Form 2100 R5.0: 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 ≥ 500/mm^3 achieved and sustained for 3 lab values)
- ○ No (ANC ≥ 500/mm^3 was not achieved)
- ○ Not applicable (ANC never dropped below 500/mm^3 at any time after the start of the preparative regimen)
- ○ Previously reported (Recipient's initial hematopoietic recovery was recorded on a previous report)

7 Date ANC ≥ 500/mm^3 (first of 3 lab values): __ __ __ __ - __ __- __ __

8 Following the initial hematopoietic recovery, was there subsequent decline in ANC to < 500/mm^3 for ≥ 3 days since the date of last report?

○ yes ○ no

9 Date of decline in ANC to < 500/mm^3 for ≥ 3 days (first of 3 days that the ANC declined): __ __ __ __ - __ __- __ __

10 Did recipient recover and maintain ANC ≥ 500/mm^3 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 transfusion 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 ≥ 20 x 10^9/L achieved?

- ○ Yes
- ○ No
- ○ Not applicable (Platelet count never dropped below 20 x 10^9/L)
- ○ Previously reported (≥ 20 x 10^9/L was achieved and reported previously)

14 Date platelets ≥ 20 x 10^9/L

○ Known ○ Unknown

15 Date platelets ≥ 20 x 10^9/L: __ __ __ __ - __ __- __ __ ☐ Date estimated

16 Was an initial platelet count ≥ 50 x 10^9/L achieved?

- ○ Yes
- ○ No
- ○ Not applicable (Patelet count never dropped below 50 x 10^9/L)
- ○ Previously reported (≥ 50 x 10^9/L was achieved and reported previously)

17 Date platelets ≥ 50 x 10^9/L
○ Known ○ Unknown

18 Date platelets ≥ 50 x 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 (Epogen)
○ Darbepoetin alfa (Aranesp)

35 KGF (palifermin, Kepivance)
○ 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: __ __ __ __ - __ __- __ __

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 10^9/L (x 10^3/mm^3) ○ x 10^6/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 10^9/L (x 10^3/mm^3) ○ x 10^6/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

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 10^9/L (x 10^3/mm^3) ○ x 10^6/L

79 CD4 (T helper cells)

○ Known ○ Unknown

80 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

81 CD8 (cytotoxic T cells)

○ Known ○ Unknown

82 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

83 CD19 (B lymphocyte cells)

○ Known ○ Unknown

84 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

85 CD20 (B lymphocyte cells)

○ Known ○ Unknown

86 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

87 CD56 (natural killer (NK) cells)

○ Known ○ Unknown

88 _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/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

Center: CRID:

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

92 NMDP donor ID: _____

93 NMDP cord blood unit ID: _____

94 Non-NMDP unrelated donor ID: _____

95 Non-NMDP cord blood unit ID: _____

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 (≥38.3°C or >100.9°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 (≥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

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

Report any acute graft-versus-host disease occurring in this reporting period in response to allogeneic HCT or cellular therapy. If this was an autologous HCT, 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, Myofortic)
yes no

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

169 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 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 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)

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 ≤ 50% of skin, no liver or gut involvement
- II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea
- III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus
- IV - Generalized erythroderma with bullous formation, or billirubin > 15 mg/dL
- Not applicable (acute GVHD present but 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

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: __ __ __ __ - __ __- __ __

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

Report any chronic graft-versus-host disease occurring in this reporting period in response to allogeneic HCT or cellular therapy. If this was an autologous HCT, 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 ≥ 16 years)
○ Lansky (recipient age ≥ 1 year and < 16 years)

Performance score:

240 Karnofsky Scale (recipient age ≥ 16 years) _____

241 Lansky Scale (recipient age ≥ 1 year and < 16 years) _____

242 Platelets: (at diagnosis of chronic GVHD) _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

243 Total serum bilirubin: (at diagnosis of chronic GVHD) _____ ○ mg/dL ○ µmol/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

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: _____

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 ≤ 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 ≥5%

○ Yes ○ No

282 Failure to thrive

○ Yes ○ No

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

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 10^9/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: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

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

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 **(If yes, report this pneumonia in the Infection section)**

○ 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

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: __ __ __ __ - __ __- __ __

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: _____

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/1.73m^2)

○ 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: __ __ __ __ - __ __- __ __

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

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 since the date of last report?

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

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 ≥ 16 years)
- ○ Lansky (recipient age ≥1 year and < 16 years)

Performance score:

652 Karnofsky Scale (recipient age ≥ 16 years) _____

653 Lansky Scale (recipient age ≥ 1 year and < 16 years) _____

654 Was the recipient pregnant at any time in this reporting period? **(Female only)**
○ Yes ○ No ○ Unknown

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: _____

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 PTLD 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: __ __ __ __ - __ __ - __ __