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
   └ Tsigenlecleucel (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 therapy: _____________________

24 Number of collections: _____________________
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Center: CRID:

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

<table>
<thead>
<tr>
<th>Cell Product Manipulation</th>
<th>Questions: 28 - 59</th>
</tr>
</thead>
</table>

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
- Globin 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)
- CD3ζ
- 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:
<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>57 Specify the tumor / cancer antigen (check all that apply)</td>
<td></td>
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<tr>
<td>AFP (alpha fetoprotein)</td>
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<tr>
<td>BCMA</td>
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<tr>
<td>CD16</td>
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<tr>
<td>CD19</td>
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<td>CD20</td>
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<td>CD22</td>
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<td>CD38</td>
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<td>CD123</td>
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<td>CD138</td>
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<tr>
<td>CD171</td>
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</tr>
<tr>
<td>CS-1 (SLAMF7)</td>
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<tr>
<td>HPV-16E6</td>
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<tr>
<td>Lewis Y</td>
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<tr>
<td>MAGE-A4</td>
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<td>MAGE-A10</td>
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<td>MUC16</td>
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<tr>
<td>NY-ESO-1</td>
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<tr>
<td>PRAME</td>
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<tr>
<td>PSCA (prostate stem cell antigen)</td>
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<tr>
<td>WT-1</td>
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<tr>
<td>Other tumor / cancer antigen</td>
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<td></td>
</tr>
<tr>
<td>58 Specify tumor / cancer antigen: ________________________________</td>
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<tr>
<td>Other Target</td>
<td></td>
<td></td>
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<tr>
<td>59 Specify other target: ________________________________</td>
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</tbody>
</table>

### Cell Product Analysis

**Questions: 60 - 68**

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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</thead>
<tbody>
<tr>
<td>60 Was transfection efficiency done? (genetically engineered cells)</td>
<td></td>
<td></td>
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<tr>
<td>61 Date: __ __ __</td>
<td></td>
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<tr>
<td>62 Transfection efficiency: __ __ __ %</td>
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<tr>
<td>63 Was transfection efficiency target achieved?</td>
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</tr>
<tr>
<td>64 Was viability of cells done?</td>
<td></td>
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<tr>
<td>65 Date: __ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66 Viability of cells: __ __ __ %</td>
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<tr>
<td>67 Method of testing cell viability</td>
<td></td>
<td></td>
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<tr>
<td>68 Specify other method: ________________________________</td>
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</tbody>
</table>

### Product Infusion

**Questions: 69 - 69**

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>69 Specify the total number of planned infusions: ________________________________ (of this product) (as part of this course of cellular therapy)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

First Name: ________________________________

Last Name: ________________________________

E-mail address: ________________________________

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**Date:** __________ - __________

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**Cellular Therapy Product Identification**

<table>
<thead>
<tr>
<th>CIBMTR Recipient ID:</th>
<th>CIBMTR Center Number:</th>
<th>Initials:</th>
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**Today's Date:**

<table>
<thead>
<tr>
<th>Month</th>
<th>Day</th>
<th>Year</th>
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</table>

**Infusion Date:**

<table>
<thead>
<tr>
<th>Month</th>
<th>Day</th>
<th>Year</th>
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**Cell Product Manipulation**

<table>
<thead>
<tr>
<th>Gene Editing</th>
<th>Bone marrow aspiration</th>
<th>Pegylated G-CSF</th>
<th>Plerixafor (Mozobil)</th>
<th>Other Genetic Manipulation</th>
</tr>
</thead>
</table>

**Collection Procedure**

<table>
<thead>
<tr>
<th>Donor Type</th>
<th>Collection Procedure</th>
<th>Non-NMDP Unrelated Donor ID:</th>
<th>NMDP Donor ID:</th>
<th>NMDP Cord Blood Unit ID:</th>
</tr>
</thead>
</table>

**Cell Product Source**

<table>
<thead>
<tr>
<th>Cell Source</th>
<th>Collection Procedure</th>
</tr>
</thead>
</table>

**Cell Viability**

<table>
<thead>
<tr>
<th>Method of Testing Cell Viability</th>
<th>Transfection Efficiency</th>
<th>WAS TATRIFICATION EFFICIENCY TARGET ACHIEVED?</th>
</tr>
</thead>
</table>

**Additional Details**

<table>
<thead>
<tr>
<th>Event Date:</th>
<th>Sequence Number:</th>
<th>Name of Product</th>
<th>Number of Collections:</th>
<th>Date of Cell Product Collection:</th>
<th>Registry or UCB Bank ID</th>
</tr>
</thead>
</table>

**Method of Testing**

<table>
<thead>
<tr>
<th>Method of Testing</th>
<th>Date of Birth</th>
<th>Is There an ISBT DIN Number Associated with the Product?</th>
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</table>

**Other Details**

<table>
<thead>
<tr>
<th>Other Tumor / Cancer Antigen</th>
<th>Other Target</th>
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</thead>
</table>

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**Other Methods**

<table>
<thead>
<tr>
<th>Other Target</th>
<th>Other Method</th>
<th>Other Construct</th>
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**Additional Information**

<table>
<thead>
<tr>
<th>Other Information</th>
<th>Other Details</th>
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**Other Virus**

<table>
<thead>
<tr>
<th>Other Virus</th>
<th>Other Details</th>
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</table>

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**Other Tumor / Cancer Antigen**

<table>
<thead>
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<th>Other Tumor / Cancer Antigen</th>
<th>Other Details</th>
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</table>

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**Summary**

- **Cell Type:** __________
- **Donor Type:** __________
- **Collection Procedure:** __________
- **Cell Viability:** __________
- **Other Details:** __________