Cellular Therapy Essential Data Follow-Up

Registry Use Only

Sequence Number:

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: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Product

1. Name of cellular therapy product *(for most recent cell therapy infusion)*
   - ☐ Axicabtagene ciloleucel (Yescarta®)
   - ☐ Brexucabtagene autoleucel (Tecartus™)
   - ☐ Ciltacabtagene autoleucel (JNJ-4528)
   - ☐ Idecabtagene vicleucel (Abecma®)
   - ☐ Letetresgene autoleucel
   - ☐ Lisocabtagene maraleucel (Breyanzi™)
   - ☐ Orvacabtagene autoleucel
   - ☐ Tisagenlecleucel (Kymriah®)
   - ☐ Other product
   - ☐ No product name

Survival

2. Date of actual contact with the recipient to determine medical status for this follow-up report:

   ___ ___ ___ ___ – ___ ___ – ___ ___
   YYYY MM DD

3. 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**
   - ☐ Dead - **Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete a Form 2900 – Recipient Death Data.**

Subsequent Cellular Infusions

All additional cellular therapy infusions given for the same indication per protocol require a separate infusion form and should be reported on the Form 4000 for this course of cellular therapy. If a cellular therapy was administered for treatment of a different indication, or in response to disease progression / no response, a new Form 4000 (Pre-CTED) must be completed.

4. Has the recipient received a new course of cellular therapy (unplanned) since the date of last report?
   - ☐ Yes – ***Go to question 5***
   - ☐ No – ***Go to question 7***

5. Specify the reason for which cellular therapy was given
   - ☐ Failure to respond or in response to disease assessment
   - ☐ New indication

6. Date of cellular therapy: ___ ___ ___ ___ - ___ ___ - ___ ___ - **Also complete a Cellular Therapy Essential Data Pre-Infusion Form 4000**
   YYYY MM DD

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

- ☐ Yes – **Also complete a Pre-TED Form 2400 for the subsequent HCT** -***Go to question 8***
- ☐ No - ***Go to question 9***

8. Date of HCT: ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

Best Response to Cellular Therapy

9. What was the best response to the cellular therapy?

- ☐ Continued complete response (CCR) *(for recipients in CR at the time of cellular therapy infusion)*
- ☐ Complete response
- ☐ Normalization of organ function
- ☐ Partial response
- ☐ Partial normalization of organ function
- ☐ No response
- ☐ Disease progression or worsening of organ function

10. Was the date of best response previously reported?

- ☐ Yes – ***Go to question 12***
- ☐ No – ***Go to question 11***

11. Date response established: ___ ___ ___ ___ – ___ ___ – ___ ___
    YYYY MM DD

Peripheral Blood Count Recovery

12. Was there evidence of initial recovery?

- ☐ Yes *(ANC ≥ 500/mm^3 achieved and sustained for 3 lab values)* – ***Go to question 13***
- ☐ No *(ANC ≥ 500/mm^3 was not achieved)* – ***Go to question 19***
- ☐ Not applicable *(ANC never dropped below 500/mm^3 at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given)* – ***Go to question 14***
- ☐ Previously reported *(recipient's initial recovery was recorded on a previous report)* – ***Go to question 19***

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

14. Following the initial recovery, was there subsequent decline in ANC to < 500/mm^3 for ≥ 3 days since the date of last report?

☐ Yes – ***Go to question 15***

☐ No– ***Go to question 19***

15. Date of decline in ANC to < 500/mm^3 for ≥ 3 days *(first of 3 days that the ANC declined)*:

___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

16. Did recipient recover and maintain ANC ≥ 500/mm^3 following the decline?

☐ Yes – ***Go to questions 17***

☐ No – ***Go to question 19***

17. Date of ANC recovery

☐ Known – ***Go to questions 18***

☐ Unknown – ***Go to question 19***

18. Date of ANC recovery: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

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

☐ Yes – ***Go to question 20***

☐ No – ***Go to question 21***

☐ Not applicable *(platelet count never dropped below 20 x 10^9/L at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given)*– ***Go to question 21***

☐ Previously reported *(≥ 20 x 10^9/L was achieved and reported previously)* – ***Go to question 21***

