

Secondary efficacy outcome 9: Partial Remission

Table 6.6-26: Partial Remission – Completeness of data (ITT)

Analysis status	Partial remission at 12 months	CSII	MDI	Total
Included	Included	86 (59.7%)	64 (43%)	150 (51.2%)
Excluded	No HbA1c measurement and no dose data	0 (0%)	2 (1.3%)	2 (0.7%)
	No dose data	57 (39.6%)	75 (50.3%)	132 (45.1%)
	No dose data and weight not recorded	0 (0%)	2 (1.3%)	2 (0.7%)
	WD from study prior to 12 months	1 (0.7%)	5 (3.4%)	6 (2%)
	Weight not recorded	0 (0%)	1 (0.7%)	1 (0.3%)

Table 6.6-27: Partial Remission – Results summary at 12m (ITT)

	CSII	MDI	Overall	Relative risk (95% CI)	p-value
Partial remission at 12 months: n (%)	86	64	150	0.74 (0.45, 1.24)	0.28
No	65 (75.6%)	43 (67.2%)	108 (72.0%)		
Yes	21 (24.4%)	21 (32.8%)	42 (28.0%)		

Table 6.6-28: Partial Remission – Results summary at 3m, 6m and 9m (ITT)

	CSII	MDI	Overall
Partial remission at 3 months: n (%)	94	91	185
No	32 (34.0%)	34 (37.4%)	66 (35.7%)
Yes	62 (66.0%)	57 (62.6%)	119 (64.3%)
Partial remission at 6 months: n (%)	79	79	158
No	39 (49.4%)	35 (44.3%)	74 (46.8%)
Yes	40 (50.6%)	44 (55.7%)	84 (53.2%)
Partial remission at 9 months: n (%)	92	68	160
No	66 (71.7%)	44 (64.7%)	110 (68.7%)
Yes	26 (28.3%)	24 (35.3%)	50 (31.3%)

Table 6.6-29: Partial Remission – Summary at each visit (ITT)

Summary	CSII				MDI				Total			
	03m	06m	09m	12m	03m	06m	09m	12m	03m	06m	09m	12m
N	94	79	92	86	91	79	68	64	185	158	160	150
1. Not in partial remission	32 (34%)	30 (38%)	51 (55.4%)	57 (66.3%)	34 (37.4%)	24 (30.4%)	30 (44.1%)	38 (59.4%)	66 (35.7%)	54 (34.2%)	81 (50.6%)	95 (63.3%)
2. Entering partial remission	62 (66%)	4 (5.1%)	0 (0%)	4 (4.7%)	57 (62.6%)	4 (5.1%)	0 (0%)	4 (6.3%)	119 (64.3%)	8 (5.1%)	0 (0%)	8 (5.3%)
3. Remaining in partial remission	0 (0%)	31 (39.2%)	18 (19.6%)	12 (14%)	0 (0%)	34 (43%)	18 (26.5%)	11 (17.2%)	0 (0%)	65 (41.1%)	36 (22.5%)	23 (15.3%)
4. In partial remission (no info from previous visit)	0 (0%)	5 (6.3%)	8 (8.7%)	5 (5.8%)	0 (0%)	6 (7.6%)	6 (8.8%)	6 (9.4%)	0 (0%)	11 (7%)	14 (8.8%)	11 (7.3%)
5. Leaving partial remission	0 (0%)	9 (11.4%)	15 (16.3%)	8 (9.3%)	0 (0%)	11 (13.9%)	14 (20.6%)	5 (7.8%)	0 (0%)	20 (12.7%)	29 (18.1%)	13 (8.7%)

Table 6.6-30: Partial Remission – Transitions from 6m to 12m (ITT)

	CSII	MDI	Total
Number in PR at 6m	31	31	62
Number still in PR at 12m	18/31 (58.1%)	15/31 (48.4%)	33/62 (53.2%)
Number not in PR at 6m	33	22	55
Number now in PR at 12m	1 (3.0%)	1 (4.6%)	2 (3.6%)

Note: Only patients with a PR Yes/No at both 6m and 12m have been included in the summary.

