

HOW AUTOMATIC VISUALIZATION OF SUMMARY RESULTS CAN SPEED UP REVIEW OF TABLES

PHUSE CONNECT - US 2018
RALEIGH

5 JUNE 2018

PRESENTED BY

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OVERVIEW

- Aim of the presentation
- Study summary
- Graphical representation
 - Subject Disposition
 - Demographic and Baseline Characteristics
 - TEAEs by System Organ Class and Preferred Term
 - Change from Baseline to Last Observation
 - Proportion of Subjects Achieving Patient Global Assessment (PtGA) Response
 - Proportion of Subjects Achieving PASI75 Response
- Study Conclusion
- Summary

AIM OF THE PRESENTATION

Demonstrate how automated visualization
can speed up review

Summary data used for this presentation is from
www.clinicaltrialsregister.eu

STUDY SUMMARY

Protocol Title

A Phase 3, Multi-site, Randomized, Double-blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of 2 Oral Doses of CP-690,550 and 1 Subcutaneous Dose of Etanercept in Subjects With Moderate to Severe Chronic Plaque Psoriasis.

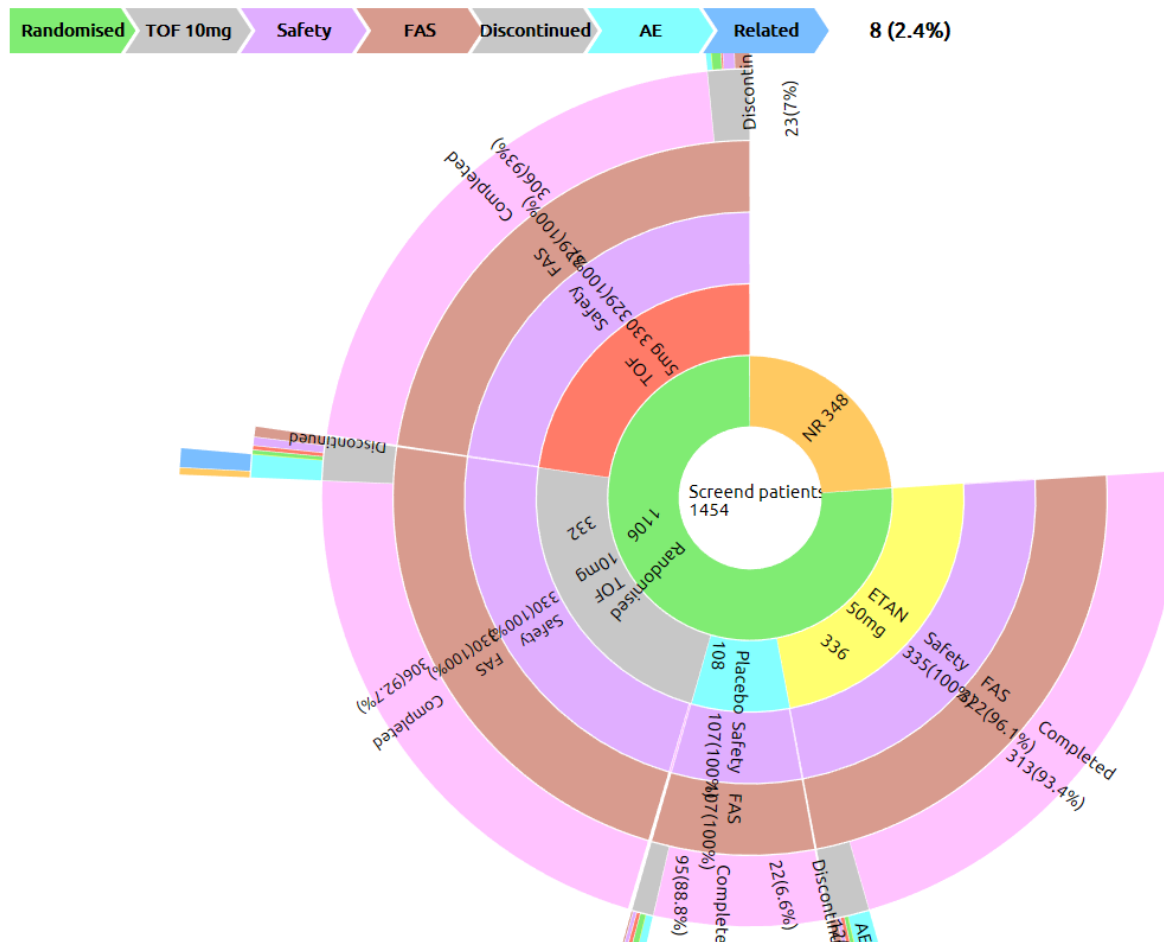
Primary objective:

- To compare of the efficacy of
- Tofacitinib (5 mg BID & 10 mg BID) VS Etanercept (50 mg [BIW]) & Placebo
- For the reduction in severity of plaque psoriasis

