IMPLEMENTATION GUIDE

Using the ISBT 128 Chain of Identity (CoI) Identifier

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance for the use of the Chain of Identity Identifier Data Structure [040] and the Chain of Identity Identifier data element ChainOfIdentityIdentifier in compliance with the *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028).

1.2 Scope

This document is a supplement to the ISBT 128 Standard Technical Specification. It provides guidance for cellular therapy collection and manufacturing facilities in the use of the Chain of Identity Identifier Data Structure [040] and the Chain of Identity Identifier data element ChainOfIdentityIdentifier. The CoI Identifier is used to communicate across the supply chain and maintain the chain of custody as medical products of human origin (MPHO) collected for cellular therapy manufacturing move through the ecosystem.

This guidance focuses on the use of the CoI Identifier in the context of cellular therapy manufacturing, but the principles can be applied to other sectors of MPHO.

This document also includes content for software developers.

This document does not address scenarios where one or more collections are manufactured into therapies for more than one patient.

The scenarios described in this document illustrate the need for the CoI Identifier to be available at all steps in the process, from the point of collection through the application of the given therapy to a specific patient. This document does not address any other aspects of final drug product labels.

1.3 Intended Audience

The intended audience of this document is staff at cellular therapy collection and processing facilities, clinical trials' sponsors, commercial manufacturers of cellular therapy products, laboratory staff, staff responsible for the clinical application of products carrying a CoI Identifier, software developers, and label/software vendors.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)
ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004)
ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing (ST-018)
ISBT 128 Standard for XML Electronic Messaging – Standardized XML Elements for Medical Products of Human Origin (ST-020)
ISBT 128 Standard Use of Clinical Trials Product Description Codes (PDCs) (ST-022)

ISBT 128 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier (ST-026)
ISBT 128 Standard ISBT 128 Dictionary of Standard Data Elements (ST-027)
ISBT 128 Standard Chain of Identity (CoI) Identifier (ST-028)
Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)
Implementation Guide: ISBT 128 Facility Identification Number (IG-034)

1.5 Other References

Standards Coordinating Body (SCB) website:
(https://www.standardscoordinatingbody.org)

ISO/IEC 15459-4-2014(E): Information technology – Automatic identification and data capture techniques – Unique Identification—Part 4 Individual products and product packages

Implementation Guide: Applying ISBT 128 Labels to Collection Products for Further Manufacture (IG-045)

ICCBBA Website (www.isbt128.org)

1.6 Overview

This document provides guidance on the use of the ISBT 128 Standard Chain of Identity Identifier and data element as specified in ST-028. Utilization of the CoI Identifier for a given therapy is a collaborative effort between the collection facility, manufacturer, and any other parties in the supply chain for a given therapy. This document includes information on items for consideration when implementing the CoI Identifier. In all cases, the specifications detailed in ISBT 128 Standard Chain of Identity (CoI) Identifier (ST-028) apply.

This guidance has been prepared in collaboration with industry stakeholders through ICCBBA's Cellular Therapy Coding and Labeling Advisory Group (CTCLAG), the Standards Coordinating Body (SCB), BioPhorum, and the Deloitte Industry Working Group.

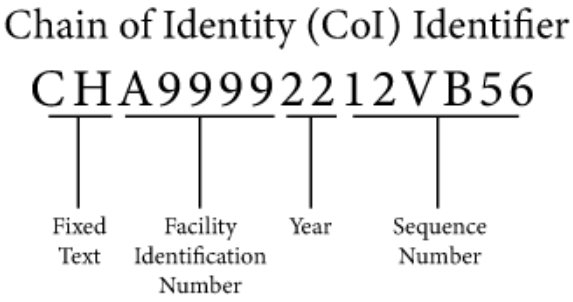
Contact the ICCBBA helpdesk (support@isbt128.org) with questions.

As a convenience for the reader, Figure 1 depicts an ISBT 128 hybrid label, designed for collection products for cellular therapy manufacturing, with an ISBT 128 CoI Identifier and Figure 2 depicts the structure of the ISBT 128 CoI Identifier. The reader should refer to *ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing* (ST-018) for details on the hybrid label format and *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028) for details on the structure of the CoI Identifier.

Figure 1 - Example of Hybrid Collection Label with ISBT 128 CoI Identifier Provided by Cellular Therapy Manufacturer

For additional label examples, refer to *ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing* (ST-018)

Figure 2 - ISBT 128 CoI Identifier Data Structure



For additional details, refer to *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028).

2 Using the CoI Identifier to Link Collection(s) Associated with a Given Therapy.

The CoI Identifier can be used to link collections/starting material for cellular therapy manufacturing with a given therapy. As defined in *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028), a given therapy is a course of cell and/or gene therapy treatment(s) that may result from the administration of a single or multiple product(s) for the *same patient* from the starting material derived from a single or multiple patient/donor collection(s). *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028) also contains definitions for Chain of Custody, Chain of Identity, and Chain of Identity Identifier.

The CoI Identifier does not replace the Donation Identification Number on collection products but is an additional identifier that is the same on all donations, autologous and/or allogeneic, associated with a given therapy. The CoI Identifier can be used to link collections to therapeutic doses in one-to-one, one-to-many, many-to-one, and many-to-many relationships. The CoI Identifier can also be associated with “backup” collections that may be needed for the given therapy. If “backup” material could be used for something other than the given therapy, then a CoI Identifier would not be applied to this collection until it is associated with the given therapy.

The CoI Identifier will typically be assigned once the scope of a given therapy is defined and before the initial starting material is collected. However, in instances where the starting material is already collected, such as a frozen cord blood unit, the CoI Identifier may be assigned once the starting material for the given therapy is identified. In these instances, alternative methods of physically associating the CoI Identifier with the collected product may be needed. For example, supplemental tie tags are often added to frozen cord blood units. The CoI Identifier should also be unambiguously linked with the Donation Identification Number in accompanying materials.

The CoI Identifier may be assigned by any entity involved in the collection or manufacturing of the given therapy. The entities involved in a given therapy should have an agreement regarding both the scope of the given therapy and who is responsible for allocating the CoI Identifier that will be used throughout the lifecycle of the biological material. See Section 3, Assignment of the CoI Identifier by an Entity for additional information regarding the agreement.

The scenarios in this section are for illustrative purposes. The information contained in the list below is common to all scenarios.

