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

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: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

11 Did **graft failure** occur?

yes no

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: __ __ __ __ - __ __- __ __

Graft versus Host Disease (Allo only)

Questions: 15 - 18

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

New Malignancy, Lymphoproliferative or Myeloproliferative Disorder

Questions: 19 - 61

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 __ __ __ __ - __ __- __ __

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

Survival

Questions: 62 - 74

62 Survival status at latest follow-up:

Alive Dead

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

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

65 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):

66 GVHD

yes no

67 Cardiac toxicity

yes no

68 Infection

yes no

69 Pulmonary toxicity

yes no

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 (velafermin)?

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

Questions: 92 - 95

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

113 Fibroblasts

yes no

114 Dendritic cells

yes no

115 Mesenchymal

yes no

116 Other

yes no

117 Specify:

_____

118 Indication:

Planned

Treat disease

Treat PTLD, EBV-Lym

Treat viral

Treat GVHD

Mixed Chimerism

Loss/Decreased Chimerism

Other

119 Specify:

_____

120 Maximum Grade of Acute Graft Versus Host Disease (GVHD):

0 I II III IV Unknown

121 If another DCI was received in this reporting period, disease status before next DCI:

CR Not in CR Not assessed

122 Were there more than 3 instances of DCI infusions in this reporting period?

yes no