



ICCBBBA

ISBT 128 Standard for Traceability

Traceability An Introduction

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1 Traceability

In the field of Medical Products of Human Origin (MPHO), traceability is the ability to bi-directionally track from a donor to recipient and from the recipient back to the donor. Traceability is recognized as an essential feature of the safe use of MPHO and is a regulatory requirement in many countries.

Effective traceability is essential to support hemovigilance and biovigilance systems and for the follow-up of MPHO in the event of product recall or lookback. Delay in the tracking of all products associated with an adverse event can result in unsafe products being clinically applied or in patients who have already received such products failing to receive timely remedial treatment.

Regulations require that traceability exists between donor and recipient, and can be followed in both directions (i.e., Lookback - track from donor to recipient, and Traceback - track from recipient to donor). However, compliance with such regulation alone may not provide a sufficiently effective traceability system to satisfy patient safety needs. Regulatory requirements for traceability may not include:

- tracking of other products derived from the same donor at the same time (e.g., tissue traceability regulation does not require tracing of organs procured at the same time as the tissue);
- the need to trace other products from the same donor given at different points in time (e.g., previous and subsequent blood donations);
- the need to trace products from individuals who may provide multiple types of MPHO over a period of time (e.g., a blood donor may also be a sperm donor)
- the need for a Chain of Identity (CoI) Identifier that allows for the linking of products used in given therapies for a single patient;
- mechanisms to ensure that the traceability path remains intact across organizational and national boundaries (regulation generally places traceability requirements on individual organizations but does not explicitly recognize that the traceability path crosses organizational boundaries and that these boundaries have to be actively managed);

- any requirement for the timeliness of traceability;
- a requirement for end-to-end audit of traceability on a regular basis.

As a result, the quality of traceability systems varies widely. In all but the most advanced systems, traceback and lookback actions tend to be complex, slow, and often incomplete. This is well illustrated in a US CDC report (Morbidity and Mortality Weekly Report, Dec 23, 2011) that dealt with the transmission of Hepatitis C virus through transplanted organs and tissues. The authors noted: “The events in this report demonstrate the importance of timely communication once a transplant transmission is suspected and the difficulty of tracking tissue to the patient or provider level should a potential transmission be recognized after tissue has been distributed.”

This importance of timely communication and action is exemplified within a second US CDC publication on the transmission of Tuberculosis following bone grafts used in spinal surgery procedures (Morbidity and Mortality Weekly Report, September 10th, 2021). The author illustrates the impact the contaminated lot of bone grafts had on the patient population due to the hospital’s traceback/lookback procedures: “The hospital’s rapid detection of this unusual cluster triggered a multistate investigation resulting in sequestration of all unused units of the contaminated product, identification of all patients who underwent surgical procedures with the contaminated product lot, and initiation of tuberculosis treatment by all living patients.”

The challenges for regulators are:

- In many cases the underlying legislation on which regulation is developed deals with specific types of MPO product causing fragmentation of the responsibility across regulatory bodies.
- Regulation is applied to individual organizations, but the traceability path crosses organizational, and sometimes regulatory, boundaries, and responsibility for managing the traceability interface is not well defined.
- Regulation applies within specific boundaries (state, country, region), but products may move across these boundaries.

2 Essential Elements of Traceability

There are several information management requirements that must be met to provide effective traceability of MPHO. These include globally unique identification, accurate data capture and transfer, and comprehensive records with effective security and robust data retention and retrieval. These requirements need to be managed within a quality management system and subject to regular audit. Each of these aspects are described in more detail below.

Unique Identification

The need for unique or distinct identifiers for donors and donation events is widely recognized and required by regulation. However, the term unique on its own is ambiguous if not associated with a domain within which uniqueness is required. For example, a hospital number is unique within a hospital domain but may not be so in the wider healthcare community nor international domain. To support traceability, unique identification needs to be established across the domain of use. Regulatory requirements for unique identification of products can be satisfied within the national domain but as MPHO move across national boundaries, an international domain is needed. For this reason, it is important to adopt an identification system that can provide globally unique identifiers with uniqueness guaranteed for the lifetime of all products. The system should also ensure that MPHO identifiers cannot be confused with identifiers used in other areas of informatics. ISBT 128 provides such a system, with identifiers that are unique over a 100-year period and with data identifiers reserved for ISBT 128 usage.

ISBT 128 specifies the fundamental elements of traceability:

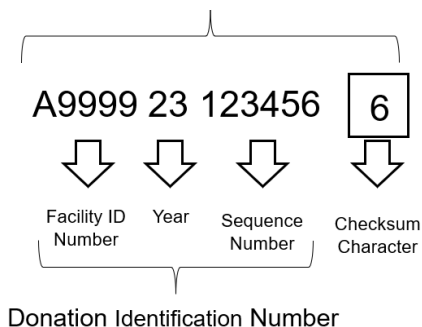
- A donation numbering system that ensures globally unique identification (DIN)
- Standardized product description coding (PDC)
- Division identification (DIV)
- Processing facility identification [FIN(P)]

The combination of these four elements provides globally unique identification for any MPHO. When combined in the order of FIN(P), PDC, DIN, and DIV, they create the standardized 29-character MPHO Unique Identifier, a single data item that provides globally unique instance identification for electronic data exchange.

