Post-Transplant Essential Data

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Registry Use Only

Sequence Number:

Date Received:

OMB No: 0915-0310

Expiration Date: 10/31/2022

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.

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

Visit:

☐ 100 day

☐ 6 months

☐ 1 year

☐ 2 years

☐ >2 years,

Specify: ___ ___

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

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.***
- ☐ Veno-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.***

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.***

☐ Veno-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.***

☐ Intracranial hemorrhage – ***Go to question 7.***

☐ Gastrointestinal hemorrhage – ***Go to question 7.***

☐ Hemorrhagic cystitis – ***Go to question 7.***

☐ Other hemorrhage – ***Go to question 6.***

Vascular

☐ Thromboembolic – ***Go to question 7.***

☐ Disseminated intravascular coagulation (DIC) – ***Go to question 7.***

☐ 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.***

☐ Persistent primary disease – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 11.***

☐ Recurrent primary disease – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 11.***

☐ Planned subsequent HCT, per protocol – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 11.***

☐ New malignancy (including PTLD and EBV lymphoma) – **Complete a Pre-TED Form 2400 for the subsequent HCT**– ***Go to question 11.***

☐ Insufficient chimerism – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 11.***

☐ Other – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 10.***

10. Specify other indication: _____

11. Source of HSCs (check all that apply):

☐ Allogeneic, related

☐ Allogeneic, unrelated

☐ Autologous

12. Has the recipient received a cellular therapy since the date of last report? (e.g. CAR-T, DCI)

☐ Yes – ***Go to question 13.*** – **Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000**

☐ No – ***Go to question 14.***

13. Date of cellular therapy: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Initial ANC Recovery

14. Was there evidence of initial hematopoietic recovery?

☐ Yes (ANC ≥ 500/mm^3 achieved and sustained for 3 lab values) – ***Go to question 15.***

☐ No (ANC ≥ 500/mm^3 was not achieved) – ***Go to question 16.***

☐ Not applicable (ANC never dropped below 500/mm^3 at any time after the start of the preparative regimen) – ***Go to question 16.***

☐ Previously reported (recipient's initial hematopoietic recovery was recorded on a previous report) – ***Go to question 16.***

15. Date ANC ≥ 500/mm^3 (first of 3 lab values): ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

16. Did late graft failure occur?

- ☐ Yes
- ☐ No

Initial Platelet Recovery

(Optional for Non-U.S. Centers)

17. Was an initial platelet count ≥ 20 x 10^9/L achieved?

- ☐ Yes – ***Go to question 18.***
- ☐ No – ***Go to question 19.***
- ☐ Not applicable - Platelet count never dropped below 20 x 10^9/L – ***Go to question 19.***
- ☐ Previously reported - ≥ 20 x 10^9/L was achieved and reported previously – ***Go to question 19.***

18. Date platelets ≥ 20 x 10^9/L: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Graft vs. Host Disease

This section is for allogeneic HCTs only. If this was an autologous HCT, 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 ≤ 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

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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 ≤ 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

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

42. Date of maximum grade of chronic GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

43. Is the recipient still taking systemic steroids? (Do not report steroids for adrenal insufficiency, or steroid dose ≤10 mg/day for adults, <0.1 mg/kg/day for children)

- ☐ Yes
- ☐ No
- ☐ Not applicable
- ☐ Unknown

44. Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?

- ☐ Yes
- ☐ No
- ☐ Not applicable
- ☐ Unknown

Liver Toxicity Prophylaxis

45. Was specific therapy used to prevent liver toxicity?

- ☐ Yes – ***Go to question 46.***
- ☒ No – ***Go to question 48.***

46. Specify therapy: (check all that apply)

- ☐ Defibrotide ***– Go to question 48.***
- ☐ N-acetylcysteine ***– Go to question 48.***
- ☐ Tissue plasminogen activator (TPA) ***– Go to question 48.***

☐ Urosodiol **– *Go to question 48.***

☐ Other – ***Go to question 47.***

47. Specify other therapy: _____

Veno-occlusive disease (VOD) / Sinusoidal obstruction syndrome (SOS)

Specify if the recipient developed VOD / SOS since the date of last report:

48. Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop since the date of last report?

☐ Yes – ***Go to question 49.***

☐ No – ***Go to question 50.***

49. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Infection

50. Did the recipient develop COVID-19 (SARS-CoV-2) since the date of last report?

☐ Yes

☐ No

51. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
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.

