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

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| --- |
| Manufacture Information |
| Date of Study Treatment ManufactureRecord 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[ ]  OtherIf 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[ ]  OtherIf Other, Specify: |  |
| Mode of Nuclease Delivery | [ ]  mRNA by Electroporation[ ]  Ribonucleoprotein by Electroporation[ ]  Adeno-associated Virus[ ]  OtherIf Other, specify: |  |
|  |  |  |
| On-target Indels | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Off-target Indels | \_\_ \_\_ \_\_ . \_\_ \_\_ | *<From UNIT codelist>* |
| Conversion | \_\_ \_\_ . \_\_ \_\_ | % |