Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

Key Fields

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:

Vital Status

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

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

2 Specify the recipient's survival status at the date of last contact
   ☐ Alive - Answers to subsequent questions should reflect clinical status since the date of last report.
   ☐ Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete a Form 2900 - Recipient Death Data.

3 Did the recipient receive a subsequent HCT since the date of last report?
   ☐ yes - Answers to subsequent questions should reflect clinical status immediately prior to the start of the preparative regimen for subsequent HCT. Also complete Subsequent HCT section.
   ☐ no

4 Has the recipient received a cellular therapy since the date of last report? (e.g. DCI)
   ☐ yes - Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000
   ☐ no

5 Date of cellular therapy: ____________________________

Granulopoiesis / Neutrophil Recovery

Questions: 6 - 12

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

6 Was there evidence of initial hematopoietic recovery?
   ☐ Yes (ANC ≥ 500/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)

7 Date ANC ≥ 500/mm³ (first of 3 lab values): ____________________________

8 Following the initial hematopoietic recovery, was there subsequent decline in ANC to < 500/mm³ for ≥ 3 days since the date of last report?
   ☐ yes ☐ no

9 Date of decline in ANC to < 500/mm³ for ≥ 3 days (first of 3 days that the ANC declined): ____________________________

10 Did recipient recover and maintain ANC ≥ 500/mm³ following the decline?
   ☐ yes ☐ no

11 Date of ANC recovery
   ☐ Known ☐ Unknown

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Megakaryopoiesis / Platelet Recovery

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

13 Was an initial platelet count ≥ 20 x 10^9/L achieved?
- Yes
- No
- Not applicable (Platelet count never dropped below 20 x 10^9/L)
- Previously reported (≥ 20 x 10^9/L was achieved and reported previously)

14 Date platelets ≥ 20 x 10^9/L
- Known
- Unknown

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

16 Was an initial platelet count ≥ 50 x 10^9/L achieved?
- Yes
- No
- Not applicable (Platelet count never dropped below 50 x 10^9/L)
- Previously reported (≥ 50 x 10^9/L was achieved and reported previously)

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

18 Date platelets ≥ 50 x 10^9/L: __________ - __________
- Date estimated

Growth Factor and Cytokine Therapy

19 Did the recipient receive hematopoietic, lymphoid growth factors or cytokines after the start of the preparatory regimen?
- Yes
- No

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

20 G-CSF
- Yes
- No

21 Date started: __________ - __________

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

23 Specify other indication: ________________________

24 Specify drug given
- Filgrastim (Neupogen)
- Pegfilgrastim (Neulasta)
- Lenograstim
- Other drug

25 Specify other drug: ________________________

26 GM-CSF
- Yes
- No

27 Date started: __________ - __________

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**Form 2100 R4.0: Post-HCT Follow-Up Data**

<table>
<thead>
<tr>
<th>28 Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>28a Planned therapy per protocol</td>
</tr>
<tr>
<td>28b Intervention for delay in cell count recovery</td>
</tr>
<tr>
<td>28c Intervention for decline in cell count</td>
</tr>
<tr>
<td>28d Anti-leukemic or tumor agent to prevent relapse</td>
</tr>
<tr>
<td>28e Anti-leukemic or tumor agent to treat relapse</td>
</tr>
<tr>
<td>28f Other indication</td>
</tr>
</tbody>
</table>

| 29 Specify other indication:                                               |
|                                                                           |

| 30 Erythropoetin (EPO)                                                     |
|                                                                           |
| 30a Yes                                                                    |
| 30b No                                                                    |

| 31 Date started: __-__-__                                                   |
|                                                                           |

<table>
<thead>
<tr>
<th>32 Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>32a Planned therapy per protocol</td>
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<tr>
<td>32c Intervention for decline in cell count</td>
</tr>
<tr>
<td>32d Other indication</td>
</tr>
</tbody>
</table>

| 33 Specify other indication:                                               |
|                                                                           |

| 34 Specify drug given                                                      |
|                                                                           |
| 34a Epoetin alfa (Epogen)                                                 |
| 34b Darbepeotin alfa (Aranesp)                                           |

| 35 KGF (palietermin, Kepivance)                                           |
|                                                                           |
| 35a Yes                                                                   |
| 35b No                                                                    |

| 36 Date started: __-__-__                                                   |
|                                                                           |

<table>
<thead>
<tr>
<th>37 Therapy</th>
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<tbody>
<tr>
<td>37a Planned therapy per protocol</td>
</tr>
<tr>
<td>37b Other indication</td>
</tr>
</tbody>
</table>

| 38 Specify other indication:                                               |
|                                                                           |

| 39 Blinded growth factor or cytokine trial                                |
|                                                                           |
| 39a Yes                                                                   |
| 39b No                                                                    |

| 40 Specify study agent:                                                   |
|                                                                           |

| 41 Date started: __-__-__                                                   |
|                                                                           |

<table>
<thead>
<tr>
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<td>42e Anti-leukemic or tumor agent to treat relapse</td>
</tr>
<tr>
<td>42f Other indication</td>
</tr>
</tbody>
</table>

| 43 Specify other indication:                                               |
|                                                                           |

| 44 Other agent                                                            |
|                                                                           |
| 44a Yes                                                                   |
| 44b No                                                                    |

| 45 Specify other agent:                                                   |
|                                                                           |

| 46 Date started: __-__-__                                                   |
|                                                                           |

<table>
<thead>
<tr>
<th>47 Therapy</th>
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<td>47d Anti-leukemic or tumor agent to prevent relapse</td>
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<tr>
<td>47e Anti-leukemic or tumor agent to treat relapse</td>
</tr>
<tr>
<td>47f Other indication</td>
</tr>
</tbody>
</table>

| 48 Specify other indication:                                               |
|                                                                           |
Form 2100 R4.0: Post-HCT Follow-Up Data

