Form 4100 R6.0: Cellular Therapy Essential Data Follow-Up Form

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: ____________________________

Product

Questions: 1 - 1

1. Name of cellular therapy product (for most recent cell therapy infusion):
   - Axicabtagene ciloleucel (Yescarta®)
   - Brexucabtagene autoleucel (Tecartus™)
   - Ciltacabtagene autoleucel (JNJ-4528)
   - Idecabtagene vicleucel
   - Letesbgene autoleucel
   - Lisocabtagene maraleucel (Breyanzi™)
   - Orvacadtagene autoleucel
   - Tisagenlecleucel (Kymriah®)
   - Other product
   - No product name

Survival

Questions: 2 - 3

2. Date of actual contact with the recipient to determine medical status for this follow-up report: ____________________________

3. 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. Complete a Form 2900 - Recipient Death Data.

Subsequent Cellular Infusions

Questions: 4 - 8

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.

4. Has the recipient received a new course of cellular therapy (unplanned) since the date of last report?
   - Yes
   - No

5. Specify the reason for which cellular therapy was given:
   - Failure to respond or in response to disease assessment
   - New indication

6. Date of cellular therapy: ____________________________ Also complete a Cellular Therapy Essential Data Pre-Infusion Form 4000

7. Did the recipient receive an HCT since the date of last report?
   - Yes - Also complete a Pre-TED Form 2400 for the subsequent HCT
   - No

8. Date of HCT: ____________________________

Best Response to Cellular Therapy

Questions: 9 - 11

Mail, fax or email this form to Minneapolis. Fax: 612-527-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.

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**Form 4100 R6.0: Cellular Therapy Essential Data Follow-Up Form**

**Peripheral Blood Count Recovery**

<table>
<thead>
<tr>
<th>Questions: 12 - 20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9</strong> Was the best response to the cellular therapy?</td>
</tr>
<tr>
<td>- Continued complete response (CCR) (for recipients in CR at the time of cellular therapy infusion)</td>
</tr>
<tr>
<td>- Complete response</td>
</tr>
<tr>
<td>- Normalization of organ function</td>
</tr>
<tr>
<td>- Partial response</td>
</tr>
<tr>
<td>- Partial normalization of organ function</td>
</tr>
<tr>
<td>- No response</td>
</tr>
<tr>
<td>- Disease progression or worsening of organ function</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>10</strong> Date of diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- yes</td>
</tr>
<tr>
<td><strong>11</strong> Date response established: ___ ___ ___ ___ ___ ___ ___</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>12</strong> Date of ANC recovery:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- yes</td>
</tr>
<tr>
<td><strong>13</strong> Date ANC ≥ 500/mm³ (first of 3 consecutive lab values): ___ ___ ___ ___ ___</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>14</strong> Following the initial recovery, was there a subsequent decline in ANC to &lt; 500/mm³ for ≥ 3 days since the date of last report?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- yes</td>
</tr>
</tbody>
</table>

| **15** Date of decline in ANC to < 500/mm³ for ≥ 3 days: (first of 3 days that the ANC declined) ___ ___ ___ ___ |

<table>
<thead>
<tr>
<th><strong>16</strong> Did recipient recover and maintain ANC ≥ 500/mm³ following the decline?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>17</strong> Date of ANC recovery:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Known</td>
</tr>
</tbody>
</table>

| **18** Date of ANC recovery: ___ ___ ___ ___ |

<table>
<thead>
<tr>
<th><strong>19</strong> Was an initial platelet count ≥ 20 x 10⁹/L achieved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- yes</td>
</tr>
</tbody>
</table>

| **20** Date platelets ≥ 20 x 10⁹/L: ___ ___ ___ ___ |

**Disease Relapse or Progression**

<table>
<thead>
<tr>
<th>Questions: 21 - 22</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>21</strong> Did a disease relapse or progression detected since the date of last report?</td>
</tr>
<tr>
<td>- yes</td>
</tr>
<tr>
<td><strong>22</strong> Date of relapse or progression: ___ ___ ___</td>
</tr>
</tbody>
</table>

