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).
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 assuring 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.

**EXCEPTED DELIVERABLES AND OUTCOMES**

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**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.