



Exciting News from the Future EGALiTE Coalition!

Accreditation and Technical Assistance Programs Coming Soon!

Prepare to apply early and be among the first to benefit from these innovative initiatives!

coordination@egalite-europe.eu

EU4Health
European Group
For Accreditation And Liaison
Of Blood-Tissues And Cells Establishments

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Layman
NOVEMBER 2024

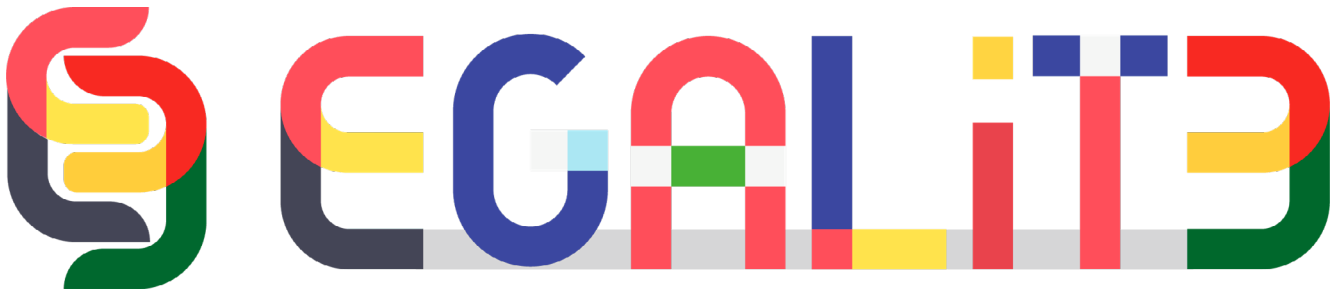


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EGALiTE

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 and scientific societies - EBMT, EBA, EEBA, EATCB, WMDA, AEBT, SETS, EHA
- ★ National Competent Authorities

EGALiTE

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

Specific Objectives

- ★ Implementation of a common European Accreditation Programme as a means to achieve mutual recognition amongst SoHO Entities.
- ★ Optimize the resources available and improve collaboration between SoHO Entities of the different Member States - Define strategies for EU self-sufficiency
- ★ Enhancing the capacity of SoHO Entities to respond rapidly and in a co-ordinated fashion to health threats
- ★ Provide contingency plans to be implemented by Health systems/ Public organisations in times of crises
- ★ Implement technical assistance for EU Member States in times of crises, to assist the implementation of best practices and optimisation of activities, and a mapping of SoHO resources
- ★ Develop an efficient database with an overview on available resources
- ★ Establish cross-sector consensus on training programmes
- ★ Achieve sustainability of EGALiTE outcomes, and implement pilot programmes allowing timely adjustments on deliverables

Stay In Touch

The **EGALiTE Coalition**, comprising representatives from the Scientific Associations EATCB (European Association of Tissue and Cells Banks) and EEBA (European Eye Banks Association), will oversee the future management of the EGALiTE Project's outcomes. For more information on upcoming EGALiTE programs and their implementation, please contact us at:

coordination@egalite-europe.eu

Technical Work developed by EGALiTE Project

Project Coordination – WP1

The Coordination team has strived for the smooth collaboration and progress of the project with all beneficiaries and partners throughout the project lifetime, and on-time delivery of outputs. Special focus was placed on work with **Scientific Societies** to ensure the future sustainability of the project's outcomes

Discussions and negotiations have taken place, namely with the scientific societies of European Eye Banks Association (EEBA), European Blood Alliance (EBA), European Association of Tissues and Cells Banks (EATCB) and EBMT.

A **Memorandum of Understanding (MoU)** has been signed by EATCB and EEBA establishing a future coalition to manage the outcomes of 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, was reviewed and discussed by the 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

The communication and dissemination strategy is defined and implemented by WP2. WP2 developed the communication-dissemination plan with the aim to raise awareness - at a scientific and wider level - to inform, promote, and facilitate knowledge-sharing amongst target audiences, making results and deliverables/outcomes achieved, available to stakeholders and the wider audience, whilst engaging them and promoting EGALiTE outputs, ensuring the correct dissemination of EGALiTE project and its outcomes, among the scientific community, medical professionals, national authorities, community officials and the general public, with a view to encouraging harmonisation and uptake of standards and systems of accreditation across the Community.

The Action targets SoHO stakeholders of different types of organisations: SoHO establishments, Collection Centres, Professionals of Medical Societies (EBMT, EBA, EEBA, EATCB, WMDA, AEBT, SETS, EHA) and National Competent Authorities, building close collaborations and synergies, achieving presence at meetings or inviting them to EGALiTE meetings.

WP2 worked on developing the Action's image and promotion, making results available to stakeholders and the wider audience, as well as the development of the project's logo and visuals, templates and the set-up of the official [website](#) and social media, all handled internally, including the monitoring-evaluation and coordination of EGALiTE social media accounts (<https://x.com/EgaliteEurope> and LinkedIn <https://www.linkedin.com/in/egaliteeurope/>) which have continued to expand base and outreach to stakeholders with tailored content, bringing to the forefront the activities and work/deliverables by the Action, while also promoting relevant EC/ EU Health Union priorities and initiatives.

WP2 supports dissemination/communication activities with the production of press releases/news items, social media, internal communication, while supporting/promoting relevant EU policy and implementation in BTC, and the project's presence at **events/conference opportunities** (e.g. EHA Collaboration Plaza June 2024, the SOHO high-level event of the EC in June 2024/2023, the EBMT 50th Annual Meeting in April 2024, EEBA Annual Congress in March 2024, the EATCB Annual Conference in November 2023).

Where required, WP2 has supported EGALiTE's presence to these events with the development, design and production of presentations, banners/posters, flyers, brochures, visual material and/or branding material, all publicly available on EGALiTE website, and circulated to all internal and external stakeholders.

The **Digital Leaflet (D2.2 /MS16)** is a public document produced on the project's initiatives and outcomes, disseminated as an information pack to healthcare professionals and health authorities, giving an overview of the project and its expected outcomes. The leaflet was produced in digital format to facilitate distribution via electronic means, allowing also for cost-effectiveness and a green approach. A shorter version of the leaflet was designed as a **4page flyer**, created for print and for distribution as hand-out material at meetings, keeping in mind a green footprint approach. Both versions are available in the corresponding file and publicly available on the website:

https://www.egalite-europe.eu/wp-content/uploads/2023/05/LEAFLET-v0_8-3a.pdf

https://www.egalite-europe.eu/wp-content/uploads/2023/07/FN_FLYER-CORRECT.pdf

Newsletters (D2.3/ MS17 edition No1, D2.4, MS19, D2.5, MS 20, editions No2 and No3) provided an overview on the project, while promoting its initiatives, outcomes and progress among internal and external publics, disseminated and distributed by email to healthcare professionals and stakeholders (e.g. partners, health authorities, tissues and blood competent authorities, national haematology associations, health professionals as well as EU Officers, Institutions, Agencies, Scientific Societies, Consortium members and more) while also published via social media. Furthermore, the team produced the **Interim Report on dissemination activities (MS18)**, this document -the **Layman Report (D2.6)** - produced to give an overview of the project for interested parties/stakeholders.

DISSEMINATION ACTIVITIES, CHANNELS & TOOLS

- EGALiTE website
- Social Media
- News items/press releases
- Newsletters
- Layman Report
- Digital Leaflet
- Deliverables (public/private)
- Events/ Exhibitions/ Conferences/ Meetings/Workshop Opportunities
- EGALiTE workshops and trainings /seminars and pilot actions
- EU Associations, Registries and collaborations/synergies
- EGALiTE Network
- EGALiTE Final Meeting & Dissemination Seminar
- Virtual/Hybrid meetings and personal communication
- Internal Communication (zoom meetings, website, email, face-to-face meetings etc)
- EGALiTE recommendations, opinion/position papers etc
- International days
- EU initiatives, priorities
- Any other

Technical Work developed by EGALiTE Project

WP2 contributes to the work of other WPs and actively participates or supports all internal and external meetings as required. WP2 also contributed to the **development of the tools** for the future outputs of EGALiTE project (e.g. online application forms etc) and the **Accreditation & TAP pilot programmes** of EGALiTE with the participation of its members of the Public CBBC (Cord Blood Bank Crete).

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**. The following activities planned and implemented by WP3, include 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

WP4 work is focused on the sustainability and the integration of EGALiTE outputs into practice across EU Entities. WP4 Leaders produced the 'procedure' to 'Apply' to the Pilot Actions of EGALiTE Project. The Pilot Actions aimed to validate the procedures defined by WP5 (Accreditation) and WP8 (TAP), acting as a simulation for the future implementation and verifying whether the outcomes of these technical WPs, are suitable, feasible, and according to the goals defined by the EGALiTE project.

