

Table 15.12.5.1: Analysis of RBC Transfusion Dependence Rate at Week 24 and at Week 12
Double-Blind Phase
Intent-to-Treat Analysis Set

	MMB (N=215)	RUX (N=217)	Total (N=432)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	150 (69.8%)	130 (59.9%)	280 (64.8%)
Transfusion Requiring, n(%)	7 (3.3%)	23 (10.6%)	30 (6.9%)
Transfusion Independent, n(%)	143 (66.5%)	107 (49.3%)	250 (57.9%)
Dependent, n(%)	65 (30.2%)	87 (40.1%)	152 (35.2%)
95% Exact CI	0.2417, 0.3685	0.3352, 0.4694	0.3068, 0.3989
Proportion Difference - Stratified CMH Method (95% CI)	-0.10 (-0.19, -0.02)		
p-value	0.019		
Proportion Difference - Unstratified Method (95% CI)	-0.10 (-0.19, -0.01)		
p-value	0.031		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.10 (-0.19, -0.01)		
p-value	0.035		
>=4 units transfused in the last 8 weeks	17 (7.9%)	43 (19.8%)	60 (13.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	24 (11.2%)	61 (28.1%)	85 (19.7%)
Last Participation date < Day 162 in DB phase	32 (14.9%)	12 (5.5%)	44 (10.2%)
Other	14 (6.5%)	29 (13.4%)	43 (10.0%)

95% Exact CI is based on Clopper-Pearson method without stratification.

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

CMH = Cochran-Mantel-Haenszel

RBC = Red Blood Cell

Source: Listing 16.3.3.2

Data Extracted: CRF data: 01JUL2019

Source: ...\\version5\\prog\\t-tf-td.sas v9.4 Output file: t-rbctd24.out 09MAR2021:19:03

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	167 (77.7%)	121 (55.8%)	288 (66.7%)
Transfusion Requiring, n(%)	20 (9.3%)	19 (8.8%)	39 (9.0%)
Transfusion Independent, n(%)	147 (68.4%)	102 (47.0%)	249 (57.6%)
Dependent, n(%)	48 (22.3%)	96 (44.2%)	144 (33.3%)
95% Exact CI	0.1694, 0.2849	0.3752, 0.5112	0.2890, 0.3800
Proportion Difference - Stratified CMH Method (95% CI)	-0.22 (-0.30, -0.15)		
p-value	<0.001		
Proportion Difference - Unstratified Method (95% CI)	-0.22 (-0.31, -0.13)		
p-value	<0.001		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.22 (-0.31, -0.13)		
p-value	<0.001		
>=4 units transfused in the last 8 weeks	22 (10.2%)	50 (23.0%)	72 (16.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	23 (10.7%)	86 (39.6%)	109 (25.2%)
Last Participation date < Day 78 in DB phase	16 (7.4%)	2 (0.9%)	18 (4.2%)
Other	14 (6.5%)	40 (18.4%)	54 (12.5%)

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Stratum 1			
Transfusion Dependence Yes and Platelet Count < 100X10E9/L	10	11	21
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	5 (50.0%)	3 (27.3%)	8 (38.1%)
Transfusion Requiring, n(%)	0	1 (9.1%)	1 (4.8%)
Transfusion Independent, n(%)	5 (50.0%)	2 (18.2%)	7 (33.3%)
Dependent, n(%)	5 (50.0%)	8 (72.7%)	13 (61.9%)
95% Exact CI	0.1871, 0.8129	0.3903, 0.9398	0.3844, 0.8189
Proportion Difference (95% CI)	-0.23 (-0.66, 0.20)		
Proportion Difference using Exact Method (95% CI)	-0.23 (-0.61, 0.23)		
>=4 units transfused in the last 8 weeks	4 (40.0%)	4 (36.4%)	8 (38.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	3 (30.0%)	4 (36.4%)	7 (33.3%)
Last Participation date < Day 162 in DB phase	1 (10.0%)	3 (27.3%)	4 (19.0%)
Other	1 (10.0%)	3 (27.3%)	4 (19.0%)