SUBJECT DISPOSITION

	Tofacitinib		Etanercept	Placebo	Total
	5 mg BID n (%)	10 mg BID n (%)	50 mg BIW n (%)	n (%)	n (%)
Screened (N=1454)					
Randomized (N)	330	332	336	108	1106
Safety analysis set ^a	329 (100)	330 (100)	335 (100)	107 (100)	1101 (100)
FAS ^b	329 (100)	330 (100)	335 (100)	107 (100)	1101 (100)
PP analysis set ^c	313 (95.1)	317 (96.1)	322 (96.1)	101 (94.4)	1053 (95.6)
Completed	306 (93.0)	306 (92.7)	313 (93.4)	95 (88.8)	1020 (92.6)
Discontinued from study ^a	23 (7.0)	24 (7.3)	22 (6.6)	12 (11.2)	81 (7.4)
Primary reason:					
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Adverse event	3 (0.9)	11 (3.3)	12 (3.6)	4 (3.7)	30 (2.7)
Related to study drug	2 (0.6)	8 (2.4)	10 (3.0)	4 (3.7)	24 (2.2)
Not related to study drug	1 (0.3)	3 (0.9)	2 (0.6)	0 (0.0)	6 (0.5)
Insufficient clinical response	5 (1.5)	2 (0.6)	2 (0.6)	3 (2.8)	12 (1.1)
Lost to follow-up	1 (0.3)	2 (0.6)	2 (0.6)	2 (1.9)	7 (0.6)
Subject no longer willing to participate in study	6 (1.8)	4 (1.2)	2 (0.6)	2 (1.9)	14 (1.3)
Other ^d	8 (2.4)	5 (1.5)	4 (1.2)	1 (0.9)	18 (1.6)

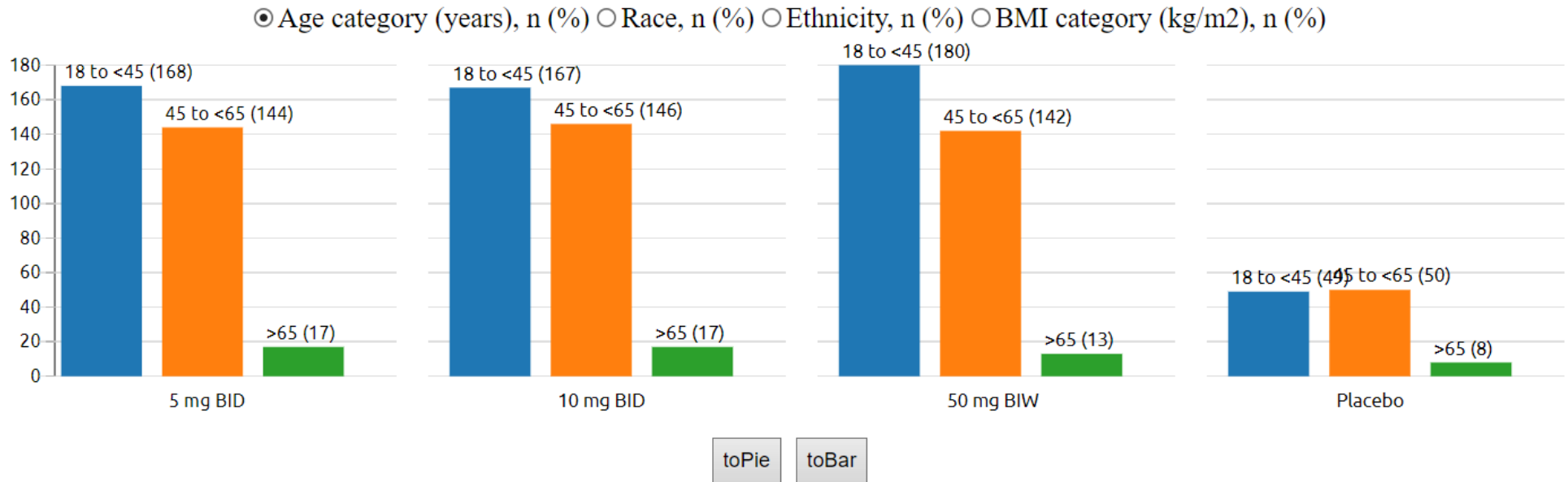
SUBJECT DISPOSITION (GRAPHICALLY)



DEMOGRAPHIC AND BASELINE CHARACTERISTICS

	Tofacitinib 5 mg BID (N=329)	Tofacitinib 10 mg BID (N=330)	Etanercept 50 mg BIW (N=335)	Placebo (N=107)	Total (N=1101)
Age category (years), n (%)					
18 to <45	168 (51.1%)	167 (50.6%)	180 (53.7%)	49 (45.8%)	564 (51.2%)
45 to <65	144 (43.8%)	146 (44.2%)	142 (42.4%)	50 (46.7%)	482 (43.8%)
≥ 65	17 (5.2%)	17 (5.2%)	13 (3.9%)	8 (7.5%)	55 (5.0%)
Race, n (%)					
White	289 (87.8%)	285 (86.4%)	292 (87.2%)	90 (84.1%)	956 (86.8%)
Black	0 (0.0%)	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Asian	16 (4.9%)	17 (5.2%)	20 (6.0%)	7 (6.5%)	60 (5.4%)
Other	23 (7.0%)	26 (7.9%)	22 (6.6%)	8 (7.5%)	79 (7.2%)
Ethnicity, n (%)					
Hispanic/Latino	83 (25.2%)	84 (25.5%)	87 (26.0%)	31 (29.0%)	285 (25.9%)
Not Hispanic/Latino	245 (74.5%)	245 (74.2%)	247 (73.7%)	74 (69.2%)	811 (73.7%)
BMI category (kg/m²), n (%)					
<18.5	2 (0.6%)	2 (0.6%)	2 (0.6%)	0 (0.0%)	6 (0.5%)
18.5 to <25	73 (22.2%)	82 (24.8%)	94 (28.1%)	25 (23.4%)	274 (24.9%)
25 to <30	145 (44.1%)	123 (37.3%)	120 (35.8%)	47 (43.9%)	435 (39.5%)
30 to <40	98 (29.8%)	110 (33.3%)	109 (32.5%)	31 (29.0%)	348 (31.6%)
≥ 40	10 (3.0%)	13 (3.9%)	10 (3.0%)	4 (3.7%)	37 (3.4%)

