ERROR CORRECTION FORM

Sequence Number: | | | | | | | | | | | | | | |

CIBMTR Recipient ID: | | | | | | | | | |

Visit:
☐ 100 day
☐ 6 month
☐ | | year

Today's Date: Month | | Day | | 2 0 Year | | |

Infusion Date: Month | | Day | | 2 0 Year | | |

CIBMTR Center Number: | | | | | |

Initials: | | |

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Today's Date: __ __ __ __ - __ __- __ __

Date of HSCT for which this form is being completed: __ __ __ __ - __ __- __ __

HSCT Type (check all that apply):

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

Product Type (check all that apply):

- Marrow
- PBSC
- Cord blood
- multiple cord blood units infused
- other product

Specify: _____

Visit:

6 months 1 year 2 years

Vital Status

Questions: 1 - 4

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

2 Did recipient receive a subsequent HSCT (bone marrow, mobilized peripheral blood stem cells, cord blood) since the date of contact from the last report?

yes **Answers to subsequent questions should reflect clinical status immediately prior to the start of the preparative regimen for subsequent HSCT. Complete Subsequent HSCT questions 395–402.**

no

3 Specify the recipient's survival status at the date of actual contact:

Alive **Answers to subsequent questions should reflect clinical status between last day of contact reported on prior follow-up form and the day of actual contact for this follow-up form (question 1).**

Dead **Answers to subsequent questions should reflect clinical status between last day of contact reported on prior follow-up form and immediately prior to death. Complete a Form 2900 – Recipient Death Data.**

4 Has the recipient received a donor cellular infusion (DCI) since the date of contact from the last report?

yes **Complete DCI Information questions 403–501.**

no

ERROR CORRECTION FORM

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Granulopoiesis / Neutrophil Recovery — Questions: 5 - 14

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

5 Did the recipient achieve an initial hematopoietic recovery (ANC >= 500/mm^3 for three consecutive lab values obtained on different days) since the date of the last report? *(check only one)*

- Yes
- No, recipient's initial hematopoietic recovery was recorded on a previous report
- No, ANC >= 500/mm^3 was not achieved* and there was no evidence of recurrent disease in the bone marrow
- No, ANC >= 500/mm^3 was not achieved * and there was documented persistent disease in the bone marrow post-HSCT
- No, recipient's ANC never dropped below 500/mm^3 at any time after the start of the preparative regimen

6 Date ANC >= 500/mm^3 (first of 3 lab values): * __ __ __ __ - __ __- __ __

7 Following the initial hematopoietic recovery (ANC >= 500/mm^3 for three consecutive lab values obtained on different days), did the recipient experience a subsequent decline in ANC to <500/mm^3 for >= 3 days since the date of the last report?

- yes
- no

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

Actual CBC on first day of decline:

9 WBC: _____

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

10 Neutrophils: _____ %

11 Did recipient recover and maintain ANC >= 500/mm^3 following the decline?

- yes
- no

12 Date of ANC recovery: __ __ __ __ - __ __- __ __ Date unknown

CBC on first day of recovery:

13 WBC: _____

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

14 Neutrophils: _____ %

ERROR CORRECTION FORM

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Megakaryopoiesis / Platelet Recovery — Questions: 15 - 18

This section relates to initial platelet recovery. All dates 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.

15 Was an initial platelet count >= 20 x 10^9/L achieved since the date of the last report?

- Yes
- No
- platelet count never dropped below 20 x 10^9/L
- >=20x10^9/L was achieved and reported previously

16 Date platelets >= 20 x 10^9/L: __ __ __ __ - __ __- __ __ date estimated Date unknown

17 Was an initial platelet count >= 50 x 10^9/L achieved since the date of the last report?

- Yes
- No
- platelet count never dropped below 50 x 10^9/L
- >=50x10^9/L was achieved and reported previously

18 Date platelets >= 50 x 10^9/L: * __ __ __ __ - __ __- __ __ date estimated Date unknown

Current Hematologic Findings — Questions: 19 - 25

19 Date of most recent hematologic testing: __ __ __ __ - __ __- __ __

20 WBC: _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

21 Neutrophils: _____ % Not tested

22 Lymphocytes: _____ % Not tested

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

Not tested

transfused RBC < 30 days from date of most current testing

24 Hematocrit: _____ % Not tested

transfused RBC < 30 days from date of most current testing

25 Platelets: _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

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Center: CRID:

transfused platelets < 7 days from date of most current testing

Immune Reconstitution

Questions: 26 - 47

Specify the immunoglobulin values from the most recent testing:

26 IgG: _____ mg/dL g/dL g/L

Not tested

27 __ __ __ __ - __ __ - __ __

28 IgM: _____ mg/dL g/dL g/L

Not tested

29 __ __ __ __ - __ __ - __ __

30 IgA: _____ mg/dL g/dL g/L

Not tested

31 __ __ __ __ - __ __ - __ __

32 Did the recipient receive supplemental intravenous immunoglobulins (IVIG)(since the date of the last report)?

yes no

33 Was therapy ongoing within one month of immunoglobulin testing?

yes no

Indication(s) for use:

34 Prophylaxis for low IgG with no active infection (polyclonal IV gamma globulin / IVIG)

yes no

35 Prophylaxis for cytomegalovirus (CMV) infection (CMV / hyperimmune gamma globulin)

yes no

36 Treatment for CMV infection

yes no

37 Treatment for respiratory syncytial virus (RSV) infection

yes no

38 Treatment for infection with low IgG (not CMV or RSV)

yes no

39 Other indication

yes no

40 Specify other indication: _____

41 Were lymphocyte analyses performed since the date of the last report?

yes no

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

Center: CRID:

42 Date of most recent testing performed: __ __ __ __ - __ __- __ __

43 CD3 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

44 CD4 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

45 CD8 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

46 CD20 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

47 CD56 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

Not tested

Chimerism Studies

Questions: 48 - 73

This section relates to chimerisms from allogeneic HSCTs only. If this was an autologous HSCT, continue with the Infection section at question 201.

48 *Allogeneic HSCTs only:* Were chimerism studies performed since the date of the last report?

yes no

49 Are chimerism laboratory reports attached to this form?

yes no

50 Were infusions from more than one donor given?

yes no

51 Specify donor gender:

male female

Single Donor (1)

Questions: 52 - 61

This section relates to chimerisms from allogeneic HSCTs only. If this was an autologous HSCT, continue with the Infection section at question 201.

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

52 Date __ __ __ __ - __ __- __ __

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

Center: CRID:

53 Method _____

54 Specify: _____

55 Cell type _____

56 Specify: _____

57 Total cells examined _____

58 Number of donor cells _____

59 Number of host cells _____

60 Percent donor cells, quantitative method _____ Presence of donor cells was detected by non-quantitative method

61 Percent host cells, quantitative method _____ Presence of host cells was detected by non-quantitative method

Multiple Donors (1) — Questions: 62 - 73

This section relates to chimerisms from allogeneic HSCTs only. If this was an autologous HSCT, continue with the Infection section at question 201.

62 NMDP Donor ID: _____

-OR-

Donor / infant date of birth: __ __ __ __ - __ __- __ __

-OR-

NMDP cord blood unit ID _____

-OR-

Non-NMDP unrelated donor ID: _____

-OR-

Non-NMDP cord blood unit ID: _____

63 Donor / infant gender:

male female

64 Date __ __ __ __ - __ __- __ __

65 Method _____

66 Specify: _____

67 Cell type _____

68 Specify: _____

69 Total cells examined _____

70 Number of donor cells _____

71 Number of host cells _____

72 Percent donor cells, quantitative _____ Presence of donor cells was detected by non-quantitative method

73 Percent host cells, quantitative _____ Presence of host cells was detected by non-quantitative method

Engraftment Syndrome — Questions: 74 - 80

74 Did engraftment syndrome occur since the date of the last report?

yes no

75 Date of onset: __ __ __ __ - __ __- __ __

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

Center: CRID:

Specify symptoms of engraftment syndrome:

76 Capillary leak syndrome

yes no

77 Fever

yes no

78 Skin rash

yes no

79 Specify amount of body surface area affected: _____ %

80 Was engraftment syndrome treated with corticosteriods?

yes no

Acute Graft vs. Host Disease (GVHD)

Questions: 81 - 128

This section relates to graft-versus-host disease from allogeneic HSCTs only. If this was an autologous HSCT, continue with the Infection section at question 201.

81 Did acute GVHD develop or persist (or a flare-up that was more severe) since the date of the last report?

yes no Unknown

82 Date of acute GVHD diagnosis: __ __ __ __ - __ __- __ __ Date was previously reported

83 Was the diagnosis based on evidence from a biopsy (histology)?

yes no

Specify result(s):

84 gastrointestinal (GI)

Positive Negative Inconclusive Not tested

85 Liver

Positive Negative Inconclusive Not tested

86 Lung

Positive Negative Inconclusive Not tested

87 Skin

Positive Negative Inconclusive Not tested

88 Other site

Positive Negative Inconclusive Not tested

89 Specify other site: _____

90 Is a copy of the pathology report attached?

yes no

91 Was the diagnosis based on clinical evidence?

yes no

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92 Maximum overall grade of acute GVHD:

I II III IV

93 Is acute GVHD still present at the date of contact for this report (question 1)?

Yes

No

progressed to chronic GVHD

Unknown

List the maximum severity of organ involvement:

94 Skin

no skin acute GVHD / rash not attributable to acute GVHD

stage 0 – no rash

stage 1 – maculopapular rash, < 25% of body surface

stage 2 – maculopapular rash, 25–50% of body surface

stage 3 – generalized erythroderma

stage 4 – generalized erythroderma with bullae formation and desquamation

95 Lower intestinal tract: (use mL/day for adult recipients and mL/m^2/day for pediatric recipients)

no gut acute GVHD / diarrhea not attributable to acute GVHD

Stage 0 – no diarrhea

stage 0 – diarrhea <= 500 mL/day or < 280 mL/m^2/day

stage 1 – diarrhea > 500 but <= 1000 mL/day or 280-555 mL/m^2/day

stage 2 – diarrhea > 1000 but <= 1500 mL/day or 556-833 mL/m^2/day

stage 3 – diarrhea > 1500 mL/day or > 833 mL/m^2/day

stage 4 – severe abdominal pain, with or without ileus

96 Upper intestinal tract:

stage 0 - no persistant nausea or vomiting

stage 1 - persistant nausea or vomiting

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☐ year

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Infusion Date: Month Day 20 Year

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Initials:

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

Center: CRID:

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97 Liver

- no liver acute GVHD / bilirubin level not attributable to acute GVHD
- stage 0 – 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)

98 Other clinical organ involvement?

yes no

Specify site:

99 Lung

yes no

100 Other site:

yes no

101 Specify other site: _____

102 Was specific therapy used to treat acute GVHD since the date of the last report?

yes no

Specify therapy administered to treat acute GVHD:

103 ALS, ALG, ATS, ATG

yes no

104 Specify source:

Horse Rabbit Other

105 Specify source: _____

106 Corticosteroids (systemic)

yes no

107 Corticosteriods (topical)

yes no

108 Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

109 ECP (extra-corporeal photopheresis)

yes no

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Retain the original form at the transplant center.

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Sequence Number:

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Infusion Date: Month Day 20 Year

CIBMTR Center Number:

Initials:

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110 FK 506 (Tacrolimus, Prograf)

yes no

111 In vivo monoclonal antibody

yes no

Specify in vivo monoclonal antibody:

112 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

113 Specify anti CD25: _____

114 Campath

yes no

115 Etanercept (Enbrel)

yes no

116 Infliximab (Remicade)

yes no

117 Other in vivo monoclonal antibody

yes no

118 Specify antibody: _____

119 In vivo immunotoxin

yes no

120 Specify immunotoxin: _____

121 Methotrexate (MTX) (Amethopterin)

yes no

122 Mycophenolate mofetil (MMF) (CellCept)

yes no

123 Sirolimus (Rapamycin, Rapamune)

yes no

124 Ursodiol

yes no

125 Blinded randomized trial

yes no

126 Specify trial agent:

_____

127 Other agent

yes no

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

Center: CRID:

128 Specify other agent:

_____

Chronic Graft vs. Host Disease (GVHD)

Questions: 129 - 200

129 Did chronic GVHD develop or persist (or a flare-up that was more severe) since the date of the last report?

- Yes
- No
- No symptoms, but recipient is receiving treatment
- Unknown

130 Date of chronic GVHD diagnosis: __ __ __ __ - __ __- __ __ Date was previously reported

131 Onset of chronic GVHD was:

- Progressive (acute GVHD progressed directly to chronic GVHD)
- Interrupted (acute GVHD resolved, then chronic GVHD developed)
- De novo (acute GVHD never developed)
- chronic GHVD flare (symptoms reactivated within 30 days of drug tapering or discontinuation)

132 Karnofsky / Lansky score at diagnosis of _____ chronic GVHD:

If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.