Current Hematologic Findings

49. Date of most recent complete blood count: __ __ __ __

50. WBC
   - Known
   - Unknown

51. WBC: ________________________ x 10^9/L (x 10^13/m3)
   - x 10^9/L

52. Neutrophils
   - Known
   - Unknown

53. Neutrophils: ________ %

54. Lymphocytes
   - Known
   - Unknown

55. Lymphocytes: ________ %

56. Hemoglobin
   - Known
   - Unknown

57. Hemoglobin: ________________________ g/dL  g/L  mmol/L

58. Hematocrit
   - Known
   - Unknown

59. Hematocrit: ________ %

60. Was RBC transfused ≤ 30 days before date of test?
   - Yes
   - No

61. Platelets
   - Known
   - Unknown

62. Platelets: ________________________ x 10^9/L (x 10^13/m3)
   - x 10^6/L

63. Were platelets transfused ≤ 7 days before date of test?
   - Yes
   - No

Immune Reconstitution

Specify the date the most recent immunoglobulin sample was collected:

64. Date sample collected: __ __ __ __

65. Did the recipient receive supplemental intravenous immunoglobulins (IVIG)?
   - yes
   - no

66. Was supplemental IVIG received in the 30 days prior to the date the sample was collected?
   - Yes
   - No

Specify the indication for which IVIG was given:

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

68. Specify other indication: ________________________

Specify the immunoglobulin values from the most recent testing:

69. IgG
   - Known
   - Unknown

70. IgG: ________________________ mg/dL  g/dL  g/L

71. IgM
   - Known
   - Unknown

72. IgM: ________________________ mg/dL  g/dL  g/L
**Form 2100 R4.0: Post-HCT Follow-Up Data**

**Key Fields**
- Sequence Number:
- Date Received: __ __ __ __ - __ __- __ __
- CIBMTR Center Number:
- CIBMTR Recipient ID:
- Infusion Date: __ __ __ __ - __ __- __ __
- CIBMTR Center Number:
- Infusion: ___

**Today’s Date:**
- Month: 2
- Day: 0
- Year: __ __

---

**Chimerism Studies**

Questions: 89 - 107

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

89 Were chimerism studies performed post-HCT? (Allogeneic HCTs only)
- yes
- no

90 Was documentation submitted to the CIBMTR? (e.g. chimerism laboratory reports)
- Yes
- No

91 Were chimerism studies assessed for more than one donor / multiple donors?
- Yes
- No

---

**Chimerism Studies (1)**

Questions: 92 - 107

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

92 NMHD donor ID:

93 NMHD cord blood unit ID:

94 Non-NMHD unrelated donor ID:

95 Non-NMHD cord blood unit ID:

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

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<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>97 Sex (donor/infant)</td>
<td>male, female</td>
</tr>
<tr>
<td>98 Date sample collected</td>
<td>__ __ __ __ - __ __- __ __</td>
</tr>
<tr>
<td>99 Method</td>
<td>Karyotyping for XXXY, Fluorescent in situ hybridization (FISH) for XXXY, Restriction fragment-length polymorphisms (RFLP), VNTR or STR, micro or mini satellite (also include AFLP), Other</td>
</tr>
<tr>
<td>100 Specify:</td>
<td></td>
</tr>
<tr>
<td>101 Cell source</td>
<td>Bone marrow, Peripheral blood</td>
</tr>
<tr>
<td>102 Cell type</td>
<td></td>
</tr>
<tr>
<td>103 Specify:</td>
<td></td>
</tr>
<tr>
<td>104 Total cells examined</td>
<td>__ __ __ __ - __ __- __ __</td>
</tr>
<tr>
<td>105 Number of donor cells</td>
<td>__ __ __ __ - __ __- __ __</td>
</tr>
<tr>
<td>106 Were donor cells detected?</td>
<td>yes, no</td>
</tr>
<tr>
<td>107 Percent donor cells</td>
<td>%</td>
</tr>
</tbody>
</table>

**Engraftment Syndrome**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>108 Did engraftment syndrome occur?</td>
<td>yes, no</td>
</tr>
<tr>
<td>109 Date of onset</td>
<td>__ __ __ __ - __ __- __ __</td>
</tr>
<tr>
<td>Specify the symptoms of engraftment syndrome:</td>
<td></td>
</tr>
<tr>
<td>110 Diarrhea</td>
<td>yes, no</td>
</tr>
<tr>
<td>111 Erythrodermic rash (involving &gt;25% of body surface area)</td>
<td>yes, no</td>
</tr>
<tr>
<td>112 Fever (&gt;38.3°C or &gt;100.9°F with no identifiable infectious etiology)</td>
<td>yes, no</td>
</tr>
<tr>
<td>113 Development of hepatic dysfunction (with either bilirubin ≥2 mg/dL or transaminase levels ≥2 times normal)</td>
<td>yes, no</td>
</tr>
<tr>
<td>114 Non-cardiogenic pulmonary edema (manifested by diffuse pulmonary infiltrates and hypoxia)</td>
<td>yes, no</td>
</tr>
<tr>
<td>115 Development of renal insufficiency (serum creatinine ≥2 times baseline)</td>
<td>yes, no</td>
</tr>
<tr>
<td>116 Transient encephalopathy</td>
<td>yes, no</td>
</tr>
<tr>
<td>117 Weight gain (≥2.5% of baseline body weight)</td>
<td>yes, no</td>
</tr>
<tr>
<td>118 Other symptom</td>
<td>yes, no</td>
</tr>
<tr>
<td>119 Specify other symptom:</td>
<td></td>
</tr>
</tbody>
</table>

**Biopsy**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>120 Was a biopsy performed?</td>
<td>yes, no</td>
</tr>
<tr>
<td>Specify site</td>
<td></td>
</tr>
<tr>
<td>121 Lower gastrointestinal (GI)</td>
<td>yes, no</td>
</tr>
</tbody>
</table>
### Acute Graft vs. Host Disease (GVHD)

Questions: 131 - 233

Report any acute graft-versus-host disease occurring in this reporting period in response to allogeneic HCT or cellular therapy. If this was an autologous HCT, continue with the Infection section.