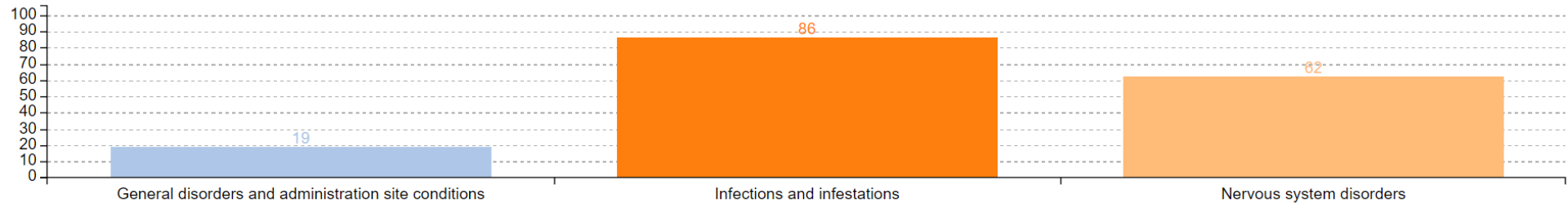
DEMOGRAPHIC AND BASELINE CHARACTERISTICS - GRAPHICAL



TREATMENT-EMERGENT NON-SERIOUS ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM

Number (%) of Subjects With Adverse Events by: System Organ Class and MedDRA (v16.1) Preferred Term	Tofacitinib 5 mg BID			Tofacitinib 10 mg BID			Etanercept 50 mg BIW			Placebo		
	n (%)	n1	n2	n (%)	n1	n2	n (%)	n1	n2	n (%)	n1	n2
Evaluable for adverse events	329			330			335			107		
With adverse events	39 (11.9)			53 (16.1)			55 (16.4)			14 (13.1)		
General disorders and administration site conditions	0	0	0	1 (0.3)	1	1	18 (5.4)	34	33	0	0	0
Injection site erythema	0	0	0	1 (0.3)	1	1	18 (5.4)	34	33	0	0	0
Infections and infestations	21 (6.4)	22	8	30 (9.1)	34	18	25 (7.5)	31	17	10 (9.3)	11	5
Nasopharyngitis	21 (6.4)	22	8	30 (9.1)	34	18	25 (7.5)	31	17	10 (9.3)	11	5
Nervous system disorders	21 (6.4)	27	17	24 (7.3)	28	16	13 (3.9)	15	8	4 (3.7)	4	2
Headache	21 (6.4)	27	17	24 (7.3)	28	16	13 (3.9)	15	8	4 (3.7)	4	2

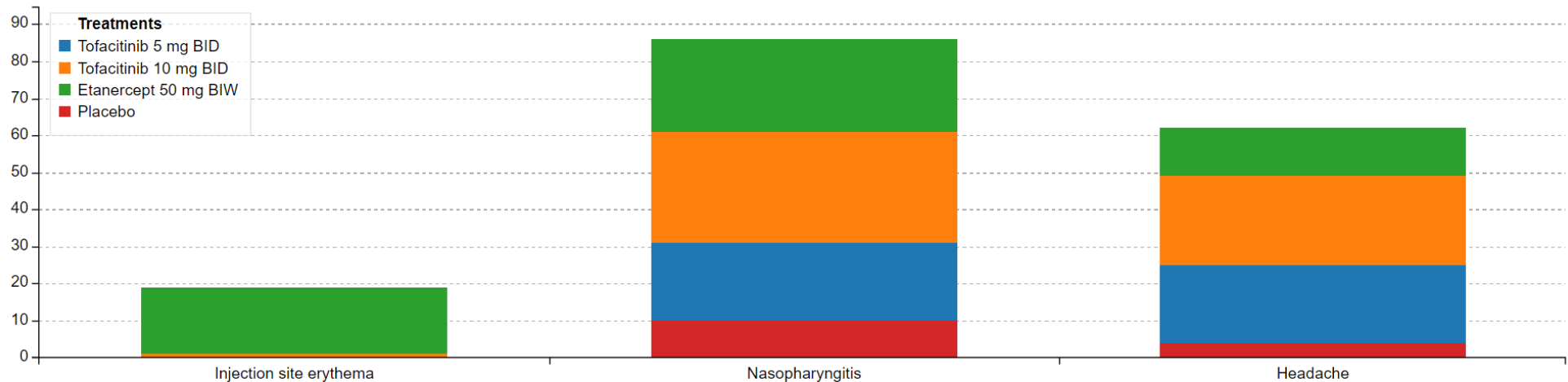
TREATMENT-EMERGENT NON-SERIOUS ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM



☒ Stacked Chart

Reset

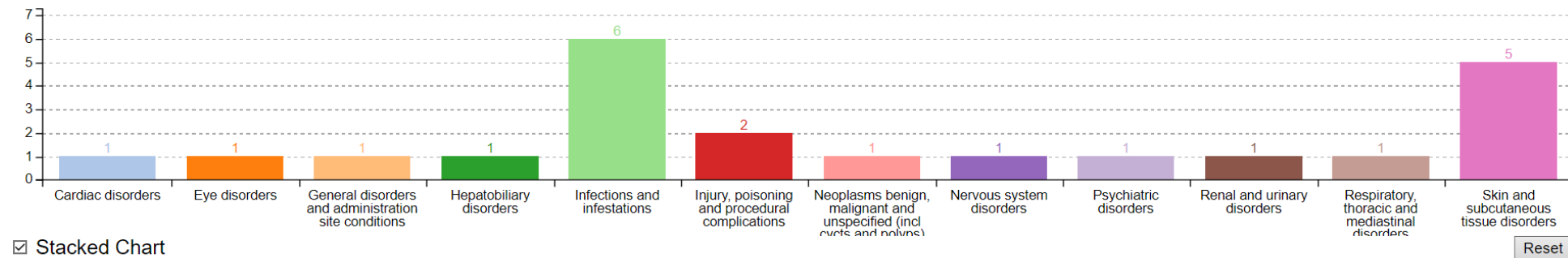
Preferred Terms from all System Organ Class



