



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.**

4. Was the recipient admitted to the hospital for the cellular therapy?

- ☐ Yes – **Go to question 5**
- ☐ No– **Go to question 7**

5. Date of first hospital admission: ____ - ____ - ____
YYYY MM DD

6. Date of first discharge: ____ - ____ - ____
YYYY MM DD

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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

15. Date response established: _____ - _____ - _____
YYYY MM DD

Peripheral Blood Count Recovery

16. Was there evidence of initial recovery?

- ☐ Yes (*ANC $\geq 500/\text{mm}^3$ achieved and sustained for 3 lab values*) – **Go to question 17**
- ☐ No (*ANC $\geq 500/\text{mm}^3$ was not achieved*) – **Go to question 23**
- ☐ Not applicable (*ANC never dropped below $500/\text{mm}^3$ at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given*) – **Go to question 23**
- ☐ Previously reported (*recipient's initial recovery was recorded on a previous report*) – **Go to question 23**

17. Date ANC $\geq 500/\text{mm}^3$ (*first of 3 consecutive lab values*): _____ - _____ - _____
YYYY MM DD

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

- ☐ Yes – **Go to question 19**
- ☐ No – **Go to question 23**

19. Date of decline in ANC to $< 500/\text{mm}^3$ for ≥ 3 days (*first of 3 days that the ANC declined*):

_____ - _____ - _____
YYYY MM DD

20. Did recipient recover and maintain ANC $\geq 500/\text{mm}^3$ following the decline?

- ☐ Yes – **Go to questions 21**
- ☐ No – **Go to question 23**

21. Date of ANC recovery

- ☐ Known – **Go to questions 22**
- ☐ Unknown – **Go to question 23**

22. Date of ANC recovery: _____ - _____ - _____
YYYY MM DD

23. Was an initial platelet count $\geq 20 \times 10^9/\text{L}$ achieved?

- ☐ Yes – **Go to question 24**
- ☐ No – **Go to question 25**
- ☐ Not applicable (*platelet count never dropped below $20 \times 10^9/\text{L}$ at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given*) – **Go to question 25**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ WBC - **Go to question 34**
- ☐ Neutrophils - **Go to question 35**
- ☐ Lymphocytes - **Go to question 36**
- ☐ Hemoglobin - **Go to question 37**
- ☐ Hematocrit - **Go to question 38**
- ☐ Platelets - **Go to question 40**

34. WBC: _____ • _____ ☐ $\times 10^9/L$ ($\times 10^3/mm^3$)
☐ $\times 10^6/L$ ($\times 1/mm^3$) ($\times 1/\mu L$) (cells / μL)

35. Neutrophils: _____ %

36. Lymphocytes: _____ %

37. Hemoglobin: _____ • _____ ☐ g/dL
☐ g/L
☐ mmol/L

38. Hematocrit: _____ • _____ %

39. Were RBCs transfused ≤ 30 days before the date the sample was drawn?

- ☐ Yes
- ☐ No

40. Platelets: _____ ☐ $\times 10^9/L$ ($\times 10^3/mm^3$)
☐ $\times 10^6/L$ ($\times 1/mm^3$) ($\times 1/\mu L$) (cells / μL)

41. Were platelets transfused ≤ 7 days before the date the sample was drawn?

- ☐ Yes
- ☐ No

42. 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.

43. 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.

44. Were tests performed to detect persistence of the cellular product since the date of last report?
- ☐ Yes – **Go to question 45**
- ☐ No – **Go to question 66**
45. Was persistence evaluated by molecular assay? *(e.g. PCR)*
- ☐ Yes – **Go to question 46**
- ☐ No – **Go to question 50**
46. Date sample collected: _____
- YYYY MM DD
47. Specify the cell source *(check all that apply)*
- ☐ Bone marrow– **Go to question 49**
- ☐ Peripheral blood– **Go to question 49**
- ☐ Tumor– **Go to question 49**
- ☐ Other source– **Go to question 48**
48. Specify other cell source: _____
49. Were the infused cells detected?
- ☐ Yes
- ☐ No

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

- ☐ Yes – **Go to question 51**
- ☐ No – **Go to question 55**

51. Date sample collected: _____ — _____ — _____
 YYYY MM DD

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

- ☐ Bone marrow— **Go to question 54**
- ☐ Peripheral blood— **Go to question 54**
- ☐ Tumor— **Go to question 54**
- ☐ Other source— **Go to question 53**

