Call for Proposals

EUROPEAN REFERENCE LABORATORY NETWORK FOR TUBERCULOSIS (ERLTB-Net) - TO STRENGTHEN TB DIAGNOSIS IN THE EUROPEAN UNION AND EUROPEAN ECONOMIC AREA

Reference: Grant/2022/DPR/13440

Deadline for submission of proposals: 2nd September 2022

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1. BACKGROUND

1.1. Tuberculosis (TB)

Tuberculosis (TB) remains an important threat to human health worldwide. In the European Union (EU) and the European Economic Area (EEA), the TB situation has improved over the past decades, but needs to remain on the agenda due to:

- A continuous global challenge with multidrug-resistant (MDR) TB and extensively drug-resistant (XDR) TB that also affects the EU/EEA Member States;
- The disproportionately high burden of disease in vulnerable populations;
- Medium to high TB incidence in some EU Member States and in several countries of neighbouring regions;
- The COVID-19 pandemic consequences resulting in a lower number of people that received care for tuberculosis;
- TB is the leading cause of death of people with HIV.

1.2. European Centre for Disease Prevention and Control (ECDC)

The ECDC Founding Regulation[1] states that ECDC, within its mandate, shall coordinate the surveillance activities at the Community level as well as other activities important for identification, assessment, and communication of emerging threats to human health from communicable diseases.

ECDC does not have any laboratories of its own and relies on Member States' laboratory expertise and capacity. According to its Founding Regulation, it is ECDC's role:

- To support networking activities of the competent bodies recognised by the Member States;
- To encourage cooperation between expert and reference laboratories;
- To foster development of sufficient capacity within the Community for diagnosis, detection, identification, and characterisation of infectious agents which may threaten public health;
- To maintain and extend cooperation and support for the implementation of quality assessment schemes.

[1] Founding Regulation (EC) No 851 /2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (http://eur-lex.europa.eu/LexUriSery/LexUriServ.do?uri=CELEX:32004R0851:EN:HTML)

The ECDC TB programme plans, implements, monitors and evaluates all aspects of TB prevention and control in the EU. This includes TB surveillance in the WHO European Region which ECDC and the WHO Regional Office for Europe have jointly coordinated since 2008.

1.3. European Reference Laboratory Network for Tuberculosis

In 2008, a situation analysis of national TB reference functions across the EU/EEA was conducted and led to the creation of the European Reference Laboratory Network for Tuberculosis (ERLN-TB). In 2014 and 2018, the European Centre for Disease Prevention and Control (ECDC) commissioned a renewal of the network (now called ERLTB-Net) involving the centres from the same Member States. Currently, one of the aims is to gradually involve new institutions from EU Enlargement Countries[2] and EU Neighbourhood Policy Countries[3].

The key roles of national reference laboratory services identified by Drobniewski et al.[4] and ECDC[5]:

(1) Reference diagnostics.

The reference laboratory has state-of-the-art validated laboratory methods in operation and the ability to deliver accurate confirmation of diagnostic results within its field of expertise. This may include the analysis of samples in a variety of areas, such as the verification of results (e.g. detection or confirmation) reported by external laboratories, the detection of specific microbial markers and the investigation of atypical samples. Reference diagnostics involve activities such as:

- identify mycobacterial cultures as *Mycobacterium tuberculosis* or non- tuberculous mycobacteria;
- analyse drug resistance of TB cultures;
- perform rapid identification and detection of at least rifampicin (RIF) resistance in patient specimens;

(2) Reference material resources.

If necessary, the reference laboratory develops and maintains — in accordance with international standards and procedures — a collection of relevant reference material that is to be shared with laboratories and organisations that request such materials. These materials can include

[2] https://ec.europa.eu/environment/enlarg/candidates.htm

[3] https://ec.europa.eu/info/business-economy-euro/economic-and-fiscal-policy-coordination/international-economic-relations/enlargement-and-neighbouring-countries/neighbouring-countries-eu_en

[4] Drobniewski, FA, V Nikolayevskyy, S Hoffner, O Pogoryelova, D Manissero, AJ Ozin. The added value of a European Union tuberculosis reference laboratory network – analysis of the national reference laboratory activities. Euro Surveill 2008;13(12)

[5] European Center for Disease Prevent and Control. Core functions of microbiology reference laboratories for communicable diseases. Stockholm: ECDC; 2010.

reference laboratory strains and cultures, clinical isolates, sera, genetic materials, etc. These resources are important for the varied purposes of quality assurance systems, method evaluation and validation. Reference material resources include resources such as:

- protocols and standard operation procedures;
- standards and external quality assessment schemes (with partners);

(3) Scientific advice.