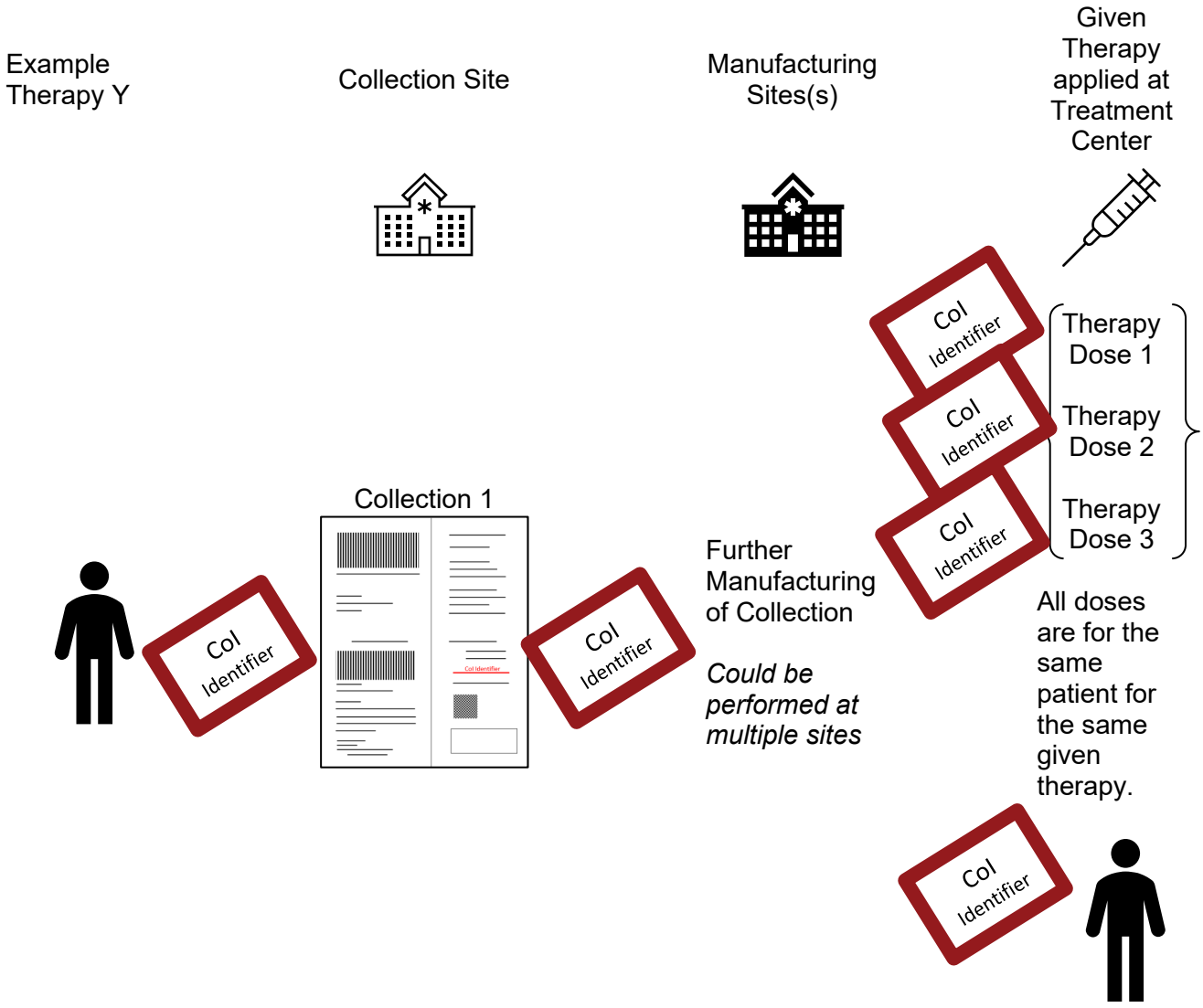
- The MPHO starting material collected for cellular therapy manufacturing is not limited to apheresis collections.
- Each collection is to be assigned a unique Donation Identification Number (DIN). For more information on the use of the DIN, see *ISBT 128 Standard Technical Specification* (ST-001)
- All entities involved in a given therapy for a specific patient should use the same CoI Identifier throughout the lifecycle of the biological material.
- The manufacturing steps could be performed at one or more than one facility.
- The CoI Identifier should be available at all steps in the process, including application of the given therapy to a specific patient, to maintain and document the chain of custody.

2.1 One-to-One Scenario

This diagram depicts the use of the CoI Identifier to link elements in a one collection to one therapeutic dose scenario. **For a given therapy, the same CoI Identifier is used throughout the lifecycle of the biological material.**

