

BMT #0201 Data Submission - Documentation for Outcome Dataset

Outcome dataset has 110 variables for 551 patients on BMT #0201 study, each patient has one record. This is the most important dataset in this data submission.

Notes in the last column of below table are provided by BMT CTN DCC to better understand the datasets submitted:

- **DRC** indicates this variable is from the BMT #0201 Data Review Committee adjudication. DRC adjudicated the data in a blinded manner based on the site-reported data in CRFs as well as some clinical notes from the sites.
- **CIBMTR** indicates this variable is data retrieval from the CIBTMR data system.
- **CRF** indicates this variable is from EMMES Case Report Form, as reported by the transplant center.
- **EMMES** indicates this variable is from EMMES Enroll System, as study implemented per protocol.
- **RECODE** indicates this variable is from computation for analysis purpose based on other data source.

Variables in OUTCOME dataset							
#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
1	GENDER	Char	1	\$X638X.	1.	Recipient Gender	CRF - DEM
2	ETHNIC	Char	3	\$X639X.	3.	Recipient Ethnicity	CRF - DEM
3	raceA	Char	1	\$RACEF.		Recipient Race (recoded)	RECODE, this is based on race and secondary race reported on DEM form and combine into several big race categories.
4	PROT	Char	5	5.	5.	BMT CTN Protocol #	EMMES, this indicates the protocol number in BMT CTN.
5	TRTRUE	Char	100	100.	100.	Treatment Arm per randomization	EMMES, this is based on randomization and indicates the assignment upon enrollment.

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
6	ENRLDAYS	Num	8		8.	Days to Enrollment Since Enrollment	RECODE, this is 0 for all subjects. All subjects enroll on the 0 th date.
7	stage	Char	100			Disease Stage	RECODE, this is computed/combined from different variables on the enrollment form ENR (for different disease) into one single variable.
8	CNSNTDAYS0	Num	8		8.	Days to Signing of Informed Consent Form Since Enrollment	RECODE, this is the number of days since randomization to the date of informed consent.
9	GVHDREG	Char	1	\$X569X.	1.	GVHD prophylaxis regimen	CRF - ENR
10	GVHDOTHR	Char	30	30.	30.	GVHD other regimen	CRF - ENR
11	CONDREGI	Char	1	\$X570X.	1.	Conditioning regimen	CRF - ENR
12	PPRIMDX	Char	1	\$X572X.	1.	Primary Disease at Enrollment	CRF - ENR
13	STRATA	Char	3	3.	3.	Recipient Risk Stratum: 001=good 002=poor	EMMES, this is one of the stratification for randomization. Please refer to the BMT Protocol #0201 Version 9 Table 5.4 for disease risk
14	HLASCORE	Char	3	3.	3.	Calc Hla Match Score	CRF - ENR
15	SITESCR	Char	3	3.	3.	Site Hla score	CRF - ENR
16	CONDNGDAY S	Num	8		8.	Days to Initiation of Conditioning Regimen Since Enrollment	RECODE, this is the number of days since randomization to the conditioning date.
17	TXDAYSTXP	Num	8		8.	Days to Hematopoietic Stem Cell Infusion Since Enrollment	RECODE, this is the number of days since randomization to the transplant date.
18	CMVSTAT	Char	1	\$X4281X.	1.	Recipient CMV Status	CRF - TXP
19	fudays	Num	8			Days to Last Follow-up Since Enrollment	RECODE, this is the last follow up data based on all available data source/CRFs, the last date of all, coded as days since randomization.
20	LASTCTDAYS	Num	8		8.	Days to Last Contact Since Enrollment	RECODE, this is the number of days since randomization to the date of last contact.

