

Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: _____

CRID: _____

Key Fields

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: ____-____-____

Recipient Data

Questions: 1 - 17

This form reflects the baseline data of the recipient for ONE course of cellular therapy and must be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic cell transplants, complete the form 2400 - Pre-Transplant Essential Data.

1 Ethnicity

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

2 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

3 Country of primary residence _____

4 State of residence of recipient (for residents of Brazil) _____

5 Province or territory of residence of recipient (for residents of Canada) _____

6 State of residence of recipient (for residents of USA) _____

7 Zip or postal code for place of recipient's residence: (USA and Canada recipients only) _____

8 Was this infusion received within the context of a clinical trial?

- Yes No

Clinical Trials (1)

Questions: 9 - 15

9 Study sponsor

- BMT CTN
- RCI BMT
- USIDNET
- COG
- Corporate / Industry
- ANZCTR
- EudraCT
- UMIN
- Investigator initiated
- Other

10 Specify corporate / industry sponsor name: _____

11 Specify ACTRN number: _____

12 Specify EudraCT number: _____

13 Specify UMIN number: _____

14 Specify other sponsor: _____

15 Specify the ClinicalTrials.gov identification number: NCT _____

16 Is the recipient receiving this infusion outside the context of a clinical trial?

- Yes No

17 Specify the reason for not being on a clinical trial (check all that apply)

- Institutional guidelines / standard treatment
- Hospital exemption
- Compassionate use

Cellular Therapy and HCT History

Questions: 18 - 32

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18 Is this the first time the recipient is being treated using a cellular therapy?

- Yes
 No (*recipient has previously been treated using cellular therapy*)
 Unknown

19 Were all prior cellular therapies (non-HCT) reported to the CIBMTR?

- Yes No Unknown

20 Specify the number of prior cellular therapies: _____

Prior Cellular Therapies (1)

Questions: 21 - 26

21 Date of the prior cellular therapy: ____ - ____ - ____ Date estimated

22 Was the cellular therapy performed at a different institution?

- Yes No

Specify the institution that performed the prior cellular therapy:

23 Name: _____

City: _____

State: _____

Country: _____

24 Specify the primary indication for the prior cellular therapy

- Autoimmune disease
 B cell lymphoproliferative disorder (*PTLD, EBV lymphoma*)
 Cardiovascular disease
 GVHD prophylaxis (*with HCT*)
 GVHD treatment (*post-HCT*)
 Immune reconstitution (*post-HCT*)
 Infection prophylaxis
 Infection treatment
 Malignant hematologic disorder
 Musculoskeletal disorder
 Neurologic disease
 Non-malignant disorder
 Ocular disease
 Prevent disease relapse (*post-HCT*)
 Promote stem cell engraftment (*e.g. co-infusion with HCT*)
 Pulmonary disease
 Relapsed, persistent or progressive disease (*post-HCT*)
 Solid tumor
 Suboptimal donor chimerism (*post-HCT*)
 Unknown
 Other indication

25 Specify other indication: _____

26 What was the cell source for the prior cellular therapy? (*check all that apply*)

- Autologous
 Allogeneic, unrelated
 Allogeneic, related

HCT History

27 Has the recipient ever had a prior HCT?

- Yes No Unknown

28 Were all prior HCTs reported to the CIBMTR?

- Yes No Unknown

Prior HCTs (1)

Questions: 29 - 32

29 Date of the prior HCT: ____ - ____ - ____

30 Was the HCT performed at a different institution?

- Yes No

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Specify the institution that performed the prior HCT:

31 Name: _____

City: _____

State: _____

Country: _____

32 Specify the HSC source(s) for the prior HCT (check all that apply)

- Autologous
 Allogeneic, unrelated
 Allogeneic, related

Product Identification

Questions: 33 - 57

33 Are any of the products, associated with this course of cell therapy, genetically modified?

- Yes No

Donor Information (1)

Questions: 34 - 53

34 Specify donor

- Autologous Allogeneic, related Allogeneic, unrelated

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

- Yes No

36 Was the product a cord blood unit?

- Yes No

37 Specify the related donor type (allogeneic, related only)

- Syngeneic (monozygotic twin)
 HLA-identical sibling (may include non-monozygotic twin)
 HLA-matched other relative
 HLA-mismatched relative

38 Was this donor used for any prior cellular therapies or HCT? (for this recipient)

- Yes No Unknown

39 NMDP cord blood unit ID: _____

40 Registry donor ID: (not applicable for related donor) _____

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

42 Global Registration Identifier for Donors (GRID) _____

43 Registry or UCB Bank ID _____

44 Specify other Registry or UCB Bank: _____

45 Donor date of birth

- Known Unknown

46 Donor date of birth: ____ - ____ - ____

47 Donor age

- Known Unknown

48 Donor age: _____ Months (use only if less than 1 year old)

years

49 Donor sex

- male female

50 Specify the total number of products: _____ (per protocol, as part of this course of cellular therapy)

51 Does your center consider this infusion to be a donor lymphocyte infusion (DLI)?

- Yes No

52 Name of cellular therapy product

- Axicabtagene ciloleucel (Yescarta®)
 Brexucabtagene autoleucel (Tecartus™)
 Ciltacabtagene autoleucel (JNJ-4528)
 Idecabtagene vicleucel
 Letetresgene autoleucel
 Lisocabtagene maraleucel (Breyanzi™)
 Orvacabtagene autoleucel
 Tisagenlecleucel (Kymriah®)
 Other product
 No product name

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Center:

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53 Specify other cellular therapy product: _____

54 In what setting is this cell therapy product infusion being planned?

- Inpatient Outpatient

Planned HCT

55 Is a subsequent HCT part of the overall treatment protocol?

- Yes No

56 Specify the HCT type

- Autologous Allogeneic

57 Specify the circumstances in which the subsequent HCT will be performed

- Regardless of response to cellular therapy
 Only if the recipient responds to cellular therapy
 Only if the recipient fails to respond or has an incomplete response

Indication for Cellular Therapy

Questions: 58 - 77

58 What was the primary indication for performing treatment with cellular therapy?

- Cardiovascular disease
 GVHD prophylaxis (*with HCT*)
 GVHD treatment (*post-HCT*)
 Immune reconstitution (*post-HCT*)
 Infection prophylaxis
 Infection treatment
 Malignant hematologic disorder - **Also complete CIBMTR Form 2402**
 Musculoskeletal disorder
 Neurologic disease
 Non-malignant disorder - **Also complete CIBMTR Form 2402**
 Ocular disease
 Prevent disease relapse (*post-HCT*)
 Pulmonary disease
 Solid tumor - **Also complete CIBMTR Form 2402**
 Suboptimal donor chimerism (*post-HCT*)
 Other indication

59 Date of diagnosis: ____ - ____ - ____

Cardiovascular

60 Specify cardiovascular disease

- AMI, acute myocardial infarction (701)
 Chronic coronary artery disease (ischemic, cardiomyopathy) (702)
 Heart failure (non-ischemic etiology) (703)
 Other cardiovascular disease (709)
 Limb ischemia (710)
 Thromboangitis obliterans (711)
 Other peripheral vascular disease (719)

61 Specify other cardiovascular disease: _____

62 Specify other peripheral vascular disease: _____

Musculoskeletal

63 Specify musculoskeletal disorder

- Avascular necrosis of femoral head (721)
 Osteoarthritis (722)
 Osteogenesis imperfecta (723)
 Traumatic joint injury (724)
 Other musculoskeletal disorder (729)

