

D8.1 – Procedures of the Technical Assistance Programme (TAP)

Knowledge gap? Apply for TAP!

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

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Acronyms

BTC	Blood, Tissues and Cells
CDA	Confidential Disclosure Agreement
EATCB	European Association of Tissue and Cell Banks
EBA	European Blood Alliance
EBMT	European Society for Blood and Marrow Transplantation
EEBA	European Eye Bank Association
EGALiTE	European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments
HSC	Hematopoietic Stem Cells
NCA	National Competent Authorities
SoHO	Substances of Human Origin
TAP	Technical Assistance Programme
WP	Work package

Introduction EGALiTE WP8

EGALiTE (European Group for Accreditation and Liaison of Blood-Tissues and Cells Establishments) is an EU funded project endorsed by the leading scientific societies in Europe in the field of the Substances of Human Origin (SoHO), namely: European Society for Blood and Marrow Transplantation (EBMT), European Blood Alliance (EBA), European Eye Bank Association (EEBA), and the European Association of Tissue and Cell Banks (EATCB). It aims to promote the harmonization of practices involving Blood, Tissues and Cells (BTC) among SoHO Entities, 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 with distinct technical capacities. One of them is to implement a Technical Assistance Programme (TAP) to assist the implementation of good practices and the optimization of activities in the different Member States. The work package (WP) 8 of the EGALiTE project has defined the TAP and all its associated procedures and documentation. Once the EU Project is finalized, the different scientific societies will ensure the implementation of the TAP in their fields of expertise:

EATCB and EEBA will manage and coordinate the EGALiTE Coalition, in charge of the Technical Assistance and Accreditation Programmes for tissues and cells.

EBMT will assist the programmes related to Hematopoietic Stem Cells (HSC).

EBA will assist stakeholders in the field of blood.

What is TAP?

TAP is a Technical Assistance Programme established by the EU-funded project EGALiTE (grant #101056852) to assist the implementation of good practices and the optimization of activities in the SoHO field in the different Member States.

Public SoHO entities (according to the proposed SoHO regulation) and/or their employees can apply for support under this programme.

A key goal of the TAP is to help applicants prepare for EGALiTE accreditation.

Possible forms of support:

- **TRAINING**

EGALITE endorses a variety conferences/ workshops/ e-learning of relevant scientific societies (national, European, international) and international organisations → see list of EGALITE endorsed events

At these events, EGALITE experts are able to present specialized technical knowledge to a large number of beneficiaries.

Respective events are announced on the EGALITE website and a link to the dedicated event webpage is given.

- **CONSULTATION**

Applicants take part in a study visit(s) to an EGALITE accredited organisation, where they are able either to learn new techniques and/or to observe the implementation of good practices.

This type of action focuses on generic practices related to SoHO activities. The assisting organization is not expected to share detailed procedures or specific knowledge¹. Instead, they demonstrate how these activities are implemented within their organization and provide guidance on adapting these procedures to different settings.

- **TRANSFER OF KNOWLEDGE**

Expert missions (on-site or virtual) are intended to instruct and guide SoHO entities in the implementation of new techniques and/or good practice in order to improve their SoHO activities and/or their quality management systems.

Expert(s) are sent to the applying SoHO institutions to provide either state of the art-information and/or in-depth advice on the transposition, implementation or enforcement of specific technical knowledge.

State of the art transfer of knowledge can also be done virtually.

Experts should be assigned by the scientific societies that are part of the EGALITE network.

¹ Sharing detailed procedures or information may, however, occur based on an individual agreement between the applicant and the expert organization.

Criteria for TAP applicants and Experts

At its initial stages of implementation (particularly during pilot actions foreseen within the EGALiTE Project), SoHO Entities from EU member state have preference in the process selection of applications for TAP.

SoHO entities with the intention to accredit new activities or accredited organisations wishing to improve quality can also apply.

