# BMT CTN #0501 Data Submission - Documentation for Outcomes Dataset

**Outcomes dataset has 128 variables for 224 patients on BMT protocol #0501 and each patient has one record.**

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

- **CRF** indicates this variable is from an EMMES Case Report Form, as reported by the transplant center. The name of the CRF is shown for easy reference.
- **EMMES** indicates this variable is from EMMES Enrollment System, as study implemented per protocol.
- **RECODE** indicates this variable is from computation for analysis purposes based on other data source. Algorithm and computation method are provided for reference.
- **ERC** indicates this variable is from the BMT #0501 Endpoint Review Committee adjudication. ERC adjudicated the data in a blinded manner based on the site-reported data in CRFs as well as some clinical notes from the sites. ERC –adjudicated outcomes should supersede the site-reported data if there would be any discrepancy.
- **CIBMTR** indicates this variable is data retrieval from the CIBTMR data system. CIBMTR data were reviewed by the CIBMTR physicians prior to the data transfer to Emmes DCC.

**Variables List**

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| 1 | PROT | Char | 5 | 5. | 5. | Protocol | EMMES - this is the protocol identifier for BMT CTN studies |
| 2 | PATID | Char | 18 | 18. | 18. | Patient ID | EMMES – this is patient identifier that can be used for any data merge between this dataset and other datasets. This is unique for each patient in BMT CTN. |
| 3 | PROJID | Char | 5 | 5. | 5. | Project ID | EMMES – this is the blinded identifier that should be used for any data merge between this dataset and other datasets. This is unique for each patient in BMT CTN. |
| 4 | SITE | Char | 5 | 5. | 5. | Site Code | EMMES - the code is unique for each site participating in the BMT CTN. |
| 5 | TRTTRUE | Char | 30 | 30. | 30. | Treatment Assignment | EMMES – this is based on randomization and indicates the assignment upon enrollment. |
| 6 | TRTCMPSP | Char | 50 | 50. | 50. | Treatment Non-compliance | ERC – this is non-compliant treatment adjudicated by ERC. Missing indicates compliance. |
| 7 | ENRLDATE | Num | 8 | MMDDYY8. | 8. | Date of Randomization | EMMES – this is the start date of the patient on this study |
| 8 | CBUINFDT | Num | 8 | MMDDYY8. | 8. | CBU Infusion Date | CRF – IFU |
| 9 | AGE_TXP | Num | 8 | 8.2 | | Age at Transplantation | RECODE - this is the computed age of years at transplantation based on DOB on CRF – DEM form |
| 10 | ETHNIC | Char | 3 | $ETHNICF. | 3. | Ethnicity | CRF – DEM |
| 11 | GENDER | Char | 1 | $GENDERF. | | Gender | CRF – DEM |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| 12 | RACEA | Char | 1 | $RACEF. | | Patient's Race | RECODE – this is based on race and secondary race reported on CRF – DEM form and combine into several big race categories. |
| 13 | CBUWEIGH | Num | 8 | 8.2 | 7.1 | Patient Body Weight at Transplant (kg) | CRF – IFU |
| 14 | PRFSTCB | Char | 2 | $PSA. | 2. | Performance Score at Baseline | CRF – ENROLL |
| 15 | PRIMDIS | Char | 1 | $PRIMDZF. | 1. | Primary Disease | CRF – ENROLL |
| 16 | STAGE | Char | 2 | $DSSTG. | | Disease Stage | RECODE – this is disease stage computed based on AMLDXSTG, ALLDXSTG, BIPDXSTG, MDSDXSTG, CMLDXSTG from CRF – ENROLL |
| 17 | DISEASE_RISK | Char | 13 | | | Disease Risk | RECODE – this is computed based on CRF – ENROLL primary disease and disease stage |
| 18 | TNC1_PRECRYO_KG | Num | 8 | 8.2 | | Cryopreserved Total Nucleated Cells for Cord Unit 1 (10^7/kg) | RECODE – this is computed based on patient's weight at transplant and pre-cryopreservation total nucleated cell count for CBU infusion # 1 on CRF - IFU |
