

EU4Health

### European Group For Accreditation And Liaison <u>Of Blood-Tissues And Cells Establi</u>shments

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### Newsletter 3

**JUNE 2024** 



# **EGALITE**

EGALITE - the European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments - is a 30-month project, which aims to promote the harmonization of practices among Collection Centers, Blood, Tissue and Cell Establishments, to encourage sustainability and collaboration among stakeholders, and the implementation of strategies to improve accessibility and sufficiency of SoHO (Substances of Human Origin) at the European level.



## **Key Goals of EGALITE**

for better accessibility and sufficiency of SOHO

The outcomes of EGALITE aim to support the activities performed in Member States with distinct technical capacities by developing and establishing:

- A European Accreditation Programme as a means to achieve mutual recognition amongst SoHO organisations
- An efficient database of resources (Collection Centres, facilities, activities etc.) which will be used to design sufficiency plans and promote the collaboration among professionals and CAs, to ensure an adequate supply of Blood, Tissues and Cells (BTC) in the different MS
- Contingency plans to assist the responsible persons in the decision making process during a crisis
- A Technical Assistance Programme to assist the implementation of good practices and optimization of activities in the different EU Member States

## Groups EGALiTE aims to assist

EGALITE project and its outcomes aim to assist SoHO stakeholders of different types of organisations:

- SoHO Establishments
- Collection Centres
- Professionals of medical societies EBMT, EBA, EEBA, EATCB, WMDA, AEBT, SETS, EHA
- National Competent Authorities

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### The impact

- Sharing Resources at EU level is expected to be simplified
- Member States will have the opportunity to easily request and obtain Technical Assistance
- The primary aim is for SoHO organisations/establishments to develop the ability to react during crises and catastrophes, as a result of improved cooperation among involved stakeholders and the immediate adoption of the developed contingency plans.
- Competent Authorities, will be able to rely on an independent group of qualified European experts

## Stay In Touch

Months eloosed (26 of 30)

To find out our future activities, and how the project's advances enhance accessibility and sufficiency of SoHO in the EU, sign-up to EGALiTE's <u>newsletter</u>

## Summary of Project's Progression:

(25 5) 50)	
Deliverables (11 of 22)	
Milestones (45 of 64)	



Overall, the aim is to develop and establish a quality programme, delivering significant benefits and utility – for citizens and health systems/organisations – on the provision of blood, tissues and cells.

## Dissemination Activities

### EGALITE at EEBA congress in Antwerp

EGALITE represented by Elba Agustí (BST) delivered a presentation at the XXXV Annual Meeting of the European Eye Bank Association on March 7th-9th, 2024, in the city of Antwerp. The action, addressed to more than 200 participants from across the EU MS, aimed to promote the future EGALITE outcomes and deliverables among key target stakeholders who are likely to have an interest to make use and benefit from it.



## Project timeline

#### Project Coordination – WP1

The 4th Coordination Meeting of WP Leaders organized by WP1 took place online on March 14th, 2024. During the meeting partners and WP Leaders discussed progress achieved so far across WPs and topics which required further deliberation. The meeting set out future actions and the necessary coordination to successfully achieve the targets outlined for the EGALITE project. Meanwhile discussions have taken place regarding the Final Dissemination Seminar and Training to be held upon the conclusion of the project in October 2024.

#### Final Dissemination Seminar in Venice, Italy

The coordinators (WP1), in collaboration with our FBOV colleagues, have announced the upcoming Final Dissemination Seminar.



Date: October 3rd, 2024



Location: Fondazione Banca degli Occhi del Veneto Onlus (Veneto Eye Bank Foundation) Padiglione Rama, Via Paccagnella, 11 - 30174 Zelarino, Venice, Italy.

This event will provide an excellent opportunity to share the outcomes of our project and celebrate our achievements.

It will also serve as the official kick-off for the implementation of our European Accreditation and Technical Assistance Programmes which will be organized alongside the auditor's training.

#### How to attend

If you are not a partner of our consortium but wish to attend this event, please inform the coordinators by sending an email to coordination@egalite-europe.eu.

#### Project Coordination – WP1

Major progress has been made by WP1 with the signing of the formal Memorandum of Understanding by EATCB and EEBA, establishing a future coalition to manage the outcomes of the EGALiTE Project. This agreement expresses the commitment of these two major European scientific societies to pursue the objectives and promote the principles and standards defined by the EGALiTE partners.

An additional supporting document, defining the responsibilities and practical procedures for each scientific society, is currently under review and discussion by the boards of both societies. This delineation is crucial for ensuring the sustainable and effective management of the EGALITE Project outcomes. It aims to facilitate a smooth transition of management once the EGALITE Project concludes, thereby ensuring the long-term sustainability of its deliverables.

#### Dissemination - WP2

EGALITE participated at the EHA congress in June 2024 as an opportunity to gain visibility, promote the project and extend outreach, while taking advantage of similar upcoming meetings such as the EATCB congress.

