

Form 2100 R6.0: Post-HCT Follow-Up Data

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: _____

Vital Status

Questions: 1 - 5

Information should come from an actual examination by the Transplant Center provider or the local provider who is following the recipient post-HCT.

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

3 Did the recipient receive a subsequent HCT since the date of last report?

- yes - **Answers to subsequent questions should reflect clinical status immediately prior to the start of the preparative regimen for subsequent HCT. Also complete Subsequent HCT section.**
- no

4 Has the recipient received a cellular therapy since the date of last report? (e.g. DCI)

- yes - **Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000**
- no

5 Date of cellular therapy: ____-____-____

Granulopoiesis / Neutrophil Recovery

Questions: 6 - 12

To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.

6 Was there evidence of initial hematopoietic 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 the preparative regimen)
- Previously reported (Recipient's initial hematopoietic recovery was recorded on a previous report)

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

8 Following the initial hematopoietic recovery, was there subsequent decline in ANC to $<$ 500/mm³ for \geq 3 days since the date of last report?

- yes no

9 Date of decline in ANC to $<$ 500/mm³ for \geq 3 days (first of 3 days that the ANC declined): ____-____-____

10 Did recipient recover and maintain ANC \geq 500/mm³ following the decline?

- yes no

11 Date of ANC recovery

- Known Unknown

12 Date of ANC recovery: ____-____-____

Megakaryopoiesis / Platelet Recovery

Questions: 13 - 18

This section relates to initial platelet recovery. All dates should reflect no transfusions in the previous 7 days. To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.

13 Was an initial platelet count \geq 20 x 10⁹/L achieved?

- Yes
- No
- Not applicable (Platelet count never dropped below 20 x 10⁹/L)
- Previously reported (\geq 20 x 10⁹/L was achieved and reported previously)

14 Date platelets \geq 20 x 10⁹/L

- Known Unknown

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

16 Was an initial platelet count \geq 50 x 10⁹/L achieved?

- Yes
- No
- Not applicable (Platelet count never dropped below 50 x 10⁹/L)
- Previously reported (\geq 50 x 10⁹/L was achieved and reported previously)

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17 Date platelets $\geq 50 \times 10^9/L$

Known Unknown

18 Date platelets $\geq 50 \times 10^9/L$: ____ - ____ - ____ Date estimated

Growth Factor and Cytokine Therapy

Questions: 19 - 48

19 Did the recipient receive hematopoietic, lymphoid growth factors or cytokines after the start of the preparatory regimen?

Yes No

Specify agents and provide dates for the first course of each agent given in this reporting period.

20 G-CSF

yes no

21 Date started: ____ - ____ - ____

22 Therapy

- Planned therapy per protocol
- Intervention for delay in cell count recovery
- Intervention for decline in cell count
- Anti-leukemic or tumor agent to prevent relapse
- Anti-leukemic or tumor agent to treat relapse
- Other indication

23 Specify other indication: _____

24 Specify drug given

- Filgrastim (Neupogen)
- Pegfilgrastim (Neulasta)
- Lenograstim
- Other drug

25 Specify other drug: _____

26 GM-CSF

yes no

27 Date started: ____ - ____ - ____

28 Therapy

- Planned therapy per protocol
- Intervention for delay in cell count recovery
- Intervention for decline in cell count
- Anti-leukemic or tumor agent to prevent relapse
- Anti-leukemic or tumor agent to treat relapse
- Other indication

29 Specify other indication: _____

30 Erythropoietin (EPO)

yes no

31 Date started: ____ - ____ - ____

32 Therapy

- Planned therapy per protocol
- Intervention for delay in cell count recovery
- Intervention for decline in cell count
- Other indication

33 Specify other indication: _____

34 Specify drug given

- Epoetin alfa (Epoen)
- Darbepoetin alfa (Aranesp)

35 KGF (palifermin, Kevivance)

Yes No

36 Date started: ____ - ____ - ____

37 Therapy

- Planned therapy per protocol
- Other indication

38 Specify other indication: _____

39 Blinded growth factor or cytokine trial

Yes No

40 Specify study agent: _____

41 Date started: ____ - ____ - ____

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42 Therapy

- Planned therapy per protocol
- Intervention for delay in cell count recovery
- Intervention for decline in cell count
- Anti-leukemic or tumor agent to prevent relapse
- Anti-leukemic or tumor agent to treat relapse
- Other indication

43 Specify other indication: _____

44 Other agent

- yes no

45 Specify other agent: _____

46 Date started: _____ - _____ - _____

47 Therapy

- Planned therapy per protocol
- Intervention for delay in cell count recovery
- Intervention for decline in cell count
- Anti-leukemic or tumor agent to prevent relapse
- Anti-leukemic or tumor agent to treat relapse
- Other indication

48 Specify other indication: _____

Current Hematologic Findings

Questions: 49 - 63

49 Date of most recent complete blood count: _____ - _____ - _____

50 WBC

- Known Unknown

51 WBC: _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

52 Neutrophils

- Known Unknown

53 Neutrophils: _____ %

54 Lymphocytes

- Known Unknown

55 Lymphocytes: _____ %

56 Hemoglobin

- Known Unknown

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

58 Hematocrit

- Known Unknown

59 Hematocrit: _____ %

60 Was RBC transfused ≤ 30 days before date of test?

- Yes No

61 Platelets

- Known Unknown

62 Platelets: _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

63 Were platelets transfused ≤ 7 days before date of test?

- Yes No

Immune Reconstitution

Questions: 64 - 88

Specify the date the most recent immunoglobulin sample was collected:

64 Date sample collected: _____ - _____ - _____

65 Did the recipient receive supplemental intravenous immunoglobulins (IVIG)?

- yes no

66 Was supplemental IVIG received in the 30 days prior to the date the sample was collected?

- Yes No

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Specify the indication for which IVIG was given:

67 Specify the indication for which IVIG was given

- Prophylaxis for low IgG with no active infection (polyclonal IV gamma globulin / IVIG)
- Active infection with normal IgG
- Active infection in the setting of low IgG
- Other indication