53. Specify other cell source: _____

54. Were the infused cells detected?

- ☐ Yes
- ☐ No

55. Was persistence evaluated by immunohistochemistry?

- ☐ Yes – **Go to question 56**
- ☐ No – **Go to question 60**

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

60. Was persistence evaluated by another method?

- ☐ Yes - **Go to question 61**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ No – **Go to question 66**

61. Specify other method:

62. Date sample collected: _____
YYYY
MM
DD

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

- ☐ Bone marrow— **Go to question 65**
- ☐ Peripheral blood— **Go to question 65**
- ☐ Tumor— **Go to question 65**
- ☐ Other source— **Go to question 64**

64. Specify other cell source:

65. Were the infused cells detected?

- ☐ Yes
- ☐ No

66. Were B-cell counts monitored after infusion?

- ☐ Yes – **Go to question 67**
- ☐ No – **Go to question 69**

67. Was there B-cell recovery?

- ☐ Yes – **Go to question 68**
- ☐ No – **Go to question 69**
- ☐ Unknown - **Go to question 69**

68. Date of B-cell recovery: _____ - _____ - _____
YYYY MM DD

Graft vs. Host Disease

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

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

- ☐ Yes— **Go to question 70**
- ☐ No — **Go to question 71**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

☐ Unknown – **Go to question 71**

70. Date of acute GVHD diagnosis: _____ – _____ – _____ – **Go to question 72**
YYYY MM DD

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

☐ Yes– **Go to question 79**

☐ No – **Go to question 81**

☐ Unknown – **Go to question 81**

72. Overall grade of acute GVHD at diagnosis

☐ I - Rash on $\leq$ 50% of skin, no liver or gut involvement

☐ II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting

☐ III - Bilirubin 3-15 mg/dL, or gut stage 2-4, diarrhea > 1000 mL/day or severe abdominal pain with or without ileus

☐ IV - Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL

☐ Not applicable (acute GVHD present but grade is not applicable)

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

73. 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

74. 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

75. Upper intestinal tract

☐ Stage 0 – No persistent nausea or vomiting

CIBMTR Center Number: _____ CIBMTR Research ID: _____

☐ Stage 1 – Persistent nausea or vomiting

76. 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)

77. Other site(s) involved with acute GVHD

☐ Yes – **Go to question 78**

☐ No – **Go to question 79**

78. Specify other site(s): _____

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

79. 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)

80. Date maximum overall grade of acute GVHD: _____ - _____ - _____
YYY Y MM DD

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

☐ Yes – **Go to questions 82**

☐ No - **Go to question 83**

☐ Unknown – **Go to question 83**

82. Date of chronic GVHD diagnosis: _____ - _____ - _____ ☐ Date estimated
YYY Y MM DD – **Go to question 84**

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

☐ Yes – **Go to questions 84**

☐ No - **Go to question 87**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

☐ Unknown – **Go to question 87**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

YYYY

MM

DD

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

- ☐ Intravenous fluids – **Go to question 103**
- ☐ Vasopressor(s) – **Go to question 100**
- ☐ Other – **Go to question 99**

99. Specify other therapy: _____

100. Specify the number of vasopressors used for therapy

- ☐ 1
- ☐ ≥ 2

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

- ☐ Phenylephrine
- ☐ Norepinephrine
- ☐ Epinephrine
- ☐ Dopamine
- ☐ Vasopressin
- ☐ Other – **Go to question 102**

102. Specify other vasopressor: _____

103. Was hypotension controlled with therapy?

- ☐ Yes
- ☐ No
- ☐ Unknown

104. Date of hypoxia onset for minimal supplemental oxygen ($FiO_2 < 40\%$): _____ - _____ - _____
YYYY MM DD

105. Date of hypoxia onset for more than minimal supplemental oxygen ($FiO_2 \geq 40\%$):

_____ - _____ - _____
YYYY MM DD

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

- ☐ Yes - **Go to question 107**
- ☐ No - **Go to question 108**
- ☐ Unknown – **Go to question 108**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