**Current Hematologic Findings**

<table>
<thead>
<tr>
<th>Questions: 23 - 33</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>23</strong> Complete blood count (CBC) sample drawn: ___ ___ ___</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>24</strong> Complete blood count results available (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- WBC</td>
</tr>
<tr>
<td>- Neutrophils</td>
</tr>
<tr>
<td>- Lymphocytes</td>
</tr>
<tr>
<td>- Hemoglobin</td>
</tr>
<tr>
<td>- Hematocrit</td>
</tr>
<tr>
<td>- Platelets</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>25</strong> WBC: ___ x 10⁹/L (x 10³/mm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- yes</td>
</tr>
</tbody>
</table>

| **26** Neutrophils: ___ % |
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Center: CRID:

**New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder**

Questions: 34 - 34

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

34 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)

**Persistence of Cells**

Questions: 35 - 59

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

35 Were tests performed to detect persistence of the cellular product since the date of last report?

- Yes
- No

36 Was persistence evaluated by molecular assay? (e.g. PCR)

- Yes
- No

37 Date sample collected:

38 Specify the cell source (check all that apply)

- Bone marrow
- Peripheral blood
- Tumor
- Other source

39 Specify other cell source:

40 Were the infused cells detected?

- Yes
- No

41 Was persistence evaluated by flow cytometry testing? (immunophenotyping)

- Yes
- No

42 Date sample collected:

43 Specify the cell source (check all that apply)

- Bone marrow
- Peripheral blood
- Tumor
- Other source

44 Specify other cell source:

45 Were the infused cells detected?

- Yes
- No

46 Were B-cell counts monitored after infusion?

- Yes
- No
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**Center:**

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**47** Was there B-cell recovery?
- Yes
- No

**48** Date of B-cell recovery: _ _ _ _ _ _ _ _ _

**49** Was persistence evaluated by immunohistochemistry?
- Yes
- No

**50** Date sample collected: _ _ _ _ _ _ _ _ _

**51** Specify the cell source (check all that apply)
- Bone marrow
- Peripheral blood
- Tumor
- Other source

**52** Specify other cell source: ____________________________

**53** Were the infused cells detected?
- Yes
- No

**54** Was persistence evaluated by another method?
- Yes
- No

**55** Specify other method: ____________________________

**56** Date sample collected: _ _ _ _ _ _ _ _ _

**57** Specify the cell source (check all that apply)
- Bone marrow
- Peripheral blood
- Tumor
- Other source

**58** Specify other cell source: ____________________________

**59** Were the infused cells detected?
- Yes
- No

**Graft vs. Host Disease**

Questions: 60 - 79

This section is for allogeneic infusions only. If this was an autologous infusion, continue to the "Toxicities" section.

**60** Did acute GVHD develop since the date of last report?
- Yes
- No
- Unknown

**61** Date of acute GVHD diagnosis: _ _ _ _ _ _ _ _ _

**62** Did acute GVHD persist since the date of last report?
- Yes
- No
- Unknown

**63** 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 or vomiting
- 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:**

**64** Skin
- Stage 0 - No rash, 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
65 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

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

67 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)

68 Other site(s) involved with acute GVHD
- Yes
- No

69 Specify other site(s): _________________________________

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

70 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 or vomiting
- III - Bilirubin 3.1-6.0 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)

71 Date maximum overall grade of acute GVHD: __ __ __ __ ‘ __ __ __ __

72 Did chronic GVHD develop since the date of last report?
- Yes
- No
- Unknown

73 Date of chronic GVHD diagnosis: __ __ __ __ ‘ __ __ __ __
- Date estimated

74 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:

75 Maximum grade of chronic GVHD (according to best clinical judgment)
- Mild
- Moderate
- Severe
- Unknown

76 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

77 Date of maximum grade of chronic GVHD: __ __ __ __ ‘ __ __ __ __

78 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

79 Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
- Yes
- No
- Not Applicable
- Unknown
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Center: CRID:

Toxicities

Questions: 80 - 170

Cytokine Release Syndrome (CRS)

80 Did the recipient experience Cytokine Release Syndrome (CRS)?
   □ Yes □ No

81 Was the date of diagnosis previously reported?
   □ Yes □ No

82 Date of CRS diagnosis: __ __ __ __ - __ __ __

83 Specify therapy given for CRS (check all that apply)
   □ Anakinra
   □ Corticosteroids
   □ Siltuximab
   □ Tocilizumab
   □ Other therapy
   □ No therapy given

84 Specify other therapy: ____________________________

85 Doses of tocilizumab given
   □ 1 □ ≥ 2

86 Indicate the symptoms of CRS (check all that apply)
   □ FEVERS (> 100.4°F or > 38°C)
   □ Hypotension requiring therapy
   □ Hypoxia requiring minimal supplemental oxygen (FiO2 < 40%)
   □ Hypoxia requiring more than minimal supplemental oxygen (FiO2 ≥ 40%)
   □ Unknown

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

88 Date of hypotension onset: __ __ __ __ - __ __ __

89 Specify therapy given for hypotension (check all that apply)
   □ Intravenous fluids
   □ Vasopressor(s)
   □ Other

90 Specify other therapy: ____________________________

91 Specify the number of vasopressors used for therapy
   □ 1 □ ≥ 2

92 Specify the vasopressor(s) used (check all that apply)
   □ Phenylephrine
   □ Norepinephrine
   □ Epinephrine
   □ Dopamine
   □ Vasopressin
   □ Other

93 Specify other vasopressor: ____________________________

94 Was hypotension controlled with therapy?
   □ Yes □ No □ Unknown

95 Date of hypoxia onset for minimal supplemental oxygen: (FiO2 < 40%)

96 Date of hypoxia onset for more than minimal supplemental oxygen: (FiO2 ≥ 40%)

97 Was positive pressure ventilatory support required? (CPAP, BIPAP, intubation and mechanical ventilation)
   □ Yes □ No □ Unknown

98 Date started: __ __ __ __ - __ __ __

99 Were there features related to macrophage activation syndrome (MAS) / hemophagocytic lymphohistiocytosis (HLH)?
   □ Yes □ No

100 Date of MAS / HLH onset: __ __ __ __ - __ __ __
101 Did the recipient have splenomegaly?
   ☐ Yes ☐ No

102 Was MAS / HLH confirmed by a bone marrow biopsy?
   ☐ Yes ☐ No

103 Specify the laboratory values collected (check all that apply)
   ☐ Fibrinogen
   ☐ Triglyceride
   ☐ None

104 Lowest fibrinogen level: ___________________________ ☐ mg/dL ☐ µg/L

105 Date fibrinogen sample collected: ___________________________

106 Highest triglyceride level: ___________________________ ☐ mg/dL ☐ mmol/L

107 Date triglyceride sample collected: ___________________________

108 Did cytokine release syndrome resolve?
   ☐ Yes ☐ No

109 Date resolved: ___________________________

Neurotoxicity (ICANS)

110 Did the recipient experience neurotoxicity (ICANS)?
   ☐ Yes ☐ No

111 Was the date of onset previously reported?
   ☐ Yes ☐ No

112 Date of neurotoxicity (ICANS) onset: ___________________________

113 Specify therapy given for neurotoxicity (check all that apply)
   ☐ Anti-epileptics
   ☐ Anakinra
   ☐ Corticosteroids
   ☐ Siltuximab
   ☐ Tocilizumab
   ☐ Other therapy
   ☐ No therapy given

114 Specify other therapy:

115 Which cognitive assessment was performed?
   ☐ CARTOX ☐ ICE ☐ None

116 What was the lowest score?
   ☐ 10
   ☐ 9
   ☐ 8
   ☐ 7
   ☐ 6
   ☐ 5
   ☐ 4
   ☐ 3
   ☐ 2
   ☐ 1
   ☐ 0
   ☐ Unable to complete assessment
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For symptoms of neurotoxicity (ICANS), report the HIGHEST grade observed in this reporting period

117 Indicate the symptoms of neurotoxicity (ICANS) (check all that apply)

- Aphasia  (speech impairment resulting in full loss of language)
- Cerebral edema
- Cerebrovascular accident  (stroke)
- Depressed level of consciousness
- Dysphasia  (speech impairment resulting in partial loss of language)
- Hallucinations
- Hemiparesis / paraparesis / other motor deficit
- Leukoencephalopathy
- Seizure
- Tremors
- Other symptom

118 Specify other symptom:

119 Specify type of cerebral edema

- Focal / local edema on neuroimaging
- Diffuse cerebral edema on neuroimaging; decerebrate or decorticate posturing; or cranial nerve VI palsy; or papilledema; or Cushing's triad

120 Date of cerebrovascular accident onset: ____________

121 Specify type of cerebrovascular accident

- Hemorrhagic   
- Ischemic

122 Specify the most severe level of depressed level of consciousness

- Awakens spontaneously
- Awakens to voice
- Awakens only to tactile stimulus
- Patient unarousable or requires vigorous or repetitive tactile stimuli to arouse; stupor or coma

123 Specify the grade of dysphasia

- 1 (awareness of receptive or expressive characteristics; not impairing ability to communicate)
- 2 (moderate receptive or expressive characteristics; impairing ability to communicate spontaneously)

124 Specify the type of seizure

- Complex partial
- Generalized tonic-clonic
- Non-convulsive status epilepticus
- Simple partial
- Status epilepticus
- Other type
- Unknown

125 Specify other type:

126 Specify the severity of the seizure

- Grade 3 (any clinical seizure focal or generalized that resolves rapidly; or non-convulsive seizures on EEG that resolve with intervention)
- Grade 4 (life-threatening prolonged seizure that is > 5 min; or repetitive clinical or electrical seizures without return to baseline in between)

127 Did neurotoxicity (ICANS) resolve?

- Yes
- No

128 Date resolved: ____________

Other toxicities

129 Hypogammaglobulinemia

- Yes
- No
- Unknown

130 Was the date of onset previously reported?

- Yes
- No

131 Date of onset: ____________

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<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>132 Did hypogammaglobulinemia resolve?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>133 Date resolved:</td>
<td></td>
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<tr>
<td>134 Did recipient require immunoglobulin replacement therapy?</td>
<td></td>
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<tr>
<td>135 Is the recipient still requiring replacement therapy?</td>
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<tr>
<td>136 Tumor lysis syndrome</td>
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<tr>
<td>137 Was the date of onset previously reported?</td>
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<tr>
<td>138 Date of onset:</td>
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<td></td>
</tr>
<tr>
<td>139 Grade</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>140 Did tumor lysis syndrome resolve?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>141 Date resolved:</td>
<td></td>
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<tr>
<td>142 Other toxicity</td>
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<td></td>
<td></td>
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<tr>
<td>143 Specify other toxicity:</td>
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<tr>
<td>144 Was the date of onset previously reported?</td>
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<tr>
<td>145 Date of onset:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>146 Did other toxicity resolve?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>147 Date resolved:</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>148 Has the recipient experienced a grade 3 organ toxicity?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>149 Specify organ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>150 Specify the toxicity</td>
<td></td>
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<tr>
<td>151 Was the date of onset previously reported?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>152 Date of onset:</td>
<td></td>
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<td></td>
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<tr>
<td>153 Did the grade 3 toxicity resolve?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>154 Date resolved:</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>155 Has the recipient experienced a grade 4 organ toxicity?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>156 Specify organ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>157 Specify the toxicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>158 Was the date of onset previously reported?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>159 Date of onset:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>160 Did the grade 4 toxicity resolve?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>161 Date resolved:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Center: 
CRID: 

156 Specify organ
- Cardiovascular
- Gastrointestinal
- Kidneys
- Liver
- Lungs
- Musculoskeletal
- Nervous system
- Other

157 Specify the toxicity

158 Was the date of onset previously reported?
- Yes
- No

159 Date of onset: __ __ __ __ __ __ __

160 Did the grade 4 toxicity resolve?
- Yes
- No

161 Date resolved: __ __ __ __ __ __ __

164 Date C-reactive protein collected: __ __ __ __ __ __ __

165 Maximum interleukin-6: __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ __ _______
Form 4100 R6.0: Cellular Therapy Essential Data Follow-Up Form

Center: 
CRID: 

174 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

175 Date of diagnosis: __ __ __ __ __

Pregnancy Status

176 Was the recipient pregnant at any time in this reporting period? (Female only)
- Yes - Also complete Pregnancy Form 3501
- No
- Unknown
- Previously reported (form 3501 already submitted for this event)

177 Was the recipient's female partner pregnant at any time in this reporting period? (Male only)
- Yes - Also complete Pregnancy Form 3501
- No
- Unknown
- Previously reported (form 3501 already submitted for this event)

First Name: __________________________
Last Name: __________________________
E-mail address: ________________________
Date: __ __ __ __ __ __