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

Disease Relapse or Progression

21. Was a disease relapse or progression detected since the date of last report?

☐ Yes – ***Go to question 22***

☐ No - ***Go to question 23***

22. Date of relapse or progression: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Current Hematologic Findings

23. Date of most recent complete blood count (CBC) sample drawn: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

24. Complete blood count results available *(check all that apply)*

- ☐ WBC - ***Go to question 25***
- ☐ Neutrophils - ***Go to question 26***
- ☐ Lymphocytes - ***Go to question 27***
- ☐ Hemoglobin - ***Go to question 28***
- ☐ Hematocrit - ***Go to question 29***
- ☐ Platelets - ***Go to question 31***

25. WBC: ___ ___ ___ ___ ___ ___ • ___
- ☐ x 10^9/L (x 10^3/mm^3)
- ☐ x 10^6/L

26. Neutrophils: ___ ___ %

27. Lymphocytes: ___ ___ %

28. Hemoglobin: ___ ___ ___ ___ • ___ ___
- ☐ g/dL
- ☐ g/L
- ☐ mmol/L

29. Hematocrit: ___ ___ ___ %

30. Were RBCs transfused ≤ 30 days before the date the sample was drawn?
- ☐ Yes
- ☐ No

31. Platelets: ___ ___ ___ ___ ___ ___ ___
- ☐ x 10^9/L (x 10^3/mm^3)
- ☐ x 10^6/L

32. Were platelets transfused ≤ 7 days before the date the sample was drawn?
- ☐ Yes
- ☐ No

33. Did the recipient receive any growth factors ≤ 7 days before the date the sample was drawn?

- ☐ Yes
- ☐ No

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Report new malignancies that are different than the indicated disease / disorder for which this cellular therapy was performed. Do NOT include relapse, progression or transformation of the same disease subtype.

34. 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 *(form 3500 has already been submitted for this event)*

Persistence of Cells

This section pertains to the evaluation of persistence of a cellular product in the recipient.

35. Were tests performed to detect persistence of the cellular product since the date of last report?

- ☐ Yes – ***Go to question 36***
- ☐ No – ***Go to question 60***

36. Was persistence evaluated by molecular assay? *(e.g. PCR)*

- ☐ Yes – ***Go to question 37***
- ☐ No – ***Go to question 41***

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

38. Specify the cell source *(check all that apply)*

- ☐ Bone marrow– ***Go to question 40***
- ☐ Peripheral blood– ***Go to question 40***
- ☐ Tumor– ***Go to question 40***
- ☐ Other source– ***Go to question 39***

39. Specify other cell source: _____

40. Were the infused cells detected?

- ☐ Yes
- ☐ No

41. Was persistence evaluated by flow cytometry testing? *(immunophenotyping)*

- ☐ Yes – ***Go to question 42***
- ☐ No – ***Go to question 49***

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

43. Specify the cell source *(check all that apply)*

- ☐ Bone marrow– ***Go to question 45***
- ☐ Peripheral blood– ***Go to question 45***
- ☐ Tumor– ***Go to question 45***
- ☐ Other source– ***Go to question 44***

44. Specify other cell source: _____

45. Were the infused cells detected?

- ☐ Yes
- ☐ No

46. Were B-cell counts monitored after infusion?

- ☐ Yes – ***Go to question 47***
- ☐ No – ***Go to question 49***

47. Was there B-cell recovery?

- ☐ Yes – ***Go to question 48***
- ☐ No – ***Go to question 49***

48. Date of B-cell recovery: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

49. Was persistence evaluated by immunohistochemistry?

- ☐ Yes – ***Go to question 50***
- ☐ No – ***Go to question 54***

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

51. Specify the cell source *(check all that apply)*

- ☐ Bone marrow– ***Go to question 53***
- ☐ Peripheral blood– ***Go to question 53***
- ☐ Tumor– ***Go to question 53***
- ☐ Other source– ***Go to question 52***

52. Specify other cell source: _____

53. Were the infused cells detected?

- ☐ Yes
- ☐ No

54. Was persistence evaluated by another method?

- ☐ Yes - ***Go to question 55***
- ☐ No – ***Go to question 60***

55. Specify other method: _____

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

57. Specify the cell source *(check all that apply)*

- ☐ Bone marrow– ***Go to question 59***
- ☐ Peripheral blood– ***Go to question 59***
- ☐ Tumor– ***Go to question 59***
- ☐ Other source– ***Go to question 58***

58. Specify other cell source: _____

59. Were the infused cells detected?

- ☐ Yes
- ☐ No

Graft vs. Host Disease

This section is for allogeneic infusions only. If this was an autologous infusion, continue to the "Toxicities" section.