| 19 | TNC1_POSTTHAW_KG | Num | 8 | 8.2 | | Infused Total Nucleated Cells for Cord Unit 1 (10^7/kg) | RECODE – this is computed based on patient's weight at transplant and post-thaw total nucleated cell count for CBU infusion # 1 on CRF - IFU |
| 20 | TNC2_PRECRYO_KG | Num | 8 | 8.2 | | Cryopreserved Total Nucleated Cells for Cord Unit 2 (10^7/kg) | RECODE – this is computed based on patient's weight at transplant and pre-cryopreservation total nucleated cell count for CBU infusion # 2 on CRF - IFU |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **21** | TNC2_POSTTHAW_KG | Num | 8 | 8.2 | | Infused Total Nucleated Cells for Cord Unit 2 (10^7/kg) | RECODE – this is computed based on patient's weight at transplant and post-thaw total nucleated cell count for CBU infusion # 2 on CRF - IFU |
| **22** | CD341_PRECRYO_KG | Num | 8 | 8.2 | | Cryopreserved CD34+ Cells for Cord Unit 1 (10^5/kg) | RECODE – this is computed based on patient's weight at transplant and pre-cryopreservation CD34 cell count for CBU infusion # 1 on CRF - IFU |
| **23** | CD341_POSTTHAW_KG | Num | 8 | 8.2 | | Infused CD34+ Cells for Cord Unit 1 (10^5/kg) | RECODE – this is computed based on patient's weight at transplant and post-thaw CD34 cell count for CBU infusion # 1 on CRF - IFU |
| **24** | CD342_PRECRYO_KG | Num | 8 | 8.2 | | Cryopreserved CD34+ Cells for Cord Unit 2 (10^5/kg) | RECODE – this is computed based on patient's weight at transplant and pre-cryopreservation CD34 cell count for CBU infusion # 2 on CRF - IFU |
| **25** | CD342_POSTTHAW_KG | Num | 8 | 8.2 | | Infused CD34+ Cells for Cord Unit 2 (10^5/kg) | RECODE – this is computed based on patient's weight at transplant and post-thaw CD34 cell count for CBU infusion # 2 on CRF - IFU |
| **26** | CRDUHLA1 | Num | 8 | HLA. | | HLA Match Score for Cord Unit 1 | ERC – this is ERC adjudicated HLA score for cord blood unit 1 based on CRF – CH1, CH2, CH3 and CIBMTR data |
| **27** | CRDUHLA2 | Num | 8 | HLA. | | HLA Match Score for Cord Unit 2 | ERC – this is ERC adjudicated HLA score for cord blood unit 2 based on CRF – CH1, CH2, CH3 and CIBMTR data |
| **28** | MINHLA | Num | 8 | HLA. | | Combined HLA Match Score | RECODE – this is the computed HLA matching score based on CIBMTR data (minimum HLA match between the first unit and the recipient or the second unit and the recipient) |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **29** | RD1_MISMATCH | Char | 1 | $BLD. | | ABO Match for Cord Unit 1 | RECODE – this is computed based on ABO data for CBU infusion #1 collected through CIBMTR |
| **30** | RD2_MISMATCH | Char | 1 | $BLD. | | ABO Match for Cord Unit 2 | RECODE – this is computed based on ABO data for CBU infusion # 2 collected through CIBMTR |
| **31** | RECIP_CMV | Char | 1 | $CMV. | | Recipient's CMV | CIBMTR (Inconclusive and Unknown were not included in multivariate analysis) |
| **32** | OSDAY | Num | 8 | | | Days of Overall Survival from Randomization | RECODE – this is the days from transplant to the death or last follow up, computed for survival analysis |
| **33** | OSMON | Num | 8 | 8.2 | | Months of Overall Survival from Randomization | RECODE – this is the months from transplant to the death or last follow up, computed for survival analysis |
| **34** | OSEVENT | Char | 9 | | | Outcome for Overall Survival | RECODE – this is the outcome for overall survival endpoint |
| **35** | OSSRVCENS | Num | 8 | | | Overall Survival Censor Indicator | RECODE – this is the censor indicator for overall survival endpoint (0=End Study, 1=Death) |
