

SUPPLEMENTARY MATERIAL

Table S1. Overview of available clinical evidence from the randomized controlled trials of biologics

Interventions	Trial	Population		Data on response/ remission with induction therapy		Data on sustained response/remission with maintenance therapy up to 1 year		
		Anti- TNF- naive UC patients	Anti-TNF- experienced UC patients	Available	Time point	Available	Re-randomization/re- allocation of treatment after induction response	Time-frame ^a
Infliximab	ACT-1 ¹	X		X	Week 8	X	No	Weeks 8–54 ^b
	ACT-2 ¹	X		X	Week 8			
Adalimumab	ULTRA 1 ²	X		X	Week 8			
	ULTRA 2 ³	X	X	X	Week 8	X	No	Weeks 8–52 ^c
Golimumab	PURSUIT-SC ⁴	X		X	Week 6			
	PURSUIT-M ⁵	X				X	Yes, at week 6 of PURSUIT-SC, which is week 0 of PURSUIT-M	Weeks 6–60 ^d
Vedolizumab	GEMINI-1 ⁶	X	X	X	Week 6	X	Yes, at week 6	Weeks 6–52 ^e

^aWeek 0 is defined as beginning of induction therapy.

^bResponse/remission at weeks 8, 30, and 54.

^cResponse/remission at both weeks 8 and 52.

^dMaintenance of response through week 54 among induction responders (week 0 in maintenance trial); maintenance of remission through week 54 among patients in remission with induction therapy (week 0 in maintenance trial).

^eResponse/remission at weeks 6 and 52.

Abbreviations: TNF, tumor necrosis factor; UC, ulcerative colitis.

Table S2. Baseline patient characteristics by trial at start of induction therapy

Trial	Interventions	Anti-TNF-naïve patients (%)	Male patients	Age (years)	Weight (kg)	Disease duration (years)	Mayo score	Concomitant therapy (%)			Disease location (%)		
								Amino-salicylates	Azathioprine	Corticosteroids	Extensive	Left-sided	Other
ACT-1 ¹	Placebo	100	59.5	41.4 ^a	76.8 ^a	6.3 ^a	8.4 ^a	70.2	29.8	63.5	45.0	55.0	0
	Infliximab 5 mg/kg	100	64.5	42.4 ^a	80.0 ^a	5.9 ^a	8.5 ^a	67.8	37.2	57.9	47.1	52.9	0
ACT-2 ¹	Placebo	100	57.7	39.3 ^a	76.1 ^a	6.5 ^a	8.5 ^a	72.4	28.5	48.8	41.7	58.3	0
	Infliximab 5 mg/kg	100	62.8	40.5 ^a	78.4 ^a	6.7 ^a	8.3 ^a	76.0	33.9	49.6	40.7	59.3	0
ULTRA 1 ²	Placebo	100	63.1	37.0 ^b	78.7 ^a	5.4 ^b	8.7 ^a	75.4	NR	67.6	56.2	32.3	11.5
	Adalimumab 160/80/40 mg	100	63.8	36.5 ^b	75.5 ^a	6.1 ^b	8.8 ^a	80.8	NR	54.6	46.2	46.9	6.9
ULTRA 2 ³	Placebo	59	61.8	41.3 ^a	77.1 ^a	8.5 ^a	8.9 ^a	63.0	32.5	56.9	48.8	39.0	12.2
	Adalimumab 160/80/40 mg	61	57.3	39.6 ^a	75.3 ^a	8.1 ^a	8.9 ^a	58.9	37.5	60.5	48.4	38.7	12.9
PURSUIT-SC ⁴	Placebo	100	52.9	39.0 ^a	NR	6.0 ^a	8.3 ^a	83.4	30.8	40.5	43.0	57.0	0
	Golimumab	100	57.4	40.4 ^a	NR	6.4 ^a	8.5 ^a	81.2	31.3	43.9	41.8	58.2	0
GEMINI-1 ⁶	Placebo	51	62.0	41.2 ^a	72.4	7.1 ^a	8.6 ^a	61.1	22.1	56.4	12.0	39.5	48.5
	Vedolizumab	58	59.0	40.1 ^a	72.4	6.1 ^a	8.5 ^a	55.6	26.2	56.0	11.1	40.9	48.0

Note: The baseline characteristics presented for the GEMINI-1 and PURSUIT trials are provided as those listed in the induction phase. The baseline characteristics for the GEMINI-1 and ULTRA-2 trials were not stratified by prior anti-TNF experience and are therefore presented for the entire population.

