

ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Today's Date:

Infusion Date:

CIBMTR Center Number:

Visit: 100 day 6 month year

Initials:

Form 4100 R4.0: 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: _____

Product

Questions: 1 - 1

1 Name of product (for most recent cell therapy infusion)

- Tisagenlecleucel (Kymriah®)
 Axicabtagene Ciloleucel (Yescarta®)
 Other product

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 Cellular Therapy Essential Data Pre-Infusion Form 4000**

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

- Yes - **Also complete Pre-TED Form 2400 for the subsequent HCT**
 No

8 Date of HCT: ____ - ____ - ____

Best Response to Cellular Therapy

Questions: 9 - 11

9 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

10 Was the date of best response previously reported?

- yes no

11 Date response established: ____ - ____ - ____

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Disease Relapse or Progression

Questions: 12 - 13

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

yes no

13 Date documented: ____ - ____ - ____

Peripheral Blood Count Recovery

Questions: 14 - 17

14 Was there evidence of initial recovery?

- Yes (ANC \geq 500/mm³ achieved and sustained for 3 lab values)
- No (ANC \geq 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)

15 Date ANC \geq 500/mm³ (first of 3 lab values): ____ - ____ - ____

16 Was an initial platelet count \geq 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 - \geq 20 x 10⁹/L was achieved and reported previously

17 Date platelets \geq 20 x 10⁹/L: ____ - ____ - ____

Current Hematologic Findings

Questions: 18 - 32

18 Date of most recent complete blood count: ____ - ____ - ____

19 WBC

Known Unknown

20 WBC: _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

21 Neutrophils

Known Unknown

22 Neutrophils: _____ %

23 Lymphocytes

Known Unknown

24 Lymphocytes: _____ %

25 Hemoglobin

Known Unknown

26 Hemoglobin: _____ g/dL g/L mmol/L

27 Hematocrit

Known Unknown

28 Hematocrit: _____ %

29 Was RBC transfused \leq 30 days before date of test?

Yes No

30 Platelets

Known Unknown

31 Platelets: _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

32 Were platelets transfused \leq 7 days before date of test?

Yes No

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Questions: 33 - 33

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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.

- 33** 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: 34 - 55

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

- 34** Were tests performed to detect persistence of the cellular product since the date of last report?
- Yes No
- 35** Was persistence evaluated by molecular assay? (e.g. PCR)
- Yes No
- 36** Date sample collected: _____ - _____ - _____
- 37** Specify the cell source
- Bone marrow Peripheral blood Tumor Other source
- 38** Specify other cell source: _____
- 39** Were the infused cells detected?
- Yes No
- 40** Was persistence evaluated by flow cytometry testing? (immunophenotyping)
- Yes No
- 41** Date sample collected: _____ - _____ - _____
- 42** Specify the cell source
- Bone marrow Peripheral blood Tumor Other source
- 43** Specify other cell source: _____
- 44** Were the infused cells detected?
- Yes No
- 45** Was persistence evaluated by immunohistochemistry?
- Yes No
- 46** Date sample collected: _____ - _____ - _____
- 47** Specify the cell source
- Bone marrow Peripheral blood Tumor Other source
- 48** Specify other cell source: _____
- 49** Were the infused cells detected?
- Yes No
- 50** Was persistence evaluated by other method?
- Yes No
- 51** Specify other method: _____
- 52** Date sample collected: _____ - _____ - _____
- 53** Specify the cell source
- Bone marrow Peripheral blood Tumor Other source
- 54** Specify other cell source: _____
- 55** Were the infused cells detected?
- Yes No

Graft vs. Host Disease

Questions: 56 - 75

This section is for allogeneic infusions only. If this was an autologous infusion, continue to question 76.

- 56** Did acute GVHD develop since the date of last report?
- Yes No Unknown
- 57** Date of acute GVHD diagnosis: _____ - _____ - _____

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Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

Center: _____ CRID: _____

58 Did acute GVHD persist since the date of last report?

- Yes No Unknown

59 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:

60 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

61 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

62 Upper intestinal tract

- Stage 0 - No persistent nausea or vomiting
- Stage 1 - Persistent nausea or vomiting

63 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)

64 Other site(s) involved with acute GVHD

- Yes No

65 Specify other site(s): _____

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

66 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)

67 Date maximum overall grade of acute GVHD: ____ - ____ - ____

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

- Yes No Unknown

69 Date of chronic GVHD diagnosis: ____ - ____ - ____ Date estimated

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

- Yes No Unknown

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					Initials: <input type="text"/>

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Center: _____ CRID: _____

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

- 71** Maximum grade of chronic GVHD (according to best clinical judgment)
 Mild Moderate Severe Unknown
- 72** 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

73 Date of maximum grade of chronic GVHD: ____ - ____ - ____

- 74** 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
- 75** Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
 Yes No Not Applicable Unknown

Toxicities

Questions: 76 - 187

- 76** Did the recipient develop Cytokine Release Syndrome (CRS) since the date of last report?
 Yes No
- 77** Date of diagnosis: ____ - ____ - ____
- 78** Was therapy given? (for CRS)
 yes no

Specify therapy given for CRS:

- 79** Specify therapy given for CRS (check all that apply)
- Corticosteroids
 - Siltuximab
 - Tocilizumab
 - Other therapy
- 80** Specify other therapy: _____

Symptoms

- 81** Fevers (≥ 100.4° F or ≥ 38° C)
 Yes No Unknown
- 82** Date of onset: ____ - ____ - ____
- 83** Hypotension requiring therapy
 Yes No Unknown
- 84** Date of onset: ____ - ____ - ____

Specify therapy given for hypotension:

- 85** Intravenous fluids
 Yes No Unknown
- 86** Vasopressor(s)
 Yes No Unknown
- 87** Specify the number of vasopressors used for therapy
 1 ≥2 Unknown
- 88** Other therapy
 yes no Unknown
- 89** Specify other therapy: _____

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Center: _____ CRID: _____

90 Was hypotension controlled with therapy?

- Yes No Unknown

91 Hypoxia requiring minimal supplemental oxygen (FiO2 <40%)

- Yes No Unknown

92 Date of onset: ____-____-____

93 Hypoxia requiring more than minimal supplemental oxygen (FiO2 ≥40%)

- Yes No Unknown

94 Date of onset: ____-____-____

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

- Yes No Unknown

96 Date started: ____-____-____

97 Did cytokine release syndrome resolve?

- Yes No

98 Date resolved: ____-____-____

Neurotoxicity

99 Neurotoxicity

- Yes No Unknown

100 Date of onset: ____-____-____

Specify symptoms of neurotoxicity. Report the highest grade observed in this reporting period:

101 Was a CARTOX-10 neurologic assessment performed?

- Yes No Unknown

102 What was the lowest CARTOX score?

- 10
 7-9
 3-6
 0-2
 Unable to be assessed

103 Depressed level of consciousness

- Yes No Unknown

104 Dysphasia / aphasia

- Yes No Unknown

105 Grade

- 1
 2
 3 (aphasia)

106 Seizure

- Yes No Unknown

107 Type

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

108 Specify other type: _____

109 Severity

- 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 (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between)

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year

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 20

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 20

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Center:

CRID:

110 Hemiparesis / paraparesis / other motor deficit

Yes No Unknown

111 Cerebral edema

Yes No Unknown

112 Grade

3 4

113 Hallucinations

Yes No Unknown

114 Tremors

Yes No Unknown

115 Cerebral vascular accident (stroke)

Yes No Unknown

116 Date of onset: ____ - ____ - ____

117 Type

Hemorrhagic Ischemic

118 Leukoencephalopathy

Yes No Unknown

Other Neurotoxicity Symptom(s) (1)

Questions: 119 - 120

119 Other symptom

Yes No Unknown

120 Specify other symptom: _____

121 Did neurotoxicity resolve?

Yes No

122 Date resolved: ____ - ____ - ____

Specify therapy given for neurotoxicity:

123 Specify therapy given for neurotoxicity (check all that apply)

Anti-epileptics

Corticosteroids

Other therapy

124 Specify other therapy: _____

Other toxicities

125 Hypogammaglobulinemia

Yes No Unknown

126 Date of onset: ____ - ____ - ____

127 Did hypogammaglobulinemia resolve?

Yes No

128 Date resolved: ____ - ____ - ____

129 Did recipient require immunoglobulin replacement therapy?

Yes No

130 Is the recipient still requiring replacement therapy?

Yes No

131 Tumor lysis syndrome

Yes No Unknown

132 Date of onset: ____ - ____ - ____

133 Grade

3 4 5

134 Other toxicity

Yes No Unknown

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Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

Center:

CRID:

135 Specify other toxicity: _____

136 Date of onset: ____-____-____

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

137 Has the recipient developed any grade 3 organ toxicity?

Yes No Unknown

138 Gastrointestinal (GI)

Yes No Unknown

139 Date of onset: ____-____-____

140 Heart

Yes No Unknown

141 Date of onset: ____-____-____

142 Kidneys

Yes No Unknown

143 Date of onset: ____-____-____

144 Liver

Yes No Unknown

145 Date of onset: ____-____-____

146 Lungs

Yes No Unknown

147 Date of onset: ____-____-____

148 Musculoskeletal

Yes No Unknown

149 Date of onset: ____-____-____

150 Neurologic

Yes No Unknown

151 Date of onset: ____-____-____

152 Other organ

Yes No Unknown

153 Date of onset: ____-____-____

154 Specify other organ: _____

155 Has the recipient developed any grade 4 organ toxicity?

Yes No Unknown

156 Gastrointestinal (GI)

Yes No Unknown

157 Date of onset: ____-____-____

158 Heart

Yes No Unknown

159 Date of onset: ____-____-____

160 Kidneys

Yes No Unknown

161 Date of onset: ____-____-____

162 Liver

Yes No Unknown

163 Date of onset: ____-____-____

164 Lungs

Yes No Unknown

165 Date of onset: ____-____-____

166 Musculoskeletal

Yes No Unknown

167 Date of onset: ____-____-____

168 Neurologic

Yes No Unknown

169 Date of onset: ____-____-____

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170 Other organ
 Yes No Unknown

171 Date of onset: ____ - ____ - ____

172 Specify other organ: _____

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

173 Interleukin-6
 Known Unknown

174 _____ pg/mL

175 Date sample collected: ____ - ____ - ____

176 Interferon gamma IFN γ
 Known Unknown

177 _____ IU/mL

178 Date sample collected: ____ - ____ - ____

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

180 _____ U/mL

181 Date sample collected: ____ - ____ - ____

182 Total serum ferritin
 Known Unknown

183 _____ ng/mL(μ g/L)

184 Date sample collected: ____ - ____ - ____

185 C-reactive protein
 Known Unknown

186 _____ mg/dL

187 Date sample collected: ____ - ____ - ____

Infection

Questions: 188 - 192

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

Yes No

Infection (1)

Questions: 189 - 192

Report each infection organism, site, and date of diagnosis

189 Organism _____

190 Specify other organism: _____

191 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

192 Date of diagnosis: ____ - ____ - ____

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ERROR CORRECTION FORM													
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Today's Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			Infusion Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			CIBMTR Center Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Visit: <input type="checkbox"/> 100 day <input type="checkbox"/> 6 month <input type="checkbox"/> <input type="text"/> year					
Month		Day		Year		Month		Day		Year		Initials: <input type="text"/> <input type="text"/>	

Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

Center: _____ CRID: _____

Functional Status

Questions: 193 - 194

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

- Yes - **Complete form 3501**
- No
- Unknown
- Previously reported (form 3501 already submitted for this event)

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

- Yes - **Complete form 3501**
- No
- Unknown
- Previously reported (form 3501 already submitted for this event)

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org.
Retain the original form at the transplant center.