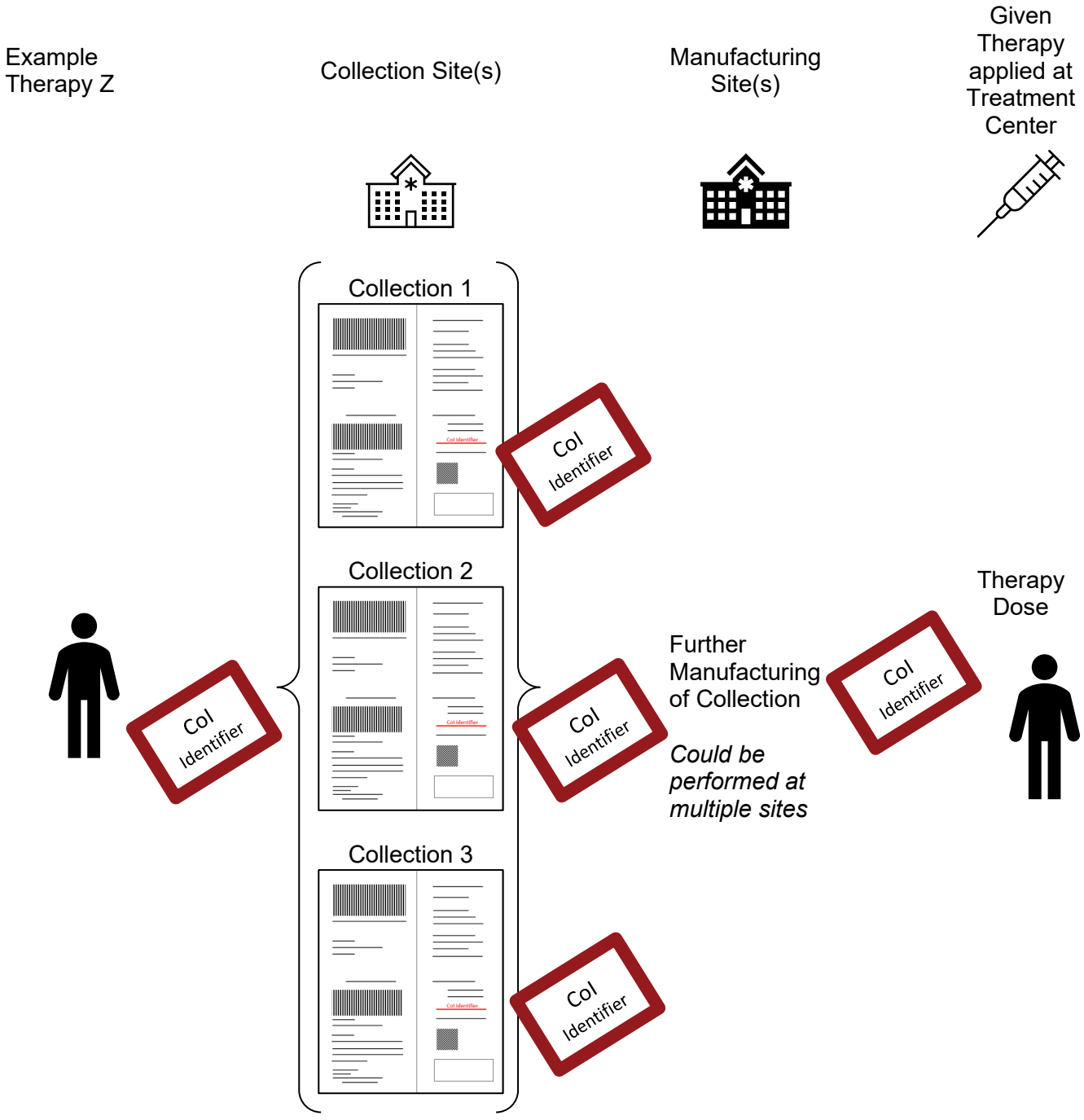
2.2 One-to-Many Scenario

This diagram depicts the use of the CoI Identifier to link elements in a one collection to multiple therapeutic doses scenario. **For a given therapy, the same CoI Identifier is used throughout the lifecycle of the biological material.**



