Form 2450 R3.0: Post-Transplant Essential Data

Center: CRID:

Key Fields

OMB No: 0915-0310
Expiration Date: 1/31/2017

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0310. Public reporting burden for this collection of information is estimated to average 0.85 hours per response when collected at 100 days post-transplant, 1.0 hours per response when collected at 6 months and 12 months post-transplant, and 1.5 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-29, Rockville, Maryland, 20857.

Sequence Number ________________
Date Received: __ __ __ __

Center Identification
CIBMTR Center Number: __________________________
EBMT Code (CIC) __________________________
Hospital: __________________________
Unit: (check only one)
Adult [n] [m] Hematology [n] [m] Oncology [n] [m] Pediatric [n] [m] Other [n] [m]
Specify: __________________________
Contact person: First Name: __________________________
Last Name: __________________________
Date of This Report: __ __ __ __
Follow-Up:
[ ] day 100 [ ] 6 months [ ] annual
[ ] specify year __________________________

Recipient Identification
CIBMTR Recipient ID: __________________________
Date of Birth: __ __ __ __
Gender: [ ] Male [ ] Female
Disease: __________________________

[ ] Allogeneic
[ ] Autologous

Chronic number of this HSCT #: __________________________
DCI: __________________________

Date of HSCT for this follow-up: __ __ __ __

Did the recipient receive a subsequent HSCT since the date of contact from the last report?
[ ] yes [ ] no

Date of subsequent HSCT: __ __ __ __

Was the subsequent HSCT indication autologous rescue?
[ ] yes [ ] no

100 Day Report Only

Questions: 1 - 7

1 Is 'Date of HSCT' same as date given on Pre-TED?
[ ] yes [ ] no

2 Was HSCT Infusion given?
[ ] yes [ ] no
3. At least 1 dose of the prep regimen was given?
   - Yes
   - No

4. Patient died during prep regimen?
   - Yes
   - No

5. This HSCT is cancelled?
   - Yes
   - No

6. This HSCT is postponed?
   - Yes
   - No

7. New estimated date: __ __ __ __

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**Initial ANC Recovery**
Questions: 8 - 11

8. Was ≥0.5 x 10^9/L achieved for 3 consecutive labs?
   - Yes
   - No
   - Never below
   - Previously reported (answer is only valid on > d100 evaluation)
   - Unknown

9. First date of 3 consecutive labs: __ __ __ __

10. Date of last assessment: __ __ __ __

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**Initial Platelet Recovery**
Questions: 12 - 14

12. Initial platelet recovery
   - Yes
   - No
   - Never below
   - Previously reported (answer is only valid on > d100 evaluation)
   - Unknown

13. Date Platelet > 20 x 10^9/L: __ __ __ __

14. Date of last assessment: __ __ __ __

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**Graft versus Host Disease (Allo only)**
Questions: 15 - 18

15. Maximum Grade of Acute GVHD
   - 0
   - I
   - II
   - III
   - IV
   - Present, grade unknown
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Partial</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Malignancy, Lymphoproliferative or Myeloproliferative Disorder</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>16 Maximum extent of Chronic GVHD during this period:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>None</td>
<td>limited</td>
<td>extensive</td>
<td>Unknown</td>
</tr>
<tr>
<td>17 Date of diagnosis of chronic GVHD: __ __ __ __ - __ __ - __ __</td>
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<tr>
<td>18 Continued from last report (answer is only valid on &gt; d100 evaluation)</td>
<td>yes</td>
<td>no</td>
<td></td>
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</tr>
<tr>
<td>19 Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear that is different from the disease for which the HSCT was performed?</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 For all new malignancies except for &quot;other skin malignancy (basal cell, squamous),&quot; was testing performed to determine the cell of origin?</td>
<td>yes</td>
<td>no</td>
<td></td>
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</tr>
<tr>
<td>21 Specify the cell origin of the new malignancy:</td>
<td>recipient (host)</td>
<td>donor</td>
<td>origin unknown</td>
<td></td>
</tr>
<tr>
<td>22 Is a copy of the cell origin evaluation (VNTR, cytogenetics, FISH) attached?</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Specify which new disease(s) occurred:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>23 Acute myeloid leukemia (AML / ANLL)</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>24 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
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<tr>
<td>25 Other leukemia, including ALL</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>26 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
<td></td>
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<tr>
<td>27 Specify other leukemia:</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>28 Breast cancer</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>29 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
<td></td>
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</tr>
<tr>
<td>30 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>32 Clonal cytogenetic abnormality without leukemia or MDS</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>33 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>34 Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>35 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>36 Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37 Date of diagnosis __ __ __ __ - __ __ - __ __</td>
<td></td>
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</tr>
</tbody>
</table>
38 Hodgkin disease
   yes  no

