

Post-Transplant Essential Data



Registry Use Only

OMB No: 0915-0310

Sequence Number:

Expiration Date: 10/31/2022

Date Received:

**Public Burden Statement:** The purpose of the data collection is to fulfill the legislative mandate to establish and maintain a standardized database of allogeneic marrow and cord blood transplants performed in the United States or using a donor from the United States. The data collected also meets the C.W. Bill Young Cell Transplantation Program requirements to provide relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0310 and it is valid until 10/31/2022. This information collection is voluntary under The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109-129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111-264 (the Act) and the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114-104. Public reporting burden for this collection of information is estimated to average 0.85 hours per response when collected at 100 days post-transplant, 0.85 hours per response when collected at 6 months post-transplant, 0.65 hours per response when collected at 1 and 2 years post-transplant, and 0.52 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov).

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CIBMTR Research ID: \_\_\_\_\_

Event date: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

YYYY MM DD

Visit:

100 day

6 months

1 year

2 years

>2 years,

Specify: \_\_\_\_\_

**Survival**

1. Date of actual contact with the recipient to determine medical status for this follow-up report: \_\_\_\_\_ —  
YYYY  
\_\_\_\_ —  
MM DD

2. Specify the recipient's survival status at the date of last contact:
- Alive - Answers to subsequent questions should reflect clinical status since the date of last report - **Go to question 7.**
  - Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death - **Go to question 3.**

3. Primary cause of death
- Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed – **Go to question 5.**
  - Acute GVHD – **Go to question 5.**
  - Chronic GVHD – **Go to question 5.**
  - Graft rejection or failure – **Go to question 5.**
  - Cytokine release syndrome – **Go to question 5.**

**Infection**

- Infection, organism not identified – **Go to question 5.**
- Bacterial infection – **Go to question 5.**
- Fungal infection – **Go to question 5.**
- Viral infection – **Go to question 5.**
- COVID-19 (SARS-CoV-2) – Go to question 5.**
- Protozoal infection – **Go to question 5.**
- Other infection – **Go to question 4.**

**Pulmonary**

- Idiopathic pneumonia syndrome (IPS) – **Go to question 5**
- Pneumonitis due to Cytomegalovirus (CMV) – **Go to question 5**
- Pneumonitis due to other virus – **Go to question 5**
- Other pulmonary syndrome (excluding pulmonary hemorrhage) – **Go to question 4.**
- Diffuse alveolar damage (without hemorrhage) – **Go to question 5.**
- Acute respiratory distress syndrome (ARDS) (other than IPS) – **Go to question 5.**

**Organ failure (not due to GVHD or infection)**

- Liver failure (not VOD) – **Go to question 5.**
- Venous-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) – **Go to question 5.**
- Cardiac failure – **Go to question 5.**
- Pulmonary failure– **Go to question 5.**
- Central nervous system (CNS) failure – **Go to question 5.**
- Renal failure – **Go to question 5.**
- Gastrointestinal (GI) failure (not liver) – **Go to question 5.**
- Multiple organ failure – **Go to question 4.**
- Other organ failure – **Go to question 4.**

**Malignancy**

- New malignancy (post-HCT or post-cellular therapy) – **Go to question 5.**
- Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed) – **Go to question 5.**

**Hemorrhage**

- Pulmonary hemorrhage – **Go to question 5.**
- Diffuse alveolar hemorrhage (DAH) – **Go to question 5.**
- Intracranial hemorrhage – **Go to question 5.**
- Gastrointestinal hemorrhage – **Go to question 5.**
- Hemorrhagic cystitis – **Go to question 5.**
- Other hemorrhage – **Go to question 4.**

**Vascular**

- Thromboembolic – **Go to question 5.**
- Disseminated intravascular coagulation (DIC) – **Go to question 5.**
- Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))– **Go to question 5.**
- Other vascular - **Go to question 4.**

**Other**

- Accidental death – **Go to question 5.**
- Suicide – **Go to question 5.**
- Other cause - **Go to question 4.**

4. Specify: \_\_\_\_\_

5. Contributing cause of death (check all that apply)

- Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed – **Go to question 7.**
- Acute GVHD – **Go to question 7.**
- Chronic GVHD – **Go to question 7.**
- Graft rejection or failure – **Go to question 7.**
- Cytokine release syndrome – **Go to question 7.**

