BID	55	2.84	1.99	1.00	1.00	2.00	4.00	8.00
		Tofacitinib 10 mg BID	44	2.32	1.38	1.00	1.00	2.00	3.00	8.00
		Placebo→5 mg	13	4.31	2.84	1.00	2.00	4.00	5.00	10.00
		Placebo→10 mg	12	2.83	2.17	1.00	1.00	2.00	4.00	8.00
	Month 24	Tofacitinib 5 mg BID	48	3.44	3.59	1.00	2.00	2.50	4.00	24.00
		Tofacitinib 10 mg BID	50	2.94	1.72	1.00	2.00	3.00	4.00	8.00
		Placebo→5 mg	11	3.73	2.37	1.00	2.00	3.00	4.00	8.00
		Placebo→10 mg	7	2.43	1.51	1.00	1.00	2.00	4.00	5.00
Number of days chores done by family/friends	Baseline	Tofacitinib 5 mg BID	158	36.28	34.40	1.00	7.00	18.50	70.00	90.00
		Tofacitinib 10 mg BID	152	30.39	34.00	0.00	5.00	15.00	45.00	180.00
		Placebo→5 mg	39	46.38	38.33	2.00	10.00	30.00	90.00	90.00
		Placebo→10 mg	34	26.47	27.59	2.00	7.00	16.50	30.00	90.00
	Month 3	Tofacitinib 5 mg BID	84	31.37	34.32	1.00	5.00	10.00	60.00	90.00
		Tofacitinib 10 mg BID	70	21.46	29.48	1.00	3.00	10.00	20.00	90.00
		Placebo→5 mg	32	35.94	37.89	1.00	3.00	15.00	90.00	90.00
		Placebo→10 mg	25	16.76	23.47	2.00	4.00	10.00	20.00	90.00
	Month 6	Tofacitinib 5 mg BID	84	29.67	33.34	1.00	5.00	10.00	55.00	90.00
		Tofacitinib 10 mg BID	66	29.65	33.02	1.00	4.00	10.00	50.00	90.00
		Placebo→5 mg	25	37.80	38.52	2.00	5.00	15.00	90.00	90.00
		Placebo→10 mg	20	20.45	30.59	1.00	3.00	7.00	20.00	90.00
	Month 12	Tofacitinib 5 mg BID	62	30.15	33.03	1.00	5.00	13.50	43.00	90.00
		Tofacitinib 10 mg BID	56	23.77	31.80	1.00	4.50	7.50	20.50	91.00
		Placebo→5 mg	16	38.38	39.32	1.00	5.50	13.50	90.00	90.00
		Placebo→10 mg	13	16.77	24.59	1.00	3.00	5.00	20.00	90.00
	Month 18	Tofacitinib 5 mg BID	55	27.95	30.25	0.00	5.00	15.00	36.00	90.00
		Tofacitinib 10 mg BID	44	29.23	34.34	2.00	5.00	12.00	30.00	90.00
		Placebo→5 mg	13	32.62	35.08	1.00	6.00	20.00	40.00	90.00

Table 165. Descriptive Statistics of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 24	Placebo→10 mg	12	17.75	24.06	1.00	5.00	12.00	17.50	90.00
		Tofacitinib 5 mg BID	48	35.94	36.30	1.00	5.50	20.00	82.50	90.00
		Tofacitinib 10 mg BID	50	24.68	29.35	1.00	5.00	11.00	30.00	90.00
		Placebo→5 mg	11	29.00	33.75	2.00	4.00	12.00	50.00	90.00
		Placebo→10 mg	7	23.00	30.06	3.00	8.00	15.00	20.00	90.00

Tofacitinib 5mg BID or tofacitinib 10mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5mg BID or placebo→10mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5mg BID or tofacitinib 10 mg BID.

BID = twice daily; ER = emergency room; Max = maximum Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; RA = rheumatoid arthritis; RA-HCRU = RA Healthcare Resource Utilization Questionnaire; St Dev = standard deviation.

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Seen any doctor/healthcare professional in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.18	0.52	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	256	0.17	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo	120	0.14	0.47	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	280	0.07	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.06	0.48	-1.00	0.00	0.00	0.00	1.00
		Placebo	60	0.12	0.52	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	39	0.18	0.45	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	37	0.14	0.63	-1.00	0.00	0.00	1.00	1.00
Total visits to doctor/healthcare professional in past 3 months	Month 3	Tofacitinib 5 mg BID	166	-1.22	4.36	-29.00	-2.00	0.00	1.00	8.00
		Tofacitinib 10 mg BID	164	-1.34	5.78	-50.00	-2.00	0.00	1.00	17.00
		Placebo	83	-1.34	4.03	-27.00	-2.00	-1.00	1.00	5.00
	Month 6	Tofacitinib 5 mg BID	200	-0.97	4.57	-31.00	-2.00	-1.00	1.00	18.00
		Tofacitinib 10 mg BID	197	-1.64	5.62	-56.00	-2.00	-1.00	0.00	10.00
		Placebo	38	-0.11	2.91	-6.00	-2.00	-1.00	2.00	9.00
		Placebo→5 mg	30	-1.93	5.09	-22.00	-4.00	-1.00	1.00	6.00
Placebo→10 mg	20	-2.60	5.94	-25.00	-2.50	-1.50	0.50	3.00		
RA related	Month 3	Tofacitinib 5 mg BID	164	-0.27	0.95	-4.00	-1.00	0.00	0.00	3.00
		Tofacitinib 10 mg BID	163	-0.40	0.88	-5.00	-1.00	0.00	0.00	2.00
		Placebo	83	-0.35	0.86	-3.00	-1.00	0.00	0.00	3.00
	Month 6	Tofacitinib 5 mg BID	197	-0.26	0.78	-3.00	-1.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	196	-0.40	0.90	-5.00	-1.00	0.00	0.00	1.00
		Placebo	37	-0.32	0.82	-3.00	-1.00	0.00	0.00	1.00
		Placebo→5 mg	29	-0.38	0.78	-2.00	-1.00	0.00	0.00	1.00
		Placebo→10 mg	20	-0.15	0.49	-1.00	0.00	0.00	0.00	1.00
Treated in a hospital emergency room in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.03	0.33	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	-0.01	0.26	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.04	0.33	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.01	0.34	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	-0.00	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	0.02	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.08	0.35	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	37	-0.03	0.16	-1.00	0.00	0.00	0.00	0.00
Number of visits to hospital ER in	Month 3	Tofacitinib 5 mg BID	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Tofacitinib 10 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
past 3 months	Month 6	Placebo	0								
		Tofacitinib 5 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00	
		Tofacitinib 10 mg BID	2	-0.50	0.71	-1.00	-1.00	-0.50	0.00	0.00	
		Placebo	0								
		Placebo→5 mg	0								
		Placebo→10 mg	0								
Admitted for overnight stay	Month 3	Tofacitinib 5 mg BID	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00	
		Tofacitinib 10 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo	0								
	Month 6	Tofacitinib 5 mg BID	2	-2.00	0.00	-2.00	-2.00	-2.00	-2.00	-2.00	
		Tofacitinib 10 mg BID	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo	0								
		Placebo→5 mg	0								
		Placebo→10 mg	0								
		Placebo	0								
	ER visit RA related	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	3	0.67	1.15	0.00	0.00	0.00	2.00	2.00
			Placebo	0							
Month 6		Tofacitinib 5 mg BID	2	-1.50	0.71	-2.00	-2.00	-1.50	-1.00	-1.00	
		Tofacitinib 10 mg BID	2	-1.00	4.24	-4.00	-4.00	-1.00	2.00	2.00	
		Placebo	0								
		Placebo→5 mg	0								
		Placebo→10 mg	0								
		Placebo	0								
Hospitalized in past 3 months		Month 3	Tofacitinib 5 mg BID	258	0.02	0.30	-1.00	0.00	0.00	0.00	1.00
			Tofacitinib 10 mg BID	257	0.04	0.25	-1.00	0.00	0.00	0.00	1.00
			Placebo	121	0.02	0.18	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.05	0.26	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	281	0.05	0.26	-1.00	0.00	0.00	0.00	1.00	
		Placebo	61	-0.03	0.31	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	40	0.03	0.16	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	37	0.03	0.16	0.00	0.00	0.00	0.00	1.00	
		Placebo	0								
	Number of visits hospitalized in past 3 months	Month 3	Tofacitinib 5 mg BID	0							
			Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
			Placebo	0							

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							
		Placebo	0							
Hospitalized length of stay	Month 3	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1							
		Placebo	0	-13.00		-13.00	-13.00	-13.00	-13.00	-13.00
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							
		Placebo	0							
Hospitalized RA related	Month 3	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo	0							
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							
		Placebo	0							
Had any outpatient surgeries in past 3 months	Month 3	Tofacitinib 5 mg BID	258	-0.00	0.22	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	256	0.02	0.22	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.02	0.20	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	-0.02	0.26	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.03	0.21	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	-0.02	0.29	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	-0.05	0.22	-1.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	37	0.03	0.16	0.00	0.00	0.00	0.00	1.00
Number of outpatient surgeries in past 3 months	Month 3	Tofacitinib 5 mg BID	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo	0							
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo	0							
Outpatient surgery RA related	Month 3	Tofacitinib 5 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo	0							
Month 6	Tofacitinib 5 mg BID	0								

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo	0							
		Placebo→5 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
Had any non-study diagnostic tests in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.05	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.00	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.04	0.42	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	280	-0.03	0.52	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.02	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	-0.05	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.05	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	37	-0.03	0.50	-1.00	0.00	0.00	0.00	1.00
Number of non-study diagnostic tests	Month 3	Tofacitinib 5 mg BID	10	-0.50	1.35	-3.00	-1.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	13	-0.69	1.70	-4.00	-1.00	0.00	0.00	2.00
		Placebo	5	-0.60	0.89	-2.00	-1.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	17	0.94	3.27	-3.00	-1.00	0.00	1.00	11.00
		Tofacitinib 10 mg BID	11	-0.18	1.83	-3.00	-1.00	0.00	2.00	2.00
		Placebo	1	-3.00		-3.00	-3.00	-3.00	-3.00	-3.00
		Placebo→5 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
		Placebo→10 mg	0							
Diagnostic tests RA related	Month 3	Tofacitinib 5 mg BID	12	-0.67	1.23	-3.00	-1.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	13	-1.08	1.89	-5.00	-1.00	0.00	0.00	1.00
		Placebo	6	-0.50	0.84	-2.00	-1.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	17	0.00	1.37	-3.00	0.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	12	-1.00	1.95	-5.00	-2.00	-1.00	0.00	3.00
		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
		Placebo→10 mg	0							
Subject in a nursing home in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.00	0.06	0.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.00	0.11	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.02	0.13	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	-0.01	0.08	-1.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	281	0.01	0.10	0.00	0.00	0.00	0.00	1.00
		Placebo	61	0.03	0.18	0.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.00	0.00	0.00	0.00	0.00	0.00	0.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→10 mg	37	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Number of days in nursing home in past 3 months	Month 3	Tofacitinib 10 mg BID	0							
	Month 6	Tofacitinib 5 mg BID	1	13.00		13.00	13.00	13.00	13.00	13.00
Used home healthcare services in past 3 months	Month 3	Tofacitinib 5 mg BID	256	0.01	0.14	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.00	0.06	0.00	0.00	0.00	0.00	1.00
		Placebo	121	0.01	0.09	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	280	0.01	0.13	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.00	0.10	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	-0.02	0.13	-1.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	40	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	37	0.03	0.16	0.00	0.00	0.00	0.00	1.00
Home healthcare services hours per day	Month 3	Tofacitinib 5 mg BID	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	3	0.67	2.08	-1.00	-1.00	0.00	3.00	3.00
		Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
Home healthcare services RA related	Month 3	Tofacitinib 5 mg BID	4	-0.25	0.50	-1.00	-0.50	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	4	0.00	0.82	-1.00	-0.50	0.00	0.50	1.00
		Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
		Placebo	0							
Required aids/devices for daily functioning in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.03	0.27	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.00	0.24	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.00	0.26	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.03	0.35	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	0.03	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	0.03	0.18	0.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.05	0.32	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	37	0.05	0.23	0.00	0.00	0.00	0.00	1.00
Aids or devices used days	Month 3	Tofacitinib 5 mg BID	17	-5.41	105.39	-200.00	-60.00	0.00	7.00	180.00
		Tofacitinib 10 mg BID	14	-7.07	71.74	-90.00	-78.00	-3.00	8.00	168.00
		Placebo	8	-47.63	58.05	-90.00	-90.00	-84.00	0.00	57.00
	Month 6	Tofacitinib 5 mg BID	14	18.07	102.87	-140.00	-23.00	2.50	75.00	231.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	13	4.85	88.64	-136.00	-35.00	0.00	30.00	192.00
		Placebo	2	20.00	98.99	-50.00	-50.00	20.00	90.00	90.00
		Placebo→5 mg	3	-82.00	78.31	-156.00	-156.00	-90.00	0.00	0.00
		Placebo→10 mg	1	-90.00		-90.00	-90.00	-90.00	-90.00	-90.00
Aids or devices RA related	Month 3	Tofacitinib 5 mg BID	18	-0.22	1.22	-3.00	-1.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	16	-0.44	1.15	-4.00	-1.00	0.00	0.00	1.00
		Placebo	8	-0.75	1.04	-2.00	-1.50	-1.00	0.00	1.00
		Placebo	1	-90.00		-90.00	-90.00	-90.00	-90.00	-90.00
	Month 6	Tofacitinib 5 mg BID	15	-0.20	1.37	-4.00	-1.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	13	-0.62	1.12	-4.00	-1.00	0.00	0.00	0.00
		Placebo	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
		Placebo	3	-1.00	1.00	-2.00	-2.00	-1.00	0.00	0.00
		Placebo→10 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
Seen any non-medical practitioners in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.00	0.19	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.02	0.23	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.02	0.18	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.01	0.20	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	0.03	0.21	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	0.00	0.18	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	37	0.03	0.16	0.00	0.00	0.00	0.00	1.00
Non-medical practitioner visits	Month 3	Tofacitinib 5 mg BID	1	12.00		12.00	12.00	12.00	12.00	12.00
		Tofacitinib 10 mg BID	4	-8.50	17.67	-35.00	-17.50	0.00	0.50	1.00
		Placebo	2	-2.50	3.54	-5.00	-5.00	-2.50	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	2	16.00	11.31	8.00	8.00	16.00	24.00	24.00
		Tofacitinib 10 mg BID	5	0.00	5.39	-8.00	-1.00	1.00	1.00	7.00
		Placebo	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	2	2.50	10.61	-5.00	-5.00	2.50	10.00	10.00
Non-medical practitioner RA related	Month 3	Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	4	-0.25	0.96	-1.00	-1.00	-0.50	0.50	1.00
		Placebo	2	-2.00	2.83	-4.00	-4.00	-2.00	0.00	0.00
	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	5	-0.20	0.45	-1.00	0.00	0.00	0.00	0.00
		Placebo	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	2	-1.00	1.41	-2.00	-2.00	-1.00	0.00	0.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Are you currently employed	Month 3	Tofacitinib 5 mg BID	257	-0.02	0.19	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	-0.01	0.26	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.01	0.24	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	280	0.01	0.27	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	-0.01	0.28	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	0.02	0.22	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.08	0.27	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	37	-0.05	0.40	-1.00	0.00	0.00	0.00	1.00
Hours of work per day	Month 3	Tofacitinib 5 mg BID	87	-0.13	6.05	-31.00	0.00	0.00	0.00	41.00
		Tofacitinib 10 mg BID	101	-0.08	2.78	-25.00	0.00	0.00	0.00	8.00
		Placebo	45	-0.53	4.86	-32.00	0.00	0.00	0.00	3.00
	Month 6	Tofacitinib 5 mg BID	86	0.17	5.34	-30.00	0.00	0.00	0.00	36.00
		Tofacitinib 10 mg BID	103	-0.59	4.44	-32.00	0.00	0.00	0.00	5.00
		Placebo	17	-0.18	0.95	-3.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	14	0.21	0.58	0.00	0.00	0.00	0.00	2.00
		Placebo→10 mg	17	-1.76	7.85	-32.00	0.00	0.00	0.00	3.00
Days of work per week	Month 3	Tofacitinib 5 mg BID	88	0.09	0.75	-2.00	0.00	0.00	0.00	3.00
		Tofacitinib 10 mg BID	101	0.16	0.76	-4.00	0.00	0.00	0.00	3.00
		Placebo	45	0.02	0.94	-3.00	0.00	0.00	0.00	5.00
	Month 6	Tofacitinib 5 mg BID	87	0.11	0.67	-1.00	0.00	0.00	0.00	3.00
		Tofacitinib 10 mg BID	103	0.09	0.72	-3.00	0.00	0.00	0.00	2.00
		Placebo	17	0.47	1.28	0.00	0.00	0.00	0.00	5.00
		Placebo→5 mg	14	-0.14	0.53	-2.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	17	0.24	1.75	-3.00	0.00	0.00	0.00	6.00
Feel well enough to work if job were available	Month 3	Tofacitinib 5 mg BID	130	-0.08	0.34	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	116	-0.09	0.44	-1.00	0.00	0.00	0.00	1.00
		Placebo	57	-0.02	0.30	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	145	-0.09	0.41	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	130	-0.15	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo	32	-0.03	0.47	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	20	-0.05	0.22	-1.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	12	0.00	0.60	-1.00	0.00	0.00	0.00	1.00
Unable to work due to RA	Month 3	Tofacitinib 5 mg BID	133	0.05	0.44	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	119	0.14	0.53	-1.00	0.00	0.00	0.00	1.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 6	Placebo	58	0.05	0.51	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	147	0.09	0.50	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	133	0.17	0.54	-1.00	0.00	0.00	0.00	1.00
		Placebo	36	0.08	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	19	-0.11	0.46	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	12	0.00	0.60	-1.00	0.00	0.00	0.00	1.00
Lost job or retired early due to RA	Month 3	Tofacitinib 5 mg BID	133	0.04	0.45	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	117	0.06	0.46	-1.00	0.00	0.00	0.00	1.00
		Placebo	57	-0.07	0.42	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	144	0.06	0.46	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	134	0.01	0.45	-1.00	0.00	0.00	0.00	1.00
		Placebo	32	-0.06	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	20	0.10	0.31	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	12	-0.08	0.29	-1.00	0.00	0.00	0.00	0.00
Work disabled due to RA	Month 3	Tofacitinib 5 mg BID	136	0.01	0.42	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	119	0.03	0.42	-1.00	0.00	0.00	0.00	1.00
		Placebo	59	0.00	0.45	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	146	-0.02	0.43	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	132	0.06	0.44	-1.00	0.00	0.00	0.00	1.00
		Placebo	34	0.09	0.51	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	19	-0.11	0.57	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	12	-0.17	0.58	-1.00	-0.50	0.00	0.00	1.00
I am retired	Month 3	Tofacitinib 5 mg BID	139	-0.03	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	125	-0.02	0.36	-1.00	0.00	0.00	0.00	1.00
		Placebo	63	0.11	0.32	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	153	-0.05	0.33	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	138	-0.04	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo	36	0.06	0.41	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	22	0.05	0.21	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	15	0.07	0.26	0.00	0.00	0.00	0.00	1.00
		Sick leave in past 3 months from work due to RA	Month 3	Tofacitinib 5 mg BID	166	0.07	0.40	-1.00	0.00	0.00
Tofacitinib 10 mg BID	187			0.11	0.39	-1.00	0.00	0.00	0.00	1.00
Placebo	87			0.06	0.44	-1.00	0.00	0.00	0.00	1.00
Month 6	Tofacitinib 5 mg BID		183	0.11	0.38	-1.00	0.00	0.00	0.00	1.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	201	0.15	0.41	-1.00	0.00	0.00	0.00	1.00
		Placebo	35	0.09	0.37	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	31	0.19	0.40	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	30	0.13	0.43	-1.00	0.00	0.00	0.00	1.00
Number of days on sick leave due to RA	Month 3	Tofacitinib 5 mg BID	11	3.00	5.29	-3.00	-1.00	1.00	8.00	13.00
		Tofacitinib 10 mg BID	10	-6.00	11.19	-29.00	-10.00	-0.50	1.00	3.00
		Placebo	10	-0.50	2.17	-4.00	-1.00	0.00	1.00	3.00
		Placebo	10	4.60	13.28	-3.00	0.00	0.50	3.00	42.00
	Month 6	Tofacitinib 5 mg BID	6	-20.67	30.61	-80.00	-21.00	-11.00	-1.00	0.00
		Tofacitinib 10 mg BID	3	-1.67	2.08	-4.00	-4.00	-1.00	0.00	0.00
		Placebo	3	0.00	1.00	-1.00	-1.00	0.00	1.00	1.00
		Placebo	2	-0.50	2.12	-2.00	-2.00	-0.50	1.00	1.00
Performed part time work in past 3 months due to RA	Month 3	Tofacitinib 5 mg BID	165	0.05	0.37	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	185	0.09	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo	87	-0.02	0.26	-1.00	0.00	0.00	0.00	1.00
		Placebo	180	0.11	0.39	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	201	0.07	0.37	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	35	0.06	0.24	0.00	0.00	0.00	0.00	1.00
		Placebo	30	0.00	0.26	-1.00	0.00	0.00	0.00	1.00
		Placebo	30	0.03	0.41	-1.00	0.00	0.00	0.00	1.00
Number of days performed part time due to RA	Month 3	Tofacitinib 5 mg BID	9	2.33	11.47	-20.00	-1.00	0.00	7.00	23.00
		Tofacitinib 10 mg BID	4	-20.00	16.51	-40.00	-31.50	-20.00	-8.50	0.00
		Placebo	7	-2.29	42.11	-82.00	-8.00	-5.00	41.00	46.00
		Placebo	3	-14.33	36.35	-55.00	-55.00	-3.00	15.00	15.00
	Month 6	Tofacitinib 5 mg BID	5	-7.80	13.03	-27.00	-15.00	-2.00	0.00	5.00
		Tofacitinib 10 mg BID	3	-16.33	23.44	-43.00	-43.00	-7.00	1.00	1.00
		Placebo	2	16.00	98.99	-54.00	-54.00	16.00	86.00	86.00
		Placebo	0							
Average hours of missed work per day due to RA	Month 3	Tofacitinib 5 mg BID	9	1.67	8.99	-8.00	-3.00	0.00	2.00	24.00
		Tofacitinib 10 mg BID	4	0.00	3.74	-4.00	-2.50	-0.50	2.50	5.00
		Placebo	7	3.71	8.20	-1.00	-1.00	1.00	3.00	22.00
		Placebo	3	1.67	2.08	0.00	0.00	1.00	4.00	4.00
	Month 6	Tofacitinib 5 mg BID	5	-2.80	1.10	-4.00	-3.00	-3.00	-3.00	-1.00
		Tofacitinib 10 mg BID	3	-1.67	1.53	-3.00	-3.00	-2.00	0.00	0.00
		Placebo								
		Placebo								

