Joint Newsletter

July, 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 fourth 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

EURO GTP II
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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....

- **WP Leaders Meeting and end users** – 15th and 16th March 2018, Liverpool

-**WP8** – 2 technical meetings (20th April 2018 Ghent and 03rd July 2018, Barcelona)

-**WP4 Coordination Meeting**- 3rd and 4th May 2018, Liverpool

-**WP6** – Meetings with end users of ocular tissues, Amniotic Membrane (Veneto, Mestre) Cardiovascular tissues, (Barcelona), Skin and acellular dermis (Brussels) and Musculoskeletal tissues (UK)

-Update of the EuroGTP II project presented by the coordinator to the **Tissues and Cells Competent Authority** meeting last June 20-21

Project Progression Summary:

Months elapsed (28 of 36)

Accomplished Milestones (48 of 73)

Deliverables Submitted (5 of 16)

End users "on board":

The development of the 3rd step of EuroGTP II's methodologies - *Definitions of Studies Extent:* ***a)*** *Use pre-clinical studies (in vitro and in vivo) to mitigate the identified risks and* ***b)*** *Design of clinical studies extent* – is being accomplished with the kind collaboration of clinicians/surgeons, embryologists and tissue bankers.

The inputs of clinicians, invited experts and partners are being gathered by the Work Packages (WP) Leaders and Coordinators, included in the deliverables of WPs 6 (Tissues), 7 (Haematopoietic Stem Cells) and 8 (Assisted Reproductive Technologies). Orthopaedics, dermatologists, ophthalmologists, and cardio surgeons, have been invited and challenged to elaborate together with the EuroGTP II representatives a general approach to the planning of clinical study follow up of T&C recipients.

The preliminary outcome shows that it depends from the kind of pathology but some elements of clinical follow up planning are common and should always be tailored to the results of the preclinical testing and the remaining risks of a validated preparation process.

The outcomes of this WPs will be ready and **open to external consultation by the end of October 2018.**

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Collaboration with GAPP Joint Action:

This project will deal with a review of regulatory and technical standards for innovation in the field of blood, tissues and cells products.

GAPP will lean on the EuroGTP II and VISTART projects and it will establish bridges with the tools developed by professionals in the EuroGTP II project. It will build the basis and further define a data model of information on clinical application of human blood, cell, and tissue therapeutics, suitable for Competent Authorities but also for other interested parties.

We invite you to visit the webpage of this initiative (www.gapp-ja.eu) and follow the progress of the new joint action that involves 26 partners from 17 Member States.

Next Meetings:

4th and 5th October 2018–, WP5 Final Technical Meeting

GTP's Management Model:

The first draft of proposal for the implementation of the Good Tissue Practice's Management Model (*GTP's Management Model*) is ready to be disclosed to our Associative and Collaborative Partners.

The document is a recommendation on how to govern the future management and implementation of the tools developed by the EuroGTP II project, and aims to propose a sustainable model, and principles for cooperation of the different organisations involved in future development, management, update and hosting of EuroGTP II contents.

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.

The VISTART WP5B group has concluded the document "Principles for Competent Authorities for the evaluation and approval of blood, tissues and cells that have been prepared with newly developed and validated processes based on clinical follow up of recipients". It has been submitted in June to the European Commission and the External Advisory Board for their evaluation.

The participants have been supported by valuable clinicians, researchers and representatives of scientific societies and competent authorities from the blood/tissues/cells/ART (BTC) fields and in addition the active participation of the coordinators of the EuroGTP II project has assured a smooth alignment between the two projects.

The deliverable is identifying seven major principles that regulatory competent authorities should apply when evaluating the quality and safety aspects of BTC processing methods. The regulatory assessment should be based on comprehensive data and should allow to take a risk-based decision about the preparation process authorization (PPA). But for improved not well known BTC products that have been prepared with novel processing methods CAs are facing some difficulties in applying the procedures foreseen for the traditional regulatory assessment. A special regulatory procedure should be in place for innovative processes that might have a beneficial impact on the patients but are not supported by sufficient data. If the expected benefit justifies the residual risks the role of clinical results should be assessed as a mean to validate the quality of the novel preparation methodology. The CA could consider to release a "conditional" authorization (instead of a full authorization) for the preparation and clinical use of the novelty until more preclinical and clinical supporting information becomes available.

The clinical follow up study plan shall be designed by the clinician and the responsible person of the blood/tissue establishment and shall be tailored for the kind of BTC and clinical application. The extent, in terms of scale, duration and complexity of the clinical study plan should be proportionate to the level of residual/unknown risks of the product. To guide the CAs the group has drafted a table that matches four major levels (negligible, low, moderate, high) of risks with four clinical follow up typologies.

Finally the document highlights that a more efficient interaction between end user and blood/tissue establishment should be assured through a formal written agreement that describes, among others, which data should be supplied in order to submit to the CAs a set of comprehensive information that complete the PPA request.

The deliverable is enriched by five annexes that comprehend the results from the survey about the existing clinical follow up rules in Member States, the methodological approach for risk analysis, the risk level table and a checklist for the evaluation by the BTC CAs of a clinical follow up plan.

For more information **www.vistart-ja.eu** | **maura.mareri@iss.it**

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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.

Updates on the EU web-based registry and data collection

The ECCTR Registry is now live.

ECCTR allows both manual input of data via the web and direct transfer of data.

This means that ECCTR avoids double entry. Two countries – the Netherlands and Sweden – already have national registries; therefore, a direct transfer option is in the process of being developed with these countries. In practice, surgeons will use their national registries, and periodically the data will be transferred from national registries to the ECCTR. The Swedish and the Dutch Partners are working to develop this interface that will link their systems with the ECCTR.

Manual input of data is also ongoing, as 30 clinics signed up for collecting data in the EU web-based registry across Europe.

ECCTR Demo video

The online demo shows the ECCTR user, utilising a step-by-step approach, how to input data into the system. The video demonstrates how to record the specifics of each surgery by means of the five forms of the EU web-based registry:

- Patient Details
- Donor Details
- Tissue Details
- Surgery Details
- Eye Details

Furthermore, the demo illustrates how to manage existing surgery records in order to finalise the transplant documentation through the addition in the Registry of the Follow-Up data and Graft Failure form.

The demo video is available online at: **http://www.ecctr.org/video/ecctr-demo-video-how-to-input-data-in-the-web-based-registry**

How to join ECCTR

Surgeons can join by visiting the website: **www.ecctr.org** and fill out an expression of interest form

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

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