

Joint Newsletter

January, 2017



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**EURO
GTP II**

Good Tissue
& cell Practices



VISTART

VIGILANCE AND INSPECTION
FOR THE SAFETY OF TRANSFUSION ASSISTED
REPRODUCTION AND TRANSPLANTATION



ECCTR

European Cornea and Cell
Transplantation Registry

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Dear Reader,

We are delighted to introduce the first edition of the joint newsletter of EuroGTP II, ECCTR and VISTART.

The project leaders intend to keep you updated about news and developments related to the EU projects and Joint Action dealing with quality, safety and efficacy issues of tissue and cell products, co-funded by the European Union's Health Programme (2014-2020).

In this way, we aim to synergise the exchange of information concerning common assessment methodology on quality, safety and efficacy of therapies with tissues and cells.

Further details of the projects are described below.

Regards,

EuroGTP II, VISTART, ECCTR



About the project....

EuroGTP II (Good Practices for demonstrating safety and quality through recipient follow-up) aims to establish good practices with regard to Tissues and Cells (T&C) preparation processes and patient follow-up procedures, to ensure their safe and effective implementation and evaluation.

This project intends to assist Tissue Establishments (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.

Tools will be developed in accordance with regulatory principles, current legislation and good practices, and will be made available to National Competent Authorities (NCAs), hence facilitating both evaluation and the authorization procedures.

Expected Outputs:

- Euro-GTP II Guide
- T&C database
- Interactive Assessment Tool
- GTP's management model

Project Meeting in Barcelona

On November 8th and 9th 2016, EuroGTP II had their 2nd Technical Meeting.

35 participants representing: National Competent Authorities (NCAs), Scientific associations, Tissue Establishments, and Academic Experts, joined together for the technical meetings.

This meeting represented also the opportunity to gather all WP leaders in follow-up and coordination committee.

Project Progression Summary:

Months elapsed (10 of 36)

28%

Accomplished Milestones (23 of 66)

34%

Deliverables Submitted (2 of 13)

15%

Development of tools:

The methodology proposed by the EuroGTP II comprises a three level analysis, and aims to:

- Evaluate novelty;
- Determine the risk associated with T&C Product/therapy/procedure;
- Provide guidance regarding the procedures required to implement the TCP by the TE and/or ORHA.

During the 2nd technical meeting, the **two first levels of this methodology were globally approved** by the associative and collaborative partners. Therefore, **a functional tool is already being developed that is able to determine the level of risk associated with the different levels of novelty**. This tool is currently being transferred to an online platform that enhances its accessibility.

The next months will be dedicated to drafting the generic follow-up methodologies (3rd level of the analysis), that will be presented in April, during the 3rd technical meeting in Budapest.

Simultaneously, the technical WP (6, 7 and 8) will detail the specific requirements applicable to Tissues, Hematopoietic Stem Cells, and ART respectively, as well as the definition of the structure and contents of the T&C Database.





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The 1st Technical Questionnaire

had the objective of identifying current practices for evaluation of T&C efficacy used by the EU stakeholders.

136 organizations from 11 countries gave their contribution and shared their practices, allowing the identification of critical requirements for the clinical use of new T&C products and therapies.

Results: The evaluation of efficacy is a concern for the large majority of the stakeholders.

The methodologies currently used by the TEs and ORHAs to collect information on efficacy and to monitor the safety of the T&C are not yet standardized, and are sometimes limited to reports of adverse events and reactions, and statistical analysis of performance indicators.

Details of a **standardized methodology that ensures a common approach for evaluation of efficacy should be developed by the EuroGTP II project.**

Collaboration with End Users:

Technical inputs from end users are received by the ORHAs collaborating with associative partners and via cooperation with other projects, such as the ECCTR Project (European Cornea and Cell Transplantation Registry). These collaborations aim to inform the development of coherent follow-up programs, in line with clinician's requirements and medical practices.

Additionally, orthopaedic surgeons from ESKA (European Society for Sports Traumatology, Knee Surgery and Arthroscopy) were invited to present their perspective regarding the use of Substances of Human Origin (SoHO), and expectations for the outcomes of our project.

An overview of the *European Allograft Initiative* (a collaboration of ESKA with International cartilage repair society (ICRS)) was presented. ESKA's experts have expose their priorities and concerns as:

- Clinical Effectiveness
- Cost efficiency
- Availability
- Awareness



Other Activities...

Dissemination

The project website (www.goodtissuepractices.eu) is already available, and it has a private section for the project follow up by the associate, collaborative partners and CHAFAE's officers.