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	0							
Performed paid work in past 3 months while bothered by RA	Month 3	Tofacitinib 5 mg BID	165	0.18	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	184	0.16	0.44	-1.00	0.00	0.00	0.00	1.00
	Month 6	Placebo	86	0.12	0.45	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	180	0.22	0.52	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	200	0.16	0.48	-1.00	0.00	0.00	0.00	1.00
		Placebo	36	0.08	0.37	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	30	0.03	0.32	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	30	0.30	0.65	-1.00	0.00	0.00	1.00	1.00
Number of days performed paid work while bothered by RA	Month 3	Tofacitinib 5 mg BID	44	-13.20	34.68	-85.00	-23.50	-1.50	0.50	84.00
		Tofacitinib 10 mg BID	41	-20.12	36.37	-87.00	-46.00	-10.00	1.00	58.00
		Placebo	23	8.61	33.36	-80.00	-7.00	0.00	15.00	88.00
	Month 6	Tofacitinib 5 mg BID	35	-14.97	36.96	-84.00	-35.00	-3.00	0.00	87.00
		Tofacitinib 10 mg BID	39	-28.13	34.15	-85.00	-55.00	-22.00	0.00	45.00
		Placebo	12	-15.92	28.52	-87.00	-25.00	-9.50	1.00	20.00
		Placebo→5 mg	9	-12.11	24.59	-54.00	-18.00	-10.00	0.00	25.00
		Placebo→10 mg	4	-10.00	7.48	-18.00	-15.00	-11.00	-5.00	0.00
Work performance in past 3 months on days bothered	Month 3	Tofacitinib 5 mg BID	144	-1.47	3.03	-9.00	-3.00	-1.00	0.00	10.00
		Tofacitinib 10 mg BID	154	-1.73	2.72	-10.00	-3.00	-1.00	0.00	6.00
		Placebo	74	-0.43	2.65	-9.00	-1.00	0.00	1.00	5.00
	Month 6	Tofacitinib 5 mg BID	149	-1.50	3.49	-10.00	-4.00	-1.00	0.00	10.00
		Tofacitinib 10 mg BID	162	-1.77	3.11	-10.00	-4.00	-1.00	0.00	8.00
		Placebo	29	-1.38	2.65	-9.00	-3.00	-1.00	0.00	5.00
		Placebo→5 mg	29	-0.62	2.01	-5.00	-2.00	0.00	1.00	4.00
		Placebo→10 mg	27	-1.78	2.29	-7.00	-3.00	-1.00	0.00	2.00
Unable to complete chores in past 3 months due to RA	Month 3	Tofacitinib 5 mg BID	254	0.23	0.51	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	251	0.27	0.57	-1.00	0.00	0.00	1.00	1.00
		Placebo	118	0.10	0.48	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	276	0.25	0.52	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	276	0.36	0.56	-1.00	0.00	0.00	1.00	1.00
		Placebo	60	0.17	0.53	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	39	0.13	0.61	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	37	0.11	0.46	-1.00	0.00	0.00	0.00	1.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Chores carried out by housekeeper due to RA	Month 3	Tofacitinib 5 mg BID	256	0.08	0.33	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	255	0.07	0.32	-1.00	0.00	0.00	0.00	1.00
		Placebo	121	0.00	0.26	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	279	0.06	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.08	0.34	-1.00	0.00	0.00	0.00	1.00
		Placebo	61	0.03	0.36	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	-0.10	0.30	-1.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	37	0.05	0.33	-1.00	0.00	0.00	0.00	1.00
Hours per day chores done by housekeeper	Month 3	Tofacitinib 5 mg BID	20	0.55	3.95	-3.00	-0.50	0.00	0.50	16.00
		Tofacitinib 10 mg BID	13	-0.69	1.65	-5.00	0.00	0.00	0.00	1.00
		Placebo	8	0.38	1.85	-2.00	-1.00	0.00	2.00	3.00
	Month 6	Tofacitinib 5 mg BID	17	-0.12	1.62	-2.00	-1.00	0.00	0.00	5.00
		Tofacitinib 10 mg BID	16	-0.13	2.90	-6.00	-1.50	0.00	2.00	5.00
		Placebo	2	-0.50	0.71	-1.00	-1.00	-0.50	0.00	0.00
		Placebo→5 mg	2	1.00	1.41	0.00	0.00	1.00	2.00	2.00
		Placebo→10 mg	2	1.00	0.00	1.00	1.00	1.00	1.00	1.00
Number of days chores done by housekeeper	Month 3	Tofacitinib 5 mg BID	20	-1.80	30.01	-69.00	-10.00	0.00	3.00	66.00
		Tofacitinib 10 mg BID	13	-1.77	8.68	-28.00	-2.00	0.00	1.00	11.00
		Placebo	8	-7.13	21.81	-46.00	-16.50	-3.50	-0.50	30.00
	Month 6	Tofacitinib 5 mg BID	17	-3.41	25.50	-45.00	-12.00	-4.00	0.00	80.00
		Tofacitinib 10 mg BID	16	-15.38	35.02	-120.00	-24.00	-5.50	1.00	33.00
		Placebo	3	14.33	59.21	-35.00	-35.00	-2.00	80.00	80.00
		Placebo→5 mg	2	2.00	2.83	0.00	0.00	2.00	4.00	4.00
		Placebo→10 mg	2	-27.50	38.89	-55.00	-55.00	-27.50	0.00	0.00
Chores carried out by family/friends due to RA	Month 3	Tofacitinib 5 mg BID	256	0.18	0.50	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	255	0.24	0.53	-1.00	0.00	0.00	1.00	1.00
		Placebo	121	0.01	0.47	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	279	0.22	0.51	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	280	0.28	0.52	-1.00	0.00	0.00	1.00	1.00
		Placebo	61	0.21	0.41	0.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	40	0.08	0.53	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	37	0.05	0.40	-1.00	0.00	0.00	0.00	1.00
Hours per day chores done by	Month 3	Tofacitinib 5 mg BID	70	0.20	10.31	-22.00	-1.00	0.00	1.00	77.00
		Tofacitinib 10 mg BID	56	-0.02	6.03	-21.00	-1.00	0.00	1.00	32.00

Table 166. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Comparisons to Placebo, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
family/friends	Month 6	Placebo	43	0.16	5.50	-22.00	-1.00	0.00	1.00	22.00
		Tofacitinib 5 mg BID	70	-1.13	3.76	-22.00	-2.00	-1.00	0.00	7.00
		Tofacitinib 10 mg BID	57	-0.54	5.32	-21.00	-2.00	0.00	1.00	22.00
		Placebo	14	0.21	1.72	-3.00	-1.00	0.00	1.00	3.00
		Placebo→5 mg	15	-2.00	6.20	-19.00	-1.00	0.00	0.00	6.00
		Placebo→10 mg	10	0.30	2.45	-2.00	-2.00	0.00	1.00	6.00
Number of days chores done by family/friends	Month 3	Tofacitinib 5 mg BID	71	-8.44	32.47	-83.00	-25.00	-3.00	0.00	88.00
		Tofacitinib 10 mg BID	56	-12.89	32.72	-88.00	-19.00	-1.50	0.00	89.00
	Month 6	Placebo	44	-4.86	37.66	-88.00	-10.00	-0.50	0.00	88.00
		Tofacitinib 5 mg BID	71	-11.85	37.20	-88.00	-29.00	0.00	2.00	88.00
		Tofacitinib 10 mg BID	56	-11.52	45.47	-120.00	-37.50	-3.00	1.00	87.00
		Placebo	15	-4.80	40.23	-83.00	-11.00	-3.00	0.00	75.00
		Placebo→5 mg	15	-12.67	29.49	-78.00	-30.00	0.00	0.00	28.00
		Placebo→10 mg	10	-3.40	33.82	-40.00	-27.00	-5.00	1.00	83.00

Tofacitinib 5mg BID or tofacitinib 10mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5mg BID or placebo→10mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5mg BID or tofacitinib 10 mg BID.

BID = twice daily; ER = emergency room; Max = maximum Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; RA = rheumatoid arthritis; RA-HCRU = RA Healthcare Resource Utilization Questionnaire; St Dev = standard deviation.

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Seen any doctor/healthcare professional in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.18	0.52	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	256	0.17	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	0.08	0.37	-1.00	0.00	0.00	0.00	1.00
		Placeb→10 mg	56	0.21	0.56	-1.00	0.00	0.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	280	0.07	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.06	0.48	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	69	0.13	0.45	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	67	0.15	0.61	-1.00	0.00	0.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	250	0.06	0.48	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	261	0.04	0.46	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	0.01	0.37	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	62	0.02	0.50	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.03	0.51	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	240	0.07	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	-0.02	0.35	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	54	0.13	0.52	-1.00	0.00	0.00	0.00	1.00
Month 24	Tofacitinib 5 mg BID	208	0.04	0.49	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 10 mg BID	215	0.06	0.50	-1.00	0.00	0.00	0.00	1.00	
	Placebo→5 mg	54	0.15	0.49	-1.00	0.00	0.00	0.00	1.00	
	Placebo→10 mg	51	0.14	0.57	-1.00	0.00	0.00	0.00	1.00	
Total visits to doctor/healthcare professional in past 3 months	Month 3	Tofacitinib 5 mg BID	166	-1.22	4.36	-29.00	-2.00	0.00	1.00	8.00
		Tofacitinib 10 mg BID	164	-1.34	5.78	-50.00	-2.00	0.00	1.00	17.00
		Placebo→5 mg	49	-2.10	4.88	-27.00	-3.00	-1.00	0.00	3.00
		Placebo→10 mg	34	-0.24	1.89	-5.00	-1.00	0.00	1.00	5.00
	Month 6	Tofacitinib 5 mg BID	200	-0.97	4.57	-31.00	-2.00	-1.00	1.00	18.00
		Tofacitinib 10 mg BID	197	-1.64	5.62	-56.00	-2.00	-1.00	0.00	10.00
		Placebo→5 mg	48	-1.38	4.57	-22.00	-3.00	-1.00	1.00	9.00
		Placebo→10 mg	40	-1.20	4.68	-25.00	-2.00	-1.00	1.00	5.00
	Month 12	Tofacitinib 5 mg BID	177	-1.44	5.00	-24.00	-2.00	-1.00	0.00	20.00
		Tofacitinib 10 mg BID	195	-1.53	5.49	-61.00	-2.00	-1.00	0.00	14.00
		Placebo→5 mg	53	-2.62	5.90	-29.00	-4.00	-1.00	0.00	10.00
		Placebo→10 mg	45	-0.71	5.95	-25.00	-2.00	-1.00	0.00	25.00
	Month 18	Tofacitinib 5 mg BID	166	-1.63	5.35	-30.00	-2.00	-1.00	0.00	18.00
		Tofacitinib 10 mg BID	174	-0.97	6.91	-59.00	-2.00	-1.00	1.00	35.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max			
RA related	Month 24	Placebo→5 mg	48	-1.90	5.61	-29.00	-3.00	-1.00	0.00	13.00			
		Placebo→10 mg	36	-2.11	4.89	-26.00	-3.00	-1.00	0.00	2.00			
		Tofacitinib 5 mg BID	146	-2.06	5.07	-27.00	-2.00	-1.00	0.00	4.00			
		Tofacitinib 10 mg BID	151	-0.99	4.86	-22.00	-2.00	-1.00	0.00	24.00			
		Placebo→5 mg	36	-3.22	6.34	-27.00	-3.50	-1.50	0.00	2.00			
		Placebo→10 mg	33	-2.00	4.96	-26.00	-3.00	-1.00	0.00	3.00			
	Month 3	Month 3	Tofacitinib 5 mg BID	164	-0.27	0.95	-4.00	-1.00	0.00	0.00	3.00		
			Tofacitinib 10 mg BID	163	-0.40	0.88	-5.00	-1.00	0.00	0.00	2.00		
		Month 6	Month 6	Placebo→5 mg	49	-0.45	0.91	-3.00	-1.00	0.00	0.00	3.00	
				Placebo→10 mg	34	-0.21	0.77	-3.00	0.00	0.00	0.00	1.00	
			Tofacitinib 5 mg BID	197	-0.26	0.78	-3.00	-1.00	0.00	0.00	2.00		
			Tofacitinib 10 mg BID	196	-0.40	0.90	-5.00	-1.00	0.00	0.00	1.00		
			Placebo→5 mg	47	-0.43	0.85	-3.00	-1.00	0.00	0.00	1.00		
			Placebo→10 mg	39	-0.15	0.54	-1.00	0.00	0.00	0.00	1.00		
		Month 12	Month 12	Tofacitinib 5 mg BID	176	-0.20	0.78	-3.00	-0.50	0.00	0.00	3.00	
				Tofacitinib 10 mg BID	195	-0.26	0.83	-6.00	0.00	0.00	0.00	2.00	
			Placebo→5 mg	53	-0.40	0.93	-3.00	-1.00	0.00	0.00	2.00		
			Placebo→10 mg	44	-0.16	0.57	-2.00	0.00	0.00	0.00	1.00		
			Month 18	Month 18	Tofacitinib 5 mg BID	166	-0.26	0.85	-4.00	-1.00	0.00	0.00	2.00
					Tofacitinib 10 mg BID	174	-0.34	0.88	-4.00	-1.00	0.00	0.00	2.00
Placebo→5 mg		48		-0.44	0.90	-3.00	-1.00	0.00	0.00	1.00			
Placebo→10 mg		36		-0.11	0.57	-1.00	0.00	0.00	0.00	2.00			
Month 24		Month 24		Tofacitinib 5 mg BID	145	-0.20	0.82	-4.00	-1.00	0.00	0.00	2.00	
				Tofacitinib 10 mg BID	151	-0.25	0.86	-6.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	36	-0.33	0.79	-3.00	-1.00	0.00	0.00	1.00			
		Placebo→10 mg	33	-0.06	0.35	-1.00	0.00	0.00	0.00	1.00			
		Treated in a hospital emergency room in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.03	0.33	-1.00	0.00	0.00	0.00	1.00	
				Tofacitinib 10 mg BID	257	-0.01	0.26	-1.00	0.00	0.00	0.00	1.00	
Placebo→5 mg				64	0.06	0.35	-1.00	0.00	0.00	0.00	1.00		
Placebo→10 mg				57	0.02	0.30	-1.00	0.00	0.00	0.00	1.00		
Month 6	Month 6		Tofacitinib 5 mg BID	281	0.01	0.34	-1.00	0.00	0.00	0.00	1.00		
			Tofacitinib 10 mg BID	281	-0.00	0.25	-1.00	0.00	0.00	0.00	1.00		
	Placebo→5 mg		70	0.04	0.36	-1.00	0.00	0.00	0.00	1.00			
	Placebo→10 mg		68	0.00	0.30	-1.00	0.00	0.00	0.00	1.00			

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 12	Tofacitinib 5 mg BID	250	0.01	0.31	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	262	-0.01	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	0.03	0.35	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	63	0.00	0.25	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.03	0.28	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	241	-0.04	0.28	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	0.05	0.29	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	55	0.05	0.23	0.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	208	0.04	0.32	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	216	-0.01	0.23	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	54	0.07	0.33	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	52	0.04	0.19	0.00	0.00	0.00	0.00	1.00
Number of visits to hospital ER in past 3 months	Month 3	Tofacitinib 5 mg BID	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Tofacitinib 10 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	0							
		Placebo→10 mg	0							
	Month 6	Tofacitinib 5 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00
		Tofacitinib 10 mg BID	2	-0.50	0.71	-1.00	-1.00	-0.50	0.00	0.00
		Placebo→5 mg	0							
		Placebo→10 mg	0							
	Month 12	Tofacitinib 5 mg BID	5	0.20	1.10	-1.00	0.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
		Placebo→5 mg	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00
		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
Month 18	Tofacitinib 5 mg BID	3	0.00	2.00	-2.00	-2.00	0.00	2.00	2.00	
	Tofacitinib 10 mg BID	3	-0.67	0.58	-1.00	-1.00	-1.00	0.00	0.00	
	Placebo→5 mg	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00	
	Placebo→10 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00	
Month 24	Tofacitinib 5 mg BID	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00	
	Tofacitinib 10 mg BID	0								
	Placebo→5 mg	0								
	Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00	
Admitted for overnight stay	Month 3	Tofacitinib 5 mg BID	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	0							

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 6	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	2	-2.00	0.00	-2.00	-2.00	-2.00	-2.00	-2.00
		Tofacitinib 10 mg BID	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	Month 12	Placebo→5 mg	0							
		Placebo→10 mg	0							
		Tofacitinib 5 mg BID	7	-0.14	0.90	-2.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 18	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
		Tofacitinib 5 mg BID	5	-0.40	0.89	-2.00	0.00	0.00	0.00	0.00
	Month 24	Tofacitinib 10 mg BID	3	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
		Tofacitinib 5 mg BID	2	-1.00	1.41	-2.00	-2.00	-1.00	0.00	0.00
	Month 3	Tofacitinib 10 mg BID	0							
ER visit RA related		Tofacitinib 5 mg BID	3	0.00	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	0								
	Month 6	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	2	-1.50	0.71	-2.00	-2.00	-1.50	-1.00	-1.00
		Tofacitinib 10 mg BID	2	-1.00	4.24	-4.00	-4.00	-1.00	2.00	2.00
	Month 12	Placebo→5 mg	0							
		Placebo→10 mg	0							
		Tofacitinib 5 mg BID	7	-0.57	1.13	-2.00	-2.00	0.00	0.00	1.00
	Month 18	Tofacitinib 10 mg BID	1	-4.00		-4.00	-4.00	-4.00	-4.00	-4.00
		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
	Month 24	Tofacitinib 5 mg BID	5	-1.20	0.84	-2.00	-2.00	-1.00	-1.00	0.00
		Tofacitinib 10 mg BID	3	-0.67	3.06	-4.00	-4.00	0.00	2.00	2.00
		Placebo→5 mg	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00
	Month 24	Tofacitinib 5 mg BID	2	-2.00	0.00	-2.00	-2.00	-2.00	-2.00	-2.00
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
		Placebo→10 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Hospitalization in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.02	0.30	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.04	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	0.02	0.13	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	57	0.02	0.23	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.05	0.26	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	0.05	0.26	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	70	0.00	0.17	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	68	0.00	0.30	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	250	0.03	0.28	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	262	0.04	0.24	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	-0.01	0.21	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	63	0.03	0.25	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.04	0.29	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	241	0.01	0.29	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	0.02	0.13	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	55	0.05	0.23	0.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	208	0.04	0.29	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	216	0.04	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	54	-0.02	0.24	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	52	0.06	0.24	0.00	0.00	0.00	0.00	1.00
Number of visits hospitalized in past 3 months	Month 3	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	0							
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
		Placebo→10 mg	0							
	Month 12	Tofacitinib 5 mg BID	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	0							
	Month 18	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 24	Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
Hospitalized length of stay	Month 3	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	-13.00		-13.00	-13.00	-13.00	-13.00	-13.00
		Placebo→10 mg	0							
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
	Month 12	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	2	-6.00	5.66	-10.00	-10.00	-6.00	-2.00	-2.00
		Tofacitinib 10 mg BID	1	-6.00		-6.00	-6.00	-6.00	-6.00	-6.00
	Month 18	Placebo→5 mg	0							
		Placebo→10 mg	0							
		Tofacitinib 5 mg BID	0							
	Month 24	Tofacitinib 10 mg BID	0							
		Tofacitinib 5 mg BID	1	24.00		24.00	24.00	24.00	24.00	24.00
		Placebo→5 mg	0							
Hospitalized RA related	Month 3	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	0							
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
	Month 12	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 18	Placebo→5 mg	0							
		Placebo→10 mg	0							
		Tofacitinib 5 mg BID	0							
	Month 24	Tofacitinib 10 mg BID	0							
		Tofacitinib 5 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00
		Tofacitinib 10 mg BID	0							

