Form 2400 R6.0: Pre-Transplant Essential Data

Key Fields

OMB No: 0915-0310
Expiration Date: 10/31/2022

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

Center Identification
CIBMTR Center Number: ________________________
EBMT Code (CIC): ___________________________

Recipient Identification
CIBMTR Research ID: (CRID) ___________________________
Event date: __ __ __ __ - __ __ __ __ 

Recipient Information

Questions: 1 - 25

1 Date of birth: __ __ __ __ - __ __ __ __

2 Sex

- male
- female

3 Ethnicity

- Hispanic or Latino
- Not Hispanic or Latino
- Not applicable (not a resident of the USA)
- Unknown

4 Race (check all that apply)

- White
- Black or African American
- Asian
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Not reported
- Unknown

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5 Race detail (check all that apply)
- Eastern European
- Mediterranean
- Middle Eastern
- North Coast of Africa
- North American
- Northern European
- Western European
- White Caribbean
- White South or Central American
- Other White
- African
- African American
- Black Caribbean
- Black South or Central American
- Other Black
- Alaskan Native or Aleut
- North American Indian
- American Indian, South or Central America
- Caribbean Indian
- South Asian
- Filipino (Pilipino)
- Japanese
- Korean
- Chinese
- Vietnamese
- Other Southeast Asian
- Guamanian
- Hawaiian
- Samoan
- Other Pacific Islander
- Unknown

6 Country of primary residence

7 State of residence of recipient (for residents of Brazil)

8 Province or territory of residence of recipient (for residents of Canada)

9 State of residence of recipient (for residents of USA)

10 NMDP Recipient ID (RID):

11 Zip or postal code for place of recipient’s residence: (USA recipients only)

(last 4 digits optional)

12 Specify blood type (recipient) (For allogeneic HCTs only)
- A
- B
- AB
- O

13 Specify Rh factor (recipient) (For allogeneic HCTs only)
- Positive
- Negative

14 Has the recipient signed an IRB / ethics committee (or similar body) approved consent form for submitting research data to the NMDP / CIBMTR?
- Yes (recipient consented)
- No (recipient declined)
- Not approached

15 Did the recipient give permission to be directly contacted by CIBMTR for future research?
- Yes (recipient provided permission)
- No (recipient declined)
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Center: CRID:

**Clinical Trials (1)**

Questions: 22 - 25

- **Study Sponsor**
- **Specify other sponsor:**
- **Study ID Number**
- **Subject ID:**

**Hematopoietic Cellular Transplant (HCT) and Cellular Therapy**

Questions: 26 - 45

- **Is a subsequent HCT planned as part of the overall treatment protocol (not as a reaction to post-HCT disease assessment)? (For autologous HCTs only)**
  - Yes
  - No
- **Specify subsequent HCT planned**
  - Autologous
  - Allogeneic
- **Has the recipient ever had a prior HCT?**
  - Yes
  - No
- **Specify the number of prior HCTs:**
- **Were all prior HCTs reported to the CIBMTR?**
  - Yes
  - No
  - Unknown

**Prior HCTs (1)**

Questions: 31 - 34

- **Date of the prior HCT:**
- **Was the prior HCT performed at a different institution?**
  - Yes
  - No
- **Specify the institution that performed the last HCT:**
  - Name:
  - City:
  - State:
  - Country:
- **What was the HPC source for the prior HCT? (check all that apply)**
  - Autologous
  - Allogeneic, unrelated
  - Allogeneic, related
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35 Reason for current HCT
- Graft failure / insufficient hematopoietic recovery
- Persistent primary disease
- Recurrent primary disease
- Planned subsequent HCT, per protocol
- New malignancy (including PTLD and EBV lymphoma)
- Insufficient chimerism
- Other

36 Date of graft failure / rejection: __ __ __ __ __
37 Date of relapse: __ __ __ __ __
38 Date of secondary malignancy: __ __ __ __ __
39 Specify other reason:

40 Has the recipient ever had a prior cellular therapy? (do not report DLIs)
- Yes
- No
- Unknown

41 Were all prior cellular therapies reported to the CIBMTR?
- Yes
- No
- Unknown

42 Date of the prior cellular therapy: __ __ __ __ __
43 Was the cellular therapy performed at a different institution?
- Yes
- No

