ERROR CORRECTION FORM

Sequence Number: | | | | | | | | | | | | | | |

CIBMTR Recipient ID: | | | | | | | | | |

Visit:
☐ 100 day
☐ 6 month
☐ | | year

Today's Date: Month | | Day | | 2 0 Year | | |

Infusion Date: Month | | Day | | 2 0 Year | | |

CIBMTR Center Number: | | | | | |

Initials: | | |

Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Visit

○ 100 day ○ 6 months ○ 1 year ○ 2 years ○ > 2 years,

Specify: _____

Survival

Questions: 1 - 6

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

2 Specify the recipient's survival status at the date of last contact

○ Alive **- Answers to subsequent questions should reflect clinical status since the date of last report**

○ Dead **- Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death**

3 Primary cause of death _____

4 Specify: _____

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Center: CRID:

5 Contributing cause of death (check all that apply)

- ☐ Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed
- ☐ Acute GVHD
- ☐ Chronic GVHD
- ☐ Graft rejection or failure
- ☐ Cytokine release syndrome
- ☐ Infection, organism not identified
- ☐ Bacterial infection
- ☐ Fungal infection
- ☐ Viral infection
- ☐ Protozoal infection
- ☐ Other infection
- ☐ Idiopathic pneumonia syndrome (IPS)
- ☐ Pneumonitis due to Cytomegalovirus (CMV)
- ☐ Pneumonitis due to other virus
- ☐ Other pulmonary syndrome (excluding pulmonary hemorrhage)
- ☐ Diffuse alveolar damage (without hemorrhage)
- ☐ Acute respiratory distress syndrome (ARDS) (other than IPS)
- ☐ Liver failure (not VOD)
- ☐ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS)
- ☐ Cardiac failure
- ☐ Pulmonary failure
- ☐ Central nervous system (CNS) failure
- ☐ Renal failure
- ☐ Gastrointestinal (GI) failure (not liver)
- ☐ Multiple organ failure
- ☐ Other organ failure
- ☐ New malignancy (post-HCT or post-cellular therapy)
- ☐ Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)
- ☐ Pulmonary hemorrhage
- ☐ Diffuse alveolar hemorrhage (DAH)
- ☐ Intracranial hemorrhage
- ☐ Gastrointestinal hemorrhage
- ☐ Hemorrhagic cystitis
- ☐ Other hemorrhage
- ☐ Thromboembolic
- ☐ Disseminated intravascular coagulation (DIC)
- ☐ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))
- ☐ Other vascular
- ☐ Accidental death
- ☐ Suicide
- ☐ Other cause

6 Specify: _____

Subsequent Cellular Infusions

Questions: 7 - 11

ERROR CORRECTION FORM

Sequence Number: | CIBMTR Recipient ID: | Visit: ☐ 100 day ☐ 6 month ☐ ☐☐ year

Today's Date: Month ☐☐ Day ☐☐ Year 20☐☐ | Infusion Date: Month ☐☐ Day ☐☐ Year 20☐☐ | CIBMTR Center Number: ☐☐☐☐☐ | Initials: ☐☐☐

Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

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.

7 Has the recipient received a new course of cellular therapy (unplanned) since the date of last report?

○ Yes ○ No

8 Specify the reason for which cellular therapy was given

○ Failure to respond or in response to disease assessment

○ New indication

9 Date of cellular therapy: __ __ __ __ - __ __- __ __ **Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000**

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

○ Yes **- Also complete Pre-TED Form 2400 for the subsequent HCT**

○ No

11 Date of HCT: __ __ __ __ - __ __- __ __

Best Response to Cellular Therapy — Questions: 12 - 14

12 What was the best response to the cellular therapy?

○ Complete response

○ Normalization of organ function

○ Partial response

○ Partial normalization of organ function

○ No response

○ Disease progression or worsening of organ function

○ Not applicable (e.g. infection prophylaxis)

○ Unknown

13 Was the date of best response previously reported?

○ yes ○ no

14 Date response established: __ __ __ __ - __ __- __ __

Disease Relapse or Progression — Questions: 15 - 16

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

○ yes ○ no

16 Date documented: __ __ __ __ - __ __- __ __

Peripheral Blood Count Recovery — Questions: 17 - 20

17 Was there evidence of initial recovery?

○ Yes (ANC ≥ 500/mm³ achieved and sustained for 3 lab values)

○ No (ANC ≥ 500/mm³ was not achieved)

○ Not applicable (ANC never dropped below 500/mm³ at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given)

○ Previously reported (recipient's initial recovery was recorded on a previous report)