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	0							
Had any outpatient surgeries in past 3 months	Month 3	Tofacitinib 5 mg BID	258	-0.00	0.22	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	256	0.02	0.22	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	0.02	0.22	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	57	0.04	0.19	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	-0.02	0.26	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.03	0.21	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	70	-0.06	0.29	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	68	0.03	0.17	0.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	250	-0.02	0.25	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	261	0.03	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	0.00	0.17	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	63	0.02	0.22	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.00	0.24	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	240	0.00	0.28	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	0.02	0.13	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	55	0.04	0.19	0.00	0.00	0.00	0.00	1.00
Month 24	Tofacitinib 5 mg BID	208	-0.01	0.29	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 10 mg BID	215	-0.01	0.29	-1.00	0.00	0.00	0.00	1.00	
	Placebo→5 mg	54	-0.04	0.19	-1.00	0.00	0.00	0.00	0.00	
	Placebo→10 mg	52	0.02	0.24	-1.00	0.00	0.00	0.00	1.00	
Number of outpatient surgeries in past 3 months	Month 3	Tofacitinib 5 mg BID	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	0							
	Month 6	Tofacitinib 5 mg BID	0			0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	2	3.50	4.95	0.00	0.00	3.50	7.00	7.00
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
	Month 18	Placebo→10 mg	0							
Tofacitinib 5 mg BID		0								
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 24	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	0							
		Placebo→10 mg	0							
Outpatient surgery RA related	Month 3	Tofacitinib 5 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	0							
	Month 6	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→5 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
	Month 12	Tofacitinib 5 mg BID	2	0.50	2.12	-1.00	-1.00	0.50	2.00	2.00
		Tofacitinib 10 mg BID	0							
		Placebo→5 mg	0							
	Month 18	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00
Month 24	Tofacitinib 5 mg BID	0								
	Tofacitinib 10 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00	
	Placebo→5 mg	0								
Had any non-study diagnostic tests in past 3 months	Month 3	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	258	0.05	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.00	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	0.08	0.45	-1.00	0.00	0.00	0.00	1.00
	Month 6	Placebo→10 mg	57	0.00	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	280	-0.03	0.52	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.02	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	70	0.07	0.49	-1.00	0.00	0.00	0.00	1.00
	Month 12	Placebo→10 mg	68	-0.10	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	250	-0.02	0.51	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	262	-0.03	0.53	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	0.06	0.49	-1.00	0.00	0.00	0.00	1.00
	Month 18	Placebo→10 mg	63	-0.06	0.40	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	234	0.04	0.48	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	241	-0.02	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	0							

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 24	Placebo→5 mg	59	-0.03	0.59	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	55	0.00	0.27	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	208	-0.01	0.47	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	216	0.03	0.49	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	54	0.02	0.53	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	52	-0.06	0.37	-1.00	0.00	0.00	0.00	1.00	
Number of non-study diagnostic tests	Month 3	Tofacitinib 5 mg BID	10	-0.50	1.35	-3.00	-1.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	13	-0.69	1.70	-4.00	-1.00	0.00	0.00	2.00	
		Placebo→5 mg	5	-0.60	0.89	-2.00	-1.00	0.00	0.00	0.00	
		Placebo→10 mg	0								
	Month 6	Tofacitinib 5 mg BID	17	0.94	3.27	-3.00	-1.00	0.00	1.00	11.00	
		Tofacitinib 10 mg BID	11	-0.18	1.83	-3.00	-1.00	0.00	2.00	2.00	
		Placebo→5 mg	2	-2.00	1.41	-3.00	-3.00	-2.00	-1.00	-1.00	
		Placebo→10 mg	0								
	Month 12	Tofacitinib 5 mg BID	16	0.13	1.71	-4.00	-1.00	0.00	1.00	3.00	
		Tofacitinib 10 mg BID	9	0.11	1.62	-1.00	-1.00	0.00	0.00	4.00	
		Placebo→5 mg	3	0.33	1.15	-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	
	Month 18	Tofacitinib 5 mg BID	11	0.09	1.30	-2.00	-1.00	0.00	1.00	3.00	
		Tofacitinib 10 mg BID	14	0.14	1.10	-1.00	-1.00	0.00	1.00	2.00	
		Placebo→5 mg	3	0.00	3.00	-3.00	-3.00	0.00	3.00	3.00	
		Placebo→10 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Month 24	Tofacitinib 5 mg BID	17	-0.06	0.83	-1.00	-1.00	0.00	1.00	1.00	
		Tofacitinib 10 mg BID	11	-0.36	0.81	-2.00	-1.00	0.00	0.00	1.00	
		Placebo→5 mg	3	1.00	4.36	-2.00	-2.00	-1.00	6.00	6.00	
		Placebo→10 mg	0								
	Diagnostic tests RA related	Month 3	Tofacitinib 5 mg BID	12	-0.67	1.23	-3.00	-1.00	0.00	0.00	1.00
			Tofacitinib 10 mg BID	13	-1.08	1.89	-5.00	-1.00	0.00	0.00	1.00
			Placebo→5 mg	5	-0.60	0.89	-2.00	-1.00	0.00	0.00	0.00
			Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
Month 6		Tofacitinib 5 mg BID	17	0.00	1.37	-3.00	0.00	0.00	1.00	2.00	
		Tofacitinib 10 mg BID	12	-1.00	1.95	-5.00	-2.00	-1.00	0.00	3.00	
		Placebo→5 mg	2	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	

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Tofacitinib 5 mg BID	17	-0.76	1.48	-4.00	-1.00	0.00	0.00	2.00	
		Tofacitinib 10 mg BID	11	-0.55	1.29	-3.00	-1.00	0.00	0.00	1.00	
		Placebo→5 mg	3	-1.00	1.00	-2.00	-2.00	-1.00	0.00	0.00	
		Placebo→10 mg	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Month 18	Tofacitinib 5 mg BID	11	-0.91	1.22	-3.00	-2.00	0.00	0.00	0.00	
		Tofacitinib 10 mg BID	14	-0.21	0.97	-2.00	-1.00	0.00	0.00	2.00	
		Placebo→5 mg	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00	
		Placebo→10 mg	3	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Month 24	Tofacitinib 5 mg BID	17	-0.47	1.07	-3.00	-1.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	11	-0.64	1.43	-3.00	-1.00	0.00	0.00	2.00	
		Placebo→5 mg	3	-0.33	0.58	-1.00	-1.00	0.00	0.00	0.00	
		Placebo→10 mg	1	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
Subject in a nursing home in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.00	0.06	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	257	0.00	0.11	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	64	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	57	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
	Month 6	Tofacitinib 5 mg BID	281	-0.01	0.08	-1.00	0.00	0.00	0.00	0.00	
		Tofacitinib 10 mg BID	281	0.01	0.10	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	70	0.01	0.12	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	68	0.01	0.12	0.00	0.00	0.00	0.00	1.00	
	Month 12	Tofacitinib 5 mg BID	250	-0.00	0.11	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	262	0.01	0.11	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	67	0.01	0.12	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	63	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
	Month 18	Tofacitinib 5 mg BID	234	-0.00	0.11	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	241	0.01	0.11	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	59	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	55	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
	Month 24	Tofacitinib 5 mg BID	208	0.00	0.07	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	216	0.01	0.10	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	54	0.02	0.14	0.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	52	0.02	0.14	0.00	0.00	0.00	0.00	1.00	
	Number of days in nursing home	Month 3	Tofacitinib 10 mg BID	0							
		Month 6	Tofacitinib 5 mg BID	1	13.00		13.00	13.00	13.00	13.00	13.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
in past 3 months	Month 12	Tofacitinib 5 mg BID	0								
	Month 18	Tofacitinib 5 mg BID	0								
	Month 24	Tofacitinib 10 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00	
Used home healthcare services in past 3 months	Month 3	Tofacitinib 5 mg BID	256	0.01	0.14	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	257	0.00	0.06	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	64	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Month 6	Placebo→10 mg	57	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	280	0.01	0.13	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	280	0.00	0.10	-1.00	0.00	0.00	0.00	1.00	
	Month 12	Placebo→5 mg	70	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo→10 mg	68	0.00	0.17	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	249	0.02	0.15	-1.00	0.00	0.00	0.00	1.00	
	Month 18	Tofacitinib 10 mg BID	261	0.01	0.09	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	67	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
		Placebo→10 mg	63	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
	Month 24	Tofacitinib 5 mg BID	233	0.02	0.16	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	240	0.01	0.09	0.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	59	0.00	0.00	0.00	0.00	0.00	0.00	0.00	
	Month 24	Placebo→10 mg	55	0.02	0.13	0.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	209	0.02	0.17	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	216	0.00	0.12	-1.00	0.00	0.00	0.00	1.00	
	Home healthcare services hours per day	Month 3	Placebo→5 mg	54	0.00	0.00	0.00	0.00	0.00	0.00	0.00
			Placebo→10 mg	52	0.02	0.14	0.00	0.00	0.00	0.00	1.00
		Month 3	Tofacitinib 5 mg BID	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00
Month 6	Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00		
	Tofacitinib 5 mg BID	3	0.67	2.08	-1.00	-1.00	0.00	3.00	3.00		
	Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00		
Month 12	Placebo->10 mg	0									
	Tofacitinib 5 mg BID	1	39.00		39.00	39.00	39.00	39.00	39.00		
Month 18	Tofacitinib 10 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00		
	Tofacitinib 5 mg BID	0									
Month 24	Tofacitinib 10 mg BID	1	2.00		2.00	2.00	2.00	2.00	2.00		
	Tofacitinib 5 mg BID	0									

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	0							
Home healthcare services RA related	Month 3	Tofacitinib 5 mg BID	4	-0.25	0.50	-1.00	-0.50	0.00	0.00	0.00
		Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	4	0.00	0.82	-1.00	-0.50	0.00	0.50	1.00
		Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
	Month 12	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 18	Tofacitinib 10 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
		Tofacitinib 5 mg BID	0							
	Month 24	Tofacitinib 10 mg BID	1	4.00		4.00	4.00	4.00	4.00	4.00
		Tofacitinib 5 mg BID	0							
Required aids/devices for daily functioning in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.03	0.27	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.00	0.24	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	0.02	0.28	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	57	-0.02	0.23	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.03	0.35	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	0.03	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	70	0.06	0.29	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	68	0.03	0.17	0.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	250	0.02	0.32	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	262	0.03	0.22	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	0.06	0.24	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	63	0.05	0.21	0.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.06	0.35	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	241	0.03	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	0.05	0.22	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	55	0.02	0.23	-1.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	208	0.06	0.33	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	216	0.04	0.25	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	54	0.04	0.33	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	52	0.02	0.14	0.00	0.00	0.00	0.00	1.00
Aids or devices used days	Month 3	Tofacitinib 5 mg BID	17	-5.41	105.39	-200.00	-60.00	0.00	7.00	180.00
		Tofacitinib 10 mg BID	14	-7.07	71.74	-90.00	-78.00	-3.00	8.00	168.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	7	-41.57	59.91	-90.00	-90.00	-78.00	0.00	57.00
	Month 6	Placebo→10 mg	1	-90.00		-90.00	-90.00	-90.00	-90.00	-90.00
		Tofacitinib 5 mg BID	14	18.07	102.87	-140.00	-23.00	2.50	75.00	231.00
		Tofacitinib 10 mg BID	13	4.85	88.64	-136.00	-35.00	0.00	30.00	192.00
		Placebo→5 mg	4	-74.00	65.91	-156.00	-123.00	-70.00	-25.00	0.00
	Month 12	Placebo→10 mg	2	0.00	127.28	-90.00	-90.00	0.00	90.00	90.00
		Tofacitinib 5 mg BID	15	6.60	120.39	-170.00	-90.00	0.00	50.00	270.00
		Tofacitinib 10 mg BID	11	79.36	152.37	-90.00	-15.00	0.00	187.00	365.00
		Placebo→5 mg	4	-45.00	51.96	-90.00	-90.00	-45.00	0.00	0.00
	Month 18	Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
		Tofacitinib 5 mg BID	10	10.90	72.97	-91.00	-5.00	0.00	60.00	146.00
		Tofacitinib 10 mg BID	11	114.73	132.68	-11.00	0.00	80.00	210.00	401.00
		Placebo→5 mg	2	-90.00	0.00	-90.00	-90.00	-90.00	-90.00	-90.00
	Month 24	Placebo→10 mg	0							
		Tofacitinib 5 mg BID	8	0.38	179.05	-166.00	-90.00	-34.00	-2.50	422.00
		Tofacitinib 10 mg BID	9	32.22	86.50	-90.00	0.00	30.00	81.00	186.00
		Placebo→5 mg	0							
Aids or devices RA related	Month 3	Tofacitinib 5 mg BID	18	-0.22	1.22	-3.00	-1.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	16	-0.44	1.15	-4.00	-1.00	0.00	0.00	1.00
		Placebo→5 mg	7	-0.71	1.11	-2.00	-2.00	-1.00	0.00	1.00
		Placebo→10 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
	Month 6	Tofacitinib 5 mg BID	15	-0.20	1.37	-4.00	-1.00	0.00	1.00	2.00
		Tofacitinib 10 mg BID	13	-0.62	1.12	-4.00	-1.00	0.00	0.00	0.00
		Placebo→5 mg	4	-0.50	1.29	-2.00	-1.50	-0.50	0.50	1.00
		Placebo→10 mg	2	0.00	1.41	-1.00	-1.00	0.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	16	0.00	1.15	-2.00	-1.00	0.00	0.50	3.00
		Tofacitinib 10 mg BID	13	0.31	2.21	-4.00	0.00	0.00	0.00	5.00
		Placebo→5 mg	4	-1.00	0.82	-2.00	-1.50	-1.00	-0.50	0.00
		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 18	Tofacitinib 5 mg BID	11	-0.18	1.08	-2.00	-1.00	0.00	0.00	2.00
		Tofacitinib 10 mg BID	12	0.50	2.39	-4.00	0.00	0.00	1.50	5.00
		Placebo→5 mg	2	-1.50	0.71	-2.00	-2.00	-1.50	-1.00	-1.00
		Placebo→10 mg	0							
	Month 24	Tofacitinib 5 mg BID	8	-0.25	1.98	-3.00	-1.00	-0.50	0.00	4.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	9	-0.22	1.39	-2.00	-1.00	0.00	0.00	3.00
		Placebo→5 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
Seen any non-medical practitioners in past 3 months	Month 3	Tofacitinib 5 mg BID	258	0.00	0.19	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	257	0.02	0.23	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	0.00	0.18	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	57	0.04	0.19	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	281	0.01	0.20	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	281	0.03	0.21	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	70	-0.01	0.12	-1.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	68	0.03	0.17	0.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	250	0.01	0.14	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	262	0.04	0.23	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	-0.01	0.12	-1.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	63	0.02	0.22	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.02	0.16	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	241	0.04	0.23	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	0.03	0.26	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	55	0.04	0.19	0.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	208	0.02	0.15	0.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	216	0.03	0.29	-1.00	0.00	0.00	0.00	1.00
Placebo→5 mg		54	0.06	0.23	0.00	0.00	0.00	0.00	1.00	
Placebo→10 mg		52	0.02	0.14	0.00	0.00	0.00	0.00	1.00	
Non-medical practitioner visits	Month 3	Tofacitinib 5 mg BID	1	12.00		12.00	12.00	12.00	12.00	12.00
		Tofacitinib 10 mg BID	4	-8.50	17.67	-35.00	-17.50	0.00	0.50	1.00
		Placebo→5 mg	1	-5.00		-5.00	-5.00	-5.00	-5.00	-5.00
		Placebo→10 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	2	16.00	11.31	8.00	8.00	16.00	24.00	24.00
		Tofacitinib 10 mg BID	5	0.00	5.39	-8.00	-1.00	1.00	1.00	7.00
		Placebo→5 mg	3	1.67	7.64	-5.00	-5.00	0.00	10.00	10.00
	Month 12	Tofacitinib 5 mg BID	3	-4.67	5.03	-10.00	-10.00	-4.00	0.00	0.00
		Tofacitinib 10 mg BID	4	0.50	2.08	-2.00	-1.00	0.50	2.00	3.00
		Placebo→5 mg	3	-7.00	3.00	-10.00	-10.00	-7.00	-4.00	-4.00
		Placebo→10 mg	0							

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
Non-medical practitioner RA related	Month 18	Tofacitinib 5 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00	
		Tofacitinib 10 mg BID	5	-3.80	16.27	-32.00	-1.00	0.00	5.00	9.00	
		Placebo→5 mg	0								
	Month 24	Tofacitinib 5 mg BID	1	-2.00		-2.00	-2.00	-2.00	-2.00	-2.00	
		Tofacitinib 10 mg BID	3	0.33	22.74	-25.00	-25.00	7.00	19.00	19.00	
	Are you currently employed	Month 3	Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00
			Tofacitinib 10 mg BID	4	-0.25	0.96	-1.00	-1.00	-0.50	0.50	1.00
			Placebo→5 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
			Placebo→10 mg	1	-4.00		-4.00	-4.00	-4.00	-4.00	-4.00
		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	5	-0.20	0.45	-1.00	0.00	0.00	0.00	0.00
			Placebo→5 mg	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00
Month 12		Tofacitinib 5 mg BID	3	0.67	1.53	-1.00	-1.00	1.00	2.00	2.00	
		Tofacitinib 10 mg BID	4	-0.75	0.96	-2.00	-1.50	-0.50	0.00	0.00	
		Placebo→5 mg	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00	
Month 18		Placebo→10 mg	0								
		Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00	
	Tofacitinib 10 mg BID	5	-0.60	0.89	-2.00	-1.00	0.00	0.00	0.00		
Month 24	Placebo→5 mg	0									
	Tofacitinib 5 mg BID	1	1.00		1.00	1.00	1.00	1.00	1.00		
		Tofacitinib 10 mg BID	3	-0.33	1.53	-2.00	-2.00	0.00	1.00	1.00	
Are you currently employed	Month 3	Tofacitinib 5 mg BID	257	-0.02	0.19	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	257	-0.01	0.26	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	64	0.02	0.22	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	57	0.00	0.27	-1.00	0.00	0.00	0.00	1.00	
	Month 6	Tofacitinib 5 mg BID	280	0.01	0.27	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	281	-0.01	0.28	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	70	0.06	0.29	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	68	-0.03	0.30	-1.00	0.00	0.00	0.00	1.00	
	Month 12	Tofacitinib 5 mg BID	249	-0.01	0.32	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	262	-0.02	0.30	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	67	0.01	0.37	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	63	-0.05	0.33	-1.00	0.00	0.00	0.00	1.00	
	Month 18	Tofacitinib 5 mg BID	233	-0.00	0.33	-1.00	0.00	0.00	0.00	1.00	