68 Specify other indication: _____

Specify the immunoglobulin values from the most recent testing:

69 IgG

- Known Unknown

70 _____ mg/dL g/dL g/L

71 IgM

- Known Unknown

72 _____ mg/dL g/dL g/L

73 IgA

- Known Unknown

74 _____ mg/dL g/dL g/L

75 Were lymphocyte analyses performed?

- yes no

Specify the date of the most recent sample:

76 Date sample collected: ____ - ____ - ____

77 CD3 (T cells)

- Known Unknown

78 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

79 CD4 (T helper cells)

- Known Unknown

80 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

81 CD8 (cytotoxic T cells)

- Known Unknown

82 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

83 CD19 (B lymphocyte cells)

- Known Unknown

84 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

85 CD20 (B lymphocyte cells)

- Known Unknown

86 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

87 CD56 (natural killer (NK) cells)

- Known Unknown

88 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

Chimerism Studies

Questions: 89 - 107

This section relates to chimerism studies from allogeneic HCTs only. If this was an autologous HCT, continue with the Infection section.

89 Were chimerism studies performed post-HCT? (Allogeneic HCTs only)

- yes no

90 Was documentation submitted to the CIBMTR? (e.g. chimerism laboratory reports)

- Yes No

91 Were chimerism studies assessed for more than one donor / multiple donors?

- Yes No

Chimerism Studies (1)

Questions: 92 - 107

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Provide date(s), method(s) and other information for all chimerism studies performed prior to date of contact (question 1).

92 NMDP cord blood unit ID: _____

93 Registry donor ID: _____

94 Non-NMDP cord blood unit ID: _____

95 Global Registration Identifier for Donors (GRID) _____

96 Date of birth: (donor/infant) ____ - ____ - ____ -OR- Age: (donor/infant) _____ Months years

97 Sex (donor/infant)

male female

98 Date sample collected: ____ - ____ - ____

99 Method

- Karyotyping for XX/XY
- Fluorescent in situ hybridization (FISH) for XX/XY
- Restriction fragment-length polymorphisms (RFLP)
- VNTR or STR, micro or mini satellite (also include AFLP)
- Other

100 Specify: _____

101 Cell source

Bone marrow Peripheral blood

102 Cell type _____

103 Specify: _____

104 Total cells examined: _____

105 Number of donor cells: _____

106 Were donor cells detected?

Yes No

107 Percent donor cells: _____ %

Engraftment Syndrome

Questions: 108 - 130

108 Did engraftment syndrome occur?

yes no

109 Date of onset: ____ - ____ - ____

Specify the symptoms of engraftment syndrome:

110 Diarrhea

Yes No

111 Erythrodermic rash (involving >25% of body surface area)

Yes No

112 Fever ($\geq 38.3^{\circ}\text{C}$ or $> 100.9^{\circ}\text{F}$ with no identifiable infectious etiology)

Yes No

113 Development of hepatic dysfunction (with either bilirubin ≥ 2 mg/dL or transaminase levels ≥ 2 times normal)

Yes No

114 Non-cardiogenic pulmonary edema (manifested by diffuse pulmonary infiltrates and hypoxia)

Yes No

115 Development of renal insufficiency (serum creatinine ≥ 2 times baseline)

Yes No

116 Transient encephalopathy

Yes No

117 Weight gain ($\geq 2.5\%$ of baseline body weight)

Yes No

118 Other symptom

Yes No

119 Specify other symptom: _____

Biopsy

120 Was a biopsy performed?

yes no

Specify site:

121 Lower gastrointestinal (GI)

Yes No

122 Skin

Yes No

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123 Other site

Yes No

124 Specify other site: _____

125 Was documentation submitted to the CIBMTR? (pathology report)

Yes No

Specify if therapy was given for engraftment syndrome:

126 Was therapy given?

yes no

127 Corticosteroids (systemic)

yes no

128 Other therapy

yes no

129 Specify other therapy: _____

130 Did engraftment syndrome resolve?

Yes No

Acute Graft vs. Host Disease (GVHD)

Questions: 131 - 233

If an allogeneic donor was used for the recipient's HCT or cellular therapy, report all acute graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue with the Infection section.

131 Was specific therapy used after the start of the preparative regimen to prevent acute GVHD? (Note: do not include growth factors reported in questions 19-48, or ex vivo T-cell depletion reported on the Product Insert. Do not include drugs given as part of the preparative regimen)

Yes No

132 ALG, ALS, ATG, ATS

yes no

133 Total dose: _____ mg/kg

134 Specify source

- ATGAM (horse)
- ATG - Fresenius (rabbit)
- Thymoglobulin (rabbit)
- Other

135 Specify other source: _____

136 Bortezomib (Velcade)

yes no

137 Corticosteroids (systemic) (e.g. prednisone, dexamethasone)

yes no

138 Cyclosporine (CSA, Neoral, Sandimmune)

yes no

139 Cyclophosphamide (Cytoxan)

yes no

140 Total dose: _____ mg/kg

141 Extra-corporeal photopheresis (ECP)

yes no

142 FK 506 (Tacrolimus, Prograf)

yes no

143 In vivo monoclonal antibody

yes no

Specify in vivo monoclonal antibody:

144 Alemtuzumab (Campath)

yes no

145 Total dose: _____ mg

146 Other in vivo monoclonal antibody

yes no

147 Specify antibody: _____

148 In vivo immunotoxin

yes no

149 Specify immunotoxin: _____

150 Methotrexate (MTX) (Amethopterin)

yes no

151 Mycophenolate mofetil (MMF) (CellCept, Myofortin)

yes no

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152 Sirolimus (Rapamycin, Rapamune)

yes no

153 Blinded randomized trial

yes no

154 Specify trial agent: _____

155 Other agent

yes no

156 Specify other agent: _____

157 Did acute GVHD develop since the date of last report?

Yes No Unknown

158 Date of acute GVHD diagnosis: ____-____-____

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

Yes No Unknown

160 Was acute GVHD evaluated by biopsy (histology)? (at diagnosis)

Yes No

Specify result(s):