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

- [ ] Yes
- [ ] No

#### Total dose: ____________________ mg/kg

Specify source:
- [ ] ATGAM (horse)
- [ ] ATG - Fresenius (rabbit)
- [ ] Thymoglobulin (rabbit)
- [ ] Other

133 Specify other source:

135 Bortezomib (Velcade)

- [ ] Yes
- [ ] No

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

- [ ] Yes
- [ ] No

138 Cyclosporine (CSA, Neoral, Sandimmune)

- [ ] Yes
- [ ] No

139 Cyclophosphamide (Cytoxan)

- [ ] Yes
- [ ] No

140 Total dose: ____________________ mg/kg

141 Extra-corporeal photopheresis (ECP)

- [ ] Yes
- [ ] No

142 FK 506 (Tacrolimus, Prograf)

- [ ] Yes
- [ ] No

143 In vivo monoclonal antibody

- [ ] Yes
- [ ] No

Specify in vivo monoclonal antibody:

- [ ] Yes
- [ ] No

145 Total dose: ____________________ mg
### Form 2100 R4.0: Post-HCT Follow-Up Data

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>146 Other in vivo monoclonal antibody</td>
<td>Yes, No</td>
</tr>
<tr>
<td>147 Specify antibody:</td>
<td></td>
</tr>
<tr>
<td>148 In vivo immunotoxin</td>
<td>Yes, No</td>
</tr>
<tr>
<td>149 Specify immunotoxin</td>
<td></td>
</tr>
<tr>
<td>150 Methotrexate (MTX) (Amethopterin)</td>
<td>Yes, No</td>
</tr>
<tr>
<td>151 Mycophenolate mofetil (MMF) (CellCept, Myfortic)</td>
<td>Yes, No</td>
</tr>
<tr>
<td>152 Sirolimus (Rapamycin, Rapamune)</td>
<td>Yes, No</td>
</tr>
<tr>
<td>153 Blinded randomized trial</td>
<td>Yes, No</td>
</tr>
<tr>
<td>154 Specify trial agent</td>
<td></td>
</tr>
<tr>
<td>155 Other agent</td>
<td>Yes, No</td>
</tr>
<tr>
<td>156 Specify other agent</td>
<td></td>
</tr>
<tr>
<td>157 Did acute GVHD develop since the date of last report?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>158 Date of acute GVHD diagnosis:</td>
<td></td>
</tr>
<tr>
<td>159 Did acute GVHD persist since the date of last report?</td>
<td>Yes, No, Unknown</td>
</tr>
<tr>
<td>160 Was acute GVHD evaluated by biopsy (histology)? (at diagnosis)</td>
<td>Yes, No</td>
</tr>
<tr>
<td><strong>Specify result(s):</strong></td>
<td></td>
</tr>
<tr>
<td>161 Skin</td>
<td>Positive, Suggestive, Negative, Inconclusive / equivocal, Not done</td>
</tr>
<tr>
<td>162 Lower gastrointestinal (GI)</td>
<td>Positive, Suggestive, Negative, Inconclusive / equivocal, Not done</td>
</tr>
<tr>
<td>163 Upper gastrointestinal (GI)</td>
<td>Positive, Suggestive, Negative, Inconclusive / equivocal, Not done</td>
</tr>
<tr>
<td>164 Liver</td>
<td>Positive, Suggestive, Negative, Inconclusive / equivocal, Not done</td>
</tr>
</tbody>
</table>
### Form 2100 R4.0: Post-HCT Follow-Up Data

**165 Lung**
- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

**166 Other site**
- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

**167 Specify other site:**

**168 Was documentation submitted to the CIBMTR? (e.g. pathology report)**
- Yes
- No

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

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

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

#### 171 Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)
- Stage 0 - No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)
- Stage 1 - Diarrhea 500-1000 mL/day (adult), or 10-19.9 mL/kg/day (pediatric)
- Stage 2 - Diarrhea 1001-1500 mL/day (adult), or 20-30 mL/kg/day (pediatric)
- Stage 3 - Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)
- Stage 4 - Severe abdominal pain, with or without ileus, and/or grossly bloody stool

#### 172 Upper intestinal tract
- Stage 0 - No persistent nausea or vomiting
- Stage 1 - Persistent nausea or vomiting

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

**174 Other site(s) involved with acute GVHD**
- Yes
- No

**175 Specify other site(s):**

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Center: CRID:

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

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

177 Date maximum overall grade of acute GVHD: ___ ___ ___ __ - ___ ___- ___ ___

Specify organ involvement at time of maximum grade:

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

179 Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)
- Stage 0 - No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult) or < 10 mL/kg/day (pediatric)
- Stage 1 - Diarrhea 500-1000 mL/day (adult) or 10-19.9 mL/kg/day (pediatric)
- Stage 2 - Diarrhea 1001-1500 mL/day (adult) or 20-30 mL/kg/day (pediatric)
- Stage 3 - Diarrhea >1500 mL/day (adult) or > 30 mL/kg/day (pediatric)
- Stage 4 - Severe abdominal pain, with or without ileus, and/or grossly bloody stool

180 Upper intestinal tract
- Stage 0 - No persistent nausea or vomiting
- Stage 1 - Persistent nausea or vomiting

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

182 Other site(s) involved with acute GVHD
- Yes  No

183 Specify other site(s):

Specify therapy given for acute GVHD:

184 Corticosteroids (topical GI) (e.g. beclomethasone, budesonide)
- Yes  No

185 Was systemic therapy used to treat acute GVHD?
- yes  no

186 ALG, ALS, ATG, ATS
- yes  no

187 Total dose: _________ mg/kg

188 Date started: ___ ___ ___ __ - ___ ___- ___ ___

189 Specify source
- ATGAM (horse)
- ATG - Fresenius (rabbit)
- Thymoglobulin (rabbit)
- Other

190 Specify other source: _____________________________________________________________________

191 Alemtuzumab (Campath)
- yes  no

192 Total dose: ___________ mg
### Form 2100 R4.0: Post-HCT Follow-Up Data

**Center:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>193 Date started:</td>
<td></td>
</tr>
<tr>
<td>194 Anti CD25 (Zenapax, Daclizumab, AntiTAC)</td>
<td></td>
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<td>195 Specify anti CD25:</td>
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<td>196 Date started:</td>
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<tr>
<td>197 Corticosteroids (systemic) (e.g. prednisone, dexamethasone)</td>
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<td>198 Date started:</td>
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<td>199 Cyclosporine (CSA, Neoral, Sandimmune)</td>
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<td>205 FK 506 (Tacrolimus, Prograf)</td>
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<td>206 Date started:</td>
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<td>207 Infliximab (Remicade)</td>
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<td>208 Date started:</td>
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<td>209 In vivo immunotoxin</td>
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<td>210 Specify immunotoxin:</td>
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<td>211 Date started:</td>
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<td>212 Mycophenolate mofetil (MMF) (CellCept, Myfortic)</td>
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<td>213 Date started:</td>
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<td>214 Pentostatin (Nipent)</td>
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<td>215 Date started:</td>
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<td>216 PUVA (Psoralen and UVA)</td>
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<td>217 Date started:</td>
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<td>218 Sirolimus (Rapamycin, Rapamune)</td>
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<td>219 Date started:</td>
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<td>220 Tocilizumab</td>
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<td>221 Date started:</td>
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<td>222 JAK 2 inhibitors</td>
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<td>223 Ruxolitinib (Jakafi)</td>
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<td>224 Date started:</td>
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<td>225 Other JAK 2 inhibitor</td>
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<td>226 Specify other JAK 2 inhibitor</td>
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<td>227 Date started:</td>
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<tr>
<td>228 Blinded randomized trial</td>
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<tr>
<td>229 Specify trial agent</td>
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</tbody>
</table>

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Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

### Chronic Graft vs. Host Disease (GVHD)

Report any chronic graft-versus-host disease occurring in this reporting period in response to allogeneic HCT or cellular therapy. If this was an autologous HCT, continue with the infection section.

234 Did chronic GVHD develop since the date of last report?
- Yes
- No
- Unknown

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

236 Did chronic GVHD persist since the date of last report?
- Yes
- No
- Unknown

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

238 Were signs of acute GVHD present at the time of chronic GVHD diagnosis (overlap syndrome)?
- Yes
- No

239 What scale was used to determine the recipient’s functional status? (at time of chronic GVHD diagnosis)
- Karnofsky (recipient age ≥ 16 years)
- Lansky (recipient age < 16 years)

**Performance score:**

240 Karnofsky Scale (recipient age ≥ 16 years) ______________________

241 Lansky Scale (recipient age < 16 years) ______________________

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

243 Total serum bilirubin: (at diagnosis of chronic GVHD) ______________________
- mg/dL
- µmol/L

244 Was chronic GVHD evaluated by biopsy (histology)? (at diagnosis)
- Yes
- No

**Specify result(s):**

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

246 Lower gastrointestinal (GI)
- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

247 Upper gastrointestinal (GI)
- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done
**Form 2100 R4.0: Post-HCT Follow-Up Data**

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

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

250 Other site
- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

251 Specify other site: ________________________________

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

**Skin:**

252 Skin
- Yes
- No

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

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

Specify skin GVHD features present at diagnosis of chronic GVHD:

255 Maculopapular rash / erythema
- Yes
- No

256 Lichen planus-like features
- Yes
- No

257 Papulosquamous lesions or ichthyosis
- Yes
- No

258 Keratosis pilaris-like GVHD
- Yes
- No

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

259 Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

260 Specify cause: ________________________________

261 Mouth
- Yes
- No

---

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Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

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

263 Lichen planus-like features
- Yes
- No

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

264 Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

265 Specify cause: __________________________

Eyes

266 Eyes
- Yes
- No

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

268 Keratoconjunctivitis sicca (KCS) confirmed by ophthalmologist?
- Yes
- No
- Not done

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

269 Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

270 Specify cause: __________________________

Gastrointestinal (GI) Tract

271 Gastrointestinal (GI) tract
- Yes
- No

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

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

273 Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

274 Specify cause: __________________________

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

275 Esophageal web / proximal stricture or ring
- Yes
- No

276 Dysphagia
- Yes
- No

277 Anorexia
- Yes
- No

278 Nausea
- Yes
- No

279 Vomiting
- Yes
- No

280 Diarrhea
- Yes
- No
Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

281 Weight loss ≥5%
   Yes No

282 Failure to thrive
   Yes No

Liver
283 Liver
   Yes No

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

Specify if any liver abnormalities were present, but explained entirely by non-GVHD causes:
285 Abnormality present but explained entirely by non-GVHD documented cause
   Yes No

Lungs
287 Lungs
   Yes No

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

289 Were pulmonary function tests performed?
   Yes No

290 Specify FEV1 percent: ___________ %

Specify if any lung abnormalities were present, but explained entirely by non-GVHD causes:
291 Abnormality present but explained entirely by non-GVHD documented cause
   Yes No

Joints and fascia
293 Joints and fascia
   Yes No

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

Specify if any joint or fascia abnormalities were present, but explained entirely by non-GVHD causes:
295 Abnormality present but explained entirely by non-GVHD documented cause
   Yes No

296 Specify cause: ___________________________________________

Genital tract
297 Genital tract
   Yes No

298 Genital tract score
   Score 0 - No signs
   Score 1 - Mild signs and females with or without discomfort on exam
   Score 2 - Moderate signs and may have symptoms with discomfort on exam
   Score 3 - Severe signs with or without symptoms
299 Currently sexually active?
   ✔ Yes ☐ No ☐ Unknown

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

300 Abnormality present but explained entirely by non-GVHD documented cause
   ✔ Yes ☐ No

301 Specify cause:

302 Maximum grade of chronic GVHD since the date of last report:
   Moderate ☐ Severe ☐ Unknown

303 Specify if chronic GVHD was limited or extensive
   Limited - Localized skin involvement and/or hepatic dysfunction due to chronic GVHD
   Extensive - One or more of the following:
   - generalized skin involvement; or,
   - liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
   - involvement of eye: Schirmer’s test with < 5 mm wetting; or
   - involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
   - involvement of any other target organ

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

   Organ specific manifestations since the date of last report:

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

305 Sclerosis of skin or fascia (e.g. scleroderma, fasciitis, morphea)
   ✔ Yes ☐ No

306 Erythematous skin rash
   ✔ Yes ☐ No

307 Joint contractures
   ✔ Yes ☐ No

308 Other skin or hair involvement (ulcers, pruritus or itching, dyspigmentation, alopecia, lichenoid skin changes, etc.)
   ✔ Yes ☐ No

309 Eyes (xerophthalmia (dry eyes), abnormal Schirmer’s test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.)
   ✔ Yes ☐ No

310 Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.)
   ✔ Yes ☐ No

311 Bronchiolitis obliterans
   ✔ Yes ☐ No

312 Other lung involvement
   ✔ Yes ☐ No

313 Upper gastrointestinal tract (esophageal involvement, chronic nausea / vomiting)
   ✔ Yes ☐ No

314 Lower gastrointestinal tract (chronic diarrhea, malabsorption, abdominal pain / cramps, etc.)
   ✔ Yes ☐ No

316 Liver
   ✔ Yes ☐ No

317 Genitourinary tract (vaginitis / stricture, etc.)
   ✔ Yes ☐ No

318 Musculoskeletal (arthritis, myositis, etc.)
   ✔ Yes ☐ No
Form 2100 R4.0: Post-HCT Follow-Up Data
Center: CRID:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>319 Thrombocytopenia (&lt;100 x 10^9/L)</td>
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<td>320 Eosinophilia</td>
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<td>321 Serositis (e.g., pleural effusion, ascites, pericardial effusion)</td>
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<tr>
<td>322 Other organ involvement</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>323 Specify site:</td>
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<tr>
<td>Specify therapy for chronic GVHD since the date of last report:</td>
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<tr>
<td>324 Corticosteroids (topical GI) (e.g. budesonide)</td>
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<tr>
<td>325 Was systemic therapy given to treat chronic GVHD?</td>
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<tr>
<td>326 Was the date therapy was first started previously reported?</td>
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<tr>
<td>327 Date therapy was first started:</td>
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<tr>
<td>Specify systemic therapy started or escalated for chronic GVHD since the date of last report:</td>
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<tr>
<td>328 ALG, ALS, ATG, ATS</td>
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<tr>
<td>329 Total dose:</td>
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<td>330 Specify source:</td>
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<tr>
<td>ATGAM (horse)</td>
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<td>ATG - Fresenius (rabbit)</td>
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<tr>
<td>Thymoglobulin (rabbit)</td>
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<tr>
<td>Other</td>
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<tr>
<td>331 Specify other source:</td>
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<tr>
<td>332 Date started:</td>
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<tr>
<td>333 Aldesleukin (interleukin-2, IL-2)</td>
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<td>334 Date started:</td>
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<tr>
<td>335 Alemtuzumab (Campath)</td>
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<td>336 Total dose:</td>
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<td>337 Date started:</td>
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<tr>
<td>338 Anti CD25 (Zenapax, Daclizumab, AntiTAC)</td>
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<td>339 Specify anti CD25:</td>
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<td>340 Date started:</td>
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<tr>
<td>341 Azathioprine</td>
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<td>343 Bortezomib (Velcade)</td>
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<td>348 Date started:</td>
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<tr>
<td>349 Interleukin inhibitors</td>
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</tbody>
</table>
Form 2100 R.4.0: Post-HCT Follow-Up Data
Center: CRID:

350 Anti-IL2
   ☐ Yes ☐ No
351 Date started: __ __ __ __

352 Anti-IL6
   ☐ Yes ☐ No
353 Date started: __ __ __ __

354 Other interleukin inhibitor
   ☐ Yes ☐ No
355 Specify other interleukin inhibitor:
356 Date started: __ __ __ __

357 Extra-corpooreal photopheresis (ECP)
   ☐ yes ☐ no
358 Date started: __ __ __ __

359 Etanercept (Enbrel)
   ☐ yes ☐ no
360 Date started: __ __ __ __

361 FK 506 (Tacrolimus, Prograf)
   ☐ yes ☐ no
362 Date started: __ __ __ __

363 Hydroxychloroquine (Plaquenil)
   ☐ Yes ☐ No
364 Date started: __ __ __ __

365 Infliximab (Remicade)
   ☐ yes ☐ no
366 Date started: __ __ __ __

367 Methotrexate (MTX) (Amethopterin)
   ☐ yes ☐ no
368 Date started: __ __ __ __

369 Mycophenolate mofetil (MMF) (CellCept, Myfortic)
   ☐ yes ☐ no
370 Date started: __ __ __ __

371 Pentostatin (Nipent)
   ☐ yes ☐ no
372 Date started: __ __ __ __

373 UV therapy
   ☐ Yes ☐ No
374 PUVA (Psoralen and UVA)
   ☐ yes ☐ no
375 Date started: __ __ __ __

376 UVB
   ☐ Yes ☐ No
377 Date started: __ __ __ __

378 Rituximab (Rituxan, MabThera)
   ☐ yes ☐ no
379 Date started: __ __ __ __

380 Sirolimus (Rapamycin, Rapamune)
   ☐ yes ☐ no
381 Date started: __ __ __ __

382 Tyrosine kinase inhibitors (TKI)
   ☐ yes ☐ no
383 Imatinib mesylate (Gleevec)
   ☐ yes ☐ no
384 Date started: __ __ __ __
Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

385 Other TKI
- Yes ☐ No ☐

386 Specify other TKI: ____________________________

387 Date started: __ __ __ __ - __ __- __ __

388 JAK 2 inhibitors
- Yes ☐ No ☐

389 Ruxolitinib (Jakafi)
- Yes ☐ No ☐

390 Date started: __ __ __ __ - __ __- __ __

391 Other JAK 2 inhibitor
- Yes ☐ No ☐

392 Specify other JAK 2 inhibitor: ____________________________

393 Date started: __ __ __ __ - __ __- __ __

394 Blinded randomized trial
- Yes ☐ No ☐

395 Specify trial agent: ____________________________

396 Date started: __ __ __ __ - __ __- __ __

397 Other agent
- Yes ☐ No ☐

398 Specify other agent: ____________________________

399 Date started: __ __ __ __ - __ __- __ __

Current GVHD Status

400 Are symptoms of GVHD still present on the date of actual contact (or present at the time of death)?
- Yes ☐ No ☐

401 Is the recipient still taking systemic steroids? (Do not report steroids for adrenal insufficiency, ≤ 10 mg/day for adults, < 0.1 mg/kg/day for children)
- Yes ☐ No ☐ Not Applicable ☐ Unknown ☐

402 Date final treatment administered
- Known ☐ Unknown ☐ Previously reported ☐

403 Date final treatment administered: __ __ __ __ - __ __- __ __

404 Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
- Yes ☐ No ☐ Not Applicable ☐ Unknown ☐