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 24	Tofacitinib 10 mg BID	241	0.01	0.37	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	59	0.05	0.34	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	55	-0.02	0.30	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 5 mg BID	207	-0.02	0.39	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	216	0.02	0.37	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	54	0.07	0.38	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	52	-0.06	0.31	-1.00	0.00	0.00	0.00	1.00	
Hours of work per day	Month 3	Tofacitinib 5 mg BID	87	-0.13	6.05	-31.00	0.00	0.00	0.00	41.00	
		Tofacitinib 10 mg BID	101	-0.08	2.78	-25.00	0.00	0.00	0.00	8.00	
		Placebo→5 mg	22	0.09	0.75	-2.00	0.00	0.00	0.00	2.00	
	Month 6	Placebo→10 mg	23	-1.13	6.78	-32.00	0.00	0.00	0.00	3.00	
		Tofacitinib 5 mg BID	86	0.17	5.34	-30.00	0.00	0.00	0.00	36.00	
		Tofacitinib 10 mg BID	103	-0.59	4.44	-32.00	0.00	0.00	0.00	5.00	
	Month 12	Placebo→5 mg	20	0.10	0.64	-1.00	0.00	0.00	0.00	2.00	
		Placebo→10 mg	28	-1.14	6.13	-32.00	0.00	0.00	0.00	3.00	
		Tofacitinib 5 mg BID	78	-0.19	5.66	-31.00	-1.00	0.00	0.00	32.00	
	Month 18	Tofacitinib 10 mg BID	98	-0.57	4.52	-32.00	0.00	0.00	0.00	8.00	
		Placebo→5 mg	19	0.21	1.44	-4.00	0.00	0.00	1.00	4.00	
		Placebo→10 mg	26	-1.04	6.45	-32.00	0.00	0.00	0.00	4.00	
	Month 24	Tofacitinib 5 mg BID	73	-0.47	4.39	-31.00	0.00	0.00	0.00	6.00	
		Tofacitinib 10 mg BID	81	-0.02	6.49	-32.00	0.00	0.00	0.00	32.00	
		Placebo→5 mg	18	-0.11	1.78	-4.00	0.00	0.00	0.00	5.00	
		Month 24	Placebo→10 mg	23	-0.04	1.15	-2.00	0.00	0.00	0.00	4.00
			Tofacitinib 5 mg BID	60	-0.68	4.76	-31.00	0.00	0.00	0.00	5.00
			Tofacitinib 10 mg BID	72	-0.53	3.78	-29.00	-0.50	0.00	0.00	4.00
			Placebo→5 mg	15	0.07	0.88	-2.00	0.00	0.00	0.00	2.00
		Month 24	Placebo→10 mg	24	-1.46	6.65	-32.00	-1.00	0.00	0.00	3.00
			Tofacitinib 5 mg BID	88	0.09	0.75	-2.00	0.00	0.00	0.00	3.00
Tofacitinib 10 mg BID			101	0.16	0.76	-4.00	0.00	0.00	0.00	3.00	
Placebo→5 mg			22	0.18	1.18	-2.00	0.00	0.00	0.00	5.00	
Days of work per week	Month 3	Placebo→10 mg	23	-0.13	0.63	-3.00	0.00	0.00	0.00	0.00	
		Tofacitinib 5 mg BID	87	0.11	0.67	-1.00	0.00	0.00	0.00	3.00	
		Tofacitinib 10 mg BID	103	0.09	0.72	-3.00	0.00	0.00	0.00	2.00	
	Month 6	Placebo→5 mg	20	0.25	1.29	-2.00	0.00	0.00	0.00	5.00	

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 12	Placebo→10 mg	28	0.18	1.36	-3.00	0.00	0.00	0.00	6.00	
		Tofacitinib 5 mg BID	79	0.18	0.89	-2.00	0.00	0.00	0.00	4.00	
		Tofacitinib 10 mg BID	98	0.00	0.69	-3.00	0.00	0.00	0.00	2.00	
	Month 18	Placebo→5 mg	19	0.00	1.15	-2.00	0.00	0.00	0.00	4.00	
		Placebo→10 mg	26	0.23	1.42	-3.00	0.00	0.00	0.00	6.00	
		Tofacitinib 5 mg BID	73	0.14	0.87	-2.00	0.00	0.00	0.00	3.00	
		Tofacitinib 10 mg BID	81	-0.02	0.79	-3.00	0.00	0.00	0.00	3.00	
		Placebo→5 mg	18	-0.11	0.47	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	23	0.52	1.41	-1.00	0.00	0.00	0.00	6.00	
	Month 24	Tofacitinib 5 mg BID	61	0.21	0.88	-3.00	0.00	0.00	0.00	3.00	
		Tofacitinib 10 mg BID	72	-0.11	0.86	-5.00	0.00	0.00	0.00	2.00	
		Placebo→5 mg	15	-0.07	0.46	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	24	0.17	1.43	-3.00	0.00	0.00	0.00	6.00	
	Feel well enough to work if job were available	Month 3	Tofacitinib 5 mg BID	130	-0.08	0.34	-1.00	0.00	0.00	0.00	1.00
			Tofacitinib 10 mg BID	116	-0.09	0.44	-1.00	0.00	0.00	0.00	1.00
Placebo→5 mg			32	0.00	0.25	-1.00	0.00	0.00	0.00	1.00	
Placebo→10 mg			25	-0.04	0.35	-1.00	0.00	0.00	0.00	1.00	
Month 6		Tofacitinib 5 mg BID	145	-0.09	0.41	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	130	-0.15	0.49	-1.00	0.00	0.00	0.00	1.00	
		Placebo→5 mg	37	-0.03	0.37	-1.00	0.00	0.00	0.00	1.00	
		Placebo→10 mg	27	-0.04	0.52	-1.00	0.00	0.00	0.00	1.00	
Month 12		Tofacitinib 5 mg BID	126	-0.14	0.47	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	119	-0.21	0.52	-1.00	-1.00	0.00	0.00	1.00	
		Placebo→5 mg	33	-0.09	0.29	-1.00	0.00	0.00	0.00	0.00	
		Placebo→10 mg	23	-0.17	0.58	-1.00	-1.00	0.00	0.00	1.00	
Month 18		Tofacitinib 5 mg BID	116	-0.16	0.49	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	110	-0.24	0.52	-1.00	-1.00	0.00	0.00	1.00	
		Placebo→5 mg	29	-0.24	0.44	-1.00	0.00	0.00	0.00	0.00	
		Placebo→10 mg	23	-0.22	0.60	-1.00	-1.00	0.00	0.00	1.00	
Month 24		Tofacitinib 5 mg BID	99	-0.12	0.44	-1.00	0.00	0.00	0.00	1.00	
		Tofacitinib 10 mg BID	99	-0.20	0.51	-1.00	-1.00	0.00	0.00	1.00	
		Placebo→5 mg	26	-0.15	0.37	-1.00	0.00	0.00	0.00	0.00	
		Placebo→10 mg	19	-0.11	0.66	-1.00	-1.00	0.00	0.00	1.00	
Unable to work		Month 3	Tofacitinib 5 mg BID	133	0.05	0.44	-1.00	0.00	0.00	0.00	1.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
due to RA	Month 6	Tofacitinib 10 mg BID	119	0.14	0.53	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	32	0.06	0.50	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	26	0.04	0.53	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	147	0.09	0.50	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	133	0.17	0.54	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	38	0.00	0.46	-1.00	0.00	0.00	0.00	1.00
	Month 12	Placebo→10 mg	29	0.03	0.57	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	128	0.11	0.51	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	120	0.14	0.55	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	34	0.24	0.50	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	24	0.29	0.62	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 5 mg BID	118	0.05	0.58	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 10 mg BID	113	0.18	0.54	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	29	0.24	0.58	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	23	0.26	0.54	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 5 mg BID	100	0.06	0.55	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	102	0.22	0.57	-1.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	25	0.36	0.57	-1.00	0.00	0.00	1.00	1.00
Month 24	Placebo→10 mg	20	0.20	0.62	-1.00	0.00	0.00	1.00	1.00	
	Tofacitinib 5 mg BID	133	0.04	0.45	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 10 mg BID	117	0.06	0.46	-1.00	0.00	0.00	0.00	1.00	
	Placebo→5 mg	32	-0.03	0.47	-1.00	0.00	0.00	0.00	1.00	
	Placebo→10 mg	25	-0.12	0.33	-1.00	0.00	0.00	0.00	0.00	
	Tofacitinib 5 mg BID	144	0.06	0.46	-1.00	0.00	0.00	0.00	1.00	
Month 6	Tofacitinib 10 mg BID	134	0.01	0.45	-1.00	0.00	0.00	0.00	1.00	
	Placebo→5 mg	37	0.05	0.40	-1.00	0.00	0.00	0.00	1.00	
	Placebo→10 mg	27	-0.11	0.42	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 5 mg BID	128	0.07	0.49	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 10 mg BID	121	0.09	0.47	-1.00	0.00	0.00	0.00	1.00	
	Placebo→5 mg	32	0.19	0.54	-1.00	0.00	0.00	0.50	1.00	
Month 12	Placebo→10 mg	23	-0.04	0.37	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 5 mg BID	117	0.08	0.49	-1.00	0.00	0.00	0.00	1.00	
	Tofacitinib 10 mg BID	111	0.05	0.50	-1.00	0.00	0.00	0.00	1.00	
	Placebo→5 mg	28	0.14	0.45	-1.00	0.00	0.00	0.00	1.00	

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 24	Placebo→10 mg	22	0.00	0.31	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 5 mg BID	99	0.03	0.44	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	101	0.01	0.48	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	25	0.12	0.44	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	19	-0.11	0.46	-1.00	0.00	0.00	0.00	1.00
Work disabled due to RA	Month 3	Tofacitinib 5 mg BID	136	0.01	0.42	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	119	0.03	0.42	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	33	-0.03	0.53	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	26	0.04	0.34	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	146	-0.02	0.43	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	132	0.06	0.44	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	37	0.03	0.60	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	28	-0.07	0.47	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	130	0.04	0.46	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	122	0.07	0.44	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	35	0.09	0.56	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	25	0.08	0.40	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	119	0.07	0.48	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	112	0.07	0.46	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	29	0.14	0.52	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	23	0.04	0.47	-1.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	101	-0.05	0.46	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	100	0.02	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	26	0.04	0.60	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	20	0.00	0.56	-1.00	0.00	0.00	0.00	1.00
I am retired	Month 3	Tofacitinib 5 mg BID	139	-0.03	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	125	-0.02	0.36	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	36	0.11	0.32	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	27	0.11	0.32	0.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	153	-0.05	0.33	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	138	-0.04	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	41	0.07	0.26	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	32	0.03	0.40	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	133	-0.06	0.38	-1.00	0.00	0.00	0.00	1.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Tofacitinib 10 mg BID	123	-0.02	0.41	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	35	0.09	0.37	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	26	0.04	0.53	-1.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	124	-0.05	0.40	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	115	-0.03	0.37	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	31	0.03	0.41	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	24	0.04	0.46	-1.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	105	-0.11	0.42	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	106	-0.08	0.36	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	27	0.07	0.47	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	20	-0.10	0.55	-1.00	0.00	0.00	0.00	1.00
Sick leave in past 3 months from work due to RA	Month 3	Tofacitinib 5 mg BID	166	0.07	0.40	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	187	0.11	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	46	0.00	0.47	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	41	0.12	0.40	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	183	0.11	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	201	0.15	0.41	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	46	0.15	0.42	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	50	0.12	0.39	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	159	0.12	0.43	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	184	0.13	0.38	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	42	0.19	0.40	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	44	0.14	0.35	0.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	151	0.11	0.39	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	164	0.13	0.42	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	36	0.22	0.42	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	39	0.15	0.37	0.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	130	0.12	0.39	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	143	0.17	0.42	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	30	0.27	0.45	0.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	40	0.10	0.30	0.00	0.00	0.00	0.00	1.00
Number of days on sick leave due to RA	Month 3	Tofacitinib 5 mg BID	11	3.00	5.29	-3.00	-1.00	1.00	8.00	13.00
		Tofacitinib 10 mg BID	10	-6.00	11.19	-29.00	-10.00	-0.50	1.00	3.00
		Placebo→5 mg	6	0.50	1.38	-1.00	0.00	0.00	1.00	3.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 6	Placebo→10 mg	4	-2.00	2.45	-4.00	-4.00	-2.50	0.00	1.00
		Tofacitinib 5 mg BID	10	4.60	13.28	-3.00	0.00	0.50	3.00	42.00
		Tofacitinib 10 mg BID	6	-20.67	30.61	-80.00	-21.00	-11.00	-1.00	0.00
	Month 12	Placebo→5 mg	4	0.00	0.82	-1.00	-0.50	0.00	0.50	1.00
		Placebo→10 mg	4	-1.50	2.08	-4.00	-3.00	-1.50	0.00	1.00
		Tofacitinib 5 mg BID	5	13.60	42.50	-20.00	-2.00	1.00	1.00	88.00
		Tofacitinib 10 mg BID	12	-4.00	7.72	-26.00	-4.00	-1.00	0.00	2.00
		Placebo→5 mg	1	-1.00		-1.00	-1.00	-1.00	-1.00	-1.00
		Placebo→10 mg	4	-1.00	2.94	-5.00	-3.00	-0.50	1.00	2.00
	Month 18	Tofacitinib 5 mg BID	7	13.00	32.88	-4.00	-2.00	0.00	9.00	87.00
		Tofacitinib 10 mg BID	5	1.60	4.28	-2.00	0.00	0.00	1.00	9.00
		Placebo→5 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
	Month 24	Placebo→10 mg	2	-1.00	0.00	-1.00	-1.00	-1.00	-1.00	-1.00
		Tofacitinib 5 mg BID	4	-2.00	8.91	-15.00	-7.50	1.00	3.50	5.00
		Tofacitinib 10 mg BID	3	-7.33	12.74	-22.00	-22.00	-1.00	1.00	1.00
		Placebo→10 mg	4	0.25	1.89	-1.00	-1.00	-0.50	1.50	3.00
Performed part time work in past 3 months due to RA	Month 3	Tofacitinib 5 mg BID	165	0.05	0.37	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	185	0.09	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	46	-0.04	0.29	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	41	0.00	0.22	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	180	0.11	0.39	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	201	0.07	0.37	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	45	0.04	0.30	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	50	0.02	0.32	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	157	0.12	0.36	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	183	0.11	0.35	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	41	0.12	0.33	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	44	0.05	0.21	0.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	150	0.13	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	163	0.08	0.38	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	35	0.06	0.34	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	39	0.08	0.27	0.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	129	0.10	0.37	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	143	0.09	0.33	-1.00	0.00	0.00	0.00	1.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	29	0.10	0.31	0.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	40	0.03	0.28	-1.00	0.00	0.00	0.00	1.00
Number of days performed part time work due to RA	Month 3	Tofacitinib 5 mg BID	9	2.33	11.47	-20.00	-1.00	0.00	7.00	23.00
		Tofacitinib 10 mg BID	4	-20.00	16.51	-40.00	-31.50	-20.00	-8.50	0.00
	Month 6	Placebo→5 mg	4	18.50	28.97	-8.00	-6.50	18.00	43.50	46.00
		Placebo→10 mg	3	-30.00	45.21	-82.00	-82.00	-8.00	0.00	0.00
		Tofacitinib 5 mg BID	3	-14.33	36.35	-55.00	-55.00	-3.00	15.00	15.00
		Tofacitinib 10 mg BID	5	-7.80	13.03	-27.00	-15.00	-2.00	0.00	5.00
		Placebo→5 mg	3	-3.67	77.85	-54.00	-54.00	-43.00	86.00	86.00
		Placebo→10 mg	2	-3.00	5.66	-7.00	-7.00	-3.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	4	-14.25	19.52	-39.00	-29.50	-11.50	1.00	5.00
	Month 18	Placebo→10 mg	2	-1.00	124.45	-89.00	-89.00	-1.00	87.00	87.00
		Tofacitinib 5 mg BID	0							
	Month 24	Tofacitinib 10 mg BID	2	-17.50	7.78	-23.00	-23.00	-17.50	-12.00	-12.00
		Placebo→5 mg	2	-23.50	28.99	-44.00	-44.00	-23.50	-3.00	-3.00
		Tofacitinib 5 mg BID	2	0.50	0.71	0.00	0.00	0.50	1.00	1.00
		Tofacitinib 10 mg BID	4	6.00	30.06	-17.00	-12.50	-4.50	24.50	50.00
Month 24	Placebo→5 mg	2	6.50	7.78	1.00	1.00	6.50	12.00	12.00	
	Placebo→10 mg	1	-87.00		-87.00	-87.00	-87.00	-87.00	-87.00	
Average hours of missed work per day due to RA	Month 3	Tofacitinib 5 mg BID	9	1.67	8.99	-8.00	-3.00	0.00	2.00	24.00
		Tofacitinib 10 mg BID	4	0.00	3.74	-4.00	-2.50	-0.50	2.50	5.00
	Month 6	Placebo→5 mg	4	6.00	10.74	-1.00	0.00	1.50	12.00	22.00
		Placebo→10 mg	3	0.67	2.08	-1.00	-1.00	0.00	3.00	3.00
		Tofacitinib 5 mg BID	3	1.67	2.08	0.00	0.00	1.00	4.00	4.00
		Tofacitinib 10 mg BID	5	-2.80	1.10	-4.00	-3.00	-3.00	-3.00	-1.00
	Month 12	Placebo→5 mg	3	-0.67	1.15	-2.00	-2.00	0.00	0.00	0.00
		Placebo→10 mg	2	-1.50	2.12	-3.00	-3.00	-1.50	0.00	0.00
		Tofacitinib 5 mg BID	0							
	Month 18	Tofacitinib 10 mg BID	4	7.50	15.42	-5.00	-1.50	2.50	16.50	30.00
		Placebo→10 mg	2	-1.00	1.41	-2.00	-2.00	-1.00	0.00	0.00
		Tofacitinib 5 mg BID	0							
		Tofacitinib 10 mg BID	2	17.50	23.33	1.00	1.00	17.50	34.00	34.00
	Month 18	Placebo→5 mg	2	-1.00	1.41	-2.00	-2.00	-1.00	0.00	0.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 24	Tofacitinib 5 mg BID	2	0.00	0.00	0.00	0.00	0.00	0.00	0.00
		Tofacitinib 10 mg BID	4	-1.00	5.23	-5.00	-5.00	-2.50	3.00	6.00
		Placebo→5 mg	2	-1.50	0.71	-2.00	-2.00	-1.50	-1.00	-1.00
		Placebo→10 mg	1	1.00		1.00	1.00	1.00	1.00	1.00
Performed paid work in past 3 months while bothered by RA	Month 3	Tofacitinib 5 mg BID	165	0.18	0.49	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	184	0.16	0.44	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	46	0.11	0.43	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	40	0.13	0.46	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	180	0.22	0.52	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	200	0.16	0.48	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	46	0.07	0.39	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	50	0.20	0.53	-1.00	0.00	0.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	158	0.23	0.46	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	184	0.21	0.46	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	42	0.19	0.55	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	44	0.27	0.50	-1.00	0.00	0.00	1.00	1.00
	Month 18	Tofacitinib 5 mg BID	150	0.26	0.52	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	161	0.17	0.54	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	35	0.20	0.63	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	39	0.33	0.53	-1.00	0.00	0.00	1.00	1.00
	Month 24	Tofacitinib 5 mg BID	128	0.18	0.51	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	143	0.23	0.48	-1.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	29	0.28	0.59	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	40	0.33	0.57	-1.00	0.00	0.00	1.00	1.00
Number of days performed paid work while bothered by RA	Month 3	Tofacitinib 5 mg BID	44	-13.20	34.68	-85.00	-23.50	-1.50	0.50	84.00
		Tofacitinib 10 mg BID	41	-20.12	36.37	-87.00	-46.00	-10.00	1.00	58.00
		Placebo→5 mg	11	19.09	26.78	-8.00	0.00	10.00	41.00	71.00
		Placebo→10 mg	12	-1.00	36.92	-80.00	-11.00	-1.00	8.00	88.00
	Month 6	Tofacitinib 5 mg BID	35	-14.97	36.96	-84.00	-35.00	-3.00	0.00	87.00
		Tofacitinib 10 mg BID	39	-28.13	34.15	-85.00	-55.00	-22.00	0.00	45.00
		Placebo→5 mg	14	-11.36	23.54	-54.00	-20.00	-7.50	0.00	25.00
		Placebo→10 mg	11	-16.45	25.94	-87.00	-19.00	-12.00	0.00	10.00
	Month 12	Tofacitinib 5 mg BID	32	-17.75	37.41	-88.00	-51.50	-6.00	1.00	65.00
		Tofacitinib 10 mg BID	33	-26.94	31.44	-88.00	-53.00	-13.00	0.00	10.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max	
	Month 18	Placebo→5 mg	7	-3.86	41.41	-60.00	-43.00	-2.00	30.00	62.00	
		Placebo→10 mg	10	-16.40	58.13	-87.00	-66.00	-14.00	5.00	85.00	
		Tofacitinib 5 mg BID	26	-20.73	41.56	-85.00	-55.00	-18.50	3.00	82.00	
		Tofacitinib 10 mg BID	24	-24.58	30.10	-75.00	-56.00	-10.00	0.00	23.00	
	Month 24	Placebo→5 mg	6	-16.83	24.21	-45.00	-45.00	-13.00	0.00	15.00	
		Placebo→10 mg	6	-29.17	37.10	-86.00	-64.00	-15.00	0.00	5.00	
		Tofacitinib 5 mg BID	29	-23.14	33.59	-85.00	-48.00	-17.00	0.00	35.00	
		Tofacitinib 10 mg BID	22	-19.09	34.26	-76.00	-50.00	-5.00	3.00	31.00	
	Work performance in past 3 months on days bothered	Month 3	Placebo→5 mg	5	-24.00	49.37	-87.00	-44.00	-20.00	-18.00	49.00
			Placebo→10 mg	6	-31.50	43.54	-88.00	-86.00	-8.50	0.00	2.00
			Tofacitinib 5 mg BID	144	-1.47	3.03	-9.00	-3.00	-1.00	0.00	10.00
			Tofacitinib 10 mg BID	154	-1.73	2.72	-10.00	-3.00	-1.00	0.00	6.00
		Month 6	Placebo→5 mg	40	-0.63	3.03	-9.00	-1.50	0.00	1.00	5.00
			Placebo→10 mg	34	-0.21	2.14	-8.00	-1.00	0.00	1.00	5.00
			Tofacitinib 5 mg BID	149	-1.50	3.49	-10.00	-4.00	-1.00	0.00	10.00
			Tofacitinib 10 mg BID	162	-1.77	3.11	-10.00	-4.00	-1.00	0.00	8.00
Month 12		Placebo→5 mg	43	-0.98	2.42	-9.00	-2.00	-1.00	0.00	5.00	
		Placebo→10 mg	42	-1.52	2.29	-7.00	-3.00	-1.00	0.00	3.00	
		Tofacitinib 5 mg BID	136	-1.82	3.71	-10.00	-4.00	-1.50	0.00	10.00	
		Tofacitinib 10 mg BID	146	-2.12	3.39	-10.00	-5.00	-2.00	0.00	7.00	
Month 18		Placebo→5 mg	36	-2.42	2.96	-9.00	-4.50	-2.50	0.00	5.00	
		Placebo→10 mg	39	-2.08	2.44	-9.00	-4.00	-1.00	0.00	1.00	
		Tofacitinib 5 mg BID	124	-2.27	3.72	-10.00	-5.00	-2.00	0.00	10.00	
		Tofacitinib 10 mg BID	130	-1.98	3.41	-10.00	-4.00	-2.00	0.00	7.00	
Month 24	Placebo→5 mg	32	-2.50	2.55	-10.00	-3.00	-2.00	-1.00	3.00		
	Placebo→10 mg	31	-2.45	2.61	-8.00	-4.00	-3.00	0.00	2.00		
	Tofacitinib 5 mg BID	109	-1.55	3.44	-9.00	-3.00	-2.00	0.00	10.00		
	Tofacitinib 10 mg BID	114	-2.00	3.39	-10.00	-4.00	-2.00	0.00	8.00		
Unable to complete chores in past 3 months due to RA	Month 3	Placebo→5 mg	28	-2.93	2.98	-10.00	-4.50	-2.00	-1.00	2.00	
		Placebo→10 mg	34	-2.29	2.78	-10.00	-4.00	-1.50	0.00	2.00	
		Tofacitinib 5 mg BID	254	0.23	0.51	-1.00	0.00	0.00	1.00	1.00	
		Tofacitinib 10 mg BID	251	0.27	0.57	-1.00	0.00	0.00	1.00	1.00	

