

Joint Newsletter

July, 2017



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 second 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....

- **WP8** – 1st Technical Meeting (3rd March, Ghent)
- **WP5** - 3rd Technical Meeting (3rd April, Budapest)
- **WP6** - 2nd Technical Meeting (4th April Budapest)
- **WP7** - 1st Technical Meeting (2nd July, Leiden)
- **WP8** - 2nd Technical meeting (3rd July, Geneva)

Project Progression Summary:

Months elapsed (16 of 36)

44%

Accomplished Milestones (31 of 66)

47%

Deliverables Submitted (2 of 13)

15%

Latest Developments:

Improvement of Risk Assessment Methodologies:

The 1st Draft of the *Generic requirements for demonstrating safety and quality* was presented to the partners during the 3rd Technical Meeting of WP5 in Budapest.

The valuable inputs given by the participants were included in a new version of the document issued on 23rd May.

In addition to the development of the Generic requirements, individual WPs (6,7 and 8) are currently identifying the specific assessment criteria and risks associated with the clinical application of Tissues, Hematopoietic Stem Cells (HSC), and Assisted Reproductive Technologies (ART). The purpose of this is to develop evaluation methodologies specific to each product group.

Interactive Assessment Tool (IAT)

Corrections and improvements proposed by EuroGTP II's partners during the last technical meetings were implemented in a new prototype version of the IAT, disclosed to all partners on 23rd May 2017.

EuroGTP II Assessment Tool

The permanent evolution of activities and the vast number of new technologies available, represents a continuous development of new Tissue and Cellular Products (TCP) and therapies by the Tissue Establishments.

Every modification in the processes associated with the donation, procurement, testing, processing, storage and distribution of TCP may have potential consequences for the quality of these products and safety of donors and receptors.



The purpose of this tool is to assist the stakeholders in the:

- Characterization of the level of novelty of TCP or therapies (**Step 1**)
- Assessment the risks associated (**Step 2**)
- Determination of the extent of studies required to assure the safety and efficacy of TCP/therapies (**Step 3**)

Start

Created by Good Tissue Practices

The **Interactive Assessment Tool Prototype** is currently under evaluation by all Collaborative and Associative Partners. Contents and functionalities are being improved, and will be validated during the next technical meeting.



Latest Developments (Cont.):

Next Meetings:

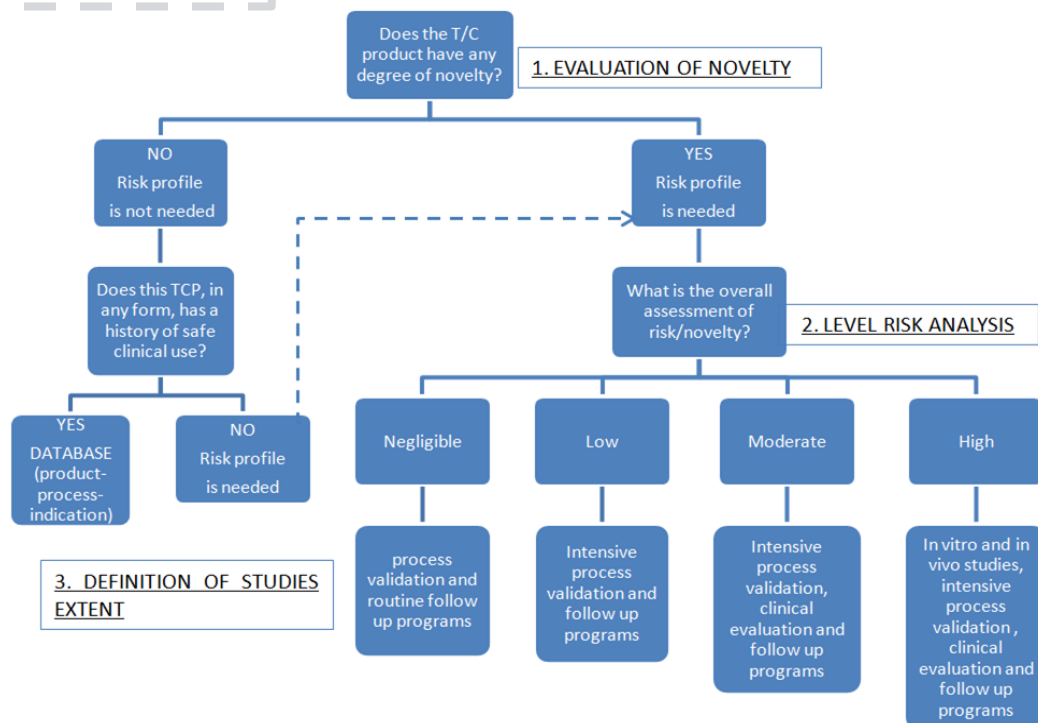
18th September – Barcelona
– Coordination/Interim Meeting

19th September – Barcelona
- technical meetings of WPs 5, 6, 7

Development of the 3rd level of analysis – Extent of studies needed:

During the last technical meeting, WP6 working groups performed exercises to determine the level of non-clinical studies and clinical evaluations required to assess quality, safety and efficacy of tissues grafts.

