

Supplemental material for Incidence of Infusion Reactions and Clinical Effectiveness of Intravenous Golimumab versus Infliximab in Patients with Rheumatoid Arthritis: The Real-World AWARE Study

Supplemental Table 1: Shifts in Imputed Categorical CDAI of biologic-naïve golimumab-IV and infliximab patients									
		Biologic-naïve golimumab-IV				Biologic-naïve infliximab			
		Baseline CDAI Category				Baseline CDAI Category			
Visit	Follow-up CDAI Category	LDA/ Remission* (n =16)	MDA (n=55)	HDA (n=144)	Total (n=215)	LDA/ Remission* (n=20)	MDA (n=54)	HDA (n=148)	Total (n=222)
Month 3	Remission (CDAI ≤ 2.8)	2 (12.5)	5 (9.1)	2 (1.4)	9 (4.2)	3 (15.0)	5 (9.3)	2 (1.4)	10 (4.5)
Month 3	LDA (CDAI >2.8 and ≤ 10)	10 (62.5)	18 (32.7)	17 (11.8)	45 (20.9)	13 (65.0)	16 (29.6)	14 (9.5)	43 (19.4)
Month 3	MDA (CDAI > 10 and ≤ 22)	4 (25.0)	27 (49.1)	38 (26.4)	69 (32.1)	2 (10.0)	30 (55.6)	36 (24.3)	68 (30.6)
Month 3	HDA (CDAI > 22)	0 (0.0)	5 (9.1)	87 (60.4)	92 (42.8)	2 (10.0)	3 (5.6)	96 (64.9)	101 (45.5)
Month 6	Remission (CDAI ≤ 2.8)	6 (37.5)	5 (9.1)	6 (4.2)	17 (7.9)	4 (20.0)	8 (14.8)	4 (2.7)	16 (7.2)
Month 6	LDA (CDAI >2.8 and ≤ 10)	6 (37.5)	28 (50.9)	31 (21.5)	65 (30.2)	12 (60.0)	23 (42.6)	23 (15.5)	58 (26.1)
Month 6	MDA (CDAI > 10 and ≤ 22)	3 (18.8)	20 (36.4)	30 (20.8)	53 (24.7)	3 (15.0)	21 (38.9)	41 (27.7)	65 (29.3)
Month 6	HDA (CDAI > 22)	1 (6.3)	2 (3.6)	77 (53.5)	80 (37.2)	1 (5.0)	2 (3.7)	80 (54.1)	83 (37.4)
Month 12	Remission (CDAI ≤ 2.8)	4 (25.0)	6 (10.9)	8 (5.6)	18 (8.4)	7 (35.0)	10 (18.5)	5 (3.4)	22 (9.9)
Month 12	LDA (CDAI >2.8 and ≤ 10)	9 (56.3)	27 (49.1)	30 (20.8)	66 (30.7)	7 (35.0)	19 (35.2)	28 (18.9)	54 (24.3)
Month 12	MDA (CDAI > 10 and ≤ 22)	2 (12.5)	21 (38.2)	32 (22.2)	55 (25.6)	5 (25.0)	15 (27.8)	43 (29.1)	63 (28.4)
Month 12	HDA (CDAI > 22)	1 (6.3)	1 (1.8)	74 (51.4)	76 (35.3)	1 (5.0)	10 (18.5)	72 (48.6)	83 (37.4)

Data shown as n (%).

* Includes both Remission and LDA categories (CDAI ≤ 10)

CDAI clinical disease activity index, HDA high disease activity, IV intravenous, LDA low disease activity, MDA moderate disease activity

Supplemental Table 2: Prescribed dose (mg/kg) by infusion visit in biologic-naïve and biologic-experienced patients who received golimumab-IV, infliximab with dose escalation, or infliximab without dose escalation (patients with imputed CDAI).

