[Q.] = extra question in FN2 application

Post-Transplant Essential Data

Note: ">100 Days Report" answer *since last report*

❍ = symbol for answer that is only valid on >d100 evaluation.

CENTER IDENTIFICATION

930. CIBMTR Ctr #___ ___ ___ ___ ___ EBMT Code (CIC)931.
932. Hospital:
933. Unit (circle one)*: **A H O P** Other, specify:933a.
*** Abbreviations, see Pre-TED pg 2**
934. Contact person: (first name)
935. (last name)
938. Date of this Report: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
939. ❑Day 100 ❑6 months ❑Annual (Annual, specify year:921.___ ___)

REGISTRY USE ONLY

901. Date Received: DE:

RECIPIENT IDENTIFICATION

940. CIBMTR recipient ID#:___ ___ ___ ___ ___ ___ ___ ___ ___ ___
941. Date of Birth: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
942. Gender: ❑ Male ❑ Female
943. Disease:

HSCT

Donor Type:944.❑ Allogeneic 945.❑ Autologous
Chronological # of this:946.HSCT#: ___ ___947.DCI#: ___ ___
948. Date of HSCT for this follow-up: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
949. Did the recipient receive a subsequent HSCT since the date of contact from the last report? ❑ Yes ❑ No
950. Specify date: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
951. Was the subsequent HSCT indication autologous rescue? ❑Yes ❑No

Yes	No	100 Day Report Only
1.❑	❑	Is 'Date of HSCT' same as date given on Pre-TED?
2.❑	❑	Was HSCT Infusion given? If ***Yes***—skip to ***Q.8***, if ***No***:
3.❑	❑	At least 1 dose of the prep regimen was given?
4.❑	❑	Patient died during prep regimen? If ***Yes***—skip to ***Q.62***
5.❑	❑	This HSCT is cancelled? If ***Yes***—skip to ***Q.62***
6.❑	❑	This HSCT is postponed? If ***Yes—complete Qs.62-74, submit form***

7. New estimated date: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

INITIAL ANC RECOVERY

8. Was ≥0.5 x 10^9/L achieved for 3 consecutive labs?
❑Yes, first date of 3 labs: 9.___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑No, last assessment: 10.___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑Never below ❍Previously reported >d100 ❑Unknown
11. Did **graft failure** occur? ❑ Yes ❑ No

INITIAL PLATELET RECOVERY

12. ***(Optional for Non-U.S. Centers)***
❑Yes, date Platelet >20 x 10^9/L:
13.___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑No, last assessment: 14.___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
❑Never below ❍Previously reported >d100 ❑Unknown

GRAFT VERSUS HOST DISEASE (Allo only)

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 >d100 ❑Extensive >d100 ❑Unknown
Date of diagnosis of chronic GVHD:
17.___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD) 18.❍ Continued from last report

All Abbreviations on Pre-TED, pg 2

19. DID A NEW MALIGNANCY, LYMPHOPROLIFERATIVE OR MYELOPROLIFERATIVE DISORDER OCCUR?

Different from the disease for which HSCT performed (not recurrence or transformation).
❑ Yes ❑ No ❑ Unknown

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. If yes, specify the cell origin of the new malignancy:
❑ Recipient (host) ❑ Donor ❑ Origin unknown

22. If yes, is a copy of the cell origin evaluation (VNTR, cytogenetics, FISH) attached? ❑ Yes ❑ No
If yes, attach a copy of the report with all identifiers removed, except for birth date and ID numbers (reference Q22 on the report)

Specify New Diseases **Date of diagnosis: YYYY MM DD**

23. ❑ Acute myeloid leukemia (AML/ANLL)
24. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
25. ❑ Other leukemia (including ALL), specify:27.
26. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
28. ❑ Breast cancer
29. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
30. ❑ Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)
31. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
32. ❑ Clonal cytogenetic abnormality without leukemia or MDS
33. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
34. ❑ Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)
35. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
36. ❑ Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)
37. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
38. ❑ Hodgkin disease
39. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
40. ❑ Lung cancer
41. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
42. ❑ Lymphoma or lymphoproliferative disease
43. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
44. Is the tumor EBV positive? ❑ Yes ❑ No ❑ Unknown
45. ❑ Melanoma 46. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
47. ❑ Other skin malignancy (basal cell, squamous), specify:49.
48. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
50. ❑ Myelodysplasia (MDS)/myeloproliferative (MPS) disorder
51. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
52. ❑ Oropharyngeal cancer (tongue, buccal mucosa)
53. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
54. ❑ Sarcoma 55. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
56. ❑ Thyroid cancer
57. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
58. ❑ Other malignancy, specify:60.
59. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___

61. *Copy of pathology report/documentation attached?* ❑*Yes* ❑*No*
Attach copy of report w/all identifiers removed, except birth date & ID numbers.
>1 new malignancy in this reporting period – copy page and repeat Qs.20-61

SURVIVAL

62. **Survival status** at latest follow-up:
❑ Alive ❑ Dead
Latest follow-up:
63. [64.] ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD) ❑ Date of death

65. Main **cause of death** (check only one main cause):
❑ Relapse/Progression/Persistent disease
❑ HSCT related causes (check as many as appropriate):
66.❑ GVHD
67.❑ Cardiac toxicity
68.❑ Infection
69.❑ Pulmonary toxicity
70.❑ Rejection/Poor graft function
71.❑ VOD
72.❑ Other:73.
❑ New malignancy
❑ Other:74.
❑ Unknown

OMB No: 0915-0310
Expiration Date: 10-31-2010

Post-Transplant Essential Data

Note: ">100 Days Report" answer *since last report*
❍ = symbol for answer that is only valid on >d100 evaluation.

