Good practices for demonstrating safety and quality through recipient follow-up - Hematopoietic Stem Cells (HSC) (WP 7)

WP Leader: Stichting TRIP

WP7 focuses on the development of methods to establish the safety and efficacy of HSC, within the general outline of validation of novel clinical cells applications. This work package will identify the risk factors associated with the different HSC and the way they are collected, processed, and applied into patients. Also an inventory will be made of methods that are currently in use to evaluate the clinical applications, like clinical trials and patients follow-up programmes. The work will be focused on determining the HSC specific criteria and/or parameters for clinical application or research with novel HSC therapies in patients.

ASSOCIATED PARTNERS

Banc de Sang i Teixits – BST (Spain, Coordinator, WP1, WP9 Leader and WP4 Co-leader); Organización Nacional de Traspantes – ONT (Spain, WP2 Leader); Ministry of Health of the Republic of Croatia – MZRH, Institute for Transplantations and Biomedicine (Croatia, WP3 Leader); National Health Service Blood and Transplant – NHSBT (United Kingdom, WP4 Co-leader); Istituto Superiore di Sanità - ISS/CNT (Italy, WP5 Leader); Krajowe Centrum Bankowania Tkanek i Komórek, National Centre for Tissue and Cell Banking – KCBTK/ NCTCB (Poland, WP6 Leader); TRIP Foundation, Netherlands Office for Hemo- and Biovigilance – TRIP (Netherlands, WP7 Leader); Ghent University Hospital, Department of Reproductive Medicine – UZGent (Belgium, WP8 Leader); Bulgarian Executive Agency of Transplantation – BEAT (Bulgaria); Semmelweis University, Health Services Management Training Center, SU – (Hungary); German Society for Tissue Transplantation gGmbH – DGFG (Germany); Saint Jean Clinic, European Homograft Bank – CSJ/EHB (Belgium); Regea Cell and Tissue Center, University of Tampere – Regea/UTA (Finland); École Royale Militaire, Koninklijke Militaire School – ERM/ KMS (Belgium).

COLLABORATING PARTNERS

European Association of Tissue Banks – EATB; European Society for Blood and Marrow Transplantation – EBMT; European Society of Human Reproduction and Embryology – ESHRE; European Eye Bank Association – EEEBA; European Directorate for the Quality of Medicines & HealthCare, Council of Europe – EDQM/CoE; Klinik Bozniki Centar Zagrabić, Banca dei Tessuti della Regione Veneto; Fondazione Banca degli Occhi del Veneto Onlus; Department of Experimental Medicine - Medical Physiopathology Division of the Rome La Sapienza University; Gruppo Italiano per il Trapianto di Midollo Pissio, Cellule Stammali Emopoietiche e Terapia Cellulare - GITMO; European Tissue Bank; Multi Tissue Centre - BISLIFE; Sanquin Blood Supply Foundation; Instituto Português do Sangue e da Transplantação.

Good practices for demonstrating safety and quality through recipient follow-up - ART (WP 8)

WP Leader: Ghent University Hospital – Department of Reproductive Medicine (UZGent)

This work package intends to determine the essential criteria and parameters for the implementation of ART products and the ART clinical applications.

This work package will also define the criteria for risk evaluation of ART and will seek a consensus in ART (through the use of the European Society of Human Reproduction and Embryology (ESHRE) network of national representatives and experts). The criteria will be tested using the Euro GTP II tools (firstly for established procedures and then for more innovative and experimental treatments).

Good Practices for demonstrating safety and quality through recipient follow-up

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Project Coordinator: Banc de Sang i Teixits (BST)
**EXPECTED DELIVERABLES AND OUTCOMES**

- **Euro-GTP II Guide**: will become a reference for TEs, ART centres and ORHAs when planning their activities according to the methodologies and criteria defined as good practices.

- **T&C Database**: will be a compendium of tissues/cells products, preparation processes, applications, therapies, current status of authorization/implementation and associated relevant biovigilance data.

- **Interactive Assessment Tool (IAT)**: will consist in an “algorithm” implemented in a user friendly online interface. This tool will be useful to implement, evaluate and authorize a novel T&C product, process or therapy.

- **GTP’s Management Model**: will propose a structure for the development of European accreditation and training programmes for TEs, ART centres and ORHAs. This model will be proposed to assure the continuity and sustainability of the outcomes of the Euro-GTP II Project, and the future update, promotion and harmonization of GTP’s standards.

**Generic Good Practices for demonstrating safety and quality through recipient follow-up (WP 5)**

WP Leader: Istituto Superiore di Sanità (ISS-CNT)

The goal of WP5 is to define a grading system for the threshold of novelty, including the factors that should be considered to determine the scope and depth of the clinical follow-up studies needed.

This work package will establish general standard principles and methodologies common to all types of Tissues and Cells, which should be used to provide sufficient clinical validation data and follow-up data for the use of safe tissues/cells products/therapies.

**Good practices for demonstrating safety and quality through recipient follow-up - Tissues (WP 6)**

WP Leader: KCBTiK - Krajowe Centrum Bankowania Tkanek i Komórek

This work package strives to define specific criteria and parameters considered essential for the implementation of tissues, preparation processes as well as clinical applications based on generic Good Practices resulting from WP5.

WP6 will also identify tissue “products”, preparation processes, clinical applications and patient follow-up programs and their respective status of validation and authorisation. These data will be used to create an inventory - T&C Database.