	Biologic-naïve Patients				Biologic-experienced Patients			
	Golimumab-IV	Dose-escalated infliximab*	Non-dose-escalated infliximab	Combined infliximab	Golimumab-IV	Dose-escalated infliximab*	Non-dose-escalated infliximab	Combined infliximab
Infusion visit 1								
Patients, N	215	172	50	222	398	234	53	287
Mean dose ± SD	2.00 ± 0.00	3.25 ± 0.62	3.36 ± 0.67	3.28 ± 0.63	2.00 ± 0.06	3.29 ± 0.79	3.35 ± 0.76	3.30 ± 0.78
Infusion visit 2								
Patients, N	213	172	49	221	395	234	50	284
Mean dose ± SD	2.00 ± 0.00	3.28 ± 0.64	3.33 ± 0.62	3.29 ± 0.64	2.00 ± 0.01	3.35 ± 0.84	3.36 ± 0.78	3.35 ± 0.83
Infusion visit 3								
Patients, N	206	171	41	212	374	232	47	279
Mean dose ± SD	2.00 ± 0.00	3.41 ± 0.78	3.33 ± 0.61	3.39 ± 0.75	2.00 ± 0.01	3.60 ± 1.17	3.31 ± 0.69	3.55 ± 1.11
Infusion visit 4								
Patients, N	180	170	37	207	331	227	35	262
Mean dose ± SD	2.00 ± 0.00	3.91 ± 1.20	3.29 ± 0.66	3.80 ± 1.15	2.00 ± 0.02	4.03 ± 1.40	3.32 ± 0.72	3.94 ± 1.35
Infusion visit 5								
Patients, N	163	159	26	185	300	216	22	238
Mean dose ± SD	2.00 ± 0.00	4.29 ± 1.38	3.37 ± 0.69	4.16 ± 1.35	2.01 ± 0.07	4.54 ± 1.74	3.45 ± 1.54	4.44 ± 1.75
Infusion visit 6								
Patients, N	142	151	22	173	263	202	16	218
Mean dose ± SD	2.00 ± 0.00	4.67 ± 1.64	3.35 ± 0.65	4.50 ± 1.61	2.00 ± 0.02	4.85 ± 1.87	3.18 ± 0.55	4.73 ± 1.86
Infusion visit 7								
Patients, N	132	147	19	166	243	181	15	196
Mean dose ± SD	2.00 ± 0.00	4.80 ± 1.66	3.41 ± 0.69	4.64 ± 1.64	2.00 ± 0.03	5.13 ± 2.00	3.09 ± 0.29	4.97 ± 2.0
Infusion visit 8								
Patients, N	119	135	18	153	224	160	12	172
Mean dose ± SD	2.00 ± 0.00	4.91 ± 1.71	3.43 ± 0.70	4.73 ± 1.69	2.00 ± 0.03	5.38 ± 2.14	3.25 ± 0.62	5.23 ± 2.14
Infusion visit 9								
Patients, N	107	127	18	145	206	140	8	148
Mean dose ± SD	2.00 ± 0.00	5.14 ± 1.75	3.31 ± 0.58	4.91 ± 1.76	2.00 ± 0.03	5.48 ± 2.09	3.25 ± 0.71	5.36 ± 2.10

*Included patients who had at least one administration consistent with dose escalation.

IV intravenous, SD standard deviation

Supplemental Table 3. Mean CDAI scores and mean change from baseline (observed data) through month 12 for golimumab-IV, dose-escalated infliximab and non-dose-escalated infliximab among patients who were biologic-naïve or biologic-experienced

	Observed Biologic-naïve Patients				Observed Biologic-experienced Patients			
	Golimumab-IV	Dose-escalated infliximab*	Non-dose-escalated infliximab	Combined infliximab	Golimumab-IV	Dose-escalated infliximab*	Non-dose-escalated infliximab	Combined infliximab
Baseline								
Patients, N	110	106	32	138	209	123	21	144
Mean ± SD	29.1 ± 14.4	31.9 ± 14.3	22.4 ± 12.9	29.7 ± 14.5	30.8 ± 15.3	33.7 ± 15.8	25.7 ± 10.8	32.6 ± 15.4
Month 6								
Score, N	98	92	27	119	196	107	18	125
Mean ± SD	12.9 ± 12.6	18.2 ± 14.9	11.4 ± 11.0	16.7 ± 14.3	18.4 ± 13.5	22.6 ± 15.1	11.8 ± 7.2	21.1 ± 14.7
Change from baseline, N	97	92	27	119	196	107	18	125
Mean ± SD	-15.7 ± 13.4	-13.4 ± 13.9	-10.2 ± 9.6	-12.7 ± 13.0	-12.3 ± 15.2	-10.3 ± 15.1	-14.1 ± 11.8	-10.8 ± 14.7
Month 12								
Score, N	111	106	32	138	209	123	21	144
Mean ± SD	13.6 ± 12.4	18.4 ± 14.2)	11.3 ± 11.8	16.8 ± 14.0	17.2 ± 14.1	21.4 ± 15.4	15.1 ± 12.7	20.5 ± 15.2
Change from baseline, N	110	106	32	138	209	123	21	144
Mean ± SD	-15.5 ± 13.8	-13.5 ± 14.3	-11.1 ± 15.2	-12.9 ± 14.5	-13.6 ± 14.4	-12.3 ± 15.4	-10.6 ± 14.1	-12.1 ± 15.1

*Included patients who had at least one administration consistent with dose escalation.

CDAI clinical disease activity index, IV intravenous, SD standard deviation