

Joint Newsletter

January, 2018



Co-funded by
the Health Programme
of the European Union



**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 third edition of the joint newsletter of EuroGTP II, ECCTR and VISTART.

The project leaders would like 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 regarding common methodologies for assessing quality, safety and efficacy of therapies using 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.

Latest events....

- **Interim Meeting** – (18th September 2017, Barcelona)
- **WP5 + WP6** - Technical Meetings (19th September 2017, Barcelona)
- **Coordination Meeting**- (29th November 2017, Leiden)
- **WP7** – 2nd Technical Meeting (18th January, Leiden)

Project Progression Summary:

Months elapsed (22 of 36)

61%

Accomplished Milestones (42 of 73)

58%

Deliverables Submitted (4 of 16)

25%

Interim Meeting:

44 participants representing EuroGTP II's Associative and Collaborative Partners, external auditors, invited observers, CHAFA (Consumers, Health, Agriculture and Food Executive Agency) and DG SANTE (Directorate General for Health and Food Safety - European Commission), were present in Barcelona during the official Interim Meeting (September 18th 2017).

This meeting aimed to present the accomplishments of the 1st half of the project, and promoted the involvement of the Scientific Associations for the future development and management of the outcomes.

Leaders of the horizontal WPs offered a summary of the management, dissemination and evaluation activities, while the technical WPs (5, 6, 7, and 8) presented and discussed the methodologies and tools developed so far.





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Latest Developments:

Development of 3rd level of methodologies

WP Leaders and Coordinators met in Leiden (29th November 2017) to determine the standardized development of contents that will be defined as 3rd step of the methodologies. These methodologies intend to facilitate the design of the studies, required to demonstrate quality and safety, following a systematic method.

A template protocol will incorporate the specific tests addressing the corresponding risks identified in the 2nd step of the methodologies.

The tests will also consider the Tissue and Cellular Therapies/Products (TCTP) preparation process indicators and the endpoints of the preclinical and clinical stages when applicable.

This standardized approach aims to facilitate the work of the leaders of the technical WPs (6, 7 and 8), to develop harmonized contents that determine the studies (pre-clinical and clinical) and follow up programs.

Next Meetings:

15th and 16th March 2018–
Liverpool Coordination, WP5
and WP6 Meeting

March – Ghent, 3rd WP8
Meeting

Tissue & Cells Database:

The Tissue and Cells (T&C) database aims to be compendium of tissues/cells products, preparation processes, applications and therapies., and will include information related with the characterization and availability of TCTP in the European Tissue Establishments .

A guidance document describing the goals and information that will be included in the database was developed in simultaneous with an online prototype.

Partners are now invited to test the suitability of this proposal, and give feedback in order to improve this tool, before the formal request to introduce data in the final database.



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



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VISTART's Update

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.

Based on the commonly agreed concept about the correlation between high risk level of a new cell based product and the extent of clinical follow up plan of the recipients, the WP5B group further developed several principles and general indications for the Competent Authority (CA) that has to assess the quality/safety profile of the novelty also taking into consideration the clinical outcome.

The deliverable that the WP5B group has to produce is in its pre-final version and it is indicating a list of general indications for the assessor of the clinical follow up plan as an integration to the Preparation Process Dossier (PPD). The typology of a clinical follow plan has to be discussed between the tissue establishment (TE) and the end user before it is submitted to the CA. The information that should be available for the evaluation of the clinical follow up plan should comprehend e.g.: evaluation of the risk benefit ratio, expected benefits in respect to other therapies, definition of safety and efficacy criteria, application method and indication to be treated, kind of patients. There are several risk factors that may be of concern and that can trigger more attention on recipients treated with new tissue/cell products. Some, like insufficient preclinical information and/or clinical experience, unknown effects of a new reagent or presence of impurities in the final product, increased probability of engraftment rejection and induction of autoimmunity or immunogenic reactions are more general, others can be very specific depending on the type of new processing methods. The document is also proposing the possibility that the CA releases a "conditioned" authorization (instead of a full authorization) for the preparation and clinical use of the novelty depending on the quantity and quality of results available at the time of submission of the preparation process authorization (PPA).

The **European Cornea and Cell Transplantation Registry (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, the ECCTR will consist of collection, storage and analysis of data, and dissemination of this 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, with recruitment of clinics and eye banks and collection of data in year two. Evaluation of the data collected, development of evidence based European guidelines and dissemination of results will take place at a final conference in year three.

ECCTR Registry Now Live

How can surgeons join?

Go to: www.ecctr.org

Fill out an expression of interest form



Once you have received your personal login credentials it is time to go online
Access the ECCTR web application: <https://ecctr.net/Home/Index/Login>

The following login screen will be displayed:



ECCTR instructional course

The course provides knowledge about the ECCTR system, informs about legal aspects of an international disease registry and shows how to enter data into the system.

The course is available online at: <http://www.ecctr.org/using-ecctr-for-clinical-improvement-online-course>

About the ECCTR Project

Leave a message

Next dissemination activities at international congresses

- XXX EEBA meeting Coimbra, Portugal 25-27 January 2018.
- 2018 Arvo Annual Meeting, Honolulu, 29 April-3 May 2018.
- 9th EuCornea Congress, Vienna 21-22 September 2018.
- 36th Congress of the ESCRS, Vienna 22-26 September 2018.

For more information www.ecctr.org | e-mail: info@ecctr.org



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