The Dissemination WP-2 launched the project leaflet several months ago, which can be downloaded from the website. This leaflet is being disseminated and distributed in national/ international congresses and meetings.

The project has been also presented in different meetings, and official websites now link to Euro- GTP II. Furthermore, Focus on Reproduction Magazine, with a large impact, included a section dedicated to the project.

Many presentations of EuroGTP II are already planned for 2017, for example in different congresses: EBMT Congress, EEBA Congress and AEBT Congress (*Asociación Española de Bancos de Tejidos*).

Evaluation

In order to timely obtain feedback from our partners regarding the organisation and usefulness of the technical meetings, **online surveys** where developed by Evaluation Work package (WP3).

Audit methodologies that should be followed when assessing the suitability of the contents produced by the EuroGTP II project, are currently being developed based on AGREE (Appraisal of Guidelines for Research and Evaluation) tools

For more information www.goodtissuepractices.eu | EuroGTPII@bst.cat



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VISTART is a Eu co-funded Joint Action (JA), meant to support EU Member States (MS) in developing and strengthening their capacity for monitoring and control quality, safety and efficacy in the field of blood, tissues and cells transplantation.

One working group will propose regulatory principles for short and long term follow up in patients treated with tissues, cells and blood prepared with novel processing methods.

Evaluation of safety and efficacy of innovative newly developed tissues, cells and blood products are a mayor concern and a specific working group (WP5 Part B) will produce a document on this topic.

International collaboration with VISTART

WP5 Part B is exploring the principles that should be applied for the evaluation of newly developed T&C preparation processes .

The part B of WP 5 intends to develop general principles that should guide CAs of the tissue, cells and blood sectors to evaluate specifically newly developed processing technologies and that should be integrated by clinical follow up information as a mean of further validation of the quality. The “**Principles for Competent Authorities for the Evaluation and Approval of Clinical Follow Up Protocols for Blood, Tissues and Cells Prepared with Newly Developed and Validated Processing Methodologies**” will represent a first document about the main criteria for assessing clinical outcome of novel products, beside the assessment of quality and safety of new processing methods. Novel technologies or changes of approved preparation processes need to be validated, especially if the processing is at an early stage. The document will describe which are the specific issues to be considered in the risk assessment and risk evaluation of those novelties, in order to define adequate clinical follow up programs.

Coordination with other projects or activities at European, National and International level

Euro-GTP II: Essentially VISTART (WP5 partB) is working on what is to be assessed by the CAs in order to authorise new tissues, cells and T&C&B products, processes and therapies/indications, and Euro-GTP II (here CNT is the leader of WP5) will determine how TEs and end users must proceed to evaluate the efficacy of these novelties. VISTART is mainly focussed on regulatory principles for CAs for the evaluation and approval of clinical follow up protocols (basic elements) for T&C&B prepared with newly developed and validated processing methodologies, instead Euro-GTP II is dedicated to follow-up programs needed to provide enough quality and safety data.

European Cornea and Cell Transplantation Registry (ECCTR): Knowing that the feedback from patients cured is usually very poor the WP5 part B group could appreciate how the ECCTR registry is successful in gathering results about the follow up period. The proposed collaboration between ECCTR and WP5 part B should be strengthened in order to combine the experience of the clinical registry and the definition of regulatory principles of VISTART on clinical follow up of tissue transplants.

In Europe, an estimated 30,000 cornea transplantations are performed annually. However, at present, only three countries in Europe, have national corneal registries: Sweden, UK and The Netherlands. As a result, it is not possible to match supply and demand on a European level, resulting in long waiting lists for corneal transplantation in many countries.

ECCTR aims to build a common assessment methodology and establish an EU web-based registry and network for academics, health professionals and authorities to assess and verify the safety quality and efficacy of corneal transplantation.

As the core methodology for development of an EU registry, ECCTR will consist of collection, storage and analysis of data and dissemination of analysis across European states.

Timeline:

The project is a three year programme, made up of development of an EU web-based registry in the first year, recruitment of clinics and eye banks and collection of data in year two, evaluation of the data collected and development of an evidence based European guidelines and dissemination of results at a final conference in year three.

Latest news:

The project steering group had its kick off meeting in Luxembourg, in May 2016 and the ECCTR had its official launch at the ESCRS and EuCornea Congresses in Copenhagen, Denmark, in September 2016.

So far, the project steering committee hold three meetings with the aim to evaluate and harmonise the information of the existing EU registries. The ECCTR partners have agreed and established the description of parameters and dataset for the new EU registry.

Next Steps

The team will be working on the development of the system and designing the online prototype database which is planned to be ready for testing by May 2017.