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
21	ENGRFT1	Char	1	\$X5627X.	1.	Engraftment	CRF - HEM
22	ANC1DAYS	Num	8		8.	Days to Neutrophil Collection 1 Since Enrollment	RECODE, this is the number of days since randomization to the date collected in form HEM.
23	ANC1SGF	Num	8	5.	5.	ANC Day 1	CRF - SGF
24	ANC1SGDAY S	Num	8		8.	Days to Neutrophil Collection 1 Since Enrollment	RECODE, this is the number of days since randomization to the date collected in form SGF.
25	GFGIVEN	Char	1	\$X5428X.	1.	Growth Factor Given	CRF - SGF
26	RSPNDGF	Char	1	\$X5429X.	1.	Respond to Growth Factor	CRF - SGF
27	relapsdays	Num	8			Days to Relapse or Progression Since Enrollment	RECODE, this is the number of days since randomization to the date collected in form RLP.
28	DAYSTRANS P	Num	8		8.	Days to Non-protocol Transplant Since Enrollment	RECODE, this is the number of days since randomization to the date collected in form FUS.
29	maxweek	Num	8			Week of Maximum aGVHD	RECODE, this is the computed week that the patient experience the maximum grade of acute GVHD by Day 98, based on GVH data.
30	maxgrade	Num	8			Maximum aGVHD Grade (Overall, by Day 98)	RECODE, this is the computed maximum grade of acute GVHD by Day 98 post transplant, based on GVH data.
31	gvhdondays	Num	8			Days to aGVHD Onset Since Enrollment	RECODE, this is the onset date of acute GVHD, computed based on GVH data, coded as days since randomization.
32	maxdays	Num	8			Days to Maximum aGVHD (By 98 Days Post Transplant) Since Enrollment	RECODE, this is the first date that patient experienced the maximum grade of acute GVHD by Day 98 post transplant, computed based on GVH data, coded as days since randomization.

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
33	stagedays234	Num	8			Days to Grades 2-4 aGVHD Since Enrollment	RECODE, this is the first date that patient experienced grade 2-4 acute GVHD by Day 98 post transplant, computed based on GVH data, coded as days since randomization.
34	stagedays34	Num	8			Days to Grades 3-4 aGVHD Since Enrollment	RECODE, this is the first date that patient experienced grade 3-4 acute GVHD by Day 98 post transplant, computed based on GVH data, coded as days since randomization.
35	SEVCGVHD	Char	1	\$X490X.	1.	Chronic GVHD Maximum Overall Severity	RECODE, this is the maximum severity that patient experienced, computed based on CGV data.
36	GRDCGVHD	Char	1	\$X491X.	1.	Chronic GVHD Maximum Overall Grade	RECODE, this is the maximum grade that patient experienced, computed based on CGV data.
37	DAYS DGNCGV	Num	8		8.	Days to First Diagnosis of cGVHD Since Enrollment	RECODE, this is the first date of chronic GVHD diagnosed, computed based on CGV data, coded in days since randomization.
38	maxgradep100	Num	8			Max aGVHD grade post Day 100	RECODE, this is the maximum grade of acute GVHD reported post Day 100 post transplant, computed based on CGV data.
39	agvp100days	Num	8			Days to aGVHD (By 100 Days Post Transplant) Since Enrollment	RECODE, this is the date of acute GVHD reported post Day 100 post transplant, computed based on CGV data, coded as days since randomization.
40	czdthprm	Char	40	\$CAUSEF.	4.	Site-reported Cause of Death	CRF - DTH
41	DTHDAYS	Num	8		8.	Days to Death Since Enrollment	RECODE, this is the number of days since randomization to the date collected in form DTH.
42	Status_DRC	Char	23			Status of Data Review by DRC	DRC, this is the status of DRC review by the data cut-off for the primary publication.
43	COD_DRC	Char	30			Primary Cause of Death By DRC	DRC, this is the DRC adjudicated primary cause of death.

