

ERROR CORRECTION FORM

Sequence Number:	CIBMTR Recipient ID:	Initials:
<input type="text"/>	<input type="text"/>	<input type="text"/>
Today's Date:	Infusion Date:	CIBMTR Center Number:
<input type="text"/> <input type="text"/> <input type="text"/> 20 <input type="text"/>	<input type="text"/> <input type="text"/> 20 <input type="text"/>	<input type="text"/>
Month Day Year	Month Day Year	

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: _____

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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

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

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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

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)

- CD3 ζ
- CD27
- CD28
- ICOS
- OX40
- 4-1BB
- EGFR
- Other construct

61 Specify other construct: _____

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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: ____ - ____ - ____

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

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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

109 Total number of cells: _____ x 10 _____

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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: ____ - ____ - ____

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