

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 \geq 16 years)
 Lansky (recipient age \geq 1 year and < 16 years)

Performance score prior to preparative regimen:

2 Karnofsky Scale (recipient age \geq 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 \geq 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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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 : 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 , 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

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? _____

Center:

CRID:

17 Rationale for change

- Inability to find suitable initially preferred donor
- Suitable donor identified, but not available in preferred time frame
- Patient clinical 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, haploidentical, 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: _____

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: ____ - ____ - ____

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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: _____

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: ____ - ____ - ____

Center:

CRID:

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: _____

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

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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: ____ - ____ - ____