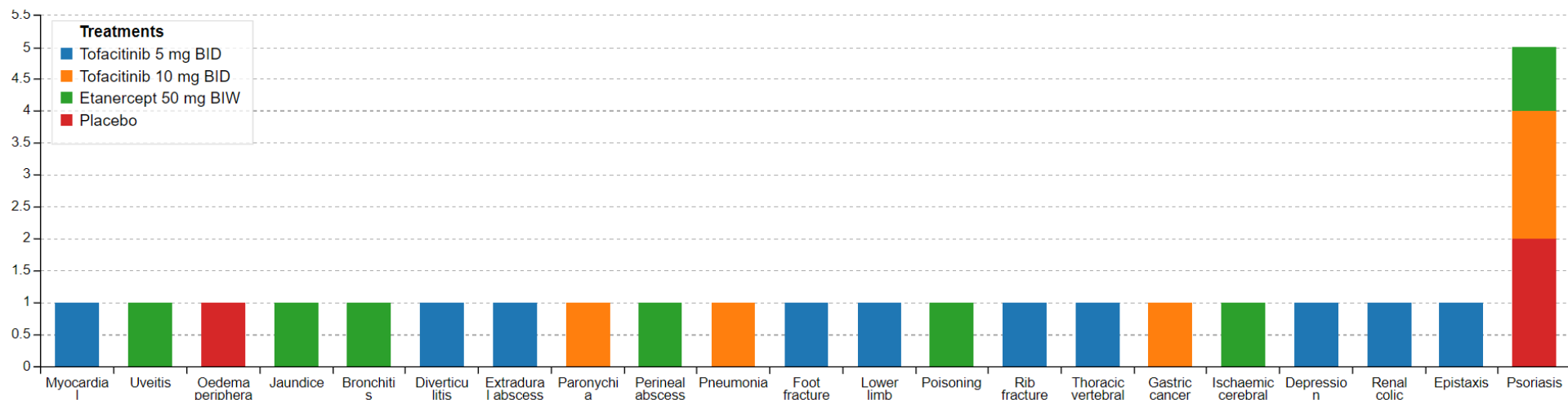
TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM

Number (%) of Subjects With Adverse Events by: System Organ Class and MedDRA (v16.1) Preferred Term	Tofacitinib 5 mg BID			Tofacitinib 10 mg BID			Etanercept 50 mg BIW			Placebo		
	n (%)	n1	n2	n (%)	n1	n2	n (%)	n1	n2	n (%)	n1	n2
Evaluable for adverse events	329			330			335			107		
With adverse events	7 (2.1)			5 (1.5)			7 (2.1)			2 (1.9)		
Cardiac disorders	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Myocardial infarction	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Eye disorders	0	0	0	0	0	0	1 (0.3)	1	1	0	0	0
Uveitis	0	0	0	0	0	0	1 (0.3)	1	1	0	0	0
General disorders and administration site conditions	0	0	0	0	0	0	0	0	0	1 (0.9)	1	1
Oedema peripheral	0	0	0	0	0	0	0	0	0	1 (0.9)	1	1
Hepatobiliary disorders	0	0	0	0	0	0	1 (0.3)	1	0	0	0	0
Jaundice	0	0	0	0	0	0	1 (0.3)	1	0	0	0	0
Infections and infestations	2 (0.6)	2	2	2 (0.6)	2	0	2 (0.6)	2	1	0	0	0
Bronchitis	0	0	0	0	0	0	1 (0.3)	1	1	0	0	0
Diverticulitis	1 (0.3)	1	1	0	0	0	0	0	0	0	0	0
Extradural abscess	1 (0.3)	1	1	0	0	0	0	0	0	0	0	0
Paronychia	0	0	0	1 (0.3)	1	0	0	0	0	0	0	0
Perineal abscess	0	0	0	0	0	0	1 (0.3)	1	0	0	0	0
Pneumonia	0	0	0	1 (0.3)	1	0	0	0	0	0	0	0
Injury, poisoning and procedural complications	1 (0.3)	5	0	0	0	0	1 (0.3)	1	0	0	0	0
Foot fracture	1 (0.3)	2	0	0	0	0	0	0	0	0	0	0
Lower limb fracture	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Poisoning	0	0	0	0	0	0	1 (0.3)	1	0	0	0	0
Rib fracture	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Thoracic vertebral fracture	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cycts and polyps)	0	0	0	1 (0.3)	1	0	0	0	0	0	0	0
Gastric cancer	0	0	0	1 (0.3)	1	0	0	0	0	0	0	0
Nervous system disorders	0	0	0	0	0	0	1 (0.3)	1	0	0	0	0
Ischaemic cerebral infarction	0	0	0	0	0	0	1 (0.3)	1	0	0	0	0
Psychiatric disorders	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Depression	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Renal and urinary disorders	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Renal colic	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Epistaxis	1 (0.3)	1	0	0	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	0	0	0	2 (0.6)	2	2	1 (0.3)	1	1	2 (1.9)	2	2
Psoriasis	0	0	0	2 (0.6)	2	2	1 (0.3)	1	1	2 (1.9)	2	2