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 6	Tofacitinib 5 mg BID	276	0.25	0.52	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	276	0.36	0.56	-1.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	69	0.13	0.57	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	67	0.15	0.50	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	244	0.27	0.51	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	258	0.34	0.53	-1.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	66	0.39	0.52	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	62	0.29	0.49	-1.00	0.00	0.00	1.00	1.00
	Month 18	Tofacitinib 5 mg BID	230	0.34	0.54	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	236	0.37	0.53	-1.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	58	0.29	0.53	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	54	0.24	0.43	0.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	207	0.30	0.54	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	213	0.32	0.53	-1.00	0.00	0.00	1.00	1.00
		Placebo→5 mg	53	0.26	0.49	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	51	0.33	0.48	0.00	0.00	0.00	1.00	1.00
Chores carried out by housekeeper due to RA	Month 3	Tofacitinib 5 mg BID	256	0.08	0.33	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	255	0.07	0.32	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	64	-0.02	0.28	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	57	0.02	0.23	-1.00	0.00	0.00	0.00	1.00
	Month 6	Tofacitinib 5 mg BID	279	0.06	0.38	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	280	0.08	0.34	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	70	-0.01	0.36	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	68	0.01	0.32	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	249	0.08	0.34	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	260	0.09	0.34	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	67	0.04	0.32	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	63	0.10	0.30	0.00	0.00	0.00	0.00	1.00
	Month 18	Tofacitinib 5 mg BID	234	0.08	0.36	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	240	0.09	0.35	-1.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	59	0.07	0.31	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	55	0.05	0.36	-1.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	209	0.09	0.36	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	215	0.07	0.34	-1.00	0.00	0.00	0.00	1.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	54	0.06	0.36	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	52	0.08	0.33	-1.00	0.00	0.00	0.00	1.00
Hours per day chores done by housekeeper	Month 3	Tofacitinib 5 mg BID	20	0.55	3.95	-3.00	-0.50	0.00	0.50	16.00
		Tofacitinib 10 mg BID	13	-0.69	1.65	-5.00	0.00	0.00	0.00	1.00
		Placebo→5 mg	4	1.75	1.26	0.00	1.00	2.00	2.50	3.00
		Placebo→10 mg	4	-1.00	1.15	-2.00	-2.00	-1.00	0.00	0.00
	Month 6	Tofacitinib 5 mg BID	17	-0.12	1.62	-2.00	-1.00	0.00	0.00	5.00
		Tofacitinib 10 mg BID	16	-0.13	2.90	-6.00	-1.50	0.00	2.00	5.00
		Placebo→5 mg	3	0.33	1.53	-1.00	-1.00	0.00	2.00	2.00
		Placebo→10 mg	3	0.67	0.58	0.00	0.00	1.00	1.00	1.00
	Month 12	Tofacitinib 5 mg BID	12	-0.33	1.37	-2.00	-1.00	-0.50	0.00	3.00
		Tofacitinib 10 mg BID	12	-0.33	2.23	-6.00	-1.00	0.00	0.00	4.00
		Placebo→5 mg	2	2.00	0.00	2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	0							
	Month 18	Tofacitinib 5 mg BID	9	0.67	2.24	-2.00	-1.00	0.00	3.00	4.00
		Tofacitinib 10 mg BID	11	0.73	3.55	-2.00	-1.00	0.00	0.00	11.00
		Placebo→5 mg	1	2.00		2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	0							
	Month 24	Tofacitinib 5 mg BID	9	-0.78	2.05	-4.00	-2.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	12	-0.83	1.99	-7.00	-1.00	0.00	0.00	0.00
		Placebo→5 mg	1	2.00		2.00	2.00	2.00	2.00	2.00
		Placebo→10 mg	0							
Number of days chores done by housekeeper	Month 3	Tofacitinib 5 mg BID	20	-1.80	30.01	-69.00	-10.00	0.00	3.00	66.00
		Tofacitinib 10 mg BID	13	-1.77	8.68	-28.00	-2.00	0.00	1.00	11.00
		Placebo→5 mg	4	-18.00	21.95	-46.00	-35.50	-13.00	-0.50	0.00
		Placebo→10 mg	4	3.75	17.67	-8.00	-6.50	-3.50	14.00	30.00
	Month 6	Tofacitinib 5 mg BID	17	-3.41	25.50	-45.00	-12.00	-4.00	0.00	80.00
		Tofacitinib 10 mg BID	16	-15.38	35.02	-120.00	-24.00	-5.50	1.00	33.00
		Placebo→5 mg	3	-10.33	21.46	-35.00	-35.00	0.00	4.00	4.00
		Placebo→10 mg	4	5.75	55.67	-55.00	-28.50	-1.00	40.00	80.00
	Month 12	Tofacitinib 5 mg BID	12	-9.92	23.67	-80.00	-8.00	-2.50	0.00	8.00
		Tofacitinib 10 mg BID	12	-0.67	23.25	-60.00	-6.00	-1.50	5.50	36.00
		Placebo→5 mg	2	-1.50	3.54	-4.00	-4.00	-1.50	1.00	1.00
		Placebo→10 mg	0							
	Month 18	Tofacitinib 5 mg BID	9	8.22	47.61	-85.00	-7.00	0.00	21.00	80.00
		Tofacitinib 10 mg BID	11	-7.18	20.25	-64.00	-6.00	0.00	0.00	11.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
		Placebo→5 mg	1	4.00		4.00	4.00	4.00	4.00	4.00
		Placebo→10 mg	0							
	Month 24	Tofacitinib 5 mg BID	9	-0.78	42.87	-80.00	-5.00	0.00	12.00	80.00
		Tofacitinib 10 mg BID	12	1.58	37.50	-68.00	-13.50	-0.50	4.50	77.00
		Placebo→5 mg	1	0.00		0.00	0.00	0.00	0.00	0.00
		Placebo→10 mg	0							
Chores carried out by family/friends due to RA	Month 3	Tofacitinib 5 mg BID	256	0.18	0.50	-1.00	0.00	0.00	0.00	1.00
		Tofacitinib 10 mg BID	255	0.24	0.53	-1.00	0.00	0.00	1.00	1.00
	Month 6	Placebo→5 mg	64	0.02	0.49	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	57	0.00	0.46	-1.00	0.00	0.00	0.00	1.00
	Month 12	Tofacitinib 5 mg BID	279	0.22	0.51	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	280	0.28	0.52	-1.00	0.00	0.00	1.00	1.00
	Month 18	Placebo→5 mg	70	0.13	0.48	-1.00	0.00	0.00	0.00	1.00
		Placebo→10 mg	68	0.13	0.42	-1.00	0.00	0.00	0.00	1.00
	Month 24	Tofacitinib 5 mg BID	249	0.24	0.49	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	260	0.30	0.51	-1.00	0.00	0.00	1.00	1.00
	Month 3	Placebo→5 mg	67	0.27	0.45	0.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	63	0.22	0.58	-1.00	0.00	0.00	1.00	1.00
	Month 6	Tofacitinib 5 mg BID	234	0.26	0.53	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	240	0.33	0.52	-1.00	0.00	0.00	1.00	1.00
	Month 12	Placebo→5 mg	59	0.25	0.51	-1.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	55	0.20	0.52	-1.00	0.00	0.00	1.00	1.00
	Month 18	Tofacitinib 5 mg BID	209	0.28	0.52	-1.00	0.00	0.00	1.00	1.00
		Tofacitinib 10 mg BID	215	0.27	0.53	-1.00	0.00	0.00	1.00	1.00
	Month 24	Placebo→5 mg	54	0.28	0.45	0.00	0.00	0.00	1.00	1.00
		Placebo→10 mg	52	0.27	0.53	-1.00	0.00	0.00	1.00	1.00
Hours per day chores done by family/friends	Month 3	Tofacitinib 5 mg BID	70	0.20	10.31	-22.00	-1.00	0.00	1.00	77.00
		Tofacitinib 10 mg BID	56	-0.02	6.03	-21.00	-1.00	0.00	1.00	32.00
	Month 6	Placebo→5 mg	24	0.58	7.28	-22.00	0.00	1.00	1.50	22.00
		Placebo→10 mg	19	-0.37	1.54	-3.00	-1.00	0.00	1.00	3.00
	Month 12	Tofacitinib 5 mg BID	70	-1.13	3.76	-22.00	-2.00	-1.00	0.00	7.00
		Tofacitinib 10 mg BID	57	-0.54	5.32	-21.00	-2.00	0.00	1.00	22.00
	Month 18	Placebo→5 mg	22	-1.41	5.21	-19.00	-1.00	0.00	0.00	6.00
		Placebo→10 mg	17	0.41	2.18	-2.00	-1.00	0.00	1.00	6.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
	Month 12	Tofacitinib 5 mg BID	55	-0.60	4.30	-22.00	-2.00	0.00	1.00	10.00
		Tofacitinib 10 mg BID	50	-1.18	5.32	-28.00	-2.00	-0.50	1.00	4.00
		Placebo→5 mg	16	-2.19	6.19	-20.00	-1.50	-0.50	0.00	6.00
		Placebo→10 mg	8	-0.50	1.31	-2.00	-2.00	0.00	0.50	1.00
	Month 18	Tofacitinib 5 mg BID	45	-0.78	3.74	-22.00	-2.00	0.00	1.00	4.00
		Tofacitinib 10 mg BID	38	-1.47	3.87	-22.00	-2.00	-1.00	0.00	3.00
		Placebo→5 mg	11	-2.64	6.90	-19.00	-2.00	0.00	1.00	4.00
		Placebo→10 mg	9	0.67	1.66	-1.00	0.00	0.00	0.00	4.00
	Month 24	Tofacitinib 5 mg BID	41	-1.66	5.17	-22.00	-2.00	-1.00	1.00	4.00
		Tofacitinib 10 mg BID	41	-0.83	3.89	-22.00	-2.00	0.00	0.00	7.00
		Placebo→5 mg	11	-3.00	7.66	-21.00	-2.00	0.00	1.00	3.00
		Placebo→10 mg	5	0.60	1.52	-1.00	0.00	0.00	1.00	3.00
Number of days chores done by family/friends	Month 3	Tofacitinib 5 mg BID	71	-8.44	32.47	-83.00	-25.00	-3.00	0.00	88.00
		Tofacitinib 10 mg BID	56	-12.89	32.72	-88.00	-19.00	-1.50	0.00	89.00
		Placebo→5 mg	25	-7.96	44.22	-88.00	-23.00	0.00	0.00	88.00
		Placebo→10 mg	19	-0.79	27.41	-70.00	-10.00	-1.00	3.00	83.00
	Month 6	Tofacitinib 5 mg BID	71	-11.85	37.20	-88.00	-29.00	0.00	2.00	88.00
		Tofacitinib 10 mg BID	56	-11.52	45.47	-120.00	-37.50	-3.00	1.00	87.00
		Placebo→5 mg	22	-10.86	32.88	-83.00	-11.00	-2.50	0.00	60.00
		Placebo→10 mg	18	-3.17	36.39	-80.00	-16.00	-2.50	1.00	83.00
	Month 12	Tofacitinib 5 mg BID	55	-10.58	34.76	-85.00	-24.00	0.00	3.00	80.00
		Tofacitinib 10 mg BID	50	-12.56	44.62	-86.00	-33.00	-4.50	3.00	84.00
		Placebo→5 mg	16	-15.94	40.19	-89.00	-37.50	-4.00	0.00	83.00
		Placebo→10 mg	8	0.38	23.71	-25.00	-13.00	-2.50	2.50	54.00
	Month 18	Tofacitinib 5 mg BID	45	-7.93	38.39	-80.00	-20.00	-5.00	4.00	80.00
		Tofacitinib 10 mg BID	38	0.21	44.56	-85.00	-10.00	0.00	10.00	85.00
		Placebo→5 mg	11	-18.00	26.28	-83.00	-23.00	-8.00	-1.00	0.00
		Placebo→10 mg	9	-25.22	41.90	-84.00	-55.00	-22.00	-6.00	54.00
	Month 24	Tofacitinib 5 mg BID	41	-10.32	40.04	-84.00	-35.00	-5.00	0.00	82.00
		Tofacitinib 10 mg BID	41	-14.22	37.75	-87.00	-31.00	-3.00	4.00	83.00
		Placebo→5 mg	11	-28.18	44.96	-87.00	-78.00	-6.00	0.00	48.00
		Placebo→10 mg	5	9.00	27.26	-15.00	-10.00	6.00	10.00	54.00

Table 167. Descriptive Statistics of Change From Baseline of RA-HCRU (RA Healthcare Resource Utilization Questionnaire) per Visit, Within Sequence Comparisons, 2-Year Analysis

Scale	Visit	Treatment	N	Mean	St Dev	Min	Q1	Q2	Q3	Max
Tofacitinib 5mg BID or tofacitinib 10mg BID subjects received this dose from Day 1; placebo subjects received this dose from Day 1 to either Month 3 or Month 6; placebo→5mg BID or placebo→10mg BID subjects received placebo from Day 1 to either Month 3 or Month 6 then changed to either tofacitinib 5mg BID or tofacitinib 10 mg BID. BID = twice daily; ER = emergency room; Max = maximum; Min = minimum; N = number of subjects; Q1 = first quartile; Q2 = second quartile; Q3 = third quartile; RA = rheumatoid arthritis; RA-HCRU = RA Healthcare Resource Utilization Questionnaire; St Dev = standard deviation.										

Safety Results:

Non-Serious Adverse Events: The most common non-serious AEs (all causality) from Baseline to Month 3 are presented in Table 168. From Baseline to Month 3, the most commonly experienced treatment emergent AE (TEAEs) by preferred term for the tofacitinib 5 mg dose were headache and nasopharyngitis. The most commonly experienced TEAEs for the tofacitinib 10 mg dose were nasopharyngitis, cough, diarrhea and upper respiratory tract infection. The most commonly experienced TEAEs for placebo were upper respiratory tract infection, arthralgia and rheumatoid arthritis. The most common treatment-related AEs from Baseline to Month 3 are presented in Table 169.

Table 168. Summary of Treatment Emergent Non-Serious Adverse Events From Baseline to Month 3 For Events With Frequency ≥2%

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)
No. of subjects with AEs; n (%)	70 (21.8)	50 (15.8)	20 (12.5)
Gastrointestinal disorders	13 (4.0)	10 (3.2)	4 (2.5)
Diarrhoea	7 (2.2)	8 (2.5)	2 (1.3)
Nausea	7 (2.2)	3 (0.9)	2 (1.3)
Infections and infestations	32 (10.0)	25 (7.9)	9 (5.6)
Nasopharyngitis	14 (4.4)	14 (4.4)	1 (0.6)
Upper respiratory tract infection	9 (2.8)	8 (2.5)	5 (3.1)
Urinary tract infection	9 (2.8)	3 (0.9)	3 (1.9)
Musculoskeletal and connective tissue disorders	5 (1.6)	3 (0.9)	5 (3.1)
Arthralgia	5 (1.6)	3 (0.9)	5 (3.1)
Nervous system disorders	18 (5.6)	4 (1.3)	3 (1.9)
Headache	18 (5.6)	4 (1.3)	3 (1.9)
Respiratory, thoracic and mediastinal disorders	1 (0.3)	8 (2.5)	1 (0.6)
Cough	1 (0.3)	8 (2.5)	1 (0.6)
Vascular disorders	11 (3.4)	4 (1.3)	1 (0.6)
Hypertension	11 (3.4)	4 (1.3)	1 (0.6)

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v13.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with adverse events; No = number; v = version.

Table 169. Summary of Treatment-Related Adverse Events From Baseline to Month 3 For Events With Frequency ≥1%

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)
Gastrointestinal disorders	30 (9.3)	19 (6.0)	11 (6.9)
Diarrhoea	2 (0.6)	1 (0.3)	2 (1.3)
Dyspepsia	5 (1.6)	3 (0.9)	2 (1.3)
Gastric ulcer	4 (1.2)	0	0
Nausea	4 (1.2)	1 (0.3)	1 (0.6)
Vomiting	3 (0.9)	0	2 (1.3)
General disorders and administration site conditions	9 (2.8)	3 (0.9)	3 (1.9)
Oedema peripheral	2 (0.6)	1 (0.3)	2 (1.3)
Infections and infestations	33 (10.3)	40 (12.7)	10 (6.3)
Herpes zoster	1 (0.3)	5 (1.6)	0
Nasopharyngitis	8 (2.5)	7 (2.2)	1 (0.6)
Sinusitis	2 (0.6)	1 (0.3)	2 (1.3)
Upper respiratory tract infection	4 (1.2)	1 (0.3)	1 (0.6)
Urinary tract infection	4 (1.2)	1 (0.3)	2 (1.3)
Investigations	16 (5.0)	23 (7.3)	5 (3.1)
Blood creatine phosphokinase increased	0	4 (1.3)	0
Weight increased	5 (1.6)	4 (1.3)	1 (0.6)
Metabolism and nutrition disorders	7 (2.2)	11 (3.5)	3 (1.9)
Dyslipidaemia	0	2 (0.6)	2 (1.3)
Hypercholesterolaemia	4 (1.2)	6 (1.9)	0
Musculoskeletal and connective tissue disorders	3 (0.9)	1 (0.3)	7 (4.4)
Rheumatoid arthritis	1 (0.3)	0	3 (1.9)
Nervous system disorders	20 (6.2)	8 (2.5)	4 (2.5)
Dizziness	5 (1.6)	1 (0.3)	2 (1.3)
Headache	14 (4.4)	1 (0.3)	2 (1.3)
Skin and subcutaneous tissue disorders	6 (1.9)	13 (4.1)	6 (3.8)
Alopecia	1 (0.3)	3 (0.9)	2 (1.3)
Rash	0	4 (1.3)	1 (0.6)
Vascular disorders	7 (2.2)	2 (0.6)	1 (0.6)
Hypertension	6 (1.9)	1 (0.3)	1 (0.6)

AEs and SAEs have not been separated out.

