



Post-Transplant Essential Data

Registry Use Only

Sequence Number: _____

Date Received: _____

OMB No: 0915-0310

Expiration Date: 10/31/2022

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CIBMTR Center Number: _____

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*

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: _____

Initial Platelet Recovery**(Optional for Non-U.S. Centers)**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 \longrightarrow
- No
- Unknown

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 cannot be graded)

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
- No

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:

— / — / —
 YYYY MM DD

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
- No

36. Specify other site(s): _____

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

- Yes
- No
- Unknown

38. Date of chronic GVHD diagnosis: __ __ / __ __ / __ __ Date estimated
 YYYY MM DD - Go to question 40

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

- Yes
- No
- Unknown

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 →
- No

46. Specify therapy (check all that apply)

- Defibrotide
- N-acetylcysteine
- Tissue plasminogen activator (TPA)
- Ursodiol
- Other therapy →

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 →
- No

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

Copy and complete questions 50 - 51 to report more than one infection.

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 →
- No

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 →
 No →
 Not done

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 →
 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.

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) ____ Months Years
 YYYY MM DD69. Sex (Donor / infant) Male Female70. Date sample collected: ____ / ____ / ____
 YYYY MM DD

71. Method

- Karyotyping for XX/XY
- Fluorescent in situ hybridization (FISH) for XX/XY
- Restriction fragment-length polymorphisms (RFLP)
- VNTR or STR, micro or mini satellite (Also include AFLP)
- Other _____

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 _____

75. Specify: _____

76. Total cells examined: _____

77. Number of donor cells: _____ - **Go to question 78**

78. Were donor cells detected?

- Yes _____
- No

79. Percent donor cells: _____ %

Copy and complete questions 63 - 79 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 101**
- No →

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 →
- No
- Not applicable

85. Date assessed:

____/____/____
YYYY MM DD

86. Was disease detected? Yes No

87. Was the disease status assessed via flow cytometry?

- Yes →
- No
- Not applicable

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 →
- No
- Not applicable

91. Was the disease status assessed via FISH?

- Yes →
- No
- Not applicable

92. Date assessed:

____/____/____
YYYY MM DD

93. Was disease detected?

- Yes No

94. Was the disease status assessed via karyotyping?

- Yes →
- No
- Not applicable

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 →
- No
- Not applicable

98. Date assessed:

— / — / —

YYYY MM DD

99. Was disease detected? Yes No

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

- Yes →
- No

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 →
- No

104. Systemic 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

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

115. Systemic therapy (check all that apply)

- Systemic therapy - **Go to question 116**
- Radiation - **Go to question 119**
- Cellular therapy - **Go to question 119**
- Blinded randomized trial - **Go to question 119**
- 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, Tasisign)
- Nivolumab
- Pembrolizumab
- Pomalidomide
- Quizartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Other systemic therapy →

117. Specify other systemic therapy:

118. Specify other therapy: _____