161 Skin

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

162 Lower gastrointestinal (GI)

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

163 Upper gastrointestinal (GI)

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

164 Liver

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

165 Lung

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

166 Other site

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

167 Specify other site: _____

168 Was documentation submitted to the CIBMTR? (e.g. pathology report)

Yes No

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169 Overall grade of acute GVHD at diagnosis

- I - Rash on \leq 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 cannot be graded)

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

170 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

171 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

172 Upper intestinal tract

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

173 Liver

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

174 Other site(s) involved with acute GVHD

- Yes No

175 Specify other site(s): _____

List the maximum severity of organ involvement since the date of last report:

176 Maximum overall grade of acute GVHD

- I - Rash on \leq 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 cannot be graded)

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

Specify organ involvement at time of maximum grade:

178 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

179 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

180 Upper intestinal tract

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

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181 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)

182 Other site(s) involved with acute GVHD

- Yes No

183 Specify other site(s): _____

Specify therapy given for acute GVHD:

184 Corticosteroids (topical GI) (e.g. beclomethasone, budesonide)

- Yes No

185 Was systemic therapy used to treat acute GVHD?

- yes no

186 ALG, ALS, ATG, ATS

- yes no

187 Total dose: _____ mg/kg

188 Date started: _____ - _____ - _____

189 Specify source

- ATGAM (horse)
- ATG - Fresenius (rabbit)
- Thymoglobulin (rabbit)
- Other

190 Specify other source: _____

191 Alemtuzumab (Campath)

- yes no

192 Total dose: _____ mg

193 Date started: _____ - _____ - _____

194 Anti CD25 (Zenapax, Daclizumab, AntiTAC)

- yes no

195 Specify anti CD25: _____

196 Date started: _____ - _____ - _____

197 Corticosteroids (systemic) (e.g. prednisone, dexamethasone)

- yes no

198 Date started: _____ - _____ - _____

199 Cyclosporine (CSA, Neoral, Sandimmune)

- yes no

200 Date started: _____ - _____ - _____

201 Extra-corporeal photopheresis (ECP)

- yes no

202 Date started: _____ - _____ - _____

203 Etanercept (Enbrel)

- yes no

204 Date started: _____ - _____ - _____

205 FK 506 (Tacrolimus, Prograf)

- yes no

206 Date started: _____ - _____ - _____

207 Infliximab (Remicade)

- yes no

208 Date started: _____ - _____ - _____

209 In vivo immunotoxin

- yes no

210 Specify immunotoxin: _____

211 Date started: _____ - _____ - _____

212 Mycophenolate mofetil (MMF) (CellCept, Myfortic)

- yes no

213 Date started: _____ - _____ - _____

214 Pentostatin (Nipent)

- yes no

215 Date started: _____ - _____ - _____

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216 PUVA (Psoralen and UVA)

yes no

217 Date started: ____-____-____

218 Sirolimus (Rapamycin, Rapamune)

yes no

219 Date started: ____-____-____

220 Tocilizumab

Yes No

221 Date started: ____-____-____

222 JAK 2 inhibitors

Yes No

223 Ruxolitinib (Jakafi)

yes no

224 Date started: ____-____-____

225 Other JAK 2 inhibitor

Yes No

226 Specify other JAK 2 inhibitor: _____

227 Date started: ____-____-____

228 Blinded randomized trial

yes no

229 Specify trial agent: _____

230 Date started: ____-____-____

231 Other agent

yes no

232 Specify other agent: _____

233 Date started: ____-____-____

Chronic Graft vs. Host Disease (GVHD)

Questions: 234 - 406

If an allogeneic donor was used for the recipient's HCT or cellular therapy, report all chronic graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue with the Infection section.

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

Yes No Unknown

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

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

Yes No Unknown

237 Onset of chronic GVHD was

- Progressive (acute GVHD present within 2 weeks prior to onset of chronic GVHD)
 Interrupted (acute GVHD resolved, then chronic GVHD developed)
 De novo (acute GVHD never developed)

238 Were signs of acute GVHD present at the time of chronic GVHD diagnosis (overlap syndrome)?

Yes No

239 What scale was used to determine the recipient's functional status? (at time of chronic GVHD diagnosis)

- Karnofsky (recipient age \geq 16 years)
 Lansky (recipient age \geq 1 year and $<$ 16 years)

Performance score:

240 Karnofsky Scale (recipient age \geq 16 years) _____

241 Lansky Scale (recipient age \geq 1 year and $<$ 16 years) _____

242 Platelets: (at diagnosis of chronic GVHD) _____ $\times 10^9/L$ ($\times 10^3/mm^3$)
 $\times 10^6/L$

243 Total serum bilirubin: (at diagnosis of chronic GVHD) _____ mg/dL $\mu mol/L$

244 Was chronic GVHD evaluated by biopsy (histology)? (at diagnosis)

Yes No

Specify result(s):

245 Skin

- Positive
 Suggestive
 Negative
 Inconclusive / equivocal
 Not done

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246 Lower gastrointestinal (GI)

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

247 Upper gastrointestinal (GI)

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

248 Liver

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

249 Lung

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

250 Other site

- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

251 Specify other site: _____

Specify organs involved and NIH scoring at diagnosis of chronic GVHD:

Skin:

252 Skin

- Yes No

253 Score percent BSA involved

- Score 0 - No BSA involved
- Score 1 - 1-18% BSA
- Score 2 - 19-50% BSA
- Score 3 - >50% BSA

254 Skin features score

- No sclerotic features
- Superficial sclerotic features "not hidebound" (able to pinch)
- Deep sclerotic features, hidebound (unable to pinch), impaired mobility, or ulceration

Specify skin GVHD features present at diagnosis of chronic GVHD:

255 Maculopapular rash / erythema

- Yes No

256 Lichen planus-like features

- Yes No

257 Papulosquamous lesions or ichthyosis

- Yes No

258 Keratosis pilaris-like GVHD

- Yes No

Specify if any skin abnormalities were present, but explained entirely by non-GVHD causes:

259 Abnormality present but explained entirely by non-GVHD documented cause

- Yes No

260 Specify cause: _____

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Mouth

261 Mouth

Yes No

262 Mouth score

- Score 0 - No symptoms
 Score 1 - Mild symptoms with disease signs but not limiting oral intake significantly
 Score 2 - Moderate symptoms with disease signs with partial limitation of oral intake
 Score 3 - Severe symptoms with disease signs on examination with major limitation of oral intake

263 Lichen planus-like features

Yes No

Specify if any mouth abnormalities were present, but explained entirely by non-GVHD causes:

264 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

265 Specify cause: _____

Eyes

266 Eyes

Yes No

267 Eyes score

- Score 0 - No symptoms
 Score 1 - Mild dry eye symptoms not affecting ADL (requirement of lubricant eye drops \leq 3x per day)
 Score 2 - Moderate dry eye symptoms partially affecting ADL (requiring lubricant eye drops $>$ 3x per day or punctal plugs), without new vision impairment due to keratoconjunctivitis sicca (KCS)
 Score 3 - Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) OR unable to work because of ocular symptoms OR loss of vision due to keratoconjunctivitis sicca (KCS)

268 Keratoconjunctivitis sicca (KCS) confirmed by ophthalmologist?

Yes No Not done

Specify if any eye abnormalities were present, but explained entirely by non-GVHD causes:

269 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

270 Specify cause: _____

Gastrointestinal (GI) Tract

271 Gastrointestinal (GI) tract

Yes No

272 Gastrointestinal (GI) tract score

- Score 0 - No symptoms
 Score 1 - Symptoms without significant weight loss ($<$ 5%)
 Score 2 - Symptoms associated with mild to moderate weight loss (5-15%) OR moderate diarrhea without significant interference with daily living
 Score 3 - Symptoms associated with significant weight loss ($>$ 15%), requires nutritional supplementation for most calorie needs OR esophageal dilation OR severe diarrhea with significant interference with daily living

Specify if any GI abnormalities were present, but explained entirely by non-GVHD causes:

273 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

274 Specify cause: _____

Specify Gastrointestinal (GI) tract GVHD features present at diagnosis of chronic GVHD:

275 Esophageal web / proximal stricture or ring

Yes No

276 Dysphagia

Yes No

277 Anorexia

Yes No

278 Nausea

Yes No

279 Vomiting

Yes No

280 Diarrhea

Yes No

281 Weight loss \geq 5%

Yes No

282 Failure to thrive

Yes No

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Liver

283 Liver

Yes No

284 Liver score

- Score 0 - Normal total bilirubin and ALT or AP <3 x ULN
- Score 1 - Normal total bilirubin with ALT ≥3 to 5 x ULN or AP ≥3 x ULN
- Score 2 - Elevated total bilirubin but ≤3 mg/dL or ALT >5 ULN
- Score 3 - Elevated total bilirubin > 3 mg/dL

Specify if any liver abnormalities were present, but explained entirely by non-GVHD causes:

285 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

286 Specify cause: _____

Lungs

287 Lungs

Yes No

288 Lung score

- Score 0 - No symptoms
- Score 1 - Mild symptoms (shortness of breath after climbing one flight of steps)
- Score 2 - Moderate symptoms (shortness of breath after walking on flat ground)
- Score 3 - Severe symptoms (shortness of breath at rest; requiring oxygen)

289 Were pulmonary function tests performed?

Yes No

290 Specify FEV1 percent: _____ %

Specify if any lung abnormalities were present, but explained entirely by non-GVHD causes:

291 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

292 Specify cause: _____

Joints and fascia

293 Joints and fascia

Yes No

294 Joints and fascia score

- Score 0 - No symptoms
- Score 1 - Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL
- Score 2 - Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate decrease ROM AND mild to moderate limitation of ADL
- Score 3 - Contractures WITH significant decrease ROM AND significant limitation of ADL (e.g. unable to tie shoes, button shirts, dress self, etc.)

Specify if any joint or fascia abnormalities were present, but explained entirely by non-GVHD causes:

295 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

296 Specify cause: _____

Genital tract

297 Genital tract

Yes No

298 Genital tract score

- Score 0 - No signs
- Score 1 - Mild signs and females with or without discomfort on exam
- Score 2 - Moderate signs and may have symptoms with discomfort on exam
- Score 3 - Severe signs with or without symptoms

299 Currently sexually active?

Yes No Unknown

Specify if any genital tract abnormalities were present, but explained entirely by non-GVHD causes:

300 Abnormality present but explained entirely by non-GVHD documented cause

Yes No

301 Specify cause: _____

Maximum grade of chronic GVHD since the date of last report:

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

Mild Moderate Severe Unknown

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

303 Specify if chronic GVHD was limited or extensive

- Limited - Localized skin involvement and/or hepatic dysfunction due to chronic GVHD
- 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

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

Organ specific manifestations since the date of last report:

Indicate if there was organ specific manifestations with chronic GVHD from the list below:

305 Sclerosis of skin or fascia (e.g. scleroderma, fasciitis, morphea)

- Yes No

306 Erythematous skin rash

- Yes No

307 Joint contractures

- Yes No

308 Other skin or hair involvement (ulcers, pruritus or itching, dyspigmentation, alopecia, lichenoid skin changes, etc.)

- yes no

309 Eyes (xerophthalmia (dry eyes), abnormal Schirmer's test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.)

- Yes No

310 Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.)

- Yes No

311 Bronchiolitis obliterans

- yes no

312 Other lung involvement

- yes no

313 Upper gastrointestinal tract (esophageal involvement, chronic nausea / vomiting)

- Yes No

314 Lower gastrointestinal tract (chronic diarrhea, malabsorption, abdominal pain / cramps, etc.)

- Yes No

315 Diarrhea

- Yes No

316 Liver

- Yes No

317 Genitourinary tract (vaginitis / stricture, etc.)

- yes no

318 Musculoskeletal (arthritis, myositis, etc.)

- yes no

319 Thrombocytopenia (< 100 x 10⁹/L)

- yes no

320 Eosinophilia

- yes no

321 Serositis (e.g., pleural effusion, ascites, pericardial effusion)

- yes no

322 Other organ involvement

- Yes No

323 Specify site: _____

Specify therapy given for chronic GVHD since the date of last report:

324 Corticosteroids (topical GI) (e.g. beclomethasone, budesonide)

- Yes No

325 Was systemic therapy given to treat chronic GVHD?

- yes no

326 Was the date therapy was first started previously reported?

- Yes No

327 Date therapy was first started: ____ - ____ - ____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

Specify systemic therapy started or escalated for chronic GVHD since the date of last report:

328 ALG, ALS, ATG, ATS

yes no

329 Total dose: _____ mg/kg

330 Specify source

- ATGAM (horse)
 ATG - Fresenius (rabbit)
 Thymoglobulin (rabbit)
 Other

331 Specify other source: _____

332 Date started: ____ - ____ - ____

333 Aldesleukin (interleukin-2, IL-2)

yes no

334 Date started: ____ - ____ - ____

335 Alemtuzumab (Campath)

yes no

336 Total dose: _____ mg

337 Date started: ____ - ____ - ____

338 Anti CD25 (Zenapax, Daclizumab, AntiTAC)

yes no

339 Specify anti CD25: _____

340 Date started: ____ - ____ - ____

341 Azathioprine

Yes No

342 Date started: ____ - ____ - ____

343 Bortezomib (Velcade)

yes no

344 Date started: ____ - ____ - ____

345 Corticosteroids (systemic) (e.g. prednisone, dexamethasone)

yes no

346 Date started or escalated: ____ - ____ - ____

347 Cyclosporine (CSA, Neoral, Sandimmune)

yes no

348 Date started: ____ - ____ - ____

349 Interleukin inhibitors

Yes No

350 Anti-IL2

Yes No

351 Date started: ____ - ____ - ____

352 Anti-IL6

Yes No

353 Date started: ____ - ____ - ____

354 Other interleukin inhibitor

Yes No

355 Specify other interleukin inhibitor: _____

356 Date started: ____ - ____ - ____

357 Extra-corporeal photopheresis (ECP)

yes no

358 Date started: ____ - ____ - ____

359 Etanercept (Enbrel)

yes no

360 Date started: ____ - ____ - ____

361 FK 506 (Tacrolimus, Prograf)

yes no

362 Date started: ____ - ____ - ____

363 Hydroxychloroquine (Plaquenil)

Yes No

364 Date started: ____ - ____ - ____

365 Infliximab (Remicade)

yes no

366 Date started: ____ - ____ - ____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

367 Methotrexate (MTX) (Amethopterin)

yes no

368 Date started: _____ - ____ - ____

369 Mycophenolate mofetil (MMF) (CellCept, Myfortic)

yes no

370 Date started: _____ - ____ - ____

371 Pentostatin (Nipent)

yes no

372 Date started: _____ - ____ - ____

373 UV therapy

Yes No

374 PUVA (Psoralen and UVA)

yes no

375 Date started: _____ - ____ - ____

376 UVB

Yes No

377 Date started: _____ - ____ - ____

378 Rituximab (Rituxan, MabThera)

yes no

379 Date started: _____ - ____ - ____

380 Sirolimus (Rapamycin, Rapamune)

yes no

381 Date started: _____ - ____ - ____

382 Tyrosine kinase inhibitors (TKI)

yes no

383 Imatinib mesylate (Gleevec)

yes no

384 Date started: _____ - ____ - ____

385 Other TKI

Yes No

386 Specify other TKI: _____

387 Date started: _____ - ____ - ____

388 JAK 2 inhibitors

Yes No

389 Ruxolitinib (Jakafi)

yes no

390 Date started: _____ - ____ - ____

391 Other JAK 2 inhibitor

Yes No

392 Specify other JAK 2 inhibitor: _____

393 Date started: _____ - ____ - ____

394 Blinded randomized trial

yes no

395 Specify trial agent: _____

396 Date started: _____ - ____ - ____

397 Other agent

yes no

398 Specify other agent: _____

399 Date started: _____ - ____ - ____

Current GVHD Status

400 Are symptoms of GVHD still present on the date of actual contact (or present at the time of death)?

Yes No

401 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

402 Date final treatment administered

Known Unknown Previously reported

403 Date final treatment administered: _____ - ____ - ____

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

Yes No Not Applicable Unknown

405 Date final treatment administered

Known Unknown Previously reported

406 Date final treatment administered: _____ - ____ - ____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

Infection Prophylaxis

Questions: 407 - 427

Select the drug in each group the recipient received **first** and **closest** to the start of the preparative regimen, even if it was started prior to the preparative regimen. Include prophylactic medications started prior to day +45 post-HCT.

407 Did the recipient receive antibacterial drug(s) for infection prophylaxis?

Yes No

Specify the **first** antibacterial drug(s) given as a single drug or as combination therapy

408 Amoxicillin clavulanate oral (Augmentin)

Yes No

409 Cefdinir oral (Omnicef)

Yes No

410 Cefpodoxime oral (Vantin)

Yes No

411 Ciprofloxacin IV or oral (Cipro)

Yes No

412 Ertapenem IV

Yes No

413 Levofloxacin IV or oral (Levaquin)

Yes No

414 Moxifloxacin IV or oral (Avelox)

Yes No

415 Vancomycin IV

Yes No

416 Other antibacterial drug

Yes No

417 Specify other antibacterial drug: _____

418 Date started: _____ - _____ - _____

419 Antiviral drugs (select one) _____

420 Specify other antiviral drug: _____

421 Date started: _____ - _____ - _____

422 Antifungal drugs (select one) _____

423 Specify other antifungal drug: _____

424 Date started: _____ - _____ - _____

425 Anti-pneumocystis (PJP) drug (select one) _____

426 Specify other anti-pneumocystis drug: _____

427 Date started: _____ - _____ - _____

Infection

Questions: 428 - 440

428 Did the patient develop a clinically significant infection since the date of last report?

Yes No

Infection (1)

Questions: 429 - 436

Report each infection organism, site, and date of diagnosis.

429 Organism _____

430 Specify other organism: _____

431 Site _____

432 Site _____

433 Site _____

434 Site _____

435 Site _____

436 Date of diagnosis: _____ - _____ - _____

437 Did the recipient develop Systemic Inflammatory Response Syndrome (SIRS) since the date of last report?

Yes No

438 Date of diagnosis: _____ - _____ - _____

439 Did the recipient develop septic shock since the date of last report?

Yes No

440 Date of diagnosis: _____ - _____ - _____

Organ Function

Questions: 441 - 615

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

Pulmonary Function

441 Did the recipient develop non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) since the date of last report?

Non-infectious interstitial pneumonitis / idiopathic pneumonia syndrome is characterized by hypoxia and chest radiographic imaging with diffuse infiltrates not caused by fluid overload or infection.

(Report infectious pneumonia in Infection section)

Yes No

442 Date of diagnosis: ____ - ____ - ____

443 Were diagnostic tests done? (other than radiographic studies)

Yes No

Diagnosis was evaluated by:

444 Bronchoalveolar lavage (BAL)

Yes No

445 Transbronchial biopsy

Yes No

446 Open / thorascopic (VATS) lung biopsy

Yes No

447 Autopsy

Yes No

448 Other diagnostic test

Yes No

449 Specify other diagnostic test: _____

450 Was an organism isolated from the sputum, BAL, or tracheal aspirate that is clinically significant?

Yes No

451 Was documentation submitted to the CIBMTR? (e.g. scan report)

Yes No

452 Did the recipient develop other non-infectious pulmonary abnormalities since the date of last report? (e.g. bronchiolitis obliterans, COP / BOOP, diffuse alveolar hemorrhage)

Yes No

453 Did the recipient develop bronchiolitis obliterans since the date of last report?

Yes No

454 Date of diagnosis: ____ - ____ - ____

455 Were diagnostic tests done? (other than radiographic studies)

Yes No

Diagnosis was evaluated by:

456 Bronchoalveolar lavage (BAL)

Yes No

457 Transbronchial biopsy

Yes No

458 Open / thorascopic (VATS) lung biopsy

Yes No

459 Autopsy

Yes No

460 Other diagnostic test

Yes No

461 Specify other diagnostic test: _____

462 Was documentation submitted to the CIBMTR? (e.g. scan report)

Yes No

463 Did the recipient develop cryptogenic organizing pneumonia (COP / BOOP)?

Yes No

464 Date of diagnosis: ____ - ____ - ____

465 Were diagnostic tests done? (other than radiographic studies)

Yes No

Diagnosis was evaluated by:

466 Bronchoalveolar lavage (BAL)

Yes No

467 Transbronchial biopsy

Yes No

468 Open / thorascopic (VATS) lung biopsy

Yes No

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

469 Autopsy

Yes No

470 Other diagnostic test

Yes No

471 Specify other diagnostic test: _____

472 Was documentation submitted to the CIBMTR? (e.g. scan report)

Yes No

473 Did the recipient develop diffuse alveolar hemorrhage?

Yes No

474 Date of diagnosis: ____ - ____ - ____

475 Were diagnostic tests done? (other than radiographic studies)

Yes No

Diagnosis was evaluated by:

476 Bronchoalveolar lavage (BAL)

Yes No

477 Transbronchial biopsy

Yes No

478 Open / thorascopic (VATS) lung biopsy

Yes No

479 Autopsy

Yes No

480 Other diagnostic test

Yes No

481 Specify other diagnostic test: _____

482 Was documentation submitted to the CIBMTR? (e.g. scan report)

Yes No

483 Did the recipient develop any other non-infectious pulmonary abnormalities?

yes no

484 Date of diagnosis: ____ - ____ - ____

485 Specify other pulmonary abnormality: _____

486 Did the recipient receive endotracheal intubation or mechanical ventilation post-HCT?

Yes No

487 Date started: ____ - ____ - ____

488 Was the recipient successfully extubated?

Yes No

489 Date extubated: ____ - ____ - ____

Liver Toxicity Prophylaxis

490 Was specific therapy used to prevent liver toxicity?

Yes No

491 Defibrotide

Yes No

492 N-acetylcysteine

Yes No

493 Tissue plasminogen activator (TPA)

Yes No

494 Ursodiol

Yes No

495 Other therapy

yes no

496 Specify other therapy: _____

Liver Function

497 Did the recipient develop non-infectious liver toxicity (excluding GVHD) since the date of last report?

Yes No

Etiology:

VOD / SOS

498 Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop since the date of last report?

Yes No

499 Date of diagnosis: ____ - ____ - ____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

Cirrhosis

500 Cirrhosis

Yes No

501 Date of diagnosis: ____ - ____ - ____

Other Etiology

502 Other etiology

Yes No

503 Specify other etiology: _____

504 Date of diagnosis: ____ - ____ - ____

505 Unknown etiology

Yes No

Thrombotic microangiopathy (TMA)

506 Did the recipient develop post-transplant thrombotic microangiopathy (TMA) or similar syndrome since the date of last report? (includes microangiopathy, thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS))

Yes No

507 Date of diagnosis: ____ - ____ - ____

Specify signs and symptoms:

508 RBC fragmentation and >2 schistocytes per high-power field on peripheral smear

Yes No

509 Increased serum LDH above institutional baseline

Yes No

510 Renal dysfunction without other explanation (doubling of serum creatinine from baseline, OR 50% decrease in creatinine clearance from baseline)

Yes No

511 Neurologic dysfunction without other explanation

Yes No

512 Negative direct and indirect Coombs test results

Yes No

513 Was TMA evaluated by biopsy?

Yes No

Specify result(s):

514 Kidney

- Positive
 Suggestive
 Negative
 Inconclusive / equivocal
 Not done

515 Other site

- Positive
 Suggestive
 Negative
 Inconclusive / equivocal
 Not done

516 Specify other site: _____

517 Was documentation submitted to the CIBMTR?

Yes No

Specify therapy for TMA

518 Was therapy given for TMA?

yes no

519 Defibrotide

Yes No

520 Eculizumab (Soliris)

Yes No

521 Rituximab (Rituxan, MabThera)

yes no

522 Plasma exchange / plasmapheresis

Yes No

523 Other therapy

yes no

524 Specify other therapy: _____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

525 Did the TMA resolve? (Normalization of renal function, LDH, and resolution or improvement in renal and/or neurologic dysfunction)

Yes No

526 Date resolved: ____-____-____

Other Organ Impairment / Disorder

527 Has the recipient developed any other clinically significant organ impairment or disorder since the date of last report?

yes no

Specify impairment / disorder:

Renal

528 Acute renal failure requiring dialysis

Yes No

529 Date of diagnosis: ____-____-____

530 Date dialysis started: ____-____-____

531 Was the recipient still on dialysis at the date of last contact?

Yes No

532 Date dialysis stopped: ____-____-____

533 Chronic kidney disease / renal impairment (persistent decrease in glomerular filtration rate to < 60 mL/min/1.73m²)

Yes No

534 Date of diagnosis: ____-____-____

535 Was the recipient placed on dialysis?

Yes No

536 Date dialysis started: ____-____-____

537 Was the recipient still on dialysis at the date of last contact?

Yes No

538 Date dialysis stopped: ____-____-____

Cardiac

539 Arrhythmia (e.g. atrial fibrillation or flutter, sick sinus syndrome, ventricular arrhythmia)

Yes No

540 Date of diagnosis: ____-____-____

541 Specify arrhythmia

Atrial fibrillation or flutter

Sick sinus syndrome

Ventricular arrhythmia

Other arrhythmia

542 Specify other arrhythmia: _____

543 Congestive heart failure

Yes No

544 Date of diagnosis: ____-____-____

545 Specify ejection fraction: _____ %

546 Coronary artery disease

Yes No

547 Date of diagnosis: ____-____-____

548 Myocardial infarction / Unstable angina

Yes No

549 Date of diagnosis: ____-____-____

550 Hypertension (HTN) requiring therapy

Yes No

551 Date of diagnosis: ____-____-____

552 Was the recipient still receiving therapy at the date of contact for this reporting period?

Yes No

Vascular

553 Deep vein thrombosis (DVT) / Pulmonary embolism (PE)

Yes No

554 Date of diagnosis: ____-____-____

555 Was the DVT catheter related?

Yes No

Neurological

556 CNS hemorrhage

Yes No

557 Date of diagnosis: ____-____-____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center:

CRID:

558 Encephalopathy (non-infectious)

Yes No

559 Date of diagnosis: ____ - ____ - ____

560 Neuropathy

Yes No

561 Date of diagnosis: ____ - ____ - ____

562 Seizures

yes no

563 Date of diagnosis: ____ - ____ - ____

564 Stroke

Yes No

565 Date of diagnosis: ____ - ____ - ____

Endocrine

566 Diabetes / hyperglycemia requiring chronic treatment

Yes No

567 Date of diagnosis: ____ - ____ - ____

568 Was the recipient still receiving therapy at the date of contact for this reporting period?

Yes No

569 Growth hormone deficiency / short stature

Yes No

570 Date of diagnosis: ____ - ____ - ____

571 Was therapy given?

yes no

572 Hypothyroidism requiring replacement therapy

Yes No

573 Date of diagnosis: ____ - ____ - ____

574 Pancreatitis

Yes No

575 Date of diagnosis: ____ - ____ - ____

Genitourinary

576 Gonadal dysfunction requiring hormone replacement (testosterone or estrogen)

Yes No

577 Date of diagnosis: ____ - ____ - ____

578 Hemorrhagic cystitis / hematuria requiring medical intervention (catheterization of bladder, extra transfusions, urology consult)

Yes No

579 Date of diagnosis: ____ - ____ - ____

Musculoskeletal

580 Avascular necrosis

Yes No

581 Date of diagnosis: ____ - ____ - ____

582 Osteonecrosis of the jaw

Yes No

583 Date of diagnosis: ____ - ____ - ____

584 Osteoporosis

Yes No

585 Date of diagnosis: ____ - ____ - ____

586 Osteoporotic fracture

Yes No

587 Date of diagnosis: ____ - ____ - ____

Psychiatric

588 Depression requiring therapy

Yes No

589 Date of diagnosis: ____ - ____ - ____

590 Anxiety requiring therapy

Yes No

591 Date of diagnosis: ____ - ____ - ____

592 Post-traumatic stress disorder (PTSD) requiring therapy

Yes No

593 Date of diagnosis: ____ - ____ - ____

Other

594 Cataracts

Yes No

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Center:

CRID:

595 Date of diagnosis: ____-____-____

596 Hyperlipidemia requiring therapy (high total cholesterol, high LDL cholesterol, and/or high triglyceride levels)

Yes No

597 Date of diagnosis: ____-____-____

598 Was the recipient still receiving therapy at the date of contact for this reporting period?

Yes No

599 Iron overload requiring therapy

Yes No

600 Date of diagnosis: ____-____-____

Specify therapy:

601 Phlebotomy

Yes No

602 Iron chelation

Yes No

603 Other therapy

yes no

604 Specify other therapy: _____

605 Mucositis requiring therapy

Yes No

606 Date of diagnosis: ____-____-____

607 Specify OMS grade

0 (none)

I (mild) - Oral soreness, erythema

II (moderate) - Oral erythema, ulcers, solid diet tolerated

III (severe) - Oral ulcers, liquid diet only

IV (life-threatening) - Oral ulcers, oral alimentation impossible

608 Other impairment or disorder

Yes No

609 Date of diagnosis: ____-____-____

610 Specify other impairment / disorder: _____

611 Has the recipient received a solid organ transplant?

Yes No

612 Specify solid organ transplanted

Heart Kidney Liver Lung Other organ

613 Specify other organ: _____

614 Date of transplant: ____-____-____

615 Specify solid organ donor type

Living related donor

Living unrelated donor

Cadaveric donor

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Questions: 616 - 639

616 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 No

New Malignancy (1)