The reference laboratory is a resource and coordination point for expertise within its specific area and shares information and advice with relevant stakeholders. This can include technical advice on methods and procedures, scientific support and advice on the interpretation and relevance of laboratory findings on pathogens to relevant public health authorities (policy makers and public health professionals). Scientific advice activities involve activities such as:

- provide clinical and relevant public health advice on the treatment of TB;
- advise on laboratory issues relating to national TB programmes;
- perform molecular typing of M. tuberculosis strains to support public health actions in geographically or time-defined settings and to answer specific questions on transmission.

(4) Collaboration and research.

The reference laboratory is at the forefront of technological and scientific development in its field of expertise, particularly in areas relevant to public health action. This would involve participation in operational research such as the validation of new diagnostics. Contacts with regional and international laboratory networks as well as related initiatives should be established and maintained. Examples of collaboration are involvement in EU and other international disease-specific networks, network activities of regional laboratories, or global initiatives via WHO or the US CDC.

(5) Monitoring, alert and response.

The reference laboratory performs or contributes to surveillance activities or has established channels of communication with the national surveillance body to regularly report incidence data and provide an 'alert function' for unusual occurrences. These can include failure of a diagnostic test, detection of changes in incidence, virulence, drug resistance, emergence of a possibly infectious disease of unknown aetiology, etc. In the case of an outbreak, the reference laboratory supports outbreak investigations, e.g. by offering diagnostic services, advice and technical expertise, and, upon request, provides surge capacity for diagnostics.

1.4. Synergy with Pan-European and global TB initiatives

The Directorate General for Research and Innovation of the European Commission has funded TB projects of public health relevance (i.e., diagnosis, vaccine and drug development) for a number of years as part of the Framework Programmes (FPs) and Horizon 2020. Further initiatives to consider are WHO's End TB Strategy, the European Tuberculosis Laboratory Initiative (ELI), together with the Global Laboratory Initiative (GLI), to strengthen the laboratories capacity for a better diagnosis and detection of TB and the STOP TB partnership, that aims in pushing TB in the political agendas. Consequently, the beneficiary might be requested to represent the network in those initiatives.

2. OBJECTIVES, ACTORS AND ACTIVITIES

2.1. Objectives of the action

- Ensure full establishment and coordination of ERLTB-Net.
- In particular, enhance the further development of ERLTB-Net and exploit synergies with other supranational/global initiatives with the capacity to serve and support EU/EEA Member States with a specific focus on TB control and elimination in the EU/EEA.
- Continue to support the EU/EEA Member States in providing reliable and timely diagnostic services.
- Support the EU/EEA Member States in implementing new laboratory techniques meeting current and future needs.
- Support the Member States and the ECDC in molecular- and genomic- based typing activities responding to public health needs in the field of TB.
- The EU Enlargement Countries[6] and/or EU Neighbourhood Policy Countries[7] might be invited to participate in some activities, e.g. meetings, EQA, trainings. Any costs related to those activities will be covered by a separate contract(s) outside the FPA, i.e. the cost will not be covered by this project and no separate contract should be signed with those countries by the beneficiary.

2.2. Main actors

Partner: party with whom the Framework Partnership Agreement (FPA) will be signed (see the model FPA, Annex IV (a)).

[6] https://ec.europa.eu/environment/enlarg/candidates.htm

[7] https://ec.europa.eu/environment/international_issues/eu_neighbourhood_en.htm

Lead partner: the leader of a consortium, if applicable.

Project leader: a person employed by the partner (or by the lead partner, if a consortium), who will act as the lead for the coordination of ERLTB-Net and is the designated contact person for liaising with ECDC and ERLTB-Net.

Project manager: a person employed by the partner (or by the lead partner, if a consortium), who will have the overall responsibility for day-to-day project coordination and management of the network.

Project scientist: a person employed by the partner (or by the lead partner, if a consortium), who will have the overall responsibility for day-to-day coordination and management of scientific activities within the project.

ERLTB-Net: a network of laboratories/laboratory experts (up to two experts per country) from EU/EEA Member States nominated by their National Competent Body. The nomination process of the ERLTB-Net members is coordinated by ECDC.

ERLTB-Net project management team: consists of 3-5 people selected from the network and/or partner in addition to the project leader and project manager. If the partner is a consortium, selected representatives of consortium members should be included. The project management team selects a chairperson to run the meetings and is expected to meet regularly throughout the project duration and not less than once every 6 months. The project management team contributes technically and strategically to the project leader's work and liaises with existing initiatives funded by ECDC, the European Commission and WHO. The ECDC contact person(s) attend the project management team meetings and participate fully in discussions and decision making.

Steering committee: may be established to oversee project activities and to ensure the quality, relevance and European added value of the project. The steering committee is appointed by ECDC, in consultation with the partner. The steering committee includes the partner (or the lead partner, if a consortium), ECDC contact person(s) and 2-3 TB/public health experts appointed and chair by ECDC.

EU Enlargement Countries[8] **and European Neighbourhood Policy Countries**[9]: The laboratories/laboratory experts from the EU Enlargement Countries and EU Neighbourhood Policy Countries nominated by their National Correspondents might participate in all ERLTB-Net activities, but not in the decision-making process influencing ECDC's future decisions; i.e. the observer status will be granted. The nomination process is coordinated by ECDC.

[8] https://ec.europa.eu/environment/enlarg/candidates.htm

[9] https://ec.europa.eu/environment/international_issues/eu_neighbourhood_en.htm

2.3. Actions and the action results of the Framework Partnership Agreement

The partner is requested to coordinate the work in agreement with and under supervision of ECDC.

The partner will assist ECDC experts in use of outputs of the network, even if such outputs are not technically considered as results, for example evaluation surveys, training material.

2.4. Definitions and acronyms:

A = main action; **R** = action result; **m** = month (used to describe timing within the expected total duration of 48 months of this FPA starting from the day FPA has been signed by all parties).

Dates in brackets are the preferred dates.

Data management and data exchange with ECDC are arranged according to the data protection rules (See Article 11.7.2 Processing of personal data by the partner of the Framework Partnership Agreement, Annex IV(a)).

AI. THE EUROPEAN REFERENCE LABORATORY NETWORK FOR TUBERCULOSIS (ERLTB-Net) IS FULLY ESTABLISHED AND ITS COORDINATION IS ENSURED

The tasks of A1 consist of setting up and ensuring continued coordination of the ERLTB-Net.

AI.1 Coordination

As per the definition of the roles of the actors in this project (see section 2.2), the partner (or the lead partner if a consortium), will coordinate ERLTB-Net. The requested results are:

R1.1.1 The ERLTB-Net with agreed members is set up by nomination of the ERLTB-Net members (m l-3). The ERLTB-Net members will be nominated by the National Competent Bodies in the Member States.

R1.1.2 Monthly virtual meetings between the partner and ECDC including providing the minutes (within one week after the teleconference).

R1.1.3 Report* on project implementation, comprising all the results of activities performed under the respective specific grant agreement (SGA).

R1.1.4 Final report* on the entire project period.

* The report will include at least the following chapters: table of contents, list of abbreviations, executive summary, introduction/background, detailed description of activities, results of activities, discussion on results/lessons

learned, and conclusions/next steps. The report should be written using British English grammar and spelling. The report should be consistently formatted throughout the document.

A1.2 ERLTB-Net project management team

As stipulated in section 2.2, the partner will propose a group of representatives from the ERLTB-Net and/or selected representatives of the partner (maximum 5 in total), who will contribute technically and strategically to the project, liaise with ECDC, the European Commission, WHO or any relevant initiative recognised by ECDC. The terms of reference for the project management team (PMT) will be developed jointly with ECDC. Non-consortium members from the ERLTB-Net can be selected to be part of the PMT. The ECDC contact person(s) attend the project management team meetings and participate fully in discussions and decision making.

It is expected that a maximum of 3 meetings (1–2-day meetings) will be necessary each year. Ideally, these are face-to-face meetings. However, if organisation of a face-to-face meeting is not possible, the meeting will be organised as a hybrid or online meeting. Online meetings will be used as an alternative to face-to-face meetings. One face-to-face or hybrid meeting should be organised back-to-back with the annual network meeting and one at ECDC premises in Stockholm, Sweden, if possible. Travel, accommodation and relevant subsistence expenses for the project management team members will be covered by the grant. The organisation of the meetings should follow the general rules described in section 2.5.

The requested results are:

- R1.2.1 ERLTB-Net project management team with agreed members is set up (m 1-3).
- R1.2.2 The terms of reference for the ERLTB-Net project management team are approved by ECDC (m 1-3).
- R1.2.3 The project management team meetings and teleconferences are organised and the minutes* of the meetings / teleconferences are provided to ECDC (within two weeks after the face-to-face meeting, and within one week after the teleconference).

