



Cellular Therapy Product

Registry Use Only

Sequence Number: _____

Date Received: _____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: _____
 YYYY MM DD

Product Identifiers

NMDP cord blood unit ID: _____

Registry donor ID: _____

Non-NMDP cord blood unit ID: _____

Global Registration Identifier for Donors (GRID): _____

Donor DOB: _____ - _____ - _____
 YYYY MM DD

Donor age: ____ ☐ Months *(use only if less than 1 year old)*

☐ Years

Donor sex: ☐ Male ☐ Female

CIBMTR Center Number:

CIBMTR Research ID:

Cellular Therapy Product Identification

If more than one type of cell therapy product is infused, each product type must be reported separately on a new F4003.

1. Name of cellular therapy product (*for most recent cell therapy infusion*)
 - ☐ Afamitresgene autoleucel – **Go to question 2**
 - ☐ Axicabtagene ciloleucel (Yescarta®) – **Go to question 2**
 - ☐ Brexucabtagene autoleucel (Tecartus™) – **Go to question 2**
 - ☐ Ciltacabtagene autoleucel (JNJ-4528) – **Go to question 2**
 - ☐ Idecabtagene vicleucel (Abecma®) – **Go to question 2**
 - ☐ Letetresgene autoleucel (brand name will go here when approved) – **Go to question 2**
 - ☐ Lisocabtagene maraleucel (Breyanzi™) – **Go to question 2**
 - ☐ Tisagenlecleucel (Kymriah®) – **Go to question 2**
 - ☐ Other product – **Go to question 3**
 - ☐ No product name (*clinical trial or study product*) – **Go to question 3**
2. Is the product out of specification? (*only for commercially available products*)
 - ☐ Yes
 - ☐ No

Cell Product Source

3. Date of cell product collection
- ☐ Known - **Go to question 4**
- ☐ Unknown – **Go to question 5**
4. Date of cell product collection: ____ - ____ - ____
- YYYY MM DD
5. What is the tissue source of the cellular product? (*check all that apply*)
- ☐ Bone marrow (BM)
- ☐ Cord blood unit (CBU)
- ☐ Peripheral blood
- ☐ Adipose tissue
- ☐ Amniotic fluid
- ☐ Cardiac tissue
- ☐ Hepatic tissue

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- ☐ Induced pluripotent stem cells (IPSC)
- ☐ Lymph node
- ☐ Neuronal tissue
- ☐ Ophthalmic tissue
- ☐ Pancreatic tissue
- ☐ Placenta
- ☐ Tumor
- ☐ Umbilical cord
- ☐ Other tissue source - **Go to question 6**
- ☐ Unknown

6. Specify other tissue source: _____

7. What is the cell type? (*check all that apply*)

Lymphocytes

- ☐ Lymphocytes (unselected)
- ☐ CD4+ lymphocytes
- ☐ CD8+ lymphocytes
- ☐ Regulatory T-cells (TREG)

Other Cells

- ☐ Cardiac progenitor cells
- ☐ Dendritic cells / tumor cell hybridomas (tumor vaccines)
- ☐ Endothelial progenitor cells
- ☐ Human umbilical cord perivascular (HUCPV) cells
- ☐ Islet cells
- ☐ Mesenchymal stromal stem cells (MSCs)
- ☐ Natural killer cells (NK cells)
- ☐ Oligodendrocytes
- ☐ Unspecified mononuclear cells
- ☐ Other cell type – **Go to question 8**

8. Specify other cell type: _____

9. Where was the cellular therapy product manufactured / processed?

- ☐ Pharmaceutical / biotech company – **Go to question 11**
- ☐ Cell processing laboratory off site – **Go to question 12**
- ☐ Cell processing laboratory at the same center as the product is being infused – **Go to question 13**

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☐ Other site – **Go to question 10**

10. Specify other site: _____ – **Go to question 12**

11. Specify pharmaceutical / biotech company

☐ Atara Biotherapeutics – **Go to question 13**

☐ Bellicum Pharmaceuticals– **Go to question 13**

☐ Bluebird Bio – **Go to question 13**

☐ Celgene – **Go to question 13**

☐ Daiichi Sankyo– **Go to question 13**

☐ Iovance Biotherapeutics – **Go to question 13**

☐ Janssen Pharmaceuticals– **Go to question 13**

☐ Juno Therapeutics – **Go to question 13**

☐ Kite Pharma – **Go to question 13**

☐ Mesoblast – **Go to question 13**

☐ Miltenyi Biotec– **Go to question 13**

☐ Novartis – **Go to question 13**

☐ Other pharmaceutical company – **Go to question 12**

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

12. Name: _____

City: _____

State: _____

Country: _____ – **Go to question 13**

Collection Procedure

This section is for autologous products only. If this was an allogeneic infusion, continue to “Cell Product Manipulation” section.

