ERROR CORRECTION FORM

Sequence Number: | | | | | | | | | | | | | |

CIBMTR Recipient ID: | | | | | | | | | | |

Visit:
☐ 100 day
☐ 6 month
☐ ___ year

Today's Date: Month ___ Day ___ Year 2 0 ___

Infusion Date: Month ___ Day ___ Year 2 0 ___

CIBMTR Center Number: | | | | | |

Initials: _____

Form 2534 R1.0: BMT CTN 1702 Monthly Update Form

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

Center Identification

CIBMTR Center Number: _____

Recipient Identification

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Visit ID

○ Initial Visit ○ Month 1 ○ Month 2 ○ Month 3 ○ Month 4 ○ Month 5 ○ Month 6 ○ > 6 months

Specify: _____

Clinical Status

Questions: 1 - 4

1 What scale was used to determine the recipient's functional status?

○ Karnofsky (recipient age ≥ 16 years)

○ Lansky (recipient age ≥ 1 year and < 16 years)

Performance score prior to preparative regimen:

2 Karnofsky Scale (recipient age ≥ 16 years)

○ 100 Normal; no complaints; no evidence of disease

○ 90 Able to carry on normal activity

○ 80 Normal activity with effort

○ 70 Cares for self; unable to carry on normal activity or to do active work

○ 60 Requires occasional assistance but is able to care for most needs

○ 50 Requires considerable assistance and frequent medical care

○ 40 Disabled; requires special care and assistance

○ 30 Severely disabled; hospitalization indicated, although death not imminent

○ 20 Very sick; hospitalization necessary

○ 10 Moribund; fatal process progressing rapidly

3 Lansky Scale (recipient age ≥ 1 year and < 16 years)

○ 100 Fully active

○ 90 Minor restriction in physically strenuous play

○ 80 Restricted in strenuous play, tires more easily, otherwise active

○ 70 Both greater restrictions of, and less time spent in, active play

○ 60 Ambulatory up to 50% of time, limited active play with assistance / supervision

○ 50 Considerable assistance required for any active play; fully able to engage in quiet play

○ 40 Able to initiate quiet activities

○ 30 Needs considerable assistance for quiet activity

○ 20 Limited to very passive activity initiated by others (e.g., TV)

○ 10 Completely disabled, not even passive play

4 Target time to start of conditioning

○ Less than 6 weeks

○ Over 6 weeks up to 12 weeks

○ Over 12 weeks up to 6 months

Recipient Socioeconomic Factors

Questions: 5 - 12

5 Zip or postal code for place of recipient's residence: _____

6 Is the recipient covered by health insurance?

○ yes ○ no

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Center: CRID:

Specify type of health insurance:

7 Specify the type of health insurance: (check all that apply)

- ☐ Private health insurance
- ☐ National Health Insurance (Government-sponsored, non-U.S.)
- ☐ Medicare (Government-sponsored, U.S., includes Medicare Advantage plans)
- ☐ Medigap (Must have Medicare coverage)
- ☐ Medicaid (Government-sponsored, U.S.)
- ☐ Children's Health Insurance Program (CHIP)
- ☐ Military related health care (TRICARE (CHAMPUS) / VA health care/ CHAMP-VA)
- ☐ Indian Health Service
- ☐ State-sponsored health plan
- ☐ Other government program
- ☐ Other health insurance coverage

8 Specify other government program: _____

9 Specify other health insurance: _____

10 Specify the recipient's marital status

- ○ single, never married
- ○ married or living with a partner
- ○ separated
- ○ divorced
- ○ widowed
- ○ Unknown

