Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
All Strata Combined			
RBC transfusion Rate in RT phase (units/month)			
N	104	52	156
Mean (SD)	1.6 (2.09)	1.8 (1.91)	1.6 (2.03)
Median	0.5	1.2	0.8
Q1, Q3	0.0, 2.4	0.0, 2.8	0.0, 2.6
Min, Max	0.0, 8.7	0.0, 7.6	0.0, 8.7
Negative Binomial Model			
Adjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.15 (0.86, 1.55)	1.44 (0.97, 2.13)	
Ratio of Rate for RBC Transfusion with 95% CI	0.80 (0.49, 1.31)	-	-
p-value	0.38	-	-
Unadjusted for Strata			
Rate of RBC transfusion with 95% CI (units/month)	1.51 (1.11, 2.06)	1.76 (1.14, 2.72)	
Ratio of Rate for RBC Transfusion with 95% CI	0.86 (0.50, 1.47)	-	-
p-value	0.58	-	-
Proportional Means Model - Supportive Analysis			
Stratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.81 (0.58, 1.14)	-	-
p-value	0.22	-	-
Unstratified			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.86 (0.59, 1.27)	-	-
p-value	0.46	-	-

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Total number of RBC transfusion unit in RT phase			
N	104	52	156
Mean (SD)	6.6 (9.30)	7.7 (8.12)	7.0 (8.91)
Median	2.0	6.0	4.0
Q1, Q3	0.0, 11.0	0.0, 10.5	0.0, 11.0
Min, Max	0.0, 38.0	0.0, 40.0	0.0, 40.0
Duration of the RT phase (months)			
N	104	52	156
Mean (SD)	4.78 (1.572)	4.83 (1.587)	4.80 (1.572)
Median	5.55	5.55	5.55
Q1, Q3	4.68, 5.60	5.45, 5.59	5.32, 5.59
Min, Max	0.23, 5.78	0.43, 5.78	0.23, 5.78

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Data Extracted: CRF data: 25JUN2019
Source: ...\version4\prog\t-rbc24.sas v9.4 Output file: t-rbc24.out 28AUG2020:11:18

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 1			
Transfusion Dependence at Baseline = 'Yes' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	37	15	52
Mean (SD)	2.0 (2.11)	2.1 (1.53)	2.0 (1.95)
Median	1.0	1.4	1.2
Q1, Q3	0.4, 3.3	0.9, 3.1	0.5, 3.2
Min, Max	0.0, 6.8	0.0, 5.0	0.0, 6.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	1.97 (1.39, 2.79)	2.14 (1.23, 3.74)	
Ratio of Rate for RBC Transfusion with 95% CI	0.92 (0.48, 1.77)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.96 (0.60, 1.54)	-	-
Total number of RBC transfusion in stratum 1 in RT phase			
N	37	15	52
Mean (SD)	10.2 (11.30)	9.7 (6.82)	10.1 (10.15)
Median	6.0	8.0	6.5
Q1, Q3	2.0, 15.0	5.0, 16.0	2.0, 15.5
Min, Max	0.0, 38.0	0.0, 25.0	0.0, 38.0

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Data Extracted: CRF data: 25JUN2019
Source: ...\version4\prog\t-rbc24.sas v9.4 Output file: t-rbc24.out 28AUG2020:11:18

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Duration of the RT phase (months) in stratum 1			
N	37	15	52
Mean (SD)	5.26 (0.837)	4.76 (1.794)	5.12 (1.196)
Median	5.55	5.55	5.55
Q1, Q3	5.49, 5.68	5.32, 5.75	5.47, 5.70
Min, Max	2.14, 5.78	0.43, 5.78	0.43, 5.78

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Data Extracted: CRF data: 25JUN2019

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 2			
Transfusion Dependence at Baseline = 'Yes' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	21	12	33
Mean (SD)	2.9 (2.72)	3.5 (2.34)	3.1 (2.57)
Median	2.2	2.9	2.5
Q1, Q3	0.7, 4.5	1.6, 5.4	1.1, 4.5
Min, Max	0.0, 8.7	1.0, 7.6	0.0, 8.7
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	2.66 (1.69, 4.18)	3.41 (1.91, 6.09)	
Ratio of Rate for RBC Transfusion with 95% CI	0.78 (0.37, 1.63)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.72 (0.40, 1.29)	-	-
Total number of RBC transfusion in stratum 2 in RT phase			
N	21	12	33
Mean (SD)	9.4 (9.56)	13.5 (9.92)	10.9 (9.74)
Median	6.0	10.0	8.0
Q1, Q3	2.0, 13.0	8.0, 16.0	4.0, 14.0
Min, Max	0.0, 32.0	5.0, 40.0	0.0, 40.0