64 Specify other musculoskeletal disorder: _____

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Neurologic

65 Specify neurologic disease:

- Acute cerebral vascular ischemia (731)
- Amyotrophic lateral sclerosis (ALS) (732)
- Autism spectrum disorder (ASD) (736)
- Cerebral palsy (753)
- Congenital hydrocephalus (754)
- Duchenne muscular dystrophy (735)
- Hemorrhagic stroke (737)
- Hypoxic ischemic encephalopathy (HIE) (738)
- Myasthenia gravis (601)
- Parkinson disease (733)
- Spinal cord injury (734)
- Transient ischemic stroke (739)
- Traumatic brain injury (748)
- Other neurologic disease (749)

66 Specify other neurologic disease: _____

Ocular

67 Specify ocular disease: _____

Pulmonary

68 Specify pulmonary disease:

- Asthma (761)
- Bronchiectasis (762)
- Bronchopulmonary dysplasia (763)
- Pulmonary fibrosis (764)
- Other pulmonary disease (769)

69 Specify other pulmonary disease: _____

Infection

Specify the organism for which the cellular therapy is being given to treat:

70 _____

71 _____

72 _____

73 _____

74 _____

75 _____

76 Specify other organism: _____

Other

77 Specify other indication: _____

Lymphodepleting Therapy Prior to Cellular Therapy

Questions: 78 - 84

78 Was lymphodepleting therapy given prior to the infusion? (does not include lines of therapy given for disease treatment, bridging therapy or maintenance)

- Yes No

79 Weight at start of lymphodepleting therapy: _____ pounds kilograms

80 Height at start of lymphodepleting therapy: _____ inches centimeters

Systemic Therapy Drugs (1)

Questions: 81 - 84

81 Drug: _____

82 Specify other drug: _____

83 Total prescribed dose: _____ mg/m²

84 Date started: ____ - ____ - ____

Toxicity Prophylaxis

Questions: 85 - 88

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85 Therapy given for the prevention of CRS (*prophylactic therapy*) (check all that apply)

- Tocilizumab
- Other
- None

86 Specify other therapy given: _____

87 Therapy given for the prevention of neurotoxicity (ICANS)? (*prophylactic therapy*) (check all that apply)

- Anti-epileptics
- Other
- None

88 Specify other therapy given: _____

Hematologic Findings Prior to Lymphodepleting Therapy

Questions: 89 - 99

89 Date complete blood count (CBC) sample drawn: _____ - _____ - _____

90 Complete blood count results available (check all that apply)

- WBC
- Neutrophils
- Lymphocytes
- Hemoglobin
- Hematocrit
- Platelets

91 WBC: _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

92 Neutrophils: _____ %

93 Lymphocytes: _____ %

94 Hemoglobin: _____ g/dL g/L mmol/L

95 Hematocrit: _____ %

96 Were RBCs transfused ≤ 30 days before the date the sample was drawn?

- Yes No

97 Platelets: _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

98 Were platelets transfused ≤ 7 days before the date the sample was drawn?

- Yes No

99 Did the recipient receive any growth factors ≤ 7 days before the start of systemic therapy?

- Yes No

Functional Status

Questions: 100 - 102

Specify the functional status of the recipient immediately prior to the cellular therapy:

100 What scale was used to determine the recipient's functional status prior to the cellular therapy

- Karnofsky (*recipient age ≥ 16 years*)
- Lansky (*recipient age ≥ 1 and < 16 years*)

101 Karnofsky Scale (recipient age ≥ 16 years) _____

102 Lansky Scale (recipient age ≥ 1 and < 16 years) _____

Comorbid Conditions

Questions: 103 - 113

Questions 103 - 106 to be completed for ALL recipients.

Questions 107 - 113 to be completed for malignant hematologic disorders and solid tumor indications ONLY.

103 Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of systemic therapy?

- Yes No

104 Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?

- Yes No

105 Was mechanical ventilation used for COVID-19 (SARS-CoV-2) infection?

- Yes No

106 Is the recipient HIV positive?

- Yes - **Also complete CIBMTR Form 2048**
- No

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

(within 3 months prior to the infusion, unless noted as ANY history in the list of coexisting diseases) Source: Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. *Blood*, 121(15), 2854-2863.