**Infection**

- Infection, organism not identified – **Go to question 7.**
- Bacterial infection – **Go to question 7.**
- Fungal infection – **Go to question 7.**
- Viral infection – **Go to question 7.**
- COVID-19 (SARS-CoV-2) – Go to question 7.**
- Protozoal infection – **Go to question 7.**
- Other infection – **Go to question 6.**

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- Pneumonitis due to other virus – **Go to question 7.**
- Other pulmonary syndrome (excluding pulmonary hemorrhage) – **Go to question 6.**
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- Renal failure – **Go to question 7.**
- Gastrointestinal (GI) failure (not liver) – **Go to question 7.**
- Multiple organ failure – **Go to question 6.**
- Other organ failure – **Go to question 6.**

**Malignancy**

- New malignancy (post-HCT or post-cellular therapy) – **Go to question 7.**
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- Other hemorrhage – **Go to question 6.**

**Vascular**

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- Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)) – **Go to question 7.**
- Other vascular - **Go to question 6.**

**Other**

- Accidental death – **Go to question 7.**
- Suicide – **Go to question 7.**
- Other cause - **Go to question 6.**

6. Specify: \_\_\_\_\_

**Subsequent Transplant**

7. Did the recipient receive a subsequent HCT since the date of last report?
- Yes – **Go to question 8.**
  - No - **Go to question 12.**

8. Date of subsequent HCT: \_\_\_\_\_

YYYY                      MM                      DD

9. What was the indication for subsequent HCT?
- Graft failure / insufficient hematopoietic recovery - **Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT – Go to question 11.**





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- II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting
- III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
- IV - Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL
- Not applicable (acute GVHD present but grade is not applicable)

**List the stage for each organ at diagnosis of acute GVHD:**

23. Skin:

- Stage 0 – no rash, no rash attributable to acute GVHD
- Stage 1 – maculopapular rash, < 25% of body surface
- Stage 2 – maculopapular rash, 25–50% of body surface
- Stage 3 – generalized erythroderma, > 50% of body surface
- Stage 4 – generalized erythroderma with bullae formation and/or desquamation

24. Lower intestinal tract: (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

- Stage 0 – no diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)
- Stage 1 – diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)
- Stage 2 – diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)
- Stage 3 – diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)
- Stage 4 – severe abdominal pain, with or without ileus, and/or grossly bloody stool

25. Upper intestinal tract:

- Stage 0 – no persistent nausea or vomiting
- Stage 1 – persistent nausea or vomiting

26. Liver:

- Stage 0 – No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)
- Stage 1 – bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)
- Stage 2 – bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)
- Stage 3 – bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)
- Stage 4 – bilirubin > 15.0 mg/dL (> 256 µmol/L)

27. Other site(s) involved with acute GVHD



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- Yes – **Go to question 28.**
- No – **Go to question 29.**

28. Specify other site(s): \_\_\_\_\_

**Specify the maximum overall grade and organ staging of acute GVHD since the date of last report**

29. Maximum overall grade of acute GVHD:

- I - Rash on  $\leq$  50% of skin, no liver or gut involvement
- II - Rash on  $>$  50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting
- III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea  $>$  1000 mL/day or severe abdominal pain with or without ileus
- IV - Generalized erythroderma with bullous formation, or bilirubin  $>$ 15 mg/dL
- Not applicable (acute GVHD present but cannot be graded)

30. Date maximum overall grade of acute GVHD: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

31. Skin:

- Stage 0 – no rash, no rash attributable to acute GVHD
- Stage 1 – maculopapular rash,  $<$  25% of body surface
- Stage 2 – maculopapular rash, 25–50% of body surface
- Stage 3 – generalized erythroderma,  $>$  50% of body surface
- Stage 4 – generalized erythroderma with bullae formation and/or desquamation

32. Lower intestinal tract: (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

- Stage 0 – no diarrhea, no diarrhea attributable to acute GVHD / diarrhea  $<$  500 mL/day (adult), or  $<$  10 mL/kg/day (pediatric)
- Stage 1 – diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)
- Stage 2 – diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)
- Stage 3 – diarrhea  $>$  1500 mL/day (adult), or  $>$  30 mL/kg/day (pediatric)
- Stage 4 – severe abdominal pain, with or without ileus, and/or grossly bloody stool