405 Date final treatment administered
- Known ☐ Unknown ☐ Previously reported ☐

406 Date final treatment administered: __ __ __ __ - __ __- __ __

Infection Prophylaxis

Questions: 407 - 427

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

407 Did the recipient receive antibacterial drug(s) for infection prophylaxis?
- Yes ☐ No ☐

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

408 Amoxicillin/clavulanate oral (Augmentin)
- Yes ☐ No ☐

409 Cefdinir oral (Omnicef)
- Yes ☐ No ☐

410 Ceftazidime oral (Vantin)
- Yes ☐ No ☐

411 Ciprofloxacin IV or oral (Cipro)
- Yes ☐ No ☐

412 Ertapenem IV
- Yes ☐ No ☐

413 Levofloxacin IV or oral (Levaquin)
- Yes ☐ No ☐
### Form 2100 R4.0: Post-HCT Follow-Up Data

**Center:**

**CRID:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Date of diagnosis</th>
<th>Organism</th>
<th>Site</th>
<th>Date started</th>
<th>Other source</th>
<th>Anti CD25</th>
<th>Date of ANC recovery</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>428 Did the patient develop a clinically significant infection since the date of last report?</td>
<td>Yes / No</td>
<td></td>
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<td>429 Report each infection organism, site, and date of diagnosis.</td>
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<td>430 Specify other organism:</td>
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<td>431 Site</td>
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<td>432 Site</td>
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<td>433 Site</td>
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<td>434 Site</td>
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<td>435 Site</td>
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<td>436 Date of diagnosis:</td>
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<td>437 Did the recipient develop Systemic Inflammatory Response Syndrome (SIRS) since the date of last report?</td>
<td>Yes / No</td>
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<td>438 Date of diagnosis:</td>
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</tr>
<tr>
<td>439 Did the recipient develop septic shock since the date of last report?</td>
<td>Yes / No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>440 Date of diagnosis:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Pulmonary Function

<table>
<thead>
<tr>
<th>Question</th>
<th>Date of diagnosis</th>
<th>Other</th>
<th>Diagnosis was evaluated by</th>
</tr>
</thead>
<tbody>
<tr>
<td>441 Did the recipient develop non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) since the date of last report?</td>
<td>Yes / No</td>
<td></td>
<td>Bronchoalveolar lavage (BAL)</td>
</tr>
<tr>
<td>442 Date of diagnosis:</td>
<td></td>
<td></td>
<td>Yes / No</td>
</tr>
<tr>
<td>443 Were diagnostic tests done? (other than radiographic studies)</td>
<td>Yes / No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>444 Diagnosis was evaluated by:</td>
<td>Bronchoalveolar lavage (BAL)</td>
<td>Yes / No</td>
<td></td>
</tr>
</tbody>
</table>

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Form 2100 R4.0: Post-HCT Follow-Up Data

<table>
<thead>
<tr>
<th>Sequence Number:</th>
<th>CIBMTR Recipient ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Today's Date:</td>
<td>Infusion Date:</td>
</tr>
<tr>
<td>Month</td>
<td>Day</td>
</tr>
<tr>
<td>Visit: 1:00 day</td>
<td>8 month</td>
</tr>
</tbody>
</table>

Center: CRID:

445 Transbronchial biopsy
- Yes
- No

446 Open / thoracoscopic (VATS) lung biopsy
- Yes
- No

447 Autopsy
- Yes
- No

448 Other diagnostic test
- Yes
- No

449 Specify other diagnostic test:

450 Was an organism isolated from the sputum, BAL, or tracheal aspirate that is clinically significant?
- Yes (If yes, report this pneumonia in the Infection section)
- No

451 Was documentation submitted to the CIBMTR? (e.g. scan report)
- Yes
- No

452 Did the recipient develop other non-infectious pulmonary abnormalities since the date of last report? (e.g. bronchiolitis obliterans, COP / BOOP, diffuse alveolar hemorrhage)
- Yes
- No

453 Did the recipient develop bronchiolitis obliterans since the date of last report?
- Yes
- No

454 Date of diagnosis: __ __ __ __ - __ __ - __ __

455 Were diagnostic tests done? (other than radiographic studies)
- Yes
- No

Diagnosis was evaluated by:

456 Bronchoalveolar lavage (BAL)
- Yes
- No

457 Transbronchial biopsy
- Yes
- No

458 Open / thoracoscopic (VATS) lung biopsy
- Yes
- No

459 Autopsy
- Yes
- No

460 Other diagnostic test
- Yes
- No

461 Specify other diagnostic test:

462 Was documentation submitted to the CIBMTR? (e.g. scan report)
- Yes
- No

463 Did the recipient develop cryptogenic organizing pneumonia (COP / BOOP)?
- Yes
- No

464 Date of diagnosis: __ __ __ __ - __ __ - __ __

465 Were diagnostic tests done? (other than radiographic studies)
- Yes
- No

Diagnosis was evaluated by:

466 Bronchoalveolar lavage (BAL)
- Yes
- No

467 Transbronchial biopsy
- Yes
- No

468 Open / thoracoscopic (VATS) lung biopsy
- Yes
- No

469 Autopsy
- Yes
- No

470 Other diagnostic test
- Yes
- No
Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

471 Specify other diagnostic test: __________________________

472 Was documentation submitted to the CIBMTR? (e.g. scan report)
  ☐ Yes ☐ No

473 Did the recipient develop diffuse alveolar hemorrhage?
  ☐ Yes ☐ No

474 Date of diagnosis: _ _ _ _ / _ _ _ _

475 Were diagnostic tests done? (other than radiographic studies)
  ☐ Yes ☐ No

Diagnosis was evaluated by:

476 Bronchoalveolar lavage (BAL)
  ☐ Yes ☐ No

477 Transbronchial biopsy
  ☐ Yes ☐ No

478 Open / thorascopic (VATS) lung biopsy
  ☐ Yes ☐ No

479 Autopsy
  ☐ Yes ☐ No

480 Other diagnostic test
  ☐ Yes ☐ No

481 Specify other diagnostic test: __________________________

482 Was documentation submitted to the CIBMTR? (e.g. scan report)
  ☐ Yes ☐ No

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

484 Date of diagnosis: _ _ _ _ / _ _ _ _

485 Specify other pulmonary abnormality:

486 Did the recipient receive endotracheal intubation or mechanical ventilation post-HCT?
  ☐ Yes ☐ No

487 Date started: _ _ _ _ / _ _ _ _

488 Was the recipient successfully extubated?
  ☐ Yes ☐ No

489 Date extubated: _ _ _ _ / _ _ _ _

Liver Toxicity Prophylaxis

490 Was specific therapy used to prevent liver toxicity?
  ☐ Yes ☐ No

491 Defibrotide
  ☐ Yes ☐ No

492 N-acetylcysteine
  ☐ Yes ☐ No

493 Tissue plasminogen activator (TPA)
  ☐ Yes ☐ No

494 Ursodiol
  ☐ Yes ☐ No

495 Other therapy
  ☐ yes ☐ no

496 Specify other therapy: __________________________

Liver Function

497 Did the recipient develop non-infectious liver toxicity (excluding GVHD) since the date of last report?
  ☐ Yes ☐ No
Form 2100 R4.0: Post-HCT Follow-Up Data

Etiology:

VOD / SOS

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

☐ Yes ☐ No

499 Date of diagnosis: __ __ __ __ - __ __- __ __

Cirrhosis

500 Cirrhosis

☐ Yes ☐ No

501 Date of diagnosis: __ __ __ __ - __ __- __ __

Other Etiology

502 Other etiology

☐ Yes ☐ No

503 Specify other etiology: ________________________________

504 Date of diagnosis: __ __ __ __ - __ __- __ __

505 Unknown etiology

☐ Yes ☐ No

Thrombotic microangiopathy (TMA)

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

☐ Yes ☐ No

507 Date of diagnosis: __ __ __ __ - __ __- __ __

Specify signs and symptoms:

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

☐ Yes ☐ No

509 Increased serum LDH above institutional baseline

☐ Yes ☐ No

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

☐ Yes ☐ No

511 Neurologic dysfunction without other explanation

☐ Yes ☐ No

512 Negative direct and indirect Coombs test results

☐ Yes ☐ No

513 Was TMA evaluated by biopsy?

☐ Yes ☐ No

Specify result(s):

514 Kidney

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

515 Other site

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

516 Specify other site:

517 Was documentation submitted to the CIBMTR?

☐ Yes ☐ No
Form 2100 R4.0: Post-HCT Follow-Up Data

Specify therapy for TMA

<table>
<thead>
<tr>
<th>518</th>
<th>Was therapy given for TMA?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>yes</td>
</tr>
<tr>
<td>☐</td>
<td>no</td>
</tr>
</tbody>
</table>

519 Diflunisole  
   ☑ Yes  ☐ No

520 Eculizumab (Soliris)  
   ☑ Yes  ☐ No

521 Rituximab (Rituxan, MabThera)  
   ☑ yes  ☐ no

522 Plasma exchange / plasmapheresis  
   ☑ Yes  ☐ No

523 Other therapy  
   ☑ yes  ☐ no

524 Specify other therapy: ________________________________

525 Did the TMA resolve? (Normalization of renal function, LDH, and resolution or improvement in renal and/or neurologic dysfunction)  
   ☑ Yes  ☐ No

526 Date resolved: _ _ _ _ _ _ _ _ _ _

Other Organ Impairment / Disorder

527 Has the recipient developed any other clinically significant organ impairment or disorder since the date of last report?  
   ☑ yes  ☐ no

Specify impairment / disorder:

Renal

528 Acute renal failure requiring dialysis  
   ☑ Yes  ☐ No

529 Date of diagnosis: _ _ _ _ _ _ _ _ _ _

530 Date dialysis started: _ _ _ _ _ _ _ _ _ _

531 Was the recipient still on dialysis at the date of last contact?  
   ☑ Yes  ☐ No

532 Date dialysis stopped: _ _ _ _ _ _ _ _ _ _

533 Chronic kidney disease / renal impairment (persistent decrease in glomerular filtration rate to < 60 mL/min/1.73m²)  
   ☑ Yes  ☐ No

534 Date of diagnosis: _ _ _ _ _ _ _ _ _ _

535 Was the recipient placed on dialysis?  
   ☑ Yes  ☐ No

536 Date dialysis started: _ _ _ _ _ _ _ _ _ _

537 Was the recipient still on dialysis at the date of last contact?  
   ☑ Yes  ☐ No

538 Date dialysis stopped: _ _ _ _ _ _ _ _ _ _

Cardiac

539 Arrhythmia (e.g. atrial fibrillation or flutter, sick sinus syndrome, ventricular arrhythmia)  
   ☑ Yes  ☐ No

540 Date of diagnosis: _ _ _ _ _ _ _ _ _ _

541 Specify arrhythmia  
   ☑ Atrial fibrillation or flutter
   ☑ Sick sinus syndrome
   ☑ Ventricular arrhythmia
   ☑ Other arrhythmia

542 Specify other arrhythmia: ________________________________

543 Congestive heart failure  
   ☑ Yes  ☐ No

544 Date of diagnosis: _ _ _ _ _ _ _ _ _ _

545 Specify ejection fraction: _____________________________ %
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Center: CRID:

546 Coronary artery disease
  - Yes  No

547 Date of diagnosis: __ __ __ __

548 Myocardial infarction / Unstable angina
  - Yes  No

549 Date of diagnosis: __ __ __ __

550 Hypertension (HTN) requiring therapy
  - Yes  No

551 Date of diagnosis: __ __ __ __

552 Was the recipient still receiving therapy at the date of contact for this reporting period?
  - Yes  No

Vascular

553 Deep vein thrombosis (DVT) / Pulmonary embolism (PE)
  - Yes  No

554 Date of diagnosis: __ __ __ __

555 Was the DVT catheter related?
  - Yes  No

Neurological

556 CNS hemorrhage
  - Yes  No

557 Date of diagnosis: __ __ __ __

558 Encephalopathy (non-infectious)
  - Yes  No

559 Date of diagnosis: __ __ __ __

560 Neuropathy
  - Yes  No

561 Date of diagnosis: __ __ __ __

562 Seizures
  - Yes  no

563 Date of diagnosis: __ __ __ __

564 Stroke
  - Yes  No

565 Date of diagnosis: __ __ __ __

Endocrine

566 Diabetes / hyperglycemia requiring chronic treatment
  - Yes  No

567 Date of diagnosis: __ __ __ __

568 Was the recipient still receiving therapy at the date of contact for this reporting period?
  - Yes  No

569 Growth hormone deficiency / short stature
  - Yes  No

570 Date of diagnosis: __ __ __ __

571 Was therapy given?
  - Yes  no

572 Hypothyroidism requiring replacement therapy
  - Yes  No

573 Date of diagnosis: __ __ __ __

574 Pancreatitis
  - Yes  No

575 Date of diagnosis: __ __ __ __

Genitourinary

576 Gonadal dysfunction requiring hormone replacement (testosterone or estrogen)
  - Yes  No

577 Date of diagnosis: __ __ __ __
578 Hemorrhagic cystitis / hematuria requiring medical intervention (catheterization of bladder, extra transfusions, urology consult)

579 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

Musculoskeletal
580 Avascular necrosis

581 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

582 Osteonecrosis of the jaw

583 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

584 Osteoporosis

585 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

586 Osteoporotic fracture

587 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

Psychiatric
588 Depression requiring therapy

589 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

590 Anxiety requiring therapy

591 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

592 Post-traumatic stress disorder (PTSD) requiring therapy

593 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

Other
594 Cataracts

595 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

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

597 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

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

Yes ☐ No ☐

599 Iron overload requiring therapy

600 Date of diagnosis: __ __ __ __
Yes ☐ No ☐

Specify therapy:

601 Phlebotomy

602 Iron chelation

603 Other therapy

604 Specify other therapy: _____________________________

605 Mucositis requiring therapy

606 Date of diagnosis: __ __ __ __
### New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

**Questions: 616 - 639**

**616 Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the HCT or cellular therapy was performed? (Include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)**

- [ ] Yes
- [ ] No

**New Malignancy (1) Questions: 617 - 639**

**617 Specify the new malignancy**

- [ ] [ ]

**618 Specify other new malignancy:**

- [ ] [ ]

**619 Date of diagnosis:**

- [ ] [ ]

**620 Was the new malignancy donor / cell product derived?**

- [ ] Yes
- [ ] No
- [ ] Not done

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

- [ ] Yes
- [ ] No

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

- [ ] Yes
- [ ] No

**Post-Transplant Lymphoproliferative Disorder**

**623 Was there EBV reactivation in the blood?**

- [ ] Yes
- [ ] No
- [ ] Unknown

**624 How was EBV reactivation diagnosed?**

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

**625 Specify other method:**

- [ ] [ ]

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

- [ ] [ ]

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

- [ ] Yes
- [ ] No

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

- [ ] [ ]

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

- [ ] Yes
- [ ] No
**Functional Status**

<table>
<thead>
<tr>
<th>Questions: 640 - 660</th>
</tr>
</thead>
<tbody>
<tr>
<td>640 Was the intent to complete the HCT procedure (conditioning, infusion, and period of recovery from neutropenia) as an outpatient?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>641 Did the recipient require an unplanned admission?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>642 Was the recipient discharged prior to the date of contact?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>643 Date first discharged from hospital post-HCT:</td>
</tr>
<tr>
<td>644 Total number of inpatient days (day 0 to day 100) in first 100 days post-HCT:</td>
</tr>
<tr>
<td>645 Recipient height (most recent)</td>
</tr>
<tr>
<td>Known</td>
</tr>
<tr>
<td>646 Recipient height:</td>
</tr>
<tr>
<td>647 Date documented:</td>
</tr>
<tr>
<td>648 Recipient weight (most recent)</td>
</tr>
<tr>
<td>Known</td>
</tr>
<tr>
<td>649 Recipient weight:</td>
</tr>
<tr>
<td>650 Date documented:</td>
</tr>
<tr>
<td>651 What scale was used to determine the recipient’s functional status?</td>
</tr>
<tr>
<td>Karnofsky (recipient age ≥ 16 years)</td>
</tr>
<tr>
<td>Lansky (recipient age &lt; 16 years)</td>
</tr>
<tr>
<td>Performance score:</td>
</tr>
<tr>
<td>652 Karnofsky Scale (recipient age ≥ 16 years)</td>
</tr>
<tr>
<td>653 Lansky Scale (recipient age &lt; 16 years)</td>
</tr>
<tr>
<td>654 Was the recipient pregnant at any time in this reporting period? (Female only)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>655 Was the recipient's female partner pregnant at any time in this reporting period? (Male only)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>
Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

656 Was the recipient or recipient's partner still pregnant at the date of last contact?
   - Yes  - No  - Unknown

657 Specify the outcome of pregnancy
   - Live birth
   - Intrauterine fetal death
   - Spontaneous abortion
   - Elective abortion
   - Unknown

658 Has the recipient smoked tobacco cigarettes since the date of last report?
   - yes  - no  - Unknown

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

660 Average number of packs per day: ______________________

Subsequent HCT

Questions: 661 - 668

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

661 Date of subsequent HCT: __________ - __________

662 Was the subsequent HCT performed at a different institution?
   - Yes  - No

Specify the institution that performed the subsequent HCT:

663 Name:____________________________

City:____________________________

State:____________________________

Country:____________________________

664 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

Specify other indication: ______________________________

Subsequent HCT Sources (1)

Questions: 666 - 668

666 Source of HSCs
   - Allogeneic, related
   - Allogeneic, unrelated
   - Autologous

667 Was the same donor used?
   - Yes  - No

668 Specify
   - Fresh, NMDP donor bone marrow
   - Fresh, non-NMDP donor bone marrow
   - Fresh, NMDP donor mobilized peripheral blood stem cells
   - Fresh, non-NMDP donor mobilized peripheral blood stem cells
   - NMDP cord blood
   - Non-NMDP cord blood
   - Cryopreserved original donor bone marrow
   - Cryopreserved original donor mobilized peripheral blood stem cells
Form 2100 R4.0: Post-HCT Follow-Up Data

Center: CRID:

First Name: ___________________________ Last Name: ___________________________

E-mail address: ___________________________ Date: ____________

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