Figure 6.6-12: Partial remission – Mean profile plots (<5 years old) (ITT)
Mean Profile Plots For Proportion Of <5 Years Old Patients In Partial Remission
Proportion In Partial Remission

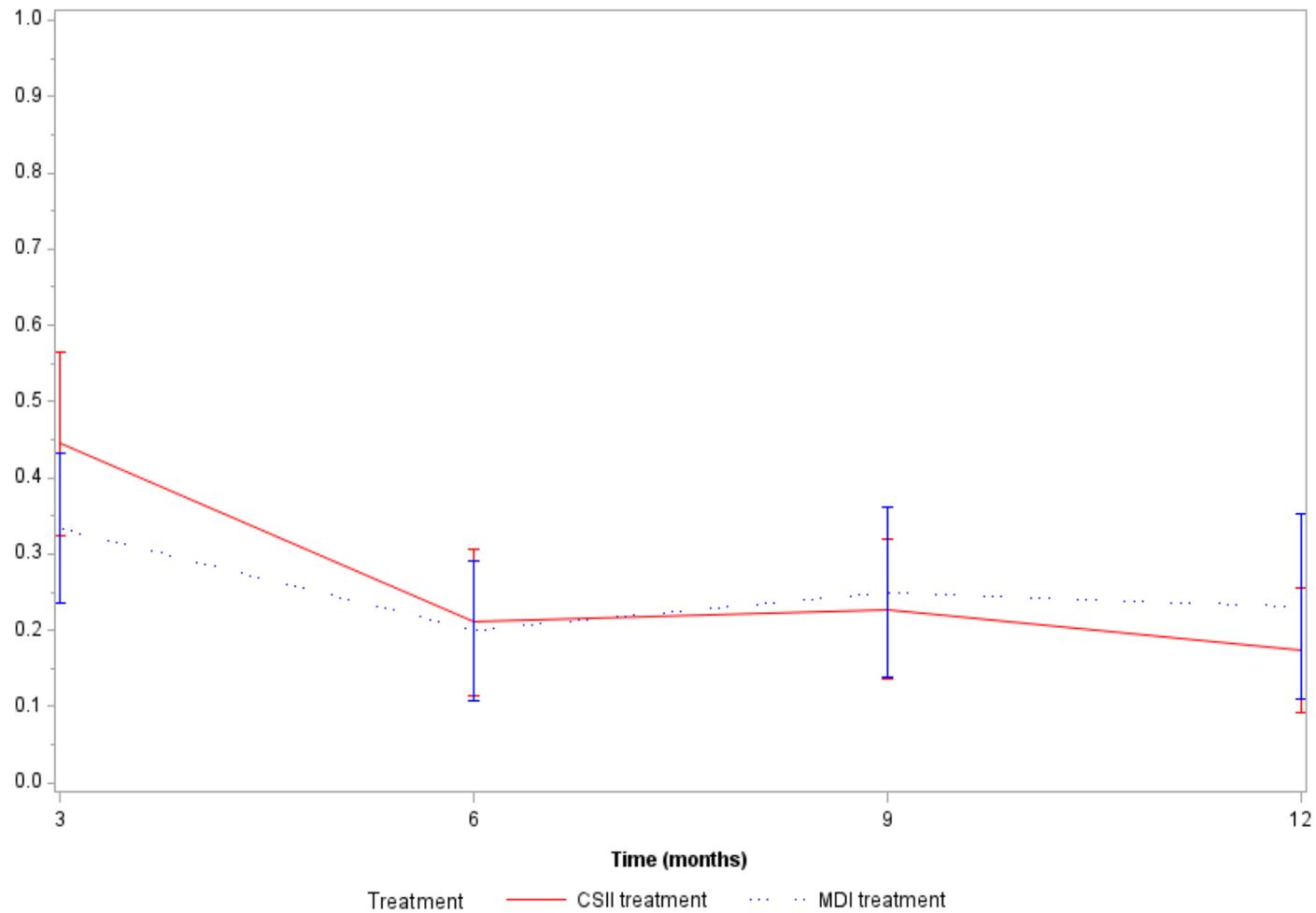


Figure 6.6-13: Partial remission – Mean profile plots (5-11 years old) (ITT)

Mean Profile Plots For Proportion Of 5-11 Years Old Patients In Partial Remission

