



Post-Cellular Therapy Essential Data

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: _____

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 $\geq 500/\text{mm}^3$ achieved and sustained for 3 lab values*) – **Go to question 8**
- No (*ANC $\geq 500/\text{mm}^3$ was not achieved*) – **Go to question 13**
- Not applicable (*ANC never dropped below $500/\text{mm}^3$ at any time post-infusion / 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 $\geq 500/\text{mm}^3$: (*first of 3 consecutive lab values*) _____ - _____ - _____
YYYY MM DD

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

- Yes – **Go to question 10**
- No – **Go to question 13**

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

11. Did recipient recover and maintain ANC $\geq 500/\text{mm}^3$ 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 $\geq 20 \times 10^9/\text{L}$ achieved?

- Yes – **Go to question 14**
- No – **Go to question 19**
- Not applicable (*platelet count never dropped below $20 \times 10^9/\text{L}$ at any time post-infusion / no lymphodepleting therapy given*) – **Go to question 19**
- Previously reported (*$\geq 20 \times 10^9/\text{L}$ was achieved and reported previously*) – **Go to question 19**

14. Date platelets $\geq 20 \times 10^9/\text{L}$: _____ - _____ - _____
YYYY MM DD

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

- Yes – **Go to questions 16**
- No – **Go to questions 19**

16. Date of decline in platelets to $< 20 \times 10^9/L$ for ≥ 3 days: *(first of 3 days that the platelets declined)*

____ - ____ - ____
YYYY MM DD

17. Did recipient recover and maintain platelets $\geq 20 \times 10^9/L$ 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**

Copy and complete questions 23 - 25 to report multiple autoimmune disorders in this reporting period.

23. Specify the autoimmune disorder

- Autoimmune cytopenias (*e.g. immune-mediated thrombocytopenia, autoimmune hemolytic anemia, autoimmune neutropenia*) – **Go to question 26**
- Colitis – **Go to question 26**
- Hepatitis – **Go to question 26**
- Nephritis – **Go to question 26**
- Pneumonitis – **Go to question 26**
- Thyroiditis – **Go to question 26**
- Other autoimmune disorder – **Go to question 24**

24. Specify other autoimmune disorder: _____

25. Date of diagnosis: _____ - _____ - _____

YYYY MM DD

Copy and complete questions 23 - 25 to report multiple autoimmune disorders in this reporting period.

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/m²/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/m²/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/m²/day or <10 mL/kg/day (pediatric)*
- Stage 1 – *Diarrhea 500 - 1000 mL/day (adult) / 280-555 mL/m²/day or 10 - 19.9 mL/kg/day (pediatric)*
- Stage 2 – *Diarrhea >1000 mL/day (adult) / 556-833 mL/m²/day or 20 - 30 mL/kg/day (pediatric)*
- Stage 3 – *Diarrhea > 1500 mL/day (adult), />833 mL/m²/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/m²/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/m²/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/m²/day or <10 mL/kg/day (pediatric)*
- Stage 1 – *Diarrhea 500 - 1000 mL/day (adult) / 280-555 mL/m²/day or 10 - 19.9 mL/kg/day (pediatric)*
- Stage 2 – *Diarrhea >1000 mL/day (adult) / 556-833 mL/m²/day or 20 - 30 mL/kg/day (pediatric)*
- Stage 3 – *Diarrhea > 1500 mL/day (adult) / >833 mL/m²/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)*

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CIBMTR Research ID: _____

- 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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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 ($\geq 100.4\text{ F or } \geq 38\text{ C}$) – **Go to question 59**
- Hypotension requiring therapy – **Go to question 60**
- Hypoxia requiring minimal supplemental oxygen ($\text{FiO}_2 < 40\%$) – **Go to question 67**
- Hypoxia requiring more than minimal supplemental oxygen ($\text{FiO}_2 \geq 40\%$) – **Go to question 68**

59. Date of fever onset: _____ - _____ - _____
YYYY MM DD60. Date of hypotension onset: _____ - _____ - _____
YYYY MM DD61. 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?

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Yes
 No

67. Date of hypoxia onset for minimal supplemental oxygen: ($FiO_2 < 40\%$)

— — — — - — — —
YYYY MM DD

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

— — — — - — — —
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 (μ g/L)

76. Date total serum ferritin collected: _____ - _____ - _____

YYYY MM DD

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

- 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
- μ kat/L

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

91. Maximum ALT (SGPT): _____ . _____

- U/L
- μ kat/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: _____ . _____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

mg/dL

μ mol/L

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

97. Lowest fibrinogen level: _____ . _____

mg/dL

mg/L

98. Maximum LDH: _____ . _____

U/L

μ kat/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 (μ g/L)

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

YYYY

MM

DD

108. Maximum triglyceride level: _____ . _____

mg/dL

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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**

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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)?

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CIBMTR Center Number: _____

CIBMTR Research ID: _____

- 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 161**

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?

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

145. Date of TIAN onset: _____ - _____ - _____
 YYYY MM DD

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*)

CIBMTR Center Number: _____

CIBMTR Research ID: _____

- Intravenous immunoglobulin (IVIG) – **Go to question 154**
- Plasma exchange – **Go to question 154**
- 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**

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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 194**

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 194**

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

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

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)
- Aspartate aminotransferase increased (AST)
- Blood bilirubin increased
- Capillary leak syndrome
- Cardiac arrhythmia
- Chills
- Chronic kidney disease
- Constipation
- Cystitis noninfective
- Diarrhea
- Dizziness
- Dyspepsia (heartburn)

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- 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
- New or worsening heart failure
- Pericardial effusion
- Pericarditis
- Productive cough
- Pulmonary edema
- Respiratory failure
- Restrictive cardiomyopathy
- 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**

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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 0**
- Unknown - **Go to question 0**

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

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

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- Dyspnea
- Encephalopathy
- Gastroenteritis
- Hepatic failure
- Hepatitis
- Hypertension
- Hypotension
- Intestinal obstruction (includes small intestine and colonic)
- Left ventricular systolic dysfunction
- Mucositis oral
- Myocardial infarction
- New or worsening heart failure
- Pericardial effusion
- Pericarditis
- Pulmonary edema
- Respiratory failure
- Restrictive cardiomyopathy
- Thromboembolic event
- 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

Infection

194. Did the recipient develop a clinically significant infection?

Yes – **Go to question 195**

No – **Go to question 199**

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

Copy and complete questions 195-198 to report more than one infection.

195. 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 mucilaginosus*
- Streptococci*, *viridans* group (all species including *mitis*, *anginosus*, *mutans*, *salivarius*, *bovis*)
- Streptococcus pneumoniae*
- Streptococcus*, Group A (*Streptococcus pyogenes*)
- Streptococcus*, Group B (*Streptococcus agalactiae*)

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- 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)**

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- 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 196**

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196. Specify other organism: _____

197. 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

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

Copy and complete questions 195 -198 to report more than one infection.

Pregnancy Status

199. 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**

200. 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**