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities;

N = number of subjects; SAE = serious adverse event; v = version.

From Months 3 to 6, the most commonly experienced TEAEs by preferred term for the tofacitinib 5 mg sequence were upper respiratory tract infection and nasopharyngitis. The most commonly experienced TEAEs for the tofacitinib 10 mg sequence were upper respiratory tract infection, bronchitis and nasopharyngitis. The most commonly experienced TEAEs for subjects receiving placebo from Months 3 to 6 were nasopharyngitis and urinary

tract infection. The most common non-serious adverse events from Month 3 to Month 6 are presented in Table 170. The most common treatment-related AEs from Month 3 to Month 6 are presented in Table 171.

Table 170. Summary of Treatment Emergent Non-Serious Adverse Events From Month 3 to Month 6 For Events With Frequency $\geq 2\%$

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=363)	Tofacitinib 10 mg BID (N=353)	Placebo (N=81)
Number of subjects with AEs; n (%)	38 (10.5)	30 (8.5)	6 (7.4)
Infections and infestations	38 (10.5)	30 (8.5)	6 (7.4)
Bronchitis	3 (0.8)	9 (2.5)	0
Nasopharyngitis	13 (3.6)	9 (2.5)	4 (4.9)
Upper respiratory tract infection	17 (4.7)	10 (2.8)	0
Urinary tract infection	6 (1.7)	2 (0.6)	2 (2.5)

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

Table 171. Summary of Treatment-Related Adverse Events From Month 3 to Month 6 For Events With Frequency $\geq 1\%$

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=81)	Placebo → Tofacitinib 5 mg BID (N=42)	Placebo → Tofacitinib 10 mg BID (N=37)
Blood and lymphatic system disorders	2 (0.6)	2 (0.6)	0	2 (4.8)	1 (2.7)
Iron deficiency anaemia	0	0	0	1 (2.4)	0
Leukopenia	0	0	0	1 (2.4)	1 (2.7)
Neutropenia	0	0	0	1 (2.4)	0
Cardiac disorders	0	0	1 (1.2)	0	0
Cardiac arrest	0	0	1 (1.2)	0	0
Ear and labyrinth disorders	2 (0.6)	0	0	1 (2.4)	0
Tinnitus	1 (0.3)	0	0	1 (2.4)	0
Eye disorders	2 (0.6)	0	0	1 (2.4)	0
Conjunctivitis	0	0	0	1 (2.4)	0
Gastrointestinal disorders	7 (2.2)	6 (1.9)	2 (2.5)	0	3 (8.1)
Constipation	2 (0.6)	0	0	0	1 (2.7)
Dyspepsia	1 (0.3)	0	1 (1.2)	0	0
Gastric ulcer	0	0	1 (1.2)	0	0
Stomatitis	0	0	0	0	2 (5.4)
Hepatobiliary disorders	1 (0.3)	0	0	1 (2.4)	1 (2.7)
Hepatotoxicity	0	0	0	1 (2.4)	0
Hypertransaminasaemia	0	0	0	0	1 (2.7)
Infections and infestations	55 (17.1)	33 (10.4)	5 (6.2)	4 (9.5)	6 (16.2)
Asymptomatic bacteriuria	0	0	1 (1.2)	0	0
Bacterial sepsis	0	0	1 (1.2)	0	0
Bronchitis	2 (0.6)	2 (0.6)	0	0	1 (2.7)
Herpes zoster	4 (1.2)	2 (0.6)	0	0	2 (5.4)
Nasopharyngitis	10 (3.1)	7 (2.2)	2 (2.5)	1 (2.4)	1 (2.7)
Oral herpes	2 (0.6)	0	0	1 (2.4)	0
Pyelonephritis	0	0	1 (1.2)	0	0
Sinusitis	4 (1.2)	2 (0.6)	0	0	0
Upper respiratory tract infection	11 (3.4)	1 (0.3)	0	2 (4.8)	3 (8.1)
Urinary tract infection	3 (0.9)	2 (0.6)	1 (1.2)	1 (2.4)	0
Vaginal infection	0	0	0	0	1 (2.7)
Investigations	17 (5.3)	15 (4.7)	1 (1.2)	2 (4.8)	0
Alanine aminotransferase increased	6 (1.9)	4 (1.3)	0	1 (2.4)	0
Aspartate aminotransferase increased	4 (1.2)	5 (1.6)	0	1 (2.4)	0
Blood creatine phosphokinase increased	1 (0.3)	1 (0.3)	0	1 (2.4)	0
Platelet count decreased	0	0	0	1 (2.4)	0
Weight increased	4 (1.2)	4 (1.3)	1 (1.2)	0	0
Metabolism and nutrition disorders	2 (0.6)	6 (1.9)	1 (1.2)	2 (4.8)	0
Hypercholesterolaemia	1 (0.3)	3 (0.9)	1 (1.2)	1 (2.4)	0
Hyperlipidaemia	1 (0.3)	0	0	1 (2.4)	0
Musculoskeletal and connective tissue disorders	2 (0.6)	1 (0.3)	0	1 (2.4)	2 (5.4)
Back pain	0	0	0	0	1 (2.7)
Muscle spasms	0	0	0	1 (2.4)	0
Pain in extremity	0	0	0	0	1 (2.7)

Table 171. Summary of Treatment-Related Adverse Events From Month 3 to Month 6 For Events With Frequency $\geq 1\%$

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=81)	Placebo → Tofacitinib 5 mg BID (N=42)	Placebo → Tofacitinib 10 mg BID (N=37)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.3)	1 (0.3)	1 (1.2)	0	0
Basal cell carcinoma	0	0	1 (1.2)	0	0
Nervous system disorders	1 (0.3)	5 (1.6)	1 (1.2)	1 (2.4)	2 (5.4)
Headache	0	1 (0.3)	0	1 (2.4)	0
Hypoaesthesia	0	0	0	0	1 (2.7)
Post herpetic neuralgia	0	0	0	0	1 (2.7)
Somnolence	0	1 (0.3)	0	0	1 (2.7)
Uraemic encephalopathy	0	0	1 (1.2)	0	0
Renal and urinary disorders	3 (0.9)	0	1 (1.2)	0	0
Diabetic nephropathy	0	0	1 (1.2)	0	0
Hydronephrosis	0	0	1 (1.2)	0	0
Renal failure acute	0	0	1 (1.2)	0	0
Vascular disorders	2 (0.6)	2 (0.6)	0	1 (2.4)	0
Hypertension	1 (0.3)	2 (0.6)	0	1 (2.4)	0

AEs and SAEs have not been separated out.

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; incl = including; MedDRA = Medical Dictionary for Regulatory Activities; N = number of subjects; SAE = serious adverse event; v = version.

Post Month 6 to Month 24 the most commonly experienced TEAEs by preferred term for the tofacitinib 5 mg and 10 mg sequences were nasopharyngitis and upper respiratory tract infection. The most common non-serious adverse events are presented in Table 172.

Table 172. Summary of Treatment Emergent Non-Serious Adverse Events Post Month 6 to Month 24 For Events With Frequency $\geq 2\%$

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=402)	Tofacitinib 10 mg BID (N=395)
Number of subjects with AEs; n (%)	196 (48.8)	207 (52.4)
Blood and lymphatic system disorders	12 (3.0)	13 (3.3)
Anaemia	12 (3.0)	13 (3.3)
Gastrointestinal disorders	36 (9.0)	38 (9.6)
Constipation	9 (2.2)	6 (1.5)
Diarrhoea	9 (2.2)	13 (3.3)
Dyspepsia	5 (1.2)	9 (2.3)
Gastritis	5 (1.2)	8 (2.0)
Nausea	9 (2.2)	8 (2.0)
General disorders and administration site conditions	8 (2.0)	9 (2.3)
Oedema peripheral	8 (2.0)	9 (2.3)
Infections and infestations	126 (31.3)	149 (37.7)
Bronchitis	16 (4.0)	20 (5.1)
Herpes zoster	18 (4.5)	27 (6.8)
Influenza	4 (1.0)	13 (3.3)
Nasopharyngitis	54 (13.4)	42 (10.6)
Pharyngitis	4 (1.0)	12 (3.0)
Sinusitis	12 (3.0)	7 (1.8)
Upper respiratory tract infection	30 (7.5)	39 (9.9)
Urinary tract infection	16 (4.0)	30 (7.6)
Injury, poisoning and procedural complications	15 (3.7)	10 (2.5)
Fall	15 (3.7)	10 (2.5)
Investigations	33 (8.2)	29 (7.3)
Alanine aminotransferase increased	16 (4.0)	15 (3.8)
Aspartate aminotransferase increased	16 (4.0)	11 (2.8)
Blood creatine phosphokinase increased	9 (2.2)	9 (2.3)
Weight increased	8 (2.0)	7 (1.8)
Metabolism and nutrition disorders	1 (0.2)	8 (2.0)
Hyperlipidaemia	1 (0.2)	8 (2.0)
Musculoskeletal and connective tissue disorders	35 (8.7)	23 (5.8)
Arthralgia	15 (3.7)	9 (2.3)
Back pain	15 (3.7)	13 (3.3)
Osteoarthritis	9 (2.2)	3 (0.8)
Nervous system disorders	10 (2.5)	10 (2.5)
Headache	10 (2.5)	10 (2.5)
Respiratory, thoracic and mediastinal disorders	16 (4.0)	20 (5.1)
Cough	15 (3.7)	12 (3.0)
Oropharyngeal pain	1 (0.2)	9 (2.3)
Skin and subcutaneous tissue disorders	9 (2.2)	14 (3.5)
Rash	9 (2.2)	14 (3.5)
Vascular disorders	19 (4.7)	16 (4.1)
Hypertension	19 (4.7)	16 (4.1)

Table 172. Summary of Treatment Emergent Non-Serious Adverse Events Post Month 6 to Month 24 For Events With Frequency $\geq 2\%$

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; No. = number; v = version.

The treatment-related AEs from Month 6 to Month 24 are presented in Table 173. The Medical Dictionary for Regulatory Activities (MedDRA) System Organ Classes (SOCs) with the most common treatment-related TEAEs from Month 6 to Month 24 were infections and infestations, investigations, and gastrointestinal disorders. The most commonly experienced treatment-related TEAEs for the tofacitinib 5 mg and 10 mg sequences were nasopharyngitis (32/321 [10.0%] and 24/316 [7.6%] subjects, respectively) and upper respiratory tract infection (18/321 [5.6%] and 20/316 [6.3%] subjects, respectively). The most commonly experienced treatment-related TEAEs for the placebo→tofacitinib 5 mg sequence were nasopharyngitis and upper respiratory tract infection (each in 5/79 [6.2%] subjects). The most commonly experienced treatment-related TEAEs for the placebo→tofacitinib 10 mg sequence were upper respiratory tract infection (8/81 [10.1%] subjects) and nasopharyngitis (6/81 [7.6%] subjects).

Table 173. Most Frequent Treatment-Emergent (Treatment-Related) AEs by System Organ Class and Preferred Term (≥2% of Subjects in Any Treatment Sequence, Post Month 6 to Month 24)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo → Tofacitinib 5 mg BID (N=79)	Placebo → Tofacitinib 10 mg BID (N=81)
Number of subjects with AEs; n (%)	160 (49.8)	165 (52.2)	30 (37.0)	36 (45.6)
Blood and lymphatic system disorders				
Anemia	4 (1.2)	8 (2.5)	1 (1.2)	1 (1.3)
Gastrointestinal disorders				
Constipation	6 (1.9)	3 (0.9)	2 (2.5)	0
Diarrhea	4 (1.2)	3 (0.9)	1 (1.2)	2 (2.5)
Infections and infestations				
Bronchitis	6 (1.9)	6 (1.9)	2 (2.5)	2 (2.5)
Herpes zoster	14 (4.4)	22 (7.0)	3 (3.7)	3 (3.8)
Influenza	1 (0.3)	7 (2.2)	1 (1.2)	0
Nasopharyngitis	32 (10.0)	24 (7.6)	5 (6.2)	6 (7.6)
Pharyngitis	3 (0.9)	8 (2.5)	0	1 (1.3)
Pneumonia	7 (2.2)	3 (0.9)	1 (1.2)	1 (1.3)
Sinusitis	8 (2.5)	1 (0.3)	1 (1.2)	1 (1.3)
Upper respiratory tract infection	18 (5.6)	20 (6.3)	5 (6.2)	8 (10.1)
Urinary tract infection	10 (3.1)	17 (5.4)	2 (2.5)	1 (1.3)
Investigations				
Alanine aminotransferase increased	9 (2.8)	8 (2.5)	2 (2.5)	3 (3.8)
Aspartate aminotransferase increased	9 (2.8)	5 (1.6)	2 (2.5)	3 (3.8)
Hepatic enzyme increased	2 (0.6)	2 (0.6)	1 (1.2)	2 (2.5)
Metabolism and nutrition disorders				
Hypercholesterolemia	5 (1.6)	5 (1.6)	1 (1.2)	2 (2.5)
Skin and subcutaneous tissue disorders				
Dermatitis contact	0	0	2 (2.5)	0
Rash	5 (1.6)	9 (2.8)	2 (2.5)	1 (1.3)
Vascular disorders				
Hypertension	3 (0.9)	7 (2.2)	2 (2.5)	0

AEs and SAEs have not been separated out.

Subjects in the placebo→tofacitinib 5 mg and placebo→tofacitinib 10 mg sequences received only tofacitinib during this time period from post Month 6 to Month 24.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

Serious Adverse Events: Table 174, Table 175, and Table 176 present SAEs by treatment as reported in the study database for Baseline to Month 3, Months 3 to 6, and post Month 6 to Month 24, respectively. The most frequently reported SAEs from Baseline to Month 3, Months 3 to 6, and post Month 6 were in the infections and infestations MedDRA SOC.

Table 174. Summary of Serious Adverse Events From Baseline to Month 3

Number (%) of Subjects With SAEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)
Number of subjects with SAEs; n (%)	11 (3.4)	6 (1.9)	5 (3.1)
Cardiac disorders	1 (0.3)	0	0
Angina pectoris	1 (0.3)	0	0
General disorders and administration site conditions	1 (0.3)	2 (0.6)	0
Device breakage	0	1 (0.3)	0
Noncardiac chest pain	0	1 (0.3)	0
Pyrexia	1 ^a (0.3)	0	0
Hepatobiliary disorders	1 (0.3)	0	0
Cholelithiasis	1 (0.3)	0	0
Infections and infestations	4 (1.2)	1 (0.3)	0
Dengue fever	1 (0.3)	0	0
Influenza	0	1 ^a (0.3)	0
<i>Pneumocystis jiroveci</i> pneumonia	1 ^a (0.3)	0	0
Pneumonia	1 (0.3)	0	0
Pneumonia viral	1 ^a (0.3)	0	0
Injury, poisoning, and procedural complications	2 (0.6)	1 (0.3)	2 (1.3)
Ankle fracture	1 (0.3)	0	0
Concussion	0	1 (0.3)	0
Contusion	0	0	1 (0.6)
Ligament sprain	0	1 (0.3)	0
Road traffic accident	0	1 (0.3)	1 (0.6)
Thoracic vertebral fracture	1 (0.3)	0	0
Tibia fracture	0	0	1 (0.6)
Musculoskeletal and connective tissue disorders	0	2 (0.6)	2 (1.3)
Fracture nonunion	0	1 (0.3)	0
Inguinal mass	0	0	1 ^b (0.6)
Osteoarthritis	0	1 (0.3)	0
Rheumatoid arthritis	0	0	1 (0.6)
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	1 (0.3)	0	0
Basal cell carcinoma	1 ^b (0.3)	0	0
Nervous system disorders	0	1 (0.3)	1 (0.6)
Carotid artery disease	0	1 (0.3)	0
Carotid artery stenosis	0	1 (0.3)	0
Polyneuropathy	0	0	1 (0.6)
Reproductive system and breast disorders	1 (0.3)	0	0
Endometriosis	1 (0.3)	0	0
Respiratory, thoracic, and mediastinal disorders	1 (0.3)	0	0
Acute respiratory distress syndrome	1 ^a (0.3)	0	0
Skin and subcutaneous tissue disorders	1 (0.3)	0	0
Skin ulcer	1 (0.3)	0	0

Table 174. Summary of Serious Adverse Events From Baseline to Month 3

Subjects are only counted once per treatment for each row.

Subjects might have reported more than 1 SAE.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with SAEs; SAE = serious adverse event; v = version.

a. Treatment-related.

b. The Investigator considered the SAE treatment-related; the Sponsor considered it unrelated.

Table 175. Summary of Serious Adverse Events From Month 3 to Month 6

Number (%) of Subjects With SAEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=363)	Tofacitinib 10 mg BID (N=353)	Placebo (N=81)
Number of subjects with SAEs; n (%)	13 (3.6)	9 (2.5)	5 (6.2)
Blood and lymphatic system disorders	1 (0.3)	0	0
Leukocytosis	1 ^a (0.3)	0	0
Thrombocytopenia	1 ^a (0.3)	0	0
Cardiac disorders	1 (0.3)	0	1 (1.2)
Cardiac arrest	0	0	1 ^b (1.2)
Coronary artery disease	1 (0.3)	0	0
Hepatobiliary disorders	1 (0.3)	0	0
Hepatosplenomegaly	1 ^a (0.3)	0	0
Infections and infestations	4 (1.1)	3 (0.8)	1 (1.2)
Bacterial sepsis	0	0	1 (1.2)
Cellulitis	2 ^c (0.6)	0	0
Cytomegalovirus viremia	0	1 ^a (0.3)	0
Enterocolitis bacterial	0	1 ^a (0.3)	0
Herpes zoster	1 (0.3)	0	0
Pyelonephritis	0	0	1 ^b (1.2)
Sepsis	1 ^a (0.3)	0	0
Sialoadenitis	0	1 ^a (0.3)	0
Injury, poisoning, and procedural complications	4 (1.2)	2 (0.6)	1 (1.2)
Femur fracture	1 (0.3)	0	0
Fracture	1 (0.3)	0	0
Maternal exposure during pregnancy ^d	1 ^a (0.3)	0	0
Radius fracture	0	1 (0.3)	0
Spinal fracture	1 (0.3)	0	0
Subdural hematoma	0	1 (0.3)	0
Upper limb fracture	0	0	1 (1.2)
Musculoskeletal and connective tissue disorders	4 (1.1)	2 (0.6)	0
Arthralgia	1 (0.3)	0	0
Back pain	1 (0.3)	0	0
Intervertebral disc protrusion	1 (0.3)	0	0
Osteoarthritis	0	1 (0.3)	0
Osteonecrosis	1 (0.3)	0	0
Spinal column stenosis	0	1 (0.3)	0
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	1 (0.3)	2 (0.6)	2 (2.5)
Basal cell carcinoma	0	0	1 ^a (1.2)
Breast cancer	0	1 ^a (0.3)	0
Metastatic squamous cell carcinoma	1 (0.3)	0	0
Ovarian granulosa-theca cell tumor	0	0	1 (1.2)
Squamous cell carcinoma of the cervix	0	1 (0.3)	0
Nervous system disorders	0	1 (0.3)	1 (1.2)
Lacunar infarction	0	1 (0.3)	0
Uraemic encephalopathy	0	0	1 ^b (1.2)
Renal and urinary disorders	1 (0.3)	0	1 (1.2)
Diabetic nephropathy	0	0	1 ^b (1.2)
Hydronephrosis	0	0	1 ^b (1.2)
Nephrolithiasis	1 (0.3)	0	0
Renal failure acute	0	0	1 (1.2)
Reproductive system and breast disorders	0	0	1 (1.2)
Metrorrhagia	0	0	1 (1.2)

Table 175. Summary of Serious Adverse Events From Month 3 to Month 6

Number (%) of Subjects With SAEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=363)	Tofacitinib 10 mg BID (N=353)	Placebo (N=81)
Respiratory, thoracic, and mediastinal disorders	0	1 (0.3)	1 (1.2)
Aspiration	0	1 (0.3)	0
Bronchiectasis	0	0	1 (1.2)

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with SAEs; SAE = serious adverse event; v = version.