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	4 (40.0%)	3 (27.3%)	7 (33.3%)
Transfusion Requiring, n(%)	2 (20.0%)	2 (18.2%)	4 (19.0%)
Transfusion Independent, n(%)	2 (20.0%)	1 (9.1%)	3 (14.3%)
Dependent, n(%)	6 (60.0%)	8 (72.7%)	14 (66.7%)
95% Exact CI	0.2624, 0.8784	0.3903, 0.9398	0.4303, 0.8541
Proportion Difference (95% CI)	-0.13 (-0.55, 0.30)		
Proportion Difference using Exact Method (95% CI)	-0.13 (-0.52, 0.32)		
>=4 units transfused in the last 8 weeks	5 (50.0%)	7 (63.6%)	12 (57.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	3 (30.0%)	8 (72.7%)	11 (52.4%)
Last Participation date < Day 78 in DB phase	1 (10.0%)	0	1 (4.8%)
Other	1 (10.0%)	5 (45.5%)	6 (28.6%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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Stratum 2			
Transfusion Dependence Yes and Platelet Count $\geq 100 \times 10^9/L$ and $\leq 200 \times 10^9/L$	21	20	41
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	9 (42.9%)	8 (40.0%)	17 (41.5%)
Transfusion Requiring, n(%)	2 (9.5%)	4 (20.0%)	6 (14.6%)
Transfusion Independent, n(%)	7 (33.3%)	4 (20.0%)	11 (26.8%)
Dependent, n(%)	12 (57.1%)	12 (60.0%)	24 (58.5%)
95% Exact CI	0.3402, 0.7818	0.3605, 0.8088	0.4211, 0.7368
Proportion Difference (95% CI)	-0.03 (-0.34, 0.28)		
Proportion Difference using Exact Method (95% CI)	-0.03 (-0.34, 0.28)		
≥ 4 units transfused in the last 8 weeks	4 (19.0%)	4 (20.0%)	8 (19.5%)
Any Hgb assessment $< 8g/dL$ in the last 8 weeks	6 (28.6%)	7 (35.0%)	13 (31.7%)
Last Participation date $<$ Day 162 in DB phase	5 (23.8%)	5 (25.0%)	10 (24.4%)
Other	3 (14.3%)	5 (25.0%)	8 (19.5%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	7 (33.3%)	3 (15.0%)	10 (24.4%)
Transfusion Requiring, n(%)	3 (14.3%)	1 (5.0%)	4 (9.8%)
Transfusion Independent, n(%)	4 (19.0%)	2 (10.0%)	6 (14.6%)
Dependent, n(%)	14 (66.7%)	17 (85.0%)	31 (75.6%)
95% Exact CI	0.4303, 0.8541	0.6211, 0.9679	0.5970, 0.8764
Proportion Difference (95% CI)	-0.18 (-0.45, 0.08)		
Proportion Difference using Exact Method (95% CI)	-0.18 (-0.47, 0.11)		
>=4 units transfused in the last 8 weeks	8 (38.1%)	10 (50.0%)	18 (43.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	10 (47.6%)	16 (80.0%)	26 (63.4%)
Last Participation date < Day 78 in DB phase	3 (14.3%)	1 (5.0%)	4 (9.8%)
Other	5 (23.8%)	10 (50.0%)	15 (36.6%)

95% Exact CI is based on Clopper-Pearson method without stratification.

Transfusion requiring is defined as being neither transfusion independent nor transfusion dependent.