107. Date started: _____ - _____ - _____
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

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

☐ Yes – **Go to question 111**

☐ No – **Go to question 121**

111. Date of MAS / HLH onset: _____ - _____ - _____
YYYY MM DD

112. Did the recipient have splenomegaly?

☐ Yes

☐ No

113. Was MAS / HLH confirmed by a bone marrow biopsy or a bone marrow aspirate?

☐ Yes

☐ No

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

☐ Fibrinogen—**Go to question 115**

☐ Triglyceride—**Go to question 117**

☐ None - **Go to question 119**

115. Lowest fibrinogen level: _____ . _____

☐ mg/dL

☐ mg/L

116. Date fibrinogen sample collected: _____ - _____ - _____
YYYY MM DD

117. Highest triglyceride level: _____ . _____

CIBMTR Center Number: _____ CIBMTR Research ID: _____

☐ mg/dL

☐ mmol/L

118. Date triglyceride sample collected: _____ - _____ - _____
YYY YYY MM DD

119. Did macrophage activation syndrome (MAS) / hemophagocytic lymphohistiocytosis (HLH) resolve?

☐ Yes—**Go to question 120**

☐ No—**Go to question 121**

120. Date resolved: _____ - _____ - _____
YYY YYY MM DD

Neurotoxicity (ICANS)

121. Did the recipient experience neurotoxicity (ICANS)?

☐ Yes—**Go to question 122**

☐ No—**Go to question 161**

122. Was the date of onset previously reported?

☐ Yes—**Go to question 124**

☐ No—**Go to question 123**

123. Date of neurotoxicity (ICANS) onset: _____ - _____ - _____
YYY YYY MM DD

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

☐ Anakinra—**Go to question 126**

☐ Anti-epileptics—**Go to question 126**

☐ Corticosteroids—**Go to question 126**

☐ Corticosteroids - Pulse dose (*methylprednisolone 1000mg/day or equivalent*)—**Go to question 126**

☐ Siltuximab—**Go to question 126**

☐ Tocilizumab—**Go to question 126**

☐ Other therapy—**Go to question 125**

☐ No therapy given—**Go to question 126**

125. Specify other therapy: _____

126. Which cognitive assessment was performed?

☐ CARTOX—**Go to question 127**

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- ☐ ICE –**Go to question 127**
- ☐ None –**Go to question 128**

127. What was the lowest score?

- ☐ 10
- ☐ 9
- ☐ 8
- ☐ 7
- ☐ 6
- ☐ 5
- ☐ 4
- ☐ 3
- ☐ 2
- ☐ 1
- ☐ 0
- ☐ Unable to complete assessment

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

128. Indicate the manifestations of neurotoxicity (ICANS) (*check all that apply*)

- ☐ Cerebral edema - **go to question 130**
- ☐ Cerebrovascular accident (*stroke*) - **go to question 133**
- ☐ Cognitive impairment- **go to question 135**
- ☐ Depressed level of consciousness - **go to question 140**
- ☐ Motor neuron disorder- **go to question 142**
- ☐ Movement disorder- **go to question 146**
- ☐ Personality change- **go to question 150**
- ☐ Seizure- **go to question 154**
- ☐ Speech impairment - **go to question 157**
- ☐ Other manifestation- **go to question 129**

129. Specify other manifestation: _____

130. 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

131. Did cerebral edema resolve?

CIBMTR Center Number: _____ CIBMTR Research ID: _____

☐ Yes—**Go to question 132**

☐ No—**Go to question 133**

132. Date resolved: _____ - _____ - _____
 YYYY MM DD

133. Date of cerebrovascular accident onset: _____ - _____ - _____
 YYYY MM DD

134. Specify type of cerebrovascular accident

☐ Hemorrhagic

☐ Ischemic

135. Specify type of cognitive impairment (*check all that apply*)

☐ Amnesia —**Go to question 137**

☐ Cognitive disorder—**Go to question 137**

☐ Concentration impairment —**Go to question 137**

☐ Confusional state —**Go to question 137**

☐ Encephalopathy—**Go to question 137**

☐ Hallucination —**Go to question 137**

☐ Leukoencephalopathy—**Go to question 137**

☐ Loss of consciousness —**Go to question 137**

☐ Mental status changes—**Go to question 137**

☐ Noninfective encephalitis—**Go to question 137**

☐ Psychomotor retardation—**Go to question 137**

☐ Other cognitive impairment—**Go to question 136**

136. Specify other cognitive impairment: _____

137. Did the cognitive impairment resolve?

☐ Yes—**Go to question 138**

☐ No—**Go to question 139**

138. Date resolved: _____ - _____ - _____
 YYYY MM DD

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

☐ Awakens spontaneously

☐ Awakens to voice

CIBMTR Center Number: CIBMTR Research ID:

- ☐ Awakens only to tactile stimulus
- ☐ Patient unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma

140. Did the depressed level of consciousness resolve?

- ☐ Yes—**Go to question 141**
- ☐ No—**Go to question 142**

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

142. Specify type of motor neuron disorder *(check all that apply)*

- ☐ Facial weakness / paralysis—**Go to question 144**
- ☐ Guillain-Barre syndrome —**Go to question 144**
- ☐ Hemiparesis—**Go to question 144**
- ☐ Myelitis —**Go to question 144**
- ☐ Paraparesis —**Go to question 144**
- ☐ Other motor neuron disorder—**Go to question 143**

143. Specify other motor neuron disorder:

144. Did the motor neuron disorder resolve?

- ☐ Yes—**Go to question 145**
- ☐ No—**Go to question 146**

145. Date resolved: ____ - ____ - ____
YYYY MM DD

146. Specify type of movement disorder (*check all that apply*)

- ☐ Action tremor—***Go to question 148***
- ☐ Ataxia —***Go to question 148***
- ☐ Cogwheel rigidity—***Go to question 148***
- ☐ Dysgraphia —***Go to question 148***
- ☐ Dyskinesia—***Go to question 148***
- ☐ Dysmetria—***Go to question 148***
- ☐ Gait disturbance —***Go to question 148***
- ☐ Myoclonus—***Go to question 148***
- ☐ Resting tremor—***Go to question 148***
- ☐ Other movement disorder—***Go to question 147***

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147. Specify other movement disorder: _____

148. Did the movement disorder resolve?

- ☐ Yes—**Go to question 149**
☐ No—**Go to question 150**

149. Date resolved: _____ - _____ - _____
YYYY MM DD

150. Specify type of personality change(s) (*check all that apply*)

- ☐ Flat affect—**Go to question 152**
☐ Personality change —**Go to question 152**
☐ Other personality change—**Go to question 151**

151. Specify other personality change: _____

152. Did the personality change(s) resolve?

- ☐ Yes—**Go to question 153**
☐ No—**Go to question 154**

153. Date resolved: _____ - _____ - _____
YYYY MM DD

154. Specify type of seizure

- ☐ Complex partial – **Go to question 156**
☐ Generalized tonic-clonic – **Go to question 156**
☐ Non-convulsive status epilepticus – **Go to question 156**
☐ Simple partial – **Go to question 156**
☐ Status epilepticus – **Go to question 156**
☐ Other type – **Go to question 155**
☐ Unknown – **Go to question 156**

155. Specify other type: _____

156. 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*)

157. Specify type of speech impairment

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- ☐ Aphasia—**Go to question 159**
- ☐ Dysphasia —**Go to question 158**

158. Specify 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*)

159. Did neurotoxicity (ICANS) resolve?

- ☐ Yes—**Go to question 160**
- ☐ No—**Go to question 161**

160. Date resolved: _____ - _____ - _____
 YYYY MM DD

Other toxicities

161. Hypogammaglobulinemia

- ☐ Yes - **Go to question 162**
- ☐ No - **Go to question 166**
- ☐ Unknown - **Go to question 166**

162. Was the date of onset previously reported?

- ☐ Yes—**Go to question 164**
- ☐ No —**Go to question 163**

163. Date of onset: _____ - _____ - _____
 YYYY MM DD

164. Did hypogammaglobulinemia resolve?

- ☐ Yes —**Go to question 165**
- ☐ No —**Go to question 166**

165. Date resolved: _____ - _____ - _____
 YYYY MM DD

166. Did recipient require immunoglobulin replacement therapy?

- ☐ Yes—**Go to question 167**
- ☐ No—**Go to question 168**

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167. Is the recipient still requiring replacement therapy?

