Post-Cellular Therapy Essential Data

CIBMTR®
A RESEARCH COLLABORATION BETWEEN THE MEDICAL COLLEGE OF WISCONSIN AND NMDP

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: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Survival

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

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

2. Specify the recipient's survival status at the date of last contact
   - ☐ Alive - Answers to subsequent questions should reflect clinical status.
   - ☐ Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete 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.

3. Did the recipient receive a subsequent infusion?
   - ☐ Yes – Also complete Indication for CIBMTR Data Reporting Form 2814.
   - ☐ No

Best Response to Cellular Therapy

4. 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
   - ☐ Not evaluated

5. Was the date of best response previously reported?
   - ☐ Yes – ***Go to question 7***
   - ☐ No – ***Go to question 6***

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

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

Peripheral Blood Count Recovery

7. Was there evidence of initial recovery?
   - ☐ Yes (*ANC ≥ 500/mm3 achieved and sustained for 3 lab values)* – ***Go to question 8***
   - ☐ No *(ANC ≥ 500/mm^3 was not achieved)* – ***Go to question 13***
   - ☐ 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 13***
   - ☐ Previously reported *(recipient's initial recovery was recorded on a previous report)* – ***Go to question 13***

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

9. Following the initial recovery, was there subsequent decline in ANC to < 500/mm^3 for ≥ 3 days?
   - ☐ Yes – ***Go to question 10***
   - ☐ No– ***Go to question 13***

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

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

11. Did recipient recover and maintain ANC ≥ 500/mm^3 following the decline?
    - ☐ Yes – ***Go to questions 12***
    - ☐ No – ***Go to question 13***

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

13. Was an initial platelet count ≥ 20 x 10^9/L achieved?
    - ☐ Yes – ***Go to question 14***
    - ☐ No – ***Go to question 19***
    - ☐ 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 19***
    - ☐ Previously reported *(≥ 20 x 10^9/L was achieved and reported previously)* – ***Go to question 19***

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

15. Following the initial platelet recovery, was there subsequent decline in platelets to < 20 x 10^9/L for ≥3 days?

☐ Yes – ***Go to questions 16***

☐ No – ***Go to questions 19***

16. Date of decline in platelets to < 20 x 10^9/L for ≥ 3 days: *(first of 3 days that the platelets declined)*
___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

17. Did recipient recover and maintain platelets ≥ 20 x 10^9/L following the decline?

☐ Yes – ***Go to questions 18***

☐ No – ***Go to questions 19***

18. Date of platelet recovery:___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Disease Relapse or Progression

19. Was a disease relapse or progression detected?

☐ Yes – ***Go to question 20***

☐ No - ***Go to question 21***

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

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

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

21. 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)*

Autoimmune Disorder

22. Was a subsequent autoimmune disorder diagnosed?

☐ Yes – ***Go to question 23***

☐ No – ***Go to question 26***

23. Specify the autoimmune disorder

- ☐ Autoimmune cytopenias *(e.g. immune-mediated thrombocytopenia, autoimmune hemolytic anemia, autoimmune neutropenia)* – ***Go to question 25***
- ☐ Colitis – ***Go to question 25***
- ☐ Hepatitis – ***Go to question 25***
- ☐ Nephritis – ***Go to question 25***
- ☐ Pneumonitis – ***Go to question 25***
- ☐ Thyroiditis – ***Go to question 25***
- ☐ Other autoimmune disorder – ***Go to question 24***

24. Specify other autoimmune disorder: _____

25. Date of diagnosis: __ __ __ __ - __ __ - __ __
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.

26. Did acute GVHD develop?

- ☐ Yes– ***Go to question 27***
- ☐ No – ***Go to question 28***
- ☐ Unknown – ***Go to question 28***

27. Date of acute GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 29***
YYYY MM DD

28. Did acute GVHD persist?

- ☐ Yes– ***Go to question 36***
- ☐ No – ***Go to question 44***
- ☐ Unknown – ***Go to question 44***

29. 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 (adult) / diarrhea 280-555 mL/m^2/day or 10-19.9 mL/kg/day (pediatric)*
- ☐ III - *Bilirubin 3-15 mg/dL, or diarrhea > 1000 mL/day or severe abdominal pain with or without ileus and/or grossly bloody stool (adult) / 556-833+ mL/m^2/day or 20-30+ mL/kg/day or severe abdominal pain, with or without ileus, and / or grossly bloody stool*
- ☐ 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.