13. Specify the method of product collection

☐ Bone marrow aspirate

☐ Cord Blood

☐ Leukapheresis

☐ Peripheral blood draw

☐ Tumor biopsy sample

☐ Other method – **Go to question 14**

CIBMTR Center Number: _____ CIBMTR Research ID: _____

14. Specify other method: _____

15. Number of collections: _____

Cell Product Manipulation

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

☐ Yes – **Go to question 17**

☐ No – **Go to question 31**

17. Specify the portion manipulated

☐ Entire product – **Go to question 19**

☐ Portion of product – **Go to question 18**

18. Was the unmanipulated portion of the product also infused?

☐ Yes

☐ No

19. Was the same manipulation method used on the entire product / all portions of the product?

☐ Yes

☐ No

20. Specify the method(s) used to manipulate the product (*check all that apply*)

☐ Cultured (*ex-vivo expansion*) – **Go to question 31**

☐ Induced cell differentiation – **Go to question 31**

☐ Cell selection - positive– **Go to question 31**

☐ Cell selection - negative– **Go to question 31**

☐ Cell selection based on affinity to a specific antigen– **Go to question 31**

☐ Genetic manipulation (*gene transfer / transduction*) – **Go to question 22**

☐ Other cell manipulation – **Go to question 21**

21. Specify other cell manipulation: _____ – **Go to question 31**

22. Specify the type(s) of genetic manipulation (*check all that apply*)

Viral transduction

☐ Lentivirus – **Go to question 31**

☐ Retrovirus – **Go to question 31**

☐ Transposon – **Go to question 31**

Non-viral transfection

- ☐ Electroporation – **Go to question 31**
- ☐ Other non-viral transfection - **Go to question 23**

Gene editing

- ☐ Gene editing - **Go to question 24**

Non-native protein expression

- ☐ Chimeric Antigen Receptor (CAR) – **Go to question 26**
- ☐ Suicide gene – **Go to question 28**
- ☐ T-cell receptor – **Go to question 31**

Other genetic manipulation

- ☐ Other genetic manipulation – **Go to question 30**

Non- viral Transfection

23. Specify other non-viral transfection: _____ – **Go to question 31**

Gene Editing

24. Specify the gene edited
- ☐ HLA
 - ☐ PDL – 1
 - ☐ TCR (T-cell receptor)
 - ☐ Other gene – **Go to question 25**

25. Specify other gene: _____ – **Go to question 31**

Non-native Protein Expression

26. Specify details of the CAR construct (*check all that apply*)
- ☐ CD3ζ
 - ☐ CD27
 - ☐ CD28
 - ☐ ICOS
 - ☐ OX40
 - ☐ 4-1BB
 - ☐ Bicistronic
 - ☐ Tandem
 - ☐ Other construct – **Go to question 27**

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27. Specify other construct: _____ – **Go to question 31**

28. Specify the suicide gene (*check all that apply*)

☐ iCasp9

☐ Other – **Go to question 29**

29. Specify other suicide gene: _____ – **Go to question 31**

Other

30. Specify other genetic manipulation: _____

31. Was the product manipulated to recognize a specific target / antigen?

☐ Yes – **Go to question 32**

☐ No – **Go to question 38**

32. Specify target (*check all that apply*)

☐ Viral – **Go to question 33**

☐ Tumor / cancer antigen – **Go to question 35**

☐ Other target – **Go to question 37**

Targets specific to viral infections

33. Specify viral target(s) (*check all that apply*)

☐ Adenovirus

☐ BK virus

☐ COVID-19 (SARS-CoV-2)

☐ Cytomegalovirus (CMV)

☐ Epstein-Barr virus (EBV)

☐ Human herpes virus 6

☐ Human Immunodeficiency Virus (HIV)

☐ Human Parainfluenza 3 (HPIV3)

☐ JC Virus (Progressive Multifocal Leukoencephalopathy (PML))

☐ Respiratory syncytial virus (RSV)

☐ Other virus – **Go to question 34**

34. Specify other virus: _____ - **Go to question 38**

Targets specific to tumors / cancer antigens

CIBMTR Center Number: _____

CIBMTR Research ID: _____

35. Specify the tumor / cancer antigen (*check all that apply*)

- ☐ AFP (alpha fetoprotein)
- ☐ BAFF-R
- ☐ BCMA
- ☐ B7H3
- ☐ CD11
- ☐ CD16
- ☐ CD19
- ☐ CD20
- ☐ CD22
- ☐ CD30
- ☐ CD33
- ☐ CD38
- ☐ CD56
- ☐ CD123
- ☐ CD138
- ☐ CD171
- ☐ CD229
- ☐ CLL1
- ☐ CS-1 (SLAMF7)
- ☐ EGFR
- ☐ GD2
- ☐ GPRC5D
- ☐ HER2
- ☐ HPV-16E6
- ☐ Integrin β 7
- ☐ Lewis-Y
- ☐ MAGE-A4
- ☐ MAGE-A10
- ☐ Mesothelin (MSLN)
- ☐ MUC16
- ☐ NKG2D
- ☐ NY-ESO-1
- ☐ PRAME
- ☐ PSCA (prostate stem cell antigen)
- ☐ SSX

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- ☐ Survivin
- ☐ TACI
- ☐ WT-1
- ☐ Other tumor / cancer antigen – **Go to question 36**

36. Specify tumor / cancer antigen: _____ - **Go to question 38**

Other target

37. Specify other target: _____

Cell Product Analysis

38. Is the percentage of genetically modified cells known?

- ☐ Yes – **Go to question 39**
- ☐ No - **Go to question 42**
- ☐ Unknown – **Go to question 42**

39. Date: _____ - _____ - _____
 YYYY MM DD

40. Percent of genetically modified cells: _____ %

41. Was the target percent of genetically modified cells achieved?

- ☐ Yes
- ☐ No

42. Was viability of cells done?

- ☐ Yes – **Go to question 43**
- ☐ No – **Go to question 47**
- ☐ Unknown – **Go to question 47**

43. Date: _____ - _____ - _____
 YYYY MM DD

44. Viability of cells: _____ %

45. Method of testing cell viability

- ☐ 7-AAD

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- ☐ Propidium iodide
- ☐ Trypan blue
- ☐ Other method – **Go to question 46**
- ☐ Unknown

46. Specify other method: _____

Product Infusion

47. 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: _____

Date: _____
 YYYY MM DD