

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

Form 2100 R3.0: 100 Days 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: _____

Vital Status Questions: 1 - 7

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

2 Did this patient receive the scheduled HSCT?

yes no

3 Reason:

patient died between start of preparative regimen and HSCT

HSCT was canceled, but patient is alive

4 Reason for cancellation: _____

5 Did recipient receive a subsequent HSCT (bone marrow, mobilized peripheral blood stem cells, cord blood) prior to day 100 after the HSCT for which this form is being completed?

yes no

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

Alive Dead

7 Has the recipient received a donor cellular infusion (DCI)?

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

Hematopoietic Reconstitution Post-HSCT Questions: 8 - 33

8 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.

9 G-CSF

yes no

10 Date G-CSF therapy started: ____-____-____

11 Therapy: _____

12 Specify drug given:

Neupogen Neulasta Lenograstim

13 GM-CSF

yes no

14 Date GM-CSF therapy started: ____-____-____

15 Therapy: _____

16 Erythropoietin

yes no

17 Date therapy started: ____-____-____

18 Therapy: _____

19 Specify drug given:

Epogen
 Aranesp (darbepoetin alfa)

20 KGF (palifermin, Kevivance)

(If used for GVHD prophylaxis, report at question 118.)

yes no

21 Date KGF therapy started: ____-____-____

22 Therapy: _____

23 Velafermin

(If used for GVHD prophylaxis, report at question 120.)

yes no

24 Date velafermin therapy started: ____-____-____

25 Therapy: _____

26 Blinded growth factor or cytokine trial

yes no

27 Specify study agent: _____

28 Date therapy started: ____-____-____

29 Therapy: _____

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

30 Other agent:

yes no

31 Specify other agent: _____

32 Date other therapy started: ____ - ____ - ____

33 Therapy: _____

Granulopoiesis/Neutrophil Recovery

Questions: 34 - 43

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

34 Is (was) there evidence of hematopoietic recovery following the initial HSCT? (check only one)

Yes, ANC $\geq 500/\text{mm}^3$ achieved and sustained for 3 lab values * with no subsequent decline

Yes, ANC $\geq 500/\text{mm}^3$ for 3 lab values * with subsequent decline in ANC to $< 500/\text{mm}^3$ for ≥ 3 days

No, ANC $\geq 500/\text{mm}^3$ was not achieved * and there was no evidence of recurrent disease in the bone marrow

No, ANC $\geq 500/\text{mm}^3$ was not achieved * and there was documented persistent disease in the bone marrow post-HSCT

ANC never dropped below $500/\text{mm}^3$ at any time after the start of the preparative regimen

35 Date ANC $\geq 500/\text{mm}^3$ (first of 3 lab values): * ____ - ____ - ____

36 Date ANC $\geq 500/\text{mm}^3$ (first of 3 lab values): * ____ - ____ - ____

37 Date of decline in ANC to $< 500/\text{mm}^3$ for ≥ 3 days (first of 3 days that the ANC declined): * ____ - ____ - ____

38 WBC: _____ $\times 10^9/\text{L}$ ($\times 10^3/\text{mm}^3$)

$\times 10^6/\text{L}$

39 Neutrophils: _____ %

40 Did recipient recover and maintain ANC $\geq 500/\text{mm}^3$ * following the decline?

yes no

41 Date of ANC recovery: ____ - ____ - ____ Date of ANC recovery unknown

CBC on first day of recovery:

42 WBC: _____ $\times 10^9/\text{L}$ ($\times 10^3/\text{mm}^3$)

$\times 10^6/\text{L}$

43 Neutrophils: _____ %

Megakaryopoiesis/Platelet Recovery

Questions: 44 - 47

44 Was an initial platelet count $\geq 20 \times 10^9/\text{L}$ achieved?

Yes

No

platelet count never dropped below $20 \times 10^9/\text{L}$

45 Date platelets $\geq 20 \times 10^9/\text{L}$: * ____ - ____ - ____ date estimated Date unknown

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Initials:

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

46 Was an initial platelet count $\geq 50 \times 10^9/L$ achieved?

- Yes
- No
- platelet count never dropped below $50 \times 10^9/L$

47 Date platelets $\geq 50 \times 10^9/L$: * _____ - _____ - _____ date estimated Date unknown

Current Hematologic Findings

Questions: 48 - 54

48 Date of most recent hematologic testing: _____ - _____ - _____

49 WBC: _____ $\times 10^9/L$ ($\times 10^3/mm^3$)
 $\times 10^6/L$

WBC not tested

50 Neutrophils: _____ % Neutrophils not tested

51 Lymphocytes: _____ % Lymphocytes not tested

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

Hemoglobin not tested

transfused RBS ≤ 30 days from date of most current testing

53 Hematocrit: _____ % Not tested

transfused RBS ≤ 30 days from date of most current testing

54 Platelets: _____ $\times 10^9/L$ ($\times 10^3/mm^3$)
 $\times 10^6/L$

Platelets not tested

transfused platelets ≤ 7 days from date of most current testing

Immune Reconstitution

Questions: 55 - 76

Specify the immunoglobulin values from the most recent testing:

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

IgG not tested

56 Date tested: _____ - _____ - _____

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

IgM not tested

58 Date tested: _____ - _____ - _____

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

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 6 month
 year

Initials:

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

IgA not tested

60 Date tested: ____ - ____ - ____

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

yes no

62 Was therapy ongoing within one month of immunoglobulin testing?

yes no

Indication(s) for use:

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

yes no

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

yes no

65 Treatment for CMV infection

yes no

66 Treatment for respiratory syncytial virus (RSV) infection

yes no

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

yes no

68 Other indication

yes no

69 Specify other indication: _____

70 Were lymphocyte analyses performed?

yes no

71 Date of most recent testing performed: ____ - ____ - ____

72 CD3 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

CD3 not tested

73 CD4 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

CD4 not tested

74 CD8 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

CD8 not tested

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Initials:

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Center: _____ CRID: _____

75 CD20 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

CD20 not tested

76 CD56 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

CD56 not tested

Chimerism Studies

Questions: 77 - 102

77 *Allogeneic HSCTs only:* Were chimerism studies performed post-HSCT?

yes no

78 Are chimerism laboratory reports attached to this form?

yes no

79 Were infusions from more than one donor given?

yes no

80 Specify donor gender:

male female

Single Donor (1)

Questions: 81 - 90

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

81 Date _____ - _____ - _____

82 Method _____

83 Specify: _____

84 Cell type _____

85 Specify: _____

86 Total cells examined _____

87 Number of donor cells _____

88 Number of host cells _____

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

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

Multiple Donors (1)

Questions: 91 - 102

91 NMDP Donor ID: _____

-or-

Donor's / infant's date of birth: _____ - _____ - _____

-or-

NMDP cord blood unit ID _____

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Initials:

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Center: _____ CRID: _____

-or-

Non-NMDP unrelated donor ID: _____

-or-

Non-NMDP cord blood unit ID: _____

92 Donor's / infant's gender:

male female

93 Date ____ - ____ - ____

94 Method _____

95 Specify: _____

96 Cell type _____

97 Specify: _____

98 Total cells examined _____

99 Number of donor cells _____

100 Number of host cells _____

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

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

Engraftment Syndrome

Questions: 103 - 109

103 Did engraftment syndrome occur?

yes no

104 Date of onset: ____ - ____ - ____

Specify the symptoms of engraftment syndrome:

105 Capillary leak syndrome

yes no

106 Fever

yes no

107 Skin rash

yes no

108 Specify amount of body surface area affected: _____ %

109 Was engraftment syndrome treated with corticosteroids?

yes no

Acute Graft vs. Host Disease (GVHD)

Questions: 110 - 187

110 Was specific therapy used after the start of the preparative regimen to prevent acute GVHD or graft rejection (*note: do not include growth factors reported in question 8, or ex vivo T-cell depletion reported on the Product Insert*), or for autologous HSCT to induce acute GVHD?