^aMean; ^bMedian.

Abbreviations: NR, not reported; NA, not applicable.

Table S3. Efficacy data from randomized controlled trials among anti-TNF-naïve patients with ulcerative colitis

Trial	Treatment	Induction		Maintenance ("at risk" population are patients starting induction)		Maintenance ("at risk" population are patients starting maintenance)		Induction				Maintenance					Induction followed by maintenance			
		Response	Remission	Sustained response	Sustained remission	Sustained response	Sustained remission	N	Response, no remission	Remission	No response	N	N ^a	Other	Ind. Remission and Maint. Remission	No Ind. Response and/or No Maint. Response	N	Other	Ind. Remission and Maint. Remission	No Ind. Response and/or No Maint. Response
ACT-1 ¹	Placebo	0.37	0.15	0.14	0.07			121	27	18	76	121		9	8	104	121	9	8	104
ACT-1 ¹	Infliximab 5 mg/kg	0.69	0.39	0.39	0.20			121	37	47	37	121		23	24	74	121	23	24	74
ACT-2 ¹	Placebo	0.29	0.06					123	29	7	87									
ACT-2 ¹	Infliximab 5 mg/kg	0.65	0.34					121	37	41	43									
ULTRA 1 ²	Placebo	0.45	0.09					130	46	12	72									
ULTRA 1 ²	Adalimumab 160/80/40 mg	0.55	0.18					130	47	24	59									
ULTRA 2 ³	Placebo	0.39	0.11	0.17	0.06			145	40	16	89	145		15	9	121	145	15	9	121
ULTRA 2 ³	Adalimumab 160/80/40 mg	0.59	0.21	0.29	0.11			150	57	32	61	150		28	16	106	150	28	16	106
PURSUIT-SC ⁴	Placebo	0.30	0.06					256	60	16	180									
PURSUIT-SC ⁴	Golimumab 200/100 mg	0.52	0.19					257	85	48	124									
PURSUIT-M ⁵	Placebo					0.30	0.25					129			33		256			233
PURSUIT-M ⁵	Golimumab 200/100/100 mg					0.50	0.39					151	54		21		257			191
GEMINI-1 ⁶	Placebo	0.26	0.07			0.35	0.05	76	15	5	56	20		6	1		76	6	1	69
GEMINI-1 ⁶	Vedolizumab 300 mg (induction)	0.53	0.23					130	39	30	61									
GEMINI-1 ⁶	Vedolizumab 300 mg q8					0.65	0.22					72		31	16		130	30	15	85