18 Date ANC ≥ 500/mm³ (first of 3 lab values): __ __ __ __ - __ __- __ __

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

○ Yes

○ No

○ 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

○ Previously reported - ≥ 20 x 10^9/L was achieved and reported previously

20 Date platelets ≥ 20 x 10^9/L: __ __ __ __ - __ __- __ __

Current Hematologic Findings — Questions: 21 - 35

21 Date of most recent complete blood count: __ __ __ __ - __ __- __ __

22 WBC

○ Known ○ Unknown

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Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

23 WBC: _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

24 Neutrophils
○ Known ○ Unknown

25 Neutrophils: _____ %

26 Lymphocytes
○ Known ○ Unknown

27 Lymphocytes: _____ %

28 Hemoglobin
○ Known ○ Unknown

29 Hemoglobin: _____ ○ g/dL ○ g/L ○ mmol/L

30 Hematocrit
○ Known ○ Unknown

31 Hematocrit: _____ %

32 Was RBC transfused ≤ 30 days before date of test?
○ Yes ○ No

33 Platelets
○ Known ○ Unknown

34 Platelets: _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

35 Were platelets transfused ≤ 7 days before date of test?
○ Yes ○ No

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Questions: 36 - 36

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

36 Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)
○ Yes **- Complete form 3500**
○ No
○ Previously reported (form 3500 has already been submitted)

Persistence of Cells

Questions: 37 - 58

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

37 Were tests performed to detect persistence of the cellular product since the date of last report?
○ Yes ○ No

38 Was persistence evaluated by molecular assay? (e.g. PCR)
○ Yes ○ No

39 Date sample collected: __ __ __ __ - __ __ - __ __

40 Specify the cell source
○ Bone marrow ○ Peripheral blood ○ Tumor ○ Other source

41 Specify other cell source: _____

42 Were the infused cells detected?
○ Yes ○ No

43 Was persistence evaluated by flow cytometry testing? (immunophenotyping)
○ Yes ○ No

44 Date sample collected: __ __ __ __ - __ __ - __ __

45 Specify the cell source
○ Bone marrow ○ Peripheral blood ○ Tumor ○ Other source

46 Specify other cell source: _____

Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

47 Were the infused cells detected?
Yes No

48 Was persistence evaluated by immunohistochemistry?
Yes No

49 Date sample collected: __ __ __ __ - __ __- __ __

50 Specify the cell source
Bone marrow Peripheral blood Tumor Other source

51 Specify other cell source: _____

52 Were the infused cells detected?
Yes No

53 Was persistence evaluated by other method?
Yes No

54 Specify other method: _____

55 Date sample collected: __ __ __ __ - __ __- __ __

56 Specify the cell source
Bone marrow Peripheral blood Tumor Other source

57 Specify other cell source: _____

58 Were the infused cells detected?
Yes No

Graft vs. Host Disease

Questions: 59 - 78

This section is for allogeneic infusions only. If this was an autologous infusion, continue to question 79.

59 Did acute GVHD develop since the date of last report?
Yes No Unknown

60 Date of acute GVHD diagnosis: __ __ __ __ - __ __- __ __

61 Did acute GVHD persist since the date of last report?
Yes No Unknown

62 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
- III - Bilirubin 3-15 mg/dL, or gut stage 2-4, diarrhea >1000 mL/day or severe abdominal pain with or without ileus
- IV - Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL
- Not applicable (acute GVHD present but grade is not applicable)

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

63 Skin
- Stage 0 - No rash, or no rash attributable to acute GVHD
- Stage 1 - Maculopapular rash, < 25% of body surface
- Stage 2 - Maculopapular rash, 25-50% of body surface
- Stage 3 - Generalized erythroderma, > 50% of body surface
- Stage 4 - Generalized erythroderma with bullae formation and/or desquamation

64 Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)
- Stage 0 - No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)
- Stage 1 - Diarrhea 500-1000 mL/day (adult), or 10-19.9 mL/kg/day (pediatric)
- Stage 2 - Diarrhea 1001-1500 mL/day (adult), or 20-30 mL/kg/day (pediatric)
- Stage 3 - Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)
- Stage 4 - Severe abdominal pain, with or without ileus, and/or grossly bloody stool

