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

	MMB (N=104)	BAT (N=52)	Total (N=156)
All Strata Combined			
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	52 (50.0%)	19 (36.5%)	71 (45.5%)
Transfusion Requiring, n(%)	7 (6.7%)	8 (15.4%)	15 (9.6%)
Transfusion Independent, n(%)	45 (43.3%)	11 (21.2%)	56 (35.9%)
Dependent, n(%)	52 (50.0%)	33 (63.5%)	85 (54.5%)
95% Exact CI	0.4003, 0.5997	0.4896, 0.7638	0.4633, 0.6247
Proportion Difference - Stratified CMH Method (95% CI)	-0.13 (-0.29, 0.03)		
p-value	0.10		
Proportion Difference - Unstratified Method (95% CI)	-0.13 (-0.30, 0.03)		
p-value	0.11		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.13 (-0.30, 0.04)		
p-value	0.13		
>=4 units transfused in the last 8 weeks	15 (14.4%)	17 (32.7%)	32 (20.5%)
Any Hgb assessment < 8g/dL in the last 8 weeks	21 (20.2%)	16 (30.8%)	37 (23.7%)
Last Participation date < Day 162 in RT phase	28 (26.9%)	10 (19.2%)	38 (24.4%)
Other	10 (9.6%)	10 (19.2%)	20 (12.8%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	51 (49.0%)	20 (38.5%)	71 (45.5%)
Transfusion Requiring, n(%)	11 (10.6%)	11 (21.2%)	22 (14.1%)
Transfusion Independent, n(%)	40 (38.5%)	9 (17.3%)	49 (31.4%)
Dependent, n(%)	53 (51.0%)	32 (61.5%)	85 (54.5%)
95% Exact CI	0.4097, 0.6090	0.4702, 0.7470	0.4633, 0.6247
Proportion Difference - Stratified CMH Method (95% CI)	-0.11 (-0.27, 0.04)		
p-value	0.15		
Proportion Difference - Unstratified Method (95% CI)	-0.11 (-0.27, 0.06)		
p-value	0.21		
Proportion Difference - Unstratified Exact Method (95% CI)	-0.11 (-0.27, 0.07)		
p-value	0.24		
>=4 units transfused in the last 8 weeks	28 (26.9%)	15 (28.8%)	43 (27.6%)
Any Hgb assessment < 8g/dL in the last 8 weeks	34 (32.7%)	18 (34.6%)	52 (33.3%)
Last Participation date < Day 78 in RT phase	14 (13.5%)	9 (17.3%)	23 (14.7%)
Other	14 (13.5%)	10 (19.2%)	24 (15.4%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 1			
Transfusion Dependence Yes and Baseline TSS <18	37	15	52
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	18 (48.6%)	5 (33.3%)	23 (44.2%)
Transfusion Requiring, n(%)	4 (10.8%)	5 (33.3%)	9 (17.3%)
Transfusion Independent, n(%)	14 (37.8%)	0	14 (26.9%)
Dependent, n(%)	19 (51.4%)	10 (66.7%)	29 (55.8%)
95% Exact CI	0.3440, 0.6808	0.3838, 0.8818	0.4133, 0.6953
Proportion Difference (95% CI)	-0.15 (-0.45, 0.14)		
Proportion Difference using Exact Method (95% CI)	-0.15 (-0.43, 0.15)		
>=4 units transfused in the last 8 weeks	6 (16.2%)	5 (33.3%)	11 (21.2%)
Any Hgb assessment < 8g/dL in the last 8 weeks	12 (32.4%)	6 (40.0%)	18 (34.6%)
Last Participation date < Day 162 in RT phase	7 (18.9%)	3 (20.0%)	10 (19.2%)
Other	6 (16.2%)	5 (33.3%)	11 (21.2%)