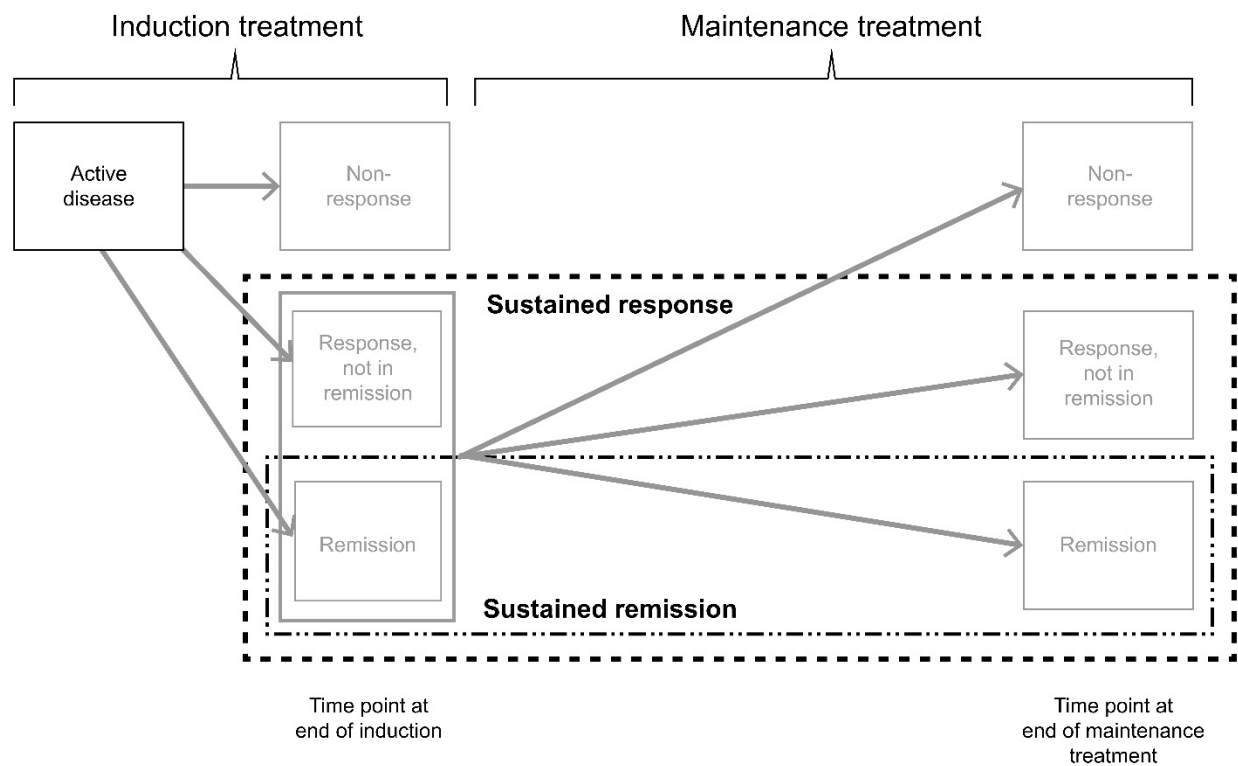
^aFor the PURSUIT-M trial, the N for the remission group does not equal the N for the response group (maintained clinical remission among those who were in clinical remission at baseline).

Table S4. Efficacy data from randomized controlled trials among anti-TNF-experienced patients with ulcerative colitis

Trial	Treatment	Induction		Maintenance ("at risk" population are patients starting induction)		Maintenance ("at risk" population are patients starting maintenance)		Induction (used for analysis)				Maintenance				Induction followed by maintenance (used for analysis)			
		Response	Remission	Sustained response	Sustained remission	Sustained response	Sustained remission	N	Response, no remission	Remission	No response	N	Other	Ind. Remission and Maint. Remission	No Ind. Response and/or No Maint. Response	N	Other	Ind. Remission and Maint. Remission	No Ind. Response and/or No Maint. Response
ULTRA 2 ³	Placebo	0.29	0.07	0.06	0.01			101	22	7	72	101	5	1	95	101	5	1	95
ULTRA 2 ³	Adalimumab 160/80/40 mg	0.37	0.09	0.15	0.05			98	27	9	62	98	10	5	83	98	10	5	83
GEMINI-1 ⁶	Placebo	0.21	0.03			0.17	0.00	63	11	2	50	18	3	0		63	2	0	61
GEMINI-1 ⁶	Vedolizumab 300 mg (induction)	0.39	0.10					82	24	8	50								
GEMINI-1 ⁶	Vedolizumab 300 mg q8 weeks					0.47	0.21					43	11	9		82	8	7	67

Figure S1. Clinical response and remission as used in example analysis.

Only patients with a successful response to induction therapy continue with maintenance therapy. Sustained response and sustained remission among all patients with moderately to severely active ulcerative colitis starting induction therapy are the outcomes of interest used to calculate the number needed to treat.



References

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6. Feagan BG, Rutgeerts P, Sands BE, et al. Vedolizumab as induction and maintenance therapy for ulcerative colitis. *N Engl J Med*. 2013;369(8):699-710.