



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, 0.64 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

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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:

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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.**
- 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.**

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- 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.**

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- 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.**
- Protozoal infection – **Go to question 7.**
- Other infection – **Go to question 6.**

Pulmonary

- Idiopathic pneumonia syndrome (IPS) – **Go to question 7.**
- Pneumonitis due to Cytomegalovirus (CMV) – **Go to question 7.**
- Pneumonitis due to other virus – **Go to question 7.**
- Other pulmonary syndrome (excluding pulmonary hemorrhage) – **Go to question 6.**
- Diffuse alveolar damage (without hemorrhage) – **Go to question 7.**
- Acute respiratory distress syndrome (ARDS) (other than IPS) – **Go to question 7.**

Organ failure (not due to GVHD or infection)

- Liver failure (not VOD) – **Go to question 7.**
- Venous-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) – **Go to question 7.**
- Cardiac failure – **Go to question 7.**
- Pulmonary failure – **Go to question 7.**
- Central nervous system (CNS) failure – **Go to question 7.**
- 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.**
- 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 7.**

Hemorrhage

- Pulmonary hemorrhage – **Go to question 7.**
- Diffuse alveolar hemorrhage (DAH) – **Go to question 7.**

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17. Was an initial platelet count $\geq 20 \times 10^9/L$ achieved?
- Yes – **Go to question 18.**
 - No – **Go to question 19.**
 - Not applicable - Platelet count never dropped below $20 \times 10^9/L$ – **Go to question 19.**
 - Previously reported - $\geq 20 \times 10^9/L$ was achieved and reported previously – **Go to question 19.**

18. Date platelets $\geq 20 \times 10^9/L$: _____

YYYY MM DD

Graft vs. Host Disease

If an allogeneic donor was used for the recipient's HCT or cellular therapy, report all graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue to Liver Toxicity Prophylaxis, question 45..

19. Did acute GVHD develop since the date of last report?
- Yes– **Go to question 20.**
 - No – **Go to question 21.**
 - Unknown – **Go to question 21.**

20. Date of acute GVHD diagnosis: _____ - **Go to question 22.**

YYYY MM DD

21. Did acute GVHD persist since the date of last report?
- Yes– **Go to question 29.**
 - No – **Go to question 37.**
 - Unknown – **Go to question 37.**

22. Overall grade of acute GVHD at diagnosis:
- 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 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

- 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 ≤ 50% of skin, no liver or gut involvement

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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 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

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- 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

41. Specify if chronic GVHD was limited or extensive:

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

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55. **Select dose(s) received**

- One dose** (*without planned second dose*)
- First dose** (*with planned second dose*)
- Second dose**
- Third dose**
- Booster dose**

56. **Date received:** _____ **Date estimated**

YYYY MM DD

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Report new malignancies that are different than the disease / disorder for which HCT was performed. Do not include relapse, progression or transformation of the same disease subtype.

57. Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)

- Yes – **Go to question 58.**
- No – **Go to question 65.**

Copy and complete questions 58.-64. 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.

58. Specify the new malignancy:

- Acute myeloid leukemia (AML / ANLL) – **Go to question 61.**
- Other leukemia – **Go to question 61.**
- Myelodysplastic syndrome (MDS) – **Go to question 61.**
- Myeloproliferative neoplasm (MPN) – **Go to question 61.**
- Myelodysplasia / myeloproliferative neoplasm (MDS / MPN)– **Go to question 61.**
- Hodgkin lymphoma – **Go to question 60.**
- Non-Hodgkin lymphoma – **Go to question 60.**
- Post-transplant lymphoproliferative disorder (PTLD)– **Go to question 60.**
- Clonal cytogenetic abnormality without leukemia or MDS – **Go to question 61.**
- Uncontrolled proliferation of donor cells without malignant transformation – **Go to question 61.**

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101. Was disease detected?

- Yes
- No

102. Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)

- Yes - **Go to question 103.**
- No - **Go to question 105.**
- Not applicable - **Go to question 105.**

103. Date assessed: _____

104. Was disease detected?

- Yes
- No

105. Was the disease status assessed by clinical/hematologic assessment?

- Yes - **Go to question 106.**
- No - **Go to question 108.**

106. Date assessed: _____

YYYY MM DD

107. 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.

108. 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 109.**
- No - **Go to question 113.**

109. Specify therapy: (check all that apply)

- Blinded randomized trial - **Go to question 113.**

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- Cellular therapy - **Go to question 113.**
- Radiation - **Go to question 113.**
- Systemic therapy - **Go to question 110.**
- Other therapy - **Go to question 112.**

110. 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
- 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 111.**

111. Specify other systemic therapy: _____

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