Results of these exercises will be further analysed in order to determine the generic requirements (WP5) appropriate for the different levels of novelty.



Tissue and Cells Database:

The T&C Database will be developed with the aim of **promoting the communication and the exchange of knowledge amongst Tissue Establishments (TEs)**.

The structure of data and the management of information is still under discussion, however partners agreed that the following data should be included:

- Product ID ;"acceptance criteria for release";
- Described applications/"Commonly used for";
- Efficacy data (list/link to references, proposed by the TEs and any relevant link to Notify Project);
- Novelty level: products may be introduced with a reference/classification of novelty level (classification proposed by VISTART)





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 regulatory principles that should be applied for the evaluation of newly developed T&C&B preparation processes.

A survey that was launched to inquire about existing requirements for approval of new processing methodologies of T&C&B confirmed that the status of “new” is considered differently among the European Competent Authorities. Likewise it has been reported that the need for clinical data of patients treated with new T&C&B is not clearly regulated or not regulated at all. The common ground is that especially for new processing methods the risks have to be identified, analysed and minimized closely before the final product can be distributed. But in case of highly innovative technologies some residual risks might not be identified and therefore clinical data can be a relevant information to complete the Q&S assessment of the novel preparation process.

The participants of WP5 Part B are now elaborating a simple matrix to classify several levels of novelties of preparation processes and of clinical application techniques. Once identified it is foreseen that several types of clinical follow plans will be can be matched to the corresponding novelty degree of the new preparation technology.

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.

Latest developments:

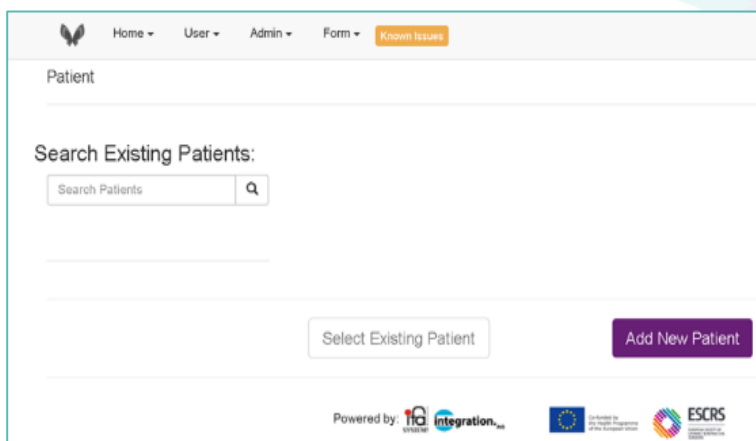
The ECCTR team has developed the EU web-based registry prototype. Below are some screenshots from the registry's website: <https://igocectrtest.azurewebsites.net/>



The screenshot shows the login interface for the ECCTR website. At the top left is the ECCTR logo and the text 'Join the ECCTR'. To the right, it says 'Track your Surgical Results'. Below this, there are two input fields: 'Username:' and 'Password:'. A purple 'Login' button with a right-pointing arrow is positioned below the password field. At the bottom of the page, there are logos for the European Union and ESCRS, along with a note: 'This Grant has received co-funding by the Health programme of the European Union under the Grant Agreement N. 709723'. At the very bottom, it says 'Powered by' followed by the 'iQ integration' logo.

