Third Consensus Statement on Terminology, Coding and Labeling of Cellular Therapy Products

In 2005 the Boards of AABB, ASTCT, ASFA, EBMT, FACT, ICCBBA, ISBT, ISCT, JACIE, NMDP, and WMDA issued a consensus statement in support of the use of ISBT 128 in the coding of hematopoietic progenitor cell and other therapeutic cell products. This statement was updated in 2011 to recognize the expanding scope of the cellular therapy field and the need for the inclusion of non-hematopoietic cellular therapy products.

With the rapid development of cellular therapies over the last ten years and a growing range of stakeholders involved in the development of new therapies the professional societies indicated below re-affirm their commitment to achieving globally standardized terminology, coding and labeling when describing cellular therapy products.

Recognizing:

- the quality and safety benefits of globally unique identification and common and consistent terminology, coding and labeling for all cellular therapy products;
- the importance of an agreed common structured terminology to describe cellular therapy products both for the labeling of product for clinical application, and in the scientific literature to describe the development of products from pre-clinical development, through clinical trials, to clinical use;
- the work done by the ISCT MSC Committee to promote the use of a standardized terminology for mesenchymal stromal cells (MSC) and their source tissue, and the subsequent harmonization between this terminology and ISBT 128;
- the widespread adoption of ISBT 128 as the global standard for the terminology, coding and labeling of cellular therapy products; and,
- the rapidly growing field of cell therapy manufacturing, and the developments within ISBT 128 to provide nonproprietary name and clinical trial specific product description codes.

The Boards of the organizations listed below:

- reaffirm their endorsement of ISBT 128 as the global standard for the terminology, coding and labeling of cellular therapy products, including those prepared via a cell therapy manufacturing process;
- encourage the international adoption of ISBT 128 standard terminology to describe cellular therapy products throughout the pre-clinical, translational, and clinical research stages and through to clinical use;
- encourage the use of this terminology throughout the scientific literature when describing cellular therapy products; and,
- encourage other relevant professional bodies, accreditation bodies, regulators, and health authorities to support this ongoing drive for global standardization.

This statement is supported by: AABB, APBMT, ASFA, ASTCT, NMDP, EBMT, EMBMT, FACT, ICCBBA, ISBT, ISCT, JACIE, LABMT, WBMT, and WMDA.

For further information on this initiative contact cellulartherapy@isbt128.org

Links to supporting documents.

ISBT 128 Standard Terminology: https://www.isbt128.org/standard-terminology

ISCT Position Paper: https://www.isct-cytotherapy.org/article/S1465-3249(19)30841-2/fulltext

Consensus ICCBBA-ISCT statement on standard nomenclature abbreviations for the tissue of origin of Mesenchymal Stromal Cells: https://doi.org/10.1016/j.jcyt.2021.04.009