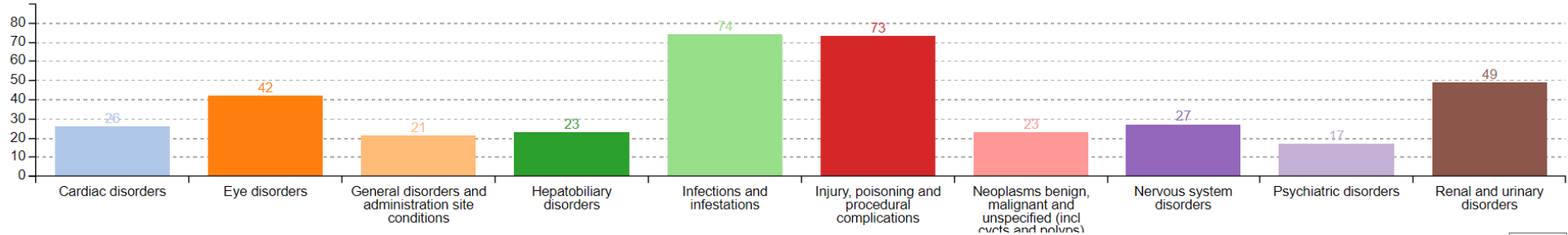
TREATMENT-EMERGENT SERIOUS ADVERSE EVENTS BY SYSTEM ORGAN CLASS AND PREFERRED TERM



Preferred Terms from all System Organ Class



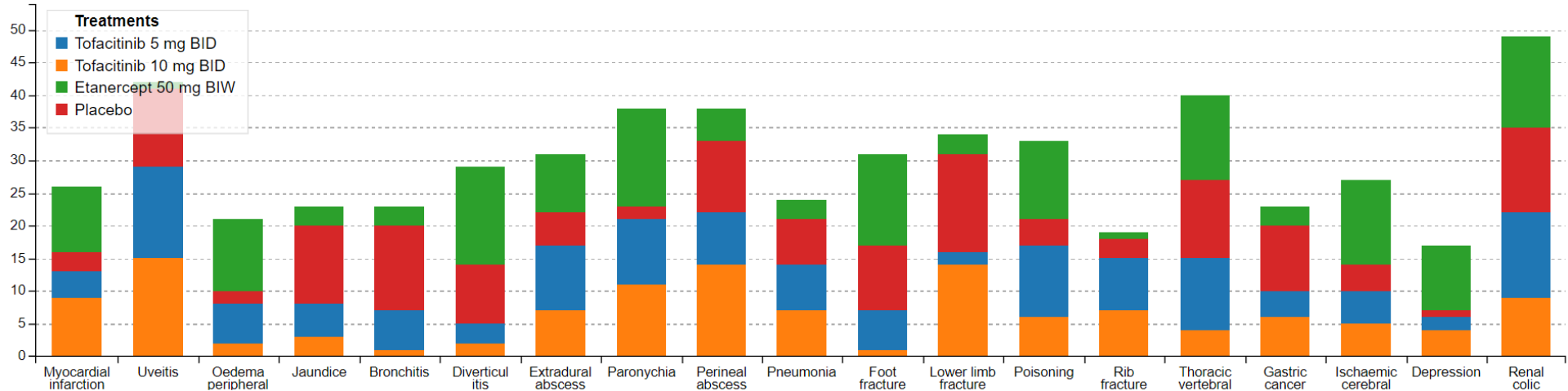
TEAES BY SOC AND PT (DUMMY DATA)



☒ Stacked Chart

Reset

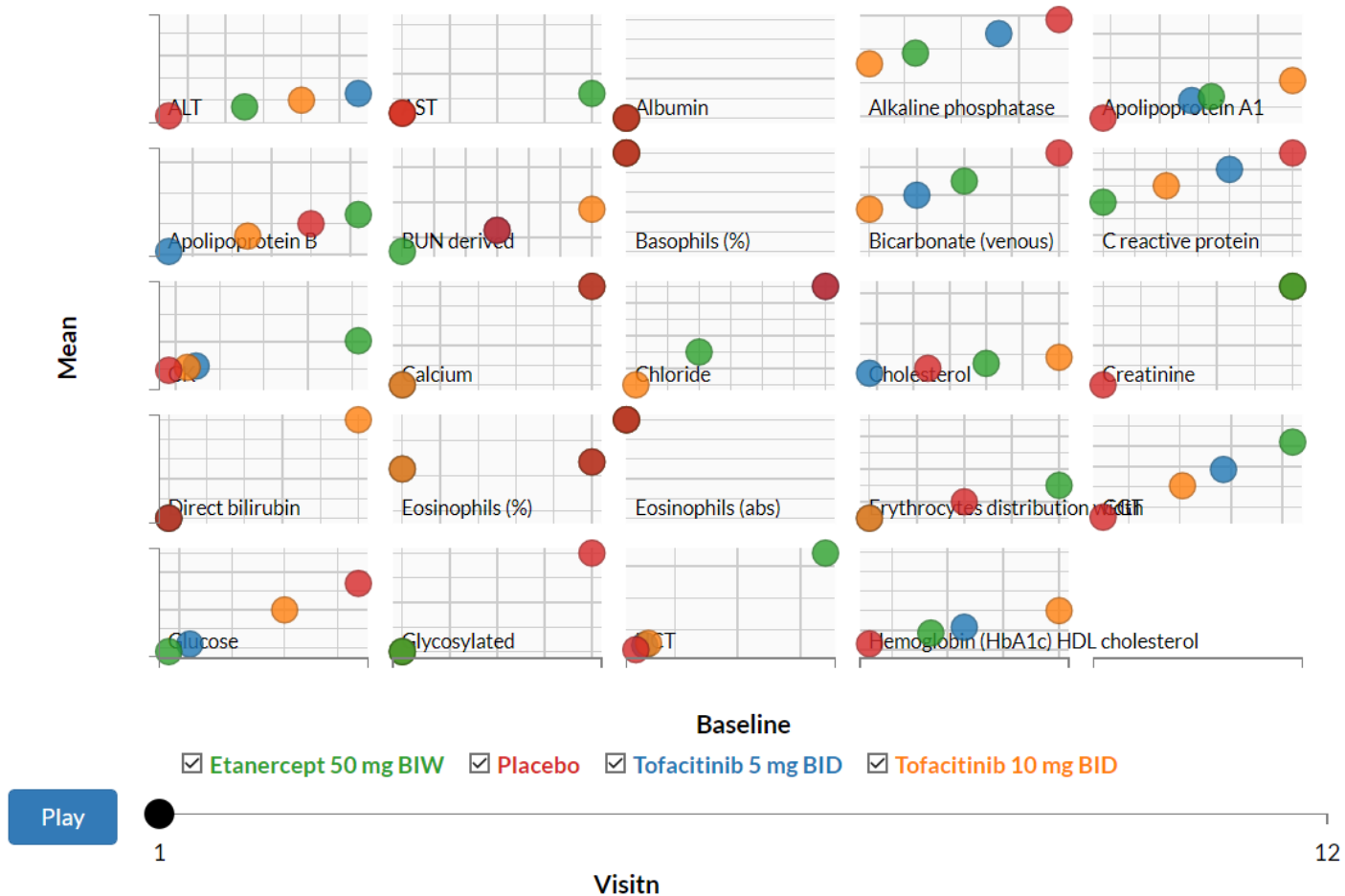
Preferred Terms from all System Organ Class