11 What is the highest educational grade the recipient completed?

- ○ No primary education / under school age : no schooling (U.S. equivalent: less than 1st grade education)
- ○ Less than primary or elementary education : some formal schooling, but less than a complete primary or elementary education (U.S. equivalent: more than 1st grade education, but less than 6th grade education)
- ○ Primary or elementary education : beginning at age 5–7 and continuing for about 4–6 years (U.S. equivalent: starts with 1st grade and ends with 6th grade)
- ○ Lower secondary education : beginning at about age 11–12 and continuing for about 2–3 years (U.S. equivalent: starts with 7th grade and typically ends with 9th grade)
- ○ Upper secondary education : beginning at about age 15–16 and continuing for about 3 years (U.S. equivalent: starts with 10th grade and ends with 12th grade)
- ○ Post-secondary, non-tertiary education : programs lasting 6 months - 2 years (U.S. equivalent: vocational programs of study)
- ○ Tertiary education , Type A: programs that provide education that is largely theoretical, lasting 3–4 years (U.S. equivalent: includes university programs that last 4 years and lead to the award of a bachelor's degree, and university programs that lead to a master's degree)Tertiary education, Type B: programs that focus on practical, technical or occupational skills with a minimum duration of 2 years of full-time enrollment (U.S. equivalent: programs typically offered at community colleges that lead to an associate's degree)
- ○ Advanced research qualification : programs that lead to the award of an advanced post-graduate degree, such as a Ph.D. (U.S. equivalent: programs devoted to advanced study and original research)
- ○ Unknown

12 What is the recipient's most recent work status? (within the last year)

- ○ Full time
- ○ Part time, by choice and not due to illness
- ○ Part time, due to illness
- ○ Unemployed, by choice and not due to illness
- ○ Unemployed, due to illness
- ○ Medical disability
- ○ Retired
- ○ Unknown

Preferred Donor Source

Questions: 13 - 29

13 Has the donor been selected?

○ Yes ○ No

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Center: CRID:

14 Was the priority ranking revised since the date of last report?

○ Yes ○ No

Donor Source Priority List (1) **Questions: 15 - 29**

15 Was the priority ranking revised more than once since the date of last report?

○ Yes ○ No

16 What number revision was this in the month? _____

17 Rationale for change

- ○ Inability to find suitable initially preferred donor
- ○ Suitable donor identified, but not available in preferred time frame
- ○ Patient clincial status warranted switch to different donor type or transplant timing
- ○ Insurance or financial consideration
- ○ Research protocol availability
- ○ Patient choice
- ○ Other

18 Specify other: _____

For questions 19-28, please indicate the donor source priority list.

19 How many alternative donor sources would you consider for this patient among the following: mismatched unrelated, halpoidentical, and cord blood: (please include any donor sources that you would potentially use for this patient's transplant)

_____

20 Which alternative donor source is the first preference?

- ○ Mismatched unrelated
- ○ Haploidentical related
- ○ Cord Blood
- ○ More than graft source infused at the same time

21 Specify multiple graft sources: _____

22 Which alternative donor source is the second preference?

- ○ Mismatched unrelated
- ○ Haploidentical related
- ○ Cord Blood
- ○ More than graft source infused at the same time

23 Specify multiple graft sources: _____

24 Which alternative donor source is the third preference?

- ○ Mismatched unrelated
- ○ Haploidentical related
- ○ Cord Blood
- ○ More than graft source infused at the same time

25 Specify multiple graft sources: _____

26 Which alternative donor source is the fourth preference?

- ○ Mismatched unrelated
- ○ Haploidentical related
- ○ Cord Blood
- ○ More than graft source infused at the same time

27 Specify multiple graft sources: _____

28 Which alternative donor source is the fifth preference?

- ○ Mismatched unrelated
- ○ Haploidentical related
- ○ Cord Blood
- ○ More than graft source infused at the same time

29 Specify multiple graft sources: _____

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Hematopoietic Cell Transplant Delay and/or Cancellation — Questions: 30 - 47

30 Has the patient started a conditioning / preparative regimen?

○ Yes ○ No

31 Has the patient gone to transplant?

○ Yes

○ No

32 Was the HCT delayed and/or cancelled?

○ Yes ○ No

Hematopoietic Cell Transplant Delay (1) — Questions: 33 - 38

33 Was the HCT delayed?

○ Yes ○ No

34 Date HCT delay decided: __ __ __ __ - __ __- __ __

35 Primary reason for HCT delay

- ○ Lack of disease response
- ○ Disease progression
- ○ Excellent disease response so transplant no longer recommended
- ○ Due to general health
- ○ Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- ○ Newly diagnosed or developed co-morbidity (including infection)
- ○ Worsening performance status, not related to a specific comorbidity
- ○ Change in donor suitability or eligibility criteria
- ○ Donor not available for requested product type
- ○ Identified donor not available for desired timeline
- ○ Lack of insurance or insurance denial
- ○ Lack of a caregiver
- ○ Transfer search or transplant to another center
- ○ Patient preference to pursue non-transplant therapy
- ○ Patient preference to stop treatment or enroll in hospice
- ○ Patient lost to follow-up
- ○ Other