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

111 ALS, ALG, ATS, ATG

yes no

112 Specify source:

Horse Rabbit Other

113 Specify source: _____

114 Corticosteroids (systemic)

yes no

115 Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

116 ECP (extra-corporeal photopheresis)

yes no

117 FK 506 (Tacrolimus, Prograf)

yes no

118 KGF (palifermin, Kevivance) (if used to prevent mucositis, report at question 20.)

yes no

119 Specify date started: ____ - ____ - ____

120 Velafermin (If used to prevent mucositis, report at question 23.)

yes no

121 Specify date started: ____ - ____ - ____

122 In vivo monoclonal antibody

yes no

Specify in vivo monoclonal antibody:

123 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

124 Specify: _____

125 Campath

yes no

126 Etanercept (Enbrel)

yes no

127 Infliximab (Remicade)

yes no

128 Other in vivo monoclonal antibody

yes no

129 Specify antibody: _____

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Center: _____ CRID: _____

130 In vivo immunotoxin

yes no

131 Specify: _____

132 Methotrexate (MTX) (Amethopterin)

yes no

133 Mycophenolate mofetil (MMF) (CellCept)

yes no

134 Sirolimus (Rapamycin, Rapamune)

yes no

135 Ursodiol

yes no

136 Blinded randomized trial

yes no

137 Specify trial agent: _____

138 Other agent

yes no

139 Specify other agent: _____

140 Did acute GVHD occur?

Yes

acute GVHD persists from prior HSCT / DCI

No

Unknown

141 Date of acute GVHD diagnosis: ____ - ____ - ____ @ Date is greater than 100 days; date is correct

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

yes no

Specify result(s):

143 gastrointestinal (GI)

Positive Negative Inconclusive Not tested

144 Liver

Positive Negative Inconclusive Not tested

145 Lung

Positive Negative Inconclusive Not tested

146 Skin

Positive Negative Inconclusive Not tested

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

147 Other site

Positive Negative Inconclusive Not tested

148 Specify other site: _____

149 Is a copy of the pathology report attached?

yes no

150 Was the diagnosis based on clinical evidence?

yes no

151 Maximum overall grade of acute GVHD:

I II III IV

152 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:

153 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

154 Lower intestinal tract: (use mL/day for adult recipients and mL/m²/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/m²/day

stage 1 – diarrhea > 500 but <= 1000 mL/day or 280-555 mL/m²/day

stage 2 – diarrhea > 1000 but <= 1500 mL/day or 556-833 mL/m²/day

stage 3 – diarrhea > 1500 mL/day or > 833 mL/m²/day

stage 4 – severe abdominal pain, with or without ileus

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

155 Upper intestinal tract:

- stage 0 - no persistent nausea or vomiting
- stage 1 - persistent nausea or vomiting

156 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)

157 Other clinical organ involvement?

- yes no

Specify site:

158 Lung

- yes no

159 Other site:

- yes no

160 Specify other site: _____

161 Was specific therapy used to treat acute GVHD?

- yes no

162 ALS, ALG, ATS, ATG

- yes no

163 Specify source:

- Horse Rabbit Other

164 Specify source: _____

165 Corticosteroids (systemic)

- yes no

166 Corticosteroids (topical)

- yes no

167 Cyclosporine (CSA) (Sandimmune, Neoral)

- yes no

168 ECP (extra-corporeal photopheresis)

- yes no

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Center: _____ CRID: _____

169 FK 506 (Tacrolimus, Prograf)

yes no

170 In vivo monoclonal antibody

yes no

Specify in vivo monoclonal antibody:

171 Anti CD25 (Zenapax, Daclizumab, AntiTAC)

yes no

172 Specify anti CD25: _____

173 Campath

yes no

174 Etanercept (Enbrel)

yes no

175 Infliximab (Remicade)

yes no

176 Other in vivo monoclonal antibody

yes no

177 Specify antibody: _____

178 In vivo immunotoxin

yes no

179 Specify immunotoxin: _____

180 Methotrexate (MTX) (Amethopterin)

yes no

181 Mycophenolate mofetil (MMF) (CellCept)

yes no

182 Sirolimus (Rapamycin, Rapamune)

yes no

183 Ursodiol

yes no

184 Blinded randomized trial

yes no

185 Specify trial agent: _____

186 Other agent

yes no

187 Specify other agent: _____

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Center: _____ CRID: _____

Chronic Graft vs. Host Disease (GVHD) Questions: 188 - 259

188 Has recipient developed clinical chronic GVHD?

Yes

chronic GVHD persists from prior HSCT / DCI

No

Unknown

189 Date of chronic GVHD diagnosis: ____ - ____ - ____ Date is less than 100 days; date is correct

190 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 GVHD flare (symptoms reactivated within 30 days of drug tapering or discontinuation)

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.

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

192 Platelet count at diagnosis of chronic GVHD: _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

193 Diagnosis was based on:

histologic evidence / biopsy proven

Clinical evidence

Both

Unknown

194 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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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

195 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

Organ Involvement

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

196 Sclerosis of skin

yes no

197 Was involvement proven by biopsy?

yes no

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

yes no

199 Was involvement proven by biopsy?

yes no

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

yes no

201 Was involvement proven by biopsy?

yes no

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

yes no

203 Was involvement proven by biopsy?

yes no

204 Bronchiolitis obliterans

yes no

205 Was involvement proven by biopsy?

yes no

206 Other lung involvement

yes no

207 Was involvement proven by biopsy?

yes no

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

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

209 Was involvement proven by biopsy?

yes no

210 Liver

yes no

211 Was involvement proven by biopsy?

yes no

212 Genitourinary tract (vaginitis / stricture, etc.)

yes no

213 Was involvement proven by biopsy?

yes no

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

yes no

215 Was involvement proven by biopsy?

yes no

216 Thrombocytopenia (< 100 x 10⁹/L)

yes no

217 Eosinophilia

yes no

218 Autoantibodies

yes no

219 Other hematologic involvement

yes no

220 Serositis

yes no

221 Was involvement proven by biopsy?

yes no

222 Weight loss

yes no

223 Other organ involvement from chronic GVHD

yes no

224 Specify site: _____

225 Was involvement proven by biopsy?

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

226 Was specific therapy used to treat chronic GVHD?

yes no

Specify:

227 ALS, ALG, ATS, ATG

yes no

228 Specify source:

Horse Rabbit Other

229 Specify source: _____

230 Azathioprine

yes no

231 Corticosteroids (systemic)

yes no

232 Corticosteroids (topical)

yes no

233 Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

234 ECP (extracorporeal photopheresis)

yes no

235 Hydroxychloroquine (Plaquenil)

yes no

236 Etretnate

yes no

237 FK 506 (Tacrolimus, Prograf)

yes no

238 In vivo monoclonal antibody

yes no

Specify:

239 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

240 Specify anti CD25: _____

241 Campath

yes no

242 Etanercept (Enbrel)

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

243 Infliximab (Remicade)

yes no

244 Other in vivo monoclonal antibody

yes no

245 Specify antibody: _____

246 Lamprene (Clofazimine)

yes no

247 Mycophenolate mofetil (MMF) (CellCept)

yes no

248 Pentostatin

yes no

249 PUVA (Psoralen and UVA)

yes no

250 Sirolimus (Rapamycin, Rapamune)

yes no

251 Thalidomide

yes no

252 Ursodiol

yes no

253 Blinded randomized trial

yes no

254 Specify trial agent: _____

255 Other agent:

yes no

256 Specify other agent: _____

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

yes no

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

yes no Unknown

259 Date final treatment administered: ____-____-____ Date unknown

Infection Questions: 260 - 297

260 Did the recipient receive any of the following agents for infection prophylaxis after the start of the preparative regimen?