44 Name: __________________________________________
City: __________________________________________
State: ________________________
Country: ________________________

45 Specify the source(s) for the prior cellular therapy (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Donor Information

46 Multiple donors?
- Yes
- No

47 Specify number of donors: __ __ __ __ __ __ __ __

48 Specify donor
- Autologous
- Allogeneic, related
- Allogeneic, unrelated

49 Specify product type (check all that apply)
- Bone marrow
- PBSC
- Single cord blood unit
- Other product

50 Specify other product: ____________________________

51 Is the product genetically modified?
- Yes
- No
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Center: CRID:

52 Specify the related donor type

- Syngeneic (monozygotic twin)
- HLA-identical sibling (may include non-monozygotic twin)
- HLA-matched other relative (does NOT include a haplo-identical donor)
- HLA-mismatched relative

53 Specify the biological relationship of the donor to the recipient

- Mother
- Father
- Child
- Sibling
- Fraternal twin
- Maternal aunt
- Maternal uncle
- Maternal cousin
- Paternal aunt
- Paternal uncle
- Paternal cousin
- Grandparent
- Grandchild
- Other biological relative

54 Specify other biological relative:

55 Degree of mismatch (related donors only)

- HLA-mismatched 1 allele
- HLA-mismatched ≥ 2 alleles (does include haplo-identical donor)

56 Specify unrelated donor type

- HLA matched unrelated
- HLA mismatched unrelated

57 Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?

- Yes
- No

58 Was this donor used for any prior HCTs? (for this recipient)

- yes
- no

59 NMDP cord blood unit ID:

60 NMDP donor ID:

61 Non-NMDP unrelated donor ID: (not applicable for related donors)

62 Non-NMDP cord blood unit ID: (include related and autologous CBUs)

63 Global Registration Identifier for Donors (GRID)

64 Is the CBU ID also the ISBT DIN number?

- Yes
- No
- Unknown

65 Specify the ISBT DIN number:

66 Registry or UCB Bank ID

67 Specify other Registry or UCB Bank:

68 Date of birth (donor / infant)

- Known
- Unknown

69 Date of birth: (donor / infant) __ __ __ __ __ __

70 Age (donor / infant)

- Known
- Unknown

71 Age: (donor / infant) __ __ __ __ __ __ __ __ __ __ __ __
- Months (use only if less than 1 year old)
- years

72 Sex (donor / infant)

- male
- female

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### Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

<table>
<thead>
<tr>
<th>Questions: 84 - 87</th>
</tr>
</thead>
<tbody>
<tr>
<td>84 What scale was used to determine the recipient's functional status?</td>
</tr>
<tr>
<td>Karnofsky (recipient age ≥ 16 years)</td>
</tr>
<tr>
<td>Lansky (recipient age ≥ 1 year and &lt; 16 years)</td>
</tr>
</tbody>
</table>

**Performance score prior to the preparative regimen:**

<table>
<thead>
<tr>
<th>Questions: 85 - 86</th>
</tr>
</thead>
<tbody>
<tr>
<td>85 Karnofsky Scale (recipient age ≥ 16 years)</td>
</tr>
<tr>
<td>86 Lansky Scale (recipient age ≥ 1 year and &lt; 16 years)</td>
</tr>
</tbody>
</table>

**Recipient CMV-antibodies (IgG or Total)**

<table>
<thead>
<tr>
<th>Questions: 87</th>
</tr>
</thead>
<tbody>
<tr>
<td>87 Reactive</td>
</tr>
<tr>
<td>Non-reactive</td>
</tr>
<tr>
<td>Indeterminate</td>
</tr>
<tr>
<td>Not done</td>
</tr>
</tbody>
</table>

### Comorbid Conditions

<table>
<thead>
<tr>
<th>Questions: 88 - 113</th>
</tr>
</thead>
<tbody>
<tr>
<td>88 Is there a history of mechanical ventilation?</td>
</tr>
<tr>
<td>yes</td>
</tr>
<tr>
<td>89 Is there a history of invasive fungal infection?</td>
</tr>
<tr>
<td>yes</td>
</tr>
<tr>
<td>90 Glomerular filtration rate (GFR) before start of preparative regimen (pediatric only)</td>
</tr>
<tr>
<td>Known</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

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Center: CRID:

91 Glomerular filtration rate (GFR): mL/min/1.73²

92 Does the recipient have known complex congenital heart disease? (corrected or uncorrected) (excluding simple ASD, VSD, or PDA repair) (pediatric only)
- Yes
- No

93 Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)?