33. Upper intestinal tract:

- Stage 0 – no persistent nausea or vomiting
- Stage 1 – persistent nausea or vomiting

34. Liver:

- Stage 0 – No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)
- Stage 1 – bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)
- Stage 2 – bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)
- Stage 3 – bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)
- Stage 4 – bilirubin > 15.0 mg/dL (> 256 µmol/L)

35. Other site(s) involved with acute GVHD

- Yes – **Go to question 36.**
- No – **Go to question 37.**

36. Specify other site(s): \_\_\_\_\_

37. Did chronic GVHD develop since the date of last report?

- Yes – **Go to questions 38.**
- No - **Go to question 39.**
- Unknown – **Go to question 39.**

38. Date of chronic GVHD diagnosis: \_\_\_\_\_  Date estimated – **Go to questions 40.**

MM DD YYYY

39. Did chronic GVHD persist since the date of last report?

- Yes – **Go to questions 40.**
- No - **Go to question 43.**
- Unknown – **Go to question 43.**

**Specify the maximum grade of chronic GVHD since the date of last report:**

40. Maximum grade of chronic GVHD: (according to best clinical judgment)

- Mild
- Moderate
- Severe
- Unknown





***Copy and complete questions 53.-59. to report each new malignancy diagnosed since the date of last report. The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.***

53. Specify the new malignancy:

- Acute myeloid leukemia (AML / ANLL) – ***Go to question 56.***
- Other leukemia – ***Go to question 56.***
- Myelodysplastic syndrome (MDS) – ***Go to question 56.***
- Myeloproliferative neoplasm (MPN) – ***Go to question 56.***
- Myelodysplasia / myeloproliferative neoplasm (MDS / MPN)– ***Go to question 56.***
- Hodgkin lymphoma – ***Go to question 55.***
- Non-Hodgkin lymphoma – ***Go to question 55.***
- Post-transplant lymphoproliferative disorder (PTLD)– ***Go to question 55.***
- Clonal cytogenetic abnormality without leukemia or MDS – ***Go to question 56.***
- Uncontrolled proliferation of donor cells without malignant transformation – ***Go to question 56.***
- Breast cancer – ***Go to question 56.***
- Central nervous system (CNS) malignancy (e.g. glioblastoma, astrocytoma) – ***Go to question 56.***
- Gastrointestinal malignancy (e.g. colon, rectum, stomach, pancreas, intestine) – ***Go to question 56.***
- Genitourinary malignancy (e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix) – ***Go to question 56.***
- Lung cancer – ***Go to question 56.***
- Melanoma – ***Go to question 56.***
- Basal cell skin malignancy – ***Go to question 56.***
- Squamous cell skin malignancy – ***Go to question 56.***
- Oropharyngeal cancer (e.g. tongue, buccal mucosa) – ***Go to question 56.***
- Sarcoma – ***Go to question 56.***
- Thyroid cancer – ***Go to question 56.***
- Other new malignancy – ***Go to question 54.***

54. Specify other new malignancy: \_\_\_\_\_ - ***Go to question 56.***

55. Is the tumor EBV positive?

- Yes
- No





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- Total mononuclear cells (lymphs & monos) – **Go to question 78.**
- T-cells (includes CD3+, CD4+, and/or CD8+) – **Go to question 78.**
- B-cells (includes CD19+ or CD20+) – **Go to question 78.**
- Granulocytes (includes CD33+ myeloid cells) – **Go to question 78.**
- NK cells (CD56+) – **Go to question 78.**
- Other – **Go to question 75.**

75. Specify: \_\_\_\_\_

76. Total cells examined: \_\_\_\_\_

77. Number of donor cells: \_\_\_\_\_ - **Go to question 80.**

78. Were donor cells detected?

- Yes - **Go to question 79.**
- No – **Go to question 80.**

79. Percent donor cells: \_\_\_\_\_ %

**Copy questions 63. – 79. if needed for multiple chimerism studies.**

#### Disease Assessment at the Time of Best Response to HCT

80. Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- Continued complete remission (CCR) - **For patients transplanted in CR- Go to question 103.**
- Complete remission (CR) - **Go to question 82.**
- Not in complete remission - **Go to question 81.**
- Not evaluated - **Go to question 103.**

