CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Post-Transplant Essential Data

Registry Use Only
Sequence Number:

Date Received:

OMB No: 0915-0310
Expiration Date: 1/31/2020

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***

   ☐ 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***
- ☐ 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:_____

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

Subsequent Transplant

7. Did the recipient receive a subsequent HCT since the date of last report?

☐ Yes →
☐ No

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: _____

11. Source of HSCs ☐ 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 **– Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000** →
☐ No

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 →
- ☐ No
- ☐ Unknown

20. Date of acute GVHD diagnosis: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD) ***- Go to question 22***

21. Did acute GVHD persist since the date of last report?

- ☐ Yes →
- ☐ No
- ☐ Unknown

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 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
- ☐ 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: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD) ☐ Date estimated ***- 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 → 46. Specify therapy: (check all that apply)

☐ Defibrotide
☐ N-acetylcysteine
☐ Tissue plasminogen activator (TPA)
☐ Ursodiol
☐ Other therapy → 47. Specify other therapy: _____

☐ No

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 → 49. Date of diagnosis: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

☐ 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.

50. 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 →

Copy and complete questions 51-57 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.

51. Specify the new malignancy

☐ Acute myeloid leukemia (AML / ANLL) ***- Go to question 54***
☐ Other leukemia ***- Go to question 54***
☐ Myelodysplastic syndrome (MDS) ***- Go to question 54***
☐ Myeloproliferative neoplasm (MPN) ***- Go to question 54***
☐ Myelodysplasia / myeloproliferative neoplasm (MDS / MPN) ***- Go to question 54***
☐ Hodgkin lymphoma ***- Go to question 53***
☐ Non-Hodgkin lymphoma ***- Go to question 53***
☐ Post-transplant lymphoproliferative disorder (PTLD) ***- Go to question 53***
☐ Clonal cytogenetic abnormality without leukemia or MDS ***- Go to question 54***
☐ Uncontrolled proliferation of donor cells without malignant transformation ***- Go to question 54***
☐ Breast cancer ***- Go to question 54***
☐ Central nervous system (CNS) malignancy (e.g. glioblastoma, astrocytoma) ***- Go to question 54***
☐ Gastrointestinal malignancy (e.g. colon, rectum, stomach, pancreas, intestine) ***- Go to question 54***
☐ Genitourinary malignancy (e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix) ***- Go to question 54***
☐ Lung cancer ***- Go to question 54***

☐ No

☐ Melanoma - ***Go to question 54***
☐ Basal cell skin malignancy - ***Go to question 54***
☐ Squamous cell skin malignancy - ***Go to question 54***
☐ Oropharyngeal cancer (e.g. tongue, buccal mucosa) - ***Go to question 54***
☐ Sarcoma - ***Go to question 54***
☐ Thyroid cancer - ***Go to question 54***
☐ Other new malignancy - ***Go to question 52***

52. Specify other new malignancy:
- Go to question 52
53. Is the tumor EBV positive? ☐ Yes ☐ No

54. Date of diagnosis: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

55. Was documentation submitted to the CIBMTR? (e.g. pathology / autopsy report or other documentation)
☐ Yes ☐ No

56. Was the new malignancy donor / cell product derived?
☐ Yes →
☐ No →
☐ Not done

57. 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.

58. Were chimerism studies performed since the date of last report?
☐ Yes →
☐ No - ***Go to question 78***

59. Was documentation submitted to the CIBMTR? (e.g. chimerism laboratory reports)
☐ Yes ☐ No

60. 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.

61. NMDP donor ID: ___ ___ ___ ___ — ___ ___ ___ ___ — ___

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

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

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

65. Global Registration Identifiers for Donors (GRID): __ (optional)

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

67. Sex (Donor / infant) ☐ Male ☐ Female

68. Date sample collected: __ __ __ __ / __ __ / __ __
YYYY MM DD

69. 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 → 70. Specify: _____

71. Cell source ☐ Bone marrow ☐ Peripheral blood

72. Cell type

- ☐ Unsorted / whole ***- Go to question 74***
- ☐ Red blood cells ***- Go to question 76***
- ☐ Hematopoietic progenitor cells (CD34+ cells) ***- Go to question 76***
- ☐ Total mononuclear cells (lymphs & monos) ***- Go to question 76***
- ☐ T-cells (includes CD3+, CD4+, and/or CD8+) ***- Go to question 76***
- ☐ B-cells (includes CD19+ or CD20+) ***- Go to question 76***
- ☐ Granulocytes (includes CD33+ myeloid cells) ***- Go to question 76***
- ☐ NK cells (CD56+) ***- Go to question 76***
- ☐ Other → 73. Specify: _____

74. Total cells examined: ___ ___ ___ ___ ___ ___

75. Number of donor cells: ___ ___ ___ ___ ***- Go to question 78***

76. Were donor cells detected?

- ☐ Yes → 77. Percent donor cells: ___ ___ ___ %
- ☐ No

Copy and complete questions 61-77 for multiple chimerism studies.

