Post-Transplant Essential Data

Registry Use Only

Sequence Number:

Date Received:

OMB No: 0915-0310
Expiration Date:

Public Burden Statement: 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 project is 0915-0310. Public reporting burden for this collection of information is estimated to average 1.25 hours per response when collected at 100 days post-transplant, 1.15 hours per response when collected at 6 and 12 months post-transplant, and 1.15 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 10-33, Rockville, Maryland, 20857.

CIBMTR Center Number: ___ ___ ___ ___ ___

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

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

YYYY MM DD

HCT type: (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Product type: (check all that apply)

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Multiple cord blood units
- ☐ Other product

  Specify: _____

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: ___ ___ ___ ___ — ___ ___ — ___ ___

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***

☐ Adult 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

- ☐ 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***

☐ 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***

☐ Adult 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:_____

If reporting more than one contributing cause of death, copy questions 5-6 and complete for each contributing cause.

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 second 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: _____

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

11. Source of HSCs:

- ☐ Allogeneic, related - **Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT**
- ☐ Allogeneic, unrelated – **Complete a Pre-TED Form 2400 for the subsequent HCT**
- ☐ Autologous

12. Has the recipient received a cellular therapy since the date of last report? (e.g. 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: ___ ___ ___ ___ - ___ ___ - ___ ___

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***

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

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.

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 31***
- ☐ Unknown – ***Go to question 31***

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
- ☐ 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/m^2/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 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
- ☐ 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. Did chronic GVHD develop since the date of last report?

☐ Yes – ***Go to questions 32***

☐ No - ***Go to question 33***

☐ Unknown – ***Go to question 33***

32. Date of chronic GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated – ***Go to questions 34***

YYYY MM DD

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

☐ Yes – ***Go to questions 34***

☐ No - ***Go to question 37***

☐ Unknown – ***Go to question 37***

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

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

☐ Mild

☐ Moderate

☐ Severe

☐ Unknown

35. 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

36. Date of maximum grade of chronic GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

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

☐ Yes

☐ No

☐ Not applicable

☐ Unknown

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

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

Liver Toxicity Prophylaxis

39. Was specific therapy used to prevent liver toxicity?

- ☐ Yes – ***Go to question 40***
- ☐ No – ***Go to question 46***

40. Defibrotide

- ☐ Yes
- ☐ No

41. N-acetylcysteine

- ☐ Yes
- ☐ No

42. Tissue plasminogen activator (TPA)

- ☐ Yes
- ☐ No

43. Ursodiol

- ☐ Yes
- ☐ No

44. Other therapy

- ☐ Yes – ***Go to question 45***
- ☐ No – ***Go to question 46***

45. Specify other therapy: _____

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

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

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

☐ Yes – ***Go to question 47***

☐ No – ***Go to question 48***

47. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___ ***- Go to question 49***

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

☐ Yes

☐ No

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.

49. 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 50***

☐ No – ***Go to question 57***

Copy and complete questions 50-56 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.

50. Specify the new malignancy:

☐ Acute myeloid leukemia (AML / ANLL) – ***Go to question 53***

☐ Other leukemia – ***Go to question 53***

☐ Myelodysplastic syndrome (MDS) – ***Go to question 53***

☐ Myeloproliferative neoplasm (MPN) – ***Go to question 53***

☐ Myelodysplasia / myeloproliferative neoplasm (MDS / MPN)– ***Go to question 53***

☐ Hodgkin lymphoma – ***Go to question 52***

☐ Non-Hodgkin lymphoma – ***Go to question 52***

☐ Post-transplant lymphoproliferative disorder (PTLD)– ***Go to question 52***

☐ Clonal cytogenetic abnormality without leukemia or MDS – ***Go to question 53***

☐ Uncontrolled proliferation of donor cells without malignant transformation – ***Go to question 53***

☐ Breast cancer – ***Go to question 53***

☐ Central nervous system (CNS) malignancy (e.g. glioblastoma, astrocytoma) – ***Go to question 53***