133 Platelet count at diagnosis of chronic GVHD: _____

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

134 Diagnosis was based on:

- histologic evidence / biopsy proven
- Clinical evidence
- Both
- Unknown

135 Maximum grade of chronic GVHD:

- 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

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136 Overall severity of chronic GVHD:

- mild – signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- moderate – signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- severe – signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

ɟan Involvement -

Indicate if there was organ involvement with chronic GVHD:

137 Sclerosis of skin

yes no

138 Was involvement proven by biopsy?

yes no

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

yes no

140 Was involvement proven by biopsy?

yes no

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

yes no

142 Was involvement proven by biopsy?

yes no

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

yes no

144 Was involvement proven by biopsy?

yes no

145 Bronchiolitis obliterans

yes **Complete bronchiolitis obliterans questions 262–270**

no

146 Was involvement proven by biopsy?

yes no

147 Other lung involvement

yes no

148 Was involvement proven by biopsy?

yes no

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

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149 Gastrointestinal tract (esophageal involvement, chronic nausea / vomiting, chronic diarrhea, malabsorption, abdominal pain / cramps, etc.)

yes no

150 Was involvement proven by biopsy?

yes no

151 Liver

yes no

152 Was involvement proven by biopsy?

yes no

153 Genitourinary tract (vaginitis / stricture, etc.)

yes no

154 Was involvement proven by biopsy?

yes no

155 Musculoskeletal (arthritis, contractures, myositis, myasthenia, etc.)

yes no

156 Was involvement proven by biopsy?

yes no

157 Thrombocytopenia (< 100 x 10^9/L)

yes no

158 Eosinophilia

yes no

159 Autoantibodies

yes no

160 Other hematologic involvement

yes no

161 Serositis

yes no

162 Was involvement proven by biopsy?

yes no

163 Weight loss

yes no

164 Other organ involvement from chronic GVHD

yes no

165 Specify site: _____

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

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166 Was involvement proven by biopsy?

yes no

167 Was specific therapy used to treat chronic GVHD?

yes no

Specify therapy:

168 ALS, ALG, ATS, ATG

yes no

169 Specify source:

Horse Rabbit Other

170 Specify source: _____

171 Azathioprine

yes no

172 Corticosteroids (systemic)

yes no

173 Corticosteroids (topical)

yes no

174 Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

175 ECP (extracorporeal photopheresis)

yes no

176 Etretinate

yes no

177 FK 506 (Tacrolimus, Prograf)

yes no

178 Hydroxychloroquine (Plaquenil)

yes no

179 In vivo monoclonal antibody

yes no

Specify:

180 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

181 Specify anti CD25: _____

182 Campath

yes no

Form 2200 R3.0: Six Months to Two Years Post-HSCT Data

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183 Etanercept (Enbrel)

yes no

184 Infliximab (Remicade)

yes no

185 Other in vivo monoclonal antibody

yes no

186 Specify antibody: _____

187 Lamprene (Clofazimine)

yes no

188 Mycophenolate mofetil (MMF) (CellCept)

yes no

189 Pentostatin

yes no

190 PUVA (Psoralen and UVA)

yes no

191 Sirolimus (Rapamycin, Rapamune)

yes no

192 Thalidomide

yes no

193 Ursodiol

yes no

194 Blinded randomized trial

yes no

195 Specify trial agent: _____

196 Other agent:

yes no

197 Specify other agent: _____

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

yes no

199 Is the recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD?

yes no Unknown

200 Date final treatment administered: __ __ __ __ - __ __- __ __ Date unknown

Date previously reported

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Infection **Questions: 201 - 237**

201 Did the recipient receive any of the following agents for infection prophylaxis since the date of last report? *(report prophylaxis immunoglobulins at questions 34-35)*

yes no Unknown

Specify agent(s) given:

202 Systemic antibacterial antibiotics

yes no

203 Nonabsorbable oral antibiotics

yes no

204 Amphotericin (Fungizone) *(non-lipid formulation)*

yes no

205 Amphotericin (e.g. Abelcet, AmBisome, Amphotec) *(lipid formulation)*

yes no

206 Caspofungin

yes no

207 Fluconazole

yes no

208 Itraconazole

yes no

209 Micafungin

yes no

210 Posaconazole

yes no

211 Ravuconazole

yes no

212 Voriconazole

yes no

213 Other systemic antifungal agent

yes no

214 Specify other antifungal agent: _____

215 Acyclovir

yes no

216 Foscarnet

yes no

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217 Ganciclovir (DHPG)

yes no

218 Valganciclovir (Valcyte)

yes no

219 Valacyclovir

yes no

220 Other antiviral agent

yes no

221 Specify other antiviral agent: _____

222 Atovaquone (Mepron)

yes no

223 Dapsone

yes no

224 Pentamidine inhaled

yes no

225 Pentamidine IV

yes no

226 Trimethoprim/sulfamethoxazole (Bactrim/Septra)

yes no

227 Other pneumocystis prophylaxis

yes no

228 Specify pneumocystis agent: _____

229 Other prophylaxis agent

yes no

230 Specify other prophylaxis agent: _____

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

yes no

Infection (1) **Questions: 232 - 235**

Report each infection organism, site and date of diagnosis.

