



Post-Transplant Essential Data

Registry Use Only

OMB No: 0915-0310
Expiration Date: 08/31/2025

Sequence Number:

Public Burden Statement: The purpose of this data collection system is to provide technical assistance and share expertise with health care organizations, health care providers and health care networks interested in implementing telehealth technology. The resource centers serve as focal points for advancing the effective use of telehealth technologies in their respective communities and regions. 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 08/31/2025. Public reporting burden for this collection of information is estimated to average 0.51 hours per response, 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.

Date Received:

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: _____

Report all findings SINCE DATE OF LAST REPORT unless otherwise specified.

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.**
- Dead - **Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete the Recipient Death Data Form 2900**

Subsequent Infusion

3. Did the recipient receive a subsequent infusion?

- Yes – **Also complete Indication for CIBMTR Data Reporting Form 2814**
- No

Initial ANC Recovery

4. Was there evidence of initial hematopoietic recovery?

- Yes (*ANC $\geq 500/mm^3$ achieved and sustained for 3 lab values*) – **Go to question 5**
- No (*ANC $\geq 500/mm^3$ was not achieved*) – **Go to question 6**
- Not applicable (*ANC never dropped below $500/mm^3$ at any time after the start of the preparative regimen*) – **Go to question 6**
- Previously reported (*recipient's initial hematopoietic recovery was recorded on a previous report*) – **Go to question 6**

5. Date ANC $\geq 500/mm^3$ (*first of 3 lab values*): _____
YYYY MM DD

6. Did late graft failure occur?

- Yes
- No

Initial Platelet Recovery

(Optional for Non-U.S. Centers)

7. Was an initial platelet count $\geq 20 \times 10^9/L$ achieved?
- Yes – **Go to question 8**
 - No – **Go to question 9**
 - Not applicable (*Platelet count never dropped below $20 \times 10^9/L$*) – **Go to question 9**
 - Previously reported (*$\geq 20 \times 10^9/L$ was achieved and reported previously*) – **Go to question 9**
8. 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 infusion, report all graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue to Liver Toxicity Prophylaxis, question 35.

9. Did acute GVHD develop?
- Yes– **Go to question 10**
 - No – **Go to question 11**
 - Unknown – **Go to question 11**
10. Date of acute GVHD diagnosis: _____ - **Go to question 12**
- YYYY MM DD
11. Did acute GVHD persist?
- Yes– **Go to question 19**
 - No – **Go to question 27**
 - Unknown – **Go to question 27**
12. 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*

CIBMTR Center Number: _____

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- IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL, and/or grossly bloody stool*
- Not applicable (*acute GVHD present but cannot be graded*)

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

13. 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*

14. 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*

15. Upper intestinal tract

- Stage 0 – *No persistent nausea or vomiting*
- Stage 1 – *Persistent nausea or vomiting*

16. 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)*

17. Other site(s) involved with acute GVHD

- Yes – **Go to question 18**
- No – **Go to question 19**

18. Specify other site(s): _____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

- *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*

33. 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
34. Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
- Yes
 - No
 - Not applicable
 - Unknown

Liver Toxicity Prophylaxis

35. Was specific therapy used to prevent liver toxicity?
- Yes – **Go to question 36**
 - No – **Go to question 38**
36. Specify therapy (*check all that apply*)
- Defibrotide – **Go to question 38**
 - Enoxaparin (Lovenox) – **Go to question 38**
 - Heparin – **Go to question 38**
 - N-acetylcysteine – **Go to question 38**
 - Tissue plasminogen activator (TPA) – **Go to question 38**
 - Ursodiol – **Go to question 38**
 - Other – **Go to question 37**
37. Specify other therapy: _____

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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

Specify if the recipient developed VOD / SOS

38. Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop?

- Yes – **Go to question 39**
- No – **Go to question 40**

39. Date of diagnosis: _____ - _____ - _____
 YYYY MM DD

Infection

Copy and complete questions 40 – 41 to report more than one infection.

40. Did the recipient develop COVID-19 (SARS-CoV-2)?

- Yes – **Go to question 41**
- No – **Go to question 42**

41. Date of diagnosis: _____ - _____ - _____
 YYYY MM DD

42. Was a vaccine for COVID-19 (SARS-CoV-2) received?

- Yes – **Go to question 43**
- No – **Go to question 47**
- Unknown – **Go to question 47**

Copy and complete questions 43-46 to report all vaccine doses received.

43. Specify vaccine brand

- AstraZeneca – **Go to question 45**
- Johnson & Johnson's / Janssen – **Go to question 45**
- Moderna – **Go to question 45**
- Novavax – **Go to question 45**
- Pfizer-BioNTECH – **Go to question 45**
- Other type – **Go to question 44**

44. Specify other type: _____

45. Select dose(s) received

CIBMTR Center Number: _____ CIBMTR Research ID: _____

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

46. Date received: _____ Date estimated
 YYYY MM DD

Copy and complete questions 43-46 to report all vaccine doses received.