60. Did acute GVHD develop since the date of last report?

- ☐ Yes– ***Go to question 61***

- ☐ No – ***Go to question 62***
- ☐ Unknown – ***Go to question 62***

61. Date of acute GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 63***
YYYY MM DD

62. Did acute GVHD persist since the date of last report?
- ☐ Yes– ***Go to question 70***
- ☐ No – ***Go to question 72***
- ☐ Unknown – ***Go to question 72***

63. Overall grade of acute GVHD at diagnosis
- ☐ I - Rash on ≤ 50% of skin, no liver or gut involvement
- ☐ II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting
- ☐ III - Bilirubin 3-15 mg/dL, or gut stage 2-4, diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
- ☐ IV - Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL
- ☐ Not applicable (acute GVHD present but grade is not applicable)

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

64. 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

65. 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

66. Upper intestinal tract

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

67. 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)

68. Other site(s) involved with acute GVHD

- ☐ Yes – ***Go to question 69***
- ☐ No – ***Go to question 70***

69. Specify other site(s): _____

Specify the MAXIMUM overall grade of acute GVHD since the date of last report:

70. 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 grade is not applicable)

71. Date maximum overall grade of acute GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

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

- ☐ Yes – ***Go to questions 73***
- ☐ No - ***Go to question 74***
- ☐ Unknown – ***Go to question 74***

73. Date of chronic GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated
YYYY MM DD – ***Go to question 75***

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

- ☐ Yes – ***Go to questions 75***
- ☐ No - ***Go to question 78***
- ☐ Unknown – ***Go to question 78***

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

75. Maximum grade of chronic GVHD *(according to best clinical judgment)*

- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Unknown

76. 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

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

78. 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

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

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

Toxicities

Cytokine Release Syndrome (CRS)

80. Did the recipient experience Cytokine Release Syndrome (CRS)?

- ☐ Yes – ***Go to question 81***
- ☐ No – ***Go to question 110***

81. Was the date of diagnosis previously reported?

- ☐ Yes–***Go to question 83***
- ☐ No –***Go to question 82***

82. Date of CRS diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

83. Specify therapy given for CRS *(check all that apply)*

- ☐ Anakinra – ***Go to question 86***
- ☐ Corticosteroids – ***Go to question 86***
- ☐ Siltuximab – ***Go to question 86***
- ☐ Tocilizumab – ***Go to question 85***
- ☐ Other therapy – ***Go to question 84***
- ☐ No therapy given – ***Go to question 86***

84. Specify other therapy: _____

85. Doses of tocilizumab given

- ☐ 1
- ☐ ≥ 2

86. Indicate the symptoms of CRS *(check all that apply)*

- ☐ Fever *(> 100.4 F or > 38 C)* – ***Go to question 87***
- ☐ Hypotension requiring therapy – ***Go to question 88***
- ☐ Hypoxia requiring minimal supplemental oxygen *(FiO2 < 40%)* – ***Go to question 95***
- ☐ Hypoxia requiring more than minimal supplemental oxygen *(FiO2 ≥ 40%)* – ***Go to question 96***
- ☐ Unknown– ***Go to question 97***

87. Date of fever onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

88. Date of hypotension onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

89. Specify therapy given for hypotension *(check all that apply)*

- ☐ Intravenous fluids – ***Go to question 94***
- ☐ Vasopressor(s) – ***Go to question 91***
- ☐ Other – ***Go to question 90***

90. Specify other therapy: _____

91. Specify the number of vasopressors used for therapy

- ☐ 1
- ☐ ≥ 2

92. Specify the vasopressor(s) used *(check all that apply)*

- ☐ Phenylephrine
- ☐ Norepinephrine
- ☐ Epinephrine
- ☐ Dopamine
- ☐ Vasopressin
- ☐ Other – ***Go to question 93***

93. Specify other vasopressor: _____

94. Was hypotension controlled with therapy?

- ☐ Yes
- ☐ No
- ☐ Unknown

95. Date of hypoxia onset for minimal supplemental oxygen *(FiO2 < 40%)*: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