Detailed requirements for the applicants are set in accordance with accreditation requirements (WP5):

- Not-for-profit organisation
- Authorized SoHO entity with any kind of SoHO activity
- EU member state

Detailed criteria for the selection of TAP Experts by the EGALiTE Coalition are detailed in the Annex 1 of this document.

EGALiTE endorsed events (annual activity plan)

Possible future endorsed events:

1) Tissues

Scientific society / Public health body	Abbreviation	Webpage
European Association of Tissue and Cell Banks	EATCB	www.eatcb.eu
European Eye Bank Association	EEBA	www.eeba.eu
European Directorate for the quality of medicine and health care	EDQM	www.edqm.eu
Österreichische Gesellschaft für Blutgruppenserologie, Transfusionsmedizin, Regenerative Medizin und Immunogenetik	ÖGBT	https://oegbt.clubdesk.com
International Placenta Stem Cell Society	IPLASS	https://www.iplassociety.org/

2) Hematopoietic stem cells (HSC)

Scientific society	Abbreviation	Webpage
European Society for Blood and Marrow Transplantation	EBMT	https://www.ebmt.org
World Marrow Donor Association	WMDA	https://wmda.info

3) Blood

society / Public health body	Abbreviation	Webpage
European Blood Alliance	EBA	https://europeanbloodalliance.eu/
Österreichische Gesellschaft für Blutgruppenserologie, Transfusionsmedizin, Regenerative Medizin und Immunogenetik	ÖGBT	https://oegbt.clubdesk.com
European Hematology Association	EHA	https://ehaweb.org
International Society of Blood Transfusion, EU-chapter	ISBT-EU	https://www.isbtweb.org
European Directorate for the quality of medicine and health care	EDQM	www.edqm.eu
Deutsche Gesellschaft für Transfusions-medicin und Immun-hämatologie	DGTI	www.dgti.de

4) Other training provider links:

<https://www.ecdc.europa.eu/en/data-tools>
<https://european-accreditation.org/information-center/newsroom/#enews>
<https://www.europebiobankweek.eu/>
<https://www.wutba.org/events?view=calendar&month=09-2023>
<https://www.aebt.org/>
<https://esot.org/>
<https://www.iplassociety.org/meetings-1>
<https://www.aibat-banchedeitessuti.com/>
<https://dtifoundation.com/training-type/tissue-banking-and-advanced-therapies/>

Assistance fields

TAP offers to provide assistance with regard to the following SoHO activities:

- Donation & donor selection
- Collection/procurement
- Testing
- Processing
- Storage and distribution (including import/export)
- Clinical administration/ use (only for HSC and blood, promoted by EBMT)
- Contingency planning
- Quality Management (including biovigilance)

Application procedure

For endorsed events, no TAP application is necessary. If you are interested in an EGALiTE endorsed event, please register directly at the relevant event.

In order to participate in TAP consultation or transfer of knowledge as a beneficiary it is necessary to apply as follows:

1. Applicant accesses the EGALiTE website and selects one of the options:

- a. Technical Assistance for SoHO Entities (except HSC and blood)
- b. Technical Assistance for HSC Activities
- c. Technical Assistance for Blood Activities

Option a.) will lead to the form “Application Form” (Annex 2) on the EGALiTE website.

Option b.) For queries regarding technical assistance for HSC, please contact JACIE at: jacie@ebmt.org or <https://www.ebmt.org/form/need-help>

Option c.) the “Application Form” (Annex 2) is available in PDF and will be sent to EBA. The TAP will be further managed by this organisation.

2. EGALiTE Coalition receives the request when option a. is selected and:

- Search for potential collaboration partners through the BTC Database
- Contact partner(s) until a viable collaboration is accepted
- Together with the collaborating partner’s representative and based on the information provided in the Application Form (and in some cases additional information requested²) by the applicant, the following is defined:
 - Aim of TAP (preparation for accreditation, sufficiency and/or improving quality and safety of SoHO and their activities, or other)
 - Cost of the action for the applicant based on the planned/extent of the action(s)
 - Detailed information about the proposed TAP includes the identification of SoHO Entity(ies) involved, estimated time, and proposed draft agenda for the TAP missions.