- ☐ Yes
☐ No

168. Tumor lysis syndrome

- ☐ Yes - **Go to question 169**
☐ No - **Go to question 174**
☐ Unknown - **Go to question 174**

169. Was the date of onset previously reported?

- ☐ Yes—**Go to question 171**
☐ No —**Go to question 170**

170. Date of onset: _____ - _____ - _____
 YYYY MM DD

171. Grade

- ☐ 3
☐ 4
☐ 5

172. Did tumor lysis syndrome resolve?

- ☐ Yes —**Go to question 173**
☐ No —**Go to question 174**

173. Date resolved: _____ - _____ - _____
 YYYY MM DD

174. Other toxicity

- ☐ Yes —**Go to question 175**
☐ No —**Go to question 180**
☐ Unknown—**Go to question 180**

Copy and complete questions 175– 179 to report more than one toxicity

175. Specify other toxicity: _____

176. Was the date of onset previously reported?

- ☐ Yes —**Go to question 178**
☐ No —**Go to question 177**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

177. Date of onset: _____ - _____ - _____
YYYY MM DD

178. Did the other toxicity resolve?

- ☐ Yes –**Go to question 179**
☐ No –**Go to question 180**

179. Date resolved: _____ - _____ - _____
YYYY MM DD

Copy and complete questions 175– 179 to report more than one toxicity

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

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

- ☐ Yes - **Go to question 181**
☐ No - **Go to question 187**
☐ Unknown - **Go to question 187**

Copy and complete questions 181- 186 to report more than one grade 3 organ toxicity

181. Specify organ

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

182. Specify the toxicity

- ☐ Abdominal pain
☐ Acute kidney injury
☐ Acute respiratory distress syndrome
☐ Alanine aminotransferase increased (ALT)
☐ Alkaline phosphatase increased
☐ Anorexia
☐ Arthralgia (joint pain)

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ Aspartate aminotransferase increased (AST)
- ☐ Blood bilirubin increased
- ☐ Capillary leak syndrome
- ☐ Cardiac arrhythmia
- ☐ Chills
- ☐ Chronic kidney disease
- ☐ Constipation
- ☐ Cystitis noninfective
- ☐ Diarrhea
- ☐ Dizziness
- ☐ Dysgeusia (taste alteration)
- ☐ Dyspepsia (heartburn)
- ☐ 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 area (not due to neuropathy)
- ☐ Myalgia (muscle pain)
- ☐ Myocardial infarction
- ☐ Nausea
- ☐ New or worsening heart failure
- ☐ Pericardial effusion
- ☐ Pericarditis
- ☐ Productive cough
- ☐ Pulmonary edema
- ☐ Respiratory failure
- ☐ Restrictive cardiomyopathy

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ Thromboembolic event
- ☐ Tremor
- ☐ Vomiting

183. Was the date of onset previously reported?

- ☐ Yes- **Go to question 185**
- ☐ No - **Go to question 184**

184. Date of onset: _____ - _____ - _____
 YYYY MM DD

185. Did the grade 3 toxicity resolve?

- ☐ Yes –**Go to question 186**
- ☐ No –**Go to question 187**

186. Date resolved: _____ - _____ - _____
 YYYY MM DD

Copy and complete questions 181- 186 to report more than one grade 3 organ toxicity

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

- ☐ Yes - **Go to question 188**
- ☐ No - **Go to question 194**
- ☐ Unknown - **Go to question 194**

Copy and complete questions 188- 193 to report more than one grade 4 organ toxicity

188. Specify organ

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

189. Specify the toxicity

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ Abdominal pain
- ☐ Acute kidney injury
- ☐ Acute respiratory distress syndrome
- ☐ Alanine aminotransferase increased (ALT)
- ☐ Alkaline phosphatase increased
- ☐ Anorexia
- ☐ Arthralgia (joint pain)
- ☐ Aspartate aminotransferase increased (AST)
- ☐ Blood bilirubin increased
- ☐ Capillary leak syndrome
- ☐ Cardiac arrhythmia
- ☐ Chills
- ☐ Chronic kidney disease
- ☐ Constipation
- ☐ Cystitis noninfective
- ☐ Diarrhea
- ☐ Dizziness
- ☐ Dysgeusia (taste alteration)
- ☐ Dyspepsia (heartburn)
- ☐ 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 (not due to neuropathy)
- ☐ Myalgia (muscle pain)
- ☐ Myocardial infarction
- ☐ Nausea

CIBMTR Center Number: _____

CIBMTR Research ID: _____

- ☐ New or worsening heart failure
- ☐ Pericardial effusion
- ☐ Pericarditis
- ☐ Productive cough
- ☐ Pulmonary edema
- ☐ Respiratory failure
- ☐ Restrictive cardiomyopathy
- ☐ Thromboembolic event
- ☐ Tremor
- ☐ Vomiting