| **36** | FUDATE | Num | 8 | MMDDYY8. | | Date of Last Follow Up | RECODE - this is based on the last follow-up date from all available data sources including CRF and ERC adjudication |
| **37** | DTHDT | Num | 8 | MMDDYY8. | 8. | Date of Death | CRF – DTH |
| **38** | COD_ERC | Num | 8 | DEATHO. | | Primary Cause of Death | ERC – this is adjudicated by ERC on patient's primary cause of death |
| **39** | DATRANSP | Num | 8 | MMDDYY8. | 8. | Date of Second Transplant | CRF – FUS |
| **40** | PRGRLPDT | Num | 8 | MMDDYY8. | 8. | Date of Disease Progression/Relapse | ERC – this is the date of progression or relapse based on relapse form and adjudicated by ERC |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **41** | RELAPSEDAY | Num | 8 | | | Days of Relapse from Transplant | RECODE – this is the days from transplant to the death, relapse, or last follow up, computed for cumulative incidence of relapse |
| **42** | RELAPSEMON | Num | 8 | 8.2 | | Months of Relapse from Transplant | RECODE – this is the months from transplant to the death, relapse, or last follow up, computed for cumulative incidence of relapse |
| **43** | RELAPSEOUTCOME | Char | 9 | | | Outcome from Relapse | RECODE – this is the outcome for relapse |
| **44** | RELAPSE_CI | Num | 8 | | | Relapse Indicator for Competing Risk | RECODE – this is the indicator for relapse competing risk (0=End Study, 1=Relapse, 2=Death) |
| **45** | ANC1DT | Num | 8 | MMDDYY8. | 8. | Date of Neutrophil Recovery | CRF – HEM |
| **46** | ANCDAY | Num | 8 | | | Days of Neutrophil Recovery from Transplant | RECODE – this is the days of neutrophil recovery, second transplant, death, or last follow up from transplant, computed for cumulative incidence of platelet recovery |
| **47** | ANCOUTCOME | Char | 9 | | | Outcome for Neutrophil Recovery | RECODE – this is the outcome for neutrophil recovery |
| **48** | ANC_CI | Num | 8 | | | Neutrophil Recovery Indicator for Competing Risk | RECODE – this is the indicator for neutrophil recovery competing risk (0=End Study, 1=Engraft, 2=Death or Secondary Transplant) |
| **49** | PL20KDT | Num | 8 | MMDDYY8. | 8. | Date of Platelet Recovery to 20K | ERC – this is ERC adjudicated date for platelet recovery to 20K based on data obtained from CIBMTR |
| **50** | PL50KDT | Num | 8 | MMDDYY8. | 8. | Date of Platelet Recovery to 50K | ERC – this is ERC adjudicated date for platelet recovery to 50K based on data obtained from CIBMTR |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **51** | PLT50DAY | Num | 8 | | | Days of Platelet Recovery to 50K from Transplant | RECODE – this is the days of platelet recovery to 50K, second transplant, death, or last follow up from transplant, computed for cumulative incidence of platelet recovery |
| **52** | PLT50OUTCOME | Char | 9 | | | Outcome for Platelet Recovery to 50K | RECODE – this is the outcome for platelet recovery to 50K. this is data reported in the primary manuscript |
| **53** | PLT50_CI | Num | 8 | | | Platelet Recovery to 50K Indicator for Competing Risk | RECODE – this is the indicator for platelet recovery competing risk (0=End Study, 1=Engraft, 2=Death or Secondary Transplant) |
| **54** | AGVH24DT | Num | 8 | MMDDYY8. | 8. | Date of Acute GVHD Grade II-IV | ERC – this is the date of onset of grades II-IV acute GVHD adjudicated by ERC |
| **55** | AGVH24DAY | Num | 8 | | | Days of Grade II-IV Acute GHVD from Transplant | RECODE – this is the days of grade II-IV acute GVHD onset, second transplant, death, or last follow up from transplant, computed for cumulative incidence of grade II-IV acute GVHD |