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Stratum 3			
Transfusion Dependence Yes and Platelet Count > 200X10E9/L	22	21	43
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	6 (27.3%)	4 (19.0%)	10 (23.3%)
Transfusion Requiring, n(%)	2 (9.1%)	1 (4.8%)	3 (7.0%)
Transfusion Independent, n(%)	4 (18.2%)	3 (14.3%)	7 (16.3%)
Dependent, n(%)	16 (72.7%)	17 (81.0%)	33 (76.7%)
95% Exact CI	0.4978, 0.8927	0.5809, 0.9455	0.6137, 0.8824
Proportion Difference (95% CI)	-0.08 (-0.34, 0.18)		
Proportion Difference using Exact Method (95% CI)	-0.08 (-0.38, 0.20)		
>=4 units transfused in the last 8 weeks	6 (27.3%)	12 (57.1%)	18 (41.9%)
Any Hgb assessment < 8g/dL in the last 8 weeks	10 (45.5%)	14 (66.7%)	24 (55.8%)
Last Participation date < Day 162 in DB phase	4 (18.2%)	0	4 (9.3%)
Other	8 (36.4%)	8 (38.1%)	16 (37.2%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	10 (45.5%)	5 (23.8%)	15 (34.9%)
Transfusion Requiring, n(%)	6 (27.3%)	3 (14.3%)	9 (20.9%)
Transfusion Independent, n(%)	4 (18.2%)	2 (9.5%)	6 (14.0%)
Dependent, n(%)	12 (54.5%)	16 (76.2%)	28 (65.1%)
95% Exact CI	0.3221, 0.7561	0.5283, 0.9178	0.4907, 0.7899
Proportion Difference (95% CI)	-0.22 (-0.50, 0.07)		
Proportion Difference using Exact Method (95% CI)	-0.22 (-0.50, 0.08)		
>=4 units transfused in the last 8 weeks	5 (22.7%)	11 (52.4%)	16 (37.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	7 (31.8%)	15 (71.4%)	22 (51.2%)
Last Participation date < Day 78 in DB phase	3 (13.6%)	0	3 (7.0%)
Other	5 (22.7%)	12 (57.1%)	17 (39.5%)

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Stratum 4			
Transfusion Dependence No and Platelet Count < 100X10E9/L	8	12	20
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	6 (75.0%)	8 (66.7%)	14 (70.0%)
Transfusion Requiring, n(%)	0	1 (8.3%)	1 (5.0%)
Transfusion Independent, n(%)	6 (75.0%)	7 (58.3%)	13 (65.0%)
Dependent, n(%)	2 (25.0%)	4 (33.3%)	6 (30.0%)
95% Exact CI	0.0319, 0.6509	0.0992, 0.6511	0.1189, 0.5428
Proportion Difference (95% CI)	-0.08 (-0.52, 0.35)		
Proportion Difference using Exact Method (95% CI)	-0.08 (-0.51, 0.37)		
>=4 units transfused in the last 8 weeks	1 (12.5%)	2 (16.7%)	3 (15.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	0	2 (16.7%)	2 (10.0%)
Last Participation date < Day 162 in DB phase	1 (12.5%)	1 (8.3%)	2 (10.0%)
Other	0	1 (8.3%)	1 (5.0%)

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	6 (75.0%)	11 (91.7%)	17 (85.0%)
Transfusion Requiring, n(%)	0	4 (33.3%)	4 (20.0%)
Transfusion Independent, n(%)	6 (75.0%)	7 (58.3%)	13 (65.0%)
Dependent, n(%)	2 (25.0%)	1 (8.3%)	3 (15.0%)
95% Exact CI	0.0319, 0.6509	0.0021, 0.3848	0.0321, 0.3789
Proportion Difference (95% CI)	0.17 (-0.22, 0.55)		
Proportion Difference using Exact Method (95% CI)	0.17 (-0.29, 0.58)		
>=4 units transfused in the last 8 weeks	1 (12.5%)	1 (8.3%)	2 (10.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	1 (12.5%)	1 (8.3%)	2 (10.0%)
Last Participation date < Day 78 in DB phase	1 (12.5%)	0	1 (5.0%)
Other	0	0	0