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: 25JUN2019

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	14 (37.8%)	4 (26.7%)	18 (34.6%)
Transfusion Requiring, n(%)	7 (18.9%)	4 (26.7%)	11 (21.2%)
Transfusion Independent, n(%)	7 (18.9%)	0	7 (13.5%)
Dependent, n(%)	23 (62.2%)	11 (73.3%)	34 (65.4%)
95% Exact CI	0.4476, 0.7754	0.4490, 0.9221	0.5091, 0.7803
Proportion Difference (95% CI)	-0.11(-0.40, 0.17)		
Proportion Difference using Exact Method (95% CI)	-0.11 (-0.40, 0.19)		
>=4 units transfused in the last 8 weeks	15 (40.5%)	6 (40.0%)	21 (40.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	21 (56.8%)	6 (40.0%)	27 (51.9%)
Last Participation date < Day 78 in RT phase	1 (2.7%)	3 (20.0%)	4 (7.7%)
Other	9 (24.3%)	5 (33.3%)	14 (26.9%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 2			
Transfusion Dependence Yes and Baseline TSS >=18	21	12	33
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	7 (33.3%)	1 (8.3%)	8 (24.2%)
Transfusion Requiring, n(%)	2 (9.5%)	0	2 (6.1%)
Transfusion Independent, n(%)	5 (23.8%)	1 (8.3%)	6 (18.2%)
Dependent, n(%)	14 (66.7%)	11 (91.7%)	25 (75.8%)
95% Exact CI	0.4303, 0.8541	0.6152, 0.9979	0.5774, 0.8891
Proportion Difference (95% CI)	-0.25 (-0.53, 0.03)		
Proportion Difference using Exact Method (95% CI)	-0.25 (-0.57, 0.11)		
>=4 units transfused in the last 8 weeks	5 (23.8%)	7 (58.3%)	12 (36.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	5 (23.8%)	5 (41.7%)	10 (30.3%)
Last Participation date < Day 162 in RT phase	8 (38.1%)	3 (25.0%)	11 (33.3%)
Other	1 (4.8%)	2 (16.7%)	3 (9.1%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	5 (23.8%)	1 (8.3%)	6 (18.2%)
Transfusion Requiring, n(%)	0	1 (8.3%)	1 (3.0%)
Transfusion Independent, n(%)	5 (23.8%)	0	5 (15.2%)
Dependent, n(%)	16 (76.2%)	11 (91.7%)	27 (81.8%)
95% Exact CI	0.5283, 0.9178	0.6152, 0.9979	0.6454, 0.9302
Proportion Difference (95% CI)	-0.15(-0.42, 0.11)		
Proportion Difference using Exact Method (95% CI)	-0.15 (-0.49, 0.21)		
>=4 units transfused in the last 8 weeks	8 (38.1%)	5 (41.7%)	13 (39.4%)
Any Hgb assessment < 8g/dL in the last 8 weeks	9 (42.9%)	7 (58.3%)	16 (48.5%)
Last Participation date < Day 78 in RT phase	5 (23.8%)	3 (25.0%)	8 (24.2%)
Other	4 (19.0%)	3 (25.0%)	7 (21.2%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 3			
Transfusion Dependence No and Baseline TSS <18	24	13	37
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	18 (75.0%)	7 (53.8%)	25 (67.6%)
Transfusion Requiring, n(%)	0	0	0
Transfusion Independent, n(%)	18 (75.0%)	7 (53.8%)	25 (67.6%)
Dependent, n(%)	6 (25.0%)	6 (46.2%)	12 (32.4%)
95% Exact CI	0.0977, 0.4671	0.1922, 0.7487	0.1801, 0.4979
Proportion Difference (95% CI)	-0.21 (-0.55, 0.12)		
Proportion Difference using Exact Method (95% CI)	-0.21 (-0.53, 0.12)		
>=4 units transfused in the last 8 weeks	0	3 (23.1%)	3 (8.1%)
Any Hgb assessment < 8g/dL in the last 8 weeks	1 (4.2%)	3 (23.1%)	4 (10.8%)
Last Participation date < Day 162 in RT phase	5 (20.8%)	1 (7.7%)	6 (16.2%)
Other	1 (4.2%)	3 (23.1%)	4 (10.8%)

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: 25JUN2019

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	18 (75.0%)	8 (61.5%)	26 (70.3%)
Transfusion Requiring, n(%)	2 (8.3%)	2 (15.4%)	4 (10.8%)
Transfusion Independent, n(%)	16 (66.7%)	6 (46.2%)	22 (59.5%)
Dependent, n(%)	6 (25.0%)	5 (38.5%)	11 (29.7%)
95% Exact CI	0.0977, 0.4671	0.1386, 0.6842	0.1587, 0.4698
Proportion Difference (95% CI)	-0.13(-0.46, 0.19)		
Proportion Difference using Exact Method (95% CI)	-0.13 (-0.46, 0.20)		
>=4 units transfused in the last 8 weeks	2 (8.3%)	2 (15.4%)	4 (10.8%)
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (8.3%)	4 (30.8%)	6 (16.2%)
Last Participation date < Day 78 in RT phase	3 (12.5%)	0	3 (8.1%)
Other	1 (4.2%)	2 (15.4%)	3 (8.1%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 4			
Transfusion Dependence No and Baseline TSS >=18	22	12	34
RBC Transfusion Dependent Rate at Week 24			
Not-Dependent, n(%)	9 (40.9%)	6 (50.0%)	15 (44.1%)
Transfusion Requiring, n(%)	1 (4.5%)	3 (25.0%)	4 (11.8%)
Transfusion Independent, n(%)	8 (36.4%)	3 (25.0%)	11 (32.4%)
Dependent, n(%)	13 (59.1%)	6 (50.0%)	19 (55.9%)
95% Exact CI	0.3635, 0.7929	0.2109, 0.7891	0.3789, 0.7281
Proportion Difference (95% CI)	0.09 (-0.27, 0.45)		
Proportion Difference using Exact Method (95% CI)	0.09 (-0.26, 0.43)		
>=4 units transfused in the last 8 weeks	4 (18.2%)	2 (16.7%)	6 (17.6%)
Any Hgb assessment < 8g/dL in the last 8 weeks	3 (13.6%)	2 (16.7%)	5 (14.7%)
Last Participation date < Day 162 in RT phase	8 (36.4%)	3 (25.0%)	11 (32.4%)
Other	2 (9.1%)	0	2 (5.9%)

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

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

	MMB (N=104)	BAT (N=52)	Total (N=156)
RBC Transfusion Dependent Rate at Week 12			
Not-Dependent, n(%)	14 (63.6%)	7 (58.3%)	21 (61.8%)
Transfusion Requiring, n(%)	2 (9.1%)	4 (33.3%)	6 (17.6%)
Transfusion Independent, n(%)	12 (54.5%)	3 (25.0%)	15 (44.1%)
Dependent, n(%)	8 (36.4%)	5 (41.7%)	13 (38.2%)
95% Exact CI	0.1720, 0.5934	0.1517, 0.7233	0.2217, 0.5644
Proportion Difference (95% CI)	-0.05(-0.41, 0.30)		
Proportion Difference using Exact Method (95% CI)	-0.05 (-0.40, 0.29)		
>=4 units transfused in the last 8 weeks	3 (13.6%)	2 (16.7%)	5 (14.7%)
Any Hgb assessment < 8g/dL in the last 8 weeks	2 (9.1%)	1 (8.3%)	3 (8.8%)
Last Participation date < Day 78 in RT phase	5 (22.7%)	3 (25.0%)	8 (23.5%)
Other	0	0	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: 25JUN2019