81. Specify disease status if not in complete remission:

- Disease detected - **Go to question 84.**
- No disease detected but incomplete evaluation to establish CR - **Go to question 84.**

82. Was the date of best response previously reported?





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- Yes - **Go to questions 92.**
- No - **Go to question 94.**
- Not applicable - **Go to question 94.**

92. Date assessed: \_\_\_\_\_  
  YYYY  MM  DD

93. Was disease detected?  
 Yes  
 No

94. Was the disease status assessed via karyotyping?  
 Yes - **Go to question 95.**  
 No - **Go to question 97.**  
 Not applicable - **Go to question 97.**

95. Date assessed: \_\_\_\_\_  
  YYYY  MM  DD

96. Was disease detected?  
 Yes  
 No

97. Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)  
 Yes - **Go to question 98.**  
 No - **Go to question 100.**  
 Not applicable - **Go to question 100.**

98. Date assessed: \_\_\_\_\_

99. Was disease detected?  
 Yes  
 No

100. Was the disease status assessed by clinical/hematologic assessment?  
 Yes - **Go to question 101.**  
 No - **Go to question 103.**

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101. Date assessed: \_\_\_\_\_  
YYYY MM DD

102. Was disease detected?

- Yes
- No

### Post-HCT Therapy

Report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

103. Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy.)

- Yes - **Go to question 104.**
- No - **Go to question 108.**

104. Specify therapy: (check all that apply)

- Blinded randomized trial - **Go to question 108.**
- Cellular therapy - **Go to question 108.**
- Radiation - **Go to question 108.**
- Systemic therapy - **Go to question 105.**
- Other therapy - **Go to question 107.**

105. Specify systemic therapy: (check all that apply)

- Alemtuzumab (Campath)
- Azacytidine (Vidaza)
- Blinatumomab
- Bortezomib (Velcade)
- Bosutinib
- Carfilzomib
- Chemotherapy
- Dasatinib (Sprycel)
- Decitabine (Dacogen)
- Gemtuzumab (Mylotarg, anti-CD33)
- Gilteritinib

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- Ibrutinib
- Imatinib mesylate (Gleevec)
- Ixazomib
- Lenalidomide (Revlimid)
- Lestaurtinib
- Midostaurin
- Nilotinib (AMN107, Tasigna)
- Nivolumab
- Pembrolizumab
- Pomalidomide
- Quizartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Other systemic therapy- **Go to question 106.**

106. Specify other systemic therapy: \_\_\_\_\_

107. Specify other therapy: \_\_\_\_\_

### Relapse or Progression Post-HCT

Report if the recipient has experienced a clinical/hematologic relapse or progression post-HCT. If the relapse or progression was detected in a previous reporting period indicate that and continue on. If the first clinical/hematologic relapse occurred since the date of last report, indicate the date it was first detected in this reporting period.

108. Did the recipient experience a clinical/hematologic relapse or progression post-HCT?

- Yes - **Go to question 109.**
- No - **Go to question 111.**

109. Was the date of the first clinical/hematologic relapse or progression previously reported?

- Yes - **Go to question 119. (only valid >day 100)**



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- Bortezomib (Velcade)
- Bosutinib
- Carfilzomib
- Chemotherapy
- Dasatinib (Sprycel)
- Decitabine (Dacogen)
- Gemtuzumab (Mylotarg, anti-CD33)
- Gilteritinib
- Ibrutinib
- Imatinib mesylate (Gleevec)
- Ixazomib
- Lenalidomide (Revlimid)
- Lestaurtinib
- Midostaurin
- Nilotinib (AMN107, Tasigna)
- Nivolumab
- Pembrolizumab
- Pomalidomide
- Quizartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Other systemic therapy- **Go to question 117.**

117. Specify other systemic therapy: \_\_\_\_\_

118. Specify other therapy: \_\_\_\_\_

### Current Disease Status

119. What is the current disease status?

- Complete remission (CR) - **Go to question 121.**