² Self-Assessment and or additional information related to the experience of the organization/professionals may be requested to better inform on the aim of the mission and define the goals and scope of the planned TAP actions.

Preparatory meetings with experts and/or applicants can be planned to define these details accurately, based on the needs and available resources.

3. Acceptance or rejection of the proposal by the applicant.

- Once the experts have been identified and selected by the EGALiTE Coalition, the applicant can accept, reject, or propose changes to the preliminary TAP agenda, duration, quotation, and other details of the proposed action(s).
- If the Applicant accepts the proposal two invoices are issued:
 - Expert/hosting fee: 90% value to be transferred to the collaborating EGALiTE Partner who will provide technical assistance. Fees will be disbursed directly to the institution. The provision of incentives to the expert(s) and the manner in which they are received will be subject to internal policies.
 - Administration fee: 10% transferred to EGALiTE Coalition.
- If the Applicant rejects the proposal (for instance, the applicant may claim that cannot cover the costs/afford such mission), the EGALiTE Coalition may try (if feasible) to re-adjust the proposal according the applicant's request, and/or informs that alternative assistance / collaboration can be negotiated directly by contacting the entities listed in the BTC Database. For this type of informal collaboration, the EGALiTE Coalition will not be further involved, and its actions stop at this step.

4. EGALiTE Coalition assists the applicant and collaborating EGALiTE Partner (if needed) in all the procedures related with planning/scheduling of the action, namely:

- Ensures that confidentiality and Experts' agreements are dully signed before the actions
- Make assessment tools and TAP forms available and updated (namely Application form, Self-Assessment Forms, etc)
- Propose and revise the contents of the Agenda of TAP Missions

5. EGALiTE Coalition handles the procedures associated with the evaluation and the reporting of the action, as applicable (Annex 3 and 4).

Only a limited amount of consultations and transfers of knowledge can be accepted per year and per SoHO type.

Expert database (TAP experts and institutions)

How to match experts with needs:

EGALiTE Coalition, EBMT and EBA will match the needs with the help of the BTC Database. Matching institutions are contacted by EGALiTE Coalition, EBMT or EBA and asked for their willingness/availability. One match with contact details is provided to the applicant.

See also guide for experts (Annex 5) for information on duties, deadlines, reports, reimbursement (Annex 6), travel arrangements (Annex 5) and Confidential Disclosure Agreement (CDA) (Annex 7).

Agreements

Details related with expert agreement are part of the expert guide (Annex 5).

Additionally, agreements for applying organisations are part of the Application Form (Annex 2) and Experts Guide (Annex 5).

Administration

- Application processing → Starts with the submission of applications in the EGALiTE website. Applications will be forwarded to the different scientific societies or public health bodies according to their scope.
- Coordination of responses to be managed by EGALiTE Coalition, EBMT or EBA.
- Standard experts' costs and fees:

For congresses and workshops no financial support is granted or additional fee is charged.

For consultation the applicant will be asked to cover travel, accommodation and insurance costs on their own. Furthermore, the expert/hosting fee as well as the administration fee needs to be paid.

For an on-site transfer of knowledge visit, a minimum daily allowance according to European Commission specifications (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/additional-information-on-unit-costs-and-contributions_en.pdf) is recommended³.

Economic aspects of travel arrangements are to be made in agreement with the inviting institution. Travel expenses, hosting and expert/organisation fees should be covered by the applying institution.

- Applicant feedback after consultation and transfer of knowledge via feedback form (Annex 3)

³ daily allowance is expected to be paid directly to assisting organization or expert.

- Expert report (Annex 4) after on-site transfer of knowledge with in-depth advice.