(report prophylaxis immunoglobulins at questions 63-64)

yes no Unknown

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

Specify agent(s) given:

261 Systemic antibacterial antibiotics

yes no

262 Nonabsorbable oral antibiotics

yes no

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

yes no

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

yes no

265 Caspofungin

yes no

266 Fluconazole

yes no

267 Itraconazole

yes no

268 Miconazole

yes no

269 Posaconazole

yes no

270 Ravuconazole

yes no

271 Voriconazole

yes no

272 Other systemic antifungal agent

yes no

273 Specify other antifungal agent: _____

274 Acyclovir

yes no

275 Foscarnet

yes no

276 Ganciclovir (DHPG)

yes no

277 Valganciclovir (Valcyte)

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

278 Valacyclovir
 yes no

279 Other antiviral agent
 yes no

280 Specify other antiviral agent: _____

281 Atovaquone (Mepron)
 yes no

282 Dapsone
 yes no

283 Pentamidine inhaled
 yes no

284 Pentamidine IV
 yes no

285 Trimethoprim/sulfamethoxazole (Bactrim/Septra)
 yes no

286 Other pneumocystis prophylaxis
 yes no

287 Specify other pneumocystis agent: _____

288 Other prophylaxis agent
 yes no

289 Specify other prophylaxis agent: _____

290 Did the recipient receive irradiated granulocyte infusions after the start of the preparative regimen to 60 days post-HSCT?
 yes no

291 Did the recipient develop a clinically significant infection after the start of the preparative regimen?
 yes no

Clinically significant infections (1)

Questions: 292 - 295

Report each infection organism, site and date of diagnosis.

292 Organism _____

The codes for "other organism, specify" should rarely be needed; check with your microbiology lab or HSCT physician before using them.

293 If other, specify: _____

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

294 Site _____

295 _____ - _____ - _____

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

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

yes no

297 Are extra pages attached?

yes no

Organ Function

Questions: 298 - 449

298 Did the recipient develop interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) after the start of preparative regimen to date of last contact (question 1)?

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

(Report bacterial and fungal pneumonia in Infection section (questions 291-295))

yes no

Pulmonary function (1)

Questions: 299 - 320

299 Date of diagnosis of IPn / IPS: ____ - ____ - ____

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

yes no

Diagnosis was evaluated by:

301 bronchoalveolar lavage (BAL)

yes no

302 transbronchial biopsy

yes no

303 open / thorascopic (VATS) lung biopsy

yes no

304 autopsy

yes no

305 Other test

yes no

306 Specify other test: _____

307 Was an organism isolated?

Yes no / idiopathic

Etiology:

308 adenovirus

yes no

309 cytomegalovirus (CMV)

yes no

310 herpes simplex (HSV1, HSV2)

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

311 human herpes virus type 6 (HHV6)

yes no

312 parainfluenza

yes no

313 respiratory syncytial virus (RSV)

yes no

314 toxoplasma

yes no

315 other virus

yes no

316 Specify other virus: _____

317 other organism

yes no

318 Specify organism: _____

319 Did the recipient experience two or more episodes of IPn / IPS after the start of preparative regimen to date of last contact (question 1)?

yes no

320 Are extra pages attached?

yes no

321 Did the recipient develop non-infectious pulmonary abnormalities (other than IPn / IPS / ARDS) after the start of preparative regimen to date of last contact (question 1)?

yes no

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

yes no

323 Date of diagnosis: ____ - ____ - ____

324 Were diagnostic tests done?

yes no

Diagnosis was evaluated by:

325 bronchoalveolar lavage (BAL)

yes no

326 transbronchial biopsy

yes no

327 open / thorascopic (VATS) lung biopsy

yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

328 autopsy
 yes no

329 Other
 yes no

330 Specify: _____

331 Did the recipient develop pulmonary hemorrhage?
 yes no

332 Date of diagnosis: ____ - ____ - ____

333 Were diagnostic tests done?
 yes no

Diagnosis was evaluated by:

334 bronchoalveolar lavage (BAL)
 yes no

335 transbronchial biopsy
 yes no

336 open / thorascopic (VATS) lung biopsy
 yes no

337 autopsy
 yes no

338 Other
 yes no

339 Specify: _____

340 Did the recipient develop cryptogenic organizing pneumonia (COP)?
 yes no

341 Date of diagnosis: ____ - ____ - ____

342 Were diagnostic tests done?
 yes no

Diagnosis was evaluated by:

343 bronchoalveolar lavage (BAL)
 yes no

344 transbronchial biopsy
 yes no

345 open / thorascopic (VATS) lung biopsy
 yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

346 autopsy
 yes no

347 Other
 yes no

348 Specify: _____

349 Did the recipient develop any other non-infectious pulmonary abnormalities?
 yes no

350 Specify other pulmonary abnormality: _____

351 Did the recipient receive endotracheal intubation or mechanical ventilation post-HSCT?
 yes no

Liver Function

352 Did the recipient develop non-infectious liver toxicity (excluding GVHD) after the start of preparative regimen to date of last contact (question 1)?
 yes no

353 Date of diagnosis: ____ - ____ - ____

Etiology:

354 cirrhosis
 yes no

355 veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS)
 yes no

356 Did the recipient receive treatment for VOD?
 yes no

357 Specify: _____

358 Did VOD resolve by day 100?
 yes no

359 Maximum bilirubin in first 100 days: _____

360 Other
 yes no

361 Specify other etiology: _____

362 Unknown
 yes no

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

363 ascites
 yes no

364 autopsy
 yes no

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

365 bilirubin > 2.0 mg

yes no

366 biopsy

yes no

367 elevated hepatic venous pressure gradient

yes no

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

yes no

369 hepatomegaly

yes no

370 right upper quadrant pain or tenderness

yes no

371 ultrasonography / doppler (abnormal portal vein flow)

yes no

372 weight gain > 5%

yes no

373 Other

yes no

374 Specify other evaluation: _____

Other Organ Impairment/Disorder

375 Has the recipient developed any other clinically significant organ impairment or disorder after the start of preparative regimen to date of last contact (question 1)?

yes no

Specify impairment/disorder:

376 avascular necrosis

yes no

377 Date of diagnosis: _____ - ____ - ____

378 cataracts

yes no

379 Date of diagnosis: _____ - ____ - ____

380 congestive heart failure (EF < 40%)

yes no

381 Date of diagnosis: _____ - ____ - ____

382 diabetes / hyperglycemia

yes no

383 Date of diagnosis: _____ - ____ - ____

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Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