Yes No

108 Specify co-existing diseases or organ impairment (check all that apply)

- Arrhythmia - Any history of any type of arrhythmia that has necessitated the delivery of a specific antiarrhythmic agent. Examples include, but are not limited to, atrial fibrillation or flutter, sick sinus syndrome, and 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, and / or ejection fraction $\leq 50\%$ (shortening fraction $< 26\%$ for pediatric recipients) on the most recent test.
- Cerebrovascular disease - Any history of transient ischemic attack, subarachnoid hemorrhage or cerebral thrombosis, embolism, or hemorrhage.
- Diabetes - Diabetes or steroid-induced hyperglycemia requiring continuous treatment with insulin or oral hypoglycemics in the last four weeks.
- Heart valve disease - Moderate or severe valve stenosis or insufficiency (mitral, aortic, tricuspid, or pulmonary) as determined by the most recent heart evaluation by an echocardiogram, prosthetic mitral or aortic valve, and / or symptomatic mitral valve prolapse. This does not include a documented medical history of heart valve disease.
- Hepatic, mild - Chronic hepatitis, bilirubin $>$ upper limit of normal to 1.5x upper limit of normal, or AST / ALT $>$ upper limit of normal to 2.5x upper limit of normal, any history of hepatitis B or hepatitis C infection.
- Hepatic, moderate / severe - Liver cirrhosis, bilirubin $>$ 1.5x upper limit of normal, or AST / ALT $>$ 2.5x upper limit of normal.
- Infection - Documented infection, fever of unknown origin, or pulmonary nodules requiring continuation of antimicrobial treatment after day 0.
- Inflammatory bowel disease - Any history of Crohn's disease or ulcerative colitis requiring treatment.
- Obesity - Recipients with a body mass index $>$ 35 kg/m² or BMI-for-age $\geq 95\%$ (pediatric recipients only) during pre-transplant work-up period.
- Peptic ulcer - Any history of a peptic ulcer confirmed by endoscopy and requiring treatment.
- Psychiatric disturbance - The presence of any mood, anxiety, or other psychiatric disorder requiring continuous treatment during the last four weeks.
- Pulmonary, moderate - Corrected diffusion capacity of carbon monoxide (e.g., DLCOc, DLCOcorr, DLCO) and / or FEV1 66-80% or dyspnea on slight activity at transplant. Use the Dinakara equation to determine the DLCOc if only an uncorrected value is provided. For recipients assessed by a post-bronchodilator test, only the pre-bronchodilator FEV1 values are considered for evaluation of pulmonary comorbidity.
- Pulmonary, severe - Corrected diffusion capacity of carbon monoxide (e.g., DLCOc, DLCOcorr, DLCO) and / or FEV1 $\leq 65\%$ or dyspnea at rest or requiring oxygen at transplant. Use the Dinakara equation to determine the DLCOc if only an uncorrected value is provided. For recipients assessed by a post-bronchodilator test, only the pre-bronchodilator FEV1 values are considered for evaluation of pulmonary comorbidity.
- Renal, moderate / severe - Serum creatinine $>$ 2 mg/dL or $>$ 177 μ mol/L; on dialysis during the 4 weeks prior to transplant; OR prior renal transplantation.
- Rheumatologic - Any history of systemic lupus erythematosus, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica requiring treatment (do NOT include degenerative joint disease, osteoarthritis).
- Prior malignancy - Any solid tumor(s) and / or hematologic malignancy(ies) that have been treated at any time point in the recipient's past history. A history of any benign tumor(s) should not be reported.

109 Was the recipient on dialysis immediately prior to start of systemic therapy?

Yes No Unknown

110 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

111 Specify other skin malignancy: (prior) _____

112 Specify other hematologic malignancy: (prior) _____

113 Specify other solid tumor: (prior) _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: _____ - _____ - _____