☐ Gastrointestinal malignancy (e.g. colon, rectum, stomach, pancreas, intestine) – ***Go to question 53***

☐ Genitourinary malignancy (e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix) – ***Go to question 53***

☐ Lung cancer – ***Go to question 53***

☐ Melanoma – ***Go to question 53***

☐ Basal cell skin malignancy – ***Go to question 53***

☐ Squamous cell skin malignancy – ***Go to question 53***

☐ Oropharyngeal cancer (e.g. tongue, buccal mucosa) – ***Go to question 53***

☐ Sarcoma – ***Go to question 53***

☐ Thyroid cancer – ***Go to question 53***

☐ Other new malignancy – ***Go to question 51***

51. Specify other new malignancy: _____ - ***Go to question 53***

52. Is the tumor EBV positive?

☐ Yes

☐ No

53. Date of diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

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

☐ Yes

☐ No

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

☐ Yes ***– Go to question 56***

☐ No ***– Go to question 57***

☐ Not done ***– Go to question 57***

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

☐ Yes

☐ No

Chimerism Studies (Cord Blood Units Only)

This section relates to chimerism studies from allogeneic HCTs using cord blood units only. If this was an autologous HCT, or an allogeneic HCT using a bone marrow or PBSC product, continue to disease assessment.

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

☐ Yes – ***Go to question 58***

☐ No – ***Go to question 76***

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

☐ Yes

☐ No

59. 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.

60. NMDP donor ID: ___ ___ ___ ___ — ___ ___ ___ ___ — ___

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

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

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

64. Date of birth: (donor / infant) ___ ___ ___ ___ — ___ ___ — ___ ___ **– OR –** Age: (donor/infant) ___ ___

YYYY MM DD

☐ Months

☐ Years

65. Sex (Donor / infant)

☐ Male

☐ Female

66. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

67. Method

☐ Karyotyping for XX/XY– ***Go to question 69***

☐ Fluorescent in situ hybridization (FISH) for XX/XY – ***Go to question 69***

☐ Restriction fragment-length polymorphisms (RFLP) – ***Go to question 69***

☐ VNTR or STR, micro or mini satellite (also include AFLP) – ***Go to question 69***

☐ Other – ***Go to question 68***

68. Specify: _____

69. Cell source

- ☐ Bone marrow
- ☐ Peripheral blood

70. Cell type

- ☐ Unsorted / whole – ***Go to question 72***
- ☐ Red blood cells – ***Go to question 74***
- ☐ Hematopoietic progenitor cells (CD34+ cells) – ***Go to question 74***
- ☐ Total mononuclear cells (lymphs & monos) – ***Go to question 74***
- ☐ T-cells (includes CD3+, CD4+, and/or CD8+) – ***Go to question 74***
- ☐ B-cells (includes CD19+ or CD20+) – ***Go to question 74***
- ☐ Granulocytes (includes CD33+ myeloid cells) – ***Go to question 74***
- ☐ NK cells (CD56+) – ***Go to question 74***
- ☐ Other – ***Go to question 71***

71. Specify: _____

72. Total cells examined: ___ ___ ___ ___ ___ ___

73. Number of donor cells: ___ ___ ___ ___***- Go to question 76***

74. Were donor cells detected?

- ☐ Yes - ***Go to question 75***
- ☐ No – ***Go to question 76***

75. Percent donor cells: ___ ___ ___ %

Copy questions 60 – 75 if needed for multiple chimerism studies.

Disease Assessment at the Time of Best Response to HCT

76. 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) - ***Go to question 78***
- ☐ Complete remission (CR) - ***Go to question 78***
- ☐ Not in complete remission - ***Go to question 77***
- ☐ Not evaluated - ***Go to question 99***

77. Specify disease status if not in complete remission:

☐ Disease detected - Go to question 80

☐ No disease detected but incomplete evaluation to establish CR - Go to question 80

78. Was the date of best response previously reported?

☐ Yes - ***Go to question 99***

☐ No - ***Go to question 79***

79. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

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

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

☐ Yes - ***Go to questions 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 via flow cytometry?

