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

Center: CRID:

Key Fields

Sequence Number: ______________________
Date Received: ______________________
CIBMTR Recipient ID: ______________________
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:**

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#### 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

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#### Subsequent Cellular Infusions

**Questions: 7 - 11**

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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: __ __ __ __ - __ __ __ __

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: __ __ __ __ - __ __ __ __

15 Was a disease relapse or progression detected since the date of last report?
   □ yes □ no

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

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 10⁹/L achieved?
   □ Yes
   □ No
   □ Not applicable - Platelet count never dropped below 20 x 10⁹/L at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given
   □ Previously reported ≥ 20 x 10⁹/L was achieved and reported previously

20 Date platelets ≥ 20 x 10⁹/L: __ __ __ __ - __ __ __ __

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

22 WBC
   □ Known □ Unknown
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23 WBC: ___________________________  x 10^9/L (x 10^3/mm^3)

24 Neutrophils
   - Known
   - Unknown

25 Neutrophils: _____________%

26 Lymphocytes
   - Known
   - Unknown

27 Lymphocytes: _____________%

28 Hemoglobin
   - Known
   - Unknown

29 Hemoglobin: ___________________________ g/dL

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)

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:

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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

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 2-3 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
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**Center:**

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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): ______________________

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**Specifying the maximum overall grade of acute GVHD:**

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 bilirubin > 15 mg/dL
- Not applicable (acute GVHD present but grade is not applicable)

70 Date maximum overall grade of acute GVHD:

- Yes
- No
- Unknown

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

71

- Yes
- No
- Unknown

**Date of chronic GVHD diagnosis:** ____________________  Date estimated __________________

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**Specifying the maximum grade of chronic GVHD:**

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

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76 Date of maximum grade of chronic GVHD:

- Yes
- No
- Unknown

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

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**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

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**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 hypogammaglobulinemia 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

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### 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 (FiO2 ≤ 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 (FiO2 > 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:
- Yes
- No
- Unknown

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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
   - Gl tract, Lower
   - Gl 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: __ __ __ __ __ __