EURO GTP II
Good Tissue & cell Practices

- EuroGTP II -

Good Practices for demonstrating safety and quality through recipient follow-up

WP8 KickOff

University Hospital Ghent

Ghent, 03.03.2017

Funded by the Health Programme of the European Union

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European Commission

Project ‘709567 / Euro-GTP II’ will receive funding from the European Union’s Health Programme (2014-2020).

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Objectives

Good practices applied to T&C preparation, processes and patient follow-up procedures, to ensure

safety and support the evaluation of the clinical efficacy

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Objectives

To develop **common Good Tissue Practices** (Euro-GTP II) for European Tissue Establishments (TE) and Organizations Responsible for Human Application (ORHA), that address the **studies extent** (retrospective, concurrent, prospective and short and long term) needed for human application of the tissues/cells in a **safe and effective** manner.

- Determining methodologies for assessing the risks associated to **novel tissues/cells**

- Determining methodologies for assessing the **extent of the studies** needed to provide enough quality, safety and efficacy data for the use of tissues/cells

- Determining the **follow up programs**, according to the inputs of the previous issues, to ensure safety and support the evaluation of the clinical efficacy

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Objectives

•Determine methodologies and follow-up studies needed to provide enough quality and safety data for the use of tissues/cells (Tissues, cells and ART);

•To come up with a compendium of tissues/cells products, preparation processes, applications and therapies – ***T&C Database***

•Produce a sustainable "GTP`s management model"

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Targets

- TEs / ART Centers
- ORHAs
- NCAs

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ORHAs – Special Role

At least **1 ORHAs per Associative Partner**

- Clinical Outcomes
- Follow-up Methodologies
- Efficacy
- Medical Registries

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Other Collaborations

- EU Joint Actions
  - ARTQHIS
  - VISTART
- ECCTR project
- Project Notify

ARTHIQS
Assisted Reproductive Technologies & Haematopoietic stem cells Improvements for Quality & Safety throughout Europe

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

ECCTR
European Cornea and Cell Transplantation Registry

NOTIFYLIBRARY
The Global Vigilance and Surveillance Database for Medical Products of Human Origin
TRANSPLANTATION, TRANSFUSION AND ASSISTED REPRODUCTION

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Collaborative Partners

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

Regulation Principles

EURO GTP II good practices

Follow-up and methodologies to assess efficacy

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Other Collaborations

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

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•Define **WHAT** has to be assessed by the CAs in order to authorize new T&C (products and therapies)

•Determine **HOW** TEs and End Users must proceed to evaluate the efficacy of novelties (and well established) T&C

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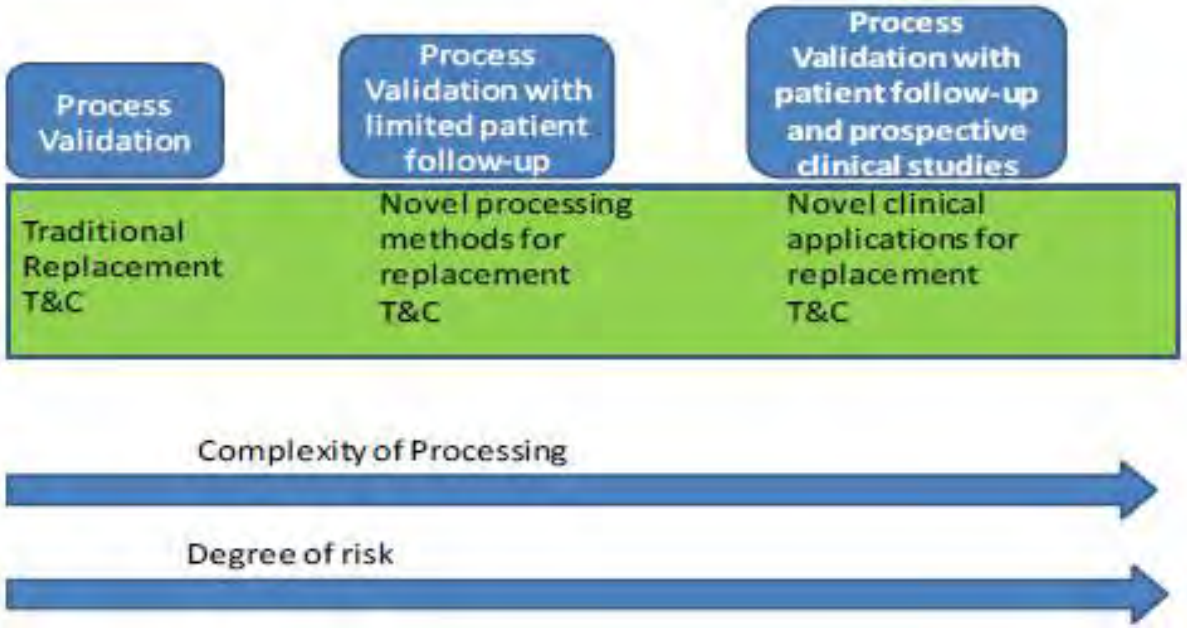
Methods and means

Common assessment methodology will be developed based on:

1. the impact of the 'novelty level' for the definition of procedures to validate T&C products and therapies.



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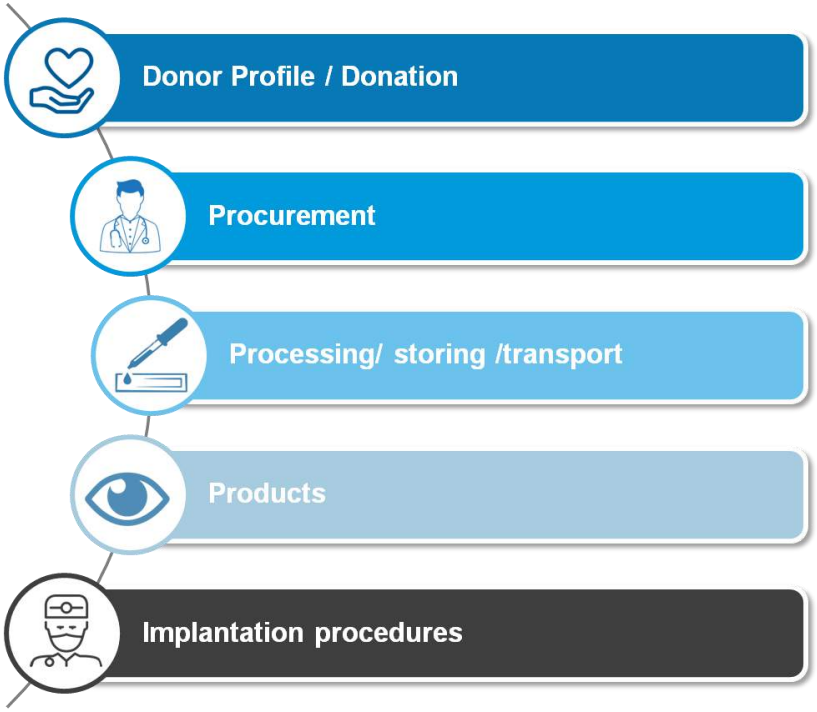
Methods and means

Common assessment methodology will be developed based on:

2. Risk factors and other aspects identified as relevant for the clinical validation and determination of follow-up programs

Donor Profile (age, gender, selection criteria, etc)
Autologous or allogeneic origin
Recovery conditions/procedures
Processing conditions/procedures
Reagents quality
Residual traces
Grade of manipulation
Use of antibiotics
Time of exposure
Complexity of the process
Microbiological related QC limitations
Storing conditions
Transport conditions
Structural/Functional integrity
Presence of vital cells
Presence of vessels
Complexity of the implant/application method



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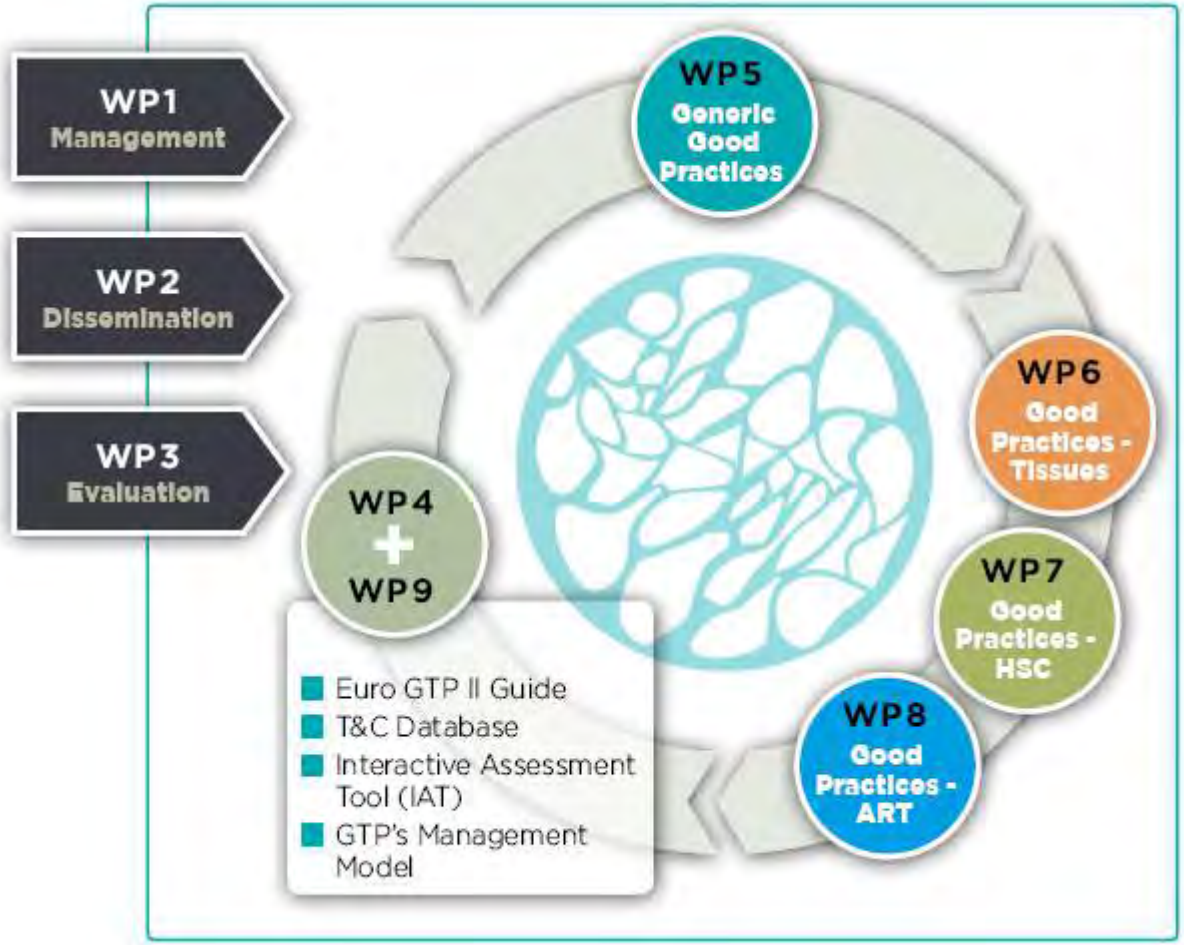
Work Packages



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Outcomes

- EuroGTP II Guide:

Definition of the **methodology to assess the novelty grade** (risk value);

- Definition of **minimum safety and efficacy data** that should be provided prior to use in routine - **Risk Based Approach methodology**
- Definition of the **validation studies, clinical studies, and follow up programs**

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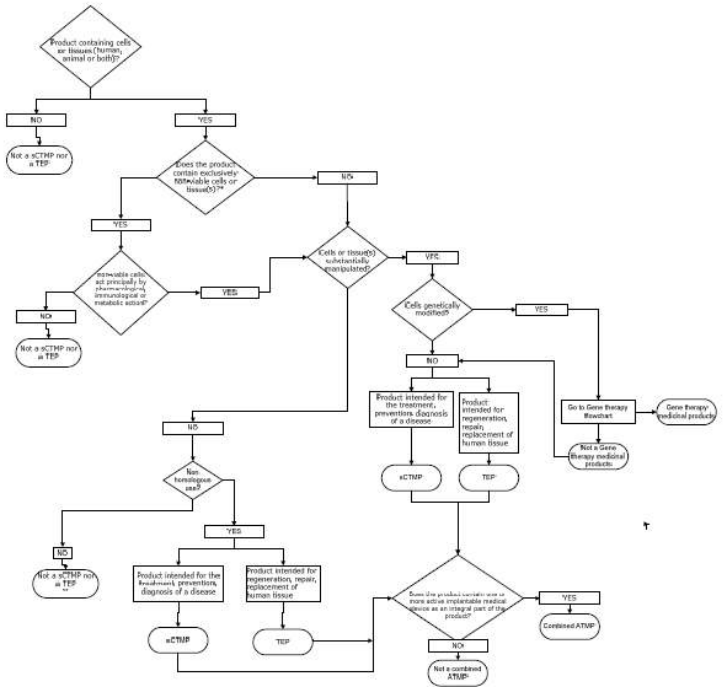
Outcomes

- Interactive assessment tool
  - will provide information related with **procedures, protocols and clinical data required to ensure quality and safety**
  - Practical **assessment of extended studies and follow-up programs** needed to implement, evaluate and authorise a novel T&C product, process or therapy.



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Does the T/C product have any degree of novelty?

1. EVALUATION OF NOVELTY

NO
Risk profile is not needed

YES
Risk profile is needed

Does this TCP, in any form, has a history of safe clinical use?

What is the overall assessment of risk/novelty?

2. LEVEL RISK ANALYSIS

YES
DATABASE (product-process-indication)

NO
Risk profile is needed

Negligible

Low

Moderate

High

process validation and routine follow up programs

Intensive process validation and follow up programs

Clinical studies and intensive process validation and follow up programs

In vitro and in vivo studies and intensive process validation and follow up programs

3. DEFINITION OF STUDIES EXTENT

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1. Evaluation of Novelty

- ○ Has this type of TCP ever been prepared and issued for clinical use by your establishment previously?
- ○ Has this type of TCP been obtained from the same donor population before by your establishment?
- ✓ Has this type of TCP been procured using the same procedure by your establishment before?
- ✗ Has this type of TCP been prepared with the same procedure (processing, decontamination and preservation) in your establishment before?

- ○ Has this type of TCP been packaged and stored using the same protocol and materials by your establishment before?
- ✓ Has this type of TCP been provided for transplantation into the intended anatomical site by your establishment before?
- ○ Has this type of TCP been applied using the proposed application method before?

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2. Level Risk Analysis

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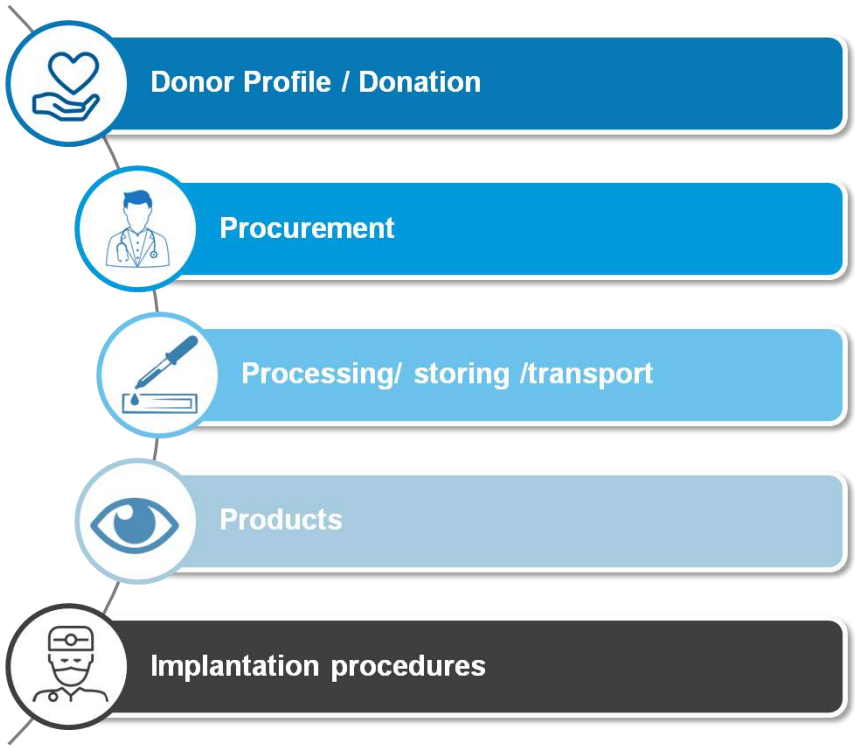

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2. Level Risk Analysis

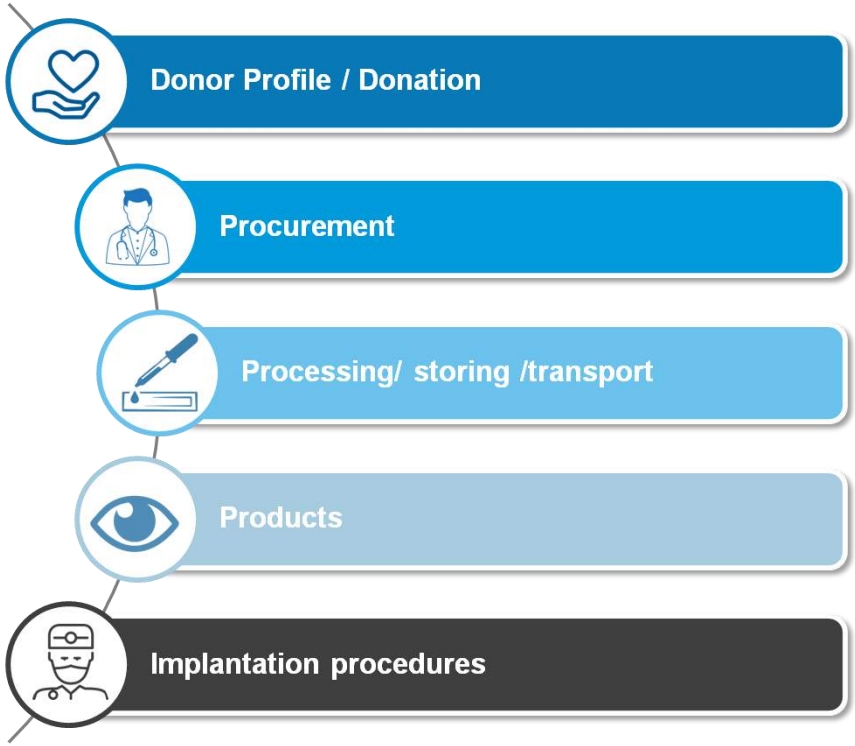
Unwanted immunogenicity

Implant failure

Disease transmission

Toxicity / Carcinogenicity

Other potential risks (can be associated with specific TCP/therapy)



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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.

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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

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• Determining the **follow up programs**, according to the inputs of the previous issues, to ensure safety and support the evaluation of the clinical efficacy

ECCTR
European Cornea and Cell Transplantation Registry

ESSKA
European Society of Sports Traumatology, Knee Surgery & Arthroscopy

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Draft principles will be presented to AP in April 2017

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T&C Database

What we know:

Targets users → Stakeholders (TEs, end users) (NCAs may also access)

Accessibility → Public (?)

Information:

- T&C characterization including obtaining processes and clinical applications,
- efficacy data available and correspondent classification as **Experimental/innovative/Established TCP/therapy**
- SARE and bibliographic references

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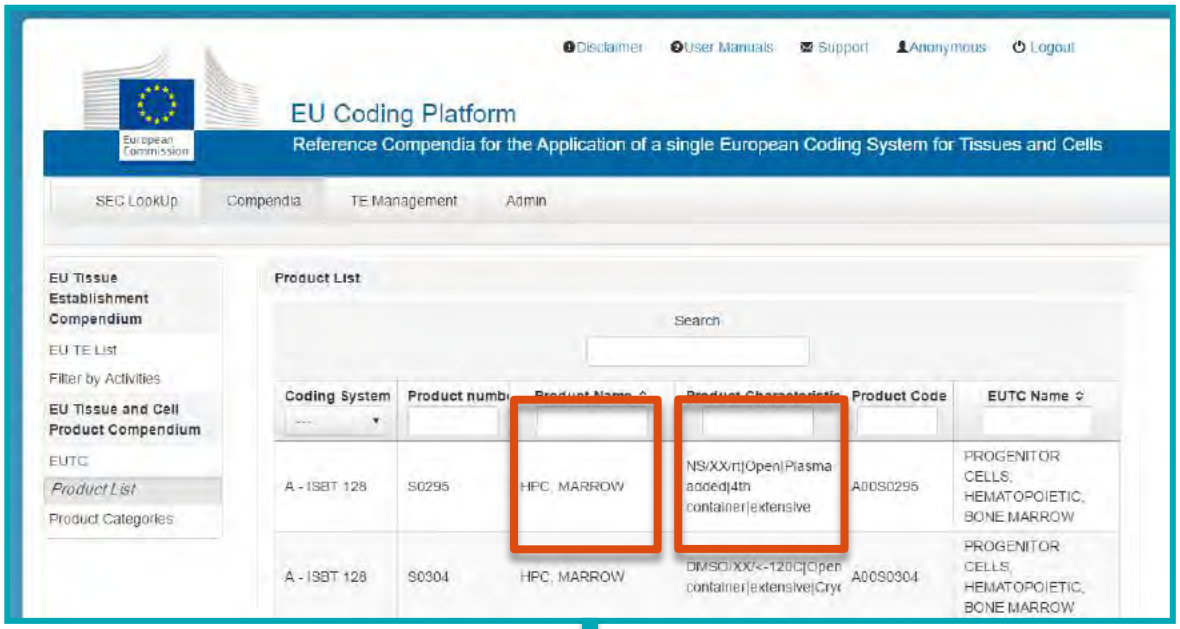
T&C Database



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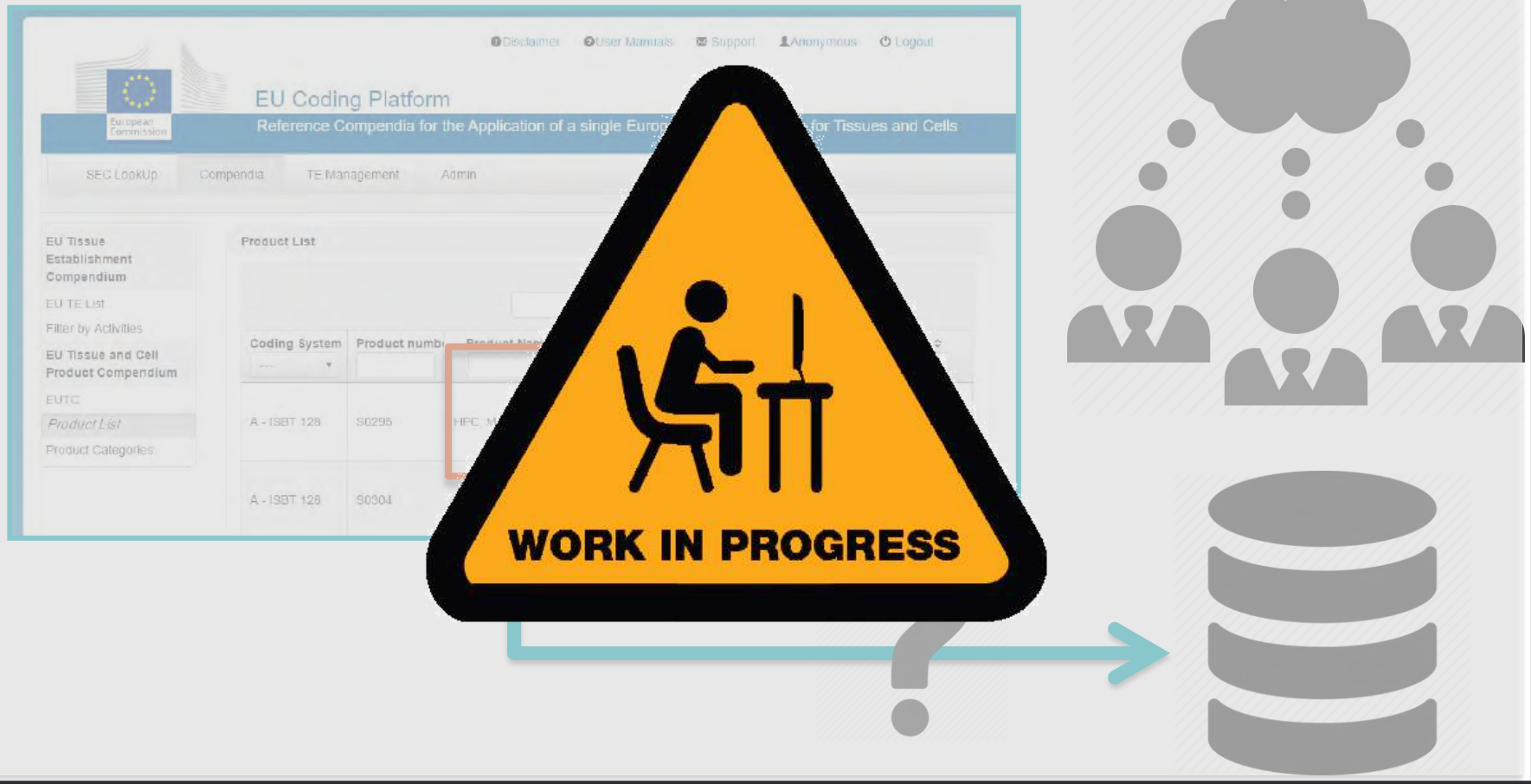