39 Date of diagnosis __ __ __ __ - __ __ - __ __

40 Lung cancer
   yes  no

41 Date of diagnosis __ __ __ __ - __ __ - __ __

42 Lymphoma or lymphoproliferative disease
   yes  no

43 Date of diagnosis __ __ __ __ - __ __ - __ __

44 Is the tumor EBV positive?
   yes  no  Unknown

45 Melanoma
   yes  no

46 Date of diagnosis __ __ __ __ - __ __ - __ __

47 Other skin malignancy (basal cell, squamous)
   yes  no

48 Date of diagnosis __ __ __ __ - __ __ - __ __

49 Specify other skin malignancy: ____________________________

50 Myelodysplasia (MDS) / myeloproliferative (MPS) disorder
   yes  no

51 Date of diagnosis __ __ __ __ - __ __ - __ __

52 Oropharyngeal cancer (tongue, buccal mucosa)
   yes  no

53 Date of diagnosis __ __ __ __ - __ __ - __ __

54 Sarcoma
   yes  no

55 Date of diagnosis __ __ __ __ - __ __ - __ __

56 Thyroid cancer
   yes  no

57 Date of diagnosis __ __ __ __ - __ __ - __ __

58 Other new malignancy
   yes  no

59 Date of diagnosis __ __ __ __ - __ __ - __ __

60 Specify other new malignancy: ____________________________

61 Is a pathology / autopsy report or other documentation attached?
   yes  no

62 Survival status at latest follow-up:
   Alive  Dead

63 Latest follow-up: __ __ __ __ - __ __ - __ __

64 Date of death: __ __ __ __ - __ __ - __ __

Survival Questions: 62 - 74
Main cause of death (check only one main cause):

- Relapse/Progression/Persistent disease
- HSCT related causes
  - new malignancy
- Other
- Unknown

(Check as many as appropriate):

- GVHD
  - yes
  - no
- Cardiac toxicity
  - yes
  - no
- Infection
  - yes
  - no
- Pulmonary toxicity
  - yes
  - no
- Rejection/Poor graft function
  - yes
  - no
- VOD
  - yes
  - no
- Other
  - yes
  - no

Specify: ______________________________

Post-HSCT Therapy

Questions: 75 - 77

- FGF (velafermin)?
  - Yes
  - masked trial
  - No
  - Unknown

- Imatinib mesylate (Gleevec, Glivec)?
  - Yes
  - masked trial
  - No
  - Unknown

- KGF (palifermin, Kepivance)?
  - Yes
  - masked trial
  - No
  - Unknown

HSCT for Non-Malignancy Disease Only

Questions: 78 - 79

- DCI given in this period?
  - yes
  - no
### Malignant Disease Evaluation for this HSCT

**Question 79** Was a CR ever achieved in response to HSCT (including any therapy as of Day 0, excluding any change in therapy in response to disease assessment)?

- Yes, post-HSCT CR achieved
- No, never in CR from HSCT
- Not evaluated

**Question 80** Date: __ __ __ __ First CR date reported previously

(Answer is only valid on > d100 evaluation)

**Question 81** Date assessed: __ __ __ __ Date of best response was previously reported

(In this period, any type, not persistent disease)

### First Relapse or Progression After HSCT

**Question 82** First relapse or progression after HSCT

- Yes
- No

If yes, answer all 3 methods. If used, give the date used and the results.

