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D7.1 – *Status Quo* Study Final Report

EUROPEAN GROUP FOR ACCREDITATION AND
LIAISON OF BLOOD-TISSUES AND CELLS ESTABLISHMENTS

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Acronyms:

ATMP	Advanced therapy medicinal products
BE	Blood Establishments
B-SCEP	Blood Supply Contingency and Emergency Plan
BTC	Blood, Tissues and Cells
CA	Competent Authority(ies)
CBB	Cord Blood Bank
COVID-19	Coronavirus disease 2019
CP	Contingency Plan(s)
DBM	Demineralized Bone Matrix
DC	Donation and Collection Centres
EBMT	European Society for Blood and Marrow Transplantation
ECDC	European Centre for Disease Prevention and Control
EEBA	European Eye Bank Association
EGALiTE	European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments
FPP	Full frozen plasma
MS	Member States
ONT	<i>Organización Nacional de Transplantes</i>
RBC	Red blood cells
SoHO	Substances of Human Origin
TE	Tissue Establishments



1. Introduction

The organizations involved in the activities with Substances of Human Origin (SoHO), saw their activities severely impacted by the Coronavirus disease 2019 (COVID-19) outbreak. This crisis has evidenced a fragile reality of the SOHO in Europe, and SoHO organizations were placed under unprecedented stress, putting their capacity to provide the adequate care needed at risk.

Beyond COVID-19 crisis, in the recent years, European countries have experienced several other crises, which caused the disruption of routine activities of Donation and Collection Centres (DC) and SoHO Establishments, affecting temporarily the ability to assess and evaluate donors, or prepare, issue and distribute Blood, Tissues and Cells (BTC) at local, regional or national levels.

EGALITE (European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments) aims to promote the harmonization of practices among DC, Blood and Tissue Establishments (BE/TE), encourage sustainability and collaboration among stakeholders and the implementation of strategies required to improve accessibility and sufficiency of SoHO at European level.

The outcomes of EGALITE aim to support the activities performed in Member States (MS) with distinct technical capacities by:

- Establishing an European Accreditation Program for donors' registers, DC, and SoHO Establishments – as a mean to achieve mutual recognition amongst SoHO organizations;
- Develop an efficient database of resources (BTC, facilities, activities and innovative techniques, etc.) which will be used to design sufficiency plans and promote the collaboration among professionals and national Competent Authorities (CAs), to ensure an adequate supply of BTC in the different MS;
- Provide contingency plans (CP) to assist the responsible persons in the decision making process during crisis;
- Implement a Technical Assistance Program to assist the implementation of good practices and optimization of activities in the different MS.



2. Aims of the *Status Quo* Study

The present study is performed by EGALITE's WP7, and aims to identify potential crisis scenarios (based on real experiences and hypothetical circumstances), management procedures and corrective & preventive measures implemented by the different MS.

The study focuses on:

- Defining situations or scenarios that would require a CP.
- 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.

3. Sources of data of the Study

Two main sources of information were used in the study:

- a) Data from DC, BE/TE and National CAs, professional/scientific societies, and it will be based on real time interviews and surveys.
- b) Other relevant documents are used to assess the needs and means available in the SoHO field in order to propose solutions based on the active cooperation between Member States:
 - Commission Staff Working Document: Evaluation of the Union legislation on blood, tissues and cells;
 - Report: Study supporting the evaluation of the EU legislation on blood and tissues and cells;
 - *Plan Nacional de Tejidos* (National Tissue Plan, Spain, *Organización Nacional de Transplantes*; ONT);
 - Annual reports of SoHO activities;
 - Eurocet data;
 - Economic landscapes of human tissues and cells for clinical application in the EU;
 - Complementary CPs (e.g. Blood Supply Contingency and Emergency Plan (B-SCEP), International Federation of Red Cross and Red Crescent Societies (ifrc.org), and European Society for Blood and Marrow Transplantation's (EBMT) therapeutic measurements in nuclear disasters);
 - European Centre for Disease Prevention and Control (ECDC) to adopt a stronger role in supporting EU MS in the prevention and control of infectious disease threats and to improve European preparedness and response ahead of future public health challenges.



4. The Survey to determine the *Status Quo*

The Survey was developed in Q3 2022 through a combined effort by all the members of EGALiTE consortium. This resulted in two different questionnaires that were directed at TE and at BE & Cord Blood Banks (CBB), respectively. Both surveys were sent out in Q4 of 2022 to the EGALiTE participants, corneal banks at the invitation of the European Eye Bank Association (EEBA), and different blood banks in Italy on recommendation of *Centro Nazionale Sangue*.

Furthermore, representatives from the National Transplantation Society and the CA in the Netherlands were interviewed.

- Attachment I shows the Survey that was sent to TE.
- Attachment II shows the Survey that was sent to BE & CBB.

5. Results of the Survey for the benefit of the *Status Quo* Study

5.1 Tissue Establishments (TE):

The Survey was sent to individuals of organizations participating in the EGALiTE project. All cornea banks registered within the EEBA were also invited by the EEBA to participate. The intention was to receive one answer per establishment.

Analysis of responses:

Table 1: Data on engagement with the TE survey	
Total of persons contacted	65
Opened	37
Survey not opened	27
Stopped during the Survey	1
Answers received	9

Among the 9 Establishments responding: 2 from Spain, 2 from Italy, further responses came from Austria, Finland, the Czech Republic, Germany and the Netherlands.

- **Spain:**
 - Banc de Sang i Teixits; regional function



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- Tissue Bank for the Center for Blood Transfusion Tissues and Cells of Córdoba (Spain); regional function
- **Italy:**
 - Fondazione Banca degli Occhi del Veneto (The Veneto Eye Bank Foundation); Regional function
 - Fondazione Banca dei Tessuti del Veneto Onlus; regional function
- **Finland:**
 - Regea Tissue Center, Tampere University; local and national function
- **Czech Republic:**
 - Oční tkanová banka Praha Vinohrady/Eye Bank Prague; national function
- **Germany:**
 - The German Society for Tissue Transplantation (DGFG); national function
- **Austria:**
 - Österreichisches Rotes Kreuz Landesverband Oberösterreich Verein (ORK); regional function
- **Netherlands:**
 - ETB-BISLIFE; national function

Key findings of responses:

Which activities are performed in your TCE?

- 100% (9/9) of the establishments have in house processing, storage and distribution;
- 44% (4/9) have exports to non-EU countries;
- 44% (4/9) have imports from non-EU countries.

Where are you distributing to?

- 100% (9/9) within own country, whereof 66% also distributing within the EU.

Do you have outsourced activities and if yes which activities and to what extent?

- 33% (3/9) have partial outsourced donor screening.
- 33% (3/9) have partial outsourced procurement.
- 100% (9/9) have partially or fully outsourced donor testing
- 22% (2/9) have partially outsourced processing and preparation
- 22% (2/9) have partially outsourced storage and distribution.
- (1 TE did not respond)



Is your TCE self-sufficient?

- 33% (3/9) are self-sufficient at regional level;
- 67% (6/9) are self-sufficient at national level

Please indicate if you have a surplus of any tissue or cells?

- 67% (6/9) of the TEs responding informed they have a surplus of tissues.
- Continuously: Surplus of skin, musculoskeletal tissue, amnion, aortic valves, facia lata, Demineralized Bone Matrix (DBM).
- Seasonally: cornea and nerves

Does your TCE have a documented Contingency Plan (CP) in place local?

- 22% (2/9) have a documented local CP in place

Does your TCE have a documented CP in place regional?

- 11% (1/9) have a documented regional CP in place

Does your TCE have a documented CP in place national?

- 0% (0/9) have a documented national CP in place

Does your TCE have a documented CP in collaboration with other MS?

- 0% (0/9) have a documented CP in place in collaboration with other MS

If your TCE has CP in place, it describes actions for unplanned events?

- 11% (1/9) include other local or regional resources.
- 89% (8/9) skipped the question

Which real contingency events have you experienced during the last 10 years:

- 100% (9/9) experienced an epidemic/pandemic; Contingency planning was a success for 33% the TEs,
- 11% (1/9) experienced a contamination of clean room(s); Contingency planning was a success
- 11% (1/9) experienced a contamination of tissues; Contingency planning was a success
- 11% (1/9) experienced a cyber-attack; there was no Contingency Plan in place
- 33% (3/9) experienced an energy failure; for 2 TEs Contingency planning was a success, for 1 there was no Contingency Plan in place



- 44% (4/9) experienced a major transport failure; for 2 TEs Contingency planning was a success, for 2 TEs Contingency planning was unsuccessful

Other events that require contingency plans, please describe and was the CP in place and successful

- Adverse weather conditions affecting all communication means
- Stock rupture of a critical material
- Unexpected absences of personnel
- Urgent transplant tissue requested by another EU Member State was unloaded by DHL Medical Express due to bad weather in Germany

Can you identify the benefits of a formal European Accreditation Programme?

- 98% (8/9): yes; 11% (1/9): no

If yes for which activities:

- Donation (incl. Donor registries), 75% (6/8)
- Donor screening/testing, 88% (7/8)
- Procurement (Collection), 75% (6/8)
- Donor testing, 75% (6/8)
- Processing, 88% (7/8)
- Storage, 88% (7/8)
- Distribution, 88% (7/8)

The TE (1) that could not identify the benefits of a formal European Accreditation Programme did not respond. Around 80% responded that there were benefits for all TCE processes

On top of the surveys the Dutch CA was interviewed. They added certain risks to the potential risks identified by the BTCs, such as supplier risks and war. Also they explained how different risks would need different approaches. A virus for example would need another approach than a shortage in critical supplies that many BTC's use.

The Dutch CA already knew about the EGALiTE project. The European Inspectorates are also working to train inspectors and align audit procedures. For this purpose the project Oversight has been started.



Overall conclusions for TE:

For the Spanish TEs, the CPs are active mostly at the local level. However, this is not the case for the Austrian TE, where the CP is active at the regional level.

The individual answers given to the question on which real contingency events were experienced and solved will be used in planning an overall CP.

Six out of nine TEs experience a surplus of tissue, mostly skin grafts, cortical bone grafts, DBM grafts, aortic valves and amnion tissue. For corneal tissues a surplus is sometimes experienced during Holiday season, when a reduced number of surgeries are being planned.

The benefits of a formal European Accreditation Programme can be identified by almost all of the TE. It is believed that this may help to harmonize the requirements of safety and quality, facilitating the exchange of tissues or/and promote the collaboration related to testing and processing activities among TEs, both in routine and during emergency/exceptional situations.

If recognized by the CAs, the accreditation programme could lead to a more robust and harmonized Authorization program.

It should be taken into consideration that the answers to the questionnaires come from 10 TEs (15%) of the 65 contacted. These TEs represent 8 (27%) of the 27 MS.

5.2 Blood Establishments (BE) and Cord Blood Banks (CBB).

The survey was sent to organisations and individuals participating in the EGALITE project. Furthermore, upon request all the blood banks in Italy were invited to participate in this Survey.

The intention was to have one answer per establishment.

Analysis of responses:

Table 2: Data on engagement with the BE and CBB survey	
Total of persons contacted	346
Opened	91
Survey not opened	255
Answers received	16 (14 BE and 2 CBB)



BEs:

Among the 14 BE responding: 2 from Spain, 9 from Italy, further responses came from Austria and the Netherlands.

- **Italy:**
 - Unità Operativa Complessa Medicina Trasfusionale dell'Azienda Ospedaliera Universitaria Integrata di Verona: local function
 - SIMT S. Eugenio, sede anche di unità di raccolta CSE e LMC: local function
 - UOC MEDICINA TRASFUSIONALE AOE CANNIZZARO CATANIA: local function
 - Establishment Medicina Trasfusionale Fondazione Policlinico Campus Biomedico, Roma (Lazio): local function
 - U.O.C. S.I.M.T. E RACCOLTA CELLULE STAMINALI, FROSINONE: local function
 - SC Immunoematology and Transfusion medicine - Cardinal Massaia Hospital – Asti: local function
 - Medicina Trasfusionale Mestre: local function
 - UOC Terapie Cellulari e Officina Trasfusionale, Toscana: regional function
 - Servizio Aziendale di Immunoematologia e Trasfusionale e di Bolzano: Province Bolzano: regional function
- **Greece**
 - GONK HOSPITAL, ATHENS, GREECE: local function
- **Spain:**
 - Valencian Community Transfusion Center: regional function
 - Banc de Sang i Teixits: regional function
- **Austria:**
 - Red Cross Blood Transfusion Service of Upper Austria: regional function
- **Netherlands**
 - Sanquin Blood Bank: national function

CBBs:

Among the 2 CBB responding: 1 from Greece, 1 from Spain

- **Greece**
 - public Cord Blood Bank of Crete: regional function
- **Spain**
 - Barcelona Cord Blood Bank (Programa Concordia BST): national function



Key findings of responses:

Which activities are performed in your BE or CBB.

- Donor selection 13/16 (81%)
- Donor screening 3/16 (19%)
- (Cord) Blood Collection 12/16 (75%)
- Donor testing 12/16 (75%)
- Processing 15/16 (94%)
- Storage 16/16 (100%)
- Distribution 16/16 (100%)
- Other 9/16 (56%)
- Export 3/16 (19%)
- Import 2/16 (13%)

Where are you distributing to:

All BEs (14/14) distribute within the country whereas the CBBs (2/2) distribute within the country and within EU MS. Three establishments also export outside the EU.

Do you have outsourced activities and if yes which activities and to what extent?

- 36% (5/14) BEs don't have any activity outsourced.
- 21% (3/14) BEs have partially outsourced donor selection, screening and collection
- 36% (5/14) BEs have partially or fully outsourced donor testing
- 7% (1/14) BE has partially outsourced preparation
- 21% (3/14) BEs have partially outsourced storage and distribution
- One CBB has partially or fully outsourced collection, testing, preparation, storage and distribution whereas the other CBB only has partially outsourced collection and fully outsourced distribution.

Is your BE or CBB self-sufficient?

For BEs, 21% (3/14) are self-sufficient at local level; 64% (9/14) are self-sufficient at regional level and 7% (1/14) is self-sufficient at national level. One BE and both CBBs mentioned they are not self-sufficient at any level.



Please indicate if you have a surplus of any blood products?

- 57% (8/14) BEs have no surplus.
- 43% (6/14) BEs have surplus

Mentioned is a surplus of Red blood cells (RBC), Full frozen plasma (FFP) and platelets.

CBB by definition have a surplus, because most of the units in stock do not match with the HLA of patients needing CBB-treatment.

Does your BE have a documented CP in place local?

- 86% (12/14) have a documented local CP in place

Does your BE have a documented CP in place regional?

- 79% (11/14) have a documented regional CP in place

Does your BE have a documented CP in place national?

- 14% (2/14) have a documented national CP in place

Does your BE have a documented CP in collaboration with other MS?

- 0% (0/14) have a documented CP in place in collaboration with other MS
- Both CBBs have a documented local CP in place; one CBB also has a documented regional CP in place, whereas the other CBB also has a documented national CP in place

Which real contingency events have you experienced during the last 10 years:

- 100% (12/12) experienced an epidemic/pandemic; Contingency planning was a success for 83% (10/12) the BEs,
- 8% (1/12) experienced a contamination of clean room(s); Contingency planning was a success
- 8% (1/12) experienced a contamination of tissues; Contingency planning was a success
- 25% (3/12) experienced a cyber-attack; Contingency planning was a success for all BEs (3/3),
- 50% (6/12) experienced an energy failure; Contingency planning was a success for all BEs (6/6),
- 8% (1/12) experienced a major transport failure; Contingency planning was a success
- 2 (of 14) BEs skipped this question.
- Both CBBs experienced an epidemic/pandemic; Contingency planning was unsuccessful for both CBBs



Other events that require CP, please describe and was the CP in place and successful

- Staff shortages
- General power cut external to the building
- Terrorist attacks,
- Emerging infections related to climate change
- Nuclear accident
- War scenarios such as the situation in Ukraine may require additional supplies of blood and medical devices
- Environmental disaster (such as fire near the BE)
- Floods; Fire or Major problems in Building;
- Other Natural disasters

Can you identify the benefits of a formal European Accreditation Programme?