65 Upper intestinal tract
- Stage 0 - No persistent nausea or vomiting
- Stage 1 - Persistent nausea or vomiting

Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

66 Liver

- ○ Stage 0 - No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)
- ○ Stage 1 - Bilirubin 2.0-3.0 mg/dL (34-52 µmol/L)
- ○ Stage 2 - Bilirubin 3.1-6.0 mg/dL (53-103 µmol/L)
- ○ Stage 3 - Bilirubin 6.1-15.0 mg/dL (104-256 µmol/L)
- ○ Stage 4 - Bilirubin >15.0 mg/dL (> 256 µmol/L)

67 Other site(s) involved with acute GVHD

○ Yes ○ No

68 Specify other site(s): _____

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

69 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
- ○ III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
- ○ IV - Generalized erythroderma with bullous formation, or billirubin > 15 mg/dL
- ○ Not applicable (acute GVHD present but grade is not applicable)

70 Date maximum overall grade of acute GVHD: __ __ __ __ - __ __- __ __

71 Did chronic GVHD develop since the date of last report?

○ Yes ○ No ○ Unknown

72 Date of chronic GVHD diagnosis: __ __ __ __ - __ __- __ __ ☐ Date estimated

73 Did chronic GVHD persist since the date of last report?

○ Yes ○ No ○ Unknown

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

74 Maximum grade of chronic GVHD (according to best clinical judgment)

○ Mild ○ Moderate ○ Severe ○ Unknown

75 Specify if chronic GVHD was limited or extensive

- ○ Limited - Localized skin involvement and/or liver dysfunction
- ○ Extensive - One or more of the following:
  - generalized skin involvement; or,
  - liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
  - involvement of eye: Schirmer's test with < 5 mm wetting; or
  - involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
  - involvement of any other target organ

76 Date of maximum grade of chronic GVHD: __ __ __ __ - __ __- __ __

77 Is the recipient still taking systemic steroids? (Do not report steroids for adrenal insufficiency, ≤ 10 mg/day for adults, < 0.1 mg/kg/day for children)

○ Yes ○ No ○ Not Applicable ○ Unknown

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

○ Yes ○ No ○ Not Applicable ○ Unknown

Toxicities

Questions: 79 - 174

79 Did the recipient develop Cytokine Release Syndrome (CRS) since the date of last report?

○ Yes ○ No

80 Date of diagnosis: __ __ __ __ - __ __- __ __

81 Was therapy given? (for CRS)

○ yes ○ no

Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

Specify therapy given for CRS:

82 Specify therapy given for CRS (check all that apply)

- ☐ Corticosteroids
- ☐ Siltuximab
- ☐ Tocilizumab
- ☐ Other therapy

83 Specify other therapy: _____

84 Did cytokine release syndrome resolve?

○ Yes ○ No

85 Date resolved: __ __ __ __ - __ __- __ __

86 Neurotoxicity

○ Yes ○ No ○ Unknown

87 Date of onset: __ __ __ __ - __ __- __ __

Specify symptoms of neurotoxicity:

88 Specify symptoms of neurotoxicity (check all that apply)

- ☐ Altered mental status
- ☐ Aphasia
- ☐ Hemiparesis or other focal motor deficit
- ☐ Seizure(s)
- ☐ Tremors
- ☐ Visual hallucinations
- ☐ Other symptom

89 Specify other symptom: _____

90 Did neurotoxicity resolve?

○ Yes ○ No

91 Date resolved: __ __ __ __ - __ __- __ __

92 Hemorrhagic stroke

○ Yes ○ No ○ Unknown

93 Date of onset: __ __ __ __ - __ __- __ __

94 Hypogammaglobulinemia

○ Yes ○ No ○ Unknown

95 Date of onset: __ __ __ __ - __ __- __ __

96 Did hypogammaglobulinema resolve?

○ Yes ○ No

97 Date resolved: __ __ __ __ - __ __- __ __

98 Did recipient require immunoglobulin replacement therapy?

○ Yes ○ No

99 Is the recipient still requiring replacement therapy?

○ Yes ○ No

100 Other toxicity

○ Yes ○ No ○ Unknown

101 Specify other toxicity: _____

102 Date of onset: __ __ __ __ - __ __- __ __

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

103 Fevers (≥ 100.4° F or ≥ 38° C)

○ Yes ○ No ○ Unknown

104 Date of onset: __ __ __ __ - __ __- __ __

105 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)

