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:
NMHD 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: 
Donor sex 

Cellular Therapy Product Identification

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

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: 

Mail, fax or email this form to Minneapolis. Fax: 612-527-5895. Email: scanform@nmdp.org.
Retain the original form at the transplant center.
**Form 4003 R3.0: Cellular Therapy Product**

Center:  
CRID:  

### Key Fields

- **Sequence Number:**
- **Date Received:**
- **Infusion Date:**
- **CIBMTR Recipient ID:**
- **CIBMTR Center Number:**

### Collection Procedure

**Questions: 12 - 14**

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

#### Collection Procedure

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

#### Cell Product Manipulation

**Questions: 15 - 46**

Mail, fax or email this form to Minneapolis. Fax: 612-527-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.
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
   - Globulin gene
   - TCR (T-cell receptor)
   - Other gene

32 Specify other gene: __________________________

33 Were cells engineered to express a non-native protein?
   - Yes
   - No
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)
   □ CD3ζ
   □ 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:
Form 4003 R3.0: Cellular Therapy Product

Center: 
CRID: 

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: ________________________________

First Name: ________________________________
Last Name: ________________________________
E-mail address: ________________________________
### Form 4003 R3.0: Cellular Therapy Product

#### Center: [Name]

**CRID:** [ID]

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**Date:** [Date]

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#### Key Fields

- **Sequence Number:** [Number]
- **Date Received:** [Date]
- **E-mail address:** [Email]
- **Last Name:** [Name]
- **Donor sex:** [Gender]
- **Donor age:** [Age]
- **Donor DOB:** [Date]
- **Non-NMDP unrelated donor ID:** [ID]
- **NMDP cord blood unit ID:** [ID]
- **CIBMTR Research ID:** [ID]
- **CIBMTR Center Number:** [ID]
- **Date Received:** [Date]
- **Sequence Number:** [Number]

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#### Product Identifiers:

- **Cellular Therapy Product:** [Type]
- **Name of product:** [Name]
- **Number of collections:** [Number]
- **Date of cell product collection:** [Date]
- **Date:** [Date]
- **Transfection efficiency:** [Efficiency]
- **Gene editing:** [Yes/No]
- **Viability of cells:** [Yes/No]
- **Was the product manipulated to recognize a specific target/antigen?** [Yes/No]
- **Were the cells in the infused product selected/modified/engineered prior to infusion?** [Yes/No]
- **Was viability of cells done?** [Yes/No]
- **Specify the type of genetic manipulation:**
  - Targets specific to viral infections
  - Targets specific to tumors
  - Other Target

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**Specify the method of product collection:**

- [Method]

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**Specify the institution/company where the cellular product was manufactured:** [Company]

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**Specify the method of delivery of the cellular product to the recipient:** [Method]

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**Specify the tumor/cancer antigen:**

- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]
- [Antigen]

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**Specify other tumor/cancer antigen:** [Antigen]

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**Specify other virus:** [Virus]

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**Specify other genetic manipulation:**

- [Manipulation]

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**Specify other non-viral transfection:**

- [Transfection]

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**Specify other cell manipulation:**

- [Manipulation]

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**Specify the protein inserted into the cellular product:** [Protein]

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**Specify details of the CAR construct:**

- [Construct]

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**Specify other construct:**

- [Construct]

---

**Specify other non-viral transfection:**

- [Transfection]

---

**Specify other gene:** [Gene]

---

**Specify other target:** [Target]

---

**Specify other virus:** [Virus]

---

**Specify other construct:** [Construct]

---

**Specify other gene:** [Gene]

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**Specify other target:** [Target]