- BEs: 86% (12/14): yes; 14% (2/14): no
- CBBs: 100% (2/2): yes

If yes for which activities:

- Donation (incl. Donor registries), 92% (11/12)
- Donor screening/testing, 83% (10/12)
- Procurement (Collection), 75% (9/12)
- Donor testing, 92% (11/12)
- Processing, 92% (11/12)
- Storage, 92% (11/12)
- Distribution, 92% (11/12)

Both BEs that could not identify the benefits of a formal European Accreditation Programme did not respond.

Overall conclusions for BE and CBB:

Only in Spain and Crete, CP are active at a national level. The other BEs and CBBs have CP only active at the local and or regional level.

The individual answers on which real contingency events were experienced and solved, will be used in planning an overall CP for SoHO establishments.



Only a few BEs answered the question about surplus, so it is hard to draw more conclusions on this topic. However, it seems to exist a surplus of FFP and RBC units. Occasionally also platelet units are more in stock than needed, but given the short shelf life, it is not a blood product that can easily be exchanged.

Both CBBs store a surplus of cord blood units. This is the case for all CBB worldwide and it is related with the nature of CBB's activities: these organisations need to maintain a wide variety of different HLA-typed products, in order to be able to match when there is a request for a cord blood unit for a given patient.

A major part of the BEs (80%) foresee benefits of an European Accreditation Programme for SoHO activities. This would help to harmonize the processes of the organizations involved in the SoHO field and enhance their credibility towards the Transfusion Centres. When the Accreditation Programme can be lined up with approval of activities by national CAs, it may ease the exchange of blood products and preparation activities.

It should be taken into consideration that the answers to the questionnaires come from 14 BEs and 2 CBBs (<5%) of the 346 contacted. These BEs represent 5 (19%) of the 27 MS.

6. Which events have experienced blood, cell and tissue establishments

The contingency events that most SoHO Establishments have experienced were: pandemic, energy failures and transport failures.

A few establishments mentioned also to have experienced contamination of cleanrooms, contamination of products and cyber-attacks. These failures were tackled mostly at a local or regional level. Other unforeseen events, not listed in the questionnaire, but mentioned by some establishments were: shortage of staff, interrupted access to critical materials and rough weather. None of the SoHO establishments mentioned to have experienced events such as compliance with the regulations, storage problems, equipment failure, human error or natural disasters.

Most BEs have a CP in place at local, regional or even national level. In contrast, the majority of all TEs have no CP in place at all. Historically this can be explained by the continuous need for blood products in the medical practice. Given the growing clinical importance of tissue replacement, it is clear that such plans need to be developed for all SoHO establishments. The importance of the *Status Quo* study lies in the fact that the establishments together can learn from each other's practices and experiences. Planning for contingencies and working together with other countries will in the end assure the continuity of the establishments.



7. What is the existing state of affairs, with regard to availability, accessibility and sufficiency of substances of human origin (SoHO) in different Member States (MS)

All responding establishments are self-sufficient at the local, regional or national level. Some have mentioned that they also distribute to other EU MS or even export SoHO's to countries outside the EU. It can be assumed that BTCs that are distributed to other EU MS or exported are most likely BTCs that are not needed at the local/regional/national level or for which there is sufficiency. This is only the case for a limited types of products. A conservative estimate following the survey is that the surplus of tissues concern skin, some bone preparations, amnion, aortic valves, fascia lata and seasonally, cornea's. The surplus of blood products seemed to consist of FFP units, RBC units, occasionally Platelet units, and Cord Blood Units.

It will be helpful to know if an establishment can help another establishment in times of crises. Therefore, a database of BTC resources (donated and final products), equipment, preparation processes, and possibly staff available should be very useful.

