ISBT 128 STANDARD

Use of Clinical Trials Product Description Codes (PDCs)

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1 Introduction

1.1 Purpose

This document is intended to provide guidance on the use of Clinical Trials Product Description Codes (PDCs).

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides guidance on the use of Clinical Trials PDCs and describes the structure of the Clinical Trials PDC Database.

1.3 Intended Audience

The intended audience of this document is staff at clinical trials facilities (managers, information technology, quality, validation, and laboratory), sponsors, and any other organization using these identifiers.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004)

ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO (ST-017)

1.5 Other Reference

ICCBBA Website (www.iccbba.org)

Implementation Guide: Product Coding [Data Structure 003 and 032] - Cellular Therapy (IG-022)

Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)

1.6 Background

In past years, some clinical trials facilities have already started using the ISBT 128 Standard. ICCBBA had previously recommended using local/facility-defined codes for clinical trials products if a suitable international code is not available. However, it was pointed out that it is preferable not to use local codes because they are not globally unique, and separate study sponsors could inadvertently use the same local codes. Consequently, facilities could receive different products labeled with the same code.

To address this concern, and avoid having to assign international terminology to a wide range of products in clinical trials, the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) approved to issue a new category of PDCs specifically for clinical trials products and to create a separate database for registering and managing these PDCs.

The purpose of this new category and supporting database is to ensure that each PDC is assigned to only one organization thus preventing duplication of a Clinical Trial PDC on a global basis.

Internationally standardized terminology will not be issued for this purpose. Facilities using Clinical Trials PDCs will have control over the eye-readable text on the product label.

Organizations wishing to use these PDCs will need to become licensed with ICCBBA and be assigned a Facility Identification Number (FIN). They could then request an allocation of Clinical Trials PDCs.

2 Clinical Trials PDC Database

2.1 Purpose

The Clinical Trials PDC Database provides a mechanism to identify the organization responsible for a specific Clinical Trials PDC.

The Clinical Trials PDC Database is separate and independent from the existing ISBT 128 Product Description Code Database.

It is freely accessible and is published on the ICCBBA website in XLSX and XML formats.

2.2 Structure

The Clinical Trials PDC Database is a version-controlled document.

The fields that comprise the database are the following: Clinical Trials PDC, FIN, Code Date, and Retire Date. See Table 1 below.

Table 1 Structure of the Clinical Trials PDC Database

Field name	Field type	Field size	Description of Information in this field
ClinicalTrialsPDCs	Short Text	5	Key field that uniquely identifies the product.
FIN	Short Text	5	The Facility Identification Number of the organization responsible for a specific Clinical Trials PDC.
CodeDate	Date/Time		Date the product was entered into the database. ISO 8601-2004 extended numeric format [YYYY]-[MM]-[DD].
RetireDate	Date/Time		Date on which the PDC was retired. The field is not populated for active codes. ISO 8601-2004 extended numeric format [YYYY]-[MM]-[DD].

2.2.1 Clinical Trials PDCs

Clinical Trials PDCs are globally unique and assigned by ICCBBA to clinical trials facilities, sponsors or other organizations that wish to use these PDCs.

Clinical Trials PDCs are not associated with ISBT 128 Standard Terminology since they are intended for clinical trials products.

Clinical Trials PDCs shall be assigned a five-character code beginning with the uppercase letter Y, with an uppercase alpha character in position 2, and numeric characters in positions 3 to 5. Examples of possible codes include YA123, YB456, YX789, and YZ999.

Clinical Trials PDCs shall be assigned in sequential order.

The reserved range allows for the assignment of up to 26,000 codes.

2.2.2 FIN (Facility Identification Number)

The FIN field contains the Facility Identification Number of the registered facility that requested and has been assigned a Clinical Trials PDC. A single FIN can be associated with multiple PDCs.

2.2.3 Code Date

The Code Date field contains the date on which a Clinical Trials PDC was entered into the database. Code Dates are recorded in the ISO 8601-2004 extended numeric format [YYYY]-[MM]-[DD].

2.2.4 Retire Date

The Retire Date field contains the date on which a Clinical Trials PDC was retired. Retire Dates are recorded in the ISO 8601-2004 extended numeric format [YYYY]-[MM]-[DD].