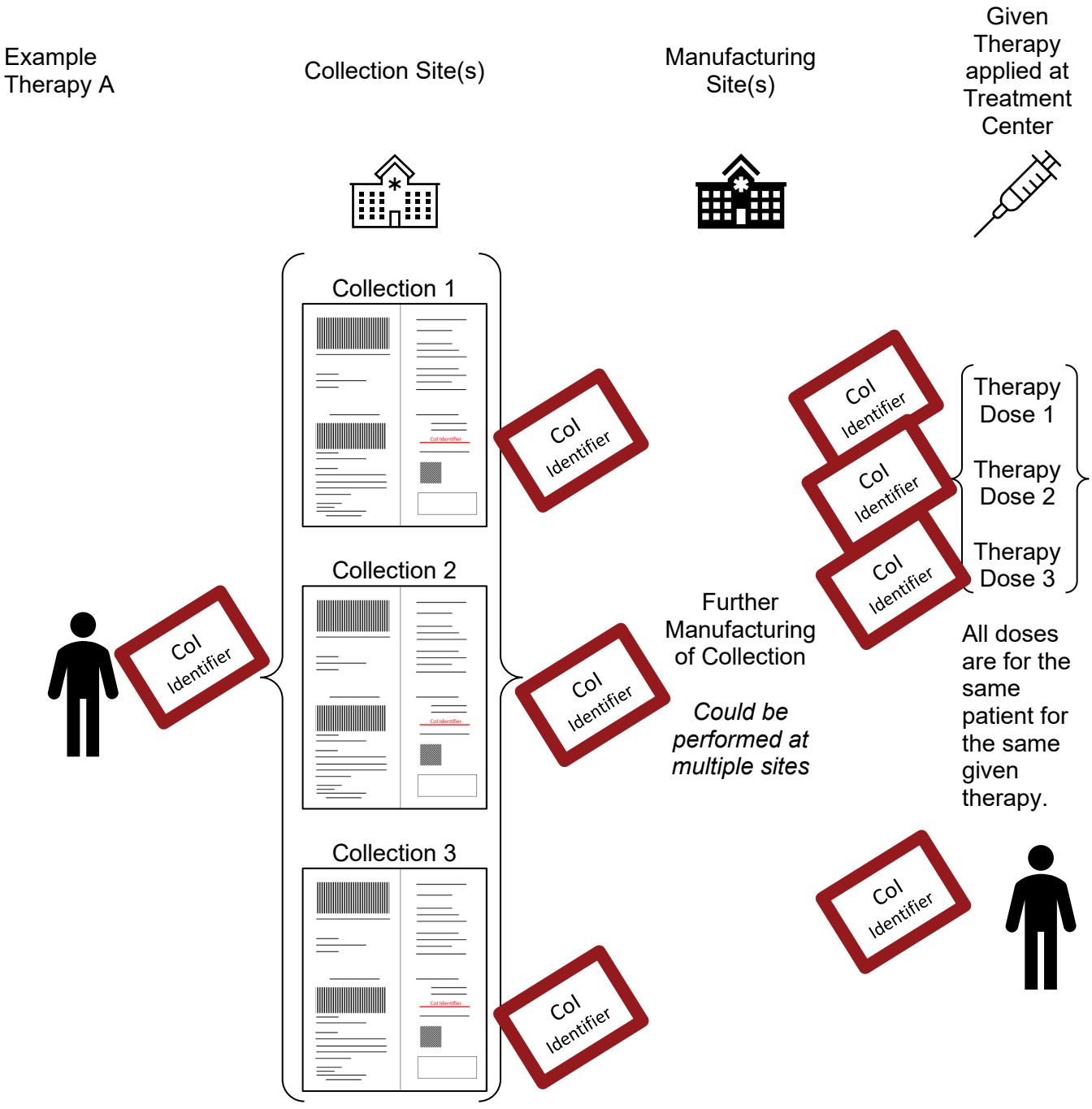
2.3 Many-to-One Scenario

This diagram depicts the use of the CoI Identifier to link elements in a multiple collection to one therapeutic dose scenario. Each collection will be assigned a unique Donation Identification Number (DIN). **For a given therapy, the same CoI Identifier is used throughout the lifecycle of the biological material.**



2.4 Many-to-Many Scenario

This diagram depicts the use of the CoI Identifier to link elements in a multiple collection to a multiple therapeutic dose scenario. Each collection, which could be from a variety of MPHO sources, will be assigned a unique Donation Identification Number (DIN). **For a given therapy, the same CoI Identifier is used throughout the lifecycle of the biological material.**



3 Assignment of the CoI Identifier by an Entity

The CoI Identifier can be allocated by any ICCBBA registered entity. Registration is necessary in order to obtain a Facility Identification Number (FIN) that is a critical component of the globally unique ISBT 128 CoI Identifier. An agreement between the entities involved in a given therapy should define who is responsible for allocating the CoI Identifier and the scope of a given therapy to be associated with a CoI Identifier.