96. Date of hypoxia onset for more than minimal supplemental oxygen *(FiO2 ≥ 40%)*:

___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

97. Was positive pressure ventilatory support required? *(CPAP, BiPAP, intubation and mechanical ventilation)*

- ☐ Yes - ***Go to question 98***
- ☐ No - ***Go to question 99***
- ☐ Unknown – ***Go to question 99***

98. Date started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

99. Were there features related to macrophage activation syndrome (MAS) / hemophagocytic lymphohistiocytosis (HLH)?

- ☐ Yes – ***Go to question 100***
- ☐ No – ***Go to question 108***

100. Date of MAS / HLH onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

101. Did the recipient have splenomegaly?

- ☐ Yes
- ☐ No

102. Was MAS / HLH confirmed by a bone marrow biopsy?

- ☐ Yes
- ☐ No

103. Specify the laboratory values collected *(check all that apply)*

- ☐ Fibrinogen –***Go to question 104***
- ☐ Triglyceride –***Go to question 106***
- ☐ None - ***Go to question 108***

104. Lowest fibrinogen level: ___ ___ ___ . ___

- ☐ mg/dL
- ☐ mg/L

105. Date fibrinogen sample collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

106. Highest triglyceride level: ___ ___ ___ . ___ ___

- ☐ mg/dL
- ☐ mmol/L

107. Date triglyceride sample collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

108. Did cytokine release syndrome resolve?

- ☐ Yes–***Go to question 109***
- ☐ No–***Go to question 110***

109. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Neurotoxicity (ICANS)

110. Did the recipient experience neurotoxicity (ICANS)?

- ☐ Yes –***Go to question 111***
- ☐ No –***Go to question 129***

111. Was the date of onset previously reported?

- ☐ Yes–***Go to question 113***
- ☐ No –***Go to question 112***

112. Date of neurotoxicity (ICANS) onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

113. Specify therapy given for neurotoxicity *(check all that apply)*

- ☐ Anti-epileptics –***Go to question 115***
- ☐ Anakinra –***Go to question 115***
- ☐ Corticosteroids –***Go to question 115***
- ☐ Siltuximab –***Go to question 115***
- ☐ Tocilizumab –***Go to question 115***
- ☐ Other therapy – ***Go to question 114***
- ☐ No therapy given –***Go to question 115***

114. Specify other therapy: _____

115. Which cognitive assessment was performed?

- ☐ CARTOX –***Go to question 116***

- ☐ ICE –***Go to question 116***
- ☐ None –***Go to question 117***

116. What was the lowest score?
    - ☐ 10
    - ☐ 9
    - ☐ 8
    - ☐ 7
    - ☐ 6
    - ☐ 5
    - ☐ 4
    - ☐ 3
    - ☐ 2
    - ☐ 1
    - ☐ 0
    - ☐ Unable to complete assessment

For symptoms of neurotoxicity (ICANS), report the HIGHEST grade observed in this reporting period:

117. Indicate the symptoms of neurotoxicity (ICANS) *(check all that apply)*
    - ☐ Aphasia *(speech impairment resulting in full loss of language)* – ***Go to question 127***
    - ☐ Cerebral edema – ***Go to question 119***
    - ☐ Cerebrovascular accident *(stroke)* – ***Go to question 120***
    - ☐ Depressed level of consciousness – ***Go to question 122***
    - ☐ Dysphasia *(speech impairment resulting in partial loss of language)* – ***Go to question 123***
    - ☐ Hallucinations – ***Go to question 127***
    - ☐ Hemiparesis / paraparesis / other motor deficit – ***Go to question 127***
    - ☐ Leukoencephalopathy – ***Go to question 127***
    - ☐ Seizure – ***Go to question 124***
    - ☐ Tremors – ***Go to question 127***
    - ☐ Other symptom – ***Go to question 118***

118. Specify other symptom: _____

119. Specify type of cerebral edema
    - ☐ Focal / local edema on neuroimaging

☐ Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's triad

120. Date of cerebrovascular accident onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

121. Specify type of cerebrovascular accident

☐ Hemorrhagic

☐ Ischemic

122. Specify the most severe level of depressed level of consciousness

☐ Awakens spontaneously

☐ Awakens to voice

☐ Awakens only to tactile stimulus

☐ Patient unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma

123. Specify the grade of dysphasia

☐ 1 *(awareness of receptive or expressive characteristics; not impairing ability to communicate)*