Additional events:

- SIGHT SoHO workshop for SoHO Inspectors and Competent Authorities, 5th-7th June, Rome
- Conference on the SoHO Regulation, 24th June 2024, Brussels organized by DG SANTE

# EGALITE at the European Commission high-level event on the new SoHO Regulation

On Monday 24th of June the European Commission organised a high-level conference to present and discuss the new SoHO regulation. The conference brought together professionals preparing and applying SoHO therapies, patient and donors, stakeholders, authorities and policy makers. The agenda focused on the new safety and quality standards of the new Regulation, the protection of donors, recipients and offspring, innovation and supply continuity. The agenda concluded with a policy session on the importance and way forward for the SoHO regulation. Rita Piteira represented Banc de Sang i Teixits and EGALiTE project at the event, participating at the session regarding the challenges of ensuring a sufficient supply of critical SoHO and the panel discussion which looked into the perspectives of professional and authorities on supply matters.





#### Evaluation – WP3

In addition to continuous monitoring and evaluation activities, WP3 has planned several crucial actions to assess the impact and quality developed by the **EGALITE Consortium**. As the project nears its completion, the following activities are being planned and implemented by WP3, including impact assessments and consultations, namely:

- Open Consultation and Impact Assessment: To be conducted once all deliverables are available
- Evaluation of the Dissemination Seminar and Auditor's Training Course: This will involve face-to-face assessments
- Final Evaluation Report of the Project

#### Integration and sustainability – WP4

Pilot actions for both the TAP and Accreditation Programmes are actively being conducted by WP4.

Two pilots of each programme are currently ongoing, with the dedicated support of our consortium partners.

These simulations aim to determine the suitability of the deliverables, namely the standards and procedures defined for the practical implementation of both accreditation and Technical Assistance Programmes. These will enable the timely identification of any shortcomings, allowing the implementation of necessary corrections, and help define the resources required for effective and sustainable management by the scientific societies. This process is crucial to ensure both programmes are ready to go live and be available to all stakeholders.

#### Accreditation Programme - WP5

Once the MoU was signed by the scientific societies, WP5 finalized the Accreditation Dossier and submitted it for evaluation by HaDEA and DG SANTE. This deliverable consolidates several documents that outline the instructions, procedures, and forms required to implement the future Accreditation Program.

The documents were developed and revised by the members of the EGALITE Consortium, Scientific Societies (EEBA, EATCB), and the External Advisory Board (EAB). All procedures and templates defined in the Accreditation Dossier, along with EGALITE Standards, have been transposed into the IT Accreditation Platform, where the Accreditation Program is being implemented.

This aims to improve the execution of all accreditation procedures, from the submission of applications by applicants to the issuance of reports by auditors and the final certification by the future EGALITE Coalition.

The customization of the IT Platform is another significant milestone achieved by WP5. This deliverable is currently being tested within the pilots promoted by WP4.

The structure of the future e-learning platform is also being populated with the didactic content needed to train future EGALiTE Auditors.

The EBMT colleagues have provided valuable support in defining the structure of the training and creating content, drawing on their knowledge and experience from JACIE's training programs.

#### BTC Database - WP6

The WP6 team has made progress in defining the specifications for the future BTC Database. Following a virtual technical meeting with experts from this working groupgroup, at the 3rd Technical Meeting on 11th March 2024, the new set of specifications has been forwarded to the external provider, who is currently implementing the new database on a platform shared with the Accreditation features.

To ensure broader access and use of the future database, it has been decided that all BTC stakeholders will be able to input a high level of data related to their activities, regardless of their involvement with the EGALITE accreditation procedures. This will provide the opportunity to monitor the resources available at SoHO entities in Europe, as previously defined in the Project Proposal.

The availability of a functional mock-up of the database is imminent and depends only on the availability and implementation which is ongoing by the external provider.

#### Contingency Plans - WP7

An overview and information on the next steps and timeline for Contingency Plans was discussed among partners. Particular emphasis was placed on the importance of integrating the outcomes of WP6 and WP7, highlighting the BTC Database as a crucial tool for connecting with appropriate stakeholders and seeking assistance during emergencies. The Contingency Plans are under development. The final deliverable is expected to be available for a final internal consultation and evaluation by the External Evaluation Board, within the upcoming weeks. A interactive online tool, is planned to assist the practical use of the contingency plans developed by the EGALITE Consortium.

#### Technical Assistance Programme - WP8

An overview was presented of the work which has been finalized, including the online form developed for submitting future **TAP applications**.

Deliverable, "D8.1 – **Procedures of the Technical Assistance Programme (TAP)**: Knowledge Gap: Apply for TAP!" by WP8 has been submitted and approved by HaDEA. It is currently being tested in real-life settings as part of the pilot actions promoted by WP4.



#### **Our Partners**

































### **Invited Experts & Collaborative entities**



























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