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

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

47. Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the infusion was performed? (*include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders*)
- Yes - **Also complete Subsequent Neoplasms Form 3500**
 - No
 - Previously reported

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

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

48. Were chimerism studies performed?
- Yes – **Go to question 49**
 - No – **Go to question 66**
49. Was documentation submitted to the CIBMTR? (*e.g. chimerism laboratory reports*) (CIBMTR recommends attaching the chimerism laboratory report)
- Yes
 - No

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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- Yes
- No

Provide date(s), method(s) and other information for all chimerism studies performed.

Copy and complete questions 51–65 for multiple chimerism studies.

51. Global Registration Identifiers for Donors (GRID): _____

52. NMDP cord blood unit ID: _____

53. Registry donor ID: _____

54. Non-NMDP cord blood unit ID: _____

55. Donor date of birth: _____ **-OR-** Donor age: _____

YYYY MM DD

- Months
- Years

56. Donor sex

- Male
- Female

57. Date sample collected: _____

YYYY MM DD

58. Method

- Karyotyping for XX/XY – **Go to question 60**
- Fluorescent in situ hybridization (FISH) for XX/XY – **Go to question 60**
- Restriction fragment-length polymorphisms (RFLP) – **Go to question 60**
- VNTR or STR, micro or mini satellite (*also include AFLP*) – **Go to question 60**
- Single nucleotide polymorphisms (SNPs) (*includes quantitative PCR, real-time PCR, sequencing, other*) – **Go to question 60**
- Other – **Go to question 59**

59. Specify: _____

60. Cell source

- Bone marrow

CIBMTR Center Number: _____ CIBMTR Research ID: _____

Peripheral blood

61. Cell type

Unsorted / whole – **Go to question 63**

Red blood cells – **Go to question 65**

Hematopoietic progenitor cells (e.g. CD34+ cells) – **Go to question 65**

Total mononuclear cells (e.g. lymphocytes & monocytes) – **Go to question 65**

T-cells (includes CD3+, CD4+, and/or CD8+) – **Go to question 65**

B-cells (includes CD19+ or CD20+) – **Go to question 65**

Granulocytes (includes CD33+ myeloid cells) – **Go to question 65**

NK cells (e.g. CD56+) – **Go to question 65**

Other – **Go to question 62**

62. Specify: _____

63. Total cells examined: _____

64. Number of donor cells: _____ - **Go to question 66**

65. Percent donor cells: _____ %

Copy and complete questions 51–65 for multiple chimerism studies.

Disease Assessment at the Time of Best Response to Infusion

66. Compared to the disease status prior to the preparative regimen, what was the best response to infusion?
(Include response to any therapy given for post-infusion 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 89**

Complete remission (CR) - **Go to question 68**

Not in complete remission - **Go to question 67**

Not evaluated - **Go to question 89**

67. Specify disease status if not in complete remission:

Disease detected - **Go to question 70**

No disease detected but incomplete evaluation to establish CR - **Go to question 70**

68. Was the date of best response previously reported?

CIBMTR Center Number: _____ CIBMTR Research ID: _____

Yes - **Go to question 89**

No - **Go to question 69**

69. Date assessed: _____
 YYYY MM DD

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

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

Yes - **Go to questions 71**

No - **Go to question 73**

Not applicable - **Go to question 73**

71. Date assessed: _____
 YYYY MM DD

72. Was disease detected?

Yes

No

73. Was the disease status assessed via flow cytometry?

Yes - **Go to question 74**

No - **Go to question 76**

Not applicable - **Go to question 76**

74. Date assessed: _____
 YYYY MM DD

75. Was disease detected?

Yes

No

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

Yes - **Go to question 77**

No - **Go to question 83**

Not applicable - **Go to question 83**

77. Was the disease status assessed via FISH?

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- Yes - **Go to questions 78**
- No - **Go to question 80**
- Not applicable - **Go to question 80**

78. Date assessed: _____

YYYY MM DD

79. Was disease detected?
- Yes
 - No

80. Was the disease status assessed via karyotyping?
- Yes - **Go to question 81**
 - No - **Go to question 83**
 - Not applicable - **Go to question 83**

81. Date assessed: _____

YYYY MM DD

82. Was disease detected?
- Yes
 - No

83. Was the disease status assessed by radiological assessment? (*e.g. PET, MRI, CT*)
- Yes - **Go to question 84**
 - No - **Go to question 86**
 - Not applicable - **Go to question 86**

84. Date assessed: _____

YYYY MM DD

85. Was disease detected?
- Yes
 - No

86. Was the disease status assessed by clinical/hematologic assessment?
- Yes - **Go to question 87**
 - No - **Go to question 89**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

87. Date assessed: _____
 YYYY MM DD

88. Was disease detected?
- Yes
 - No

Post-Infusion Therapy

In questions 89-93, report therapy given 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.