The agreement can be documented in a variety of ways. Potential documents include but are not limited to: Site Training documents for clinical trial/commercial activities, Pharmacy Manual, and/or legal contract. The agreement could also be added to existing agreements between the entities.

The CoI Identifier should be available to all entities across the supply chain ecosystem to maintain and document the chain of custody.

3.1 Assignment of the CoI Identifier by a Sponsor Entity

If the CoI Identifier is allocated by the sponsor entity, it should be available to the collection facility prior to the collection of starting material. If starting material, such as a frozen cord blood unit, is already collected, then the CoI Identifier can be assigned at the point of association of the existing starting material with a given therapy.

3.2 Assignment of the CoI Identifier by a Manufacturing Entity

If the CoI Identifier is allocated by the manufacturing entity, it should be available to the collection facility prior to the collection of starting material. If starting material, such as a frozen cord blood unit, is already collected, then the CoI Identifier can be assigned at the point of association of the existing starting material with a given therapy.

3.3 Assignment of the CoI Identifier by a Collection Entity

If the CoI Identifier is allocated by the collection entity, it should be available to the sponsor/manufacturing entity prior to the collection of starting material. If starting material, such as a frozen cord blood unit, is already collected, then the CoI Identifier may be assigned at the point of association of the existing starting material with a given therapy.

4 Using the CoI Identifier on a Non-ISBT 128 Label

When the ISBT 128 CoI Identifier is utilized on the hybrid label defined in *ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing* (ST-018) it is encoded in the 2-D Data Matrix symbol on the label. Only ISBT 128 standardized data structures shall be encoded in this 2-D Data Matrix symbol.

If the ISBT 128 CoI Identifier is utilized on a non-ISBT 128 label, it may be encoded with either a linear bar code or 2-D Data Matrix symbol as defined in ST-028. When both ISBT 128 and non-ISBT 128 symbologies are present on a label, the text “ISBT 128” may be printed to identify the location of ISBT 128 information. The requirements for data identifiers within the bar code and a check sum to facilitate verification of manual entry still apply. ISBT 128 information and non-ISBT 128 information should not be mixed in a single 2-D Data Matrix symbol. See *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014) for additional information.

5 Becoming a CoI Identifier Issuing Organization

ICCBBA is a recognized Issuing Agency of unique identifiers under ISO/IEC 15459. This allows ICCBBA to maintain and assign globally unique identifiers to registered organizations.

The unique identifier assigned to an Issuing Organization is a Facility Identification Number (FIN). The FIN is a key component in a variety of ISBT 128 data structures, including the Donation Identification Number (DIN) and CoI Identifier. See *Implementation Guide ISBT 128 Facility Identification Number* (IG-034) for other applications of the FIN.

Each facility with a FIN then becomes an Issuing Organization for the ISBT 128 data structures that utilize the FIN. A facility must be currently licensed with ICCBBA to issue ISBT 128 CoI Identifiers.

5.1 Steps to Become a CoI Identifier Issuing Organization

5.1.1 ICCBBA licensed facilities

- You may proceed to issue CoI Identifiers following *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028)
- Notify ICCBBA of your intent to issue CoI Identifiers on your annual return form available on the ICCBBA website https://www.isbt128.org/registration-licensing

5.1.2 ICCBBA non-licensed facilities

- Complete the facility registration form, available on the ICCBBA website https://www.isbt128.org/registration-licensing
- Indicate your MPHO area (cellular therapy) as well as your intent to assign CoI Identifiers.
- Submit the form following the directions on the website.

5.1.3 Maintain ICCBBA licensed status

- Complete an annual return form each year.
- Changes to your organization may also be submitted at any point during the year by submitting an update to your facility's contact information.