232 Organism _____

233 If other, specify: _____

Do not report fever in the absence of infection. Report the most specific site of infection.

234 Site _____

235 Date of diagnosis: __ __ __ __ - __ __- __ __

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236 Did the recipient develop more than 7 infections post-HSCT?

yes no

237 Are extra pages attached?

yes no

Organ Function

Questions: 238 - 389

Interstitial pneumonitis / idiopathic pneumonia syndrome is characterized on chest x-ray by hypoxia and diffuse interstitial infiltrates not caused by fluid overload.

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

yes no

Pulmonary function (1)

Questions: 239 - 258

239 Date of diagnosis of IPn / IPS: __ __ __ __ - __ __- __ __

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

yes no

Diagnosis was evaluated by:

241 bronchoalveolar lavage (BAL)

yes no

242 transbronchial biopsy

yes no

243 open / thorascopic (VATS) lung biopsy

yes no

244 autopsy

yes no

245 Other test

yes no

246 Specify other test: _____

247 Was an organism isolated?

Yes no / idiopathic

Etiology:

248 adenovirus

yes no

249 cytomegalovirus (CMV)

yes no

250 herpes simplex (HSV1, HSV2)

yes no

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251 human herpes virus type 6 (HHV6)

yes no

252 parainfluenza

yes no

253 respiratory syncytial virus (RSV)

yes no

254 toxoplasma

yes no

255 other virus

yes no

256 Specify other virus: _____

257 other organism

yes no

258 Specify organism: _____

259 Did the recipient experience two or more episodes of IPn / IPS since the date of the last report?

yes no

260 Are extra pages attached?

yes no

261 Did the recipient develop non-infectious pulmonary abnormalities (other than IPn / IPS / ARDS) since the date of the last report?

yes no

262 Did the recipient develop bronchiolitis obliterans after the start of preparative regimen to date of last contact (question 1)?

yes no

263 Date of diagnosis: __ __ __ __ - __ __- __ __

264 Were diagnostic tests done?

yes no

Diagnosis was evaluated by:

265 bronchoalveolar lavage (BAL)

yes no

266 transbronchial biopsy

yes no

267 open / thoracopic (VATS) lung biopsy

yes no

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Center: CRID:

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268 autopsy

yes no

269 Other

yes no

270 Specify: _____

271 Did the recipient develop pulmonary hemorrhage?

yes no

272 Date of diagnosis: __ __ __ __ - __ __- __ __

273 Were diagnostic tests done?

yes no

Diagnosis was evaluated by:

274 bronchoalveolar lavage (BAL)

yes no

275 transbronchial biopsy

yes no

276 open / thorascopic (VATS) lung biopsy

yes no

277 autopsy

yes no

278 Other

yes no

279 Specify: _____

280 Did the recipient develop cryptogenic organizing pneumonia (COP)?

yes no

281 Date of diagnosis: __ __ __ __ - __ __- __ __

282 Were diagnostic tests done?

yes no

Diagnosis was evaluated by:

283 bronchoalveolar lavage (BAL)

yes no

284 transbronchial biopsy

yes no

285 open / thorascopic (VATS) lung biopsy

yes no

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286 autopsy

yes no

287 Other

yes no

288 Specify: _____

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

yes no

290 Specify other pulmonary abnormality: _____

291 Did the recipient receive endotracheal intubation or mechanical ventilation post-HSCT?

yes no

Liver Function

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

yes no

293 Date of diagnosis: __ __ __ __ - __ __- __ __

Etiology:

294 cirrhosis

yes no

295 veno-occlusive disease (VOD) / sinusodial obstruction syndrome (SOS)

yes no

296 Did the recipient receive treatment for VOD?

yes no

297 Specify: _____

298 Did VOD resolve?

yes no

299 Maximum bilirubin since last report: _____

300 Other

yes no

301 Specify other etiology: _____

302 Unknown

yes no

Specify diagnosis of liver toxicity by clinical signs and symptoms / evaluation:

303 ascites

yes no

304 autopsy

yes no

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305 bilirubin > 2.0 mg

yes no

306 biopsy

yes no

307 elevated hepatic venous pressure gradient

yes no

308 elevated liver enzymes (e.g., alkaline phosphatase, ALT, AST, LDH, GGT)

yes no

309 hepatomegaly

yes no

310 right upper quadrant pain or tenderness

yes no

311 ultrasonography / doppler (abnormal portal vein flow)

yes no

312 weight gain > 5%

yes no

313 Other

yes no

314 Specify other evaluation: _____

Other Organ Impairment / Disorder

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

yes no

Specify impairment / disorder:

316 avascular necrosis

yes no

317 Date of diagnosis: __ __ __ __ - __ __- __ __

318 cataracts

yes no

319 Date of diagnosis: __ __ __ __ - __ __- __ __

320 congestive heart failure (EF < 40%)

yes no

321 Date of diagnosis: __ __ __ __ - __ __- __ __

322 diabetes / hyperglycemia

yes no

323 Date of diagnosis: __ __ __ __ - __ __- __ __

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324 gonadal dysfunction / infertility requiring hormone replacement (testosterone or estrogen)

yes no

325 Date of diagnosis: __ __ __ __ - __ __- __ __

326 growth hormone deficiency / growth disturbance

yes no

327 Date of diagnosis: __ __ __ __ - __ __- __ __

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

yes no

329 Date of diagnosis: __ __ __ __ - __ __- __ __

330 hypothyroidism

yes no

331 Date of diagnosis: __ __ __ __ - __ __- __ __

332 myocardial infarction

yes no

333 Date of diagnosis: __ __ __ __ - __ __- __ __

334 pancreatitis

yes no

335 Date of diagnosis: __ __ __ __ - __ __- __ __

336 post-transplant microangiopathy-thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), or similar syndrome

yes no

337 Date of diagnosis: __ __ __ __ - __ __- __ __

338 Did the recipient receive plasmapheresis?

yes no

339 renal failure severe enough to warrant dialysis

yes no

340 Date of diagnosis: __ __ __ __ - __ __- __ __

341 Did the recipient receive dialysis?

yes no

342 stroke / seizure

yes no

343 Date of diagnosis: __ __ __ __ - __ __- __ __

344 Other impairment or disorder

yes no

345 Date of diagnosis: __ __ __ __ - __ __- __ __

346 Specify other impairment / disorder: _____

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New Malignancy

347 Did a new malignancy, lymphoproliferative or myeloproliferative disorder develop since the date of the last report that is different from the disease for which the HSCT was performed?

yes no

348 For all new malignancies except for "other skin malignancy (basal cell, squamous)," was testing performed to determine the cell of origin?

Yes

No

the only new malignancy in this reporting period was "other skin malignancy (basal cell, squamous)"

349 Specify the cell origin of the new malignancy:

recipient (host) donor origin unknown

350 Is a copy of the cell origin evaluation (VNTR, cytogenetics, FISH) attached?

yes **Attach a copy of the report with all identifiers removed, except for birth date and ID numbers. Reference question 350 on the report.**

no

Specify which new disease(s) occurred:

351 Acute myeloid leukemia (AML / ANLL)

yes no

352 Date of diagnosis: __ __ __ __ - __ __- __ __

353 Other leukemia, including ALL

yes no

354 Date of diagnosis: __ __ __ __ - __ __- __ __

355 Specify other leukemia: _____

356 Breast cancer

yes no

357 Date of diagnosis: __ __ __ __ - __ __- __ __

358 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)

yes no

359 Date of diagnosis: __ __ __ __ - __ __- __ __

360 Clonal cytogenetic abnormality without leukemia or MDS

yes no

361 Date of diagnosis: __ __ __ __ - __ __- __ __

362 Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)

yes no

363 Date of diagnosis: __ __ __ __ - __ __- __ __

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364 Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)

yes no

365 Date of diagnosis: __ __ __ __ - __ __- __ __

366 Hodgkin disease

yes no

367 Date of diagnosis: __ __ __ __ - __ __- __ __

368 Lung cancer

yes no

369 Date of diagnosis: __ __ __ __ - __ __- __ __

370 Lymphoma or lymphoproliferative disease

yes no

371 Date of diagnosis: __ __ __ __ - __ __- __ __

372 Is the tumor EBV positive?

yes no

373 Melanoma

yes no

374 Date of diagnosis: __ __ __ __ - __ __- __ __

375 Other skin malignancy (basal cell, squamous)

yes no

376 Date of diagnosis: __ __ __ __ - __ __- __ __

377 Specify other skin malignancy: _____

378 Myelodysplasia (MDS) / myeloproliferative (MPS) disorder

yes no

379 Date of diagnosis: __ __ __ __ - __ __- __ __

380 Oropharyngeal cancer (tongue, buccal mucosa)

yes no

381 Date of diagnosis: __ __ __ __ - __ __- __ __

382 Sarcoma

yes no

383 Date of diagnosis: __ __ __ __ - __ __- __ __

384 Thyroid cancer

yes no

385 Date of diagnosis: __ __ __ __ - __ __- __ __

386 Other new malignancy

yes no

387 Date of diagnosis: __ __ __ __ - __ __- __ __

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388 Specify other new malignancy: _____

389 Is a pathology / autopsy report or other documentation attached?

- yes **Attach a copy of the report with all identifiers removed, except for birth date and ID numbers. Reference question 389 on the report.**
- no

Survival and Functional Status

Questions: 390 - 394

If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.