CHANGE FROM BASELINE TO LAST OBSERVATION

Parameter	Unit	Tofacitinib 5 mg BID			Tofacitinib 10 mg BID			Etanercept 50 mg BIW			Placebo		
		Mean			Mean			Mean			Mean		
		N	Baseline	Change From Baseline	N	Baseline	Change From Baseline	N	Baseline	Change From Baseline	N	Baseline	Change From Baseline
HGB	g/dL	326	15.6	-0.1	329	15.8	-0.3	333	15.6	0.1	105	15.4	0.1
Indirect bilirubin	mg/dL	327	0.3	0.0	329	0.4	0.	332	0.3	0.0	105	0.3	0.0
LDH	IU/L	325	175.4	7.7	328	172.2	17.2	332	175.8	-11.8	105	179.9	-3.1
LDL derived	mg/dL	326	113.7	4.3	324	113.6	5.5	330	115.0	-2.0	103	112.9	0.2
Lymphocytes (%)	%	326	25.5	2.4	329	25.3	2.6	333	25.7	7.0	105	26.0	1.1
Lymphocytes (abs)	10**3/mm**3	326	1.8	0.1	329	1.7	0.0	333	1.8	0.3	105	1.8	0.1
MCH	pg	326	31.2	0.1	329	31.2	0.3	333	31.2	0.0	105	31.3	-0.4
MCHC	g/dL	326	33.4	0.1	329	33.4	0.1	333	33.3	0.1	105	33.2	-0.2
MCV	10**-15 L	326	95.9	0.0	329	95.7	0.2	333	95.8	-0.1	105	96.1	-0.3
Monocytes (%)	%	326	5.9	0.3	329	5.9	0.4	333	5.9	0.6	105	5.9	0.1
Monocytes (abs)	10**3/mm**3	326	0.4	0.0	329	0.4	0.0	333	0.4	0.0	105	0.4	0.0
Neutrophils (%)	%	326	65.9	-2.4	329	65.9	-2.2	333	65.4	-7.8	105	65.1	-1.9
Platelets	10**3/mm**3	324	251.6	-10.4	329	243.6	-2.2	331	249.2	-18.2	104	254.2	-4.4
Potassium	MEQ/L	327	4.2	0.0	329	4.1	0.0	333	4.2	0.0	105	4.2	0.0
Red blood cell count	10**6/mm**3	326	5.2	0.0	329	5.2	-0.1	333	5.2	0.0	105	5.1	0.1
Reticulocyte count (%)	%	326	1.5	0.1	329	1.4	0.2	333	1.5	0.0	105	1.5	-0.1
Reticulocytes (abs)	10**3/mm**3	326	69.0	5.2	329	68.9	7.7	333	69.1	-0.4	105	68.5	-3.7
Sodium	MEQ/L	327	140.9	-0.1	329	140.7	0.0	333	140.8	-0.1	105	141	-0.1
Total bilirubin	mg/dL	327	0.6	0.1	329	0.6	0.0	333	0.5	0.	105	0.5	0.0
Total neutrophils (abs)	10**3/mm**3	326	4.8	-0.4	329	4.7	-0.5	333	4.7	-0.9	105	4.9	-0.3
Total protein	g/dL	327	7.3	0.0	329	7.3	0.0	333	7.3	0.0	105	7.3	0.0
Triglycerides	mg/dL	327	80.8	7.1	329	84.4	1.0	333	81.8	7.3	105	90.8	-2.2
Urine specific gravity		327	1.0	3.1	328	1.0	3.1	333	4.1	0.0	105	1.0	0.0
Urine pH		327	6.0	0.0	328	6.0	0.0	333	6.0	0.0	105	6.0	-0.1
White blood cell count	10**3/mm**3	326	7.1	-0.3	329	7.1	-0.5	333	7.1	-0.6	105	7.3	-0.2