☐ 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 cytogenetic testing (karyotyping or FISH)?

☐ Yes - ***Go to question 87***

☐ No - ***Go to question 93***

☐ Not applicable - ***Go to question 93***

87. Was the disease status assessed via FISH?

☐ Yes - ***Go to questions 81***

☐ No - ***Go to question 83***

☐ Not applicable - ***Go to question 83***

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

89. Was disease detected?

☐ Yes

☐ No

90. Was the disease status assessed via karyotyping?

☐ Yes - ***Go to question 91***

☐ No - ***Go to question 93***

☐ Not applicable - ***Go to question 93***

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

92. Was disease detected?

☐ Yes

☐ No

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

☐ Yes - ***Go to question 94***

☐ No - ***Go to question 96***

☐ Not applicable - ***Go to question 96***

94. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___

95. Was disease detected?

☐ Yes

☐ No

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

☐ Yes - ***Go to question 97***

☐ No - ***Go to question 99***

97. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___

98. 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.

99. 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 100***

☐ No - ***Go to question 162***

100. Systemic therapy

☐ Yes ***– Go to question 101***

☐ No ***– Go to question 156***

101. Monoclonal antibody (mAb)

☐ Yes - ***Go to question 102***

☐ No - ***Go to question 111***

102. Alemtuzumab (Campath)

☐ Yes

☐ No

103. Bispecific mAb

☐ Yes – ***Go to question 104***

☐ No – ***Go to question 107***

104. Blinatumomab

☐ Yes

☐ No

105. Other bispecific mAb

☐ Yes

☐ No

106. Specify other bispecific mAb: _____

107. Gemtuzumab (Mylotarg, anti-CD33)

☐ Yes

☐ No

108. Rituximab (Rituxan, MabThera)

☐ Yes

☐ No

109. Other mAb

☐ Yes

☐ No

110. Specify other mAb:_____

111. Tyrosine kinase inhibitors (TKI)

☐ Yes ***– Go to question 112***

☐ No ***– Go to question 118***

112. Bosutinib

☐ Yes

☐ No

113. Dasatinib (Sprycel)

☐ Yes

☐ No

114. Imatinib mesylate (Gleevec)

☐ Yes

☐ No

115. Nilotinib (AMN107, Tasignal)

☐ Yes

☐ No

116. Other TKI

☐ Yes ***– Go to question 117***

☐ No***– Go to question 118***

117. Specify other TKI:_____

118. FLT3 inhibitors

☐ Yes **– *Go to question 119***

☐ No **– *Go to question 127***

119. Gilteritinib

☐ Yes

☐ No

120. Lestaurtinib

☐ Yes

☐ No

121. Midostaurin

☐ Yes

☐ No

122. Quizartinib

☐ Yes

☐ No

123. Sorafenib

☐ Yes

☐ No

124. Sunitinib

☐ Yes

☐ No

125. Other FLT3 inhibitor

☐ Yes **– *Go to question 126***

☐ No**– *Go to question 127***

126. Specify other FLT3 inhibitor:_____

127. Hypomethylating agents

☐ Yes **– *Go to question 128***

☐ No **– *Go to question 132***

128. Azacytidine (Vidaza)

☐ Yes

☐ No

129. Decitabine (Dacogen)

☐ Yes

☐ No

130. Other hypomethylating agent

☐ Yes ***– Go to question 131***

☐ No***– Go to question 132***

131. Specify other hypomethylating agent:_____

132. Proteasome inhibitors