390 Which scale was used, Karnofsky or Lansky? Specify the functional status of the recipient on the date of last actual contact.

- Karnofsky
- Lansky

_____

391 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

392 Specify other occupation: _____

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393 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

394 Specify retirement status:

- with a source of income
- no source of income

Subsequent HSCT/DCI

Questions: 395 - 501

Complete this section if the recipient received a subsequent HSCT (question 2, answered "yes"). If no subsequent HSCTs were performed, continue with the DCI section at question 403.

395 Date of subsequent HSCT: __ __ __ __ - __ __- __ __

396 Was the subsequent HSCT performed at a different institution?

- yes
- no

397 Name: _____

City: _____ State / Country: _____

398 What was the indication for subsequent HSCT?

- no hematopoietic recovery
- partial hematopoietic recovery
- graft failure / rejection after achieving initial hematopoietic recovery
- persistent primary disease
- recurrent primary disease
- Planned second HSCT, per protocol
- new malignancy
- stable, mixed chimerism
- declining chimerism
- Other

399 Specify other indication: _____

HSCT Multiple Source (1)

Questions: 400 - 402

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400 Source of HSCs:

allogeneic related | allogeneic unrelated | Autologous

401 Was the same donor used?

yes | no

402 Specify:

- fresh, original NMDP donor bone marrow
- fresh, original non-NMDP donor bone marrow
- fresh, new NMDP donor bone marrow
- fresh, new non-NMDP donor bone marrow
- fresh, original NMDP donor mobilized peripheral blood stem cells
- fresh, original non-NMDP donor mobilized peripheral blood stem cells
- fresh, new NMDP donor mobilized peripheral blood stem cells
- fresh, new 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

Donor Cellular Infusion (DCI) Information (1) — Questions: 403 - 501

This section captures information on DCIs (question 7, answered "yes") from any donor source (unstimulated peripheral blood mononuclear cells, T cells, NK cells, other cells). Complete this DCI section for all infusions given in a 10 week period. If more than 10 weeks have elapsed between DCIs, copy and complete this section for each 10 week period. If the recipient did not receive any DCIs, continue with the signature lines at question 502.

403 Date the first DCI was given: __ __ __ __ - __ __- __ __

404 Specify the number of cell infusions given within 10 weeks of the first DCI: _____

405 Was the DCI infusion performed at a different institution?

yes | no

406 Name: _____

City: _____ State / Country: _____

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

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Sequence Number: | CIBMTR Recipient ID: | Visit: ☐ 100 day ☐ 6 month ☐ year

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407 Indication for DCI:

- planned as part of initial HSCT protocol
- treatment for relapsed, persistent or progressive disease
- treatment for B cell lympho-proliferative disorder (PTLD, EBV lymphoma)
- treatment for GVHD
- viral infection
- stable, mixed chimerism
- loss of / decreased donor T-cell chimerism
- Other

Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to DCI (question 403).

408 Molecular

Positive Negative not done / unknown

409 Date: __ __ __ __ - __ __- __ __

410 Cytogenetic

Positive Negative not done / unknown

411 Date: __ __ __ __ - __ __- __ __

412 clinical evidence / hematologic

Positive Negative not done / unknown

413 Date: __ __ __ __ - __ __- __ __

414 Was chemotherapy used to attempt to induce disease response prior to the first DCI?

yes no

415 Date of administration of final chemotherapy dose: __ __ __ __ - __ __- __ __

416 Specify viral organism code: _____

417 Date documented: __ __ __ __ - __ __- __ __

418 Specify other indication: _____

419 What was the recipient's disease status immediately prior to the first DCI?

- first complete remission post-HSCT (no hematologic evidence of disease)
- therapy-induced complete remission after persistent disease or relapse post-HSCT
- Relapse or progression
- Persistent disease
- not evaluated post-HSCT

420 Date disease status was established prior to the first DCI: __ __ __ __ - __ __- __ __

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Sequence Number: | CIBMTR Recipient ID: | Visit: ☐ 100 day ☐ 6 month ☐ year

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If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.

