

Form 4006 R2.0: Cellular Therapy Infusion

Center: _____

CRID: _____

Key Fields

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: ____-____-____

Cellular Therapy Product Identification

Questions: 1 - 27

If more than one type of cell therapy product is infused, each product type must be reported separately.

1 Specify donor

Autologous Allogeneic, related Allogeneic, unrelated

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

Yes No

3 Was the product a cord blood unit?

Yes No

4 NMDP cord blood unit ID: _____

5 NMDP donor ID: _____

6 Non-NMDP unrelated donor ID: *(not applicable for related donor)* _____

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

8 Is there an ISBT DIN number associated with the product?

Yes No

9 Is the CBU ID also the ISBT DIN number?

yes no

10 Specify the ISBT DIN number: _____

11 Registry or UCB Bank ID: _____

12 Specify other Registry or UCB Bank: _____

13 Date of birth (donor / infant)

Known Unknown

14 Date of birth: (donor / infant) ____-____-____

15 Age (donor / infant)

Known Unknown

16 Age: (donor / infant) _____ Months (use only if less than 1 year old)

years

17 Sex (donor / infant)

male female

Specify any identifiers associated with this cell product:

18 Cell product ID

Yes No

19 Cell product ID: _____

20 Batch number

Yes No

21 Batch number: _____

22 Lot number

Yes No

23 Lot number: _____

24 Where was the cellular therapy product manufactured / processed?

- Pharmaceutical / biotech company
- Cell processing laboratory off site
- Cell processing laboratory at the same center as the product is being infused
- Other site

25 Specify other site: _____

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26 Specify pharmaceutical / biotech company

- Atara Biotherapeutics
- Bellicum Pharmaceuticals
- Bluebird Bio
- Celgene
- Juno Therapeutics
- Kite Pharma
- Mesoblast
- Novartis
- Other pharmaceutical company

Specify the institution / company where the cellular product was manufactured:

27 Name: _____

City: _____

State: _____

Country: _____

Cell Product Source

Questions: 28 - 33

28 Date of cell product collection

- Known
- Unknown

29 Date of cell product collection: ____ - ____ - ____

30 What is the tissue source of the cellular product? (check all that apply)

- Bone marrow
- Cord blood unit
- Peripheral blood
- Adipose tissue
- Amniotic fluid
- Cardiac tissue
- Hepatic tissue
- Neuronal tissue
- Ophthalmic tissue
- Pancreatic tissue
- Placenta
- Tumor
- Umbilical cord
- Other tissue source
- Unknown

31 Specify other tissue source: _____

32 What is the cell type? (check all that apply)

- Lymphocytes (unselected)
- CD4+ lymphocytes
- CD8+ lymphocytes
- Natural killer cells (NK cells)
- Dendritic cells / tumor cell hybridomas (tumor vaccines)
- Mesenchymal stromal stem cells (MSCs)
- Unspecified mononuclear cells
- Endothelial progenitor cells
- Human umbilical cord perivascular (HUCPV) cells
- Cardiac progenitor cells
- Islet cells
- Oligodendrocytes
- Other cell type

33 Specify other cell type: _____

Collection Procedure

Questions: 34 - 39

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This section is for autologous infusions only.

34 Did the recipient have more than one mobilization event to acquire cells?

yes no

35 Specify the total number of mobilization events performed for this cellular therapy: (regardless of the number of collections or which collections were used) _____

36 Number of collections: _____

37 Specify the method of product collection

Bone marrow aspirate Leukapheresis Byoptic sample Other method

38 Specify other method: _____

Specify all agents used in the mobilization events reported above:

39 Specify agent(s) used in the mobilization events (check all that apply)

- G-CSF
- GM-CSF
- Pegylated G-CSF
- Plerixafor (Mozobil)
- Other CXCR4 inhibitor

Cell Product Manipulation

Questions: 40 - 72

40 Were the cells in the infused product selected / modified / engineered prior to infusion?

Yes No

41 Specify the portion manipulated

Entire product Portion of product

42 Was the unmanipulated portion of the product also infused?

Yes No

43 Was the same manipulation method used on the entire product / all portions of the product?

Yes No

Specify all methods used to manipulate the product:

44 Specify method(s) used to manipulate the product (check all that apply)

- Cultured (ex-vivo expansion)
- Induced cell differentiation
- Cell selection - positive
- Cell selection - negative
- Cell selection based on affinity to a specific antigen
- Genetic manipulation (gene transfer / transduction)
- Other cell manipulation

45 Specify other cell manipulation: _____

Specify the type of genetic manipulation:

46 Transfection

Yes No

47 Viral transfection

yes no

48 Lentivirus

Yes No

49 Retrovirus

Yes No

50 Non-viral transfection

yes no

51 Transposon

Yes No

52 Electroporation

Yes No

53 Other non-viral transfection

Yes No

54 Specify other non-viral transfection: _____

55 Gene editing

Yes No

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56 Specify gene

- CCR5 Factor IX Factor VIII Other gene

57 Specify other gene: _____

58 Were cells engineered to express a non-native antigen receptor?

- Yes No

59 Specify the construct utilized

- T-cell receptor
 Chimeric Antigen Receptor (CAR)