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
44	dthdays_DRC	Num	8			Days to Confirmed Death Since Enrollment	RECODE, this the DRC confirmed death date, coded as days since randomization.
45	RelapseDays_DRC	Num	8			Days to Confirmed Relapse Since Enrollment	RECODE, this is the DRC adjudicated/confirmed relapse date, coded as days since randomization.
46	aGVHDgradeby100_DRC	Num	8			Acute GVHD maximum Grade by Day 100 by DRC	DRC, this is the DRC adjudicated/confirmed maximum grade of Acute GVHD by Day 100 post transplant
47	aGVHDdaysby100_DRC	Num	8			Days to Confirmed aGVHD Onset (By 100 Days Post Transplant) Since Enrollment	RECODE, this is the DRC adjudicated/confirmed acute GVHD onset date by Day 100 post transplant, coded as days since randomization.
48	aGVHDgradeafter100_DRC	Num	8			Acute GVHD maximum Grade After Day 100 by DRC	DRC, this is the DRC adjudicated/confirmed maximum grade of Acute GVHD after Day 100 post transplant.
49	aGVHDdaysafter100_DRC	Num	8			Days to Confirmed aGVHD Onset (After 100 Days Post Transplant) Since Enrollment	RECODE, this is the DRC adjudicated/confirmed acute GVHD onset date by Day 100 post transplant, coded as days since randomization.
50	cGVHDdays_DRC	Num	8			Days to First Confirmed cGVHD Onset Since Enrollment	RECODE, this is the DRC adjudicated/confirmed chronic GVHD first onset date, coded as days since randomization.
51	cGVHDgrade_DRC	Char	10			Chronic GVHD maximum Grade by DRC	DRC, this is the DRC adjudicated/confirmed chronic GVHD maximum grade
52	ISPeriod	Char	13			Assess Period for Immunosuppressive Therapy at 2 years	RECODE, this is the computed assess period including start day and end day to evaluate the immunosuppressive therapy at the 2-year visit if applicable
53	IStherapy	Char	4			Immunosuppressive used at 2 years post transplant?	RECODE, this is the computed variable to indicate if patient get off immunosuppressive therapy at the 2-year visit if applicable

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
54	age	Num	8			Age at Enrollment(yrs)	RECODE, this is the computed age of years at enrollment based on DOB on DEM form
55	death	Char	3			Death Reported?	RECODE, this is the indicator to tell if patient reported death on the study, computed based on DTH data
56	ae	Char	3			Adverse Event Reported?	RECODE, this is the indicator to tell if patient reported Grades 3-5 adverse events on the study, computed based on AE data
57	czdthsnd	Char	117			Site-reported Secondary COD (combined)	RECODE, this is the combined secondary cause of death, computed based on DTH data
58	sectxp	Char	3			Non-protocol Specified Transplant?	RECODE, this is the indicator to tell if patient reported a second transplant, computed based on FUS data
59	ose_srvtm	Num	8			Overall Survival Post Randomization (days)	RECODE, this the days from randomization to death or last follow up, computed for survival analysis
60	ose_srvtm_mon	Num	8			Overall Survival Post Randomization (months)	RECODE, this is the months from randomization to death or last follow up
61	ose_outcome	Char	9			Overall Survival Post Randomization Outcome	RECODE, this is the outcome for overall survival endpoint
62	ose_srvcens	Num	8			Overall Survival Post Randomization Censor Indicator (1 means event)	RECODE, this is the censor indicator for overall survival endpoint
63	ost_srvtm	Num	8			Overall Survival Post Transplant (days)	RECODE, this the days from transplant to the death or last follow up, computed for survival analysis
64	ost_srvtm_mon	Num	8			Overall Survival Post Transplant (months)	RECODE, this is the months from transplant to the death or last follow up
65	ost_outcome	Char	9			Overall Survival Post Transplant Outcome	RECODE, this is the outcome for overall survival endpoint

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
66	ost_srvcens	Num	8			Overall Survival Post Transplant Censor Indicator (1 means event)	RECODE, this is the censor indicator for overall survival endpoint
67	dfs_srvtm	Num	8			Disease-Free Survival Post Transplant (days)	RECODE, this the days from transplant to the death, relapse or last follow up, computed for disease-free survival
68	dfs_srvtm_mon	Num	8			Disease-Free Survival Post Transplant (months)	RECODE, this is the months from transplant to the death, relapse or last follow up
69	dfs_outcome	Char	10			Disease-Free Survival Post Transplant Outcome	RECODE, this is the outcome for disease-free survival endpoint
70	dfs_srvcens	Num	8			Disease-Free Survival Post Transplant Censor Indicator (1 means event)	RECODE, this is the censor indicator for disease-free survival endpoint
71	ancday	Num	8			Neutrophil Recovery Post Transplant (days)	RECODE, this is the days from transplant to date of neutrophil recovery
72	ancoutcome	Char	9			Neutrophil Recovery Post Transplant Outcome	RECODE, this is the outcome for neutrophil recovery endpoint
73	ancens	Num	8			Neutrophil Recovery Post Transplant Censor Indicator (1 means event)	RECODE, this is the censor indicator for neutrophil recovery endpoint
74	anc_CI	Num	8			Neutrophil Recovery Post Transplant Indicator for Cumulative Incidence (1 means event)	RECODE, this is the indicator for cumulative incidence of neutrophil recovery
75	TRMday	Num	8			Treatment-related Mortality Post Transplant (days)	RECODE, this is the days from transplant to date of treatment-related mortality
76	TRMmon	Num	8			Treatment-related Mortality Post Transplant (months)	RECODE, this is the months from transplant to date of treatment-related mortality

