



# European Group For Accreditation And Liaison Of Blood- Tissues And Cells Establishments

EU4Health Web-InfoDay 2024

Mag. Dr. Simone Hennerbichler-Lugscheider

**2022:**

- ~ 53.000 blood donations
- ~ 3.500 apheresis
- ~ 570 tissue donations  
(allogeneic + autologous)

## BLOOD PRODUCTS + MEDICINAL PRODUCTS



clean rooms  
for separation of blood  
components  
(GMP class D)



Plasma  
Erythrocytes  
Thrombocytes  
Serum eye drops  
+  
medicinal products + ATPs  
for clinical studies



## CELL AND TISSUE PRODUCTS



Cornea, DMEK, sclera

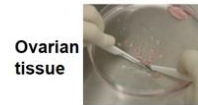
Heart valve and aorta

Amnion

clean rooms for cell and  
tissue banking  
(GMP class D, C, B, A)



Cranial bone



Ovarian  
tissue



Peripheral blood stem cells

## OTHER AREAS:

- Blood + tissue donation
- Outpatient clinics
- Hematology,  
Coagulation,  
Immunhematology
- PCR- and ELISA-  
screening of products  
and patient samples
- Microbiology,  
Immunogenetics,  
Immunology
- R&D:  
Tissue Regeneration  
with LBI Trauma

# Substances of Human Origin (SoHO)

Setting standards to save lives

Blood, tissues, cells and organs are used in a variety of medical therapies. Based on these substances of human origin (SoHO) save lives (e.g. blood transfusion, organ transplantation, bone marrow transplantation, and in vitro fertilisation). Despite their benefits, the use of SoHO carries risks, in particular the transmission of diseases. The European Commission is addressing these risks through its mandate to set high standards of quality and safety with Art. 168(4)(a) of the Treaty on the functioning of the EU. To this end, the Commission is developing legislation and developing guidance, assisting national authorities, accompanied by vigilance activities and project support. The overall objective is to ensure that the use of SoHO is safe, effective and accessible.

ACC

EU4Health Web-

[https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin\\_en](https://health.ec.europa.eu/blood-tissues-cells-and-organs/overview/proposal-regulation-substances-human-origin_en)



English

Search

## Public Health

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### New EU rules on substances of human origin

#### PAGE CONTENTS

#### Commission proposal

#### Next steps

#### Latest updates

#### Documents

On 14 December 2023, a political agreement was reached on the Commission's proposal for a Regulation on standards of quality and safety for substances of human origin intended for human application.

- [Press release](#)
- [Factsheet](#)

The [agreed text](#), prior to legal-linguistic revision, is available on the Council website.

The [Commission Proposal](#) was tabled in July 2022.

- [Press release](#)
- [MEMO](#)

The new EU rules, which should now be endorsed in the course of 2024:

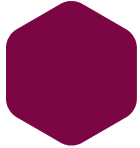
- support the **continued provision of SoHO therapies**, now and in the future, based on **high safety and quality standards** and up-to-date technical rules
- extend protective measures** to new groups of patients, to donors and to offspring born from medically assisted reproduction
- improve **harmonisation** across Member States, facilitating **cross-border exchange** of SoHO and **improving patient access** to the therapies they need
- create conditions for **safe, effective and accessible innovation** in a unique sector driven by public health services and voluntary and unpaid donations
- improve **crisis preparedness and resilience** to safeguard access to therapies
- implement **digital-ready policies**
- contribute to the **European Health Union** by pooling of technical expertise and achieving economies of scale.

As the Directives it repeals, the proposed Regulation has Article 168(4)(a) of the Treaty on the Functioning of the European Union as its legal basis. Feedback on the proposal was collected from 14 July 2022 to 08 September 2022 on the [Have your Say Portal](#).



up For  
Blood-  
ments

-Lugscheider



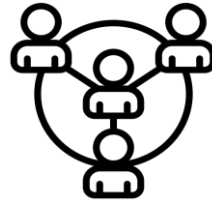
# European Project



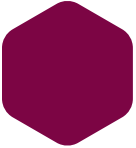
May 2022 – October 2024



Blood, Tissues and HSC



Consortium of 25 Organizations  
(Beneficiaries + External Experts)



# Goals

## European Accreditation Program

as a means to achieve mutual recognition amongst SoHO organisations.

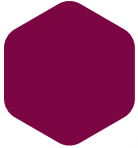
## Optimize resources and improve collaboration

Definition of strategies to promote self sufficiency in the EU.

## Enhancing the ability of SoHO organisations to respond during crisis

Ensure supply of essential SoHO in routine and during crisis, and define technical assistance programs