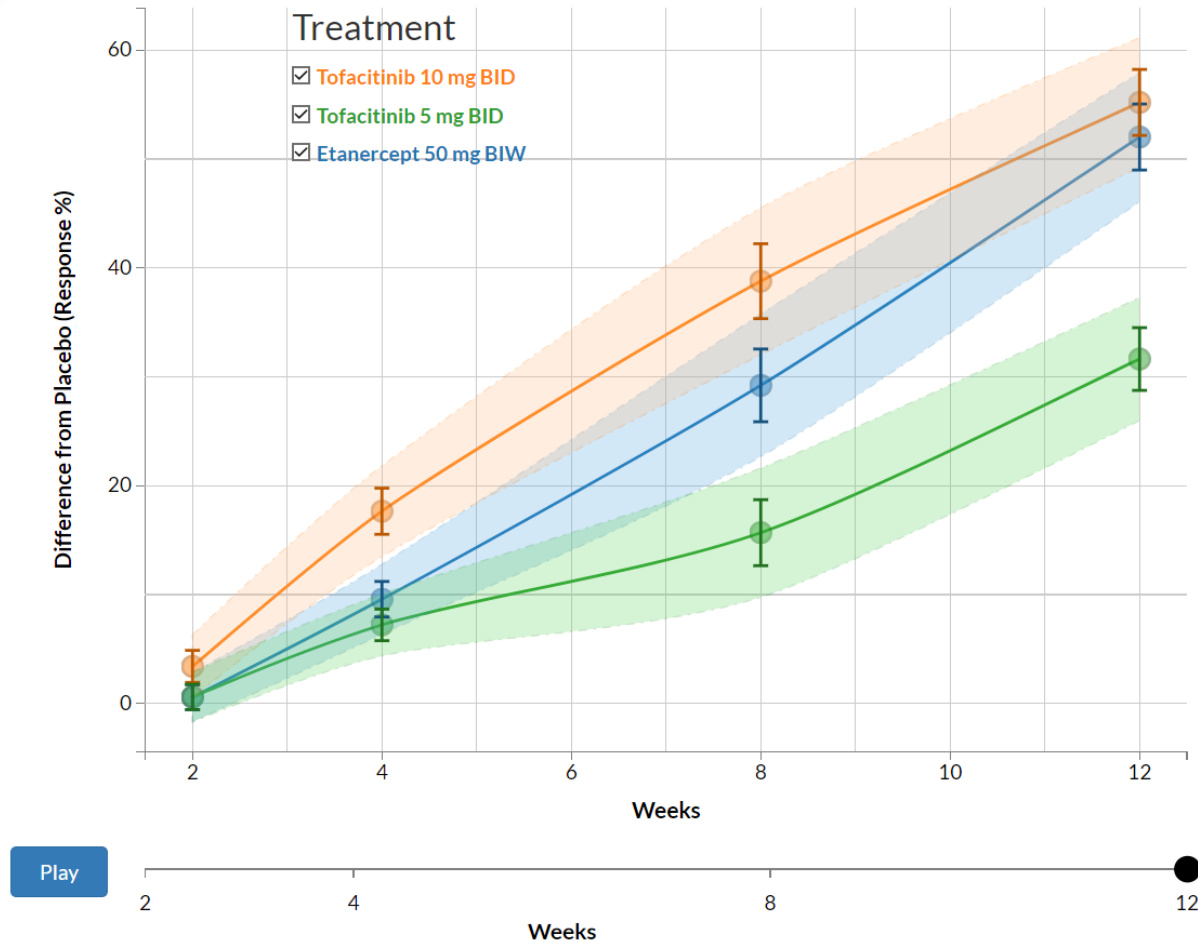
CHANGE FROM BASELINE TO LAST OBSERVATION (LAB RESULTS)



PROPORTION OF SUBJECTS ACHIEVING PATIENT GLOBAL ASSESSMENT (PTGA) RESPONSE (DIFFERENCE FROM PLACEBO)

Visit Treatment	Response			Difference From Placebo (Active - Placebo)		
	N	n (%)	SE	Diff	SE	95% CI
Week 2						
Tofacitinib 5 mg BID	324	5 (1.54)	0.68	0.60	1.16	-1.68, 2.88
Tofacitinib 10 mg BID	322	14 (4.35)	1.14	3.40	1.47	0.52, 6.29
Etanercept 50 mg BIW	331	5 (1.51)	0.67	0.57	1.15	-1.69, 2.83
Placebo	106	1 (0.94)	0.94			
Week 4						
Tofacitinib 5 mg BID	319	23 (7.21)	1.45	7.21	1.45	4.37, 10.05
Tofacitinib 10 mg BID	323	57 (17.65)	2.12	17.65	2.12	13.49, 21.80
Etanercept 50 mg BIW	324	31 (9.57)	1.63	9.57	1.63	6.36, 12.77
Placebo	100	0 (0.00)	0.00			
Week 8						
Tofacitinib 5 mg BID	313	62 (19.81)	2.25	15.68	3.03	9.76, 21.61
Tofacitinib 10 mg BID	317	136 (42.90)	2.78	38.78	3.44	32.04, 45.51
Etanercept 50 mg BIW	315	105 (33.33)	2.66	29.21	3.34	22.67, 35.75
Placebo	97	4 (4.12)	2.02			
Week 12						
Tofacitinib 5 mg BID	306	100 (32.68)	2.68	31.63	2.88	25.99, 37.27
Tofacitinib 10 mg BID	304	171 (56.25)	2.85	55.20	3.03	49.26, 61.14
Etanercept 50 mg BIW	309	164 (53.07)	2.84	52.02	3.03	46.09, 57.95
Placebo	95	1 (1.05)	1.05			

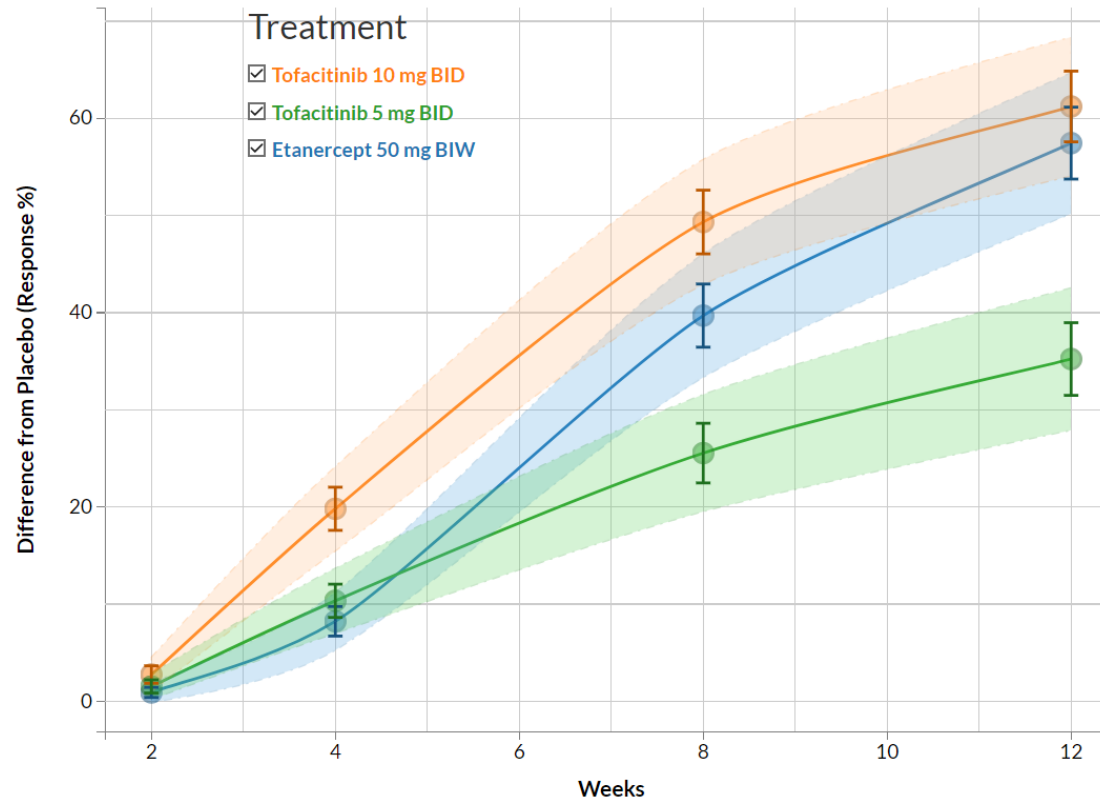
PROPORTION OF SUBJECTS ACHIEVING PATIENT GLOBAL ASSESSMENT (PTGA) RESPONSE (DIFFERENCE FROM PLACEBO)



PROPORTION OF SUBJECTS ACHIEVING PASI75 RESPONSE (DIFFERENCE FROM PLACEBO)

Visit Treatment	Response			Difference From Placebo (Active - Placebo)		
	N	n (%)	SE	Diff	SE	95% CI
Week 2						
Tofacitinib 5 mg BID	326	5 (1.53)	0.68	1.53	0.68	0.20, 2.87
Tofacitinib 10 mg BID	327	9 (2.75)	0.90	2.75	0.90	0.98, 4.53
Etanercept 50 mg BIW	331	3 (0.91)	0.52	0.91	0.52	-0.11, 1.93
Placebo	106	0 (0.00)	0			
Week 4						
Tofacitinib 5 mg BID	319	33 (10.34)	1.71	10.34	1.71	7.00, 13.69
Tofacitinib 10 mg BID	323	64 (19.81)	2.22	19.81	2.22	15.47, 24.16
Etanercept 50 mg BIW	328	27 (8.23)	1.52	8.23	1.52	5.26, 11.21
Placebo	102	0 (0.00)	0			
Week 8						
Tofacitinib 5 mg BID	315	90 (28.57)	2.55	25.54	3.07	19.52, 31.57
Tofacitinib 10 mg BID	319	167 (52.35)	2.80	49.32	3.28	42.88, 55.76
Etanercept 50 mg BIW	323	138 (42.72)	2.75	39.69	3.25	33.33, 46.06
Placebo	99	3 (3.03)	1.72			
Week 12						
Tofacitinib 5 mg BID	313	130 (41.53)	2.79	35.22	3.74	27.89, 42.55
Tofacitinib 10 mg BID	311	210 (67.52)	2.66	61.21	3.64	54.07, 68.35
Etanercept 50 mg BIW	309	197 (63.75)	2.73	57.44	3.70	50.18, 64.69
Placebo	95	6 (6.32)	2.50			

PROPORTION OF SUBJECTS ACHIEVING PASI75 RESPONSE (DIFFERENCE FROM PLACEBO)



Play



STUDY CONCLUSION

- Tofacitinib 10 mg BID was non-inferior to Etanercept 50 mg BIW
- Tofacitinib 10 mg BID and Etanercept 50 mg BIW were superior to Placebo at Week 12 for both PASI75 and PGA “clear” or “almost clear” endpoints

SUMMARY

- Visualisation can help to speed up review of summary data
- Important to select appropriate graphical representation
- Require a stable results database structure
- Reusable charts
 - Instantly available without further programming
 - Interactive and memorable
 - Drill down in the future to the raw data
 - Automatic presentation from the results

QUESTIONS OR COMMENTS?



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