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
77	TRMoutcome	Char	9			Treatment-related Mortality Post Transplant Outcome	RECODE, this is the outcome for treatment-related mortality endpoint
78	TRMcens	Num	8			Treatment-related Mortality Post Transplant Censor Indicator (1 means event)	RECODE, this is the censor indicator for treatment-related mortality endpoint
79	TRM_CI	Num	8			Treatment-related Mortality Post Transplant Indicator for Cumulative Incidence (1 means event)	RECODE, this is the indicator for cumulative incidence of treatment-related mortality
80	relapseday	Num	8			Relapse Post Transplant (days)	RECODE, this is the days from transplant to date of relapse
81	relapsemon	Num	8			Relapse Post Transplant (months)	RECODE, this is the months from transplant to date of relapse
82	relapseoutcome	Char	9			Relapse Post Transplant Outcome	RECODE, this is the outcome for relapse post transplant
83	relapsecens	Num	8			Relapse Post Transplant Censor Indicator (1 means event)	RECODE, this is the censor indicator for relapse endpoint
84	relapse_CI	Num	8			Relapse Post Transplant Indicator for Cumulative Incidence (1 means event)	RECODE, this is the indicator for cumulative incidence of relapse
85	DAGE	Num	8	4.	4.	Donor age	CIBMTR
86	DGENDER	Char	1	\$X2641X.	1.	Donor gender	CIBMTR
87	DETHNIC	Char	1	\$X2647X.	1.	Donor ethnicity	CIBMTR
88	DRACE	Char	2	\$X2648X.	2.	Donor race	RECODE, this is based on race reported from DNR form and combined into several big categories
89	DCMVST	Char	1	\$X3382X.	1.	Donor CMV status	CIBMTR

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
90	reasonnotxp	Char	200			Reason for No Transplant and Status	RECODE, this is to indicate the reason why patient did not proceed to the study transplant
91	maxaGVHDgradeoverall	Num	8			Maximum Acute GVHD overall across the study	RECODE, this is the combined variable to indicate the overall maximum acute GVHD grade (by Day 100 and after Day 100)
92	treatcross	Char	18			Treatment Crossover?	RECODE, this is to indicate if patient had treatment crossover, which means they did not receive the graft type as randomized, but received another graft
93	csf	Num	8			Planned Growth factor use (within 12 days) 0- No 1- Yes	CIBMTR
94	daysdx	Num	8			Days to Disease Diagnosis Since Enrollment	RECODE, from CIBMTR, coded as days since randomization.
95	hlamismatch	Num	8			Number of HLA Mismatch	RECODE
96	karnofcat	Num	8			Karnofsky score at baseline	CIBMTR, to indicate the performance score prior to initiation of the conditioning regimen
97	atggp	Num	8			ATG usage (1=received ATG, 0 =did not receive ATG)	CIBMTR, to indicate use of antithymocyte globulin
98	p20day	Num	8			Days to platelet recovery to 20k or last contact or censoring	CIBMTR, this is days from transplant to the date of platelet recovery to >20K
99	p20cens	Num	8			1=Platelet recovery to 20K, 0=no platelet recovery	CIBMTR, this is the indicator if patient achieved platelet recovery to >20K
100	p50day	Num	8			Days to platelet recovery to 50k or last contact or censoring	CIBMTR, this is days from transplant to the date of platelet recovery to >20K
101	p50cens	Num	8			1=platelet recovery to 50K, 0=no platelet recovery	CIBMTR, this is the indicator if patient achieved platelet recovery to >20K
102	cd34p_kg	Num	8			CD34+ cell dose/kg	CIBMTR

Variables in OUTCOME dataset

#	Variable	Type	Len	Format	Infor- mat	Label	Data Source / Notes
103	rand_donor_id	Char	9			Randomized donor ID	RECODE, this is the randomized donor ID created from the donor ID collected in form DNR.
104	rand_id	Char	10			Randomized subject ID	RECODE, this is the randomized subject ID created from the subject ID collected in the original forms.