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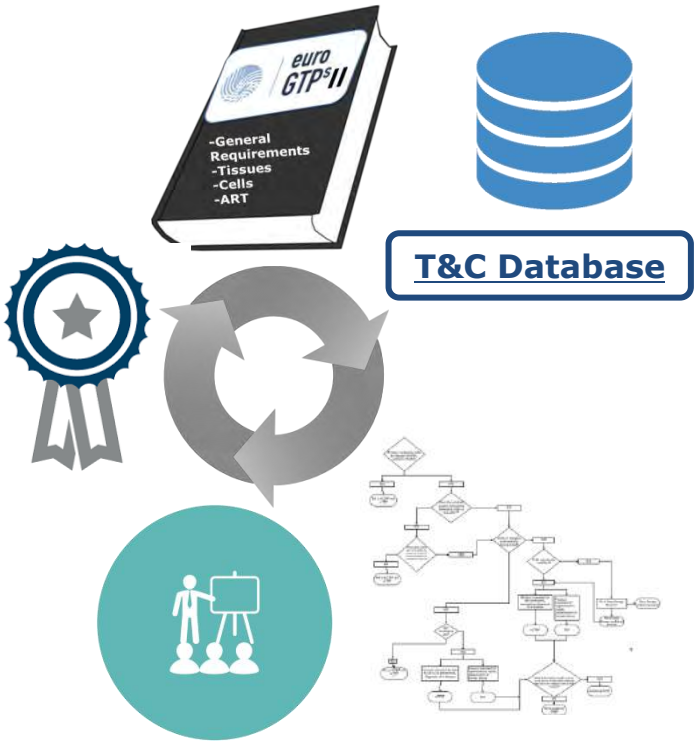
Sustainability of the outcomes

- Definition of technical requirements;

- Identification of organisations with know-how and resources for long term update



EBMT European Society for Blood and Marrow Transplantation
EEBA EUROPEAN EYE BANK ASSOCIATION
ATB
eshre Science Moving People Moving Science

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Next Meetings

WP8 ART – 3rd March, Ghent

WP5 Generic + WP6 Tissues – 3rd and 4th April, Budapest

WP7 HSC – (Informal WP's kickoff) 27th March (EBMT Congress)

