4006: Cellular Therapy Infusion

> ! This form **must** be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic stem cell transplants, complete a form 2400 – Pre-Transplant Essential Data.

The Form 4006 is designed to capture product- and infusion-specific information for all products given to a recipient as part of cellular therapy. In addition to use in research, this information is used for quality assurance measures, both by the NMDP and the Cord Blood Banks.

If more than one type of cellular therapy product is infused, each product type must be analyzed and reported on a separate form 4006. Products from the same donor but obtained using different manufacturing steps are considered different products and require multiple 4006 forms, one for each product.

However, a series of collections from the same donor that uses the same collection method and mobilization cycle, even if the collections are performed on different days, should be considered a single cellular therapy product if only one set of manufacturing steps are applied to the collected material. Also, even if there are different cells being manipulated or modified by different methods and at the end of the manufacturing process are combined for a single infusion or administration, it will be considered a single product and it will require a single Form 4006.

For more information see Appendix D and Appendix E.

Manual Updates:
Sections of the Forms Instruction Manual are frequently updated. In addition to documenting the changes within each manual section, the most recent updates to the manual can be found below. For additional information, select the manual section and review the updated text.

Date	Manual Section	Add/ Remove/ Modify	Description

5/24/17	4006: Cellular Therapy Infusion	Modify	Updated instructions for questions 23-26. New text is highlighted red and removed text has been struck out. *If the product was manufactured by a cell processing laboratory at the same center as the product is being infused, continue with question 27. If the product is from an NMDP donor used for a prior HCT, please select this option.* *If the product was manufactured by another site that does not fit a category listed above, specify the other site in question 24. ~~and report the name and location in question 26.~~*
7/29/16	4006: Cellular Therapy Infusion	Add	Version 1 Released

Q1-26: Cellular Therapy Product Identification

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

Question 1 & 2: Specify donor:

Indicate the donor type for this product.

An **autologous product** has cells collected from the recipient for his/her own use.

> If the product was autologous (marrow, PBSC, other product), select “autologous” and continue with question 17.
>
> If the product was an autologous cord blood unit, select “autologous cord blood unit” and continue with question 6.

An **unrelated donor (allogeneic, unrelated)** is a donor who shares no known ancestry with the recipient. Include adoptive parents/children or stepparents/children. Distinguish if the product in an NMDP product or a non-NMDP product. Examples of non-NMDP donor registries include, but are not limited to: St. Louis Cord Blood Bank, Anthony Nolan, and StemCyte International Cord Blood Center.

> If the product was an NMDP unrelated cord blood unit, select “NMDP unrelated cord blood unit” and continue with question 3.
>
> If the product was from an NMDP unrelated donor (marrow, PBSC, other product), select “NMDP unrelated donor” and continue with question 4.
>
> If the product was from a non-NMDP unrelated donor and was facilitated through another registry, select “non-NMDP unrelated donor” and continue with question 5.
>
> If the product was a non-NMDP cord blood unit, select “non-NMDP cord blood unit” and continue with question 6.

A **related donor (allogeneic or syngeneic, related)** is a blood-related relative. This includes monozygotic (identical twins), non-monozygotic (dizygotic, fraternal, non-identical) twins, siblings, parents, aunts, uncles, children, cousins, half-siblings, etc.

If the product was from a related donor (marrow, PBSC, other product), select “related donor” and continue with question 12.

If the product was a related cord blood unit, select “related cord blood unit” and continue with question 6.

Other donor includes “third party” donor products obtained from pharmaceutical companies or other corporate entities. Specify the other donor in question 2.

Question 3: NMDP Cord Blood Unit ID:

Report the NMDP Cord Blood Unit ID. This information is included on the product label, the product insert accompanying the product, and within the NMDP search/product documentation. The ID is always numeric and begins with “9” (e.g., 9000-0000-0). If the product ID does not begin with a “9,” the product may not be an NMDP cord blood unit and the source of the product should be double-checked. Continue with question 17.

Question 4: NMDP Donor ID:

Report the NMDP Donor ID (e.g., 0000-0000-0). This ID is unique for each donor and is assigned by the NMDP. This information is included on the product label, the product insert accompanying the product, and within the NMDP search/product documentation. Continue with question 17.

Question 5: Non-NMDP unrelated donor ID: (not applicable for related donor)

Report the non-NMDP unrelated donor ID. Do not complete this field if the recipient has an NMDP donor, a related donor, or a cord blood donor. This ID is often located on the product label, the product insert accompanying the product, and the registry-specific search/product documentation. Continue with question 10.

Question 6: Non-NMDP cord blood unit ID: (include related and autologous CBUs):

Report the non-NMDP cord blood unit ID. Examples of non-NMDP donor registries include, but are not limited to: St. Louis Cord Blood Bank and StemCyte International Cord Blood Center. This ID is often located on the product label, the paperwork accompanying the product, and registry specific search/product documentation. Enter the non-NMDP cord blood ID. Note that some cord blood banks can ship their units either through the NMDP or directly to the center. Carefully review the accompanying documentation to determine which is appropriate for your unit. You may wish to consult with your center’s Transplant Coordinator, as he or she will have insight as to how the product was acquired. Continue with question 7.

Question 7: Is there an ISBT DIN number associated with the product?

Report “yes” if there is an International Society of Blood Transfusion (ISBT) Donation Identification Number (DIN) associated with the product. If the product is a cord blood unit, continue with question 8, else continue with question 9.

Report “no” if there isn’t ISBT DIN associated with the product and continue with question 10.

Question 8: Is the CBU ID also the ISBT DIN number?

Report “yes” if the non-NMDP CBU ID is the same as the International Society of Blood Transfusion (ISBT) Donation Identification Number (DIN) and continue with question 10. If the product has an ISBT label on it, the ISBT DIN number is in the upper left-hand corner and consists of a letter followed by 12 numbers, two numbers on the end, and a letter in a box. Example below:

Please find additional information regarding the ISBT DIN numbers and traceability at http://www.iccbba.org/docs/public/introduction_traceability.pdf. For example, you may see a barcode with an alphanumeric string below it.

If the CBU ID is not the same as the ISBT DIN number, select “no” and continue with question 9.

Question 9: Specify the ISBT DIN number:

If you answered “yes” to question 7 and the product is not a cord blood unit or you answered “no” to question 8, and the CBU ID is not the ISBT DIN, report the ISBT DIN number using the letter, 12 digits, 2 numbers on end, and the letter in the box.

Question 10: Registry or UCB Bank ID:

Specify the registry used to obtain the adult donor or umbilical cord blood unit. The Bone Marrow Donors Worldwide codes have been adopted to avoid submitting the entire name and address of the donor registry.

The registry code for NMDP donors is USA1 and for NMDP cord units is U1CB.

Some common banks that do not list with BMDW have been added to the Form 2006 revision 4 list, including St Louis Cord Blood Bank (SLCBB) and Viacord (VIAC).

If the donor was found through DKMS, report the registry that facilitated the cellular therapy product. Some registries may be listed more than once with BMDW (once for marrow/PBSC products and differently for cord blood products). Ensure that the appropriate code for the product was selected, because distribution of data is dependent on the code.

If the registry code cannot be determined using the BMDW website, select "other registry" and continue to question 11.

Question 11: Specify other Registry or UCB Bank:

If the BMDW website does not list a match code for the adult donor registry or cord blood bank, provide the registry's official name in the "Specify other registry" field.

Please ensure that the registry you are entering under "other" is not already listed in the pull-down list for question 10. Entries such as NMDP adult donors, NMDP cords, and New York Cord Bank each have their own entries above.

Question 12 & 13: Date of birth (donor / infant):

For related donors only, report if the donor's/infant's date of birth is "known" or "unknown" for question 12. If the donor's/infant's date of birth is known, report the date of birth (YYYY-MM-DD) in question 13. If the donor's/infant's date of birth is unknown, continue with question 14.

Question 14 & 15: Age (donor / infant):

For related donors only, report if the donor's/infant's age is "known" or "unknown" for question 14. If the donor's/infant's age is known, report the donor's/infant's age at the time of product collection in question 15. Report the age in months if the recipient is less than 1 year old, otherwise report the age in years. If the donor's/infant's age at collection is unknown, continue with question 16.

Question 16: Sex (donor / infant):

For related donors only, indicate the donor's biological sex as "male" or "female." For cord blood units, report the infant's sex.

Question 17 & 18: Cell product ID:

Report if the product has a Cell product ID in question 17 and specify the ID in question 18.

Question 19 & 20: Batch number:

Report if the product has a Batch number in question 19 and specify the Batch number in question 20.

Question 21 & 22: Lot number:

Report if the product has a Lot number in question 21 and specify the Lot number in question 22.

Question 23-26: Where was the cellular therapy product manufactured?

If the product was manufactured by a pharmaceutical or biotech company, select the company from the list in question 25.

If the product was manufactured by a cell processing laboratory off site, report the name and location of the company in question 26.

If the product was manufactured by a cell processing laboratory at the same center as the product is being infused, continue with question 27. If the product is from an NMDP donor used for a prior HCT, please select this option.

If the product was manufactured by another site that does not fit a category listed above, specify the other site in question 24.

Q27-32: Cell Product Source

Questions 27-32 Reporting more than one cell type

FormsNet3SM application: Complete questions 27-32 for each cell type infused as part of this product by adding an additional instance in the FormsNet application.
Paper form submission: Copy questions 27-32 and complete for each cell type infused as part of this product.

This section allows for multiple selections. For example, if the product consists of two different types of lymphocytes, the source of cells will be peripheral blood and the cell types will be CD4+ and CD8+ lymphocytes. Also, in the case of tumor vaccine, the sources will be tumor and peripheral blood and the cell type will be dendritic cells/tumor cell hybridomas.

Question 27 & 28: Date of cell product collection:

Report if the date of cell product collection is “known” or “unknown” for question 27. If the date of cell product collection is known, report the date (YYYY-MM-DD) in question 28. If the date of cell product collection is unknown, continue with question 29.

Question 29 & 30: What is the tissue source of the cellular product?

Select from the drop-down menu the tissue source of the cellular product. If the source is selected as ‘Other tissue source’, specify the other source in question 30 or continue with question 31.

Question 31 & 32: What is the cell type?

Select from the drop-down menu the cell type of the cellular product. If the cell type is selected as ‘Other cell type’, specify the other cell type in question 32 or continue with question 33.

Q33-76: Cell Product Manipulation

This section specifies any manipulation that was done to manufacture the final cellular therapy product.

Question 33: Were the cells in the infused product selected / modified / engineered prior to infusion?

Indicate “yes” if the cells contained in the product were selected (i.e. selective retention of a population of desired cells through recognition of specified characteristics), modified or genetically engineered and continue with question 34. Indicate “no” if the cells contained in the product were not selected, modified or genetically engineered in any way prior to infusion and continue with question 77.

Question 34: Specify the portion manipulated:

Indicate the portion of the product that was manipulated. If the entire product was manipulated, select “entire product” and continue with question 36. If a portion of the product was removed and manipulated, select “portion of product” and continue with question 35.

Question 35: Was the unmanipulated portion of the product also infused?

Indicate “yes” if the unmanipulated portion of the product was also infused. Indicate “no” if the unmanipulated portion of the product was not infused.

Question 36: Was the same manipulation method used on the entire product / all portions of the product?

If the same manipulation was used on the entire product or all portions of the product, indicate “yes”. If different manipulation methods were used indicate “no”. All of the manipulations for each portion of the product should be reported in questions 37-55.

Question 37-55: Specify all methods used to manipulate the product:

Indicate the method(s) of manipulation. Answer each question as “yes” or “no” and do **not** leave any responses blank.

> **Steps in Manipulation**
> If the manipulation consists of several steps, individual steps do not need to be reported as separate manipulations. For example, washing that is part of CD34+ expansion does not need to be reported as a separate manipulation. Similarly, T-cell depletion that is part of expansion does not need to be reported.
> In the cases above, if T-cell depletion and/or washing are done as standalone manipulations, they should be reported.

Question 37: Cultured:

Indicate “yes” if the cells were placed in culture to increase in number (i.e. to expand) allowing for sufficient cells for infusion. Indicate “no” if the cells were not cultured.

Question 38: Induced cell differentiation:

Indicate “yes” if the cells were placed in culture to give rise to cellular elements with biological characteristics other than those of the cells being cultured (i.e. mesenchymal stromal cells cultured to make osteoblasts; pluripotent stem cells cultured to make neural cell precursors). Usually, the description of the process would include the term “differentiation of cells X into cells Y”. This scenario can be seen in regenerative medicine indications.

Question 39: Cell selection (positive or negative):

Indicate “yes” if the cellular product underwent positive selection to isolate the target cell population by using an antibody that specifically binds that population (e.g. CD3+ selection); or, if the product underwent negative selection which involves the depletion of all cell types except the cell population of interest. Indicate “no” if the product did not undergo positive or negative selection.

Question 40: Cell selection based on affinity to a specific antigen:

Indicate “yes” if the cellular product underwent selection to isolate the target population based on the ability of the target population to bind or recognize a specific antigen (e.g. a T cell population recognizing viral proteins or a protein associated with a cancer).

Question 41: Genetic manipulation (gene transfer / transduction):

Indicate “yes” if the cells were manipulated via gene transfer, a process by which copies of a gene are inserted into living cells in order to induce synthesis of the gene’s product; or transduction, a process by which foreign DNA is introduced into a cell by a virus or viral vector. These techniques deliberately alter the genetic material of an organism in order to make them capable of making new substances or performing new or different functions. If “yes” continue with question 43. Indicate “no” if the cells were not genetically manipulated and continue with question 51.

Question 42: Transfection:

Indicate “yes” if the product underwent transfection, a process of deliberately introducing naked or purified nucleic acids by viral or non-viral methods into eukaryotic cells. Indicate “no” if the product did not undergo transfection.

Question 43: Viral transfection:

Indicate “yes” if the product underwent viral transfection. Viral transfection occurs when there is gene transfer by infection of a cell with nucleic acid by a virus, followed by viral replication in the affected cell. Indicate “no” if the product did not undergo viral transfection.

Question 44: Lentivirus:

Indicate “yes” if a Lentivirus was used for the viral transfection. Lentiviruses are members of the genus of retroviruses that have long incubation periods and cause chronic, progressive, usually fatal disease in humans and other animals. Indicate “no” if a Lentivirus was not used for the viral transfection.

Question 45: Retrovirus:

Indicate “yes” if a Retrovirus was used for the viral transfection. Retroviruses are any group of RNA viruses that insert a DNA copy of their genome into the host cell to replicate. HIV is an example of a Retrovirus. Indicate “no” if a Retrovirus was not used for the viral transfection.

Question 46: Non-viral transfection:

Indicate “yes” if non-viral transfection was used to manipulate the product. Non-viral transfection is the process of deliberately introducing naked or purified nucleic acids into eukaryotic cells. Indicate “no” if non-viral transfection was not used to manipulate the cellular product.

Question 47: Transposon:

Indicate “yes” if transposons were used to manipulate the product. Transposons are discrete mobile sequences in the genome that can transport themselves directly from one part of the genome to another without the use of a vehicle such as phage or plasmid DNA. They are able to move by making DNA copies of their RNA transcripts which are then incorporated into the genome at a new site. Indicate “no” if the cellular product did not undergo non-viral transfection using transposons.

Question 48: Electroporation:

Indicate “yes” if electroporation was used to manipulate the product. Electroporation is a process of introducing DNA or chromosomes into cells using a pulse of electricity to briefly open the pores in the cell membranes. Indicate “no” if electroporation was not used to manipulate the product.

Questions 49-50: Other non-viral transfection:

Indicate “yes” if a different non-viral transfection method not previously listed was utilized. Specify the other non-viral transfection method in question 50. Indicate “no” if a different non-viral transfection method was not used.

Question 51: Gene editing:

Indicate “yes” if the cells underwent a type of genetic engineering in which DNA is inserted or removed from a genome using artificially engineered nucleases. Indicate “no” if the cells did not undergo gene editing.

Question 52: Specify gene:

Indicate which gene was used for the gene editing manipulation.

Question 53: Specify other genetic manipulation:

If the gene reported in Q52 was “other”, specify in question 53.

Questions 54-55: Other genetic manipulation:

Indicate “yes” if a different genetic manipulation not previously listed was used and specify in question 55.

Question 56: Were cells engineered to express a non-native antigen receptor?

Indicate “yes” if the cells underwent a type of genetic engineering in which a gene is transferred which codes for an antigen receptor other than one that may already be naturally present in the cell (e.g. T-cells have natural T-cell receptors [TCRs]; a transgenic TCR or a Chimeric Antigen Receptor [CAR] are non-native antigen receptors). Indicate “no” if the cells did not undergo transfer of such a gene.

Question 57: Specify the construct utilized:

Specify if a T-cell receptor or Chimeric Antigen Receptor (CAR) construct was used as part of the genetic manipulation process.

Question 58 & 59: Specify details of the CAR construct:

The CAR construct consist of several genes that can exert different functions, such as augment the immune response by co-stimulation, increase affinity, and increase the time it persists in the circulation without being cleared. The CAR construct information is usually unique and may influence its effect against the disease or the severity of side effects. Specify which construct(s) was used in the making of the Chimeric Antigen Receptor (CAR). If a construct was utilized that is not in the list, check “other construct” and specify in question 59.

For more information related to the different constructs and their functions, see this article: https://www.jci.org/articles/view/80010.

Questions 58-59 Reporting more than one CAR construct

FormsNet3SM application: Complete questions 58-59 for each CAR construct utilized by adding an additional instance in the FormsNet application.
Paper form submission: Copy questions 58-59 and complete for each CAR construct utilized.

Question 60 & 61: Was the product manipulated to recognize a specific target/antigen?

Indicate “yes” if the cells were cultured or engineered so that the majority of cells in the end product are able to recognize or bind to a chosen target (e.g. proteins from a virus or a protein from a tumor). Specify the target in question 61. Indicate “no” if this was not the case and continue with question 75.

Question 62 & 69: Specify targets specific to viral infections:

If the product was manipulated to recognize a specific target/antigen and the target is specific to viral infections, indicate the target(s) by selecting “yes” or “no” for each question. **Do not leave any responses blank.**

Question 70 & 72: Specify targets specify to tumors

If the product was manipulated to recognize a specific target/antigen and the target is specific to tumors, indicate the target(s) by selecting “yes” or “no” for each question. **Do not leave any responses blank.**

Question 73 & 74: Other target:

If the product was manipulated to recognize a specific target/antigen and the target is “other target”, select “yes” for question 73 and specify the target in question 74.

Question 75 & 76: Other cell manipulation:

If the method used to manipulate the product is “other cell manipulation”, select “yes” for question 75 and specify the manipulation in question 76.

Q77-85: Cell Product Analysis

Question 77: Was transfection efficiency done? (genetically engineered cells)

Indicate “yes” if transfection efficiency was determined on the genetically engineered cells. Indicate “no” if transfection efficiency was not determined and continue with question 81.

Question 78: Date:

Specify the date (YYYY-MM-DD) when the transfection efficiency was determined..

Question 79: Transfection efficiency:

Transfection efficiency is calculated as a percentage of transfected cells from all cells in the sample. There are a number of methods used to determine transfection efficiency including flow cytometry, fluorometry, microscopy, real-time quantitative PCR, etc.

Question 80: Was transfection efficiency target achieved?

Indicate “yes” if the transfection efficiency target was achieved. Indicate “no” if the transfection efficiency target was not achieved.

Question 81-83: Viability of cells:

If the viability of the cells was quantified, select “done” and report the date viability was tested in question 82 and the percentage of viable cells in question 83.

Question 84 & 85: Method of testing cell viability:

Indicate the method of testing viability.

> 7-AAD (7-aminoactinomycin D) and Propidium iodide are compounds that can stain dead cells but will not cross the membrane of living cells. Cytometric techniques are used to calculate the percentage of viable cells in a sample.
>
> Trypan Blue is a technique where the dead cells become stained when in contact with the compound, but living cells remain impermeable to the dye. Cells are counted under a microscope to determine the percentage of viable cells in a sample.

If both methods of viability testing are performed, report 7-AAD results. If the cell viability was tested using a different method, select “other method” and specify the method in question 85.

Q86-124: Product Infusion

Question 86: Date of this product infusion:

Report the date (YYYY-MM-DD) this product was infused. If the product was infused over multiple days, report the first date of infusion.

Question 87: Was the entire volume of product infused?

Indicate “yes” if the entire volume of the product received was infused and continue with question 90. Indicate “no” if only a portion of the product received was infused and continue with question 88.

Question 88 & 89: Specify what happened to the reserved portion:

Report if the product was “discarded,” “cryopreserved for future use,” or “other fate.” If “other fate” is selected, report the outcome of this product in question 89.

Question 90 & 91: Specify the route of product infusion:

Report the route by which the product was infused.

Intravenous refers to infusion into the veins – examples include infusion via central line or via catheter.
Intramedullary refers to infusion into the marrow cavity within a bone, such as directly into the left or right iliac crest.
Intraperitoneal refers to infusion within the peritoneal cavity.
Intra-arterial refers to infusion within an artery or arteries.
Intramuscular refers to infusion within a muscle.
Intrathecal refers to infusion within the cerebrospinal fluid at any level of the cerebrospinal axis, including injection into the cerebral ventricles.
Intraorgan refers to an infusion within an organ such as the heart, liver, lungs, etc.. Specify the site in question 92.
Locally in the tissue refers to an infusion in a restricted area of the body or in a tumor that cannot be classified as intraorgan.

If the route of infusion is not one of the above options, select “other route of infusion” and specify the infusion route in question 91.

Question 92 & 93: Specify the site of intraorgan administration of cells:

If the route of product infusion was intraorgan, specify the site of intraorgan administration. If the site of infusion is not in the option list, select “other site” and specify the site in question 93.

Question 94: Recipient weight used for this infusion:

Report the recipient’s actual body weight used for this infusion. This weight is usually documented on the infusion orders or admitting orders. Report weight to the nearest whole kilogram or pound (round up if 0.5 or greater). Do not report adjusted body weight, lean body weight, or ideal body weight.

Question 95: Recipient height at infusion:

Report the recipient’s height at infusion. This height is usually documented on the admitting orders. Report height to the nearest whole centimeter or inch (round up if 0.5 or greater).

> **!** **Questions 96-124 Reporting cell doses**
> Report the total number of cells (not cells per kilogram) contained in the product administered, not corrected for viability.

This section collects the total number of cells in a specific product that were infused. All the cells that were listed in question 31 are included here. Only respond to the cells that are applicable to this infusion.

Question 96 & 97: Total number of cells administered:

Report the total cell count contained in the product administered, not corrected for viability. If the type of cells are not specified or were unselected lymphocytes report the total number of cells present at time of the infusion.

Question 98 & 99: Lymphocytes (unselected) administered:

If yes, report the total number of lymphocytes administered in the product in question 99.

Question 100 & 101: CD4+ lymphocytes administered:

If yes, report the total number of CD4+ cells administered in the product in question 101. The lab report may display this value as CD3+CD4+.

Question 102 & 103: CD8+ lymphocytes administered:

If yes, report the total number of CD8+ cells administered in the product in question 103. The lab report may display this value as CD3+CD8+.

Question 104 & 105: Natural killer cells (NK cells) administered:

If yes, report the total number of natural killer cells (NK cells) administered in the product in question 105. NK cells are a type of cytotoxic lymphocyte critical to the innate immune system. They usually express CD56 on their cell surface.

Question 106 & 107: Dendritic cells / tumor cell hybridomas administered:

If yes, report the total number of dendritic cells or tumor cell hybridomas administered in the product in question 107. Dendritic cells are antigen-presenting cells (also known as accessory cells) of the immune system. Their main function is to process antigen material and present it on the cell surface to the T-cells of the immune system.

Question 108 & 109: Mesenchymal stromal stem cells (MSCs) administered:

If yes, report the total number of MSCs administered in the product in question 109. MSCs are multipotent stromal cells that can differentiate into a variety of cell types, including: osteoblasts (bone cells), chondrocytes (cartilage cells), myocytes (muscle cells) and adipocytes (fat cells).

Question 110 & 111: Unspecified mononuclear cells administered:

If yes, report the total number of unspecified mononuclear cells administered in the product in question 111. A mononuclear cell is defined as any blood cell with a round nucleus (i.e., a lymphocyte, a monocyte, or a macrophage). These blood cells are a critical component in the immune system to fight infection and adapt to intruders.

Question 112 & 113: Endothelial progenitor cells administered:

If yes, report the total number of endothelial progenitor cells (EPCs) in the product in question 113. EPC is a term that is applied to multiple different cell types that play roles in the regeneration of the endothelial lining of blood vessels.

Question 114 & 115: Human umbilical cord perivascular (HUCPV) cells administered

If yes, report the total number of human umbilical cord perivascular (HUCPV) cells in the product in question 115. HUCPV cell is a term that is applied to mesenchymal, non-hematopoietic, non-endothelial cells that are isolated from the umbilical cord.

Question 116 & 117: Cardiac progenitor cells administered:

If yes, report the total number of cardiac progenitor cells administered in the product in question 117. Cardiac progenitor cells are tissue-specific stem progenitor cells within the heart.

Question 118 & 119: Islet cells administered:

If yes, report the total number of islet cells administered in the product in question 119. Islet cells are found in the pancreas. The pancreas contains clusters of cells that produce hormones and these clusters are known as islets.

Question 120 & 121: Oligodendrocytes administered:

If yes, report the total number of oligodendrocytes administered in the product in question 121. Oligodendrocytes are glial cells similar to an astrocyte but with fewer protuberances. These cells produce myelin in the central nervous system.

Question 122-124. Other cell type administered:

If a different cell type not previously mentioned was infused, report the total number administered in the infusion in question 123. Specify the other cell type in question 124.