☐ Yes ***– Go to question 133***

☐ No ***– Go to question 138***

133. Bortezomib (Velcade)

☐ Yes

☐ No

134. Carfilzomib

☐ Yes

☐ No

135. Ixazomib

☐ Yes

☐ No

136. Other proteasome inhibitor

☐ Yes ***– Go to question 137***

☐ No ***– Go to question 138***

137. Specify other proteasome inhibitor:_____

138. Immune modulating agents

☐ Yes ***– Go to question 139***

☐ No ***– Go to question 144***

139. Lenalidomide (Revlimid)

☐ Yes

☐ No

140. Pomalidomide

☐ Yes

☐ No

141. Thalidomide (Thalomid)

☐ Yes

☐ No

142. Other immune modulating agent

☐ Yes ***– Go to question 143***

☐ No ***– Go to question 144***

143. Specify other immune modulating agent: _____

144. PD1 inhibitor

☐ Yes ***– Go to question 145***

☐ No ***– Go to question 149***

145. Nivolumab

☐ Yes

☐ No

146. Pembrolizumab

☐ Yes

☐ No

147. Other PD1 inhibitor

☐ Yes ***– Go to question 148***

☐ No ***– Go to question 149***

148. Specify other PD1 inhibitor: _____

149. BTK inhibitors

☐ Yes ***– Go to question 150***

☐ No ***– Go to question 153***

150. Ibrutinib

☐ Yes

☐ No

151. Other BTK inhibitor

☐ Yes ***– Go to question 152***

☐ No ***– Go to question 153***

152. Specify other BTK inhibitor:_____

153. Chemotherapy

☐ Yes – ***Go to question 154***

☐ No – ***Go to question 155***

154. Specify chemotherapy drugs: _____

155. Other systemic therapy

☐ Yes ***– Go to question 156***

☐ No ***– Go to question 157***

156. Specify other systemic therapy**:** _____

157. Radiation

☐ Yes

☐ No

158. Cellular therapy

☐ Yes

☐ No

159. Blinded randomized trial

☐ Yes

☐ No

160. Other therapy

☐ Yes – ***Go to question 161***

☐ No – ***Go to question 162***

161. Specify other therapy***:*** _____

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

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.

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

- ☐ Yes - ***Go to question 163***
- ☐ No - ***Go to question 165***

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

- ☐ Yes - ***Go to question 165*** **(only valid >day 100)**
- ☐ No - ***Go to question 164***

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

Intervention for relapsed disease, persistent disease, progressive disease, or decreased/loss of chimerism

165. Was intervention given for relapsed, persistent or progressive disease, or decreased/loss of chimerism since the date of last report?

- ☐ Yes - ***Go to question 166***
- ☐ No - ***Go to question 236***

166. Specify reason for which intervention was given:

- ☐ Persistent disease
- ☐ Relapsed / progressive disease
- ☐ Decrease / loss of chimerism

Specify the method(s) of detection for which intervention was given:

167. Clinical/hematologic

- ☐ Yes
- ☐ No

168. Radiological (e.g. PET, MRI, CT)

- ☐ Yes
- ☐ No

169. Cytogenetic

☐ Yes

☐ No

170. Flow cytometry

☐ Yes

☐ No

171. Disease specific molecular marker

☐ Yes

☐ No

172. Chimerism testing

☐ Yes

☐ No

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

Specify intervention(s):

