

# ERROR CORRECTION FORM

Sequence Number:

CIBMTR Recipient ID:

Initials:

Today's Date:

Infusion Date:

CIBMTR Center Number:

## Form 4003 R3.0: Cellular Therapy Product

Center: \_\_\_\_\_ CRID: \_\_\_\_\_

### Key Fields

Sequence Number: \_\_\_\_\_

Date Received: \_\_\_\_-\_\_\_\_-\_\_\_\_

CIBMTR Center Number: \_\_\_\_\_

CIBMTR Research ID: \_\_\_\_\_

Event date: \_\_\_\_-\_\_\_\_-\_\_\_\_

#### Product Identifiers:

NMDP cord blood unit ID: \_\_\_\_\_

Non-NMDP unrelated donor ID: \_\_\_\_\_

Non-NMDP cord blood unit ID: \_\_\_\_\_

Global Registration Identifier for Donors (GRID) \_\_\_\_\_

Donor DOB: \_\_\_\_-\_\_\_\_-\_\_\_\_

Donor age: \_\_\_\_\_  Months (use only if less than 1 year old)

years

Donor sex  male  female

### Cellular Therapy Product Identification

Questions: 1 - 1

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

#### 1 Name of product

- Tisagenlecleucel
- Axicabtagene ciloleucel
- Lisocabtagene maraleucel
- Idecabtagene vicleucel
- Other product

### Cell Product Source

Questions: 2 - 11

#### 2 Date of cell product collection

- Known  Unknown

3 Date of cell product collection: \_\_\_\_-\_\_\_\_-\_\_\_\_

#### 4 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

5 Specify other tissue source: \_\_\_\_\_

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# ERROR CORRECTION FORM

Sequence Number:

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 20 

Month Day Year

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

- Lymphocytes (unselected)
- CD4+ lymphocytes
- CD8+ lymphocytes
- Cytotoxic T lymphocytes (CTLs)
- Natural killer cells (NK cells)
- Dendritic cells / tumor cell hybridomas
- 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

7 Specify other cell type: \_\_\_\_\_

8 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

9 Specify other site: \_\_\_\_\_

10 Specify pharmaceutical / biotech company

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

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

11 Name: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Country: \_\_\_\_\_

### Collection Procedure

Questions: 12 - 14

This section is for autologous products only. If this was an allogeneic infusion, continue to question 15.

12 Specify the method of product collection

- Bone marrow aspirate
- Leukapheresis
- Byoptic sample
- Other method

13 Specify other method: \_\_\_\_\_

14 Number of collections: \_\_\_\_\_

### Cell Product Manipulation

Questions: 15 - 46

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

Yes  No

16 Specify the portion manipulated

Entire product  Portion of product

17 Was the unmanipulated portion of the product also infused?

Yes  No

18 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:

19 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

20 Specify other cell manipulation: \_\_\_\_\_

### Specify the type of genetic manipulation:

21 Transfection

Yes  No

22 Viral transduction

Yes  No

23 Lentivirus

Yes  No

24 Retrovirus

Yes  No

25 Non-viral transfection

yes  no

26 Transposon

Yes  No

27 Electroporation

Yes  No

28 Other non-viral transfection

Yes  No

29 Specify other non-viral transfection: \_\_\_\_\_

30 Gene editing

Yes  No

31 Specify gene

- ABCD1
- CCR5
- Factor IX
- Factor VIII
- Globlin gene
- TCR (T-cell receptor)
- Other gene

32 Specify other gene: \_\_\_\_\_

33 Were cells engineered to express a non-native protein?

Yes  No

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CRID:

**34** Specify the protein inserted into the cellular product

- T-cell receptor
- Chimeric Antigen Receptor (CAR)
- Suicide gene

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

- CD3 $\zeta$
- CD27
- CD28
- ICOS
- OX40
- 4-1BB
- EGFR
- Other construct

**36** Specify other construct: \_\_\_\_\_

**37** Specify suicide gene: \_\_\_\_\_

**38** Other genetic manipulation

- Yes  No

**39** Specify other genetic manipulation: \_\_\_\_\_

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

- Yes  No

**41** Specify target (check all that apply)

- Viral
- Tumor / cancer antigen
- Other target

### Targets specific to viral infections

**42** 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

**43** Specify other virus: \_\_\_\_\_

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**Targets specific to tumors**

44 Specify the tumor / cancer antigen (check all that apply)

- AFP (alpha fetoprotein)
- BCMA
- CD16
- CD19
- CD20
- CD22
- CD30
- CD33
- CD38
- CD123
- CD138
- CD171
- CS-1 (SLAMF7)
- HPV-16E6
- Lewis Y
- MAGE-A4
- MAGE-A10
- MUC16
- NY-ESO-1
- PRAME
- PSCA
- WT-1
- Other tumor / cancer antigen

45 Specify tumor / cancer antigen: \_\_\_\_\_

**Other Target**

46 Specify other target: \_\_\_\_\_

**Cell Product Analysis**

Questions: 47 - 55

47 Was transfection efficiency done? (genetically engineered cells)

- Yes  No  Unknown

48 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

49 Transfection efficiency: \_\_\_\_\_ %

50 Was transfection efficiency target achieved?

- Yes  No

51 Was viability of cells done?

- Yes  No  Unknown

52 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

53 Viability of cells: \_\_\_\_\_ %

54 Method of testing cell viability

- 7-AAD  Propidium iodide  Trypan blue  Other method

55 Specify other method: \_\_\_\_\_

**Product Infusion**

Questions: 56 - 56

56 Specify the total number of planned infusions: \_\_\_\_\_ (of this product) (as part of this course of cellular therapy)

First Name: \_\_\_\_\_

Last Name: \_\_\_\_\_

E-mail address: \_\_\_\_\_

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