- a. Treatment-related.
- b. The Investigator considered the SAE treatment-related; the Sponsor considered it unrelated.
- c. Both SAEs considered treatment-related.
- d. This is not considered an SAE in the safety database.

Table 176. Summary of Serious Adverse Events Post Month 6 to Month 24

Number (%) of Subjects With SAEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=402)	Tofacitinib 10 mg BID (N=395)
Number of subjects with SAEs; n (%)	57 (14.2)	47 (11.9)
Blood and lymphatic system disorders	0	1 (0.3)
Anemia	0	1 ^a (0.3)
Cardiac disorders	5 (1.2)	3 (0.8)
Acute myocardial infarction	1 (0.2)	0
Angina unstable	0	1 (0.3)
Bundle branch block right	1 ^a (0.2)	0
Cardiac arrest	1 ^b (0.2)	0
Cardiac failure	1 (0.2)	1 ^a (0.3)
Cardiac failure congestive	1 (0.2)	0
Myocardial infarction	0	2 ^c (0.5)
Ear and labyrinth disorders	1 (0.2)	0
Tympanic membrane perforation	1 (0.2)	0
Eye disorders	0	1 (0.3)
Necrotizing retinitis	0	1 (0.3)
Gastrointestinal disorders	4 (1.0)	4 (1.0)
Colitis ischemic	0	1 (0.3)
Colonic polyp	1 (0.2)	0
Enterocolitis	0	1 ^a (0.3)
Gastritis	1 ^a (0.2)	0
Gastritis erosive	0	1 ^a (0.3)
Hematemesis	0	1 ^a (0.3)
Ileus	1 (0.2)	0
Impaired gastric emptying	0	1 (0.3)
Umbilical hernia	1 (0.2)	0
General disorders and administration site conditions	0	4 (1.0)
Chest pain	0	3 (0.8)
Drug ineffective	0	1 ^a (0.3)
Drug interaction	0	1 ^a (0.3)
Hepatobiliary disorders	3 (0.7)	1 (0.3)
Biliary colic	1 (0.2)	0
Cholecystitis	0	1 (0.3)
Cholecystitis acute	1 (0.2)	0
Cholelithiasis	1 (0.2)	0
Infections and infestations	16 (4.0)	17 (4.3)
Abscess limb	0	1 ^a (0.3)
Arthritis bacterial	0	1 ^a (0.3)
Bronchitis bacterial	0	1 (0.3)
Bronchopneumonia	1 (0.2)	0
Disseminated tuberculosis	0	1 (0.3)
Diverticulitis	0	1 (0.3)
Gastroenteritis	0	1 ^a (0.3)
Herpes zoster	1 (0.2)	3 ^a (0.8)
Intervertebral discitis	1 ^a (0.2)	0
Lower respiratory tract infection	1 ^a (0.2)	0
Lymph node tuberculosis	0	1 ^a (0.3)
Pericarditis tuberculous	0	1 ^a (0.3)
Pneumonia	9 ^d (2.2)	3 ^c (0.8)
Pneumonia primary atypical	1 ^a (0.2)	0
Pyelonephritis acute	1 (0.2)	0
Tuberculous pleurisy	0	1 ^a (0.3)

Table 176. Summary of Serious Adverse Events Post Month 6 to Month 24

Number (%) of Subjects With SAEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=402)	Tofacitinib 10 mg BID (N=395)
Upper respiratory tract infection	0	1 (0.3)
Urinary tract infection	1 (0.2)	4 ^f (1.0)
Injury, poisoning, and procedural complications	5 (1.2)	6 (1.5)
Dislocation of vertebra	0	1 (0.3)
Fall	1 (0.2)	0
Femur fracture	0	1 (0.3)
Foot fracture	1 (0.2)	0
Humerus fracture	1 (0.2)	2 (0.5)
Ilium fracture	1 (0.2)	0
Injury	0	1 (0.3)
Laceration	1 (0.2)	0
Meniscus lesion	1 (0.2)	0
Spinal compression fracture	0	1 (0.3)
Investigations	1 (0.2)	0
Transaminases increased	1 (0.2)	0
Musculoskeletal and connective tissue disorders	10 (2.5)	7 (1.8)
Arthralgia	1 (0.2)	2 (0.5)
Intervertebral disc protrusion	0	2 (0.5)
Lumbar spinal stenosis	0	1 (0.3)
Musculoskeletal chest pain	1 (0.2)	0
Osteoarthritis	3 (0.7)	1 (0.3)
Osteonecrosis	1 (0.2)	0
Rheumatoid arthritis	3 (0.7)	0
Spinal column stenosis	0	1 (0.3)
Spinal osteoarthritis	1 (0.2)	0
Neoplasms benign, malignant and unspecified (including cysts and polyps)	6 (1.5)	6 (1.5)
Breast cancer	1 ^a (0.2)	0
Cervix carcinoma	1 ^a (0.2)	0
Cervix carcinoma Stage 0	0	1 ^a (0.3)
Diffuse large B-cell lymphoma	0	1 ^a (0.3)
Lung cancer metastatic	1 ^a (0.2)	0
Lung neoplasm malignant	0	1 (0.3)
Lymphoma	0	1 ^a (0.3)
Metastatic gastric cancer	0	1 ^a (0.3)
Prostate cancer	2 (0.5)	0
Uterine leiomyoma	1 (0.2)	1 (0.3)
Nervous system disorders	2 (0.5)	3 (0.8)
Cervical myelopathy	0	1 (0.3)
Sciatica	1 (0.2)	1 (0.3)
Transient ischemic attac	0	1 (0.3)
Ulnar tunnel syndrome	1 (0.2)	0
Pregnancy, puerperium, and perinatal conditions	0	1 (0.3)
Abortion missed	0	1 ^a (0.3)
Unintended pregnancy	0	1 ^a (0.3)
Psychiatric disorders	0	1 (0.3)
Depression	0	1 (0.3)
Renal and urinary disorders	4 (1.0)	2 (0.5)
Nephrolithiasis	3 (0.7)	2 (0.5)
Renal failure acute	1 (0.2)	0
Reproductive system and breast disorders	1 (0.2)	0

Table 176. Summary of Serious Adverse Events Post Month 6 to Month 24

Number (%) of Subjects With SAEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=402)	Tofacitinib 10 mg BID (N=395)
Pelvic adhesions	1 (0.2)	0
Respiratory, thoracic, and mediastinal disorders	6 (1.5)	4 (1.0)
Bronchiectasis	0	1 ^a (0.3)
Chronic obstructive pulmonary disease	0	2 (0.5)
Interstitial lung disease	1 ^a (0.2)	0
Nasal polyps	0	1 (0.3)
Pulmonary embolism	1 ^a (0.2)	1 (0.3)
Pulmonary fibrosis	1 (0.2)	0
Respiratory arrest	1 ^b (0.2)	0
Respiratory disorder	1 (0.2)	0
Vocal cord polyp	1 (0.2)	0
Skin and subcutaneous tissue disorders	1 (0.2)	0
Skin ulcer	1 ^a (0.2)	0
Vascular disorders	0	1 (0.3)
Infarction	0	1 (0.3)

Subjects are only counted once per treatment for each row.

Includes data up to 999 days after last dose of study drug.

MedDRA (v14.1) coding dictionary applied.

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.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with SAEs; SAE = serious adverse event; v = version.

- a. Treatment-related.
- b. The Investigator considered the SAE treatment-related; the Sponsor considered it unrelated.
- c. One of the AEs was treatment-related.
- d. Three of the SAEs were considered treatment-related.
- e. One of the SAEs was considered treatment-related.
- f. Three of the AEs were considered treatment-related. The fourth AE was considered unrelated by the Investigator and treatment-related by the Sponsor.

Permanent Discontinuations due to Adverse Events: Summaries of AEs resulting in withdrawal from Baseline to Month 3, from Months 3 to 6 and Month 6 to Month 24 are provided in Table 177, Table 178 and Table 179. From Baseline up to Month 6, a total of 33 subjects (16, 13, and 4 in the tofacitinib 5 mg, tofacitinib 10 mg, and placebo sequences, respectively) withdrew from the study due to AEs considered treatment-related, while a total of 12 subjects (5, 5, and 2 in the tofacitinib 5 mg, tofacitinib 10 mg, and placebo sequences, respectively) withdrew due to AEs considered not related to treatment.

Table 177. Treatment-Emergent Adverse Events Resulting in Discontinuation by System Organ Class and Preferred Term (Up to Month 3)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)
Blood and lymphatic system disorders	0	3 (0.9)	0
Iron deficiency anaemia	1 (0.3)	0	0
Pancytopenia	0	1 (0.3)	0
Thrombocytopenia	0	1 (0.3)	0
Gastrointestinal disorders	1 (0.3)	1 (0.3)	1 (0.6)
Abdominal distension	0	1 (0.3)	0
Abdominal pain	1 (0.3)	0	0
Diarrhoea	0	0	1 (0.6)
General disorders and administration site conditions	2 (0.6)	0	0
Chest pain	1 (0.3)	0	0
Face oedema	1 (0.3)	0	0
Infections and infestations	5 (1.6)	2 (0.6)	0
Dengue fever	1 (0.3)	0	0
Influenza	0	1 (0.3)	0
<i>Pneumocystis jiroveci</i> pneumonia	1 (0.3)	0	0
Pneumonia	1 (0.3)	0	0
Pneumonia viral	1 (0.3)	0	0
Skin infection	0	1 (0.3)	0
Upper respiratory tract infection	1 (0.3)	0	0
Investigations	4 (1.2)	1 (0.3)	0
Alanine aminotransferase increased	1 (0.3)	1 (0.3)	0
Aspartate aminotransferase increased	0	1 (0.3)	0
Blood pressure increased	1 (0.3)	0	0
Hepatic enzyme increased	1 (0.3)	0	0
White blood cell count decreased	1 (0.3)	0	0
Musculoskeletal and connective tissue disorders	1 (0.3)	2 (0.6)	4 (2.5)
Arthralgia	1 (0.3)	2 (0.6)	0
Myalgia	0	0	1 (0.6)
Rheumatoid arthritis	0	0	3 (1.9)
Nervous system disorders	4 (1.2)	0	0
Headache	4 (1.2)	0	0
Respiratory, thoracic and mediastinal disorders	2 (0.6)	1 (0.3)	0
Acute respiratory distress syndrome	1 (0.3)	0	0
Dyspnoea	1 (0.3)	1 (0.3)	0
Skin and subcutaneous tissue disorders	1 (0.3)	0	0
Alopecia	1 (0.3)	0	0

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.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects, n = number of subjects with AEs; v = version.

Table 178. Treatment-Emergent Adverse Events Resulting in Discontinuation by System Organ Class and Preferred Term (Month 3 to Month 6)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=81)
Blood and lymphatic system disorders	1 (0.3)	0	0
Leukocytosis	1 (0.3)	0	0
Thrombocytopenia	0	1 (0.3)	0
Gastrointestinal disorders	1 (0.3)	0	0
Haemorrhoidal haemorrhage	1 (0.3)	0	0
General disorders and administration site conditions	1 (0.3)	0	0
Inflammation	1 (0.3)	0	0
Hepatobiliary disorders	1 (0.3)	0	0
Hepatosplenomegaly	1 (0.3)	0	0
Infections and infestations	6 (1.9)	2 (0.6)	0
Cellulitis	2 (0.6)	0	0
Enterocolitis bacterial	0	1 (0.3)	0
Herpes zoster	1 (0.3)	0	0
Oesophageal candidiasis	1 (0.3)	0	0
Sepsis	1 (0.3)	0	0
Sialoadenitis	0	1 (0.3)	0
Upper respiratory tract infection	1 (0.3)	0	0
Injury, poisoning and procedural complications	2 (0.6)	1 (0.3)	0
Femur fracture	1 (0.3)	0	0
Spinal fracture	1 (0.3)	0	0
Subdural haematoma	0	1 (0.3)	0
Investigations	1 (0.3)	2 (0.6)	0
Alanine aminotransferase increased	0	1 (0.3)	0
Aspartate aminotransferase increased	0	1 (0.3)	0
Gamma-glutamyltransferase increased	0	1 (0.3)	0
Weight increased	1 (0.3)	1 (0.3)	0
Musculoskeletal and connective tissue disorders	1 (0.3)	0	0
Rheumatoid arthritis	1 (0.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.3)	2 (0.6)	1 (1.2)
Basal cell carcinoma	0	0	1 (1.2)
Breast cancer	0	1 (0.3)	0
Metastatic squamous cell carcinoma	1 (0.3)	0	0
Squamous cell carcinoma of the cervix	0	1 (0.3)	0
Nervous system disorders	0	1 (0.3)	0
Lacunar infarction	0	1 (0.3)	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.2)
Bronchiectasis	0	0	1 (1.2)
Skin and subcutaneous tissue disorders	0	3 (0.9)	0
Dermatitis	0	1 (0.3)	0
Rash	0	1 (0.3)	0
Rash erythematous	0	1 (0.3)	0
Skin swelling	0	1 (0.3)	0

Table 178. Treatment-Emergent Adverse Events Resulting in Discontinuation by System Organ Class and Preferred Term (Month 3 to Month 6)

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.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; incl = including; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

The most frequent TEAEs resulting in discontinuation from post Month 6 to Month 24 were pneumonia (occurring in 7 [2.2%], 1 [0.3%], and 2 [2.5%] subjects in the tofacitinib 5 mg, tofacitinib 10 mg, and placebo→tofacitinib 10 mg sequences, respectively) and herpes zoster and urinary tract infection (each occurring in 1 [0.3%] and 4 [1.3%] subjects in the tofacitinib 5 mg and tofacitinib 10 mg sequences, respectively) (Table 179).

Table 179. Treatment-Emergent Adverse Events (All Causalities) Resulting in Discontinuation by System Organ Class and Preferred Term (Post Month 6 to Month 24)

Number (%) of Subjects With AEs By: MedDRA System Organ Class Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo → Tofacitinib 5 mg BID (N=81)	Placebo → Tofacitinib 10 mg BID (N=79)
Blood and lymphatic system disorders	2 (0.6)	0	0	0
Anemia	2 (0.6)	0	0	0
Cardiac disorders	0	0	1 (1.2)	0
Cardiac failure congestive	0	0	1 (1.2)	0
Eye disorders	0	0	0	1 (1.3)
Necrotizing retinitis	0	0	0	1 (1.3)
Gastrointestinal disorders	3 (0.9)	1 (0.3)	1 (1.2)	0
Diarrhea	0	0	1 (1.2)	0
Enterocolitis	0	1 (0.3)	0	0
Mouth ulceration	0	0	1 (1.2)	0
Nausea	1 (0.3)	0	0	0
Oral discomfort	1 (0.3)	0	0	0
Pancreatitis	1 (0.3)	0	0	0
Vomiting	1 (0.3)	0	0	0
General disorders and administration site conditions	0	1 (0.3)	1 (1.2)	0
Edema peripheral	0	1 (0.3)	0	0
Pyrexia	0	0	1 (1.2)	0
Hepatobiliary disorders	1 (0.3)	0	0	0
Hepatic steatosis	1 (0.3)	0	0	0
Infections and infestations	13 (4.0)	14 (4.4)	1 (1.2)	4 (5.1)
Abscess limb	0	1 (0.3)	0	0
Arthritis bacterial	0	1 (0.3)	0	0
Bronchopneumonia	0	0	1 (1.2)	0
Disseminated tuberculosis	0	0	0	1 (1.3)
Diverticulitis	0	0	0	1 (1.3)
Furuncle	0	1 (0.3)	0	0
Gastroenteritis	0	1 (0.3)	0	0
Herpes zoster	1 (0.3)	4 (1.3)	0	0
Infected skin ulcer	0	1 (0.3)	0	0
Intervertebral discitis	1 (0.3)	0	0	0
Lower respiratory tract infection	1 (0.3)	0	0	0
Lymph node tuberculosis	0	2 (0.6)	0	0
Pericarditis tuberculous	0	1 (0.3)	0	0
Pneumonia	7 (2.2)	1 (0.3)	0	2 (2.5)
Pneumonia primary atypical	1 (0.3)	0	0	0
Pyelonephritis acute	1 (0.3)	0	0	0
Tuberculous pleurisy	0	1 (0.3)	0	0
Urinary tract infection	1 (0.3)	4 (1.3)	0	0
Injury, poisoning, and procedural complications	1 (0.3)	0	0	1 (1.3)
Ilium fracture	1 (0.3)	0	0	0
Injury	0	0	0	1 (1.3)
Investigations	1 (0.3)	5 (1.6)	3 (3.7)	0
Alanine aminotransferase increased	1 (0.3)	1 (0.3)	0	0
Aspartate aminotransferase increased	1 (0.3)	1 (0.3)	0	0
Blood alkaline phosphatase increased	0	1 (0.3)	0	0

Table 179. Treatment-Emergent Adverse Events (All Causalities) Resulting in Discontinuation by System Organ Class and Preferred Term (Post Month 6 to Month 24)

Number (%) of Subjects With AEs By: MedDRA System Organ Class Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo → Tofacitinib 5 mg BID (N=81)	Placebo → Tofacitinib 10 mg BID (N=79)
Blood creatine phosphokinase increased	0	1 (0.3)	0	0
Blood creatinine increased	0	2 (0.6)	1 (1.2)	0
Gamma-glutamyltransferase increased	0	1 (0.3)	0	0
Liver function test abnormal	0	0	1 (1.2)	0
Lymphocyte count decreased	0	1 (0.3)	0	0
Transaminases increased	0	0	1 (1.2)	0
Metabolism and nutrition disorders	1 (0.3)	0	0	0
Decreased appetite	1 (0.3)	0	0	0
Musculoskeletal and connective tissue disorders	2 (0.6)	0	0	2 (2.5)
Intervertebral disc protrusion	0	0	0	2 (2.5)
Osteonecrosis	1 (0.3)	0	0	0
Rheumatoid arthritis	1 (0.3)	0	0	0
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	5 (1.6)	5 (1.6)	1 (1.2)	1 (1.3)
Breast cancer	1 (0.3)	0	0	0
Cervix carcinoma	1 (0.3)	0	0	0
Cervix carcinoma Stage 0	0	1 (0.3)	0	0
Diffuse large B-cell lymphoma	0	1 (0.3)	0	0
Lung cancer metastatic	1 (0.3)	0	0	0
Lung neoplasm	0	1 (0.3)	0	0
Lung neoplasm malignant	0	0	0	1 (1.3)
Lymphoma	0	1 (0.3)	0	0
Metastatic gastric cancer	0	1 (0.3)	0	0
Prostate cancer	1 (0.3)	0	1 (1.2)	0
Uterine leiomyoma	1 (0.3)	0	0	0
Renal and urinary disorders	0	0	1 (1.2)	0
Renal failure acute	0	0	1 (1.2)	0
Respiratory, thoracic, and mediastinal disorders	2 (0.6)	2 (0.6)	0	0
Bronchiectasis	0	1 (0.3)	0	0
Chronic obstructive pulmonary disease	0	1 (0.3)	0	0
Interstitial lung disease	1 (0.3)	0	0	0
Throat irritation	1 (0.3)	0	0	0
Skin and subcutaneous tissue disorders	2 (0.6)	0	0	0
Alopecia	1 (0.3)	0	0	0
Skin ulcer	1 (0.3)	0	0	0
Vascular disorders	0	1 (0.3)	0	0
Infarction	0	1 (0.3)	0	0

Subjects in the placebo→tofacitinib 5 mg and placebo→tofacitinib 10 mg sequences received only tofacitinib during this time period from post Month 6 to Month 24.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

Dose Reductions or Temporary Discontinuations due to Adverse Events: Summaries of AEs resulting in temporary discontinuations or dose reductions due to AEs are provided in

Table 180, Table 181 and Table 182. The most frequent TEAEs resulting in temporary discontinuation of study drug during Months 0 through 3 were vomiting (3 [0.9%] subjects) and pyrexia (2 [0.6%] subjects) in the tofacitinib 5 mg group and nasopharyngitis (6 [1.9%] subjects) and gastroenteritis and herpes zoster (3 [0.9%] subjects each) in the tofacitinib 10 mg group (Table 180).