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Stratum 5			
Transfusion Dependence No and Platelet Count $\geq 100 \times 10^9/L$ and $\leq 200 \times 10^9/L$	45	43	88
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	37 (82.2%)	30 (69.8%)	67 (76.1%)
Transfusion Requiring, n(%)	1 (2.2%)	6 (14.0%)	7 (8.0%)
Transfusion Independent, n(%)	36 (80.0%)	24 (55.8%)	60 (68.2%)
Dependent, n(%)	8 (17.8%)	13 (30.2%)	21 (23.9%)
95% Exact CI	0.0800, 0.3205	0.1718, 0.4613	0.1542, 0.3414
Proportion Difference (95% CI)	-0.12 (-0.31, 0.06)		
Proportion Difference using Exact Method (95% CI)	-0.12 (-0.33, 0.08)		
≥ 4 units transfused in the last 8 weeks	1 (2.2%)	4 (9.3%)	5 (5.7%)
Any Hgb assessment $< 8g/dL$ in the last 8 weeks	2 (4.4%)	9 (20.9%)	11 (12.5%)
Last Participation date $<$ Day 162 in DB phase	4 (8.9%)	2 (4.7%)	6 (6.8%)
Other	1 (2.2%)	1 (2.3%)	2 (2.3%)

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	42 (93.3%)	25 (58.1%)	67 (76.1%)
Transfusion Requiring, n(%)	2 (4.4%)	3 (7.0%)	5 (5.7%)
Transfusion Independent, n(%)	40 (88.9%)	22 (51.2%)	62 (70.5%)
Dependent, n(%)	3 (6.7%)	18 (41.9%)	21 (23.9%)
95% Exact CI	0.0140, 0.1827	0.2701, 0.5787	0.1542, 0.3414
Proportion Difference (95% CI)	-0.35 (-0.52, -0.18)		
Proportion Difference using Exact Method (95% CI)	-0.35 (-0.54, -0.15)		
>=4 units transfused in the last 8 weeks	1 (2.2%)	6 (14.0%)	7 (8.0%)
Any Hgb assessment < 8g/dL in the last 8 weeks	0	14 (32.6%)	14 (15.9%)
Last Participation date < Day 78 in DB phase	1 (2.2%)	0	1 (1.1%)
Other	1 (2.2%)	5 (11.6%)	6 (6.8%)

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Stratum 6			
Transfusion Dependence No and Platelet Count > 200X10E9/L	109	110	219
RBC Transfusion Dependent Rate at Week 24			
Non-Dependent, n(%)	87 (79.8%)	77 (70.0%)	164 (74.9%)
Transfusion Requiring, n(%)	2 (1.8%)	10 (9.1%)	12 (5.5%)
Transfusion Independent, n(%)	85 (78.0%)	67 (60.9%)	152 (69.4%)
Dependent, n(%)	22 (20.2%)	33 (30.0%)	55 (25.1%)
95% Exact CI	0.1310, 0.2895	0.2163, 0.3948	0.1951, 0.3140
Proportion Difference (95% CI)	-0.10 (-0.21, 0.02)		
Proportion Difference using Exact Method (95% CI)	-0.10 (-0.23, 0.03)		
>=4 units transfused in the last 8 weeks	1 (0.9%)	17 (15.5%)	18 (8.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	3 (2.8%)	25 (22.7%)	28 (12.8%)
Last Participation date < Day 162 in DB phase	17 (15.6%)	1 (0.9%)	18 (8.2%)
Other	1 (0.9%)	11 (10.0%)	12 (5.5%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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RBC Transfusion Dependent Rate at Week 12			
Non-Dependent, n(%)	98 (89.9%)	74 (67.3%)	172 (78.5%)
Transfusion Requiring, n(%)	7 (6.4%)	6 (5.5%)	13 (5.9%)
Transfusion Independent, n(%)	91 (83.5%)	68 (61.8%)	159 (72.6%)
Dependent, n(%)	11 (10.1%)	36 (32.7%)	47 (21.5%)
95% Exact CI	0.0515, 0.1734	0.2408, 0.4233	0.1622, 0.2750
Proportion Difference (95% CI)	-0.23 (-0.33, -0.12)		
Proportion Difference using Exact Method (95% CI)	-0.23 (-0.35, -0.10)		
>=4 units transfused in the last 8 weeks	2 (1.8%)	15 (13.6%)	17 (7.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (1.8%)	32 (29.1%)	34 (15.5%)
Last Participation date < Day 78 in DB phase	7 (6.4%)	1 (0.9%)	8 (3.7%)
Other	2 (1.8%)	8 (7.3%)	10 (4.6%)

95% Exact CI is based on Clopper-Pearson method without stratification.

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