3 Use of Clinical Trials PDCs

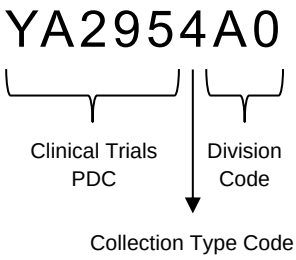
Clinical Trials PDCs are standardized global identifiers allocated by ICCBBA, which may be used by organizations licensed with ICCBBA, including clinical trials facilities, clinical trial sponsors, and cell and gene therapy manufacturers.

The *ISBT 128 Technical Specification* (ST-001) contains the specifications for encoding Clinical Trials PDCs within the Product Code [Data Structure 003] and the Processor Product Identification Code [Data Structure 034].

The encoding and interpretation of “tds” within the Product Code [Data Structure 003] shall be the same as for cellular therapy products (S codes). Refer to the *ISBT 128 Standard Labeling of Cellular Therapy Products* (ST-004) for additional information.

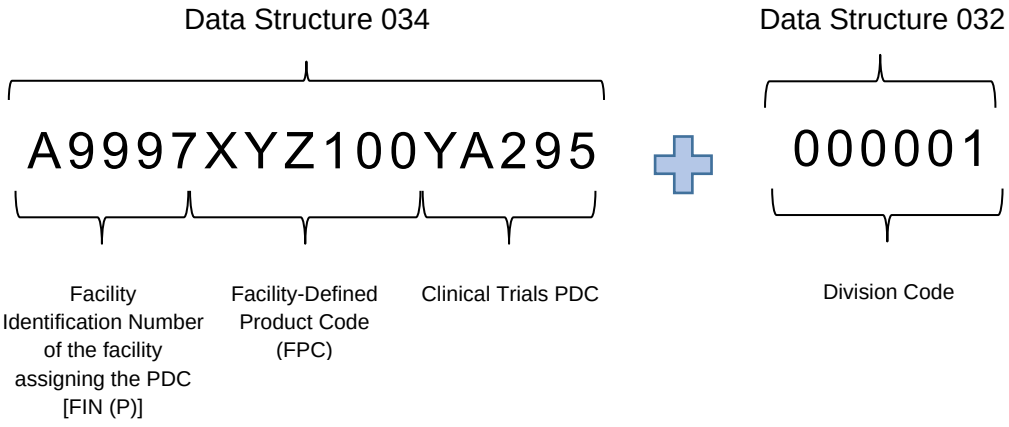
Figure 1 shows an example of the information encoded within the Product Code [Data Structure 003]: Clinical Trials PDC, Collection Type Code, and Division Code.

Figure 1 Information encoded within Product Code [Data Structure 003]



When the Processor Product Identification Code [Data Structure 034] is used to encode a Clinical Trials PDC—along with the Facility Identification Number of the facility assigning the PDC [FIN (P)] and the Facility-Defined Product Code (FPC)—it shall be used in conjunction with the Product Divisions [Data Structure 032]. Figure 2 shows an example of the information encoded within these data structures.

Figure 2 Information encoded within Processor Product Identification Code [Data Structure 034] and Product Divisions [Data Structure 032]



A Clinical Trials PDC may be retired when it is no longer needed because the clinical trial has been approved or it has ended. Facilities may request ICCBBA to retire a Clinical Trials PDC but it is not required.

3.1 Traceability

To support the traceability of medical products of human origin (MPHO), the following ISBT 128 data elements are essential and required to appear on ISBT 128 labels:

- Donation Identification Number (DIN)
- Product Description Code (PDC)
- Division Code (DIV)

In addition, the Processing Facility Identifier [FIN(P)] may be required for unique identification in some circumstances, and for some products such as medical devices containing an MPHO component.

These data elements can be encoded within data structures which may appear on an ISBT 128 label in the following combinations:

- Donation Identification Number [Data Structure 001] in conjunction with the Product Code [Data Structure 003].