60 Specify details of the CAR construct (check all that apply)

- CD3ζ
 CD27
 CD28
 ICOS
 OX40
 4-1BB
 EGFR
 Other construct

61 Specify other construct: _____

62 Suicide gene

- Yes No

63 Specify suicide gene: _____

64 Other genetic manipulation

- Yes No

65 Specify other genetic manipulation: _____

66 Was the product manipulated to recognize a specific target/antigen?

- Yes No

67 Specify target

- Viral
 Tumor / cancer antigen
 Other target

Targets specific to viral infections

68 Specify viral target(s) (check all that apply)

- Adenovirus
 BK virus
 Cytomegalovirus (CMV)
 Epstein-Barr virus (EBV)
 Human herpes virus 6
 Human Immunodeficiency Virus (HIV)
 Other virus

69 Specify other virus: _____

Targets specific to tumors

70 Specify the tumor / cancer antigen

- CD19 CD20 CD22 CD30 CD33 CD138 BCMA Lewis Y Other tumor / cancer antigen

71 Specify tumor / cancer antigen: _____

Other Target

72 Specify other target: _____

Cell Product Analysis

Questions: 73 - 81

73 Was transfection efficiency done? (genetically engineered cells)

- Yes No Unknown

74 Date: ____ - ____ - ____

75 Transfection efficiency: _____ %

76 Was transfection efficiency target achieved?

- Yes No

77 Was viability of cells done?

- Yes No Unknown

78 Date: ____ - ____ - ____

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79 Viability of cells: _____ %

80 Method of testing cell viability

- 7-AAD Propidium iodide Trypan blue Other method

81 Specify other method: _____

Product Infusion

Questions: 82 - 120

82 Date of this product infusion: ____ - ____ - ____

83 Was the entire volume of product infused?

- Yes No

84 Specify what happened to the reserved portion

- Discarded
 Cryopreserved for future use
 Other fate

85 Specify other fate: _____

86 Specify the route of product infusion

- Intravenous
 Intramedullary
 Intraperitoneal
 Intra arterial
 Intramuscular
 Intrathecal
 Intraorgan
 Locally in the tissue
 Other route of infusion

87 Specify other route of infusion: _____

88 Specify the site of intraorgan administration of cells

- Bone Heart Liver Pancreas Kidney Brain Lung Other site

89 Specify other site: _____

Cell doses

90 Recipient weight used for this infusion: _____ pounds kilograms

91 Recipient height used for this infusion: _____ inches centimeters

Report the total number of cells (not cells per kilogram) contained in the product administered, not corrected for viability

92 Total number of cells administered

- Known Unknown

93 Total number of cells: _____ x 10 _____

94 Lymphocytes (unselected) administered

- Yes No

95 Total number of cells: _____ x 10 _____

96 CD4+ lymphocytes administered

- Yes No

97 Total number of cells: _____ x 10 _____

98 CD8+ lymphocytes administered

- Yes No

99 Total number of cells: _____ x 10 _____

100 Natural killer cells (NK cells) administered

- Yes No

101 Total number of cells: _____ x 10 _____

102 Dendritic cells / tumor cell hybridomas administered

- Yes No

103 Total number of cells: _____ x 10 _____

104 Mesenchymal stromal stem cells (MSCs) administered

- Yes No

105 Total number of cells: _____ x 10 _____

106 Unspecified mononuclear cells administered

- Yes No

107 Total number of cells: _____ x 10 _____

108 Endothelial progenitor cells administered

- Yes No

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Center: _____

CRID: _____

109 Total number of cells: _____ x 10 _____

110 Human umbilical cord perivascular (HUCPV) cells administered

Yes No

111 Total number of cells: _____ x 10 _____

112 Cardiac progenitor cells administered

Yes No

113 Total number of cells: _____ x 10 _____

114 Islet cells administered

Yes No

115 Total number of cells: _____ x 10 _____

116 Oligodendrocytes administered

Yes No

117 Total number of cells: _____ x 10 _____

118 Other cell type administered

Yes No

119 Specify other cell type: _____

120 Total number of cells: _____ x 10 _____

Concomitant Therapy

Questions: 121 - 124

121 Did the recipient receive concomitant therapy?

Yes No

122 Specify drugs (check all that apply)

- Atezolizumab (Tecentriq)
- Avelumab (Bavencio)
- Durvalumab
- GM-CSF
- IL-2
- IL-15
- Ipilimumab (Yervoy)
- Lenalidomide (Revlimid)
- Nivolumab (Opdiva)
- Pembrolizumab (Keytruda)
- Pomalidomide
- Other

123 Specify other drug: _____

124 Specify time point

Simultaneous Post cell therapy Unknown

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____