| **56** | AGVH24OUTCOME | Char | 9 | | | Outcome for Grade II-IV Acute GVHD | RECODE – this is the outcome for grade II-IV acute GVHD |
| **57** | AGVH24_CI | Num | 8 | | | Grade II-IV Acute GVHD Indicator for Competing Risk | RECODE – this is the indicator for grade II-IV acute GHVD competing risk (0=End Study, 1=AGVH24, 2=Death or Secondary Transplant) |
| **58** | AGVH34DT | Num | 8 | MMDDYY8. | 8. | Date of Acute GVHD Grade III-IV | ERC – this is the date of onset of grades III-IV acute GVHD adjudicated by ERC |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **59** | AGVH34DAY | Num | 8 | | | Days of Grade III-IV Acute GVHD from Transplant | RECODE – this is the days of grades III-IV acute GVHD onset, second transplant, death, or last follow up from transplant, computed for cumulative incidence of grade III-IV acute GVHD |
| **60** | AGVH34OUTCOME | Char | 9 | | | Outcome for Grade III-IV Acute GVHD | RECODE – this is the outcome for grade III-IV acute GVHD |
| **61** | AGVH34_CI | Num | 8 | | | Grade III-IV Acute GVHD Indicator for Competing Risk | RECODE – this is the indicator for grade II-IV acute GHVD competing risk (0=End Study, 1=AGVH34, 2=Death or Secondary Transplant) |
| **62** | MAXAGVHD | Char | 1 | $X12126X. | 1. | Maximum Acute GVHD Grade | ERC – this is the maximum grade of acute GVHD adjudicated by ERC |
| **63** | CGVHDT | Num | 8 | MMDDYY8. | 8. | Chronic GVHD Onset Date | ERC – this is the date of onset of chronic GVHD adjudicated by ERC |
| **64** | CGVHDDAY | Num | 8 | | | Days of Chronic GVHD from Transplant | RECODE – this is the days of chronic GVHD onset, second transplant, death, or last follow up from transplant, computed for cumulative incidence of chronic GVHD |
| **65** | CGVHDMON | Num | 8 | 8.2 | | Months of Chronic GVHD from Transplant | RECODE – this is the months of chronic GVHD onset, second transplant, death, or last follow up from transplant, computed for cumulative incidence of chronic GVHD |
| **66** | CGVHDOUTCOME | Char | 9 | | | Outcome for Chronic GVHD | RECODE – this is the outcome for chronic GVHD |
| **67** | CGVHD_CI | Num | 8 | | | Chronic GVHD Indicator for Competing Risk | RECODE – this is the indicator for chronic GHVD competing risk (0=End Study, 1=CGVHD, 2=Death or Secondary Transplant) |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **68** | MAXCGVDT | Num | 8 | MMDDYY8. | 8. | Date of Maximum Chronic GVHD Grade | ERC – this is the date of onset of maximum grade of GVHD adjudicated by ERC |
| **69** | MAXCGVHD | Char | 1 | $X12127X. | 1. | Maximum Chronic GVHD Grade | ERC – this is the maximum grade of chronic GVHD adjudicated by ERC |
| **70** | ECGVHDT | Num | 8 | MMDDYY8. | | Date of Extensive Chronic GVHD Onset | RECODE – this is the date of extensive chronic GVHD onset, computed based on MAXCGVDT and MAXCGVHD |
| **71** | ECGVHDDAY | Num | 8 | | | Days of Extensive Chronic GVHD Onset from Transplant | RECODE – this is the days of extensive chronic GVHD onset, second transplant, death, or last follow up from transplant, computed for cumulative incidence of chronic GVHD |
| **72** | ECGVHDMON | Num | 8 | 8.2 | | Months of Extensive Chronic GVHD Onset from Transplant | RECODE – this is the months of extensive chronic GVHD onset, second transplant, death, or last follow up from transplant, computed for cumulative incidence of chronic GVHD |
| **73** | ECGVHDOUTCOME | Char | 9 | | | Outcome for Extensive Chronic GVHD | RECODE – this is the outcome for extensive chronic GVHD |