The log in screen

The user is identified through the system with a single user ID

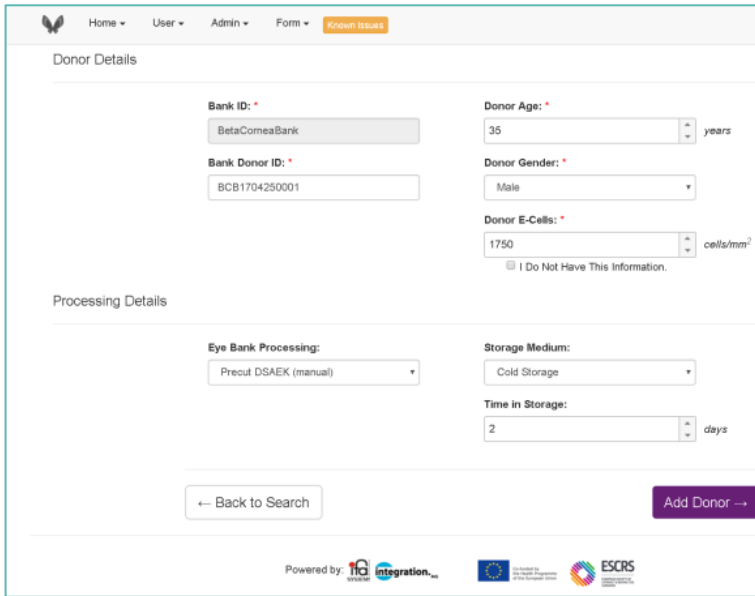


The screenshot shows the 'Patient' section of the ECCTR website. At the top, there is a navigation menu with 'Home', 'User', 'Admin', and 'Form' dropdowns, and a 'Known Issues' button. Below the navigation, the word 'Patient' is displayed. A section titled 'Search Existing Patients:' contains a search input field with the placeholder text 'Search Patients' and a magnifying glass icon. Below the search field, there are two buttons: 'Select Existing Patient' and 'Add New Patient'. At the bottom of the page, there are logos for the European Union and ESCRS, and the text 'Powered by' followed by the 'iQ integration' logo.

Step 1 - Patient

As the ECCTR keeps a global patient dictionary in the background, it is possible for a user to look up not only patients created on a specific site but also using the patient's ECCTR patient ID issued by the ECCTR

Look up an existing patient
Add a new patient

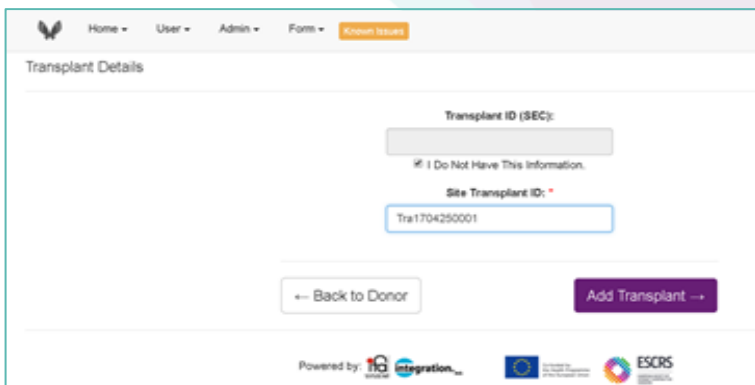


The screenshot shows the 'Donor Details' form. At the top, there is a navigation bar with 'Home', 'User', 'Admin', 'Form', and 'Known Issues'. The form is divided into two main sections: 'Donor Details' and 'Processing Details'. In the 'Donor Details' section, there are fields for 'Bank ID' (BetaCameaBank), 'Bank Donor ID' (BCB1704250001), 'Donor Age' (35 years), 'Donor Gender' (Male), and 'Donor E-Cells' (1750 cells/mm²). There is also a checkbox for 'I Do Not Have This Information.' In the 'Processing Details' section, there are fields for 'Eye Bank Processing' (Precut DSAEK (manual)) and 'Storage Medium' (Cold Storage). Below these fields, there is a 'Time in Storage' field (2 days). At the bottom of the form, there are two buttons: '← Back to Search' and 'Add Donor →'. The footer of the form includes logos for 'Powered by: integration', the European Union flag, and 'ESCRS'.

Step 2 – Donor

As the ECCTR also keeps a global donor dictionary in the background, it is possible for a user to check if a donor is already known by the ECCTR and use this record instead of entering the data manually

