



Blood - Tissue - Cells

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

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DIGITAL LEAFLET



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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

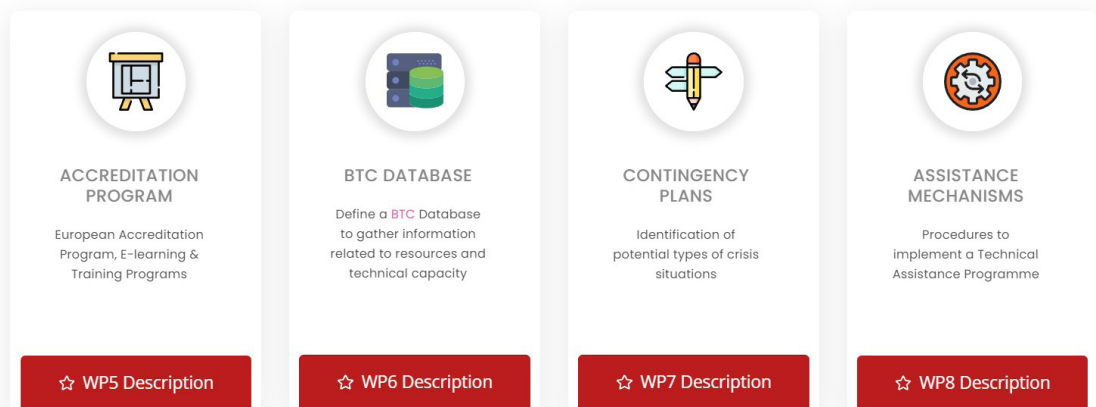
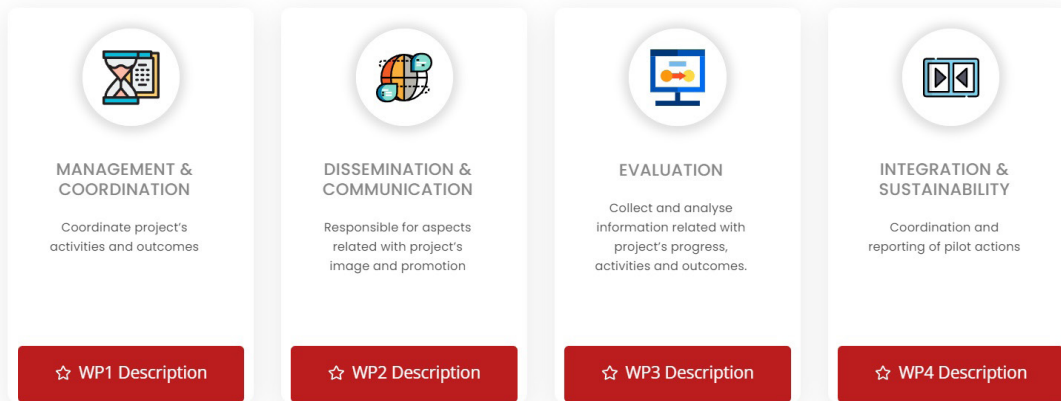
for better accessibility and sufficiency of SOHO

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

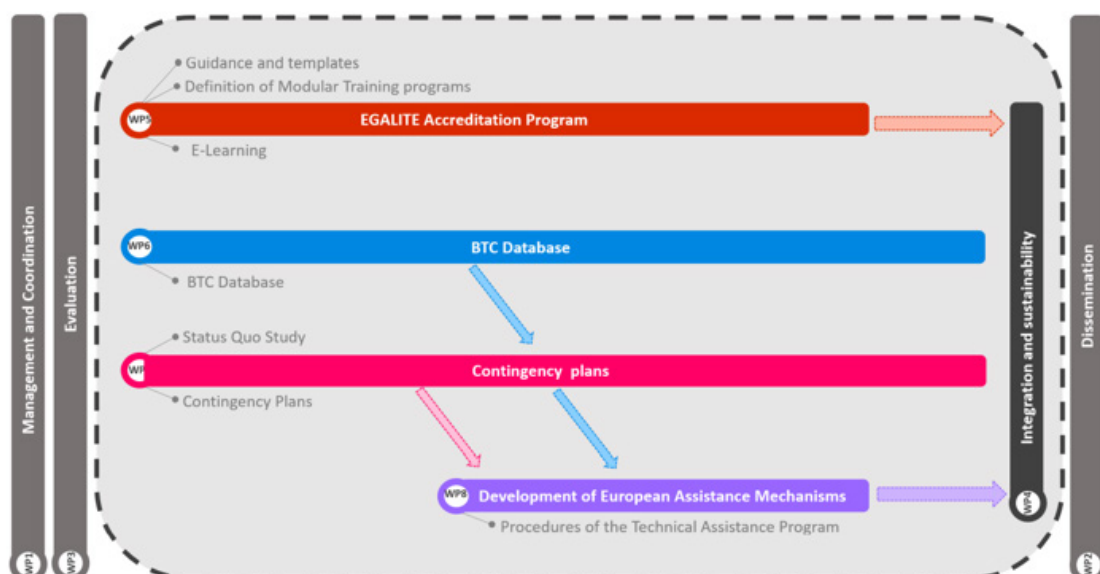
- ★ A European Accreditation Program as a means to achieve mutual recognition amongst SoHO organisations
- ★ An efficient database of resources (Collection Centres, facilities, activities and innovative techniques, etc.) which will be used to design sufficiency plans and promote the collaboration among 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 Program to assist the implementation of good practices and optimization of activities in the different EU Member States

