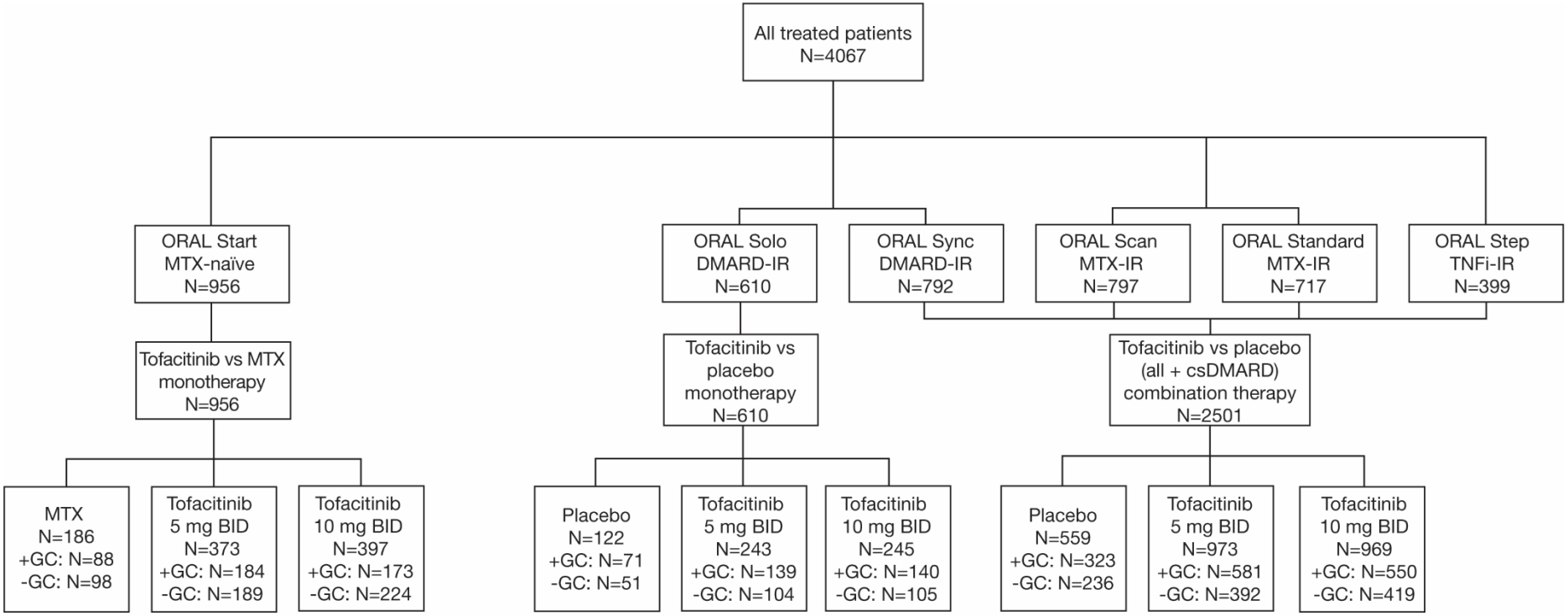
Online supplement to: Effect of Glucocorticoids on the Clinical and Radiographic Efficacy of Tofacitinib in Patients with Rheumatoid Arthritis: A Posthoc Analysis of Data from 6 Phase III Studies. *The Journal of Rheumatology*. doi:10.3899/jrheum.170486

Supplementary Figure 1.



Supplementary Figure 1. Flow chart of patient distribution indicating patient populations, phase 3 studies, and treatment groups

DMARD-IR: patients with an inadequate response to ≥1 csDMARD or bDMARD
BID, twice daily; csDMARD, conventional synthetic disease modifying antirheumatic drug; DMARD, disease-modifying antirheumatic drug; GC, glucocorticoid; IR, inadequate responder; MTX, methotrexate; TNFi, tumor necrosis factor inhibitor

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Supplementary Table 1. Baseline demographics and disease characteristics in (A) phase 3 monotherapy studies and (B) pooled phase 3 combination therapy studies

A)