Disease Assessment at the Time of Best Response to HCT

78. 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 101***
- ☐ Complete remission (CR) ***- Go to question 80***
- ☐ Not in complete remission ***- Go to question 79***
- ☐ Not evaluated ***- Go to question 101***

79. Specify disease status if not in complete remission:

☐ Disease detected ***- Go to question 82***

☐ No disease detected but incomplete evaluation to establish CR ***- Go to question 82***

80. Was the date of best response previously reported?

☐ Yes ***- Go to question 101***

☐ No →

81. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

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

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

☐ Yes →
- 83. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- 84. Was disease detected? ☐ Yes ☐ No

☐ No

☐ Not applicable

85. Was the disease status assessed via flow cytometry?

☐ Yes →
- 86. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- 87. Was disease detected? ☐ Yes ☐ No

☐ No

☐ Not applicable

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

☐ Yes →

89. Was the disease status assessed via FISH?

☐ Yes →
- 90. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- 91. Was disease detected? ☐ Yes ☐ No

☐ No

☐ Not applicable

92. Was the disease status assessed via karyotyping?

☐ Yes →
- 93. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- 94. Was disease detected? ☐ Yes ☐ No

☐ No

☐ Not applicable

95. Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)
- ☐ Yes →
  - 96. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
  - 97. Was disease detected? ☐ Yes ☐ No
- ☐ No
- ☐ Not applicable

98. Was the disease status assessed by clinical / hematologic assessment?
- ☐ Yes →
  - 99. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
  - 100. Was disease detected? ☐ Yes ☐ No
- ☐ 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.

101. 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 →
  - 102. Systemic therapy (check all that apply)
    - ☐ Systemic therapy ***- Go to question 103***
    - ☐ Radiation
    - ☐ Cellular therapy
    - ☐ Blinded randomized trial
    - ☐ Other therapy ***- Go to question 105***
  - 103. 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
- ☐ No

- ☐ Midostaurin
- ☐ Nilotinib (AMN107, Tasigna)
- ☐ Nivolumab
- ☐ Pembrolizumab
- ☐ Pomalidomide
- ☐ Quizartinib
- ☐ Rituximab (Rituxan, MabThera)
- ☐ Sorafenib
- ☐ Sunitinib
- ☐ Thalidomide (Thalomid)
- ☐ Other systemic therapy →

104. Specify other systemic therapy: _____

105. 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.

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

- ☐ Yes →
- ☐ No

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

- ☐ Yes **(only valid >day 100)**
- ☐ No →

108. Date first seen: __ __ __ __ / __ __ / __ __
YYYY MM DD

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

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

- ☐ Yes →
- ☐ No

110. Specify reason for which intervention was given:

- ☐ Persistent disease
- ☐ Relapsed / progressive disease

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

- ☐ Clinical/hematologic
- ☐ Radiological (e.g. PET, MRI, CT)
- ☐ Cytogenetic
- ☐ Flow cytometry
- ☐ Disease specific molecular marker

112. Date intervention started: __ __ __ __ / __ __ / __ __
YYYY MM DD

113. Systemic therapy (check all that apply)

- ☐ Systemic therapy ***- Go to question 114***
- ☐ Radiation
- ☐ Cellular therapy
- ☐ Blinded randomized trial
- ☐ Other therapy ***- Go to question 116***

114. Specify system therapy: (check all that apply)

- ☐ Alemtuzumab (Campath)
- ☐ Azacytidine (Vidaza)
- ☐ Blinatumomab
- ☐ Bortezomib (Velcade)
- ☐ Bosutinib
- ☐ Carfilzomib
- ☐ Chemotherapy Dasatinib (Sprycel)
- ☐ 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 →

115. Specify other systemic therapy:
_____

116. Specify other therapy:_____

Current Disease Status

117. What is the current disease status?

- ☐ Complete remission (CR) ***- Go to question 119***
- ☐ Not in complete remission ***- Go to question 118***
- ☐ Not evaluated ***- Go to signature line***

118. Specify disease status if not in complete remission:

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

119. Date of most recent disease assessment

☐ Known → 120. Date of most recent disease assessment: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

☐ Unknown

First Name: _____

Last Name:_____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)