TAP processes

Flow chart applicant:



Flow chart EGALITE Coalition:



Flow chart after completion of TAP:



Annexes



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Annex 1. Criteria for TAP Applicants and Experts

(Including criteria for pilot actions within EGALiTE Project)



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To be used for self-assessment for applicant as well as checklist for piloTAP/TAP

<u>Criteria for applicants</u>	<u>Yes</u>	<u>No</u>
Completed application form	☐	☐
Applicant's organisation is located in an EU member state	☐	☐
Applicant's organisation is a not-for-profit organisation	☐	☐
Applicant's organisation is a National Competent Authority (NCA) authorized SoHO entity with any kind of SoHO activity	☐	☐



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To be used as checklist for piloTAP/TAP experts and their organisations

<u>General criteria for TAP experts/organisations</u>	<u>Yes</u>	<u>No</u>
Same language or fluent English skills	☐	☐
Short travel distance (not applicable for virtual TAP)	☐	☐
Experts should be active professionals or retired no longer than two years ago.	☐	☐
Working in his/her field of expertise for more than five years	☐	☐
Current working position at a non-for-profit organisation	☐	☐
Be able to show documented evidence of continuous education and training in the field of expertise	☐	☐
International activity in relevant scientific and technical communities (demonstrated by congress attendances, publication list, lectures, poster, etc.)	☐	☐
The TAP expert/organisation is a member of EATCB, EEBA or similar society or association (recommended requirement).	☐	☐

<u>Criteria for TAP organisation involved in consultation:</u>	<u>Yes</u>	<u>No</u>
General criteria for TAP experts/organisations (see above)	☐	☐
Consulted organisation holds a valid NCA authorization as SoHO entity for the SoHO activity required by the applicant (at least five years active, with a sufficient number of procedures to guarantee demonstration during consultation)	☐	☐
In addition, the consulted organisation must be EGALiTE accredited (if applicant intends to do EGALiTE accreditation)	☐	☐

<u>Criteria for TAP experts doing state of the art transfer-of-knowledge:</u>	<u>Yes</u>	<u>No</u>
General criteria for TAP experts/organisations (see above)	☐	☐

<u>Criteria for TAP experts doing in-depth-advice transfer-of-knowledge:</u>	<u>Yes</u>	<u>No</u>
General criteria for TAP experts/organisations (see above)	☐	☐
Expert coming from organisation that holds a valid NCA authorization as SoHO entity for the SoHO activity required by the applicant (at least five years active, with a sufficient number of procedures)	☐	☐
EGALiTE auditor acts as TAP expert (if applicant intends to do EGALiTE accreditation)	☐	☐

Annex 2. TAP application form



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EGALITE-TAP APPLICATION FORM

APPLICATION TYPE

- ☐ Consultation (study visit)
☐ Transfer of knowledge on-site: expert mission for state-of-the-art information
☐ Transfer of knowledge virtual: expert mission for state-of-the-art information
☐ Transfer of knowledge (only on-site): expert mission for in-depth advice

SoHOs AND ACTIVITIES

Activity(ies) for which you are requesting technical assistance

Donors		Type of SoHO	
Living Autologous		Adipose tissue	
		Amniotic Membrane	
		Blood	
		Cardiovascular	
		Hematopoietic Stem Cells	
Living Allogenic		Blood	
		Cord Blood	
		Hematopoietic Stem Cells	
		Musculoskeletal	
		Nerves	
Deceased Donor		Ocular Tissues	
		Serum Eye Drops	
		Skin	
		Others (Breast Milk, faecal microbiota, etc)	

Activities in the scope of the TAP mission:

- ☐ donation and donor selection
☐ collection/procurement
☐ testing
☐ processing
☐ storage and distribution (including import/export)
☐ clinical administration/use (HSC only)
☐ contingency planning
☐ quality management (including biovigilance)

Please detail your interests and needs / starting point(s) (i.e. provide information on the *status quo* of the activities for which you are requesting assistance). For example, you may inform on your level of compliance with EGALiTE standards, rationale for the need for implementation of new technique/activity, identify a specific lack of knowledge related to the EGALiTE Standards, etc.:

Considering the interests and needs above mentioned please define the specific goals / end point(s) for which the TAP is requested (e.g. Implement a new technique, start a new activity, become EGALiTE accredited, increase donation rates, improve production, etc):

GOAL 1: _____

GOAL 2: _____

GOAL 3: _____

1) CONTACT DETAILS

Last name:	
First name:	
Organisation name:	
Institute address:	
Postal Code:	
City:	
Country:	



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Telephone number of applicant (including country/city codes):		
E -mail-address of applicant		
Organisation Details	<u>Legal form</u> ☐ Public, not-for-profit according to WHO guiding principles ☐ Private, not-for-profit according to WHO guiding principles	
<u>Who will attend the TAP other than the applicant?</u> Please list...		
<u>Have you already been authorized by the NCA for one of the following SoHO activities?</u>		
Hematopoietic Stem Cells (HSC)⁴	If yes, please specify your activity and type of HSC	Last authorization date
☐ donor selection		
☐ collection/donation		
☐ testing		
☐ processing		
☐ storage and distribution		
☐ clinical administration/use		
☐ no HSC activity		
Tissues and Cells	If yes, please specify your activity and type of Tissue and Cells	Last authorization date
☐ donor selection		
☐ collection/donation		
☐ testing		
☐ processing		
☐ storage and distribution		
☐ clinical administration/use		
☐ no tissue/cell activity		
Blood	If yes, please specify your activity and type of Blood Component	Last authorization date
☐ donor selection		
☐ collection/donation		

⁴ Cord Blood Bank's activities included in the section "Tissues and Cells".

☐ testing		
☐ processing		
☐ storage and distribution		
☐ clinical administration/use		
☐ no blood activity		

☐ no SoHO authorization yet

Please provide information related with your relevant national authority (name, contact and website if available):

2) LANGUAGE PROFICIENCY	
Language	Proficiency

Please use the following level descriptions:

- native speaker
- fluent
- good command / good working knowledge
- basic communication skills / working knowledge

3) EDUCATION WORK EXPERIENCE	
IMPORTANT!	
Please add a CV for every visitor in case of a study-visit application, containing details on education and work experience	
Current position	
Description of your current duties:	

4) GDPR (data protection)		
Personal data must be processed in compliance with the applicable EU on data protection (in particular, GDPR Regulation 2016/679)		
I hereby confirm that I have truthfully completed the application form:		
Self-assessment for applicants	Yes	No
Completed application form	☐	☐
Applicant's organisation is located in an EU member state	☐	☐
Applicant's organisation is a not-for-profit organisation	☐	☐
Applicant's organisation is a NCA authorized SoHO entity with any kind of SoHO activity	☐	☐
NAME OF APPLICANT	SIGNATURE OF APPLICANT	DATE (YYYY-MM-DD)
I hereby confirm that the application of our employee is in our interest:		
NAME AND FUNCTION OF ORGANISATION'S REPRESENTATIVE	SIGNATURE OF ORGANISATION'S REPRESENTATIVE	DATE (YYYY-MM-DD)

EGALiTE-TAP Matching protocol (to be filled out by EGALiTE coalition)	
Receipt stamp	
Expert/Institution search	
Date of search: DD/MM/YYYY	Name of EGALiTE coalition administrator
Database search results	
Matching Expert/Institution contacts	
1) Date of contact of institutions: DD/MM/YYYY	Name of EGALiTE coalition administrator
Name of institution	Contact way
Date of reply DD/MM/YYYY	Outcome ☐ Yes, available ☐ No, not available
2) Date of contact of institutions: DD/MM/YYYY	Name of EGALiTE coalition administrator
Name of institution	Contact way
Date of reply DD/MM/YYYY	Outcome ☐ Yes, available ☐ No, not available
3) Date of contact of institutions: DD/MM/YYYY	Name of EGALiTE coalition administrator
Name of institution	Contact way
Date of reply DD/MM/YYYY	Outcome ☐ Yes, available ☐ No, not available