174. Systemic therapy

☐ Yes ***– Go to question 175***

☐ No ***– Go to question 231***

175. Monoclonal antibody (mAb)

☐ Yes ***– Go to question 176***

☐ No ***– Go to question 185***

176. Alemtuzumab (Campath)

☐ Yes

☐ No

177. Bispecific mAb

☐ Yes – ***Go to question 178***

☐ No – ***Go to question 181***

178. Blinatumomab

☐ Yes

☐ No

179. Other bispecific mAb

☐ Yes

☐ No

180. Specify other bispecific mAb:_____

181. Gemtuzumab (Mylotarg, anti-CD33)

☐ Yes

☐ No

182. Rituximab (Rituxan, MabThera)

☐ Yes

☐ No

183. Other mAb

☐ Yes ***– Go to question 184***

☐ No ***– Go to question 185***

184. Specify other mAb:_____

185. Tyrosine kinase inhibitors (TKI)

☐ Yes ***– Go to question 186***

☐ No ***– Go to question 192***

186. Bosutinib

☐ Yes

☐ No

187. Dasatinib (Sprycel)

☐ Yes

☐ No

188. Imatinib mesylate (Gleevec)

☐ Yes

☐ No

189. Nilotinib (AMN107, Tasignal)

☐ Yes

☐ No

190. Other TKI

☐ Yes **– *Go to question 191***

☐ No **– *Go to question 192***

191. Specify other TKI:_____

192. FLT3 inhibitors

☐ Yes **– *Go to question 193***

☐ No **– *Go to question 201***

193. Gilteritinib

☐ Yes

☐ No

194. Lestaurtinib

☐ Yes

☐ No

195. Midostaurin

☐ Yes

☐ No

196. Quizartinib

☐ Yes

☐ No

197. Sorafinib

☐ Yes

☐ No

198. Sunitinib

☐ Yes

☐ No

199. Other FLT3 inhibitor

☐ Yes **– *Go to question 200***

☐ No **– *Go to question 201***

200. Specify other FLT3 inhibitor:_____

201. Hypomethylating agents

☐ Yes **– *Go to question 202***

☐ No **– *Go to question 206***

202. Azacytidine (Vidaza)

☐ Yes

☐ No

203. Decitabine (Dacogen)

☐ Yes

☐ No

204. Other hypomethylating agent

☐ Yes **– *Go to question 205***

☐ No **– *Go to question 206***

205. Specify other hypomethylating agent:_____

206. Proteasome inhibitors

☐ Yes **– *Go to question 207***

☐ No **– *Go to question 212***

207. Bortezomib (Velcade)

☐ Yes

☐ No

208. Carfilzomib

☐ Yes

☐ No

209. Ixazomib

☐ Yes

☐ No

210. Other proteasome inhibitor

☐ Yes **– *Go to question 211***

☐ No **– *Go to question 212***

211. Specify other proteasome inhibitor:_____

212. Immune modulating agents

☐ Yes **– *Go to question 213***

☐ No **– *Go to question 218***

213. Lenalidomide (Revlimid)

☐ Yes

☐ No

214. Pomalidomide

☐ Yes

☐ No

215. Thalidomide (Thalomid)

☐ Yes

☐ No

216. Other immune modulating agent

☐ Yes **– *Go to question 217***

☐ No **– *Go to question 218***

217. Specify other immune modulating agent: _____

218. PD1 inhibitor

☐ Yes **– *Go to question 219***

☐ No **– *Go to question 223***

219. Nivolumab

☐ Yes

☐ No

220. Pembrolizumab

☐ Yes

☐ No

221. Other PD1 inhibitor

☐ Yes **– *Go to question 222***

☐ No **– *Go to question 223***

222. Specify other PD1 inhibitor: _____

223. BTK inhibitors

☐ Yes **– *Go to question 225***

☐ No **– *Go to question 227***

224. Ibrutinib

☐ Yes

☐ No

225. Other BTK inhibitor

☐ Yes **– *Go to question 226***

☐ No **– *Go to question 227***

226. Specify other BTK inhibitor:_____

227. Chemotherapy

☐ Yes **– *Go to question 228***

☐ No **– *Go to question 229***

228. Specify chemotherapy drugs: _____

229. Other systemic therapy

☐ Yes **– *Go to question 230***

☐ No **– *Go to question 231***

230. Specify other systemic therapy**:** _____

231. Radiation

☐ Yes

☐ No

232. Cellular therapy

☐ Yes

☐ No

233. Blinded randomized trial

☐ Yes

☐ No

234. Other therapy

☐ Yes – ***Go to question 235***

☐ No – ***Go to question 236***

235. Specify other therapy***:*** _____

Current Disease Status

236. What is the current disease status?

☐ Complete remission (CR) - ***Go to question 238***

☐ Not in complete remission - ***Go to question 237***

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

237. Specify disease status if not in complete remission:

☐ Disease detected

☐ No disease detected but incomplete evaluation to establish CR

238. Date of most recent disease assessment

☐ Known – ***Go to question 239***

☐ Unknown – ***Go to First Name***

239. Date of most recent disease assessment: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

First Name: _____

Last Name: _____

E-mail address: _____

Date: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD