Form 2450 R4.0: Post-Transplant Essential Data

Center: CRID:

Key Fields

OMB No: 0915-0310

Expiration Date: 1/31/2020

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0310. Public reporting burden for this collection of information is estimated to average 1.25 hours per response when collected at 100 days post-transplant, 1.15 hours per response when collected at 6 months and 12 months post-transplant, and 1.15 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-29, Rockville, Maryland, 20857.

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

HCT type: (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Product type: (check all that apply)

- ☐ Bone marrow
- ☐ PBSC
- ☐ Single cord blood unit
- ☐ Multiple cord blood units
- ☐ Other product

Specify: _____

Visit

○ 100 day ○ 6 months ○ 1 year ○ 2 years ○ > 2 years,

Specify: _____

Survival

Questions: 1 - 6

1 Date of actual contact with the recipient to determine medical status for this follow-up report: __ __ __ __ - __ __- __ __

2 Specify the recipient's survival status at the date of last contact

- ○ Alive **- Answers to subsequent questions should reflect clinical status since the date of last report.**
- ○ Dead **- Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death.**

3 Primary cause of death _____

4 Specify: _____

Contributing COD (1)

Questions: 5 - 6

5 Contributing cause of death _____

6 Specify: _____

Subsequent Transplant

Questions: 7 - 13

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

○ yes ○ no

8 Date of subsequent HCT: __ __ __ __ - __ __- __ __

9 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**

10 Specify other indication: _____

11 Source of HSCs

- ○ Allogeneic, related
- ○ Allogeneic, unrelated
- ○ Autologous

12 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

13 Date of cellular therapy: __ __ __ __ - __ __- __ __

Initial ANC Recovery

Questions: 14 - 16

14 Was there evidence of initial hematopoietic recovery?

- Yes (ANC ≥ 500/mm³ achieved and sustained for 3 lab values)
- No (ANC ≥ 500/mm³ was not achieved)
- Not applicable (ANC never dropped below 500/mm³ at any time after the start of the preparative regimen)
- Previously reported (Recipient's initial hematopoietic recovery was recorded on a previous report)

15 Date ANC ≥ 500/mm³ (first of 3 lab values): __ __ __ __ - __ __- __ __

16 Did late graft failure occur?

- Yes
- No

Initial Platelet Recovery

Questions: 17 - 18

(Optional for Non-U.S. Centers)

17 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

18 Date platelets ≥ 20 x 10^9/L: __ __ __ __ - __ __- __ __

Graft vs. Host Disease

Questions: 19 - 38

This section is for allogeneic HCTs only. If this was an autologous HCT, continue to Liver Toxicity Prophylaxis.

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

- Yes
- No
- Unknown

20 Date of acute GVHD diagnosis: __ __ __ __ - __ __- __ __

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

- Yes
- No
- Unknown

22 Overall grade of acute GVHD at diagnosis

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

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

23 Skin

- Stage 0 -No rash, no rash attributable to acute GVHD
- Stage 1 -Maculopapular rash, < 25% of body surface
- Stage 2 -Maculopapular rash, 25-50% of body surface
- Stage 3 -Generalized erythroderma, >50% of body surface
- Stage 4 -Generalized erythroderma with bullae formation and/or desquamation

24 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

25 Upper intestinal tract

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

26 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)

27 Other site(s) involved with acute GVHD

○ Yes ○ No

28 Specify other site(s): _____

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

29 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)

30 Date maximum overall grade of acute GVHD: __ __ __ __ - __ __- __ __

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

○ Yes ○ No ○ Unknown

32 Date of chronic GVHD diagnosis: __ __ __ __ - __ __- __ __ ☐ Date estimated

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

○ Yes ○ No ○ Unknown

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

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

○ Mild ○ Moderate ○ Severe ○ Unknown

35 Specify if chronic GVHD was limited or extensive

- ○ Limited - localized skin involvement and/or liver dysfunction
- ○ Extensive -one or more of the following:
  - -generalized skin involvement; or
  - -liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or
  - -involvement of eye: Schirmer's test with < 5mm wetting; or
  - -involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
  - -involvement of any other target organ

36 Date of maximum grade of chronic GVHD: __ __ __ __ - __ __- __ __

37 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

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

○ Yes ○ No ○ Not Applicable ○ Unknown

Liver Toxicity Prophylaxis

Questions: 39 - 45

39 Was specific therapy used to prevent liver toxicity?

○ Yes ○ No

40 Defibrotide

○ Yes ○ No

41 N-acetylcysteine

○ Yes ○ No

42 Tissue plasminogen activator (TPA)

○ Yes ○ No

43 Ursodiol

○ Yes ○ No

44 Other therapy

○ yes ○ no

45 Specify other therapy: _____

Veno-occlusive disease (VOD) /Sinusoidal obstruction syndrome (SOS)

Questions: 46 - 47

Specify if the recipient developed VOD/SOS since the date of last report:

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

○ Yes ○ No

47 Date of diagnosis: __ __ __ __ - __ __- __ __

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Questions: 48 - 55

Report new malignancies that are different than the disease/disorder for which HCT was performed. Do not include relapse, progression or transformation of the same disease subtype.

48 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: 49 - 55

The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

49 Specify the new malignancy _____

50 Specify other new malignancy: _____

51 Is the tumor EBV positive?

○ yes ○ no

52 Date of diagnosis: __ __ __ __ - __ __- __ __

53 Was documentation submitted to the CIBMTR? (e.g. pathology/autopsy report or other documentation)

○ Yes ○ No

54 Was the new malignancy donor / cell product derived?

○ Yes ○ No ○ Not done

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

○ yes ○ no

Chimerism Studies (Cord Blood Units Only)

Questions: 56 - 74

This section relates to chimerism studies from allogeneic HCTs using cord blood units only. If this was an autologous HCT, or an allogeneic HCT using a bone marrow or PBSC product, continue to disease assessment.

56 Were chimerism studies performed since the date of last report?

○ yes ○ no

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

○ Yes ○ No

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

○ Yes ○ No

Chimerism Studies (Cord Blood Units Only) (1)

Questions: 59 - 74

Provide date(s), method(s) and other information for all chimerism studies performed since the date of last report.

59 NMDP donor ID: _____

60 NMDP cord blood unit ID: _____

61 Non-NMDP unrelated donor ID: _____

62 Non-NMDP cord blood unit ID: _____

63 Date of birth: (donor/infant) __ __ __ __ - __ __- __ __ **-OR-** Age: (donor/infant) _____ ○ Months ○ years

64 Sex (Donor/infant)

○ male ○ female

65 Date sample collected: __ __ __ __ - __ __- __ __

66 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

67 Specify: _____

68 Cell source

○ Bone marrow ○ Peripheral blood

69 Cell type

- ○ Unsorted / whole
- ○ Red blood cells
- ○ Hematopoietic progenitor cells (CD34+ cells)
- ○ Total mononuclear cells (lymphs & monos)
- ○ T-cells (includes CD3+, CD4+, and/or CD8+)
- ○ B-cells (includes CD19+ or CD20+)
- ○ Granulocytes (includes CD33+ myeloid cells)
- ○ NK cells (CD56+)
- ○ Other

70 Specify: _____

71 Total cells examined: _____

72 Number of donor cells: _____

73 Were donor cells detected?

○ Yes ○ No

74 Percent donor cells: _____ %

Disease Assessment at the Time of Best Response to HCT

Questions: 75 - 97

75 Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)

- ○ Continued complete remission (CCR) (*For recipients already in CR prior to the start of the preparative regimen.*)
- ○ Complete remission (CR)
- ○ Not in complete remission
- ○ Not evaluated

76 Specify disease status if not in complete remission

- ○ Disease detected
- ○ No disease detected but incomplete evaluation to establish CR

77 Was the date of best response previously reported?

○ yes ○ no

78 Date assessed: __ __ __ __ - __ __- __ __

Specify the method(s) used to assess the disease status at the time of best response:

79 Was the disease status assessed by molecular testing? (e.g. PCR)

○ Yes ○ No ○ Not Applicable

80 Date assessed: __ __ __ __ - __ __- __ __

81 Was disease detected?

○ yes ○ no

82 Was the disease status assessed via flow cytometry?

○ Yes ○ No ○ Not Applicable

83 Date assessed: __ __ __ __ - __ __- __ __

84 Was disease detected?

○ yes ○ no

85 Was the disease status assessed by cytogenetic testing? (karyotyping or FISH)

○ Yes ○ No ○ Not Applicable

86 Was the disease status assessed via FISH?

○ Yes ○ No ○ Not Applicable

87 Date assessed: __ __ __ __ - __ __- __ __

88 Was disease detected?

○ yes ○ no

89 Was the disease status assessed via karyotyping?

○ Yes ○ No ○ Not Applicable

90 Date assessed: __ __ __ __ - __ __- __ __

91 Was disease detected?

○ yes ○ no

92 Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)

○ Yes ○ No ○ Not Applicable

93 Date assessed: __ __ __ __ - __ __- __ __

94 Was disease detected?

○ yes ○ no

95 Was the disease status assessed by clinical / hematologic assessment?
yes no

96 Date assessed: __ __ __ __ - __ __- __ __

97 Was disease detected?
yes no

Post-HCT Therapy

Questions: 98 - 160

Report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

98 Was therapy given since the date of the last report for reasons other than relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy)
yes no

99 Systemic therapy
yes no

100 Monoclonal antibody (mAb)
Yes No

101 Alemtuzumab (Campath)
yes no

102 Bispecific mAb
Yes No

103 Blinatumomab
Yes No

104 Other bispecific mAb
Yes No

105 Specify other bispecific mAb: _____

106 Gemtuzumab (Mylotarg, anti-CD33)
yes no

107 Rituximab (Rituxan, MabThera)
yes no

108 Other mAb
yes no

109 Specify other mAb: _____

110 Tyrosine kinase inhibitors (TKI)
yes no

111 Bosutinib
Yes No

112 Dasatinib (Sprycel)
yes no

113 Imatinib mesylate (Gleevec)
yes no

114 Nilotinib (AMN107, Tasigna)
yes no

115 Other TKI
Yes No

116 Specify other TKI: _____

117 FLT3 inhibitors
Yes No

118 Gilteritinib
Yes No

119 Lestaurtinib
Yes No

120 Midostaurin
Yes No

121 Quizartinib
Yes No

122 Sorafenib
yes no

123 Sunitinib
Yes No

124 Other FLT3 inhibitor
Yes No

125 Specify other FLT3 inhibitor: _____

126 Hypomethylating agents
Yes No

127 Azacytidine (Vidaza)
yes no

128 Decitabine (Dacogen)
yes no

129 Other hypomethylating agent
Yes No

130 Specify other hypomethylating agent: _____

131 Proteasome inhibitors
Yes No

132 Bortezomib (Velcade)
yes no

133 Carfilzomib
yes no

134 Ixazomib
Yes No

135 Other proteasome inhibitor
Yes No

136 Specify other proteasome inhibitor: _____

137 Immune modulating agents
Yes No

138 Lenalidomide (Revlimid)
yes no

139 Pomalidomide
yes no

140 Thalidomide (Thalomid)
yes no

141 Other immune modulating agent
Yes No

142 Specify other immune modulating agent: _____

143 PD1 inhibitor
Yes No

144 Nivolumab
Yes No

145 Pembrolizumab
Yes No

146 Other PD1 inhibitor
Yes No

147 Specify other PD1 inhibitor: _____

148 BTK inhibitors
Yes No

149 Ibrutinib
Yes No

150 Other BTK inhibitor
Yes No

151 Specify other BTK inhibitor: _____

152 Chemotherapy
yes no

153 Specify chemotherapy drugs: _____

154 Other systemic therapy
yes no

155 Specify other systemic therapy: _____

156 Radiation
yes no

157 Cellular therapy
yes no

158 Blinded randomized trial
yes no

159 Other therapy
yes no

160 Specify other therapy: _____

Relapse or Progression Post-HCT

Questions: 161 - 234

Report if the recipient has experienced a clinical/hematologic relapse or progression post HCT. If the relapse or progression was detected in a previous reporting period indicate that and continue on. If the first clinical/hematologic relapse occurred since the date of last report, indicate the date it was first detected in this reporting period.