89. Was therapy given for reasons other than relapsed, persistent, or progressive disease? *(Include any maintenance and consolidation therapy.)*

- Yes - **Go to question 90**
- No - **Go to question 94**

90. Specify therapy *(check all that apply)*

- Blinded randomized trial - **Go to question 98**
- Cellular therapy - **Go to question 98**
- Radiation - **Go to question 98**
- Systemic therapy - **Go to question 91**
- Other therapy - **Go to question 93**

91. Specify systemic therapy *(check all that apply)*

- Alemtuzumab (Campath) - **Go to question 93**
- Azacytidine (Vidaza) - **Go to question 93**
- Blinatumomab - **Go to question 93**
- Bortezomib (Velcade) - **Go to question 93**
- Bosutinib - **Go to question 93**
- Brentuximab vendotin - **Go to question 93**
- Carfilzomib - **Go to question 93**
- Daratumumab (Darzalex) - **Go to question 93**
- Dasatinib (Sprycel) - **Go to question 93**
- Decitabine (Dacogen) - **Go to question 93**
- Gemtuzumab (Mylotarg, anti-CD33) - **Go to question 93**

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- Gilteritinib - **Go to question 93**
- Ibrutinib - **Go to question 93**
- Imatinib mesylate (Gleevec) - **Go to question 93**
- Ixazomib - **Go to question 93**
- Lenalidomide (Revlimid) - **Go to question 93**
- Lestaurtinib - **Go to question 93**
- Midostaurin - **Go to question 93**
- Nilotinib (AMN107, Tasigna) - **Go to question 93**
- Nivolumab - **Go to question 93**
- Pembrolizumab - **Go to question 93**
- Pomalidomide - **Go to question 93**
- Quizartinib - **Go to question 93**
- Rituximab (Rituxan, MabThera) - **Go to question 93**
- Sorafenib - **Go to question 93**
- Sunitinib - **Go to question 93**
- Thalidomide (Thalomid) - **Go to question 93**
- Other systemic therapy- **Go to question 92**

92. Specify other systemic therapy: _____

93. Specify other therapy: _____

94. Did a fecal microbiota transplant (FMT) occur?

- Yes – **Go to question 95**
- No – **Go to question 98**

95. Date of FMT: _____
 YYYY MM DD

96. Specify the indication for the FMT

- Graft versus host disease (GVHD) – **Go to question 98**
- Clostridium difficile – **Go to question 98**
- Other – **Go to question 97**

97. Specify other indication: _____

Relapse or Progression Post-Infusion

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

98. Did the recipient experience a clinical/hematologic relapse or progression post-infusion?

- Yes - **Go to question 99**
- No - **Go to question 101**

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

- Yes - **Go to question 109** (only valid >day 100)
- No - **Go to question 100**

100. Date first seen: _____

YYYY MM DD

Intervention for relapsed disease, persistent disease, or progressive disease

101. Was intervention given for relapsed, persistent or progressive disease?

- Yes - **Go to question 102**
- No - **Go to question 109**

102. Specify reason for which intervention was given

- Persistent disease
- Relapsed / progressive disease

103. 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)

104. Date intervention started: _____

YYYY MM DD

105. Specify therapy (*check all that apply*)

- Blinded randomized trial - **Go to question 109**
- Cellular therapy - **Go to question 109**
- Radiation - **Go to question 109**
- Systemic therapy - **Go to question 106**
- Other therapy - **Go to question 108**

106. Specify systemic therapy (*check all that apply*)

- Alemtuzumab (Campath) - **Go to question 108**
- Azacytidine (Vidaza) - **Go to question 108**
- Blinatumomab - **Go to question 108**
- Bortezomib (Velcade) - **Go to question 108**
- Bosutinib - **Go to question 108**
- Carfilzomib - **Go to question 108**
- Chemotherapy - **Go to question 108**
- Daratumumab (Darzalex) - **Go to question 108**
- Dasatinib (Sprycel) - **Go to question 108**
- Decitabine (Dacogen) - **Go to question 108**
- Gemtuzumab (Mylotarg, anti-CD33) - **Go to question 108**
- Gilteritinib - **Go to question 108**
- Ibrutinib - **Go to question 108**
- Imatinib mesylate (Gleevec) - **Go to question 108**
- Ixazomib - **Go to question 108**
- Lenalidomide (Revlimid) - **Go to question 108**
- Lestaurtinib - **Go to question 108**
- Midostaurin - **Go to question 108**
- Nilotinib (AMN107, Tasigna) - **Go to question 108**
- Nivolumab - **Go to question 108**
- Pembrolizumab - **Go to question 108**
- Pomalidomide - **Go to question 108**
- Quizartinib - **Go to question 108**
- Rituximab (Rituxan, MabThera) - **Go to question 108**
- Sorafenib - **Go to question 108**
- Sunitinib - **Go to question 108**
- Thalidomide (Thalomid) - **Go to question 108**

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- Venetoclax - **Go to question 108**
- Other systemic therapy- **Go to question 107**

107. Specify other systemic therapy: _____

108. Specify other therapy: _____

Current Disease Status

109. What is the current disease status?

- Complete remission (CR) - **Go to question 111**
- Not in complete remission - **Go to question 110**
- Not evaluated – **End of form**

110. Specify disease status if not in complete remission

- Disease detected
- No disease detected but incomplete evaluation to establish CR

111. Date of assessment of current disease status: _____

YYYY MM DD