94 Specify co-existing diseases or organ impairment (check all that apply)
- Arthritis
  - Any history of atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring treatment
- Cardiac
  - Any history of coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive heart failure, myocardial infarction, OR ejection fraction ≤ 50% on the most recent test
- Cerebrovascular disease
  - Any history of transient ischemic attack, subarachnoid hemorrhage or cerebral thrombosis, embolism, or hemorrhage
- Diabetes
  - Requiring treatment with insulin or oral hypoglycemic drugs in the last 4 weeks but not diet alone
- Heart valve disease
  - At least a moderate to severe degree of valve stenosis or insufficiency as determined by Echo; prosthetic mitral or aortic valve; or symptomatic mitral valve prolapse
- Hepatic, mild
  - Bilirubin > upper limit of normal to 1.5 x upper limit of normal, or AST / ALT > upper limit of normal to 2.5 x upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection
- Hepatic, moderate / severe
  - Liver cirrhosis, bilirubin > 1.5 x upper limit of normal, or AST / ALT > 2.5 x upper limit of normal
- Infection
  - Includes a documented infection, fever of unknown origin, or pulmonary nodules suspicious for fungal pneumonia or a positive PPD test requiring prophylaxis against tuberculosis. Patients must have started antimicrobial treatment before Day 0 with continuation of antimicrobial treatment after Day 0.

95 Was the recipient on dialysis immediately prior to start of preparative regimen?
- Yes
- No
- Unknown

96 Specify prior malignancy (check all that apply)
- Breast cancer
- Central nervous system (CNS) malignancy (e.g., glioblastoma, astrocytoma)
- Gastrointestinal malignancy (e.g., colon, rectum, stomach, pancreas, intestine, esophageal)
- Genitourinary malignancy (e.g., kidney, bladder, ovary, testicle, genitalia, uterus, cervix, prostate)
- Leukemia (includes acute or chronic leukemia)
- Lung cancer
- Lymphoma (includes Hodgkin & non-Hodgkin lymphoma)
- MDS / MPN
- Melanoma
- Multiple myeloma / plasma cell disorder (PCD)
- Oropharyngeal cancer (e.g., tongue, buccal mucosa)
- Sarcoma
- Thyroid cancer
- Other skin malignancy (basal cell, squamous)
- Other hematologic malignancy
- Other solid tumor

97 Specify other skin malignancy: (prior)

98 Specify other hematologic malignancy: (prior)

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Center:  CRID:  

**Use results within 4 weeks prior to the start of the preparative regimen, report results from the test performed closest to the start date. Biomarkers according to the augmented HCT comorbidity index Source: Biol Blood Marrow Transplant. 2015 Aug; 21(8): 1418-1424.**

100 Serum ferritin (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)
   - Known
   - Unknown

101 Date sample collected: ____________

102 Upper limit of normal for your institution:
   - Known
   - Unknown

103 Serum albumin (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)
   - Known
   - Unknown

104 Date sample collected: ____________

105 Upper limit of normal for your institution:
   - g/dL
   - g/L

106 Platelets (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)
   - Known
   - Unknown

107 Date sample collected: ____________

108 Upper limit of normal for your institution:
   - x 10^9/L (x 10^3/mm^3)
   - x 10^10/L

109 Were platelets transfused ≤ 7 days before date of test?
   - Yes
   - No
   - Unknown

110 Did the recipient have a prior solid organ transplant?
   - Yes
   - No

111 Specify organ
   - Bowel
   - Heart
   - Kidney(s)
   - Liver
   - Lung(s)
   - Pancreas
   - Other organ

112 Specify other organ: ________________________

113 Year of prior solid organ transplant: ________________________

**Pre-HCT Preparative Regimen (Conditioning) Questions: 114 - 128**

114 Height at initiation of pre-HCT preparative regimen: ____________
   - inches
   - centimeters

115 Actual weight at initiation of pre-HCT preparative regimen: ____________
   - pounds
   - kilograms

116 Was a pre-HCT preparative regimen prescribed?
   - Yes
   - No

117 Classify the recipient’s prescribed preparative regimen (Allogeneic HCTs only)
   - Myeloablative
   - Non-myeloablative (NST)
   - Reduced intensity (RIC)

