**Key Requirements and Definitions for Chain of Identity Identifier**

The origin of biological starting material is critical to the safe manufacture of Cell and Gene Therapies (CGT) of which there are two modalities, Autologous and Allogeneic. In both autologous and allogeneic therapies, the identification of the starting material source and tracking and tracing the resultant drug product to the intended recipient is critical to the success and safety of the CGT.

In the context of CGT, Chain of Custody (COC) is a series of events within a supply chain to ensure the correct drug product is given to the correct recipient. These events are often performed by different individuals or organizations. These individuals or organizations receive, transport, modify, and deliver biological material. Key to the preservation of chain of custody is knowing with absolute certainty the identity of the person who provided the critical starting material for the CGT. The association of donor biological material with intended recipient(s) throughout the supply chain is described as Chain of Identity (COI). As both COI and COC are critical to the safety of CGT, it follows that that COI and COC identifiers, processes, and records are essential to demonstrating adequate control of biological material.

There is an increasing number of CGT supply chains. Additionally, COC and COI of CGT processes lack standardized definitions and strategies. Manufacturers and stakeholders may interpret the CGT regulations differently. As a result, each CGT supply chain may use different identifiers, tracking systems, and processes. Although effective on their own, implementing several systems at a single health care institution can be time consuming and challenging to implement effectively. Consequences include risk to patient safety, increased compliance risk, difficulty in scaling the therapies, and incompatibility between stakeholder implementation.

A matrix team of experts designed these definitions and key requirements for a COI identifier. The use of this COI standard enables the consistent and efficient tracking of CGT throughout the processes of collection, production, and delivery of medicinal product.

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**COI Identifier:** A unique end-to-end code used to identify the cell or gene therapy that enables a bidirectional link between the donor(s) and the intended recipient(s). The systematic exchange of the COI identifier along with labeling and verification steps (manual and electronic) maintains the COC.

**Chain of Identity (COI):** The permenant and transparent association of a cell or gene therapy’s unique identifiers from procurement of tissue or cells throughout the full products(s) lifecycle including post treatment monitoring.

**Chain of Custody (COC):** Concurrent, permanent, auditable documentation illustrating the guardianship of a cell or gene therapy product from its origin through its final disposition.

What are the key requirements of a COI identifier for an autologous or directed allogeneic therapy?

* Globally unique and immutable
* Enable a linkage among critical pieces of information throughout the lifecycle of the therapy
* Compatible with Automatic Identification and Data Capture (AIDC) technology while also having a manual entry possibility, supported by additional features to reduce risk of data corruption
* Have a standard format to allow compatibility with resources or systems of parties throughout the supply chain
* Human readable
* Maximum possible length remains functional and useful (i.e., will still fit on limited real estate in-process and final product labels)

**Globally unique and immutable**

The COI identifier shall be a distinctive ID that is assigned once and not reused. The COI identifier shall be unique across all entities. The COI identifier issuing agency(ies) shall ensure global uniqueness i.e., following ISO/IEC 15459.

The COI identifier shall not be changeable. It shall be created once and forever associated with the donor(s), recipient(s), and therapy(ies). The COI identifier could have additional characters/suffixes added in order to facilitate association with the therapy throughout the lifecycle as needed.

**Enable a linkage among critical pieces of information throughout the lifecycle of the therapy**

The critical information could be stored in a central repository if necessary or located within a single company or entity. Participants along the network shall be able to read the COI identifier and have the resources to interpret relevant portions of linked information.

The COI identifier shall be associated with a patient throughout the patient's lifetime.

There may be a need for a COI identifier to be assigned in cases where the specific therapy is unknown and tracking is necessary.

**Compatible with Automatic Identification and Data Capture (AIDC) technology while also having a manual entry possibility, supported by additional features to reduce risk of data corruption**

The COI identifier will need to be compatible with AIDC technology so that digital information is able to be captured and shared. References and standards for AIDC can be found at <https://www.aimglobal.org/about.html> and <https://www.iso.org/committee/45332/x/catalogue/>

**Have a standard format to allow compatibility with resources or systems of parties throughout the supply chain**

The COI identifier shall have guidelines around formatting so that the identifier can be used throughout the supply chain within various different software and manual applications

All parties throughout the supply chain shall be able to use and read the COI identifier.

**Human readable**

The COI identifier shall have a format that can be readable by the human eye. The length of the COI shall be of appropriate length for reasonable human comprehension.

**Maximum possible length remains functional and useful (i.e. will still fit on limited real estate in-process and FDP labels)**

The COI identifier needs to fit on, be affixed, and remain readable on all of the required labels that may be necessary throughout the supply chain.