	ORAL Start (MTX-naïve)						**ORAL Solo (DMARD-IR)**					
	MTX (N = 186)		**Tofacitinib 5 mg BID (N = 373)**		**Tofacitinib 10 mg BID (N = 397)**		**Placebo (N = 122)**		**Tofacitinib 5 mg BID (N = 243)**		**Tofacitinib 10 mg BID (N = 245)**	
	+GC (N = 88)	-GC (N = 98)	+GC (N = 184)	-GC (N = 189)	+GC (N = 173)	-GC (N = 224)	+GC (N = 71)	-GC (N = 51)	+GC (N = 139)	-GC (N = 104)	+GC (N = 140)	-GC (N = 105)
Caucasian race, n (%)	59 (67.0)	68 (69.4)	101 (54.9)	138 (73.0)	98 (56.6)	168 (75.0)	53 (74.6)	35 (68.6)	83 (59.7)	70 (67.3)	97 (69.3)	71 (67.6)
Female, n (%)	67 (76.1)	78 (79.6)	150 (81.5)	136 (72.0)	148 (85.5)	179 (79.9)	62 (87.3)	43 (84.3)	121 (87.1)	86 (82.7)	123 (87.9)	93 (88.6)
Age, years, mean (SD)	49.7 (13.6)	48.0 (13.1)	50.4 (11.5)	50.2 (12.9)	49.3 (13.3)	49.3 (12.3)	48.9 (12.1)	50.8 (12.7)	51.7 (11.6)	53.0 (11.5)	50.7 (12.1)	54.6 (10.7)

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RA disease duration, years, mean (SD)	3.1 (4.8)	2.5 (4.8)	3.0 (5.5)	2.9 (5.4)	3.7 (5.1)	3.1 (6.0)	7.9 (7.2)	7.4 (7.2)	9.1 (8.7)	6.6 (6.8)	9.1 (8.9)	7.9 (7.6)
Weight, kg, mean (SD)	69.5 (17.5)	72.1 (18.8)	68.6 (16.6)	72.4 (16.2)	69.5 (17.2)	72.6 (19.6)	70.6 (17.4)	75.2 (20.4)	69.0 (19.1)	76.6 (20.9)	69.1 (20.3)	75.0 (18.4)
RF+, n (%)	72 (81.8)	85 (86.7)	150 (81.5)	157 (83.1)	136 (78.6)	188 (83.9)	41 (57.7)	23 (45.1)	108 (78.3)	63 (60.6)	98 (70.5)	60 (57.7)
Anti-CCP+ (≥60 units), n (%)	79 (89.8)	82 (83.7)	154 (83.7)	163 (86.2)	140 (80.9)	182 (81.3)	47 (67.1)	30 (58.8)	108 (77.7)	64 (62.1)	100 (71.4)	69 (66.3)
CRP >7 mg/L, n (%)	64 (72.7)	67 (68.4)	114 (62.0)	137 (72.5)	112 (64.7)	148 (66.1)	44 (62.0)	29 (58.0)	103 (74.6)	64 (61.5)	102 (72.9)	62 (59.6)
CRP mg/L, mean (SD)	24.6 (26.9)	27.1 (34.3)	24.7 (31.3)	20.7 (22.2)	20.2 (23.2)	20.3 (24.5)	21.4 (30.8)	12.5 (11.3)	26.3 (29.8)	18.0 (22.0)	20.6 (19.5)	16.8 (20.2)

Baseline GC dose, mg/day, mean (SD) [median]	6.2 (3.2) [5.0]	0.0 (0.0) [0.0]	7.1 (6.3) [5.0]	0.0 (0.0) [0.0]	8.3 (16.6) [5.0]	0.0 (0.0) [0.0]	7.0 (2.9) [5.0]	0.0 (0.0) [0.0]	6.9 (2.7) [5.0]	0.0 (0.0) [0.0]	6.4 (2.7) [5.0]	0.0 (0.0) [0.0]
CDAI, mean (SD)	38.8 (12.5)	39.3 (14.0)	39.7 (13.2)	38.8 (12.1)	39.2 (12.8)	37.4 (12.2)	43.1 (12.2)	38.5 (12.7)	40.4 (11.9)	41.1 (12.1)	40.5 (12.6)	40.9 (14.3)
DAS28-4(ESR), mean (SD)	6.6 (0.9)	6.6 (1.1)	6.7 (1.0)	6.6 (1.0)	6.6 (1.0)	6.5 (1.0)	6.8 (0.9)	6.5 (0.9)	6.7 (0.9)	6.7 (1.0)	6.7 (0.9)	6.7 (1.0)
HAQ-DI, mean (SD)	1.5 (0.7)	1.6 (0.7)	1.6 (0.6)	1.5 (0.6)	1.6 (0.7)	1.4 (0.7)	1.6 (0.7)	1.4 (0.6)	1.5 (0.6)	1.5 (0.7)	1.6 (0.6)	1.3 (0.7)
Pain VAS, mean (SD)	59.3 (21.5)	58.8 (25.5)	59.2 (23.3)	59.2 (24.4)	63.9 (22.6)	59.5 (23.2)	64.4 (22.0)	58.1 (19.8)	59.8 (23.6)	63.5 (20.2)	64.2 (23.3)	59.0 (23.8)
mTSS, mean (SD) (ORAL Start only)	17.3 (28.8)	15.6 (30.1)	17.5 (35.5)	20.9 (41.2)	20.7 (40.2)	15.4 (35.9)	N/A	N/A	N/A	N/A	N/A	N/A