118 Was irradiation planned as part of the pre-HCT preparative regimen?
   - Yes
   - No

119 What was the prescribed radiation field?
   - Total body
   - Total body by intensity-modulated radiation therapy (IMRT)
   - Total lymphoid or nodal regions
   - Thoracoabdominal region

120 Total prescribed dose: (dose per fraction x total number of fractions) ____________
   - Gy
   - cGy

121 Date started: ____________

122 Was the radiation fractionated?
   - Yes
   - No

123 Total number of fractions: ________________________
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### Preparative Regimen (1)

Questions: 124 - 128

<table>
<thead>
<tr>
<th>Drug</th>
<th>Questions: 124 - 128</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specify drug:</td>
<td>mg/m²</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date started:</th>
<th>Oral</th>
<th>IM</th>
<th>Both</th>
</tr>
</thead>
</table>

### Additional Drugs Given In the Peri-Transplant Period

Questions: 129 - 137

<table>
<thead>
<tr>
<th>ALG, ALS, ATG, ATS</th>
<th>Questions: 129 - 137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total prescribed dose:</th>
<th>mg/kg</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Specify source</th>
<th>ATGAM (horse)</th>
<th>ATG-Fresenius (rabbit)</th>
<th>Thymoglobulin (rabbit)</th>
<th>Other</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Specify other source:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Alemtuzumab (Campath)</th>
<th>Questions: 129 - 137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total prescribed dose:</th>
<th>mg/m²</th>
<th>mg/kg</th>
<th>mg</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Defibrotide</th>
<th>Questions: 129 - 137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>KGF</th>
<th>Questions: 129 - 137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ursodiol</th>
<th>Questions: 129 - 137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

### GVHD Prophylaxis

Questions: 138 - 140

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 141.

<table>
<thead>
<tr>
<th>Was GVHD prophylaxis planned?</th>
<th>Questions: 138 - 140</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
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139 Specify drugs / intervention (check all that apply)
   - Abatacept
   - Anti CD 25 (Zanapax, Dacizumab, AntiTAC)
   - Blinded randomized trial
   - Bortezomib
   - CD34 enriched (CD34+ selection)
   - Corticosteroids (systemic)
   - Cyclophosphamide (Cytoxan)
   - Cyclosporine (CSA, Neoral, Sandimmune)
   - Extra-corporeal photopheresis (ECP)
   - Ex-vivo T-cell depletion
   - Filgotinib
   - Maraviroc
   - Methotrexate (MTX) (Amethopterin)
   - Mycophenolate mofetil (MMF) (Cellcept)
   - Ruxolitinib
   - Sirolimus (Rapamycin, Rapamune)
   - Tacrolimus (FK 506)
   - Tocilizumab
   - Other agent

140 Specify other agent: ___________________________ (do not report ATG, campath)

Post-HCT Disease Therapy Planned as of Day 0

141 Is additional post-HCT therapy planned?
   - yes
   - no
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Questions 142 – 143 are optional for non-U.S. centers

142 Specify post-HCT therapy planned (check all that apply)

- Azacytidine (Vidaza)
- Blinatumomab
- Bortezomib (Velcade)
- Bosutinib
- Brentuximab
- Carfilzomib
- Cellular therapy (e.g. DCI, DLI)
- Crenolanib
- Daratumumab
- Dasatinib
- Decitabine
- Elotuzumab
- Enasidenib
- Gilotinib
- Ibrutinib
- Imanitib mesylate (Gleevec, Glenvec)
- Intrathecal therapy (chemotherapy)
- Ivosidenib
- Ixazomib
- Lenalidomide (Revlimid)
- Lestaurtinib
- Local radiotherapy
- Midostaurin
- Nilotinib
- Obinutuzumab
- Pacritinib
- Ponatinib
- Quizartinib
- Rituximab (Rituxan, MabThera)
- Sorafenib
- Sunitinib
- Thalidomide (Thalomid)
- Other therapy
- Unknown

143 Specify other therapy: __________________________

First Name: __________________________
Last Name: __________________________
E-mail address: __________________________
Date: __ __ __ __ __ __ __ __ __ __