36 Specify other: _____

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Center: CRID:

37 Contributing causes for HCT delay (check all that apply)

- ☐ Lack of disease response
- ☐ Disease progression
- ☐ Excellent disease response so transplant no longer recommended
- ☐ Due to general health
- ☐ Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- ☐ Newly diagnosed or developed co-morbidity (including infection)
- ☐ Worsening performance status, not related to a specific comorbidity
- ☐ Change in donor suitability or eligibility criteria
- ☐ Donor not available for requested product type
- ☐ Identified donor not available for desired timeline
- ☐ Lack of insurance or insurance denial
- ☐ Lack of a caregiver
- ☐ Transfer search or transplant to another center
- ☐ Patient preference to pursue non-transplant therapy
- ☐ Patient preference to stop treatment or enroll in hospice
- ☐ Patient lost to follow-up
- ☐ Other

38 Specify other: _____

39 Was the HCT cancelled?

○ Yes ○ No

40 Date of HCT Cancellation: __ __ __ __ - __ __- __ __

41 Primary reason for transplant cancellation

- ○ Lack of disease response
- ○ Disease progression
- ○ Excellent disease response so transplant no longer recommended
- ○ Due to general health
- ○ Patient death **- Also complete Form 2900**
- ○ Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- ○ Newly diagnosed or developed co-morbidity (including infection)
- ○ Worsening performance status, not related to a specific comorbidity
- ○ Change in donor suitability or eligibility criteria
- ○ Donor not available for requested product type
- ○ Identified donor not available for desired timeline
- ○ Lack of insurance or insurance denial
- ○ Lack of a caregiver
- ○ Transfer search or transplant to another center
- ○ Patient preference to pursue non-transplant therapy
- ○ Patient preference to stop treatment or enroll in hospice
- ○ Patient lost to follow-up
- ○ Other

42 Date of death: __ __ __ __ - __ __- __ __

43 Specify other: _____

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Center: CRID:

44 Contributing causes for HCT cancellation (check all that apply)

- ☐ Lack of disease response
- ☐ Disease progression
- ☐ Excellent disease response so transplant no longer recommended
- ☐ Due to general health
- ☐ Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- ☐ Newly diagnosed or developed co-morbidity (including infection)
- ☐ Worsening performance status, not related to a specific comorbidity
- ☐ Change in donor suitability or eligibility criteria
- ☐ Donor not available for requested product type
- ☐ Identified donor not available for desired timeline
- ☐ Lack of insurance or insurance denial
- ☐ Lack of a caregiver
- ☐ Transfer search or transplant to another center
- ☐ Patient preference to pursue non-transplant therapy
- ☐ Patient preference to stop treatment or enroll in hospice
- ☐ Patient lost to follow-up
- ☐ Other

45 Specify other: _____

46 On how many unrelated donors was a sample requested but not received? _____

47 On how many related donors was a sample requested but not received? _____

Substudy Enrollment

Questions: 48 - 54

48 Did the recipient proceed to transplant with a 8/8 HLA-matched unrelated donor or haploidentical family member donor?

○ Yes ○ No

49 At the time of transplant did the recipient have AML or ALL in first complete remission or early stage MDS?

○ Yes ○ No

50 Specify the recipient's conditioning regimen

- ○ Cyclophosphamide and total body irradiation ± fludarabine
- ○ Cyclophosphamide and busulfan ± total body irradiation
- ○ Fludarabine and melphalan ± total body irradiation
- ○ Fludarabine and busulfan
- ○ Fludarabine and myeloablative dose total body irradiation
- ○ None of the above

51 Specify the recipient's GVHD prophylaxis

- ○ Calcineurin-inhibitor and methotrexate or mycophenolate mofetil ± antithymocyte globulin
- ○ Calcineurin-inhibitor and sirolimus
- ○ Post-transplant cyclophosphamide ± others
- ○ None of the above

52 Is the recipient at least 8 years old?

○ Yes ○ No

53 Is the recipient free of any psychosocial conditions that would prevent study compliance?

○ Yes ○ No

54 Is the recipient able to read English or Spanish?

- ○ Yes
- ○ No

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __

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