☐ 2 *(moderate receptive or expressive characteristics; impairing ability to communicate spontaneously)*

124. Specify the type of seizure

☐ Complex partial – ***Go to question 126***

☐ Generalized tonic-clonic – ***Go to question 126***

☐ Non-convulsive status epilepticus – ***Go to question 126***

☐ Simple partial – ***Go to question 126***

☐ Status epilepticus – ***Go to question 126***

☐ Other type – ***Go to question 125***

☐ Unknown – ***Go to question 126***

125. Specify other type: _____ – ***Go to question 126***

126. Specify the severity of the seizure

☐ Grade 3 *(any clinical seizure focal or generalized that resolves rapidly; or non-convulsive seizures on EEG that resolve with intervention)*

☐ Grade 4 *(life-threatening prolonged seizure that is > 5 min; or repetitive clinical or electrical seizures without return to baseline in between)*

127. Did neurotoxicity (ICANS) resolve?

☐ Yes–***Go to question 128***

☐ No–***Go to question 129***

128. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Other toxicities

129. Hypogammaglobulinemia

☐ Yes - ***Go to question 130***

☐ No - ***Go to question 136***

☐ Unknown - ***Go to question 136***

130. Was the date of onset previously reported?

☐ Yes–***Go to question 132***

☐ No –***Go to question 131***

131. Date of onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

132. Did hypogammaglobulinemia resolve?

☐ Yes –***Go to question 133***

☐ No –***Go to question 134***

133. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

134. Did recipient require immunoglobulin replacement therapy?

☐ Yes–***Go to question 135***

☐ No–***Go to question 136***

135. Is the recipient still requiring replacement therapy?

☐ Yes

☐ No

136. Tumor lysis syndrome

☐ Yes - ***Go to question 137***

☐ No - ***Go to question 142***

☐ Unknown - ***Go to question 142***

137. Was the date of onset previously reported?

- ☐ Yes–***Go to question 139***
- ☐ No –***Go to question 138***

138. Date of onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

139. Grade
- ☐ 3
- ☐ 4
- ☐ 5

140. Did tumor lysis syndrome resolve?
- ☐ Yes –***Go to question 141***
- ☐ No –***Go to question 142***

141. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

142. Other toxicity
- ☐ Yes –***Go to question 143***
- ☐ No –***Go to question 148***
- ☐ Unknown–***Go to question 148***

Copy and complete questions 143– 147 to report more than one toxicity

143. Specify other toxicity: _____

144. Was the date of onset previously reported?
- ☐ Yes –***Go to question 146***
- ☐ No –***Go to question 145***

145. Date of onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

146. Did the other toxicity resolve?
- ☐ Yes –***Go to question 147***
- ☐ No –***Go to question 148***

147. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Specify if the recipient has experienced any of the following since the date of last report:

148. Has the recipient experienced a grade 3 organ toxicity?

- ☐ Yes - ***Go to question 149***
- ☐ No - ***Go to question 155***
- ☐ Unknown - ***Go to question 155***

Copy and complete questions 149- 154 to report more than one grade 3 organ toxicity

149. Specify organ

- ☐ Cardiovascular
- ☐ Gastrointestinal
- ☐ Kidneys
- ☐ Liver
- ☐ Lungs
- ☐ Musculoskeletal
- ☐ Nervous system
- ☐ Other

150. Specify the toxicity

- ☐ Abdominal pain
- ☐ Acute kidney injury
- ☐ Acute respiratory distress syndrome
- ☐ Alanine aminotransferase increased (ALT)
- ☐ Alkaline phosphatase increased
- ☐ Anorexia
- ☐ Arthralgia
- ☐ Aspartate aminotransferase increased (AST)
- ☐ Blood bilirubin increased
- ☐ Capillary leak syndrome
- ☐ Cardiac arrhythmia
- ☐ Chills
- ☐ Chronic kidney disease
- ☐ Constipation
- ☐ Cystitis noninfective
- ☐ Diarrhea
- ☐ Dizziness
- ☐ Dysgeusia