190. Was the date of onset previously reported?

- ☐ Yes- **Go to question 192**
- ☐ No - **Go to question 191**

191. Date of onset: _____ - _____ - _____
 YYYY MM DD

192. Did the grade 4 toxicity resolve?

- ☐ Yes –**Go to question 193**
- ☐ No –**Go to question 194**

193. Date resolved: _____ - _____ - _____
 YYYY MM DD

Copy and complete questions 188- 193 to report more than one grade 4 organ toxicity

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

- ☐ C-reactive protein –**Go to question 195**
- ☐ Interleukin-6 –**Go to question 198**
- ☐ Soluble interleukin-2 receptor α (*sIL2RA* or *soluble CD25*) –**Go to question 200**
- ☐ Total serum ferritin –**Go to question 202**
- ☐ None –**Go to question 204**

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

195. Maximum C-reactive protein: ____ . ____
□ mg/dL

CIBMTR Center Number: _____ CIBMTR Research ID: _____

☐ mg/L

196. Date C-reactive protein collected: _____ - _____ - _____
YYYY MM DD

197. C-reactive protein upper limit of normal for your institution: : _____ • _____

198. Maximum interleukin-6: _____

☐ pg/mL

☐ IU/mL

199. Date Interleukin-6 collected: _____ - _____ - _____
YYYY MM DD

200. Maximum soluble interleukin-2 receptor α : _____

☐ pg/mL

☐ IU/mL

☐ U/mL

201. Date soluble interleukin-2 receptor α collected: _____ - _____ - _____
YYYY MM DD

202. Maximum total serum ferritin: _____ ng/mL (μ g/L)

203. Date serum ferritin collected: _____ - _____ - _____
YYYY MM DD

Infection

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

☐ Yes – **Go to question 205**

☐ No – **Go to question 209**

Report each infection organism, site, and date of diagnosis

Copy and complete questions 205-208 to report more than one infection

205. Organism

☐ 121 Acinetobacter (all species)

☐ 125 Bordetella pertussis (whooping cough)

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ 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 chelonae*
- ☐ 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*

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ 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 mucilaginosus
- ☐ 181 Streptococcus, alpha-hemolytic
- ☐ 182 Streptococcus, Group B
- ☐ 178 Streptococcus pneumoniae
- ☐ 168 Treponema (syphilis)
- ☐ 169 Vibrio (all species)
- ☐ 502 Suspected bacterial infection
- ☐ 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)

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ 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 Chikungunya 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)

CIBMTR Research ID: _____

- ☐ 320 Rotavirus (all species)
- ☐ 315 Rubella Virus
- ☐ 302 Varicella Virus
- ☐ 348 West Nile Virus (WNV)
- ☐ 504 Suspected viral infection
- ☐ 405 Trypanosoma cruzi (Chaga's disease)
- ☐ 404 Cryptosporidium (all species)
- ☐ 403 Giardia (lamblia)
- ☐ 406 Helminths (all species)
- ☐ 407 Strongyloides stercoralis
- ☐ 402 Toxoplasma gondii
- ☐ 777 Other organism – **Go to question 206**

206. Specify other organism: _____

207. 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

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

Copy and complete questions 205-208 to report more than one infection

209. Was a vaccine for COVID-19 (SARS-CoV-2) received since the date of last report?

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CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ Yes – **Go to question 210**
- ☐ No – **Go to question 214**
- ☐ Unknown – **Go to question 214**

Copy and complete questions 210-213 to report all vaccine doses received

210. Specify vaccine brand:

- ☐ AstraZeneca– **Go to question 212**
- ☐ Johnson & Johnson's / Janssen– **Go to question 212**
- ☐ Moderna– **Go to question 212**
- ☐ Novavax – **Go to question 212**
- ☐ Pfizer-BioNTech– **Go to question 212**
- ☐ Other type – **Go to question 211**

211. Specify other type: _____

212. Select dose(s) received

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

213. Date received: _____ ☐ Date estimated

YYYY MM DD

Copy and complete questions 210-213 to report all vaccine doses received

Pregnancy Status

214. 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**

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

CIBMTR Center Number: _____ CIBMTR Research ID: _____

- ☐ 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***

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ – ____ – ____

YYYY

MM

DD