| **74** | ECGVHD_CI | Num | 8 | | | Extensive Chronic GVHD Indicator for Competing Risk | RECODE – this is the indicator for extensive chronic GHVD competing risk (0=End Study, 1=eCGVHD, 2=Death or Secondary Transplant) |
| **75** | DFSDAY_TXP | Num | 8 | | | Days of Disease-free Survival from Transplant | RECODE – this is the days from transplant to the death, relapse, or last follow up, computed for survival analysis |
| **76** | DFSMON_TXP | Num | 8 | 8.2 | | Months of Disease-free Survival from Transplant | RECODE – this is the months from transplant to the death, relapse, or last follow up, computed for survival analysis |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **77** | DFSEVENT | Char | 9 | | | Outcome of Disease-free Survival | RECODE – this is the outcome for disease-free survival endpoint |
| **78** | DFSSRVCENS | Num | 8 | | | Disease-free Survival Censor Indicator | RECODE – this is the censor indicator for disease-free survival endpoint (0=End Study, 1=Death or Relapse) |
| **79** | TRMDAY | Num | 8 | | | Days of Treatment-related Mortality from Transplant | RECODE – this is the days from transplant to the death, relapse, or last follow up, computed for cumulative incidence of treatment-related mortality |
| **80** | TRMMON | Num | 8 | 8.2 | | Months of Treatment-related Mortality from Transplant | RECODE – this is the months from transplant to the death, relapse, or last follow up, computed for cumulative incidence of treatment-related mortality |
| **81** | TRMOUTCOME | Char | 9 | | | Outcome for Treatment-related Mortality | RECODE – this is the outcome for treatment-related mortality |
| **82** | TRM_CI | Num | 8 | | | Treatment-related Mortality Indicator for Competing Risk | RECODE – this is the indicator for treatment-related mortality competing risk (0=End Study, 1=Death, 2=Relapse) |
| **83** | INFSEV | Char | 1 | $INFSEV. | | Maximum Severity of Infectious Episode | RECODE – this is computed based on patient's infection data reported on CRF – INF |
| **84** | AGECAT | Char | 1 | $AGEC. | | Age Group (<10 vs. >=10) | RECODE – this is computed based on patient's age at randomization |
| **85** | ETHNICA | Char | 1 | $ETHNICB. | | Ethnicity (Hispanic vs. Non-Hispanic) | RECODE – this is dichotomized ethnicity for multivariate analyses |
| **86** | PRIMDIS_NEW2 | Char | 1 | $DS. | | Disease Diagnosis (ALL vs. AML vs. Others) | RECODE – this is recoded primary disease for multivariate analyses |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **87** | PSCAT | Char | 1 | $PSC. | | Performance Score (>=90 vs. <90) | RECODE – this is dichotomized performance score for multivariate analyses |
| **88** | RACEB | Char | 1 | $RACEB. | | Race (White vs. Non-white) | RECODE – this is dichotomized race for multivariate analyses |
| **89** | HLACAT | Char | 1 | $HLAC. | | Donor-Recipient HLA Matching (3/6 and 4/6 vs. 5/6 and 6/6) | RECODE – this is dichotomized HLA match score for multivariate analyses |
| **90** | OSDAY_2YEAR | Num | 8 | | | Days of Overall Survival from Randomization For Multivariate Analysis | RECODE – this is the days from transplant to the death or last follow up, computed for multivariate analysis for overall survival, censored at 2 years |
| **91** | OSMON_2YEAR | Num | 8 | 8.2 | | Months of Overall Survival from Randomization For Multivariate Analysis | RECODE – this is the months from transplant to the death or last follow up, computed for multivariate analysis for overall survival |
| **92** | OSSRVCENS_2YEAR | Num | 8 | | | Overall Survival Censor Indicator For Multivariate Analysis | RECODE – this is the censor indicator for overall survival endpoint (0=End Study, 1=Death) used in the overall survival multivariate analysis |