161 Did the recipient experience a clinical/hematologic relapse or progression post-HCT?
Yes No

162 Was the date of clinical/hematologic relapse or progression previously reported?
Yes **(only valid > day 100)**
No

163 Date first seen: __ __ __ __ - __ __- __ __

Intervention for relapsed disease, persistent disease, progressive disease, or decreased/loss of chimerism

164 Was intervention given for relapsed, persistent or progressive disease, or decreased/loss of chimerism since the date of last report?
Yes No

165 Specify reason for which intervention was given
Persistent disease
Relapsed / progressive disease
Decrease / loss of chimerism

Specify the method(s) of detection for which intervention was given:

166 Clinical/hematologic
yes no

167 Radiological (e.g. PET, MRI, CT)
Yes No

168 Cytogenetic
yes no

169 Flow cytometry
yes no

170 Disease specific molecular marker
Yes No

171 Chimerism testing
Yes No

172 Date intervention started: __ __ __ __ - __ __- __ __

Specify intervention(s):

173 Systemic therapy
yes no

174 Monoclonal antibody (mAb)
Yes No

175 Alemtuzumab (Campath)
yes no

176 Bispecific mAb
Yes No

177 Blinatumomab
Yes No

178 Other bispecific mAb
Yes No

179 Specify other bispecific mAb: _____

180 Gemtuzumab (Mylotarg, anti-CD33)
yes no

181 Rituximab (Rituxan, MabThera)
yes no

182 Other mAb
yes no

183 Specify other mAb: _____

184 Tyrosine kinase inhibitors (TKI)
yes no

185 Bosutinib
Yes No

186 Dasatinib (Sprycel)
yes no

187 Imatinib mesylate (Gleevec)
yes no

188 Nilotinib (AMN107, Tasigna)
yes no

189 Other TKI
Yes No

190 Specify other TKI: _____

191 FLT3 inhibitors
Yes No

192 Gilteritinib
Yes No

193 Lestaurtinib
Yes No

194 Midostaurin
Yes No

195 Quizartinib
Yes No

196 Sorafenib
yes no

197 Sunitinib
Yes No

198 Other FLT3 inhibitor
Yes No

199 Specify other FLT3 inhibitor: _____

200 Hypomethylating agents
Yes No

201 Azacytidine (Vidaza)
yes no

202 Decitabine (Dacogen)
yes no

203 Other hypomethylating agent
Yes No

204 Specify other hypomethylating agent: _____

205 Proteasome inhibitors
Yes No

206 Bortezomib (Velcade)
yes no

207 Carfilzomib
yes no

208 Ixazomib
Yes No

209 Other proteasome inhibitor
Yes No

210 Specify other proteasome inhibitor: _____

211 Immune modulating agents
Yes No

212 Lenalidomide (Revlimid)
yes no

213 Pomalidomide
yes no

214 Thalidomide (Thalomid)
yes no

215 Other immune modulating agent
Yes No

216 Specify other immune modulating agent: _____

217 PD1 inhibitor
Yes No

218 Nivolumab
Yes No

219 Pembrolizumab
Yes No

220 Other PD1 inhibitor
Yes No

221 Specify other PD1 inhibitor: _____

222 BTK inhibitors
Yes No

223 Ibrutinib
Yes No

224 Other BTK inhibitor
Yes No

225 Specify other BTK inhibitor: _____

226 Chemotherapy
yes no

227 Specify chemotherapy drugs: _____

228 Other systemic therapy
yes no

229 Specify other systemic therapy: _____

230 Radiation
yes no

231 Cellular therapy
yes no

232 Blinded randomized trial
yes no

233 Other therapy
yes no

234 Specify other therapy: _____

Current Disease Status

Questions: 235 - 238

235 What is the current disease status?
- Complete remission (CR)
- Not in complete remission
- Not evaluated

236 Specify disease status if not in complete remission
- Disease detected
- No disease detected but incomplete evaluation to establish CR

237 Date of most recent disease assessment
Known Unknown

238 Date of most recent disease assessment: __ __ __ __ - __ __- __ __

First Name: _____ Last Name: _____
E-mail address: _____ Date: __ __ __ __ - __ __- __ __