8. Which situations or scenarios would require a contingency plan

SoHO establishments are facilities that collect, process, store, and distribute donated human SoHO for use in transfusion, implant/transplantation or as source for advanced therapy medicinal products (ATMPs). They are subject to a variety of risks that could potentially disrupt their operations and compromise the safety and efficacy of the BTC products they provide.

Some potential risks that SoHO establishments may face include:

1. **Quality control:** Ensuring the safety and efficacy of BTC is a critical function of SoHO establishments. Risks to quality control include issues such as contamination, improper storage, or inaccurate labelling of BTC.
2. **Compliance:** SoHO establishments must comply with a range of regulations and standards governing the collection, processing, storage, and distribution of BTC. Risks related to compliance include the inability of compliance with regulations, lack of oversight, or inadequate record-keeping.
3. **Availability of staff:** SoHO establishments rely heavily on highly trained and skilled employees. Many functions require prolonged intensive training programmes for operators to perform their



tasks. Shortage of staff may lead to reduced access to donation and limitation of the capacity for preparation/processing.

4. **Suppliers:** SoHO establishments use specific (often CE-marked) materials, media and instruments for their processes. Should a supplier which is dominant in a particular field terminate its activities or should a particular antibiotic supplement not be available anymore, it could cause a problem for the access to certain BTC.
5. **Storage and transportation:** BTC must be stored and transported under specific conditions to maintain their safety and efficacy. Risks to storage and transportation include issues such as equipment failure, power outages, or natural disasters.
6. **Data security:** SoHO establishments maintain sensitive personal and medical information about donors and recipients, including their identification information, medical history, and test results. Risks to data security include unauthorized access, data breaches, or cyber-attacks.
7. **Human error:** SoHO establishments rely on the accuracy and attention to detail of staff to ensure the safety and efficacy of their products. Risks related to human error include issues such as miscommunication, mishandling of tissue samples, or failure to follow procedures.
8. **Public health emergencies:** SoHO establishments may be impacted by public health emergencies such as pandemics, which can cause disruptions to the supply chains, increase demand of SoHO, or even temporary suspension of BTC collection.
9. **Social unrest** (large scale demonstrations, riots, *coup d'état*, war): SoHO establishments can only function in an organized society, where there is free and safe movement of people, continuous access to services and supplies, and hospitals that can operate orderly. In case of serious social unrest access to donations can be interrupted, staff may not be available, operations may be ceded due to lack of critical supplies or services.
10. **Natural Disasters and Nuclear Accidents:** SoHO establishments can be affected by natural disasters such as hurricanes, earthquakes, flooding, wildfires or by nuclear and radiation accidents where ionizing radiation and radioactive waste are being spilled in the environment. Those can cause damage to the facilities, equipment, and even BTC in storage. These events may likely lead to suspension of operations.



9. What are the views and thoughts regarding the relevance of realizing a European Accreditation Programme for SoHO activities and organizations involved in the SoHO field

Nearly all SoHO establishments that filled out the questionnaires foresee benefits of an European Accreditation Programme for SoHO activities. This would help to harmonize the processes of the organizations involved in the SoHO field and enhance their credibility towards the Transfusion and Transplantation Centres. When (and if) the Accreditation Programme can be lined up with approval of activities by national CAs, it may ease the exchange of donated or final SoHO materials and preparation/processing activities.

Also, global events such as a pandemic, climate change or a war such as in Ukraine show the need to complement it with coordinated responses for SoHO activities.

The accreditation programme will also benefit the EU members with limited human/economical resources. To become accredited they will receive technical assistance from other MS, and through this, they will be able to provide better care to patients, when therapeutic use of SoHO materials is involved.



Attachment I: Survey sent to Tissue Establishments

Survey / Interview Script

1. Name of the Tissues Establishment (TE): _____
2. Indicate if you are working with cells HPC, MNC for cell therapy
3. Local, regional, national
4. Country: _____
5. Nature of TE: not for profit, profit, private, public

Regular Activities

What activities are performed in your TE?

- ☐ Donor screening/ donor selection
- ☐ Procurement (Recovery/Retrieval)
- ☐ Donor testing
- ☐ Processing/Preparation
- ☐ Storage
- ☐ Distribution
 - ☐ Within your country
 - ☐ To other EU MS
- ☐ Import (from non-EU)
- ☐ Export (to non-EU)
- ☐ Other:.....