426 Hodgkin disease

yes no

427 Date of diagnosis _____ - _____ - _____

428 Lung cancer

yes no

429 Date of diagnosis _____ - _____ - _____

430 Lymphoma or lymphoproliferative disease

yes no

431 Date of diagnosis _____ - _____ - _____

432 Is the tumor EBV positive?

yes no

433 Melanoma

yes no

434 Date of diagnosis _____ - _____ - _____

435 Other skin malignancy (basal cell, squamous)

yes no

436 Date of diagnosis _____ - _____ - _____

437 Specify other skin malignancy: _____

438 Myelodysplasia (MDS) / myeloproliferative (MPS) disorder

yes no

439 Date of diagnosis _____ - _____ - _____

440 Oropharyngeal cancer (tongue, buccal mucosa)

yes no

441 Date of diagnosis _____ - _____ - _____

442 Sarcoma

yes no

443 Date of diagnosis _____ - _____ - _____

444 Thyroid cancer

yes no

445 Date of diagnosis _____ - _____ - _____

446 Other new malignancy

yes no

447 Date of diagnosis _____ - _____ - _____

448 Specify other new malignancy: _____

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ERROR CORRECTION FORM					
Sequence Number:	<input type="text"/>	CIBMTR Recipient ID:	<input type="text"/>		
Today's Date:	Infusion Date:	CIBMTR Center Number:	Visit:		
<input type="text"/> / <input type="text"/> / <input type="text" value="20"/>	<input type="text"/> / <input type="text"/> / <input type="text" value="20"/>	<input type="text"/>	<input type="checkbox"/> 100 day <input type="checkbox"/> 6 month <input type="checkbox"/> <input type="text"/> year		
Month	Day	Year	Month	Day	Year
			Initials: <input type="text"/>		

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

449 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 449 on the report.
- no

Functional Status

Questions: 450 - 453

450 Was the recipient discharged from the hospital after HSCT?

- Yes
- No
- not applicable, therapy and HSC infusion given as outpatient

451 Date first discharged from hospital post-HSCT: ____ - ____ - ____

452 Total number of inpatient days (day 0 to day 100) in first 100 days post-HSCT _____

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.

453 Which scale was used, Karnofsky or Lansky?

- Karnofsky Lansky

Specify the functional status of the recipient on the date of last actual contact. _____

Subsequent HSCT

Questions: 454 - 461

454 Date of subsequent HSCT: ____ - ____ - ____

455 Was the subsequent HSCT performed at a different institution?

- yes no

Specify the institution that performed the subsequent HSCT:

456 Name: _____

City: _____ State / Country: _____

457 What was the indication for subsequent HSCT? _____

Subsequent autologous HSCTs performed for engraftment reasons (options 1–3) do not require separate report forms to be completed.

All other subsequent HSCTs will require a separate follow-up report form completed for each infusion.

458 Specify other indication: _____

Subsequent Product(s) Information (1)

Questions: 459 - 461

459 Source of HSCs:

- Allogeneic, related
- Allogeneic, unrelated
- Autologous

460 Was the same donor used?

- yes no

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ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Today's Date:

Infusion Date:

CIBMTR Center Number:

Visit: 100 day 6 month year

Initials:

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

461 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

Questions: 462 - 560

DCI (1)

Questions: 462 - 560

462 Date the first DCI was given: ____ - ____ - ____

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

464 Was the DCI infusion performed at a different institution?

- yes no

Specify the institution that performed the DCI:

465 Name: _____

City: _____ State / Country: _____

466 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

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ERROR CORRECTION FORM										
Sequence Number: <input type="text"/>					CIBMTR Recipient ID: <input type="text"/>					Visit: <input type="checkbox"/> 100 day <input type="checkbox"/> 6 month <input type="checkbox"/> <input type="text"/> year
Today's Date: <input type="text"/>		Infusion Date: <input type="text"/>		CIBMTR Center Number: <input type="text"/>			Initials: <input type="text"/>			
Month	Day	20	Year	Month	Day	20	Year			

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

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 462).

467 Molecular

Positive Negative not done / unknown

468 Date: _____ - ____ - ____

469 Cytogenetic

Positive Negative not done / unknown

470 Date: _____ - ____ - ____

471 clinical evidence / hematologic

Positive Negative not done / unknown

472 Date: _____ - ____ - ____

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

yes no

474 Date of administration of final chemotherapy dose: _____ - ____ - ____

475 Specify viral organism code: _____

476 Date documented: _____ - ____ - ____ (document chimerism testing beginning at question 81 or question 91)

477 Specify other indication: _____

478 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

479 Date disease status was established prior to the first DCI: _____ - ____ - ____

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

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

Specify DCI source:

481 collected at the time of PBSC mobilization and collection

yes no

482 negative fraction of CD34 selected PBSC

yes no

483 negative fraction of CD34 selected bone marrow

yes no

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

yes no

485 Date of Apheresis: _____ - ____ - ____

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ERROR CORRECTION FORM									
Sequence Number:					CIBMTR Recipient ID:				
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Today's Date:			Infusion Date:			CIBMTR Center Number:			Visit:
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Month	Day	Year	Month	Day	Year				Initials:
		20			20				<input type="text"/>