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Duration of the RT phase (months) in stratum 2			
N	21	12	33
Mean (SD)	4.39 (1.885)	4.54 (1.832)	4.45 (1.838)
Median	5.52	5.54	5.52
Q1, Q3	2.89, 5.55	3.79, 5.55	2.89, 5.55
Min, Max	0.23, 5.78	0.66, 5.78	0.23, 5.78

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 3			
Transfusion Dependence at Baseline = 'No' and TSS < 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	24	13	37
Mean (SD)	0.5 (0.94)	0.7 (1.24)	0.6 (1.05)
Median	0.0	0.0	0.0
Q1, Q3	0.0, 0.3	0.0, 0.9	0.0, 0.4
Min, Max	0.0, 3.1	0.0, 3.8	0.0, 3.8
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.45 (0.14, 1.41)	0.72 (0.16, 3.19)	
Ratio of Rate for RBC Transfusion with 95% CI	0.62 (0.09, 4.05)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	0.43 (0.12, 1.54)	-	-
Total number of RBC transfusion in stratum 3 in RT phase			
N	24	13	37
Mean (SD)	1.5 (3.54)	4.0 (6.88)	2.4 (5.02)
Median	0.0	0.0	0.0
Q1, Q3	0.0, 1.5	0.0, 5.0	0.0, 2.0
Min, Max	0.0, 14.0	0.0, 21.0	0.0, 21.0

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Duration of the RT phase (months) in stratum 3			
N	24	13	37
Mean (SD)	4.84 (1.638)	5.39 (0.606)	5.03 (1.382)
Median	5.55	5.55	5.55
Q1, Q3	5.49, 5.55	5.52, 5.59	5.49, 5.55
Min, Max	0.49, 5.78	3.38, 5.72	0.49, 5.78

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Stratum 4			
Transfusion Dependence at Baseline = 'No' and TSS >= 18 at Baseline			
RBC transfusion Rate in RT phase (units/month)			
N	22	12	34
Mean (SD)	0.7 (1.24)	0.7 (0.93)	0.7 (1.12)
Median	0.0	0.4	0.0
Q1, Q3	0.0, 1.9	0.0, 1.4	0.0, 1.8
Min, Max	0.0, 3.7	0.0, 2.4	0.0, 3.7
Negative Binomial Model			
Rate of RBC transfusion with 95% CI (units/month)	0.76 (0.33, 1.78)	0.77 (0.24, 2.40)	
Ratio of Rate for RBC Transfusion with 95% CI	1.00 (0.24, 4.12)	-	-
Proportional Means Model - Supportive Analysis			
Ratio of Mean Cumulative Function for RBC Transfusion with 95% CI	1.02 (0.40, 2.63)	-	-
Total number of RBC transfusion in stratum 4 in RT phase			
N	22	12	34
Mean (SD)	3.3 (5.74)	3.5 (4.34)	3.4 (5.22)
Median	0.0	2.0	0.0
Q1, Q3	0.0, 6.0	0.0, 5.5	0.0, 6.0
Min, Max	0.0, 17.0	0.0, 13.0	0.0, 17.0

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1

Table 15.12.3.1: Analysis of Rate of RBC Transfusion
Randomized Treatment Phase
Intent-to-Treat Analysis Set

	MMB (N=104)	BAT (N=52)	Total (N=156)
Duration of the RT phase (months) in stratum 4			
N	22	12	34
Mean (SD)	4.29 (1.944)	4.60 (1.815)	4.40 (1.878)
Median	5.50	5.55	5.52
Q1, Q3	3.22, 5.59	3.99, 5.59	3.22, 5.59
Min, Max	0.49, 5.78	0.49, 5.65	0.49, 5.78

Proportional means model is Andersen-Gill model with robust sandwich variance estimate
RBC = Red Blood Cell
Source: Listing 16.3.3.1.1