Labeling of clinical trial and manufactured cellular therapy (CT) final products using ISBT 128

The Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) have prepared this Technical Bulletin document to help users recognize various labeling scenarios that may apply to cellular therapy products.

The ISBT 128 Standard is used for the labeling of all types of medical products of human origin, and its adoption in the field of cellular therapy is supported by the major accreditation bodies. Sites of clinical application are familiar with ISBT 128 final labeling of CT products, and systems exist to support the automated capture of critical safety and traceability information.

Recent collaboration between ICCBBA and the Standards Coordinating Body has resulted in the development of a standard for the ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing (ST-018) and collection facilities are starting to implement this standard.

The development of an ISBT 128 label for final product allows the same key identifiers to be used throughout the product cycle from donor to recipient, and provides the end user with a familiar and consistent labeling approach.

The existing ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004) can be used for this purpose, and product description codes (PDC) have been developed to accommodate a range of situations:

- International PDCs are based on the internationally standardized ISBT 128 terminology and provide generic product descriptions that can be used across manufacturers.

- Nonproprietary Name PDCs (NNPDC) are linked to a specific International Nonproprietary Name (INN) allocated by the World Health Organization INN committee, or to a US Adopted Name allocated by the USAN Council. Manufacturers with products that have an INN/USAN can register with ICCBBA and have an NNPDC assigned to their product.

- Clinical Trial PDCs (CTPDC) are a range of PDCs that can be assigned to a specific sponsor/manufacturer to allow them to identify their products with a globally unique PDC prior to the allocation of an INN/USAN. Sponsors/manufacturers can register with ICCBBA and purchase a range of CTPDC for their sole use. The codes are linked only to the sponsor/manufacturer and are not associated with any specific terminology. It is the responsibility of the sponsor/manufacturer to provide the interpretation of the code.

It is however recognized that specific labeling requirements for manufactured CT final products may not be fully addressed in the current standard. ICCBBA is therefore planning to develop a specific standard for clinical trial and manufactured CT final products.