30. Skin *(at diagnosis)*
    - ☐ Stage 0 – *No rash, no rash attributable to acute GVHD*
    - ☐ Stage 1 – *Rash on < 25% of skin*
    - ☐ Stage 2 – *Rash on 25–50% of skin*
    - ☐ Stage 3 – *Rash on > 50% of skin*
    - ☐ Stage 4 – *Generalized erythroderma with bullous formation*

31. Lower intestinal tract *(at diagnosis)*
    - ☐ Stage 0 – *No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult) / <280 mL/m^2/day or <10 mL/kg/day (pediatric)*
    - ☐ Stage 1 – *Diarrhea 500 - 1000 mL/day (adult) / 280-555 mL/m^2/day or 10 - 19.9 mL/kg/day (pediatric)*
    - ☐ Stage 2 – *Diarrhea >1000 mL/day (adult) / 556-833 mL/m^2/day or 20 - 30 mL/kg/day (pediatric)*
    - ☐ Stage 3 – *Diarrhea > 1500 mL/day (adult), / >833 mL/m^2/day or > 30 mL/kg/day (pediatric)*
    - ☐ Stage 4 – *Severe abdominal pain, with or without ileus, and / or grossly bloody stool*

32. Upper intestinal tract *(at diagnosis)*
    - ☐ Stage 0 – *No persistent nausea or vomiting*
    - ☐ Stage 1 – *Persistent nausea or vomiting*

33. Liver *(at diagnosis)*
    - ☐ 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)*

34. Other site(s) involved with acute GVHD
    - ☐ Yes – ***Go to question 35***
    - ☐ No – ***Go to question 36***

35. Specify other site(s): _____

Specify the maximum overall grade and maximum organ staging of acute GVHD.

36. 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 (adult) / diarrhea 280-555 mL/m^2/day or 10-19.9 mL/kg/day (pediatric)*
- ☐ III - *Bilirubin 3-15 mg/dL or diarrhea > 1000 mL/day or severe abdominal pain with or without ileus and / or grossly bloody stool (adult) / 556-833+ mL/m^2/day or 20-30+ mL/kg/day or severe abdominal pain, with or without ileus, and / or grossly bloody stool (pediatric)*
- ☐ IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL*
- ☐ Not applicable *(acute GVHD present but cannot be graded)*

37. First date of maximum overall grade of acute GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

38. Skin *(maximum stage)*

- ☐ Stage 0 – *No rash, no rash attributable to acute GVHD*
- ☐ Stage 1 – *Rash on < 25% of skin*
- ☐ Stage 2 – *Rash on 25–50% of skin*
- ☐ Stage 3 – *Rash on > 50% of skin*
- ☐ Stage 4 – *Generalized erythroderma with bullous formation*

39. Lower intestinal tract *(maximum stage)*

- ☐ Stage 0 – *No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult) / <280 mL/m^2/day or <10 mL/kg/day (pediatric)*
- ☐ Stage 1 – *Diarrhea 500 - 1000 mL/day (adult) / 280-555 mL/m^2/day or 10 - 19.9 mL/kg/day (pediatric)*
- ☐ Stage 2 – *Diarrhea >1000 mL/day (adult) / 556-833 mL/m^2/day or 20 - 30 mL/kg/day (pediatric)*
- ☐ Stage 3 – *Diarrhea > 1500 mL/day (adult) / >833 mL/m^2/day or > 30 mL/kg/day (pediatric)*
- ☐ Stage 4 – *Severe abdominal pain, with or without ileus, and / or grossly bloody stool*

40. Upper intestinal tract *(maximum stage)*

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

41. Liver *(maximum stage)*

- ☐ 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)*

42. Other site(s) involved with acute GVHD

- ☐ Yes – ***Go to question 43***
- ☐ No – ***Go to question 44***

43. Specify other site(s):_____

44. Did chronic GVHD develop?

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

45. Date of chronic GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 47***
YYYY MM DD

46. Did chronic GVHD persist?

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

Specify the maximum overall grade of chronic GVHD.

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

- ☐ Mild
- ☐ Moderate
- ☐ Severe

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

49. 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 *(recipient did not receive systemic steroids within the reporting period)*
- ☐ Unknown

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

- ☐ Yes
- ☐ No
- ☐ Not applicable *(recipient did not receive non-steroid immunosuppressive agents within the reporting period)*

☐ Unknown

Toxicities

Cytokine Release Syndrome (CRS)

51. Did the recipient experience cytokine release syndrome (CRS)?
    - ☐ Yes – ***Go to question 52***
    - ☐ No – ***Go to question 81***

Copy and complete questions 52 - 80 to report multiple CRS events in this reporting period.

52. Was the date of diagnosis previously reported?
    - ☐ Yes– ***Go to question 54***
    - ☐ No – ***Go to question 53***

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

54. Specify therapy given for CRS *(check all that apply)*
    - ☐ Anakinra – ***Go to question 56***
    - ☐ Corticosteroids – ***Go to question 56***
    - ☐ Corticosteroids - pulse dose *(methylprednisolone 1000 mg/day or equivalent)* – ***Go to question 56***
    - ☐ Dasatinib – ***Go to question 56***
    - ☐ Emapalumab – ***Go to question 56***
    - ☐ Etoposide – ***Go to question 56***
    - ☐ Ruxolitinib– ***Go to question 56***
    - ☐ Siltuximab – ***Go to question 56***
    - ☐ Tocilizumab – ***Go to question 56***
    - ☐ Other therapy – ***Go to question 55***
    - ☐ No therapy given – ***Go to question 58***

55. Specify other therapy: _____

56. Start date of first therapy: __ __ __ __ - __ __ - __ __
    YYYY MM DD

57. Doses of tocilizumab given
    - ☐ 1
    - ☐ ≥ 2

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

- ☐ Fevers *(≥ 100.4 F or ≥ 38 C)* – ***Go to question 59***
- ☐ Hypotension requiring therapy – ***Go to question 60***
- ☐ Hypoxia requiring minimal supplemental oxygen *(FiO2 < 40%)* – ***Go to question 67***
- ☐ Hypoxia requiring more than minimal supplemental oxygen *(FiO2 ≥ 40%)* – ***Go to question 68***

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

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

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

- ☐ Intravenous fluids – ***Go to question 66***
- ☐ Vasopressor(s) – ***Go to question 63***
- ☐ Other – ***Go to question 62***

62. Specify other therapy: _____

63. Specify the number of vasopressors used for therapy

- ☐ 1
- ☐ ≥ 2

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

- ☐ Dopamine – ***Go to question 66***
- ☐ Epinephrine – ***Go to question 66***
- ☐ Norepinephrine – ***Go to question 66***
- ☐ Phenylephrine – ***Go to question 66***
- ☐ Vasopressin – ***Go to question 66***
- ☐ Other – ***Go to question 65***

65. Specify other vasopressor: _____

66. Was hypotension controlled with therapy?

- ☐ Yes
- ☐ No

67. Date of hypoxia onset for minimal supplemental oxygen: *(FiO2 < 40%)*

___ ___ ___ ___ - ___ ___ - ___ ___

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

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

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

- ☐ C-reactive protein **– *Go to question 70***
- ☐ Interleukin-6 **– *Go to question 73***
- ☐ Total serum ferritin **– *Go to question 75***
- ☐ None **– *Go to question 77***

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

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

72. C-reactive protein upper limit of normal for your institution: ___ ___ ___ ___ ___ • ___

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

74. Date interleukin-6 collected: ___ ___ ___ ___ - ___ ___ - ___ ___
    YYYY MM DD

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

76. Date total serum ferritin collected: ___ ___ ___ ___ - ___ ___ - ___ ___
    YYYY MM DD

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

- ☐ Yes - ***Go to question 78***
- ☐ No - ***Go to question 79***

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

79. Did cytokine release syndrome resolve?

- ☐ Yes – ***Go to question 80***
- ☐ No – ***Go to question 81***

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

Copy and complete questions 52 - 80 to report multiple CRS events in this reporting period.

Immune Effector Cell-Associated Hemophagocytic Lymphohistiocytosis-Like Syndrome (IEC-HS)

81. Were features consistent with immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS) present?

- ☐ Yes – ***Go to question 82***
- ☐ No – ***Go to question 113***

82. Date of IEC-HS onset: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

83. Specify therapy given for IEC-HS *(check all that apply)*

- ☐ Anakinra – ***Go to question 85***
- ☐ Corticosteroids **– *Go to question 85***
- ☐ Corticosteroids - pulse dose *(methylprednisolone 1000 mg/day or equivalent)* – ***Go to question 85***
- ☐ Emapalumab – ***Go to question 85***
- ☐ Etoposide – ***Go to question 85***
- ☐ Ruxolitinib– ***Go to question 85***
- ☐ Other therapy – ***Go to question 84***
- ☐ No therapy given – ***Go to question 86***

84. Specify other therapy: _____

85. Date of last dose of therapy: __ __ __ __ - __ __ - __ __
YYYY MM DD

IEC-HS clinical features

86. Did the recipient have splenomegaly?

- ☐ Yes
- ☐ No

87. Was hemophagocytosis confirmed by a bone marrow biopsy or a bone marrow aspirate?

☐ Yes

☐ No

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

☐ AST (SGOT) – ***Go to question 89***

☐ ALT (SGPT) – ***Go to question 91***

☐ CXCL9 – ***Go to question 93***

☐ Direct bilirubin – ***Go to question 95***

☐ Fibrinogen – ***Go to question 97***

☐ LDH – ***Go to question 98***

☐ Prothrombin time (PT) – ***Go to question 100***

☐ Partial thromboplastin (PTT) – ***Go to question 102***

☐ Soluble interleukin-2 receptor α *(sIL2RA or soluble CD25)* – ***Go to question 104***

☐ Total serum ferritin – ***Go to question 106***

☐ Triglyceride – ***Go to question 108***

☐ None - ***Go to question 109***

89. Maximum AST (SGOT): __ __ __ . __ __

☐ U/L

☐ µkat/L

90. Upper limit of normal for your institution: __ __ __ . __ __

91. Maximum ALT (SGPT): __ __ __ . __ __

☐ U/L

☐ µkat/L

92. Upper limit of normal for your institution: __ __ __ . __ __

93. Maximum CXCL-9: __ __ __ . __ __ pg/mL

94. Upper limit of normal for your institution: __ __ __ . __ __

95. Maximum direct bilirubin: __ __ __ . __

☐ mg/dL

☐ µmol/L

96. Upper limit of normal for your institution: __ __ __ . __

97. Lowest fibrinogen level: ___ ___ ___ . ___

- ☐ mg/dL
- ☐ mg/L

98. Maximum LDH: __ __ __ __ __ . __ __

- ☐ U/L
- ☐ µkat/L

99. Upper limit of normal for your institution: __ __ __ __ __ . __ __

100. Maximum prothrombin time (PT) :___ ___. ___ ___ seconds

101. Upper limit of normal for your institution: __ __ __ __ __ . __ __

102. Maximum partial thromboplastin (PTT):___ ___. ___ ___ seconds

103. Upper limit of normal for your institution: __ __ __ __ __ . __ __

104. Maximum soluble interleukin-2 receptor α: ___ ___ ___ ___ ___

- ☐ pg/mL
- ☐ IU/mL
- ☐ U/mL

105. Date soluble interleukin-2 receptor α collected: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

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

107. Date total serum ferritin collected: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

108. Maximum triglyceride level: ___ ___ ___ . ___ ___

- ☐ mg/dL
- ☐ mmol/L

109. Was there a fever associated with IEC-HS?

- ☐ Yes
- ☐ No
- ☐ Unknown

110. Were there organ toxicities associated with IEC-HS? *(check all that apply)*

- ☐ Direct hyperbilirubinemia
- ☐ Hepatic transaminase elevation *(>5 x ULN (if baseline was normal) or >5 x baseline if baseline was abnormal)*
- ☐ Hypoxia
- ☐ Pulmonary edema
- ☐ Pulmonary infiltrates
- ☐ Renal insufficiency

111. Did IEC-HS resolve?

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

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

Neurotoxicity

ICANS

113. Did the recipient experience immune effector cell-associated neurotoxicity syndrome (ICANS)?

- ☐ Yes – ***Go to question 114***
- ☐ No – ***Go to question 127***

Copy and complete questions 114 – 126 to report multiple ICANS events in this reporting period.

114. Was the date of onset previously reported?

- ☐ Yes – ***Go to question 116***
- ☐ No – ***Go to question 115***

115. Date of ICANS onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

116. Specify therapy given for ICANS *(check all that apply)*

- ☐ Anakinra –***Go to question 118***
- ☐ Anti-epileptics –***Go to question 118***
- ☐ Corticosteroids –***Go to question 118***

- ☐ Corticosteroids - pulse dose *(methylprednisolone 1000 mg/day or equivalent)* – ***Go to question 118***
- ☐ Siltuximab –***Go to question 118***
- ☐ Other therapy – ***Go to question 117***
- ☐ No therapy given –***Go to question 118***

117. Specify other therapy: _____

118. What was the lowest ICE score?

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

For manifestations of ICANS, report the MAXIMUM grade observed for this event.

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

- ☐ Cerebral edema - ***Go to question 120***
- ☐ Depressed level of consciousness - ***Go to question 121***
- ☐ Motor findings - ***Go to question 122***
- ☐ Seizure - ***Go to question 124***

120. Specify type of cerebral edema

- ☐ Clinical concern for cerebral edema / elevated intracranial pressure
- ☐ Diffuse cerebral edema on neuroimaging
- ☐ Focal / local edema on neuroimaging

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

- ☐ Awakens spontaneously
- ☐ Awakens to voice
- ☐ Awakens only to tactile stimulus

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

122. Specify type of motor findings *(check all that apply)*

☐ Hemiparesis – ***Go to question 124***

☐ Paraparesis – ***Go to question 124***

☐ Other motor neuron disorder – ***Go to question 123***

123. Specify other motor neuron disorder: _____

124. 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)*

125. Did ICANS resolve?

☐ Yes – ***Go to question 126***

☐ No – ***Go to question 127***

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

Copy and complete questions 114 – 126 to report multiple ICANS events in this reporting period.

Parkinsonism

127. Did the recipient experience parkinsonism?

☐ Yes – ***Go to question 128***

☐ No – ***Go to question 136***

Copy and complete questions 128 – 135 to report multiple parkinsonism events in this reporting period.

128. Was the date of onset previously reported?

☐ Yes – ***Go to question 130***

☐ No – ***Go to question 129***

129. Date of parkinsonism onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

130. Specify therapy given for parkinsonism *(check all that apply)*

☐ Anakinra –***Go to question 132***

- ☐ Corticosteroids –***Go to question 132***
- ☐ Corticosteroids-pulse dose *(methylprednisolone 1000 mg/day or equivalent)* – ***Go to question 132***
- ☐ Cyclophosphamide –***Go to question 132***
- ☐ IT chemotherapy –***Go to question 132***
- ☐ Ruxolitinib –***Go to question 132***
- ☐ Other therapy –***Go to question 131***
- ☐ No therapy given –***Go to question 132***

131. Specify other therapy: _____

132. Indicate the manifestations of parkinsonism *(check all that apply)*

- ☐ Anosmia– ***Go to question 134***
- ☐ Bradykinesia – ***Go to question 134***
- ☐ Dyskinesia – ***Go to question 134***
- ☐ Flat affect – ***Go to question 134***
- ☐ Gait disturbance – ***Go to question 134***
- ☐ Impaired swallowing – ***Go to question 134***
- ☐ Resting tremor– ***Go to question 134***
- ☐ Rigidity – ***Go to question 134***
- ☐ Other manifestation – ***Go to question 133***

133. Specify other manifestation: _____

134. Did parkinsonism resolve?

- ☐ Yes – ***Go to question 135***
- ☐ No – ***Go to question 136***

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

Copy and complete questions 128 – 135 to report multiple parkinsonism events in this reporting period.

Cranial nerve palsy (III, VI, VII)

136. Did the recipient experience cranial nerve palsy (III, VI, VII)?

- ☐ Yes – ***Go to question 137***
- ☐ No – ***Go to question 143***

137. Was the date of onset previously reported?

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

138. Date of cranial nerve palsy onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

139. Specify therapy given for cranial nerve palsy (III, VI, VII) *(check all that apply)*

- ☐ Anakinra – ***Go to question 141***
- ☐ Anti-epileptics – ***Go to question 141***
- ☐ Corticosteroids – ***Go to question 141***
- ☐ Corticosteroids - pulse dose *(methylprednisolone 1000 mg/day or equivalent)* – ***Go to question 141***
- ☐ Cyclophosphamide – ***Go to question 141***
- ☐ IT chemotherapy – ***Go to question 141***
- ☐ Intravenous immunoglobulin (IVIG) – ***Go to question 141***
- ☐ Ruxolitinib –***Go to question 141***
- ☐ Other therapy – ***Go to question 140***
- ☐ No therapy given – ***Go to question 141***

140. Specify other therapy: _____

141. Did cranial nerve palsy (III, VI, VII) resolve?

- ☐ Yes – ***Go to question 142***
- ☐ No – ***Go to question 143***

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

Tumor inflammation-associated neurotoxicity (TIAN)

143. Did the recipient experience tumor inflammation-associated neurotoxicity (TIAN)?

- ☐ Yes – ***Go to question 144***
- ☐ No – ***Go to question 150***

Copy and complete questions 144 – 149 to report multiple TIAN events in this reporting period.

144. Was the date of onset previously reported?

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

145. Date of TIAN onset: __ __ __ __ - __ __ - __ __

146. Specify therapy given for TIAN *(check all that apply)*

- ☐ Anakinra – ***Go to question 148***
- ☐ Corticosteroids – ***Go to question 148***
- ☐ Corticosteroids - pulse dose *(methylprednisolone 1000 mg/day or equivalent)* – ***Go to question 148***
- ☐ Intrathecal / intraventricular therapy – ***Go to question 148***
- ☐ Tocilizumab – ***Go to question 148***
- ☐ Other therapy – ***Go to question 147***
- ☐ No therapy given – ***Go to question 148***

147. Specify other therapy: _____

148. Did TIAN resolve?

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

149. Date resolved: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

Copy and complete questions 144 – 149 to report multiple TIAN events in this reporting period.

Guillain-Barre Syndrome (GBS)

150. Did the recipient experience Guillain-Barre syndrome?

- ☐ Yes – ***Go to question 151***
- ☐ No – ***Go to question 157***

151. Was the date of onset previously reported?

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

152. Date of Guillain-Barre syndrome onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

153. Specify therapy given for Guillain-Barre syndrome *(check all that apply)*

- ☐ Intravenous immunoglobulin (IVIG) – ***Go to question 155***
- ☐ Plasma exchange – ***Go to question 155***
- ☐ Other therapy – ***Go to question 154***

154. Specify other therapy: _____

155. Did Guillain-Barre syndrome resolve?

- ☐ Yes– ***Go to question 156***
- ☐ No– ***Go to question 157***

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

Other neurotoxicities

Copy and complete questions 157– 160 to report multiple other neurotoxicity events in this reporting period.

157. Other neurotoxicity

- ☐ Ataxia – ***Go to question 159***
- ☐ Cerebrovascular accident *(stroke)* – ***Go to question 159***
- ☐ Dysmetria – ***Go to question 159***
- ☐ Leukoencephalopathy – ***Go to question 159***
- ☐ Myelitis – ***Go to question 159***
- ☐ Myoclonus – ***Go to question 159***
- ☐ Other neurotoxicity – ***Go to question 158***
- ☐ None – ***Go to question 161***

158. Specify other neurotoxicity: _____

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

160. Specify type of cerebrovascular accident

- ☐ Hemorrhagic
- ☐ Ischemic

Copy and complete questions 157 – 160 to report multiple other neurotoxicity events in this reporting period.

Other toxicities

Hypogammaglobulinemia

161. Did recipient receive immunoglobulin replacement therapy?

- ☐ Yes – ***Go to question 162***
- ☐ No – ***Go to question 168***

162. Specify the reason the recipient received immunoglobulin therapy

- ☐ Prophylaxis
- ☐ Replacement
- ☐ Unknown

163. Date of first administration of immunoglobulin therapy: __ __ __ __ - __ __ - __ __
YYYY MM DD

164. Did the immunoglobulin therapy stop?

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

165. Date of last immunoglobulin therapy infusion: __ __ __ __ - __ __ - __ __
YYYY MM DD

166. Has the recipient's immunoglobulin level recovered?

- ☐ Yes – ***Go to question 167***
- ☐ No – ***Go to question 168***
- ☐ Not applicable – ***Go to question 168***

167. Date recovery: __ __ __ __ - __ __ - __ __
YYYY MM DD

Tumor lysis syndrome

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

Other toxicity

174. Other toxicity

- ☐ Yes – ***Go to question 175***
- ☐ No – ***Go to question 180***

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

175. Specify other toxicity: _____

176. Was the date of onset previously reported?

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

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 other toxicity.

Infection

180. Did the recipient develop a clinically significant infection?

- ☐ Yes – ***Go to question 181***
- ☐ No – ***Go to question 185***

Report each infection organism, site, and date of diagnosis.

Copy and complete questions 181-184 to report more than one infection.

181. Organism

- ☐ Achromobacter xylosoxidans
- ☐ Acinetobacter (all species)
- ☐ Actinomyces (all species)
- ☐ Bacillus cereus
- ☐ Bacteroides fragilis
- ☐ Bordetella pertussis (whooping cough)
- ☐ Burkholderia cepacia
- ☐ Campylobacter (all species)
- ☐ Capnocytophaga (all species)
- ☐ Chlamydia pneumoniae
- ☐ Citrobacter (all species, including freundii)
- ☐ Clostridioides difficile (previously Clostridium difficile)
- ☐ Clostridium (all species except difficile)
- ☐ Corynebacterium jeikeium
- ☐ Cutibacterium acnes (previously, Propionibacterium acnes)
- ☐ Enterobacter (all species)
- ☐ Enterococcus, vancomycin resistant (VRE)
- ☐ Enterococcus (all species)
- ☐ Escherichia (also E. coli)
- ☐ Fusobacterium (all species)
- ☐ Haemophilus influenzae
- ☐ Haemophilus non-influenzae
- ☐ Klebsiella (all species)
- ☐ Lactobacillus (all species, including bulgaricus, acidophilus)
- ☐ Legionella pneumophila
- ☐ Legionella non-pneumophila
- ☐ Leptospira (all species)
- ☐ Leptotrichia buccalis
- ☐ Leuconostoc (all species)

- ☐ Listeria monocytogenes
- ☐ Micrococcus, NOS
- ☐ Moraxella catarrhalis
- ☐ Mycobacterium abscessus
- ☐ Mycobacterium avium - intracellulare (MAC, MAI)
- ☐ Mycobacterium cheloneae
- ☐ Mycobacterium fortuitum
- ☐ Mycobacterium haemophilum
- ☐ Mycobacterium kansasii
- ☐ Mycobacterium marinum
- ☐ Mycobacterium mucogenicum
- ☐ Mycobacterium tuberculosis (tuberculosis, Koch bacillus)
- ☐ Mycoplasma (all species)
- ☐ Neisseria gonorrhoeae
- ☐ Neisseria meningitidis
- ☐ Nocardia (all species)
- ☐ Pasteurella multocida
- ☐ Proteus (all species)
- ☐ Pseudomonas aeruginosa
- ☐ Pseudomonas non-aeruginosa
- ☐ Rhodococcus (all species)
- ☐ Rickettsia (all species)
- ☐ Rothia (all species)
- ☐ Salmonella (all species)
- ☐ Serratia marcescens
- ☐ Shigella (all species)
- ☐ Staphylococcus aureus (Methicillin Resistant)
- ☐ Staphylococcus aureus (Methicillin Sensitive)
- ☐ Staphylococcus epidermidis
- ☐ Staphylococcus coagulase negative (excluding Staphylococcus epidermidis)
- ☐ Stenotrophomonas maltophilia
- ☐ Stomatococcus mucilaginosis
- ☐ Streptococci, viridans group (all species including mitis, anginosus, mutans, salivarius, bovis)
- ☐ Streptococcus pneumoniae
- ☐ Streptococcus, Group A (Streptococcus pyogenes)
- ☐ Streptococcus, Group B (Streptococcus agalactiae)

- ☐ Treponema (syphilis)
- ☐ Vibrio (all species)
- ☐ Yersinia enterocolitica
- ☐ Suspected bacterial infection
- ☐ Aspergillus flavus
- ☐ Aspergillus fumigatus
- ☐ Aspergillus niger
- ☐ Aspergillus terreus
- ☐ Aspergillus ustus
- ☐ Aspergillus, NOS
- ☐ Blastomyces (all species, including dermatitidis)
- ☐ Candida albicans
- ☐ Candida auris
- ☐ Candida parapsilosis
- ☐ Candida non-albicans (excluding C. parapsilosis and C. auris)
- ☐ Coccidioides (all species)
- ☐ Cryptococcus gattii
- ☐ Cryptococcus neoformans
- ☐ Fusarium (all species)
- ☐ Histoplasma (all species, including capsulatum)
- ☐ Lomentospora prolificans
- ☐ Mucorales (all species including Rhizopus, Mucor, Rhizomucor, Absidia, Lichtheimia, Cunninghamella species)
- ☐ Pneumocystis (PCP / PJP)
- ☐ Scedosporium (all species)
- ☐ Suspected fungal infection
- ☐ Adenovirus
- ☐ Astrovirus
- ☐ BK Virus
- ☐ Chikungunya Virus
- ☐ Coronavirus (excluding COVID-19 (SARS-CoV-2))
- ☐ COVID-19 (SARS-CoV-2)
- ☐ Cytomegalovirus (CMV)
- ☐ Dengue Virus
- ☐ Enterovirus D68 (EV-D68)
- ☐ Enterovirus except polioviruses and D68 (including echoviruses and coxsackieviruses)
- ☐ Epstein-Barr Virus (EBV)

- ☐ Hepatitis A Virus
- ☐ Hepatitis B Virus
- ☐ Hepatitis C Virus
- ☐ Hepatitis E Virus
- ☐ Herpes Simplex Virus (HSV)
- ☐ Human herpesvirus 6 (HHV-6)
- ☐ Human Immunodeficiency Virus 1 or 2
- ☐ Human metapneumovirus
- ☐ Human Papillomavirus (HPV)
- ☐ Human Parainfluenza Virus (all species)
- ☐ Human T-lymphotropic Virus 1 or 2
- ☐ Influenza A Virus
- ☐ Influenza B Virus
- ☐ Influenza, NOS
- ☐ JC Virus (Progressive Multifocal Leukoencephalopathy (PML))
- ☐ Measles Virus (Rubeola)
- ☐ Mumps Virus
- ☐ Norovirus
- ☐ Parvovirus B19
- ☐ Polioviruses
- ☐ Respiratory Syncytial Virus (RSV)
- ☐ Rhinovirus (all species except Rhinovirus / enterovirus (not differentiated))
- ☐ Rhinovirus / enterovirus (not differentiated)
- ☐ Rotavirus (all species)
- ☐ Rubella Virus
- ☐ Sapovirus
- ☐ Varicella Virus
- ☐ West Nile Virus (WNV)
- ☐ Suspected viral infection
- ☐ Cryptosporidium (all species)
- ☐ Giardia (lambia)
- ☐ Helminths (all species)
- ☐ Strongyloides stercoralis
- ☐ Toxoplasma gondii
- ☐ Trypanosoma cruzi (Chaga's disease)
- ☐ Other organism – **Go to question 182**

182. Specify other organism: _____

183. 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

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

Copy and complete questions 181 -184 to report more than one infection.

Pregnancy Status

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

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

186. 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 End of form***
- ☐ Unknown – ***Go to End of form***
- ☐ Previously reported *(form 3501 already submitted for this event)* – ***Go to End of form***