Pilot Actions for both the TAP and Accreditation Programmes were conducted during **June-July 2024** by WP4. Two pilots of each programme took place with the dedicated support of Consortium partners.

These simulations aimed 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 enabled the timely identification of any shortcomings, allowing the implementation of necessary corrections, and helped define the resources required for effective and sustainable management by the scientific societies. This process was crucial to ensure both programmes are ready to go live and be available to all stakeholders.

Accreditation Programme - WP5

WP5 focused on the definition of the scope of the future EGALiTE Accreditation Programme and associated “[Accreditation Dossier](#)” which define the procedures of the Accreditation process. This includes the Accreditation Guide; Applicants’ Guide; Application Form; Audit Procedure & Auditors Guidance; Standards; and Sustainability plan. A demonstrator of the platform was presented by EBMT. The platform was developed by EBMT and tailored according the procedures defined for the future EGALiTE accreditation Programme, and encompasses all features associated with Jacie’s accreditation procedures.

WP5 also developed:

- The [EGALiTE Standards](#), which apply to all activities performed by SoHO Entities and all activities on SoHO preparations, including donor recruitment, selection, evaluation, testing and SoHO collection/ procurement, sampling, testing, processing, preservation, storage, release and distribution for clinical application.

- [Generic Standards for SoHO Entities](#)
- [Standards for Ocular tissues](#)
- [Standards for Amniotic Membrane](#)
- [Standards for Skin](#)
- [Standards for Cardiovascular Tissues](#)
- [Standards for Musculoskeletal Tissues](#)
- [Standards for Umbilical Cord Blood Progenitors](#)
- [Standards for Adipose Tissue](#)
- [Standards for Human Milk](#)
- [Standards for Blood Components for Topical Use or Injection](#)
- [Standards for Intestinal Microbiota](#)

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 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 and tested within the pilots promoted by WP4.

The WP5 was also responsible for the definition of training programmes for the future EGALiTE Auditors, including an e-learning populated with the didactic content needed to train future [EGALiTE Auditors](#) and a face-to-face training.

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

Technical Work developed by EGALiTE Project

BTC Database - WP6

WP6 Leaders performed a survey among partners to determine the features and specifications of the future **BTC Database**.

Based on partners' inputs, the BTC Database includes technical information that aims to assist professionals and promote the collaboration among peers. This information is intended to provide data about accredited establishments, while giving a general overview of establishment and their capabilities. Minimum information on products are included as well as the terms / fields used in database are clearly defined, so that all users enter data with the same understanding.

The **BTC Database** is implemented on the same IT platform as the **Accreditation Platform**. This unique solution aims simplify its future management and use by the scientific societies.

The aim was to develop a unique solution – a common platform for managing accreditation and database – in order to promote the introduction of the data required by the BTC Database simultaneously with the introduction of information required for the application for accreditation. This also aims to simplify the future management of these outcomes by the scientific societies.

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**.

Contingency Plans - WP7

The WP7 completed the **Status Quo Study**, which aimed to identify potential crisis scenarios (based on real experiences and hypothetical circumstances), management procedures and corrective and preventive measures implemented by the different Member States.

The study focused on:

- Defining situations or scenarios that would require a contingency plan.
- Determining the existing state of affairs, with regard to availability, accessibility and sufficiency of SoHO in different MS.
- Identifying views and thoughts regarding the relevance of realizing a European Accreditation Programme for SoHO activities and organizations involved in the SoHO field.

WP7 leaders, together with EGALiTE Consortium members developed specific **Contingency Plans** for several different potential scenarios, outlining clear steps to be taken, considering both short-term and long-term strategies.

The goal is to provide practical tools to assist the Responsible Persons at the SoHO-E in the decision-making process during a crisis, support planning in the search for long-term sufficiency of SoHO, and provides a comprehensive overview of the key components of contingency planning in the field of SoHO, along with practical tools and strategies for implementation. It consolidates common methodologies and recommendations from reference documents produced by different EU stakeholders and organizations across the different fields of SoHO.

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. A [interactive online tool](#), has been developed and is publicly available to assist the practical use of the contingency plans developed by the EGALiTE Consortium.

Technical Assistance Programme - WP8

[TAP procedure](#) (D8.1) includes all the information required by the applicants to accede to the future programme, namely the information related to possible forms of support, assistance fields, application procedures, experts' database and criteria, TAP process and administration, technical assistance programme and more.

In addition to the TAP procedure, the WP8 leaders prepared forms, for submitting the future TAP Applications, prepared the documents of the TAP application form, the guide for experts, confidentiality agreements, feedback and report forms.

