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
- Hematology
- Oncology
- Pediatric
- Other

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

Chronological 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

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

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### 100 Day Report Only  
Questions: 1 - 7

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Is 'Date of HSCT' same as date given on Pre-TED?</td>
<td></td>
<td></td>
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<tr>
<td>2  Was HSCT Infusion given?</td>
<td></td>
<td></td>
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<tr>
<td>3  At least 1 dose of the prep regimen was given?</td>
<td></td>
<td></td>
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<tr>
<td>4  Patient died during prep regimen?</td>
<td></td>
<td></td>
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<tr>
<td>5  This HSCT is cancelled?</td>
<td></td>
<td></td>
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<tr>
<td>6  This HSCT is postponed?</td>
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<tr>
<td>7  New estimated date: __ __ __ __ - __ __ __ __</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Initial ANC Recovery  
Questions: 8 - 11

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>never below</th>
<th>previously reported</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>8  Was ≥0.5 x 10^9/L achieved for 3 consecutive labs?</td>
<td></td>
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<tr>
<td>9  First date of 3 consecutive labs: __ __ __ __ - __ __ __ __</td>
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<tr>
<td>10 Date of last assessment: __ __ __ __ - __ __ __ __</td>
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<tr>
<td>11 Did graft failure occur?</td>
<td></td>
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</tr>
</tbody>
</table>

### Initial Platelet Recovery  
Questions: 12 - 14

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>never below</th>
<th>previously reported</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Initial platelet recovery</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>13 Date Platelet &gt; 20 x 10^9/L: __ __ __ __ - __ __ __ __</td>
<td></td>
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</tr>
<tr>
<td>14 Date of last assessment: __ __ __ __ - __ __ __ __</td>
<td></td>
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</tr>
</tbody>
</table>
15 Maximum Grade of Acute GVHD

0
I
II
III
IV
Present, grade unknown

16 Maximum extent of Chronic GVHD during this period:

None
limited
extensive
Unknown

17 Date of diagnosis of chronic GVHD: __ __ __ __ - __ __ - __ __

18 Continued from last report (answer is only valid on > d100 evaluation)

yes
no

19 Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear that is different from the disease for which the HSCT was performed?

yes
no

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

Yes
No

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

21 Specify the cell origin of the new malignancy:

recipient (host)
donor
origin unknown

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

yes
no

Specify which new disease(s) occurred:

23 Acute myeloid leukemia (AML / ANLL)

yes
no

24 Date of diagnosis __ __ __ __ - __ __ - __ __

25 Other leukemia, including ALL

yes
no

26 Date of diagnosis __ __ __ __ - __ __ - __ __

27 Specify other leukemia: __________________________
28 Breast cancer
   yes  no

29 Date of diagnosis __ __ __ __ - __ __- __ __

30 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)
   yes  no

31 Date of diagnosis __ __ __ __ - __ __- __ __

32 Clonal cytogenetic abnormality without leukemia or MDS
   yes  no

33 Date of diagnosis __ __ __ __ - __ __- __ __

34 Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)
   yes  no

35 Date of diagnosis __ __ __ __ - __ __- __ __

36 Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)
   yes  no

37 Date of diagnosis __ __ __ __ - __ __- __ __

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 __ __ __ __ - __ __- __ __
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Date of Diagnosis</th>
<th>Other New Malignancy</th>
<th>Date of Diagnosis</th>
<th>Other New Malignancy</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oropharyngeal cancer (tongue, buccal mucosa)</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>Date of diagnosis</td>
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<tr>
<td>Sarcoma</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Date of diagnosis</td>
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<tr>
<td>Thyroid cancer</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Date of diagnosis</td>
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<tr>
<td>Other new malignancy</td>
<td>yes</td>
<td>no</td>
<td></td>
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<td></td>
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<tr>
<td>Date of diagnosis</td>
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<tr>
<td>Is a pathology / autopsy report or other documentation attached?</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Survival status at latest follow-up: Alive</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Latest follow-up</td>
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<tr>
<td>Date of death</td>
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<tr>
<td>Main cause of death (check only one main cause):</td>
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<tr>
<td>Relapse/Progression/Persistent disease</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<tr>
<td>HSCT related causes</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>new malignancy</td>
<td>yes</td>
<td>no</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Other</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Unknown</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>(Check as many as appropriate):</td>
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<tr>
<td>GVHD</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Cardiac toxicity</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Infection</td>
<td>yes</td>
<td>no</td>
<td></td>
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<tr>
<td>Pulmonary toxicity</td>
<td>yes</td>
<td>no</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
70 Rejection/Poor graft function
   yes  no

71 VOD
   yes  no

72 Other
   yes  no

73 Specify: ________________________________

74 Specify: ________________________________

Post-HSCT Therapy

Questions: 75 - 77

75 FGF (velafenrin)?
   Yes  masked trial  No  Unknown

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

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

HSCT for Non-Malignancy Disease Only

Questions: 78 - 78

78 DCI given in this period?
   yes  no

Malignant Disease Evaluation for this HSCT

Questions: 79 - 81

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)?
   Recipient already in CR at start of preparative regimen (N/Apl)
   Yes, post-HSCT CR achieved
   No, never in CR from HSCT
   Not evaluated

80 Date: __ __ __ __ - __ __ __ __ First CR date reported previously
   (answer is only valid on > d100 evaluation)

81 Date assessed: __ __ __ __ - __ __ __ __ Date of best response was previously reported

First Relapse or Progression After HSCT

Questions: 82 - 91

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

82 First relapse or progression after HSCT
   yes  no
If yes, answer all 3 methods. If used, give the date used and the results.

83 Relapse/progression detected by molecular method:
- Yes
- No
  - previously reported (answer is only valid on > d100 evaluation)
  - Not evaluated

84 Date first seen: __ __ __ __

85 Date of Assessment: __ __ __ __

86 Relapse/progression detected by cytogenetic/FISH method:
- Yes
- No
  - previously reported (answer is only valid on > d100 evaluation)
  - Not evaluated

87 Date first seen: __ __ __ __

88 Date of Assessment: __ __ __ __

89 Relapse/progression detected by clinical/hematological method:
- Yes
- No
  - previously reported (answer is only valid on > d100 evaluation)
  - Not evaluated

90 Date first seen: __ __ __ __

91 Date of Assessment: __ __ __ __

---

**Additional Treatment**

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
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.

Molecular

Yes  no / not evaluated

Disease detected?

yes  no

If yes, was the status considered a disease relapse or progression?

yes  no

Date latest assessed: __ __ __ __

Cytogenetic/FISH

Yes  no / not evaluated

Disease detected?

yes  no

If yes, was the status considered a disease relapse or progression?

yes  no

Date latest assessed: __ __ __ __

Clinical/Hematologic

Yes  no / not evaluated

Disease detected?

yes  no

If yes, was the status considered a disease relapse or progression?

yes  no

Date latest assessed: __ __ __ __

Was a previous HSCT performed for a different disease than this HSCT?

yes  no

Give status of original disease

CR  Not in CR

Date determined: __ __ __ __

Donor Cellular Infusion (DCI)

Questions: 100 - 122

Donor Cellular Infusion (DCI) (1)

Questions: 110 - 121

Date of DCI: __ __ __ __

Total #DCI in 10 weeks

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

Lymphocytes

yes  no

Fibroblasts

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