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B)

	Pooled data from 4 phase 3 studies of tofacitinib in combination with csDMARDs[a] (DMARD-IR)					
	Placebo + csDMARDs (N = 559)		**Tofacitinib 5 mg BID + csDMARDs (N = 973)**		**Tofacitinib 10 mg BID + csDMARDs (N = 969)**	
	+GC (N = 323)	-GC (N = 236)	+GC (N = 581)	-GC (N = 392)	+GC (N = 550)	-GC (N = 419)
Caucasian race, n (%)	206 (63.8)	145 (61.4)	347 (59.7)	237 (60.5)	307 (55.8)	266 (63.5)
Female, n (%)	264 (81.7)	184 (78.0)	491 (84.5)	329 (83.9)	458 (83.3)	356 (85.0)
Age, years, mean (SD)	52.3 (12.0)	54.2 (11.5)	53.8 (11.4)	52.9 (12.2)	52.7 (11.2)	52.4 (12.2)
RA disease duration, years, mean (SD)	8.9 (7.7)	10.5 (9.9)	8.8 (7.9)	9.1 (8.3)	9.4 (8.1)	8.9 (8.3)
Weight, kg, mean (SD)	71.0 (20.8)	74.1 (22.8)	70.4 (19.3)	71.4 (20.3)	70.6 (18.7)	71.8 (19.4)

RF+, n (%)	230 (71.7)	164 (69.8)	415 (72.4)	266 (68.6)	402 (73.4)	289 (69.6)
Anti-CCP+ (≥60 units), n (%)	246 (77.1)	177 (76.3)	447 (77.5)	298 (77.6)	416 (76.2)	307 (74.7)
CRP >7 mg/L, n (%)	199 (61.6)	138 (58.5)	358 (61.8)	208 (53.1)	348 (63.3)	237 (56.8)
CRP mg/L, mean (SD)	16.6 (17.7)	14.4 (17.2)	17.8 (21.9)	14.8 (19.7)	18.8 (26.0)	14.8 (18.4)
Baseline GC dose, mg/day, mean (SD) [median]	6.3 (3.1) [5.0]	0.0 (0.0) [0.0]	6.1 (3.0) [5.0]	0.0 (0.0) [0.0]	6.1 (3.0) [5.0]	0.0 (0.0) [0.0]
CDAI, mean (SD)	36.8 (12.7)	36.7 (12.8)	36.8 (12.2)	36.4 (12.5)	36.4 (11.9)	36.1 (12.8)
DAS28-4(ESR), mean (SD)	6.3 (1.0)	6.3 (1.0)	6.4 (1.0)	6.4 (1.0)	6.3 (1.0)	6.4 (1.0)

HAQ-DI, mean (SD)	1.5 (0.7)	1.3 (0.7)	1.5 (0.7)	1.4 (0.7)	1.5 (0.7)	1.4 (0.7)
Pain VAS, mean (SD)	57.7 (22.3)	55.9 (24.2)	60.2 (22.6)	57.5 (23.6)	59.7 (22.1)	57.0 (24.0)

[a]ORAL Scan, ORAL Standard, ORAL Sync, and ORAL Step

Efficacy endpoints are based on the FAS population. All other parameters are based on the treated patient population. The results are presented by GC use at baseline: with or without (±) GC. Mean values are presented for continuous variables

N, number of patients randomized and treated; denominators for each characteristic differ depending upon the number of evaluable patients

BID, twice daily; CCP, cyclic citrullinated peptide; CDAI, Clinical Disease Activity Index; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DAS28-4(ESR), Disease Activity Score in 28 joints using the erythrocyte sedimentation rate; DMARD, disease-modifying antirheumatic drug; FAS, full analysis set; GC, glucocorticoids; HAQ-DI, Health Assessment Questionnaire-Disability Index; IR, inadequate response; mTSS, modified Total Sharp Score; MTX, methotrexate; N/A; not available; RA, rheumatoid arthritis; RF+, rheumatoid factor-positive; SD, standard deviation; VAS, visual analog scale.