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: _____

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

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/mm^3 achieved and sustained for 3 lab values)
- ○ No (ANC ≥ 500/mm^3 was not achieved)
- ○ Not applicable (ANC never dropped below 500/mm^3 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/mm^3 (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

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: _____

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

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

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

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

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: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __