|  |  |
| --- | --- |
| Study Treatment Category | Hematopoietic Progenitor Cell, Apheresis (HPC-A)  Hematopoietic Progenitor Cell, Marrow (HPC-M)  Hematopoietic Progenitor Cell, Cord Blood (HPC-C) |

|  |  |  |
| --- | --- | --- |
| Manufacture Information | | |
| Date of Study Treatment Manufacture  Record the date of study treatment manufacture using this format (DD‑MON‑YYYY). If study treatment manufacture occurred a significant amount of time prior to the start of the study, it is acceptable to have an incomplete date. | \_\_ \_\_ - \_\_ \_\_ \_\_ - \_\_ \_\_ \_\_ \_\_ | |
| Findings About Study Treatment | Result | Unit |
| Cells | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| CD34 | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Colonies Formed | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Globin Chain of Interest, Qualitative | Positive  Negative |  |
| Globin Chain of Interest, Quantitative | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Additional Drug Product Potency Assays | Yes  No |  |
| If Yes, Specify |  | |

|  |  |
| --- | --- |
| Study Treatment Subcategory | Integrating Vector  Gene Editing Nuclease  Stem Cell Expansion |

If Integrating Vector, complete this section only.

|  |  |  |
| --- | --- | --- |
| Findings About Study Treatment | Result | Unit |
| Type of Integrating Vector | Retrovirus  Lentivirus  Other  If Other, Specify: |  |
| Study Treatment Vector Copy Number | \_\_ \_\_ \_\_ \_\_. \_\_ \_\_ | *<From UNIT codelist>* |
| Integrating Vector Positive Cells/Cells | \_\_ \_\_ . \_\_ \_\_ | % |
| Study Treatment Vector Copy Number/Cell | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |

If Gene Editing Nuclease, complete this section only.

|  |  |  |
| --- | --- | --- |
| Findings About Study Treatment | Result | Unit |
| Type of Editing | CRISPR-Cas 9  Zinc Finger Nucleases  Transcription Activator-Like Effector Nucleases  Cytosine Base Editing  Other  If Other, Specify: |  |
| Mode of Nuclease Delivery | mRNA by Electroporation  Ribonucleoprotein by Electroporation  Adeno-associated Virus  Other  If Other, specify: |  |
|  |  |  |
| On-target Indels | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Off-target Indels | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Conversion | \_\_ \_\_ . \_\_ \_\_ | % |