

# 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 4003 R2.0: Cellular Therapy Product

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

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

### Key Fields

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

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

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

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

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

### Cellular Therapy Product Identification

Questions: 1 - 19

1 Name of product

- Tisagenlecleucel (Kymriah®)  
 Axicabtagene Ciloleucel (Yescarta®)  
 Other product

2 Specify donor

- Autologous  Allogeneic, related  Allogeneic, unrelated

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

- Yes  No

4 Was the product a cord blood unit?

- Yes  No

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

6 NMDP donor ID: \_\_\_\_\_

7 Non-NMDP unrelated donor ID: *(not applicable for related donor)* \_\_\_\_\_

8 Non-NMDP cord blood unit ID: *(include related and autologous CBUs)* \_\_\_\_\_

9 Global Registration Identifier for Donors (GRID) *(optional)* \_\_\_\_\_

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

- Yes  No

11 Is the CBU ID also the ISBT DIN number?

- yes  no

12 Specify the ISBT DIN number: \_\_\_\_\_

13 Registry or UCB Bank ID: \_\_\_\_\_

14 Specify other Registry or UCB Bank: \_\_\_\_\_

15 Date of birth (donor / infant)

- Known  Unknown

16 Date of birth: (donor / infant) \_\_\_\_ - \_\_\_\_ - \_\_\_\_

17 Age (donor / infant)

- Known  Unknown

18 Age: (donor / infant) \_\_\_\_\_  Months (use only if less than 1 year old)

- years

19 Sex (donor / infant)

- male  female

### Cell Product Source

Questions: 20 - 21

20 Date of cell product collection

- Known  Unknown

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

### Collection Procedure

Questions: 22 - 27

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

- yes  no

23 Specify the total number of mobilization events performed for this cellular \_\_\_\_\_ (regardless of the number of collections or which collections were used)

24 Number of collections: \_\_\_\_\_

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- 25 Specify the method of product collection
- Bone marrow aspirate  Leukapheresis  Byoptic sample  Other method

26 Specify other method: \_\_\_\_\_

**Specify all agents used in the mobilization events reported above:**

- 27 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: 28 - 59

- 28 Were the cells in the infused product selected / modified / engineered prior to infusion?
- Yes  No

- 29 Specify the portion manipulated
- Entire product  Portion of product

- 30 Was the unmanipulated portion of the product also infused?
- Yes  No

- 31 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:**

- 32 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

33 Specify other cell manipulation: \_\_\_\_\_

**Specify the type of genetic manipulation:**

- 34 Transfection
- Yes  No

- 35 Viral transduction
- Yes  No

- 36 Lentivirus
- Yes  No

- 37 Retrovirus
- Yes  No

- 38 Non-viral transfection
- yes  no

- 39 Transposon
- Yes  No

- 40 Electroporation
- Yes  No

- 41 Other non-viral transfection
- Yes  No

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

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Center:

CRID:

### 43 Gene editing

Yes  No

### 44 Specify gene

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

45 Specify other gene: \_\_\_\_\_

### 46 Were cells engineered to express a non-native protein?

Yes  No

### 47 Specify the protein inserted into the cellular product

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

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

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

49 Specify other construct: \_\_\_\_\_

50 Specify suicide gene: \_\_\_\_\_

### 51 Other genetic manipulation

Yes  No

52 Specify other genetic manipulation: \_\_\_\_\_

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

Yes  No

### 54 Specify target (check all that apply)

- Viral
- Tumor / cancer antigen
- Other target

### Targets specific to viral infections

### 55 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

56 Specify other virus: \_\_\_\_\_

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### Targets specific to tumors

57 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 (prostate stem cell antigen)
- WT-1
- Other tumor / cancer antigen

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

### Other Target

59 Specify other target: \_\_\_\_\_

## Cell Product Analysis

Questions: 60 - 68

60 Was transfection efficiency done? (genetically engineered cells)

- Yes  No  Unknown

61 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

62 Transfection efficiency: \_\_\_\_\_ %

63 Was transfection efficiency target achieved?

- Yes  No

64 Was viability of cells done?

- Yes  No  Unknown

65 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

66 Viability of cells: \_\_\_\_\_ %

67 Method of testing cell viability

- 7-AAD  Propidium iodide  Trypan blue  Other method

68 Specify other method: \_\_\_\_\_

## Product Infusion

Questions: 69 - 69

69 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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		2	0		
Month	Day	Year			

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