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

Nucleated cells: _____ x10 Specify exponent: _____

506 Mesenchymal cells not tested

Mesenchymal cells: _____ x10 Specify exponent: _____

507 Were dendritic cells infused?

yes no

508 Were fibroblasts infused?

yes no

509 Were any other cell types infused?

(not including cell types reported in questions 500-508)

yes no

510 Specify other cell type(s): _____

511 Were the cells cryopreserved prior to infusion?

yes no

512 Specify portion cryopreserved:

all cells portion of cells

513 Were the cells manipulated prior to infusion?

yes no

514 Specify portion manipulated:

all cells portion of cells

Specify all methods used to manipulate the cells:

515 ABO incompatibility

yes no

Specify method:

516 buffy coat preparation

yes no

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

yes no

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

yes no

519 plasma removal

yes no

520 sedimentation (i.e., hetastarch)

yes no

521 other

yes no

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

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

522 Specify other method: _____

523 dextran-albumin wash

yes no

524 ex-vivo expansion

yes no

525 genetic manipulation (gene transfer / transduction)

yes no

526 volume reduction

yes no

527 CD34+ selection

yes no

528 Specify manufacturer:

CliniMACS / CliniMax Isolex other manufacturer

529 Specify other manufacturer: _____

530 T-cell depletion

yes no

Specify method:

531 Antibody affinity column

yes -Report antibodies used for T-cell depletion at question 543.

no

532 Antibody coated plates

yes -Report antibodies used for T-cell depletion at question 543.

no

533 Antibody coated plates and soybean lectin

yes -Report antibodies used for T-cell depletion at question 543.

no

534 Antibody + complement

yes -Report antibodies used for T-cell depletion at question 543.

no

535 Antibody + toxin

yes -Report antibodies used for T-cell depletion at question 543.

no

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ERROR CORRECTION FORM									
Sequence Number:					CIBMTR Recipient ID:				
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Today's Date:			Infusion Date:			CIBMTR Center Number:			Visit:
<input type="text"/> Month	<input type="text"/> Day	<input type="text"/> 2 <input type="text"/> 0 <input type="text"/> Year	<input type="text"/> Month	<input type="text"/> Day	<input type="text"/> 2 <input type="text"/> 0 <input type="text"/> Year	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			<input type="checkbox"/> 100 day <input type="checkbox"/> 6 month <input type="checkbox"/> <input type="text"/> year
Initials:									<input style="width: 100%;" type="text"/>

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

536 Immunomagnetic beads

yes -Report antibodies used for T-cell depletion at question 543.
 no

537 Elutriation

yes no

538 CD34 affinity column plus sheep red blood cell rosetting

yes no

539 Other

yes no

540 Specify other method: _____

541 Other cell manipulation

yes no

542 Specify other cell manipulation: _____

543 Were antibodies used during graft manipulation?

yes no

Specify antibodies:

544 Anti CD2

yes no

545 Anti CD4

yes no

546 Anti CD5

yes no

547 Anti CD6

yes no

548 Anti CD7

yes no

549 Anti CD8

yes no

550 Anti CD34

yes no

551 Anti TCR alpha / beta (T10-B9)

yes no

552 OKT-3

yes no

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

Form 2100 R3.0: 100 Days Post-HSCT Data

Center: _____ CRID: _____

553 Other CD3
 yes no

554 Specify other CD3: _____

555 Anti CD52
 yes no

Specify antibodies:

556 campath-NOS
 yes no

557 campath-1G
 yes no

558 campath-1H
 yes no

559 Other antibody
 yes no

560 Specify other antibody: _____

First Name: _____ Last Name: _____

Phone number: _____ Fax number: _____

E-mail address: _____

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