| **93** | DFSDAY_TXP_2YEAR | Num | 8 | | | Days of Disease-free Survival from Transplant For Multivariate Analysis | RECODE – this is the days from transplant to the death, or relapse, or last follow up, computed for multivariate analysis for disease-free survival, censored at 2 years |
| **94** | DFSMON_TXP_2YEAR | Num | 8 | 8.2 | | Months of Disease-free Survival from Transplant For Multivariate Analysis | RECODE – this is the months from transplant to the death, or relapse, or last follow up, computed for multivariate analysis for disease-free survival, censored at 2 years |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **95** | DFSSRVCENS_TXP_2YEAR | Num | 8 | | | Disease-free Survival Censor Indicator For Multivariate Analysis | RECODE – this is the censor indicator for overall survival endpoint (0=End Study, 1=Death) used in the disease-free survival multivariate analysis |
| **96** | CD19IRF_0100 | Num | 8 | 6. | | CD19 at Day 100 (cells/uL) | CRF – this is CD19+ cells at Day 100 from CRF – IRF |
| **97** | CD19IRF_0180 | Num | 8 | 6. | | CD19 at Day 180 (cells/uL) | CRF – this is CD19+ cells at Day 180 from CRF – IRF |
| **98** | CD19IRF_0365 | Num | 8 | 6. | | CD19 at Day 365 (cells/uL) | CRF – this is CD19+ cells at Day 365 from CRF – IRF |
| **99** | CD3IRF_0100 | Num | 8 | 6. | | CD3 at Day 100 (cells/uL) | CRF – this is CD3 cells at Day 100 from CRF – IRF |
| **100** | CD3IRF_0180 | Num | 8 | 6. | | CD3 at Day 180 (cells/uL) | CRF – this is CD3 cells at Day 180 from CRF – IRF |
| **101** | CD3IRF_0365 | Num | 8 | 6. | | CD3 at Day 365 (cells/uL) | CRF – this is CD3 cells at Day 365 from CRF – IRF |
| **102** | CD4IRF_0100 | Num | 8 | 6. | | CD4 at Day 100 (cells/uL) | CRF – this is CD4 cells at Day 100 from CRF – IRF |
| **103** | CD4IRF_0180 | Num | 8 | 6. | | CD4 at Day 180 (cells/uL) | CRF – this is CD4 cells at Day 180 from CRF – IRF |
| **104** | CD4IRF_0365 | Num | 8 | 6. | | CD4 at Day 365 (cells/uL) | CRF – this is CD4 cells at Day 365 from CRF – IRF |
| **105** | CD56IRF_0100 | Num | 8 | 6. | | CD56+/CD16+ at Day 100 (cells/uL) | CRF – this is CD56+/CD16+ cells at Day 100 from CRF – IRF |
| **106** | CD56IRF_0180 | Num | 8 | 6. | | CD56+/CD16+ at Day 180 (cells/uL) | CRF – this is CD56+/CD16+ cells at Day 180 from CRF – IRF |
| **107** | CD56IRF_0365 | Num | 8 | 6. | | CD56+/CD16+ at Day 365 (cells/uL) | CRF – this is CD56+/CD16+ cells at Day 365 from CRF – IRF |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **108** | CD8IRF_0100 | Num | 8 | 6. | | CD8 at Day 100 (cells/uL) | CRF – this is CD8 cells at Day 100 from CRF – IRF |
| **109** | CD8IRF_0180 | Num | 8 | 6. | | CD8 at Day 180 (cells/uL) | CRF – this is CD8 cells at Day 180 from CRF – IRF |
| **110** | CD8IRF_0365 | Num | 8 | 6. | | CD8 at Day 365 (cells/uL) | CRF – this is CD8 cells at Day 365 from CRF – IRF |
| **111** | IGAIRF_0100 | Num | 8 | 4. | | IgA at Day 100 (mg/dL) | CRF – this is IgA at Day 100 from CRF – IRF |
| **112** | IGAIRF_0180 | Num | 8 | 4. | | IgA at Day 180 (mg/dL) | CRF – this is IgA at Day 180 from CRF – IRF |
| **113** | IGAIRF_0365 | Num | 8 | 4. | | IgA at Day 365 (mg/dL) | CRF – this is IgA at Day 365 from CRF – IRF |
| **114** | IGEIRF_0100 | Num | 8 | 4. | | IgE at Day 100 (IU/mL) | CRF – this is IgG at Day 100 from CRF – IRF |
| **115** | IGEIRF_0180 | Num | 8 | 4. | | IgE at Day 180 (IU/mL) | CRF – this is IgG at Day 180 from CRF – IRF |
| **116** | IGEIRF_0365 | Num | 8 | 4. | | IgE at Day 365 (IU/mL) | CRF – this is IgG at Day 365 from CRF – IRF |
