



ISBT 128 STANDARD

ISBT 128 Dictionary of Standard Data Elements

Version 1.0.0

October 2021

Tracking Number ICCBBA ST-027

ISBN-13: 978-1-933243-94-8



Published by:
ICCBBA

PO Box 11309, San Bernardino, CA 92423-1309 USA

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1 Introduction

1.1 Purpose

The purpose of this document is to provide a dictionary of standard data elements.

1.2 Scope

The document describes the data elements defined within ISBT 128 and identifies the corresponding unique resource identifier for each element. These data elements are for use in electronic messages.

1.3 Intended Audience

The intended audience of this document is electronic message developers, software developers, and staff working in facilities collecting, processing and using Medical Products of Human Origin (MPHO) (management, information technology, quality, validation, laboratory, and clinical application).

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard for XML (ST-020)

ISBT 128 Data References for use in Electronic Messages (RT042)

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

Implementation Guide: Use of Product Divisions [Data Structure 032] (IG-023)

Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)

Date and Time – Representations for Data Interchange (ISO 8601-1:2019)

1.6 Background

The ISBT 128 Standard is well established and in widespread use for the coding of information related to medical products of human origin (MPHO), and the labeling of these products using bar coding.

Information encoded using ISBT 128 has previously been described using data structures – information packets specifically designed to be suitable for use in linear bar

codes. Data structure design had to take into consideration the capacity of the linear bar code, and the available space on the label and this led to the necessity for data compression.

As a consequence of these limitations ISBT 128 data structures often combine several distinct data elements into a single data structure. In addition, to reduce the number of data structures required on one label, some data elements may be encoded in more than one data structure. This approach, while essential to meet bar coding requirements, leads to complexity in coding and decoding of the data elements.

With the transition to the use of electronic messages to transmit ISBT 128 information the need for data compression is relaxed, and there needs to be a far greater focus on the separation of data elements and the simplicity of coding/decoding.

For this reason, ICCBBA have re-visited the way in which ISBT 128 information is defined and have developed a dictionary of data elements for use in electronic messaging. The information carried in these elements maps to the same information carried in data structures to ensure that information from either source is consistent.

This dictionary defines the data elements and provides the mapping to allow transition between data element and data structure. This information is supplementary to the data structure definitions in the ISBT 128 Technical Specification and existing rules regarding the use of ISBT 128 in bar codes are unaffected.

The first version of the data element dictionary focuses on the essential data elements required for traceability, and some of the other more commonly used data elements. Future versions will expand the list to cover all data elements used within ISBT 128.

2 Data Element Dictionary Structure

The data dictionary is laid out in the following format:

URI: Each data element is identified by a unique resource identifier (URI) in the form of a uniform resource locator (URL). This URL references a page on the ICCBBA website that carries the data element definition.

Data Element Name: This is the name commonly used to describe the data element.

XML Element Tag: This is an XML element tag based on the data element name. It contains no spaces and uses UpperCamelCase format.

Purpose: This text describes the purpose of the data element.

Type: This describes the data type of the information carried in the data element. Types include:

String	A sequence of ASCII characters that provides a direct representation of information.
Coding	A string that is interpreted by direct lookup in a specified ISBT 128 reference table or alternative reference specified within the ISBT 128 Standard.
Compound	A combination of elements that together form a valid concept. The constituent elements will be of the String or Coding data type.
DateTime	A date time conforming to ISO 8601-1:2019.
DSformat	The data content from a specified ISBT 128 data structure. This may include a combination of data elements representing multiple concepts and will need to be interpreted following the same rules for the corresponding data structure.

Format: Defines the format of the data in terms of character sets and lengths.

Description: Provides additional information about the data element.

Requirements: Specifies rules that apply to the data element.

Examples: One or more examples of valid data.

Associated Reference Tables for Coding Values: For coded elements, provides links to reference tables used to code/decode the information.

ISBT 128 Data Structures Linked with this Data Element: Cross reference to the ISBT 128 Data Structures that carry the data element.

3 Data Element Dictionary

3.1 ABO RhD

URI: <https://www.isbt128.org/uri/ABORhD>

Data Element Name: ABO RhD

XML Element Tag: ABORhD

Purpose: Provides the fundamental blood grouping information of ABO type and RhD status.

Type: Coding

Format: Two-character alphanumeric code

Description:

This element contains the basic ABO/RhD status. More detailed information on ABO and Rh antigens may be provided in the Red Cell Antigens data element, but this remains the core information used in selection of blood units.

Requirements: The value shall be one of the values represented in reference table RT500.

Examples: 62

Associated Reference Tables for Coding Values: RT500

ISBT 128 Data Structures Linked with this Data Element:

DS-002: the ABO RhD information may be combined with other information on intended use and a compound code value used.

3.2 Division Identifier

URI: <https://www.isbt128.org/uri/DivisionIdentifier>

Data Element Name: Division Identifier

XML Element Tag: DivisionIdentifier

Purpose:

Identifies individual items of the same product type allocated with the same Donation Identification Number

Type: String

Format:

Six-character alphanumeric string. Leading and trailing zeros, if present, are significant.

Description:

Identifies individual items of a particular product type allocated with the same Donation Identification Number. Combined with the Donation Identification Number and Product Description Code, and in some very specific cases the Processing Facility Identifier, provides a globally unique identifier for the item.

The Division Identifier forms one component of the MPHO Unique Identifier data element.

Requirements:

When mapping from a two-character division code in Data Structure 003, trailing zeros shall be added, thus a division code of Ab shall be represented in the Division Identifier as Ab0000, and a division code of B0 shall be represented as B00000.