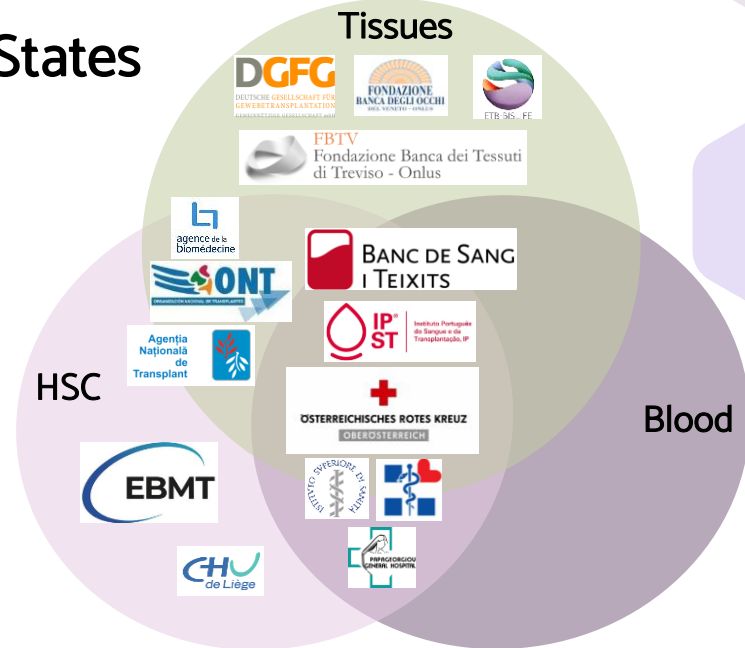


# 15 Beneficiaries

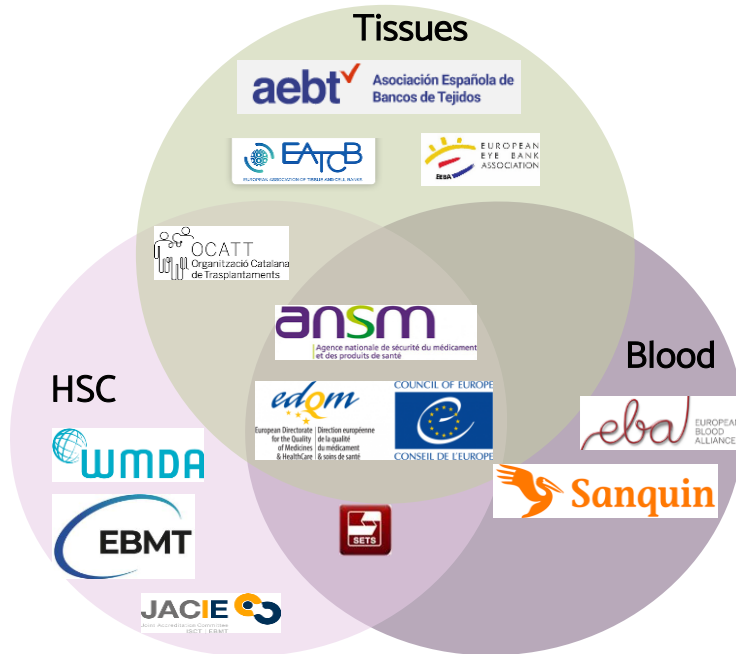


## 10 Member States









- Blood and Tissue Establishments
- Competent Authorities
- Scientific Societies



# External Experts from 10 Organisations



# Work Packages

WP1	Management and Coordination of the Project	 BANC DE SANG I TEIXITS	Spain
WP2	Dissemination & Communication		Greece
WP3	Evaluation		Portugal + Italy
WP4	Integration and sustainability		Spain
WP5	EGALiTE Accreditation Program		EU + Spain
WP6	BTC Database		Germany
WP7	Contingency plans		Netherlands
WP8	Develop of European Assistance Mechanisms		Austria





# European Accrediation Program WP5

## Harmonisation/ mutual recognition



### Establish EGALiTE

- practical procedures, rules and by-laws
- Accreditation guide
- long-term sustainability



### Establish a Network

- potential auditees
- potential collaborators



### Audit guidance and harmonized report templates and procedures



### Face-to-face programmes and E-learning Platform to facilitate future EU Training

- Potential auditor

# BTC Database WP6

## Optimize resources and improve collaboration



### BTC Database

- Activities and Preparation Processes
- Facilities and equipment available
- Ability to process for 3<sup>rd</sup> parties
- Sufficiency levels
- Accreditation status
- Access to donors/donation centers
- Etc.



**Map of Resources** (will allow the visualization of the resources currently available in the different Member States)



# Contingency Plans WP7

## Enhancing the ability of SoHO organisations to respond during crisis



**Contingency Plans:** action plans which shall be activated in case of the different scenarios of crisis.

- Tools
- Guidance

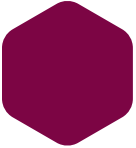
# Technical Assistance Programme WP8

## Implementation and optimization of good practices



**Technical Assistance Programme** (propose the mechanisms to fund and coordinate the participation of EGALiTE accredited experts in the activities requested by Procurement Organisations/donation centers, Blood and Tissue Establishments, Hospital Blood Banks, and Competent Authorities of any European Member State)

- workshops, congresses
- Study visits
- Expert missions



# EGALiTE status

- ✓ EGALiTE's **Accreditation Process** (scope, tools, auditors and other requirements)
- ✓ EGALiTE's **Accreditation Guide** + Standards (based on EDQM Guides and other references)
- ✓ Specifications and requirements of the new **BTC Database**
- ✓ Technical Assistance Programme (**TAP**)
- ✓ Tools and guidance for the **Contingency Plans**
- ✓ **Sustainability plan** for project outcome and take-over by scientific societies (EEBA and EATCB)



# THANKS!

## Any questions?

- ◆ [dissemination@egalite-europe.eu](mailto:dissemination@egalite-europe.eu)
- ◆ [www.egalite-europe.eu/](http://www.egalite-europe.eu/)