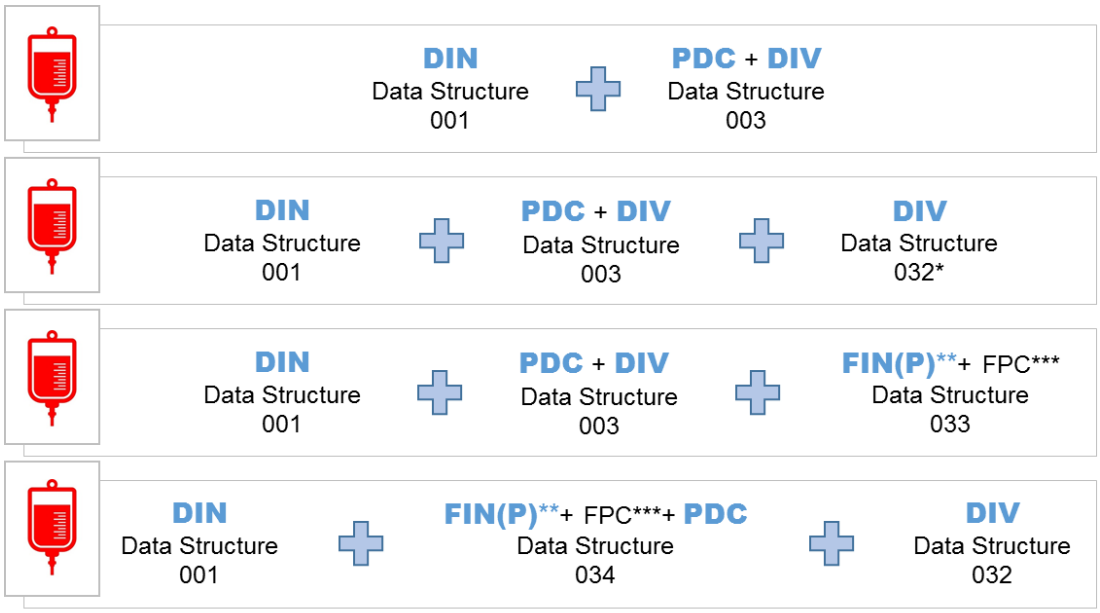
  When the Product Code [Data Structure 003] is used in conjunction with the Product Divisions [Data Structure 032]—to encode a large number of product divisions—the Product Divisions [Data Structure 032] becomes part of the unique identification of a product and is essential for traceability. Refer to the *Implementation Guide: Product Coding [Data Structure 003 and 032] - Cellular Therapy* (IG-022) for guidance on how to use these data structures.

- Donation Identification Number [Data Structure 001] in conjunction with the Product Code [Data Structure 003] and the Processing Facility Information Code [Data Structure 033]. Refer to the *Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* (IG-031) for an explanation of when the FIN(P) is required for traceability.

- Donation Identification Number [Data Structure 001] in conjunction with the Processor Product Identification Code [Data Structure 034] and the Product Divisions [Data Structure 032]. Refer to the *ISBT 128 Standard Coding and Labeling of Medical Devices Containing MPHO* (ST-017) for specifications on the use of these data structures.

Figure 3 illustrates the ISBT 128 essential data elements in the data structures and combinations referred above.

Figure 3 ISBT 128 Essential Data Elements Encoded in Data Structures



*Data Structure 032 can be used in conjunction with Data Structure 003 to encode a large number of product divisions
**FIN(P) is required for some products such as medical devices containing an MPHO component
***FPC is the acronym for Facility-defined Product Code (non-essential data element)

Additionally, ISBT 128 essential data elements—DIN, PDC, DIV, and FIN(P)—can be encoded in a single MPHO Unique Identifier for use in electronic messages such as HL7. Refer to the *ISBT 128 Standard Technical Specification* (ST-001) for specifications on the use of ISBT 128 standardized data in electronic messaging.

3.2 Clinical Trials PDCs and Product Descriptions

Internationally standardized terminology is not associated with Clinical Trials PDCs since they are intended for clinical trials products.

Facilities using Clinical Trials PDCs need to assign a Product Description to these PDCs and need to specify the eye-readable text to appear on the product label.

Product Descriptions assigned to Clinical Trials PDCs shall be retained permanently for traceability purposes. Once a Product Description has been assigned to a Clinical Trials PDC, it shall not be changed.

Care shall be taken in interpreting these Product Descriptions as these will be specific to the supplier.

Software systems reading Clinical Trials PDCs shall ensure that they interpret a PDC based on information provided by the supplier.