Annex 3. TAP applicant feedback form

FEEDBACK FORM			
1) APPLICANT DETAILS			
Last name:			
First name:			
Institution (name, address)			
SOHOS AND ACTIVITIES			
<i>Activity(ies) for which you requested technical assistance</i>			
Donors		Type of SoHO	
Living Autologous		Adipose tissue	
		Amniotic Membrane	
		Blood	
		Cardiovascular	
		Hematopoietic Stem Cells	
Living Allogenic		Blood	
		Cord Blood	
		Hematopoietic Stem Cells	
		Musculoskeletal	
		Nerves	
		Ocular Tissues	
Deceased Donor		Serum Eye Drops	
		Skin	
		Others (Breast Milk, faecal microbiota, etc)	
Activities in the scope of the TAP mission: ☐ donation and donor selection ☐ collection/procurement ☐ testing ☐ processing ☐ storage and distribution (including import/export) ☐ clinical administration/use (HSC only) ☐ contingency planning ☐ quality management (including biovigilance)			
Date of visit:		DDMMYYYY	

Type of visit:	
☐ Consultation (study visit) ☐ Transfer of knowledge on-site: expert mission for state-of-the-art information ☐ Transfer of knowledge virtual: expert mission for state-of-the-art information ☐ Transfer of knowledge (only on-site): expert mission for in-depth advice	
For consultations: institution visited	
For transfer of knowledge: visiting expert and their institution	
Language used during visit/mission	
2) EVALUATION	
Please score the quality of your visit/mission from 1 (poor) to 5 (excellent)	
	Your score
I have learnt many new/relevant things	
I can use the acquired knowledge in my routine work	
In case of study visit: The visit was well organized	
Overall impressions	
Administration by EGALiTE was helpful	
Achievement of goal 1 (from application form)	
Achievement of goal 2 (from application form)	
Achievement of goal 3 (from application form)	



3) MAIN TOPICS COVERED DURING VISIT/MISSION (details on goal 1-3)		
SIGNATURE OF APPLICANT	NAME	DATE (YYYY-MM-DD)
To be filled out by EGALiTE coalition		
Received and evaluated at EGALiTE coalition	NAME ADMINISTRATOR	DATE (YYYY-MM-DD)



Annex 4. Expert report form



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EXPERT REPORT FORM For in-depth advice	
1) EXPERT	
Last name:	
First name:	
Position of expert	
Institution (name, address)	
Country	
Telephone number	
E-mail	
2) VISITED INSTITUTION	
Institution (name, address)	
Country	
Telephone number	
E-mail	
3) AIM OF THE MISSION	
Aim:	
Date of visit:	DDMMYYYY

4) ANALYSIS



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5) RECOMMENDATIONS

		(YYYY-MM-DD)
SIGNATURE OF EXPERT	NAME	DATE
To be filled out by EGALiTE Coalition		
Sent to applicant by EGALiTE coalition		(YYYY-MM-DD)
	NAME ADMINISTRATOR	DATE

Annex 5. TAP expert guide

(Including expert agreement and conflict of interest)



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TAP EXPERT GUIDE

TAP is a Technical Assistance Programme established by the EU-funded project EGALiTE (grant #101056852) and should assist the implementation of good practices and optimization of activities in the SoHO field in the different Member States.

Public or private, both not-for-profit, SoHO entities (according to the principle of financial neutrality defined in the new SoHO regulation) and/or their co.workers can apply and can be supported by this programme.

It is inspired by the Technical Assistance and Information Exchange programme (TAEIX, and its associated programme TAIEX Regio Peer to Peer), promoted by the European Commission and motivated by the numerous requests for technical assistance, received annually by some beneficiaries of the EGALiTE project.