**Question 83** Relapse/progression detected by molecular method:

- Yes
- No

(previously reported (answer is only valid on > d100 evaluation)

Not evaluated

**Question 84** Date first seen: __ __ __ __

**Question 85** Date of Assessment: __ __ __ __

**Question 86** Relapse/progression detected by cytogenetic/FISH method:

- Yes
- No

(previously reported (answer is only valid on > d100 evaluation)

Not evaluated

**Question 87** Date first seen: __ __ __ __

**Question 88** Date of Assessment: __ __ __ __

**Question 89** Relapse/progression detected by clinical/hematological method:

- Yes
- No

(previously reported (answer is only valid on > d100 evaluation)

Not evaluated

**Question 90** Date first seen: __ __ __ __

**Question 91** Date of Assessment: __ __ __ __

### Additional Treatment

**Question 92** Additional treatment

- Yes
- No
Specify:

93 DCI (allo only)
  yes  Go to DCI section questions 110-122
  no

94 Planned (given regardless of disease status/assessment post-HSCT)
  yes  no

95 Not planned (given for relapse, progression, or persistent disease)
  yes  no

Method of Latest Disease Assessment
Questions: 96 - 109

* In some circumstances, disease may be detected by molecular or cytogenetic testing, but may not be considered a relapse or progression. It should still be reported.

96 Molecular *
  yes  no / not evaluated

97 Disease detected?
  yes  no

98 If yes, was the status considered a disease relapse or progression?
  yes  no

99 Date latest assessed: __ __ __ __

100 Cytogenetic/FISH *
  yes  no / not evaluated

101 Disease detected?
  yes  no

102 If yes, was the status considered a disease relapse or progression?
  yes  no

103 Date latest assessed: __ __ __ __

104 Clinical/Hematologic
  yes  no / not evaluated

105 Disease detected?
  yes  no

106 Date latest assessed: __ __ __ __

107 Was a previous HSCT performed for a different disease than this HSCT?
  yes  no

108 Give status of original disease
  CR  Not in CR

109 Date determined __ __ __ __

Donor Cellular Infusion (DCI)
Questions: 110 - 122

Donor Cellular Infusion (DCI) (1)
Questions: 110 - 121

110 Date of DCI: __ __ __ __

111 Total #DCI in 10 weeks

Type of cell(s) (check all that apply):

112 Lymphocytes
  yes  no
<p>| | | | | | | |</p>
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<tbody>
<tr>
<td>113</td>
<td>Fibroblasts</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>114</td>
<td>Dendritic cells</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>115</td>
<td>Mesenchymal</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>116</td>
<td>Other</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>117</td>
<td>Specify:</td>
<td></td>
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<tr>
<td>118</td>
<td>Indication:</td>
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<td></td>
<td>Planned</td>
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<tr>
<td></td>
<td>Treat disease</td>
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<td></td>
<td>Treat PTLD, EBV-Lym</td>
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<td></td>
<td>Treat viral</td>
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<td></td>
<td>Treat GVHD</td>
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<td></td>
<td>Mixed Chimerism</td>
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<td>Loss/Decreased Chimerism</td>
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<td></td>
<td>Other</td>
<td></td>
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<tr>
<td>119</td>
<td>Specify:</td>
<td></td>
<td></td>
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<tr>
<td>120</td>
<td>Maximum Grade of Acute Graft Versus Host Disease (GVHD):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>0</td>
<td>I</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>Unknown</td>
</tr>
<tr>
<td>121</td>
<td>If another DCI was received in this reporting period, disease status before next DCI:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>CR</td>
<td>Not in CR</td>
<td>Not assessed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>122</td>
<td>Were there more than 3 instances of DCI infusions in this reporting period?</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>