| **117** | IGGIRF_0100 | Num | 8 | 5. | | IgG at Day 100 (mg/dL) | CRF – this is IgM at Day 100 from CRF – IRF |
| **118** | IGGIRF_0180 | Num | 8 | 5. | | IgG at Day 180 (mg/dL) | CRF – this is IgM at Day 180 from CRF – IRF |
| **119** | IGGIRF_0365 | Num | 8 | 5. | | IgG at Day 365 (mg/dL) | CRF – this is IgM cells at Day 365 from CRF – IRF |
| **120** | IGMIRF_0100 | Num | 8 | 5. | | IgM at Day 100 (mg/dL) | CRF – this is IgE at Day 100 from CRF – IRF |
| **121** | IGMIRF_0180 | Num | 8 | 5. | | IgM at Day 180 (mg/dL) | CRF – this is IgE at Day 180 from CRF – IRF |

| # | Variable | Type | Len | Format | Informat | Label | Data Source/Notes |
|---|---|---|---|---|---|---|---|
| **122** | IGMIRF_0365 | Num | 8 | 5. | | IgM at Day 365 (mg/dL) | CRF – this is IgE at Day 365 from CRF – IRF |
| **123** | LMYPHIRF_0100 | Num | 8 | 4. | | Percent lymphocyte of CD45+ cells at Day 100 (%) | CRF – this is percent lymphocyte of CD45+ cells at Day 100 from CRF – IRF |
| **124** | LMYPHIRF_0180 | Num | 8 | 4. | | Percent lymphocyte of CD45+ cells at Day 180 (%) | CRF – this is percent lymphocyte of CD45+ cells at Day 180 from CRF – IRF |
| **125** | LMYPHIRF_0365 | Num | 8 | 4. | | Percent lymphocyte of CD45+ cells at Day 365 (%) | CRF – this is percent lymphocyte of CD45+ cells at Day 365 from CRF – IRF |
| **126** | WBCIRF_0100 | Num | 8 | 6. | | WBC at Day 100 (10^9/L) | CRF – this is WBC at Day 100 from CRF – IRF |
| **127** | WBCIRF_0180 | Num | 8 | 6. | | WBC at Day 180 (10^9/L) | CRF – this is WBC at Day 180 from CRF – IRF |
| **128** | WBCIRF_0365 | Num | 8 | 6. | | WBC at Day 365 (10^9/L) | CRF – this is WBC at Day 365 from CRF – IRF |

**Algorithm used for the Recode and ERC Adjudications**

**Algorithm for Acute GVHD Grade**:

- The acute GVHD algorithm calculates the grade based on the organ (skin, GI and liver) stage and etiology/biopsy reported on the weekly GVHD form.
- If none of the etiologies for skin, upper GI, lower GI, or liver are reported as GVHD, then the overall grade is 0
- If multiple etiologies are specified for lower GI or liver, the organ system will be down-staged by 1.
- If an upper GI biopsy is negative, upper GI symptoms are down-staged.
- If GVHD is not listed as an etiology for upper GI then upper GI symptoms are down-staged.
- Each organ contributes to the overall grade; while to get an overall grade, it does not necessarily need all organ symptoms. Different organ/stage determine different grade. Details below:

| Acute GVHD Grade | Organ Involvement/stage |
|---|---|
| **Grade 0** | No skin rash and<br>No protracted nausea and vomiting and<br>No diarrhea or diarrhea < 500 mL/day and<br>Bilirubin < 2.0 mg/dL |
| **Grade I** | Skin rash 25-50% and<br>No diarrhea or diarrhea < 500 mL/day and<br>Bilirubin < 2.0 mg/dL |
| **Grade II** | Skin rash >50% or<br>Diarrhea >500 mL/day or<br>Bilirubin 2.0 - 3.0 mg/dL or<br>Persistent nausea/vomiting |
| **Grade III** | Skin-No rash to Rash > 50% with<br>Diarrhea > 1000 mL/day or severe abdominal pain or<br>Bilirubin 3.1 – 15 mg/dL |
| **Grade IV** | Skin-Generalized Erythroderma with Bullus<br>Formation and Desquamation or<br>Bilirubin > 15 mg/dL |

**Algorithm for Chronic GVHD**: Limited vs Extensive (Definition from CIBMTR forms)

- Limited – localized skin involvement and/or hepatic dysfunction due to chronic GVHD
- Extensive – one or more of the following:
    1. generalized skin involvement; or,
    2. liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
    3. involvement of eye: Schirmer's test with < 5 mm wetting; or
    4. involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
    5. involvement of any other target organ