- ☐ Dyspepsia
- ☐ Dyspnea
- ☐ Edema limbs
- ☐ Encephalopathy
- ☐ Fatigue
- ☐ Gastroenteritis
- ☐ Headache
- ☐ Hepatic failure
- ☐ Hepatitis
- ☐ Hypertension
- ☐ Hypotension
- ☐ Intestinal obstruction (includes small intestine and colonic)
- ☐ Left ventricular systolic dysfunction
- ☐ Mucositis oral
- ☐ Muscle weakness, generalized or specific area
- ☐ Myalgia
- ☐ Myocardial infarction
- ☐ Nausea
- ☐ New or worsening heart failure
- ☐ Pericardial effusion
- ☐ Pericarditis
- ☐ Productive cough
- ☐ Pulmonary edema
- ☐ Respiratory failure
- ☐ Restrictive cardiomyopathy
- ☐ Thromboembolic event
- ☐ Tremor
- ☐ Vomiting

151. Was the date of onset previously reported?

- ☐ Yes- ***Go to question 153***
- ☐ No - ***Go to question 152***

152. Date of onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

153. Did the grade 3 toxicity resolve?

- ☐ Yes –***Go to question 154***
- ☐ No –***Go to question 155***

154. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

155. Has the recipient experienced a grade 4 organ toxicity?

- ☐ Yes - ***Go to question 156***
- ☐ No - ***Go to question 162***
- ☐ Unknown - ***Go to question 162***

Copy and complete questions 156- 161 to report more than one grade 4 organ toxicity

156. Specify organ

- ☐ Cardiovascular
- ☐ Gastrointestinal
- ☐ Kidneys
- ☐ Liver
- ☐ Lungs
- ☐ Musculoskeletal
- ☐ Nervous system
- ☐ Other

157. Specify the toxicity

- ☐ Abdominal pain
- ☐ Acute kidney injury
- ☐ Acute respiratory distress syndrome
- ☐ Alanine aminotransferase increased (ALT)
- ☐ Alkaline phosphatase increased
- ☐ Anorexia
- ☐ Arthralgia
- ☐ Aspartate aminotransferase increased (AST)
- ☐ Blood bilirubin increased
- ☐ Capillary leak syndrome
- ☐ Cardiac arrhythmia
- ☐ Chills
- ☐ Chronic kidney disease
- ☐ Constipation

- ☐ Cystitis noninfective
- ☐ Diarrhea
- ☐ Dizziness
- ☐ Dysgeusia
- ☐ Dyspepsia
- ☐ Dyspnea
- ☐ Edema limbs
- ☐ Encephalopathy
- ☐ Fatigue
- ☐ Gastroenteritis
- ☐ Headache
- ☐ Hepatic failure
- ☐ Hepatitis
- ☐ Hypertension
- ☐ Hypotension
- ☐ Intestinal obstruction (includes small intestine and colonic)
- ☐ Left ventricular systolic dysfunction
- ☐ Mucositis oral
- ☐ Muscle weakness, generalized or specific area
- ☐ Myalgia
- ☐ Myocardial infarction
- ☐ Nausea
- ☐ New or worsening heart failure
- ☐ Pericardial effusion
- ☐ Pericarditis
- ☐ Productive cough
- ☐ Pulmonary edema
- ☐ Respiratory failure
- ☐ Restrictive cardiomyopathy
- ☐ Thromboembolic event
- ☐ Tremor
- ☐ Vomiting

158. Was the date of onset previously reported?

- ☐ Yes- ***Go to question 160***
- ☐ No - ***Go to question 159***

159. Date of onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

160. Did the grade 4 toxicity resolve?

- ☐ Yes –***Go to question 161***
- ☐ No –***Go to question 162***

161. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

162. Specify the laboratory values collected *(check all that apply)*

- ☐ C-reactive protein –***Go to question 163***
- ☐ Interleukin-6 –***Go to question 165***
- ☐ Soluble interleukin-2 receptor α *(sIL2RA or soluble CD25)* –***Go to question 167***
- ☐ Total serum ferritin –***Go to question 169***
- ☐ None –***Go to question 171***

Specify the MAXIMUM lab results since the date of last report:

163. Maximum C-reactive protein: ___ ___ . ___
- ☐ mg/dL
- ☐ mg/L

164. Date C-reactive protein collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

165. Maximum interleukin-6: ___ ___ ___
- ☐ pg/mL
- ☐ IU/mL

166. Date Interleukin-6 collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

167. Maximum soluble interleukin-2 receptor α: ___ ___ ___ ___ ___
- ☐ pg/mL
- ☐ IU/mL
- ☐ U/mL

168. Date soluble interleukin-2 receptor α collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

169. Maximum total serum ferritin:___ ___ ___ ___ ___ ng/mL (µg/L)

170. Date serum ferritin collected: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Infection

171. Did the recipient develop a clinically significant infection since the date of last report?

- ☐ Yes – ***Go to question 172***
- ☐ No – ***Go to question 176***

Report each infection organism, site, and date of diagnosis

Copy and complete questions 172-175 to report more than one infection

172. Organism

- ☐ 121 Acinetobacter (all species)
- ☐ 125 Bordetella pertussis (whooping cough)
- ☐ 157 Pseudomonas or Burkholderia cepacia
- ☐ 128 Campylobacter (all species)
- ☐ 129 Capnocytophaga (all species)
- ☐ 171 Chlamydia (pneumoniae)
- ☐ 130 Citrobacter (freundii, other species)
- ☐ 131 Clostridium (all species except difficile)
- ☐ 132 Clostridium difficile
- ☐ 173 Corynebacterium jeikeium
- ☐ 134 Enterobacter (all species)
- ☐ 177 Enterococcus, vancomycin resistant (VRE)
- ☐ 135 Enterococcus (all species)
- ☐ 136 Escherichia (also E. coli)
- ☐ 139 Fusobacterium (all species)
- ☐ 187 Haemophilus influenzae
- ☐ 188 Haemophilus non-influenzae
- ☐ 146 Klebsiella (all species)
- ☐ 147 Lactobacillus (bulgaricus, acidophilus, other species)
- ☐ 189 Legionella pneumophila

- ☐ 190 Legionella non-pneumophila
- ☐ 103 Leptospira (all species)
- ☐ 148 Leptotrichia buccalis
- ☐ 149 Leuconostoc (all species)
- ☐ 104 Listeria monocytogenes
- ☐ 151 Micrococcus, NOS
- ☐ 118 Mycobacterium abscessus
- ☐ 112 Mycobacterium avium - intracellulare (MAC, MAI)
- ☐ 108 Mycobacterium cheloneae
- ☐ 109 Mycobacterium fortuitum
- ☐ 114 Mycobacterium haemophilum
- ☐ 115 Mycobacterium kansasii
- ☐ 116 Mycobacterium marinum
- ☐ 117 Mycobacterium mucogenicum
- ☐ 110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)
- ☐ 105 Mycoplasma (all species)
- ☐ 183 Neisseria gonorrhoeae
- ☐ 184 Neisseria meningitidis
- ☐ 106 Nocardia (all species)
- ☐ 153 Pasteurella multocida
- ☐ 155 Proteus (all species)
- ☐ 185 Pseudomonas aeruginosa
- ☐ 186 Pseudomonas non-aeruginosa
- ☐ 159 Rhodococcus (all species)
- ☐ 107 Rickettsia (all species)
- ☐ 160 Salmonella (all species)
- ☐ 161 Serratia marcescens
- ☐ 162 Shigella (all species)
- ☐ 180 Staphylococcus aureus (Methacillin Resistant)
- ☐ 179 Staphylococcus aureus (Methacillin Sensitive)
- ☐ 158 Stenotrophomonas maltophilia
- ☐ 166 Stomatococcus mucilaginosis
- ☐ 181 Streptococcus, alpha-hemolytic
- ☐ 182 Streptococcus, Group B
- ☐ 178 Streptococcus pneumoniae
- ☐ 168 Treponema (syphilis)