- Look up an existing donor
- Add a new donor

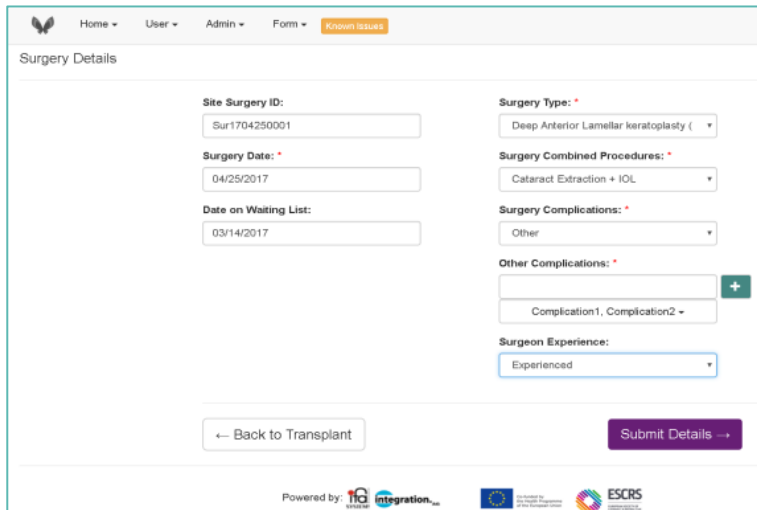


The screenshot shows the 'Transplant Details' form. At the top, there is a navigation bar with 'Home', 'User', 'Admin', 'Form', and 'Known Issues'. The form is divided into two main sections: 'Transplant Details' and 'Processing Details'. In the 'Transplant Details' section, there are fields for 'Transplant ID (SEC)' (I Do Not Have This Information), 'Site Transplant ID' (Tra1704250001). In the 'Processing Details' section, there are fields for 'Eye Bank Processing' (Precut DSAEK (manual)) and 'Storage Medium' (Cold Storage). Below these fields, there is a 'Time in Storage' field (2 days). At the bottom of the form, there are two buttons: '← Back to Donor' and 'Add Transplant →'. The footer of the form includes logos for 'Powered by: integration', the European Union flag, and 'ESCRS'.

Step 3 – Transplant

As the ECCTR knows all already used transplants, it can verify if a transplant was used already with other surgery documentation, and notify the user as well as a supervising committee in case duplicate use is recognised.

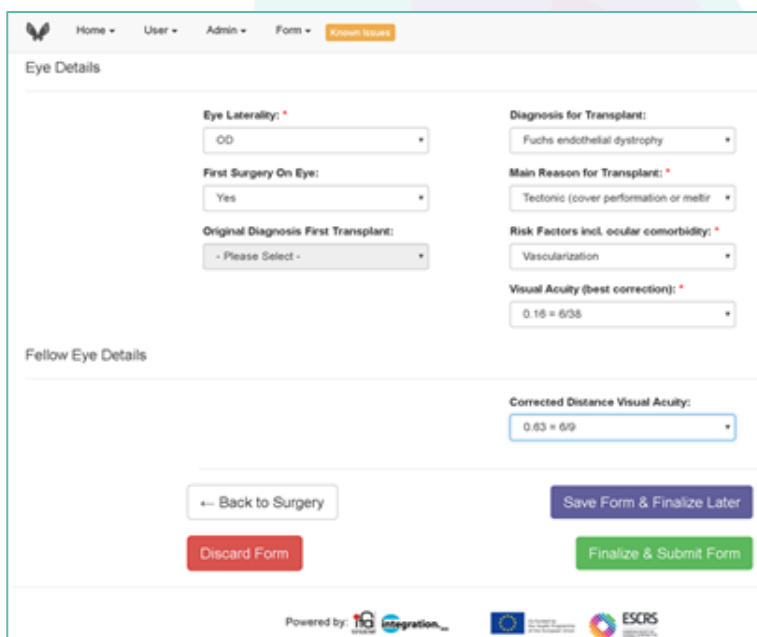
The ECCTR is prepared to propose a transplant list for the donor selected in workflow Step 2.



The screenshot shows the 'Surgery Details' form. It includes fields for Site Surgery ID (Sur1704250001), Surgery Date (04/25/2017), Date on Waiting List (03/14/2017), Surgery Type (Deep Anterior Lamellar keratoplasty), Surgery Combined Procedures (Cataract Extraction + IOL), Surgery Complications (Other), and Surgeon Experience (Experienced). There is a 'Submit Details' button and a 'Back to Transplant' button. The form is powered by TIC integration and is part of the ECCTR project.

Surgery screen

The 'Other Complication' control allows users to document multiple complications in a 'pseudo' coded way



The screenshot shows the 'Eye Details' form. It includes fields for Eye Laterality (OD), First Surgery On Eye (Yes), Original Diagnosis First Transplant (Please Select), Diagnosis for Transplant (Fuchs endothelial dystrophy), Main Reason for Transplant (Tectonic (cover performance or mabr)), Risk Factors incl. ocular comorbidity (Vascularization), Visual Acuity (best correction) (0.16 = 6/38), and Corrected Distance Visual Acuity (0.63 = 6/9). There are buttons for 'Back to Surgery', 'Save Form & Finalize Later', 'Discard Form', and 'Finalize & Submit Form'. The form is powered by TIC integration and is part of the ECCTR project.

Eye detail screen

As this is the last step of the assistant-driven documentation, the user can select 'Save Form & Finalize Later' to save the form, and be able to modify/complete the data later or 'Finalize & Submit Form' to permanently save it.

Next steps:

All partners are still testing and finalising the registry

The Veneto Eye Bank Foundation and European Eye Bank Association are working on the recruitment of the clinics across Europe. Data collection for clinics and universities will be starting shortly.