52. 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 53.***

☐ No – ***Go to question 60.***

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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

56. Date of diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

57. Was documentation submitted to the CIBMTR? (e.g. pathology / autopsy report or other documentation)

- ☐ Yes
- ☐ No

58. Was the new malignancy donor / cell product derived?

- ☐ Yes – ***Go to question 59.***
- ☐ No – ***Go to question 59.***
- ☐ Not done – ***Go to question 60.***

59. Was documentation submitted to the CIBMTR? (e.g. cell origin evaluation (VNTR, cytogenetics, FISH))

- ☐ Yes
- ☐ No

Chimerism Studies (Cord Blood Units, Beta Thalassemia, and Sickle Cell Disease Only)

This section relates to chimerism studies from allogeneic HCTs using cord blood units or for recipients whose primary disease is beta thalassemia or sickle cell disease. If this was an autologous HCT, or an allogeneic HCT using a bone marrow or PBSC product, or a different primary disease, continue to disease assessment.

60. Were chimerism studies performed since the date of last report?

- ☐ Yes – ***Go to question 61.***
- ☐ No – ***Go to question 80.***

61. Was documentation submitted to the CIBMTR? (e.g. chimerism laboratory reports)

- ☐ Yes
- ☐ No

62. Were chimerism studies assessed for more than one donor / multiple donors?

- ☐ Yes
- ☐ No

Provide date(s), method(s) and other information for all chimerism studies performed since the date of last report.

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

63. NMDP donor ID: ___ ___ ___ ___ — ___ ___ ___ ___ — ___

64. NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

65. Non-NMDP unrelated donor ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

66. Non-NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

67. Global Registration Identifiers for Donors (GRID): __

68. Date of birth: (donor / infant) ___ ___ ___ ___ — ___ ___ — ___ ___ **– OR –** Age: (donor/infant) ___ ___
YYYY MM DD
☐ Months
☐ Years

69. Sex (Donor / infant)
- ☐ Male
- ☐ Female

70. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

71. Method
- ☐ Karyotyping for XX/XY– ***Go to question 73.***
- ☐ Fluorescent in situ hybridization (FISH) for XX/XY – ***Go to question 73.***
- ☐ Restriction fragment-length polymorphisms (RFLP) – ***Go to question 73.***
- ☐ VNTR or STR, micro or mini satellite (also include AFLP) – ***Go to question 73.***
- ☐ Other – ***Go to question 72.***

72. Specify: _____

73. Cell source
- ☐ Bone marrow
- ☐ Peripheral blood

74. Cell type
- ☐ Unsorted / whole – ***Go to question 76.***
- ☐ Red blood cells – ***Go to question 78.***
- ☐ Hematopoietic progenitor cells (CD34+ cells) – ***Go to question 78.***

- ☐ 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?

☐ Yes - ***Go to question 103.***

☐ No - ***Go to question 83.***

83. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Specify the method(s) used to assess the disease status at the time of best response:

84. Was the disease status assessed by molecular testing (e.g. PCR)?

☐ Yes - ***Go to questions 85.***

☐ No - ***Go to question 87.***

☐ Not applicable - ***Go to question 87.***

85. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

86. Was disease detected?

☐ Yes

☐ No

87. Was the disease status assessed via flow cytometry?

☐ Yes - ***Go to question 88.***

☐ No - ***Go to question 90.***

☐ Not applicable - ***Go to question 90.***

88. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

89. Was disease detected?

☐ Yes

☐ No

90. Was the disease status assessed by cytogenetic testing (karyotyping or FISH)?

☐ Yes - ***Go to question 91.***

☐ No - ***Go to question 97.***

☐ Not applicable - ***Go to question 97.***

91. Was the disease status assessed via FISH?

☐ 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.***

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

- ☐ 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)**

☐ No - ***Go to question 110.***

110. Date first seen: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Intervention for relapsed disease, persistent disease, or progressive disease

111. Was intervention given for relapsed, persistent or progressive disease since the date of last report?

☐ Yes - ***Go to question 112.***

☐ No - ***Go to question 119.***

112. Specify reason for which intervention was given:

☐ Persistent disease

☐ Relapsed / progressive disease

113. Specify the method(s) of detection for which intervention was given: (check all that apply)

☐ Clinical/hematologic

☐ Cytogenetic

☐ Disease specific molecular marker

☐ Flow cytometry

☐ Radiological (e.g. PET, MRI, CT)

114. Date intervention started: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

115. Specify therapy: (check all that apply)

☐ Blinded randomized trial - ***Go to question 119.***

☐ Cellular therapy - ***Go to question 119.***

☐ Radiation - ***Go to question 119.***

☐ Systemic therapy - ***Go to question 116.***

☐ Other therapy - ***Go to question 118.***

116. 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 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.***

☐ Not in complete remission - ***Go to question 120.***

☐ Not evaluated - ***Go to First Name***

120. Specify disease status if not in complete remission:

☐ Disease detected

☐ No disease detected but incomplete evaluation to establish CR

121. Date of most recent disease assessment

☐ Known – ***Go to question 122.***

☐ Unknown – ***Go to First Name***

122. Date of most recent disease assessment: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

First Name: _____

Last Name: _____

E-mail address: _____

Date: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD