



## 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**

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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  $\geq 3$  days?

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

10. Date of decline in ANC to  $< 500/\text{mm}^3$  for  $\geq 3$  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

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

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

16. Date of decline in platelets to  $< 20 \times 10^9/L$  for  $\geq 3$  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/m<sup>2</sup>/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<sup>2</sup>/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<sup>2</sup>/day or <10 mL/kg/day (pediatric)*
- ☐ Stage 1 – *Diarrhea 500 - 1000 mL/day (adult) / 280-555 mL/m<sup>2</sup>/day or 10 - 19.9 mL/kg/day (pediatric)*
- ☐ Stage 2 – *Diarrhea >1000 mL/day (adult) / 556-833 mL/m<sup>2</sup>/day or 20 - 30 mL/kg/day (pediatric)*
- ☐ Stage 3 – *Diarrhea > 1500 mL/day (adult), / >833 mL/m<sup>2</sup>/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  $\leq$  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 (adult) / diarrhea 280-555 mL/m<sup>2</sup>/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<sup>2</sup>/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<sup>2</sup>/day or  $<10$  mL/kg/day (pediatric)*
- ☐ Stage 1 – *Diarrhea 500 - 1000 mL/day (adult) / 280-555 mL/m<sup>2</sup>/day or 10 - 19.9 mL/kg/day (pediatric)*
- ☐ Stage 2 – *Diarrhea  $>1000$  mL/day (adult) / 556-833 mL/m<sup>2</sup>/day or 20 - 30 mL/kg/day (pediatric)*
- ☐ Stage 3 – *Diarrhea  $> 1500$  mL/day (adult) /  $>833$  mL/m<sup>2</sup>/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 ( $< 34$   $\mu$ mol/L)*
- ☐ Stage 1 – *Bilirubin 2.0–3.0 mg/dL (34–52  $\mu$ mol/L)*
- ☐ Stage 2 – *Bilirubin 3.1–6.0 mg/dL (53–103  $\mu$ mol/L)*

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- ☐ 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



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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: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

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YYYY MM DD

57. Doses of tocilizumab given

- ☐ 1  
☐  $\geq 2$

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 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  
☐  $\geq 2$

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?

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☐ 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 ( $\mu\text{g/L}$ )

76. Date total serum ferritin collected: \_\_\_\_\_

YYYY

MM

DD

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

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☐ 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 (*methyprednisolone 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**

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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  $\alpha$  (*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  
☐  $\mu$ kat/L

90. Upper limit of normal for your institution: \_\_\_\_\_ . \_\_\_\_\_

91. Maximum ALT (SGPT): \_\_\_\_\_ . \_\_\_\_\_

- ☐ U/L  
☐  $\mu$ 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: \_\_\_\_\_ . \_\_\_\_\_

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☐ mg/dL

☐  $\mu\text{mol/L}$

96. Upper limit of normal for your institution: \_\_\_\_\_ . \_\_\_\_\_

97. Lowest fibrinogen level: \_\_\_\_\_ . \_\_\_\_\_

☐ mg/dL

☐ mg/L

98. Maximum LDH: \_\_\_\_\_ . \_\_\_\_\_

☐ U/L

☐  $\mu\text{kat/L}$

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  $\alpha$ : \_\_\_\_\_

☐ pg/mL

☐ IU/mL

☐ U/mL

105. Date soluble interleukin-2 receptor  $\alpha$  collected: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
YYYY MM DD

106. Maximum total serum ferritin: \_\_\_\_\_ ng/mL ( $\mu\text{g/L}$ )

107. Date total serum ferritin collected: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
YYYY MM DD

108. Maximum triglyceride level: \_\_\_\_\_ . \_\_\_\_\_

☐ mg/dL

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☐ 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





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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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☐ 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?

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- ☐ 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*)

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- ☐ 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: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
YYY Y 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: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
YYY Y 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: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
YYY Y 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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183. Was the date of onset previously reported?

184. Date of onset: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 YYYY MM DD

☐ Yes – **Go to question 186**

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☐ 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

CIBMTR Research ID:

190. Was the date of onset previously reported?

191. Date of onset: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
 YYYY MM DD

☐ Yes – **Go to question 193**

☐ No – **Go to question 194**

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

194. Did the recipient develop a clinically significant infection?

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☐ 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)

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- ☐ *Listeria monocytogenes*
- ☐ *Micrococcus*, NOS
- ☐ *Moraxella catarrhalis*
- ☐ *Mycobacterium abscessus*
- ☐ *Mycobacterium avium* - intracellulare (MAC, MAI)
- ☐ *Mycobacterium chelonae*
- ☐ *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 (lamblia)
- ☐ 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**