Table 180. Most Frequent Treatment-Emergent Adverse Events (All Causalities) Leading to Temporary Discontinuation by System Organ Class and Preferred Term (Baseline to Month 3)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)
Cardiac disorders	1 (0.3)	0	1 (0.6)
Angina pectoris	1 (0.3)	0	0
Supraventricular tachycardia	0	0	1 (0.6)
Gastrointestinal disorders	4 (1.2)	3 (0.9)	2 (1.3)
Abdominal pain	0	0	1 (0.6)
Diarrhoea	0	1 (0.3)	0
Gingivitis	1 (0.3)	0	0
Nausea	1 (0.3)	0	1 (0.6)
Stomatitis	0	0	1 (0.6)
Vomiting	3 (0.9)	2 (0.6)	1 (0.6)
General disorders and administration site conditions	2 (0.6)	1 (0.3)	0
Device breakage	0	1 (0.3)	0
Pyrexia	2 (0.6)	0	0
Hepatobiliary disorders	1 (0.3)	1 (0.3)	0
Cholelithiasis	1 (0.3)	0	0
Hepatitis	0	1 (0.3)	0
Infections and infestations	9 (2.8)	21 (6.6)	1 (0.6)
Acute tonsillitis	0	1 (0.3)	0
Bronchitis	0	1 (0.3)	0
Bronchitis bacterial	0	1 (0.3)	0
Folliculitis	0	2 (0.6)	0
Gastroenteritis	0	3 (0.9)	0
Gastroenteritis viral	1 (0.3)	0	0
Gastrointestinal infection	0	1 (0.3)	0
Genital herpes	0	1 (0.3)	0
Herpes simplex	0	1 (0.3)	0
Herpes zoster	1 (0.3)	3 (0.9)	0
Lower respiratory tract infection	1 (0.3)	0	0
Nasopharyngitis	1 (0.3)	6 (1.9)	0
Pharyngitis	0	1 (0.3)	0
Pneumonia mycoplasmal	1 (0.3)	0	0
Purulent discharge	0	0	1 (0.6)
Sinusitis	1 (0.3)	1 (0.3)	0
Tooth infection	1 (0.3)	0	0
Urethritis	0	1 (0.3)	0
Urinary tract infection	1 (0.3)	0	0
Viral infection	1 (0.3)	0	0
Injury, poisoning and procedural complications	1 (0.3)	0	0
Thoracic vertebral fracture	1 (0.3)	0	0
Investigations	3 (0.9)	2 (0.6)	1 (0.6)
Alanine aminotransferase increased	1 (0.3)	1 (0.3)	0
Aspartate aminotransferase increased	1 (0.3)	0	0
Blood creatinine increased	1 (0.3)	0	0
Blood pressure increased	1 (0.3)	0	0
Blood urea increased	1 (0.3)	0	0
Body temperature increased	0	1 (0.3)	0
Liver function test abnormal	0	0	1 (0.6)
Musculoskeletal and connective tissue disorders	1 (0.3)	2 (0.6)	1 (0.6)

Table 180. Most Frequent Treatment-Emergent Adverse Events (All Causalities) Leading to Temporary Discontinuation by System Organ Class and Preferred Term (Baseline to Month 3)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)
Fracture nonunion	0	1 (0.3)	0
Joint swelling	0	0	1 (0.6)
Osteoarthritis	0	1 (0.3)	0
Synovial cyst	1 (0.3)	0	0
Nervous system disorders	1 (0.3)	1 (0.3)	0
Carotid artery disease	0	1 (0.3)	0
Carotid artery stenosis	0	1 (0.3)	0
Headache	1 (0.3)	0	0
Renal and urinary disorders	0	1 (0.3)	0
Renal colic	0	1 (0.3)	0
Reproductive system and breast disorders	1 (0.3)	0	0
Endometriosis	1 (0.3)	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.3)	1 (0.3)	0
Cough	0	1 (0.3)	0
Upper respiratory tract inflammation	1 (0.3)	0	0
Skin and subcutaneous tissue disorders	1 (0.3)	0	0
Skin ulcer	1 (0.3)	0	0
Vascular disorders	1 (0.3)	0	0
Hypertension	1 (0.3)	0	0

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.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

The most frequent TEAEs resulting in temporary discontinuation of study drug during Months 3 through 6 were herpes zoster in the tofacitinib 5 mg sequence (4 [1.2%] subjects), aspartate transaminase increased in the tofacitinib 10 mg sequence (3 [0.9%] subjects), and herpes zoster (2 [5.4%] subjects) in the placebo→tofacitinib 10 mg sequence. No TEAE resulted in temporary discontinuation of study drug in >1 subject in the placebo or placebo→tofacitinib 5 mg sequences (Table 181).

Table 181. Most Frequent Treatment-Emergent Adverse Events (All Causalities) Leading to Temporary Discontinuation by System Organ Class and Preferred Term (Month 3 to Month 6)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)	Placebo → Tofacitinib 5 mg BID (N=81)	Placebo → Tofacitinib 10 mg BID (N=79)
Cardiac disorders	1 (0.3)	0	0	0	0
Coronary artery disease	1 (0.3)	0	0	0	0
Gastrointestinal disorders	2 (0.6)	2 (0.6)	0	0	0
Diarrhoea	0	1 (0.3)	0	0	0
Gastritis	0	1 (0.3)	0	0	0
Gastritis erosive	1 (0.3)	0	0	0	0
Vomiting	1 (0.3)	0	0	0	0
General disorders and administration site conditions	1 (0.3)	1 (0.3)	0	0	0
Malaise	1 (0.3)	0	0	0	0
Oedema peripheral	0	1 (0.3)	0	0	0
Hepatobiliary disorders	0	0	0	1 (2.4)	0
Hepatotoxicity	0	0	0	1 (2.4)	0
Infections and infestations	15 (4.7)	10 (3.2)	0	0	3 (8.1)
Bronchitis	1 (0.3)	1 (0.3)	0	0	1 (2.7)
Cytomegalovirus viraemia	0	1 (0.3)	0	0	0
Gastroenteritis	3 (0.9)	1 (0.3)	0	0	0
Gastrointestinal infection	1 (0.3)	0	0	0	0
Herpes zoster	4 (1.2)	1 (0.3)	0	0	2 (5.4)
Influenza	0	2 (0.6)	0	0	0
Nasopharyngitis	0	1 (0.3)	0	0	0
Pharyngitis	1 (0.3)	1 (0.3)	0	0	0
Pneumonia	2 (0.6)	0	0	0	0
Respiratory tract infection	0	1 (0.3)	0	0	0
Sinusitis	1 (0.3)	1 (0.3)	0	0	0
Upper respiratory tract infection	2 (0.6)	0	0	0	1 (2.7)
Viral upper respiratory tract infection	1 (0.3)	0	0	0	0
Injury, poisoning and procedural complications	1 (0.3)	1 (0.3)	1 (1.2)	0	0
Fracture	1 (0.3)	0	0	0	0
Radius fracture	0	1 (0.3)	0	0	0
Upper limb fracture	0	0	1 (1.2)	0	0
Investigations	2 (0.6)	4 (1.3)	0	0	0
Alanine aminotransferase increased	1 (0.3)	2 (0.6)	0	0	0
Aspartate aminotransferase increased	0	3 (0.9)	0	0	0
Blood creatine phosphokinase increased	1 (0.3)	0	0	0	0
Hepatic enzyme increased	0	1 (0.3)	0	0	0
Musculoskeletal and connective tissue disorders	3 (0.9)	2 (0.6)	0	0	0
Back pain	1 (0.3)	0	0	0	0
Intervertebral disc protrusion	1 (0.3)	0	0	0	0
Osteoarthritis	0	1 (0.3)	0	0	0
Osteonecrosis	1 (0.3)	0	0	0	0

Table 181. Most Frequent Treatment-Emergent Adverse Events (All Causalities) Leading to Temporary Discontinuation by System Organ Class and Preferred Term (Month 3 to Month 6)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo (N=160)	Placebo → Tofacitinib 5 mg BID (N=81)	Placebo → Tofacitinib 10 mg BID (N=79)
Spinal column stenosis	0	1 (0.3)	0	0	0
Renal and urinary disorders	1 (0.3)	0	0	0	0
Nephrolithiasis	1 (0.3)	0	0	0	0
Reproductive system and breast disorders	0	0	1 (1.2)	0	0
Metrorrhagia	0	0	1 (1.2)	0	0
Respiratory, thoracic and mediastinal disorders	0	1 (0.3)	0	0	0
Aspiration	0	1 (0.3)	0	0	0
Skin and subcutaneous tissue disorders	0	1 (0.3)	0	0	0
Skin ulcer	0	1 (0.3)	0	0	0

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.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

The most frequent TEAEs resulting in temporary discontinuation of study drug post Month 6 to Month 24 were herpes zoster (6 [1.9%], 13 [4.1%], 1 [1.2%], and 2 [2.5%] subjects in the tofacitinib 5 mg, tofacitinib 10 mg, placebo→tofacitinib 5 mg and placebo→tofacitinib 10 mg sequences, respectively) and nasopharyngitis (6 [1.9%], 7 [2.2%], 1 [1.2%], and 4 [5.1%] subjects in the tofacitinib 5 mg, tofacitinib 10 mg, placebo→tofacitinib 5 mg, and placebo→tofacitinib 10 mg sequences, respectively (Table 182).

Table 182. Most Frequent Treatment-Emergent Adverse Events (All Causalities) Leading to Temporary Discontinuation by System Organ Class and Preferred Term (≥1% of Subjects in Any Treatment Sequence, Post Month 6 to Month 24)

Number (%) of Subjects With AEs By: MedDRA System Organ Class and Preferred Term	Tofacitinib 5 mg BID (N=321)	Tofacitinib 10 mg BID (N=316)	Placebo → Tofacitinib 5 mg BID (N=81)	Placebo → Tofacitinib 10 mg BID (N=79)
Ear and labyrinth disorders				
Vertigo	0	0	0	1 (1.3)
Gastrointestinal disorders				
Umbilical hernia	0	0	1 (1.2)	0
Hepatobiliary disorders				
Cholecystitis acute	0	0	1 (1.2)	0
Infections and infestations				
Bronchitis	2 (0.6)	4 (1.3)	1 (1.2)	0
Cellulitis	0	1 (0.3)	0	1 (1.3)
Erysipelas	0	0	1 (1.2)	0
Folliculitis	0	0	1 (1.2)	0
Herpes zoster	6 (1.9)	13 (4.1)	1 (1.2)	2 (2.5)
Influenza	0	5 (1.6)	1 (1.2)	1 (1.3)
Localized infection	0	1 (0.3)	0	1 (1.3)
Lower respiratory tract infection	0	0	1 (1.2)	0
Nasopharyngitis	6 (1.9)	7 (2.2)	1 (1.2)	4 (5.1)
Otitis media	0	0	1 (1.2)	1 (1.3)
Pharyngitis	1 (0.3)	2 (0.6)	0	1 (1.3)
Pneumonia	3 (0.9)	2 (0.6)	1 (1.2)	0
Sinusitis	3 (0.9)	0	1 (1.2)	1 (1.3)
Upper respiratory tract infection	3 (0.9)	5 (1.6)	0	1 (1.3)
Urinary tract infection	1 (0.3)	4 (1.3)	0	0
Vulvovaginal candidiasis	0	1 (0.3)	1 (1.2)	0
Injury, poisoning, and procedural complications				
Dislocation of vertebra	0	0	0	1 (1.3)
Investigations				
Alanine aminotransferase increased	2 (0.6)	2 (0.6)	1 (1.2)	0
Aspartate aminotransferase increased	1 (0.3)	1 (0.3)	1 (1.2)	0
Musculoskeletal and connective tissue disorders				
Arthralgia	0	2 (0.6)	1 (1.2)	0
Skin and subcutaneous tissue disorders				
Dermatitis contact	0	0	1 (1.2)	0

Subjects in the placebo→tofacitinib 5 mg and placebo→tofacitinib 10 mg sequences received only tofacitinib during this time period from post Month 6 to Month 24.

MedDRA (v14.1) coding dictionary applied.

AE = adverse event; BID = twice daily; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of subjects; n = number of subjects with AEs; v = version.

Death: A total of 11 subjects who received at least one dose of study drug, including one subject on placebo, died. Six subjects died while on treatment (the reason for their discontinuation was death): 4 in the tofacitinib 5 mg sequence (1 subject each due to pneumonia; probable acute myocardial infarction; cardiac arrest and respiratory arrest; and heart failure and pneumonia) and 1 in the tofacitinib 10 mg sequence (asphyxia caused by aspiration of a glycerin swab) and 1 in the placebo→tofacitinib 5 mg sequence (renal failure

acute, cardiac arrest, other AEs). Three subjects died after withdrawing due to AEs considered related to treatment (acute respiratory distress syndrome and pneumonia viral in 1 subject in the tofacitinib 5 mg sequence; lung cancer metastatic in 1 subject in the tofacitinib 5 mg sequence; and renal failure acute in 1 subject in the placebo→tofacitinib 5 mg sequence). Two subjects died after withdrawing due to nontreatment-related AEs: 1 subject in the tofacitinib 5 mg sequence withdrew due to multi-organ failure and 1 subject in the tofacitinib 10 mg sequence withdrew due to an AE of chronic obstructive pulmonary disease. One additional subject who was randomized to the tofacitinib 10 mg sequence died before receiving study medication.

CONCLUSIONS:

Conclusions (Based on 0 to 12 Month Data):

- Treatment with tofacitinib (5 mg or 10 mg BID) was efficacious compared with placebo in reducing the signs and symptoms of RA in subjects with RA as measured by the ACR20 response rate at Month 6 and demonstrated statistically significant differences from placebo as early as Month 1.
- Treatment with tofacitinib (10 mg BID) was efficacious compared with placebo in structure preservation as measured by mTSS at Month 6, and demonstrated a statistically significant difference in change from Baseline compared to placebo. The change from Baseline in the mTSS in the tofacitinib 5 mg group was consistent with the change in mTSS in the tofacitinib 10 mg group, but the change from Baseline to Month 6 in the tofacitinib 5 mg group missed achieving statistical significance compared to placebo ($p=0.0792$). The magnitude of progression in the placebo group was substantially less than anticipated, which limited the ability to demonstrate separation from placebo for tofacitinib.
- In a secondary analysis of proportions of subjects showing no radiographic progression (change from Baseline in mTSS ≤ 0.5 units), tofacitinib (5 mg BID and 10 mg BID) was superior to placebo at Months 6 and 12.
- Evaluation of subsets of subjects with poor prognostic factors for radiographic progression (as measured at Baseline) indicated a consistent pattern of benefit of both the tofacitinib 5 mg and 10 mg BID doses compared with placebo in structure preservation.
- The cumulative distribution plots of changes from Baseline in mTSS, erosion scores, and JSN scores for the tofacitinib 5 mg BID and 10 mg BID groups were similar to one another and similarly different from the plots for the placebo group.
- Treatment with tofacitinib (10 mg BID) was efficacious compared with placebo in improving the physical function status of subjects with RA as measured by HAQ-DI response rate at Month 3, and demonstrated statistically significant differences from placebo as early as Month 1.

- Because of the stepwise analysis of the primary endpoints, improvement in HAQ-DI at Month 3 could not be declared statistically significant for the tofacitinib 5 mg group compared to placebo. However, the difference was nominally significant.
- The proportion of subjects treated with tofacitinib 10 mg BID achieving DAS28-4(ESR) <2.6 at Month 6 was significantly greater than the proportion in the placebo group, and demonstrated statistically significant differences from placebo as early as Month 3.
- Because of the stepwise analysis of the primary endpoints, DAS28-4(ESR) <2.6 response rate at Month 6 could not be declared statistically significant for the tofacitinib 5 mg group compared to placebo. However, the difference was nominally significant.
- Treatment with tofacitinib (5 mg BID or 10 mg BID) was efficacious compared with placebo in ACR20, ACR50, ACR70, HAQ-DI, DAS28-4(ESR), and DAS28-3(CRP) beginning at Month 1.
- Improvements in subjects treated with tofacitinib were consistently greater in the 10 mg BID group compared to the 5 mg BID group for all components of ACR assessments (joint counts, Patient Assessment of Arthritis Pain, Patient Global Assessment of Arthritis, Physician Global Assessment of Arthritis, CRP, and HAQ-DI scores) and the DAS28 scores.
- In general, treatment with tofacitinib (5 mg or 10 mg BID) resulted in significant improvements compared to placebo in subjects' self-assessed (1) pain, (2) global assessment of arthritis, (3) health-related quality of life (every domain of the SF-36 as well as both component summary scores), (4) fatigue, (5) health utility, (6) sleep (MOS-SS overall sleep problems and sleep problem summary), and (7) productivity (WLQ Output Demand subscale for the 10 mg BID group only).
- Subjects who received placebo for 3 to 6 months and then advanced to tofacitinib (5 mg BID or 10 mg BID) showed improvement after advancement in all efficacy measures (ACR20, ACR50, ACR70, HAQ-DI, and the DAS28 scores).
- Efficacy responses were sustained in the tofacitinib 5 mg BID and 10 mg BID treatment groups through Month 12.
- The most frequently reported AEs were those coding to the MedDRA SOCs of infections and infestations and gastrointestinal disorders, and the frequencies of these AEs were higher in the tofacitinib groups compared to placebo but similar in the 2 tofacitinib groups (5 mg BID and 10 mg BID).
- There were more discontinuations due to AEs in the tofacitinib 5 mg BID and 10 mg BID groups compared with the placebo group.
- The frequencies of SAEs were similar across the treatment groups in this study.

- Changes in laboratory parameters observed for tofacitinib 5 mg BID and 10 mg BID relative to placebo were consistent with expectations, including decreases in neutrophil counts and increases in hemoglobin, creatinine levels, transaminases, creatine kinase (CK), high density lipoprotein (HDL), low density lipoprotein (LDL), and total cholesterol levels.
- Changes in systolic and diastolic blood pressure (BP) were small and variable across treatment groups, with no clear dose-response relationship.
- The proportions of subjects meeting the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) criteria for Stage 1 or 2 hypertension remained relatively stable throughout the 12 months of therapy with no consistent change across dose groups.
- Subjects treated with tofacitinib 5 or 10 mg showed increases in mean weight from Baseline and placebo-treated subjects also showed increases in mean weight after advancement to tofacitinib therapy; the clinical significance of these results is unknown.
- The safety profiles of tofacitinib 5 mg BID and 10 mg BID were similar to those seen in previous Phase 2 studies of tofacitinib in subjects with active RA.

Efficacy Conclusions (Based on Month 12 to Month 24 Data):

- High rates of nonprogression in mTSS (change from Baseline ≤ 0.5 units) were demonstrated in the tofacitinib 5 mg and 10 mg groups at Months 12 and 24.
- Treatment with tofacitinib (5 mg BID or 10 mg BID) resulted in sustained improvements in ACR20, ACR50, ACR70, HAQ-DI, DAS28-4(ESR), and DAS28-3(CRP) through Month 24.
- Treatment with tofacitinib (5 mg BID or 10 mg BID) resulted in sustained improvements in components of ACR assessments and the DAS28 scores (joint counts, Patient Assessment of Arthritis Pain, Patient Global Assessment of Arthritis, Physician Global Assessment of Arthritis, CRP, HAQ-DI scores, and ESR) through Month 24.
- In general, treatment with tofacitinib (5 mg BID or 10 mg BID) resulted in clinically meaningful improvements in subjects' self-assessed (1) pain, (2) global assessment of arthritis, (3) health-related quality of life (every domain of the SF-36 as well as both component summary scores), (4) fatigue, (5) health utility, (6) sleep (MOS-SS), and (7) physical function (HAQ-DI) through Month 24.

Safety Conclusions (Based on Month 0 to Month 24):

- The most frequently reported AEs were those coding to the MedDRA SOCs of infections and infestations and gastrointestinal disorders, and the frequencies of these

AEs were higher in the tofacitinib groups compared to placebo but similar in the 2 tofacitinib groups (5 mg BID and 10 mg BID).

- Discontinuations due to AEs were similar among treatments from Months 0 to 3, Months 3 to 6, and post Month 6 to Month 24.
- The frequencies of SAEs were similar across the treatment groups from Months 0 to 3, Months 3 to 6, and post Month 6 to Month 24.
- A total of 11 subjects who received at least one dose of study drug, including one subject on placebo, died. One additional subject who was randomized to the tofacitinib 10 mg sequence died before receiving study medication.
- Changes in laboratory parameters observed for tofacitinib 5 mg BID and 10 mg BID relative to placebo were consistent with expectations, including decreases in neutrophil counts and increases in hemoglobin, creatinine levels, transaminases, CK, HDL, LDL, and total cholesterol levels.
- Changes in systolic and diastolic BP were small and variable across treatment groups, with no dose-response relationship.
- The proportions of subjects meeting the JNC7 criteria for Stage 1 or 2 hypertension remained relatively stable throughout the 24 months of therapy with no consistent change across dose groups.
- Subjects treated with tofacitinib 5 or 10 mg showed increases in mean weight from Baseline and placebo-treated subjects also showed increases in mean weight after advancement to tofacitinib therapy; the clinical significance of these results is unknown.
- The safety profiles of tofacitinib 5 mg BID and 10 mg BID were similar to those seen in previous Phase 2 and Phase 3 studies of tofacitinib in subjects with active RA.