EGALiTE Technical Assistance Programme TAP aims primarily to provide assistance to SoHO entities of any European Member State, in contrast to TAIEX which is focused on assistance to 3rd countries.

The present expert guide defines the mechanisms to manage and coordinate the Technical Assistance missions requested by the above mentioned interested parties.

A. Role of the Expert in Transfer of knowledge

Expert missions (on-site or virtual) are intended to advise and help SoHO entities and their co-workers to implement and improve their SoHO activities and/or quality management systems.

Expert(s) are sent to the beneficiary institutions to provide state of the art-information or in-depth advice on the transposition, implementation or enforcement of a specific technical knowledge. They should be assigned by the scientific associations being part of EGALiTE coalition and EBMT and EBA in their fields of expertise.

After giving in depth advice, the expert has to file a report on the observations during his/her visit/mission including recommendations (see expert report form).

1. Financial Compensation and travel arrangements

Fees defined by the EGALiTE Coalition are publicly available on the website. These do not foresee any profit for the experts and organisations involved, but aim to compensate the time dedicated to TAP activities.

As a general rule, the EGALiTE Coalition may grant a daily allowance (covering accommodation, meals and local transportation) according to the established rates applicable to the place to be visited. For transfer of knowledge on-site a minimum daily allowance according to European Commission specifications (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/additional-information-on-unit-costs-and-contributions_en.pdf) is recommended.

Economic travel arrangements need to be made in agreement with the inviting institution. Travel expenses (including travel insurance) and expert fees should be covered by the applicant.

The expert fee should be used by the institution the expert belongs to, to compensate the invested time for the visit, writing and submitting the report.

Accommodation can be provided, except if the expert is residing in the town or within 50 km of the venue.

Any proof of payment for claiming reimbursement shall be submitted by the expert, no later than 30 days of the end date of the event together with original supporting documents.

Payment of the expert fee shall only be undertaken upon the submission of the expert report (in case of in-depth advice).

Full and accurate bank details must be provided to ensure that the transfer is executed without delay. The Swift/BIC Code and/or the IBAN number must be indicated as these are mandatory for payments within the EU Member States. Without this information, no payment can be made to the experts or his/her institution (see reimbursement claim form).

2. Practical Arrangements

The organisation of the logistical aspects as well as economic travel arrangements need to be made in agreement with the inviting institution. This is also applicable for the visit agenda.

The expert should check before the visit whether s/he will need a visa or not and if his/her passport/ID meets the required validity period. Experts are solely responsible for making all the necessary arrangements for obtaining their visa in due time. Subject to the prior agreement with the EGALITE Coalition, all necessary costs related to obtaining the visa can be reimbursed.

If an expert cannot be present at short notice, s/he must immediately contact the inviting party as well as the EGALITE Coalition. Furthermore, the expert should cancel all travel and accommodation arrangements (done by herself/himself) on her/his own.

Travel insurance arrangements should be made by the expert himself and the costs can then be passed to the applicant.

The EGALITE TAP as well as the inviting institution shall be under no liability in respect of sickness, accident or medical expenses incurred by the experts in connection with their assignment. This includes also capital indemnity in case of death or invalidity due to accident or sickness/illness.

B. Role of the organisations in consultation activities

Consultations (study visits) are intended to advise and help other SoHO entities and their co-workers to learn new techniques or to observe good practices.

Applicant(s) are forwarded to the reference institutions (part of the EGALITE Network, i.e. SoHO entities with knowhow recognized by the scientific societies, ideally accredited) to receive state of the art-information as well as specific technical knowledge.

Interested parties applying for TAP consultation will be supported by EGALITE Coalition, EBMT or EBA to find the adequate SoHO Entity to be visited.

The expert organisation needs to check and eventually accept their availability for consultation.

1. Financial Compensation and travel arrangements

For consultation the applicant is covering travel and accommodation costs on his own.

Hosting and administration fees should be covered by the applicant.

