## 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.

## 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).

## ASSOCIATED PARTNERS

Banc de Sang I Teixits – BST (Spain, Coordinator, *WP1, WP9* Leader and *WP4* Co-leader); Organización Nacional de Trasplantes – 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 – KCBTiK/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 – EEBA; European Directorate for the Quality of Medicines & HealthCare, Council of Europe – EDQM/CoE; Klinički Bolnički Centar Zagreb; 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 Psseo, Cellule Staminali Emopoietiche e Terapia Cellulare - GITMO; European Tissue Bank; Multi Tissue Centre - BISLIFE; Sanquin Blood Supply Foundation; Instituto Português do Sangue e da Transplantação.

Co-funded by the Health Programme of the European Union

**Grant Agreement number: 709567 —HP-PJ-2015**
April 2016 – March 2019

*"This brochure is part of the project / joint action '709567 / Euro-GTP II' which has received funding from the European Union's Health Programme (2014-2020). The sole responsibility lies with the author; the Executive Agency is not responsible for any use that may be made of the information contained therein".*

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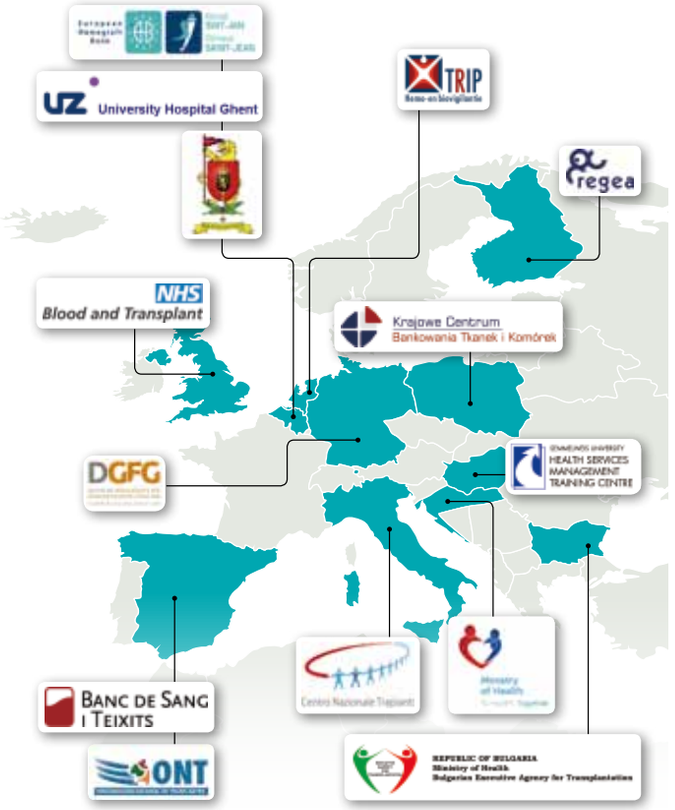
EURO GTP II
Good Tissue & cell Practices

# Good Practices

**for demonstrating safety and quality through recipient follow-up**




**Project Coordinator:** Banc de Sang i Teixits (BST)

**Euro-GTP II** aims to set up the good practices applied to Tissues and Cells (T&C) preparation processes and patient follow-up procedures to ensure their safe and effective implementation and evaluation.

Euro-GTP II will give continuity to the first Euro-GTP project, which has developed European Good Tissue Practices for the activities carried out in tissue establishments (TE).

The outputs of the Euro-GTP II project will provide tools for **assessing and verifying quality, promoting safety and assure efficacy of therapies** with human tissues, Hematopoietic Stem Cells (HSC) and Assisted Reproductive Technologies (ART), addressing mainly the implementation of **novel** T&C preparation processes and clinical indications, but also the need for retrospective studies where weaknesses or insufficient safety data currently exist.

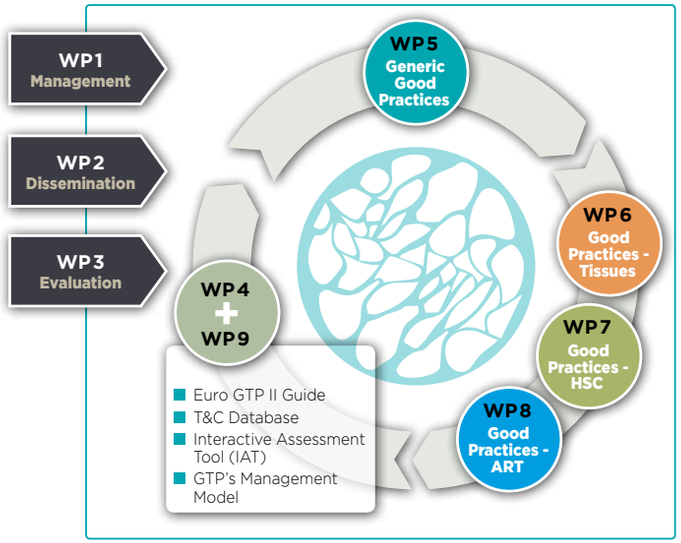
This project intends to assist TEs, ART centres and Organizations Responsible for Human Application (ORHAs), in the implementation of technical requirements defined for the assessment and verification of the quality, safety and efficacy of therapies with human T&C. Moreover, these tools will be developed in accordance with regulatory principles, legislation and good practices, and will be made available to National Competent Authorities (NCAs), hence facilitating also the evaluation and the authorization procedures.

Euro-GTP II will contribute to the (2014-2020) Health Program through the development of **common European Good Practices** required for human application of the tissues/cells in a safe and effective manner. The four core work packages will determine:

- Methodologies for assessing **the risk associated to novel tissues/cells** and for assessing **the extent of the studies needed** to provide quality, safety and efficacy data for the tissues/cells applications.
- The **follow-up programmes** in order to assure safety and efficacy and to confirm the validation of the processing methods.

## 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 use to create **an inventory** - T&C Database.