EGALiTE

EGALiTE Work Packages



EGALiTE Work Plan



Key Expected Outcomes

Establish EGALiTE

Establishing EGALiTE as a formal entity, will require the definition of a financial management model able to ensure sustainability, without pursuing financial profit.

EGALiTE Partners will lead the discussion regarding the definition and adoption of practical procedures, rules and by-laws required, to ensure the appropriate representation of experts, transparency, and guarantee the long-term sustainability of projects outcomes.

EU Accreditation Programme

The implementation of an EU Accreditation Programme to promote equal access to SoHO within EU Member States, with the aim to be sustainable and recognized by all stakeholders at the EU level – same quality and safety for all donors and patients.

The EDQM Guides currently provide a comprehensive set of standards, which cover all SOHO activities, processing and distribution. These practices will be implemented as standards for accreditation, and WMDA, JACIE and EDQM's B-QM Programme, will be used as a model to develop the common European accreditation standards.

The accreditation system will include: training programmes and certifications mechanisms for professionals and auditors.

BTC Database

A BTC Database will be produced to gather technical and practical information which will enable the active collaboration among peers.

The IT platform will provide the ability to share resources (donations, BTC, facilities) according to availability and clinical needs.

The new BTC database will be harmonized with the minimum dataset defined by the EDQM, and shall include additional information required for the definitions of sufficiency and contingency plans, namely:

- ★ Include information related with the activities of the different SOHO Entities
- ★ Information related with the facilities/clean rooms and technologies available
- ★ Capacity to process BTC to third parties
- ★ Level(s) of sufficiency
- ★ Status of Accreditation(s)
- ★ any other necessary info deemed appropriate

EGALiTE

Contingency Plans

EGALiTE will define action plans which shall be activated in case of a crisis and according to the crisis scenario occurring.

The contingency plans will propose procedures to assist the responsible persons in the decision-making process during a crisis.

This deliverable will rely on the collaboration among accredited SoHO establishments in Europe. These plans foresee different scenarios which SoHO Entities are temporarily unable to perform their normal activities. The plans aim to:

- ★ provide support for professionals, and optimize the use of all resources during a crisis
- ★ will consider the possible exchange of donated SoHO, staff or BTC for transfusion/transplant
- ★ will include the definition of (hemo- and bio) vigilance procedures which aim to oversight of the execution of the plans by the EGALiTE
- ★ define clinical recommendations/ procedures for donor evaluation and selection and patient care, based on collected data whenever possible

Technical Assistance Programme

The definition of the Technical Assistance Programme is inspired by the Technical Assistance and Information Exchange (TAEIX) instrument of the European Commission.

However, the EGALiTE Technical Assistance Programme will provide assistance to SoHO Entities, and Competent Authorities of any European Member State.

The activities proposed for the Technical Assistance Programme include:

- ★ **Workshops:** EGALiTE experts to present specific areas of technical knowledge in workshops to a large number of beneficiary officials
- ★ **Expert missions:** EGALiTE expert(s) to be sent to the beneficiary administration to provide in-depth advice on the transposition, implementation or enforcement of specific technical knowledge
- ★ **Study visits:** Applicants to take part in a study visit to an accredited organisation

The Technical Assistance Programme will propose the mechanisms to fund and coordinate the participation of EGALiTE accredited experts in the activities requested by the different Member States.

EGALiTE

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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Stay In Touch

If you wish to learn first about EGALiTE's recent advantages or current activities, do not hesitate to subscribe to our [newsletter](#).



EGALiTE

The EGALiTE Team

15 Beneficiaries
10 Member States

- 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)

Specific Objectives



Implementation of a common European Accreditation Program 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