6 Electronic Transmission of the CoI Identifier

In order to leverage ISBT 128 data structures in software, software vendors that support the use of ISBT 128 data structures are required to be licensed with ICCBBA. This section contains notes for software developers.

As previously stated, the CoI Identifier may be available in eye-readable, linear bar codes, or 2-D symbols on MPHO labels. When the ISBT 128 CoI Identifier is utilized on the hybrid label defined in *ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing* (ST-018) it is encoded in the 2-D Data Matrix symbol on the label. If the ISBT 128 CoI Identifier is utilized on a non-ISBT 128 label, it may be encoded with either a linear bar code or 2-D Data Matrix Symbol as defined in ST-028. Data identifiers are used within bar codes to designate which data structure the bar code contains. The data identifiers for the CoI Identifier are &/. The eye-readable presentation of the CoI Identifier will include a boxed manual entry checksum as specified in *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028).

When encoded in an electronic message, the checksum, and data identifier for the CoI Identifier are not present. In lieu of these elements, data element tags are used to designate discrete data elements within an electronic message. The XML element tag associated with the CoI Identifier is ChainOfIdentityIdentifier. The full definition of the Chain of Identity Identifier data element may be found in *ISBT 128 Standard ISBT 128 Dictionary of Standard Data Elements* (ST-027).

The most common use case for an electronic message containing the CoI Identifier is within an MPHO product XML element which is intended to provide the data set associated with a single MPHO product, identified by the MPHO unique identifier as defined in *ISBT 128 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier* (ST-026), for transfer throughout the supply chain e.g., to/from the collection site, manufacture site, or a health care organization that will distribute the cellular therapy product. The CoI Identifier should be encoded within the MPHO product XML element. An example can be found in Appendix A Sample MPHO Product XML Elements using the CoI Identifier.

Further information on electronic messaging of ISBT 128 information is available in the *ISBT 128 Standard for XML Electronic Messaging – Standardized XML Elements for Medical Products of Human Origin* (ST-020) and *ISBT 128 Dictionary of Standard Data Elements* (ST-027).

This document should be reviewed in the context of *ISBT 128 Standard Technical Specification* (ST-001), and the additional references found in this section.

Appendix A: Sample MPHO Product XML Elements using the ISBT 128 CoI Identifier

Example XML Message
An example message is shown below. (Some optional fields have been omitted.)

<MPHOProduct xsi:schemaLocation="https://www.isbt128.org/uri/MPHOProduct.xsd">
<MPHOUniqueIdentifier Identifier="https://www.isbt128.org/uri/MPHOUniqueIdentifier"
value="W0000S1292W000023123456000000"/>
<DonationIdentificationNumber
Identifier="https://www.isbt128.org/uri/DonationIdentificationNumber"
value="W000023123456"/>
<CollectionDateTime Identifier="https://www.isbt128.org/uri/CollectionDateTime" value="2023-03-02T14:49:32-06:00"/>
<ProductDescriptionCode Identifier="https://www.isbt128.org/uri/ProductDescriptionCode"
value="S1292"/>
<CollectionType Identifier="https://www.isbt128.org/uri/CollectionType" value="1"/>
<DivisionIdentifier Identifier="https://www.isbt128.org/uri/DivisionIdentifier" value="000000"/>
<ExpirationDateTime Identifier="https://www.isbt128.org/uri/ExpirationDateTime" value="2023-09-09T20:49:32"/>
<ChainOfIdentityIdentifier Identifier="https://www.isbt128.org/uri/ChainOfIdentityIdentifier"
value= "CHW00002312VB56"/>
</MPHOProduct>

END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification
ST-018 ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing
ST-020 ISBT 128 Standard for XML
ST-022 ISBT 128 Standard Use of Clinical Trials Product Description Codes (PDCs)
ST-026 ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier
ST-027 ISBT 128 Dictionary of Standard Data Elements
ST-028 ISBT 128 Standard Chain of Identity Identifier
IG-045 Applying ISBT 128 Labels to Collection Products for Further Manufacture