Do you have outsourced activities?

- ☐ No
- ☐ Yes
 - ☐ If yes, which activities and to what extend (partial or full)?

	Activity outsourced	Partial	Full	Contingency Plan in place? Y/N/unknown
Donor screening / selection				
Procurement				
Donor Testing				
Processing/Preparation				
Storage				
Distribution				
Other				



Is your TE self-sufficient¹?

- ☐ Yes
 - ☐ At local level (ex.: Hospital level)
 - ☐ At regional level (ex.: provincial or regional level)
 - ☐ At national level
- ☐ Yes, **only on rare occasions** do we need to cooperate with other TE to ensure sufficiency
- ☐ **Occasionally**, we need to cooperate with other TE to ensure sufficiency
- ☐ No, we **often** rely on Tissues and cells prepared and distributed by other TE to fulfil the need of clinicians

Please indicate if you often have a surplus² of any tissues and cells:

- ☐ Yes

If yes, please indicate:

 - ☐ Which Tissues and cells
 - ☐ Estimated total annual volume/amount
 - ☐ Whether the surplus is constant or seasonal (e.g. only during holiday or festive periods).
- ☐ No

Contingency Activities

(A project contingency plan is an established, pragmatic set of actions that your team will follow if a predetermined risk materializes and makes your initial plan impossible)

Does your TE have a documented Contingency Plan (CP) in place?

- Yes,
 - ☐ Based on alternative local resources
 - ☐ Based on collaboration with alternative regional organizations
 - ☐ Based on collaboration with alternative national organizations
 - ☐ Based on collaboration with organizations of other MS
- No

If your TE has CP(s) in place, it describes actions/measures for:

¹ For the purpose of this survey, self-sufficiency is defined as the ability to provide enough tissues to fulfil the need of clinicians within for example three months (tissues with short expiry dates might have specific considerations)

² Surplus is defined when you have more Tissues and cells available than you can distribute and/or the ability to generate issuable stock to assist other establishments in case of emergency



- unplanned events (e.g. contamination of the facilities, natural catastrophes, epidemic/pandemic events)
 - Does the CP include own department resources?
 - Does the CP include other resources of your entity?
 - Does the CP include other local, regional, or national resources?
 - Does the CP include other international resources?

Please fill the table with real contingency events experienced by your organization during the last 10 years

	Cause	Activities affected	Summary of actions adopted to restore	Was the event foreseen in your CP?	Was the CP successful ?	Which other actions would have been needed?	Time required to re-establish normal activities	Summary of actions adopted to ensure minimum supply of SoHO	Any other local, national, or international resources would have helped?
Epidemics/Pandemic									
Contamination Tissue/Blood									
Contamination Clean room(s)									
Cyber attack									
Energy Failure									
Major transport failure									
Other Events									



Regarding the implementation of a future accreditation programme³:

Can you identify the benefits of a formal European Accreditation Programme specifically tailored to organizations working with SoHO (integrated/in coordination with the already existing JACIE Programme : <https://www.ebmt.org/accreditation/about-jacie>).

- ☐ No
- ☐ Yes

If yes, for which activities

- ☐ Donation (incl. Donor registries)
- ☐ Donor screening
- ☐ Procurement (Recovery/Retrieval)
- ☐ Donor testing
- ☐ Processing
- ☐ Storage
- ☐ Distribution

Please share your views and thoughts regarding the relevance of realizing a European Accreditation Programme for SoHO activities and organizations involved in the SoHO field: _____

³ Accreditation is how an organisation can demonstrate that it is performing in accordance with internationally agreed standards. Accreditation Program provides formal recognition by peers that your organization complies with the quality and safety standards and best practices defined for BTC activities at EU level. It aims to be a certification of excellence of the activities and processes carried out by organisations in Europe working with SoHO.



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Attachment II: Survey sent to Blood Establishments

Survey / Interview Script

Name of the Blood Establishment (BE): _____

Indicate whether you are a Cord Blood bank

Local, regional, national BE

Country: _____

Nature of BE: Not for profit, for profit, private, public

Regular Activities

What activities are performed in your BE?