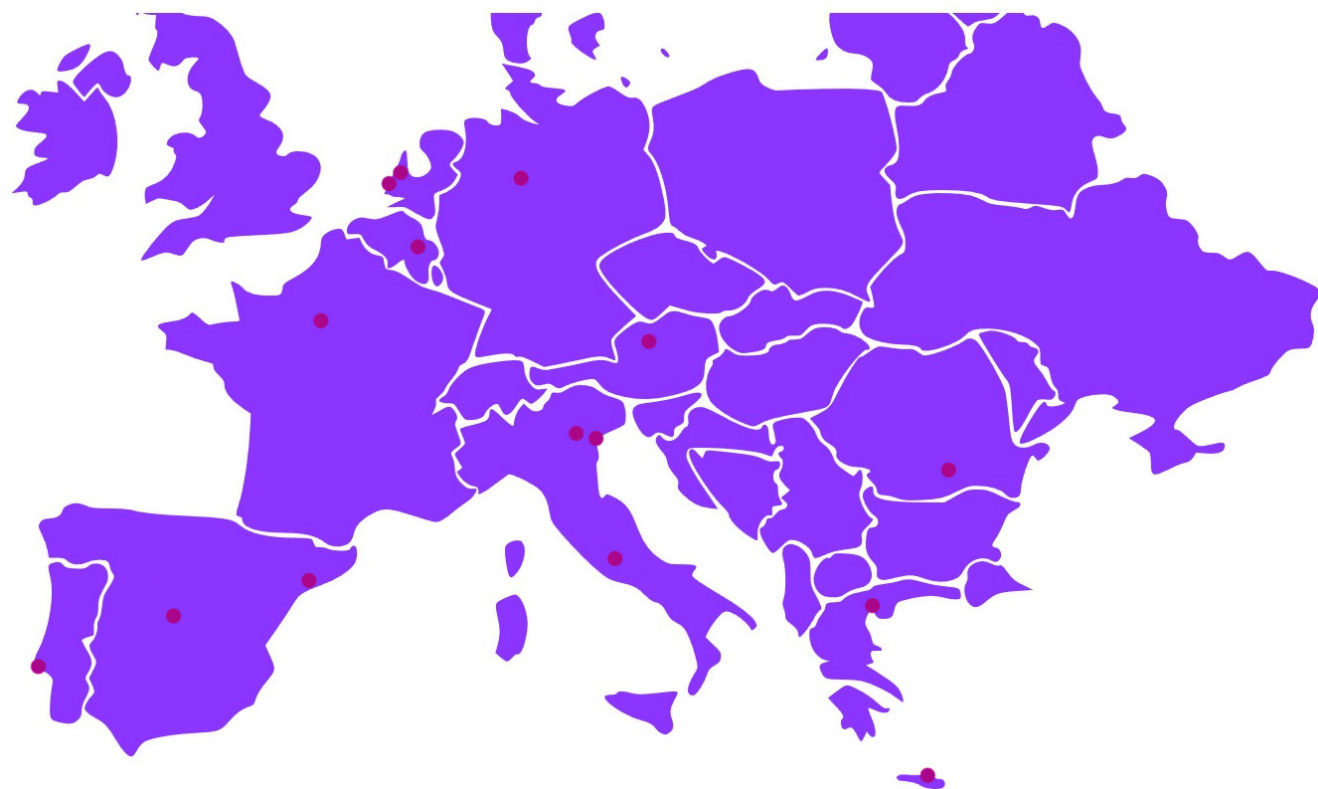


Establish cross-sector consensus on training programmes



Achieve sustainability of EGALiTE outcomes, and implement pilot programmes allowing timely adjustments on deliverables

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.



THE IMPACT

The primary aim is for SoHO Entities 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

Sharing Resources at EU level is expected to be simplified

Member States will have the opportunity to easily request and obtain Technical Assistance

Competent Authorities, will be able to rely on an independent group of qualified European experts

Project's Sustainability

★ The proposal foresees the creation of independent accreditation committees and the definition of the responsibilities, possible funding mechanisms and procedures associated with the future maintenance and management of EGALiTE outcomes and activities.

★ Extensive work is foreseen on **implementing pilot actions** at a national (Spain) and EU level.

★ A close collaboration with scientific societies and other accreditation programmes is envisaged to ensure the sustainability of the deliverables and outcomes by EGALiTE, and its integration and continuity following the project's completion.

List of Abbreviations

AEBT - Asociación Española de Bancos de Tejidos
BST - Banc de Sang i Teixits
BE - Blood Establishment(s)
BTC - Blood, Tissues and Cells
B-QM - Blood Quality Management Programme
CA - Competent Authorities
DG SANTE - Directorate General (of Health)
EATCB - European Association of Tissue and Cell Banks
EBA - European Blood Alliance
EBMT - European Society for Blood and Marrow Transplantation
EC - European Commission
EDQM - European Directorate for the Quality of Medicines
EEBA - European Eye Bank Association
EGALiTE - European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments
EHA - European Hematology Association
HSC - Haematopoietic Stem Cells

ISCT - International Society for Cellular Therapy
JACIE - Joint Accreditation Committee of the ISCT (International Society for Cellular Therapy) and the EBMT
ONT - Organizacion Nacional de Transplantes
PO - Procurement Organisation(s)
HaDEA - European Health and Digital Executive Agency
MS - Member State(s)
WP - Work Packages
SETS - Spanish Society of Blood Transfusion
SoHO - Substances of Human Origin
SoHO V&S - Vigilance and Surveillance of Substances of Human Origin Project – Tissue Establishment(s)
STS - Sociedad Española de Transfusión Sanguínea y Terapia Celular
TAEIX - Technical Assistance and Information Exchange
TE - Tissue Establishments
WMDA - World Marrow Donor Association

Said about EGALiTE



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



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