All these outcomes were validated by the WP4's pilot actions.

The procedures were tested in real-life settings as part of the pilot actions promoted by WP4 and are expected to be a useful tool for organisation and stakeholders for compliance of the best European practices, aligned with the requirements of the new SoHO Regulation (Regulation - 2024/1938).

To gain insights into each Work Package and beneficiaries involved visit:

www.egalite-europe.eu/wps-beneficiaries

Main Outcomes of EGALiTE



Accreditation Programme

- Accreditation Dossier
- Accreditation Manual
- Accreditation Platform (The platform will be publicly available as soon as the programme go live)
- Training for Auditors BTC Database
- Generic Standards for SoHO Establishments
- Specific Standards for SoHO



- Contingency planning in SoHO Entities
- Interactive Tool & Template for the Definition of Contingency Plans
- Status Quo Study identifying potential crises scenarios including management and preventative measures & contingency plans, for implementation by EU MS to achieve sufficiency & accessibility of SoHOS



- Procedures for the Technical Assistance Programme (TAP)



- Pilot Actions
- Sustainability & Integration plans

Dissemination Seminar and Final Event

The event was organized in close collaboration with FBOV and held in conjunction with the face-to-face training for future EGALiTE Auditors.

The participants included representatives from the following groups: Beneficiaries, Invited Experts officers from DG SANTE and the project's evaluators.

The closing meeting had four main objectives: Present the work developed by the individual WPs; Disseminate the project's outcomes and promote the implementation of and engagement with future accreditation and technical assistance programs;

Celebrate the consortium's achievements and express gratitude for the hard work of all participants.



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.



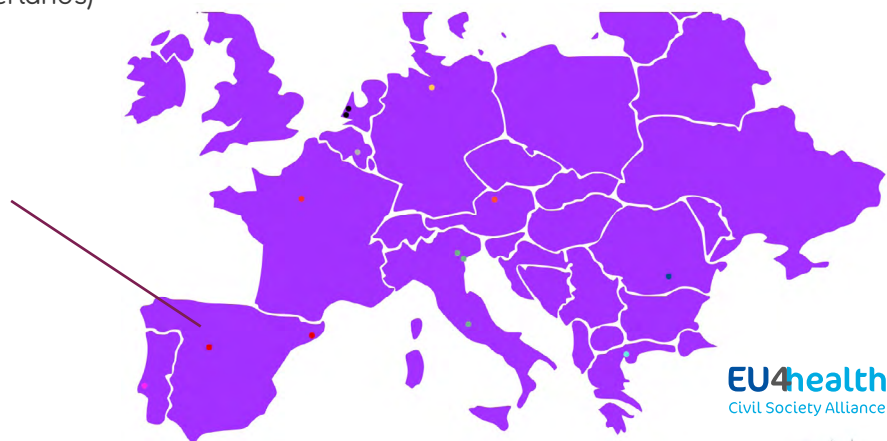


The EGALiTE Team

- Agence De La Biomedecine (France)
- Agentia Nationala De Transplant (Romania)
- Banc De Sang I Teixits (Spain)
- Centre Hospitalier Universitaire De Liege (Belgium)
- Deutsche Gesellschaft für Gewebetransplantation gGmbH (Germany)
- 7th Health Region Crete (Greece)
- European Society For Blood And Marrow Transplantation (The Netherlands)
- Fondazione Banca Degli Occhi Del Veneto Onlus (Italy)
- Fondazione Banca Dei Tessuti Di Treviso Onlus (Italy)
- Instituto Portugues Do Sangue E Da Transplantacao (Portugal)
- Istituto Superiore Di Sanita (Italy)
- Organización Nacional De Trasplantes (Spain)
- Österreichisches Rotes Kreuz Landesverband Oberösterreich Verein (Austria)
- Papageorgiou General Hospital (Greece)
- Stichting Etb-Bislife (The Netherlands)

15 Beneficiaries
10 Member States

Project Coordinator
Banc de Sang I Teixits (BST, Spain)



Connect With Experts on our
Social Media Channels

LinkedIn: [@egaliteurope](#) || X: [@EgaliteEurope](#) || Website: www.egalite-europe.eu

EU4health
Civil Society Alliance





The quality programme will deliver significant benefits and utility in relation to the provision of tissues, blood and cells within exceptional emergency situations.

European Commission

PROPOSAL EVALUATION

Our Partners



Invited Experts & Collaborative entities



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