When mapping from a three-digit division code in Data Structure 003, leading zeros shall be added, thus a division code of 123 shall be represented in the Division Identifier as 000123, and a division code of 004 shall be represented as 000004.

When mapping from Data Structure 032 on the label, the Division Identifier shall be identical to the six-character data string of this data structure. See IG-023 for further information on Data Structure 032.

Examples:

002933
000001
ABAA00
Ab0000

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-003 – uses a shortened form of division identifier, which may be either a three-digit number or a two-character alpha value. See Requirements above for mapping into Division Identifier.

DS-032 – uses a six-character form of division identifier that can be mapped directly into the Division Identifier data element.

3.3 Donation Identification Number

URI: <https://www.isbt128.org/uri/DonationIdentificationNumber>

Data Element Name: Donation Identification Number

XML Element Tag: DonationIdentificationNumber

Purpose:

The Donation Identification Number (DIN) identifies one of the following: a donation event [collection or recovery]; a product pool; for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product; a fertilized oocyte/embryo formed through ART.

Type: String

Format:

Thirteen-character string. The following limitations on character values apply:

Character Position	Type
1	alphanumeric {A–N; P–Z; 1–9}
2-3	alphanumeric {A–N; P–Z; 0–9}
4-13	numeric {0–9}

Description:

The DIN is a globally unique identifier managed by ICCBBA as an issuing Agency. ICCBBA assigns Facility Identification Numbers to Issuing Organizations and maintains a register of all such organizations. Issuing organizations assign DINs in accordance with ISBT 128 Standard requirements.

The DIN forms one component of the MPH0 Unique Identifier data element.

Requirements:

The DIN shall be formed from a sequential combination of the five-character Facility Identification Number of the facility issuing the identifier as assigned by ICCBBA, the last two digits of the year associated with the allocation of the DIN, and a six-digit sequence number.

The facility issuing the identifier shall ensure that each DIN it allocates is unique within its range of assigned FINs through a 100-year period.

Further information on DIN allocation, presentation, and the use of check characters is provided in IG-033.

Examples: A999921123456

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-001: contains the thirteen-character DIN.

3.4 Expiration Date and Time ISO

URI: <https://www.isbt128.org/uri/ExpirationDateTime>

Data Element Name: Expiration Date and Time ISO

XML Element Tag: ExpirationDateTime

Purpose: Provides the expiration date and time in a format specified in ISO 8601-1:2019.

Type: DateTime

Format:

Date and time in format:

Date expressed as YYYY-MM-DD

The letter 'T'

Time expressed as HH:MM:SS

Optionally, an offset from UTC expressed as + or - followed by the offset as HH:MM

Description: This element contains the expiration date and time of the product.

Requirements:

If expiration is at the end of the day then the time shall be represented as 23:59:00.

Offset is required for all products that are being shipped across time zones and where expiration is to a specified time.

When mapping from expiration dates held in DS-004 and DS-005 the date shall be transformed from the YYYYJJJ format used in these data structures to the ISO format used in this data element.

When mapping from DS-004 a time of 23:59:00 shall be used.

Examples:

2021-09-21T23:59:00

2021-03-02T14:49:32-06:00

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-004

DS-005

DS-031

3.5 MPHO Unique Identifier

URI: <https://www.isbt128.org/uri/MPHOUniqueIdentifier>

Data Element Name: MPHO Unique Identifier

XML Element Tag: MPHOUniqueIdentifier

Purpose: Provides a globally unique instance identifier for a medical product of human origin.

Type: String

Format: 29-character alphanumeric string.

Description:

This element is constructed from four other elements which together create a globally unique identifier for an MPHO Product instance. The elements included are the Processing Facility Identification Number (5 characters), Product Description Code (5 characters), Donation Identification Number (13 characters), and the Division Identifier (6 characters).

Requirements:

The MPHO Unique Identifier shall be created by combining information from the Processing Facility Identification Number, Product Description Code, Donation Identification Number, and the Division Identifier as they appear on the product label.

If the Processing Facility Identification Number is not encoded on the product label, then the Processing Facility Identification Number element shall be set to five zeros.

Examples:

W9999T0123W000018123456000123
00000E0001A999921123456000000

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

See the entries for the corresponding constituent data elements.

3.6 Product Description Code

URI: <https://www.isbt128.org/uri/ProductDescriptionCode>

Data Element Name: Product Description Code

XML Element Tag: ProductDescriptionCode

Purpose:

Provides an internationally agreed description of the product or, a unique description of a clinical trial product provided by the sponsor/manufacturer, or for products with limited usage, a national or local product description code.

Type: Coding

Format: Five-character string

Description:

The product description code provides a means to identify a product type in an internationally consistent manner. This is particularly important for product crossing national boundaries and is valuable in biovigilance across all MPHO.

The Product Description Code forms one component of the MPHO Unique Identifier data element.

Requirements:

The value shall be either:

- 1) An international code that appears in the Product Description Code database table (RT064) published and maintained by ICCBBA.
- 2) A code assigned to a clinical trial sponsor/manufacturer to uniquely encode their product.
- 3) A national or local code with value taken from a range specified for such use in the ISBT 128 Standard. These codes do not have internationally specified definitions and can only be interpreted by reference to the labeler.

Examples: E0001

Associated Reference Tables for Coding Values: RT064

ISBT 128 Data Structures Linked with this Data Element:

DS-003 – PDC is included in this data structure.

DS-034 – PDC is included in this data structure.