CIBMTR Center #: ☐☐☐☐☐ CIBMTR Recipient ID#: ☐☐☐☐☐☐☐☐☐ Report represents: ❑Day 100 ❑6 months ❑Annual

POST-HSCT THERAPY *(Optional for Non-U.S. Centers)*

		Yes	Masked Trial	No	Unk
75.	FGF (velafermin)?	❑	❑	❑	❑
76.	Imatinib mesylate (Gleevec, Glivec)?	❑	❑	❑	❑
77.	KGF (palifermin, Kepivance)?	❑	❑	❑	❑

HSCT FOR NON-MALIGNANT DISEASE ***ONLY***

78. DCI given in this period?
- ❑ Yes, ***also complete 'DCI' section on pg 2: starting at Q.110***
- ❑ No, ***send only pg 1***

MALIGNANT DISEASE EVALUATION FOR THIS HSCT
(*non-malignant disease skip disease evaluation*)

79. **WAS A CR EVER ACHIEVED IN REPONSE TO HSCT (including any therapy planned 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, date:
  80. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
  ❍ First CR date reported previously
- ❑ No, never in CR >d100 from HSCT, date assessed:
  81. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
  ❑ Date of best response was previously reported
- ❑ Not evaluated

82. **FIRST RELAPSE OR PROGRESSION AFTER HSCT**
(in this period, *any type,* not persistent disease)
- ❑ Yes, answer all 3 methods. If used, give the date used and the results.
- ❑ No—*(skip to 'Additional Treatment' below)*

83. Relapse/progression detected by **molecular method:**
- ❑ Yes, Date first seen: 84. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
- ❑ No, Date of Assessment: 85. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
- ❍ Previously reported >d100 ❑ Not evaluated

86. Relapse/progression detected by **cytogenetic/FISH method:**
- ❑ Yes, Date first seen: 87. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
- ❑ No, Date of Assessment: 88. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
- ❍ Previously reported >d100 ❑ Not evaluated

89. Relapse/progression detected by **clinical/hematological method:**
- ❑ Yes, Date first seen: 90. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
- ❑ No, Date of Assessment: 91. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)
- ❍ Previously reported >d100 ❑ Not evaluated

ADDITIONAL TREATMENT?

92. ❑ Yes ❑ No—*(skip to 'Method' Q.97 below)*

	Yes	No	
93.	❑	❑	**DCI (allo only)** *(also complete 'DCI' section)*
94.	❑	❑	**Planned** (given regardless of disease status/assessment post-HSCT)
95.	❑	❑	**Not planned** (given for relapse, progression, or persistent disease)

METHOD OF LATEST DISEASE ASSESSMENT
(record most recent of each)

* 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.

Method	Disease detected? No	Yes	Not evaluated
Molecular* [96.]	97. ❑	❑	❑

98. If yes, was the status considered a disease relapse or progression? ❑ Yes ❑ No

METHOD OF LATEST DISEASE ASSESSMENT *continued*

Method	Disease detected? No	Yes	Not evaluated
Cytogenetic/FISH* [100.]	101. ❑	❑	❑

Date latest assessed: 99. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

102. If yes, was the status considered a disease relapse or progression? ❑ Yes ❑ No

Method	Disease detected? No	Yes	Not evaluated
Clinical/Hematologic [104.]	105. ❑	❑	❑

Date latest assessed 103. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

Date latest assessed 106. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

[107.] **If a previous HSCT was performed for a different disease than this HSCT, give status of original disease and date determined**:

108. ❑ CR ❑ Not in CR Date 109. ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

DONOR CELLULAR INFUSION (DCI)

110. Date of **first** DCI: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

111. Total # DCI in 10 weeks_____
Type of cell(s) (check all that apply):

112. ❑ Lymphocytes 113. ❑ Fibroblasts 114. ❑ Dendritic cells
115. ❑ Mesenchymal 116. ❑ Other, specify 117._____

118. Indication:
- ❑ Planned
- ❑ Treat disease
- ❑ Treat PTLD, EBV-Lym
- ❑ Treat viral
- ❑ Treat GVHD
- ❑ Mixed Chimerism
- ❑ Loss/Decreased Chimerism
- ❑ Other, specify: 119._____

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. Date of **second** DCI: ___ ___ ___ ___ - ___ ___ - ___ ___ (YYYY - MM - DD)

123. Total # DCI in 10 weeks_____
Type of cell(s) (check all that apply):

124. ❑ Lymphocytes 125. ❑ Fibroblasts 126. ❑ Dendritic cells
127. ❑ Mesenchymal 128. ❑ Other, specify 129._____

130. Indication:
- ❑ Planned
- ❑ Treat disease
- ❑ Treat PTLD, EBV-Lym
- ❑ Treat viral
- ❑ Treat GVHD
- ❑ Mixed Chimerism
- ❑ Loss/Decreased Chimerism
- ❑ Other, specify: 131._____

132. Maximum Grade of Acute Graft Versus Host Disease (GVHD): ❑ 0 ❑ I ❑ II ❑ III ❑ IV ❑ Unknown

133. If another DCI was received in this reporting period, disease status before next DCI: ❑ CR ❑ Not in CR ❑ Not assessed

146. Were there more than 2 instances of DCI infusions in this reporting period? ❑ Yes ❑ No
If yes, copy this page and continue numbering third, fourth, etc.