- ☐ 169 Vibrio (all species)
- ☐ 210 Aspergillus, NOS
- ☐ 211 Aspergillus flavus
- ☐ 212 Aspergillus fumigatus
- ☐ 213 Aspergillus niger
- ☐ 215 Aspergillus terreus
- ☐ 214 Aspergillus ustus
- ☐ 270 Blastomyces (dermatitidis)
- ☐ 201 Candida albicans
- ☐ 208 Candida non-albicans
- ☐ 271 Coccidioides (all species)
- ☐ 222 Cryptococcus gattii
- ☐ 221 Cryptococcus neoformans
- ☐ 230 Fusarium (all species)
- ☐ 261 Histoplasma (capsulatum)
- ☐ 241 Mucorales (all species)
- ☐ 260 Pneumocystis (PCP / PJP)
- ☐ 242 Rhizopus (all species)
- ☐ 272 Scedosporium (all species)
- ☐ 240 Zygomycetes, NOS
- ☐ 503 Suspected fungal infection
- ☐ 304 Adenovirus
- ☐ 341 BK Virus
- ☐ 344 Coronavirus (excluding COVID-19 (SARS-CoV-2))
- ☐ 350 COVID-19 (SARS-CoV-2)
- ☐ 303 Cytomegalovirus (CMV)
- ☐ 347 Chikaugunya Virus
- ☐ 346 Dengue Virus
- ☐ 325 Enterovirus (ECHO, Coxsackie)
- ☐ 327 Enterovirus D68 (EV-D68)
- ☐ 326 Enterovirus (polio)
- ☐ 328 Enterovirus, NOS
- ☐ 318 Epstein-Barr Virus (EBV)
- ☐ 306 Hepatitis A Virus
- ☐ 307 Hepatitis B Virus
- ☐ 308 Hepatitis C Virus

- ☐ 340 Hepatitis E
- ☐ 301 Herpes Simplex Virus (HSV)
- ☐ 317 Human herpesvirus 6 (HHV-6)
- ☐ 309 Human Immunodeficiency Virus 1 or 2
- ☐ 343 Human metapneumovirus
- ☐ 322 Human Papillomavirus (HPV)
- ☐ 349 Human T-lymphotropic Virus 1 or 2
- ☐ 310 Influenza, NOS
- ☐ 323 Influenza A Virus
- ☐ 324 Influenza B Virus
- ☐ 342 JC Virus (Progressive Multifocal Leukoencephalopathy (PML))
- ☐ 311 Measles Virus (Rubeola)
- ☐ 312 Mumps Virus
- ☐ 345 Norovirus
- ☐ 316 Human Parainfluenza Virus (all species)
- ☐ 314 Respiratory Syncytial Virus (RSV)
- ☐ 321 Rhinovirus (all species)
- ☐ 320 Rotavirus (all species)
- ☐ 315 Rubella Virus
- ☐ 302 Varicella Virus
- ☐ 348 West Nile Virus (WNV)
- ☐ 405 Trypanosoma cruzi (Chaga's disease)
- ☐ 404 Cryptosporidium (all species)
- ☐ 403 Giardia (lambia)
- ☐ 406 Helminths (all species)
- ☐ 407 Strongyloides stercoralis
- ☐ 402 Toxoplasma gondii
- ☐ 777 Other organism – ***Go to question 173***

173. Specify other organism: _____

174. Site *(check all that apply)*

- ☐ Blood
- ☐ Bone
- ☐ CNS
- ☐ Eyes
- ☐ Genital area

- ☐ GI tract, Lower
- ☐ GI tract, Upper
- ☐ Joints
- ☐ Liver/Spleen
- ☐ Lung
- ☐ Sinus and/or Upper respiratory tract
- ☐ Skin, cellulitis
- ☐ Skin, necrotizing fasciitis
- ☐ Urinary tract, Lower
- ☐ Urinary tract, Upper

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

Pregnancy Status

176. Was the recipient pregnant at any time in this reporting period? **(Female only)**

- ☐ Yes – **Also complete Pregnancy Form 3501**
- ☐ No – ***Go to First Name***
- ☐ Unknown – ***Go to First Name***
- ☐ Previously reported *(form 3501 already submitted for this event)* – ***Go to First Name***

177. Was the recipient's female partner pregnant at any time in this reporting period? **(Male only)**

- ☐ Yes – **Also complete Pregnancy Form 3501**
- ☐ No – ***Go to First Name***
- ☐ Unknown – ***Go to First Name***
- ☐ Previously reported *(Form 3501 already submitted for this event)* – ***Go to First Name***

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

First Name: _____

Last Name: _____

E-mail address: _____

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

YYYY MM DD