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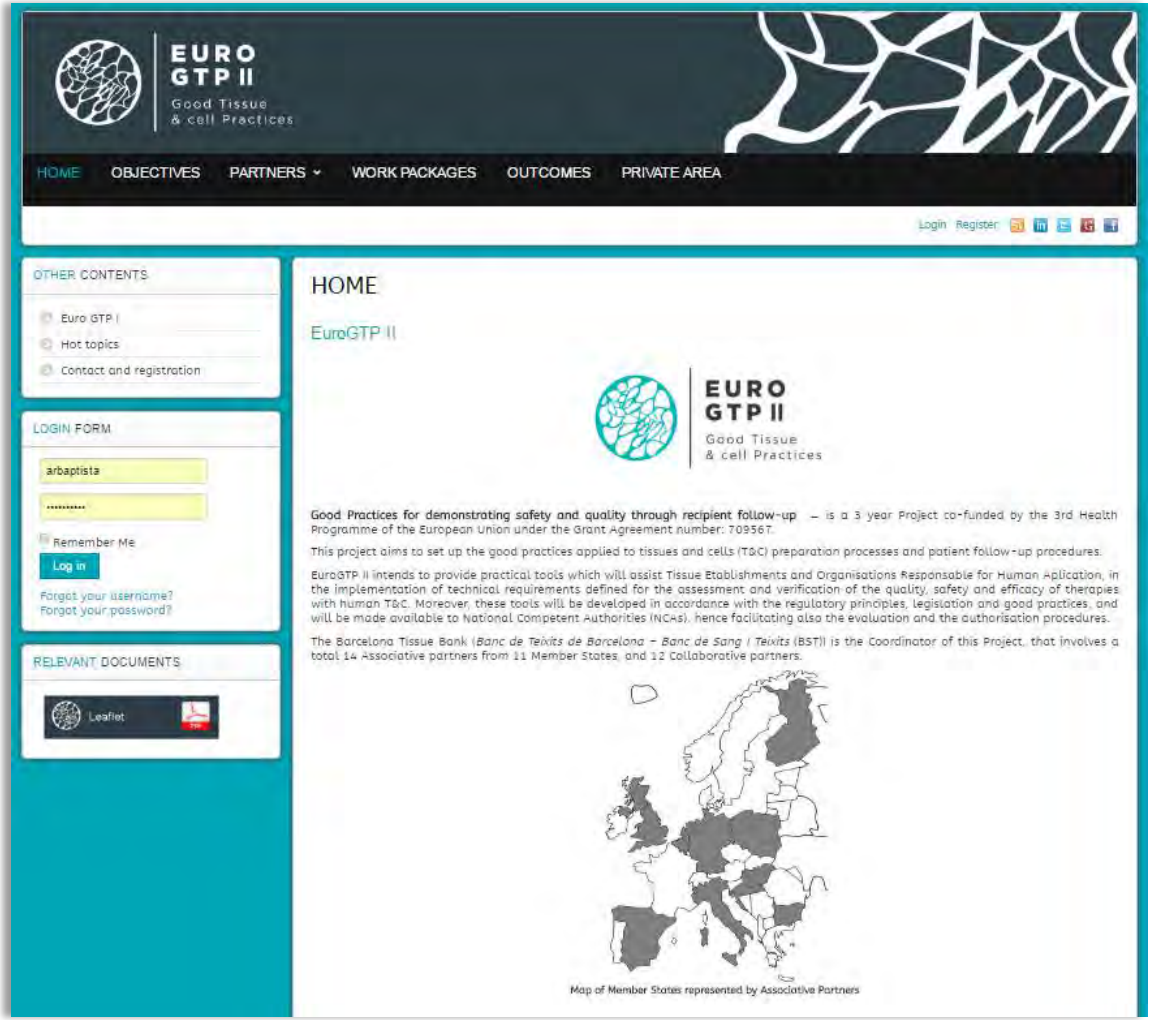
http://www.goodtissuepractices.eu/



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Thank you!

EuroGTPII@bst.cat

http://www.goodtissuepractices.eu/

Barcelona Tissue Bank
Banc de Sang i Teixits

Centro Nazionale Trapianti · ONT · Ministarstvo zdravlja · NHS Blood and Transplant · Krajowe Centrum Bankowania Tkanek i Komórek · TRIP Hemo- en biovigilantie · UZ Universitair Ziekenhuis Gent

Kliniek SINT-JAN Clinique SAINT-JEAN · Executive Agency for Transplantation · regea · DGFG Deutsche Gesellschaft für Gewebetransplantation