421 Specify the functional status of the recipient immediately prior to the first DCI: _____

Specify DCI source:

422 collected at the time of PBSC mobilization and collection

yes no

423 negative fraction of CD34 selected PBSC

yes no

424 negative fraction of CD34 selected bone marrow

yes no

425 apheresis at a different time than collection of PBSC used for allogeneic HSCT

yes no

426 Date of Apheresis: __ __ __ __ - __ __- __ __

427 isolated from a unit(s) of whole blood

yes no

428 Specify number of units: _____

429 Were the donor cells collected by leukapheresis?

yes no

430 Date of first leukapheresis: __ __ __ __ - __ __- __ __

431 Date of last leukapheresis: __ __ __ __ - __ __- __ __

432 Number of leukaphereses: _____

433 Did the donor receive treatment to enhance cell collection prior to donation?

yes no

Specify treatment(s) given:

434 Growth factors

yes no

Specify agent:

435 G-CSF

yes no

436 GM-CSF

yes no

437 Other agent

yes no

438 Specify other agent: _____

439 Other treatment

yes no

440 Specify other treatment: _____

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ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Visit:
☐ 100 day
☐ 6 month
☐ year

Today's Date: Month Day 20 Year

Infusion Date: Month Day 20 Year

CIBMTR Center Number:

Initials:

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Center: CRID:

For each DCI given, report the total number of cells infused. If the cells were cryopreserved, report the totals after processing, but before cryopreservation.

441 CD3+ cells: _____ x10 Specify exponent: _____

CD3+ cells not tested

442 CD4+ cells: _____ x10 Specify exponent: _____

CD4+ cells not tested

443 CD8+ cells: _____ x10 Specify exponent: _____

CD8+ cells not tested

444 CD34+ cells: _____ x10 Specify exponent: _____

CD34+ cells not tested

445 NK cells: _____ x10 Specify exponent: _____

NK cells not tested

446 Nucleated cells: _____ x10 Specify exponent: _____

Nucleated cells not tested

447 Mesenchymal cells: _____ x10 Specify exponent: _____

Mesenchymal cells not tested

448 Were dendritic cells infused?

yes no

449 Were fibroblasts infused?

yes no

450 Were any other cell types infused?
(Not including cell types reported in questions 441-449)

yes no

451 Specify other cell type(s): _____

452 Were the cells cryopreserved prior to infusion?

yes no

453 Specify portion cryopreserved:

all cells portion of cells

454 Were the cells manipulated prior to infusion?

yes no

455 Specify portion manipulated:

all cells portion of cells

Specify all methods used to manipulate the cells:

456 ABO incompatibility

yes no

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Center: CRID:

Specify method:

457 buffy coat preparation

yes no

458 cell separator (i.e., COBE Spectra)

yes no

459 density gradient separation (i.e., Ficoll)

yes no

460 plasma removal

yes no

461 sedimentation (i.e., hetastarch)

yes no

462 other

yes no

463 Specify other method: _____

464 dextran-albumin wash

yes no

465 ex-vivo expansion

yes no

466 genetic manipulation (gene transfer / transduction)

yes no

467 volume reduction

yes no

468 CD34+ selection

yes no

469 Specify manufacturer:

CliniMACS / CliniMax Isolex Other

470 Specify other manufacturer: _____

471 T-cell depletion

yes no

Specify method:

472 Antibody affinity column

yes **Report antibodies used for T-cell depletion at question 484.**

no

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473 Antibody coated plates

yes **Report antibodies used for T-cell depletion at question 484.**

no

474 Antibody coated plates and soybean lectin

yes **Report antibodies used for T-cell depletion at question 484.**

no

475 Antibody + complement

yes **Report antibodies used for T-cell depletion at question 484.**

no

476 Antibody + toxin

yes **-Report antibodies used for T-cell depletion at question 484.**

no

477 Immunomagnetic beads

yes **Report antibodies used for T-cell depletion at question 484.**

no

478 Elutriation

yes no

479 CD34 affinity column plus sheep red blood cell rosetting

yes no

480 Other

yes no

481 Specify other method: _____

482 Other cell manipulation

yes no

483 Specify other cell manipulation: _____

484 Were antibodies used during graft manipulation?

yes no

485 Anti CD2

yes no

486 Anti CD4

yes no

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487 anti CD5

yes no

488 anti CD6

yes no

489 anti CD7

yes no

490 anti CD8

yes no

491 anti CD34

yes no

492 anti TCR alpha / beta (T10-B9)

yes no

493 OKT-3

yes no

494 other CD3

yes no

495 Specify other CD3: _____

496 anti CD52

yes no

Specify antibodies:

497 campath-NOS

yes no

498 campath-1G

yes no

499 campath-1H

yes no

500 other antibody

yes no

501 Specify other antibody: _____

First Name: _____ Last Name: _____

Phone number: _____ Fax number: _____

E-mail address: _____

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