Questions: 617 - 639

Report each new malignancy diagnosed since the date of last report. The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

617 Specify the new malignancy _____

618 Specify other new malignancy: _____

619 Date of diagnosis: ____-____-____

620 Was the new malignancy donor / cell product derived?

Yes No Not done

621 Was documentation submitted to the CIBMTR? (e.g. cell origin evaluation (VNTR, cytogenetics, FISH))

yes no

622 Was documentation submitted to the CIBMTR? (e.g. pathology report, autopsy report)

Yes No

Post-Transplant Lymphoproliferative Disorder

623 Was there EBV reactivation in the blood?

Yes No Unknown

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Center:

CRID:

624 How was EBV reactivation diagnosed?

- Qualitative PCR of blood
- Quantitative PCR of blood
- Other method

625 Specify other method: _____

626 Quantitative EBV viral load of blood: (at diagnosis of EBV) _____ copies/mL

627 Was a quantitative PCR of blood performed again after diagnosis?

- Yes No

628 Highest EBV viral load of blood: _____ copies/mL

629 Was there lymphomatous involvement? (e.g. a mass)

- Yes No

Specify sites of PTLD involvement:

630 Bone marrow

- yes no

631 Central nervous system (brain or cerebrospinal fluid)

- Yes No

632 Liver

- yes no

633 Lung

- yes no

634 Lymph nodes

- yes no

635 Spleen

- yes no

636 Other site

- yes no

637 Specify other site: _____

638 Was PTLD confirmed by biopsy?

- Yes No

639 Was documentation submitted to the CIBMTR? (e.g. pathology report)

- Yes No

Functional Status

Questions: 640 - 664

640 Was the intent to complete the HCT procedure (conditioning, infusion, and period of recovery from neutropenia) as an outpatient?

- Yes No

641 Did the recipient require an unplanned admission?

- Yes No

642 Was the recipient discharged prior to the date of contact?

- Yes No

643 Date first discharged from hospital post-HCT: ____ - ____ - ____

644 Total number of inpatient days (day 0 to day 100) in first 100 days post-HCT: _____

645 Recipient height (most recent)

- Known Unknown

646 Recipient height: _____ inches centimeters

647 Date documented: ____ - ____ - ____

648 Recipient weight (most recent)

- Known Unknown

649 Recipient weight: _____ pounds kilograms

650 Date documented: ____ - ____ - ____

651 What scale was used to determine the recipient's functional status?

- Karnofsky (recipient age \geq 16 years)
- Lansky (recipient age \geq 1 year and $<$ 16 years)

Performance score:

652 Karnofsky Scale (recipient age \geq 16 years) _____

653 Lansky Scale (recipient age \geq 1 year and $<$ 16 years) _____

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

- Yes No Unknown

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Center:

CRID:

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

- Yes No Unknown

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

- Yes No Unknown

657 Specify the outcome of pregnancy

- Live birth
 Intrauterine fetal death
 Spontaneous abortion
 Elected abortion
 Unknown

658 Has the recipient smoked tobacco cigarettes since the date of last report?

- yes no Unknown

659 Average number of packs per day (20 cigarettes per pack)

- Known Unknown

660 Average number of packs per day: _____

661 Specify the category which best describes the recipient's current occupation. If the recipient is not currently employed, check the box which best describes his/her last job:

- Professional, technical, or related occupation
 Manager, administrator, or proprietor
 Clerical or related occupation
 Sales occupation
 Service occupation
 Skilled craft or related occupation
 Equipment / vehicle operator or related occupation
 Laborer
 Farmer
 Member of the military
 Homemaker
 Student
 Under school age
 Not previously employed
 Unknown
 Other

662 Specify other occupation: _____

663 What is the recipient's current or most recent work status during this reporting period?

- full time
 part time
 unemployed
 medical disability
 retired
 recipient < 16 years old
 Unknown

664 Specify retirement status:

- with a source of income
 no source of income

Subsequent HCT

Questions: 665 - 672

Complete this section if the recipient received a subsequent HCT (question 3, answered "yes"). If no subsequent HCTs were performed, continue to the signature section.

665 Date of subsequent HCT: ____ - ____ - ____

666 Was the subsequent HCT performed at a different institution?

- Yes No

Specify the institution that performed the subsequent HCT:

667 Name: _____
City: _____
State: _____
Country: _____

Form 2100 R6.0: Post-HCT Follow-Up Data

Center: _____

CRID: _____

668 What was the indication for subsequent HCT?

- Graft failure / insufficient hematopoietic recovery - **Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT**
- Persistent primary disease - **Complete a Pre-TED Form 2400 for the subsequent HCT**
- Recurrent primary disease - **Complete a Pre-TED Form 2400 for the subsequent HCT**
- Planned second HCT, per protocol - **Complete a Pre-TED Form 2400 for the subsequent HCT**
- New malignancy (including PTLN and EBV lymphoma) - **Complete a Pre-TED Form 2400 for the subsequent HCT**
- Insufficient chimerism - **Complete a Pre-TED Form 2400 for the subsequent HCT**
- Other - **Complete a Pre-TED Form 2400 for the subsequent HCT**

669 Specify other indication: _____

Subsequent HCT Sources (1)

Questions: 670 - 672

670 Source of HSCs

- Allogeneic, related
- Allogeneic, unrelated
- Autologous

671 Was the same donor used?

- Yes No

672 Specify

- Fresh, NMDP donor bone marrow
- Fresh, non-NMDP donor bone marrow
- Fresh, NMDP donor mobilized peripheral blood stem cells
- Fresh, non-NMDP donor mobilized peripheral blood stem cells
- NMDP cord blood
- Non-NMDP cord blood
- Cryopreserved original donor bone marrow
- Cryopreserved original donor mobilized peripheral blood stem cells

First Name: _____ Last Name: _____

E-mail address: _____ Date: _____ - _____ - _____