Accurate Data Capture and Transfer

Traceability depends on an unbroken chain of information between the donation event and the clinical application of MPHO. Errors in the recording or transfer of key identifiers can cause breaks in the chain making traceability difficult and sometimes impossible. Manual transcription is prone to particular types of error including transposition and omission of characters. To prevent this, a checksum can be used. The checksum is an additional character added to the identifier that is printed alongside the human readable form of the identifier and is utilized in manual data entry. The checksum is calculated from the identifier, and receiving systems can re-calculate the checksum. A discrepancy between the printed value and the calculated value indicates that the user has made an error in data entry. Checksums must be specifically designed to detect the most common types of human error and ISO Standards exist to define them.

Donation Identification Number + Checksum Character



Modern bar codes used for electronic data capture have their own in-built checksum systems making errors extremely rare. However, ensuring that label printers are in good condition and labels are regularly validated is critical.

Accuracy of data also includes the need to ensure coded information is interpreted consistently by both the sender and receiver of the information. For this reason, ISBT 128 provides internationally standardized terminology for product descriptions and reference tables associated with other specific pieces of critical information to ensure a common understanding.

Comprehensive Records

Traceability depends on records that maintain an unbroken chain of information. Every organization involved in the handling of MPHO from donation through to clinical application has a responsibility to retain comprehensive traceability records, covering the segment of the traceability pathway that they are responsible for, so it can be readily searched. These records need to carry the unique combination of identifiers for the MPHO (donation identification number, product identifier, division identifier, and if applicable, processing facility identifier). The records need to include the following information:

- Source (donor information for collection facilities, or the providing organization for facilities further down the chain),
- Destination (facility the product was transferred to, or patient information of the organization responsible for clinical application).

Each element of MPHO identification is carried within standardized data structures on a product's label. If there is any change in identifiers (e.g., a new donation number issued to identify a pooled product), then records need to be maintained to provide a bi-directional link between the old and new identifiers.

Records need to be secure and meet applicable privacy and confidentiality regulations, particularly if they contain personal information. Records also need to be securely stored in a manner that prevents their degradation. MPHO records need to be retained for long periods to satisfy regulation, and this means record retention must be actively managed. Manual (paper) records need to be stored in an environment that prevents physical deterioration and ensures security. Paper and inks need to be validated to ensure that they will not fade significantly over time. Electronic records need to be managed to ensure that they remain accessible as technology develops. This may require records to be transferred to newer forms of media during their lifetime.

Quality System and Audit

Records need to be managed according to strict procedures as part of the quality management system of the organization. Regular audits should be performed, and this should include testing of records spread across the storage lifetime. Older records are more prone to loss or deterioration, and this should be prevented by active assessment and management.

3 The Role of ICCBBA

ICCBBA is the not-for-profit standards body responsible for the management, development, and distribution of the ISBT 128 Standard. It maintains a staff to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports the Technical Advisory Groups that include experts from both the transfusion/transplantation community and relevant manufacturers of equipment or software that use ISBT 128.

Registration and license fees collected by ICCBBA are used to support these functions.

Through its activities ICCBBA provides the management support to sustain the standardization of information essential to support traceability in the complex MPHO environment. In particular it delivers:

- 1) Stability – users can be confident in the stability of the Standard to satisfy the long time periods over which information must be retained (e.g., European Commission requirements for data to be stored and traceable for 30 years).
- 2) User focus – the user communities are the experts in their fields, and ICCBBA, through its Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs.
- 3) Flexibility – as clinical and scientific knowledge grows, there is rapid development with changing information needs. ICCBBA ensures that the Standard is flexible enough to accommodate these needs.
- 4) Responsiveness – in these rapidly developing medical fields ICCBBA ensures that the Standard can respond to user needs in a timely manner.
- 5) Globalization – ISBT 128 is an international standard with worldwide endorsement.
- 6) Compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility (e.g. the Single European Code).

Blood, cellular therapy, tissue, organ, banked human milk, and other facilities labeling MPHO, as well as manufacturers of equipment or software that uses ISBT 128, are required to register with ICCBBA and pay a registration fee and an annual license fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA website at www.iccbba.org, contact our helpdesk at support@isbt128.org or call us at +1 909 793 6516.

Editor:
Karen Moniz
Technical Director
ICCBBA

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Published by:
ICCBBA

PO Box 11309, San Bernardino, CA 92423-1309 USA
www.iccbba.org

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[ST-001 ISBT 128 Standard Technical Specification](#)

[ST-026 ISBT 128 Standard for the Medical Products of Human Origin \(MPHO\) Unique Identifier](#)