○ Yes ○ No

Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

106 Rigors
Yes No Unknown

107 Date of onset: __ __ __ __ - __ __- __ __

108 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

109 Malaise / fatigue
Yes No Unknown

110 Date of onset: __ __ __ __ - __ __- __ __

111 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

112 Anorexia
Yes No Unknown

113 Date of onset: __ __ __ __ - __ __- __ __

114 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

115 Myalgias / arthralgias
Yes No Unknown

116 Date of onset: __ __ __ __ - __ __- __ __

117 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

118 Nausea / vomiting
Yes No Unknown

119 Date of onset: __ __ __ __ - __ __- __ __

120 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

121 Other constitutional symptom
Yes No Unknown

122 Specify other constitutional symptom: _____

123 Date of onset: __ __ __ __ - __ __- __ __

124 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

125 Hypoxia requiring minimal supplemental oxygen (Fi02 ≤ 40%)
Yes No Unknown

126 Date of onset: __ __ __ __ - __ __- __ __

127 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

128 Hypoxia requiring more than minimal supplemental oxygen (Fi02 > 40%)
Yes No Unknown

129 Date of onset: __ __ __ __ - __ __- __ __

130 Was mechanical ventilator support required?
Yes No Unknown

131 Date started: __ __ __ __ - __ __- __ __

132 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

133 Hypotension requiring therapy
Yes No Unknown

134 Date of onset: __ __ __ __ - __ __- __ __

135 Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
Yes No

Specify therapy given for hypotension:

136 Intravenous fluids
Yes No Unknown

ERROR CORRECTION FORM

Sequence Number: | CIBMTR Recipient ID: | Visit: ☐ 100 day ☐ 6 month ☐ year

Today's Date: Month Day 20 Year | Infusion Date: Month Day 20 Year | CIBMTR Center Number: | Initials:

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Center: CRID:

137 Vasopressor(s)
○ Yes ○ No ○ Unknown

138 Specify the number of vasopressors used for therapy
○ 1 ○ ≥2 ○ Unknown

139 Other therapy
○ yes ○ no ○ Unknown

140 Specify other therapy: _____

141 Was hypotension controlled with therapy?
○ Yes ○ No ○ Unknown

142 Has the recipient developed any grade 4 organ toxicity?
○ Yes ○ No ○ Unknown

143 Liver
○ Yes ○ No ○ Unknown

144 Date of onset: __ __ __ __ - __ __- __ __

145 Lungs
○ Yes ○ No ○ Unknown

146 Date of onset: __ __ __ __ - __ __- __ __

147 Heart
○ Yes ○ No ○ Unknown

148 Date of onset: __ __ __ __ - __ __- __ __

149 Kidneys
○ Yes ○ No ○ Unknown

150 Date of onset: __ __ __ __ - __ __- __ __

151 Gastrointestinal (GI)
○ Yes ○ No ○ Unknown

152 Date of onset: __ __ __ __ - __ __- __ __

153 Musculoskeletal
○ Yes ○ No ○ Unknown

154 Date of onset: __ __ __ __ - __ __- __ __

155 Neurologic
○ Yes ○ No ○ Unknown

156 Date of onset: __ __ __ __ - __ __- __ __

157 Other organ
○ Yes ○ No ○ Unknown

158 Date of onset: __ __ __ __ - __ __- __ __

159 Specify other organ: _____

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

160 Interleukin-6
○ Known ○ Unknown

161 _____ pg/mL

162 Date sample collected: __ __ __ __ - __ __- __ __

163 Interferon gamma IFN γ
○ Known ○ Unknown

164 _____ IU/mL

165 Date sample collected: __ __ __ __ - __ __- __ __

166 Soluble interleukin-2 receptor α (sIL2RA or soluble CD25)
○ Known ○ Unknown

167 _____ U/mL

168 Date sample collected: __ __ __ __ - __ __- __ __

169 Total serum ferritin
○ Known ○ Unknown

170 _____ ng/mL(µg/L)

171 Date sample collected: __ __ __ __ - __ __- __ __

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Form 4100 R3.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

172 C-reactive protein

○ Known ○ Unknown

173 _____ mg/dL

174 Date sample collected: __ __ __ __ - __ __- __ __

Infection — Questions: 175 - 179

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

○ Yes ○ No

Infection (1) — Questions: 176 - 179

176 Organism _____

177 Specify other organism: _____

178 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

179 Date of diagnosis: __ __ __ __ - __ __- __ __

Functional Status — Questions: 180 - 183

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

○ Yes ○ No ○ Unknown

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

○ Yes ○ No ○ Unknown

182 Was the recipient or recipient's partner still pregnant at the date of last contact?

○ Yes ○ No ○ Unknown

183 Specify the outcome of pregnancy

- ○ Live birth
- ○ Intrauterine fetal death
- ○ Spontaneous abortion
- ○ Elected abortion
- ○ Unknown

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __

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