The hosting fee should be used for the expert institution to compensate the invested time for the consultation.

2. Practical Arrangements

For consultation the applicant is arranging travel and accommodation on his own, in agreement with the visited expert organisation. Any necessary additional arrangements (e.g. visa, travel insurance) need to be made by the applicant himself.

C. Expert Agreement

Personal data related to the participants will be processed in accordance with the GDPR, the privacy statement of the EGALiTE Coalition as well as the inviting/ visited institution.

_____ (NAME OF EXPERT ORGANISATION)

Hereby I, _____ (NAME OF EXPERT or EXPERT ORGANISATION REPRESENTATIVE), certify that I have read and understood the above mentioned guidelines and agree with them. Furthermore, I agree to act as an expert/ expert organisation in the EGALiTE transfer of knowledge/ consultation according to EGALiTE TAP for the following applicant:

_____ (APPLICANT ORGANISATION)

☐ **In case of transfer of knowledge**, I declare that I am qualified by medical/scientific training and experience for the purpose and do not have any conflict of interest related to the planned transfer of knowledge of the EGALiTE TAP.

Date and signature of expert

☐ **In case of consultation**, I declare that my organisation is qualified by medical/scientific experience for the purpose and does not have any conflict of interest related to the planned consultation of the EGALiTE TAP.

Date and signature of expert organisation representative

Annex 6. Reimbursement Form TAP Experts



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REIMBURSEMENT FORM (EGALITE Transfer of knowledge)	
CONTACT DETAILS	
Last name	
First name	
Organisation name	
Institute address	
Postal Code	
City	
Country	
Telephone number of applicant (including country/city codes)	
E-mail-address	
JOURNEY DETAILS	
Date, place	
Purpose	☐ Transfer of knowledge on-site: expert mission for state-of-the-art information ☐ Transfer of knowledge (only on-site): expert mission for in-depth advice

	Travel costs	
Means of transport (bus, plane, train,...)	Currency	Amount
All claims for reimbursement of travel expenses must be accompanied by relevant tickets (or a copy) and invoice.		
DAILY ALLOWANCE		
Daily allowance will be calculated and automatically reimbursed by the EGALiTE coalition.		
METHOD OF PAYMENT		
Payment will be made by bank transfer to the account indicated below after having received the completed expert report.		
Account holder		
Country of bank		
BIC/SWIFT		
IBAN		
I certify that the amounts stated above are the costs actually incurred for my journey and that I have not claimed the reimbursement of these costs from any other organisation.		
Date	Signature	

Annex 7. Mutual confidentiality agreement

(CDA- confidential disclosure agreement)



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MUTUAL CONFIDENTIALITY AGREEMENT

This mutual confidentiality agreement (short “agreement”) signed _____ (DATE) by and between:

EXPERT

(For mutual experts involved in the TAP, it is expected that one representative from each participating organization will sign the mutual confidentiality agreement.)

_____ (NAME OF EXPERT)

_____ (ADDRESS)

APPLICANT ORGANISATION

_____ (NAME OF APPLICANT REPRESENTATIVE)

_____ (POSITION)

_____ (ADDRESS)

Which are referred to as “party”/”parties”.

Whereas, the parties wish to disclose certain confidential and proprietary information for the purpose of enabling transfer of knowledge within the EGALITE TAP.

Each recipient shall not use or duplicate any confidential information (except as necessary to perform the TAP transfer of knowledge) and shall keep confidential and not disclose any confidential information to anyone outside of the organisation, unless the discloser has, in its sole discretion, previously and expressly consented to such use, duplication or disclosure in writing.

Each party agrees to protect the other parties confidential information with at least the same degree of care as it exercises to protect its own highly confidential information of like character, but in no event less than reasonable care.

Excluded from this is the disclosure of confidential information to Health Authorities according to applicable law.

The signatories, with duly authorization, hereto warrant to execute this agreement unrestrictedly.

Date and signature of organisation representative

Date and signature of expert