CHALLENGES IN IMPLEMENTATION OF THE GLOBAL REGISTRATION IDENTIFIER FOR DONORS (GRID.)

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This document sets out the challenges that professional organizations are facing and their efforts to develop a global standardization of coding and labelling for cellular therapy products, to assure the traceability and to reduce the risk of misidentification of donors or their donations due to the lack of global uniqueness of identifiers.

- The Single European Code (SEC) was foreseen in Article 10 of the Directive 2006/17/UE and is compulsory to be used starting with 2014. In September 2015, was approved an EU joint project called Vigilance and Inspection for the Safety of Transfusion, Assisted Reproduction and Transplantation - VISTART (National Agency of Transplant and National Registry of Hematopoietic Stem Cell Voluntary Donors are part of consortium). The task of this consortium is to provide technical support and guidance to EU Tissue and Cell Competent Authorities and to Tissue Establishments across the EU in the implementation of the SEC for tissues and cells together with the ISBT 128 standard. Each of the transplant centres, HLA testing laboratories, apheresis and collection centres, donor centres, should have in place a unique donation and product code for all HPC products produced in and imported to EU countries.
- The cellular therapy accreditation bodies: AABB, JACIE, FACT and WMDA all require accredited cellular therapy facilities to use ISBT 128 standard terminology and to have an ISBT 128 implementation plan in place. Global standardization using ISBT 128 is essential to support secure and reliable traceability on a global basis for the large proportion of cell therapy products which are distributed across national borders.
- In this context, WMDA has a Memorandum of Understanding with ICCBBA to assign and manage the list of issuing organization numbers and support the development of associated standards documents. Representatives from WMDA and ICCBBA have been working together to develop the structure of the Global Registration Identifier for Donors (GRID). The goal of the project is to create a system for assigning a globally unique identifier to potential hematopoietic stem cell registry donors. Given the global nature of the work done by hematopoietic stem cell donor registries, a system to uniquely identify potential donors on a global scale is needed to facilitate communication and prevent errors in identification of donors. A standard machine-readable format for a GRID that can be used by electronic process control systems, as well as a standard format for the human-readable version, has been developed.

The WMDA has a GRID Implementation Working Group who is tasked with assisting with the delivery and the implementation of this concept within the unrelated donor community. They will provide support and guidance to interconnected registration organizations on all operational matters related to the GRID.

Key words: global standardisation, coding, labelling, unrelated donors, unrelated hematopoietic stem cell transplantation.