- ☐ Donor selection
- ☐ Collection of blood
- ☐ Donor testing
- ☐ Processing of Blood Components
- ☐ Storage
- ☐ Distribution
 - ☐ Within your country
 - ☐ To other EU MS
- ☐ Import (from non-EU)
- ☐ Export (to non-EU)
- ☐ Other:.....

Do you have outsourced activities?

- ☐ No
- ☐ Yes
 - ☐ If yes, which activities and to what extend (partial or full)?

	Activity outsourced	Partial	Full	Contingency Plan in place? Y/N/unknown
Donor screening / selection				
Procurement				
Donor Testing				
Processing/Preparation				
Storage				
Distribution				
Other				

Is your BE self-sufficient⁴?

- ☐ Yes
 - ☐ At local level (ex.: Hospital level)

⁴ For the purpose of this survey, self-sufficiency is defined as the ability to provide enough BC products to fulfil the need of clinicians within for example three months (BC products with short expiry dates might have specific considerations)



- At regional level (ex.: provincial or regional level)
- At national level
- Yes, **only on rare occasions** do we need to cooperate with other BE to ensure sufficiency
- **Occasionally**, we need to cooperate with other BE to ensure sufficiency
- No, we **often** rely on blood or cell product(s) prepared and distributed by other BE to fulfil the need of clinicians

Please indicate if you often have a surplus⁵ of any blood and cells (BC):

- Yes
 - If yes, please indicate:
 - Which blood or cell product(s)
 - Estimated total annual amount
 - Whether the surplus is constant or seasonal (e.g. only during holiday or festive periods).
- No

Contingency Activities

(A project contingency plan is an established, pragmatic set of actions that your team will follow to be able to react in an efficient and adequate way to a sudden emergency situation or an emerging issue that may result in a disruption of the supply)

Does your BE have a documented Contingency Plan (CP) in place?

- Yes,
 - Based on alternative local resources
 - Based on collaboration with alternative regional organizations
 - Based on collaboration with alternative national organizations
 - Based on collaboration with organizations of other MS
- No

If your BE has CP(s) in place, it describes actions/measures for:

- unplanned events (e.g. contamination of the facilities, natural catastrophes, epidemic/pandemic events)
 - Does the CP include own department resources?
 - Does the CP include other resources of your entity?
 - Does the CP include other local, regional, or national resources?
 - Does the CP include other international resources?

⁵ Surplus is defined when you have more BTC available than you can distribute and/or the ability to generate issuable stock to assist other establishments in case of emergency



Please fill the table with real contingency events experienced by your organization during the last 10 years

	Cause	Activities affected	Summary of actions adopted to restore	Was the event foreseen in your CP?	Was the CP successful ?	Which other actions would have been needed?	Time required to re-establish normal activities	Summary of actions adopted to ensure minimum supply of SoHO	Any other local, national, or international resources would have helped?
Epidemics/ Pandemic									
Contamination Tissue/Blood/components									
Contamination Clean room(s)									
Cyber attack									
Energy Failure									
Major transport failure									
Other Events									

Regarding the implementation of a future accreditation programme⁶:

Can you identify the benefits of a formal European Accreditation Programme specifically tailored to organizations working with SoHO .

- ☐ No
- ☐ Yes

If yes, for which activities

- ☐ Donation (incl. Donor registries)
- ☐ Donor screening/testing
- ☐ Procurement (Collection)
- ☐ Donor testing
- ☐ Processing
- ☐ Storage

⁶ Accreditation is the means by which an organisation can demonstrate that it is performing in accordance with internationally agreed standards. Accreditation Program provides formal recognition by peers that your organization complies with the quality and safety standards and best practices defined for BTC activities at EU level. It aims to be a certification of excellence of the activities and processes carried out by organisations in Europe working with SoHO.



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- Distribution

Please share your views and thoughts regarding the relevance of realizing a European Accreditation Programme for SoHO activities and organizations involved in the SoHO field: _____



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