Proportion In Partial Remission

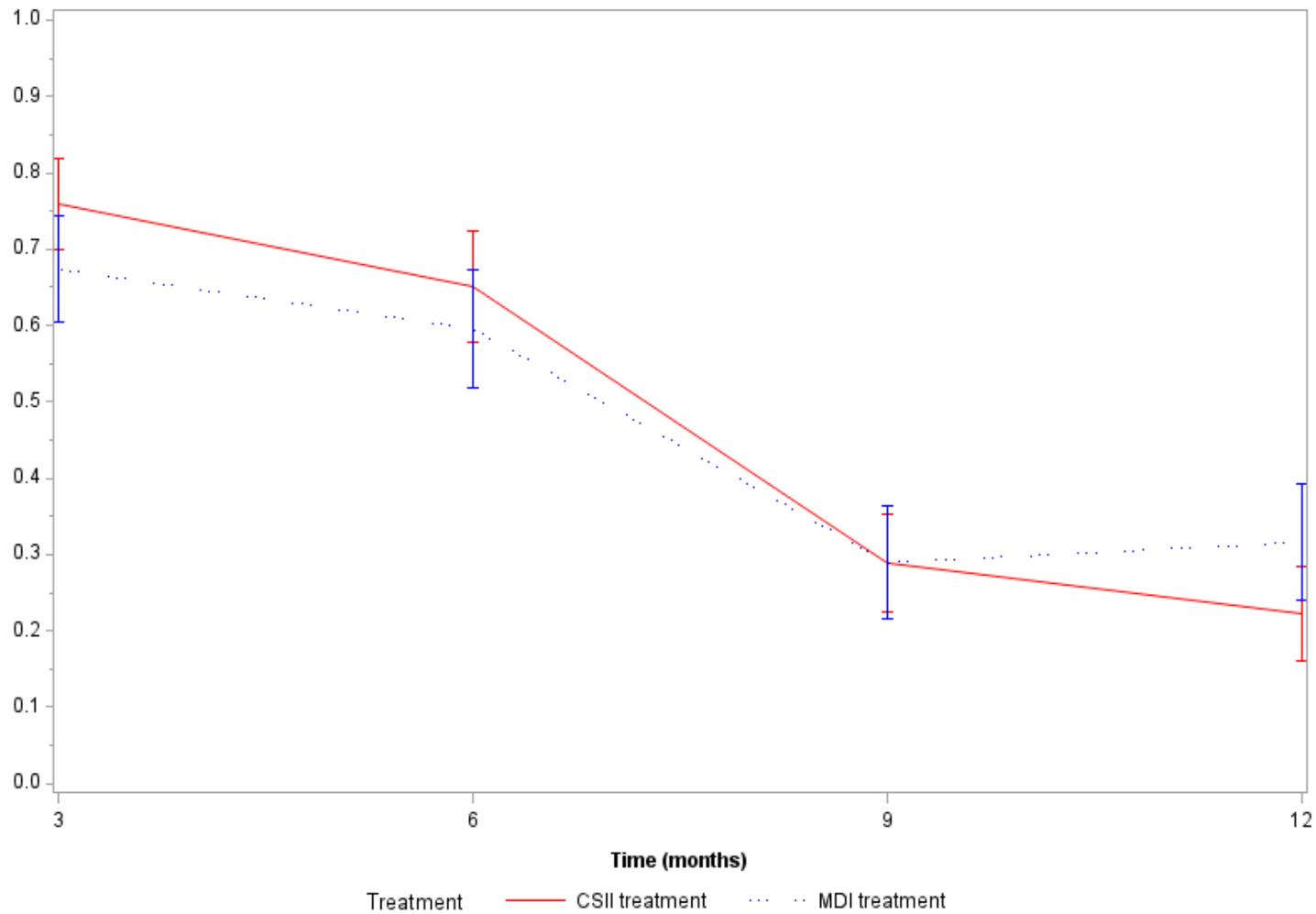


Figure 6.6-14: Partial remission – Mean profile plots (12+ years old) (ITT)

Mean Profile Plots For Proportion Of 12+ Years Old Patients In Partial Remission

Proportion In Partial Remission