* The minutes should include at least the following: title of the meeting, date and time, venue, list of attendees, list of apologies, list of abbreviations, detailed description of discussion, summary of decisions with agreed deadlines and personal responsibilities. The minutes should be written using British English grammar and spelling. The minutes should be consistently formatted throughout the document.

A1.3 Annual meeting and large capacity building workshop

The partner, (or the lead partner if a consortium), will organise one meeting and large capacity building workshop for the ERLTB-Net members every year in one of the EU/EEA Member States. The organisation of these meetings should follow the general rules described in section 2.5. In addition:

- The meeting and large capacity building workshop ideally is a face-to-face or hybrid meeting. The event will be attended by ERLTB-Net members and include nominated individuals from all EU/EEA Member States, plus any additional participant(s) requested by ECDC. Other country representatives and invited colleagues from relevant organisations (e.g. WHO, European Commission) may attend as observers, but on their own funding.

- By default, one ERLTB-Net member per EU/EEA Member States should be invited. If the budget of the SGA allows, then an additional ERLTB-Net member (e.g. molecular typing contact, former support expert still working in TB) can be invited from the Member States. The other members of the network can attend events either online or face-to-face at their own cost.

- Ideally, the number of participants, including invited speakers, should not exceed 50 individuals, excluding representatives from EU enlargement countries and/or ENP countries, ECDC employees and invited colleagues from relevant organisations.

- The agenda and the main topics for the meeting and the agenda for the large capacity building workshop will be agreed with and approved by ECDC.

- The format of the meeting and the large capacity building workshop will be agreed in advance with ECDC, taking into account the expected epidemiological and socio-economic situation at the time point of the meeting. The preferred format would be hybrid format whenever it is possible.

The requested results are:

R1.3.1 The annual meeting and large capacity building workshop are organised and implemented.

R1.3.2 A detailed report* on the annual meeting and the large capacity building workshop is provided (within one month after the event).

* The report should include at least the following chapters: table of contents, list of abbreviations, executive summary, introduction/background, detailed description of activities, results of activities, discussion on results/lessons learned, and conclusions/next

steps. The report should be written using British English grammar and spelling. The report should be consistently formatted throughout the document.

A2. EXTERNAL QUALITY ASSESSMENT (EQA) SCHEMES FOR TB LABORATORY METHODS ARE DESIGNED AND SCHEMES FOR NEW METHODS ARE ESTABLISHED

The partner will, in accordance with the ECDC EQA strategy (to be provided by ECDC), maintain and further develop the existing EQA schemes for TB laboratory diagnostic methods routinely used by the laboratories in the EU/EEA. Every year one EQA round for the ERLTB-Net members will be organised. During the EQA implementation, related on- going activities/projects funded by the European Commission should be identified and taken into account. It should be assessed how the ERLTB-Net EQA activities interact with global initiatives supported by the WHO to build synergies and avoid duplication of efforts.

The partner is not expected to be a specialist in all techniques covered by the EQA schemes proposed. Arrangements with appropriate specialists among ERLTB-Net members - or other institutes or private companies - can be used to fulfil part or all the EQA tasks (A2). In general:

- The partner will prepare an approach on how to provide EQA schemes to the ERLTB-Net member laboratories and promote their participation (a minimum of 10 laboratories for EQA round). The EQA schemes are to cover diagnostic methods routinely used by the participating laboratories in the EU/EEA (e.g. culture, microscopy, molecular assays), first and second-line drug susceptibility testing (e.g. phenotypic, molecular assays, WGS) and molecular typing methods (e.g. WGS,) to ensure that the ERLTB-Net member laboratories produce valid and comparable data.

- The partner will develop EQA schemes for new diagnostic methods and genotyping techniques.

- The partner will work with the ECDC contact person(s) at all steps during implementation of EQA.

- The ERLTB-Net project management team will guide the development of EQA methods, protocols, services, and follow-up training by the network.

A2.1 Establishment of the current performance

Using experiences from existing TB EQA initiatives, the partner will design a proficiency round in agreed areas of TB diagnostic services (e.g. microscopy, culture, drug susceptibility testing, molecular diagnostic

assays) including molecular typing (e.g. WGS) to confirm or establish a new baseline of performance for ERLTB-Net members and to help identify future needs for collaboration and training within the network (refer to A3 of training and use of task forces to improve proficiency testing performance).

The requested results are:

R2.1.1 Summary report on EQA performance for all methods included in the ERLTB-Net EQA. For methods that were also in the past EQA exercises, a comparison with results in previous years should be made. This summary report establishes the baseline EQA performance.

A2.2 Development of future EQA schemes

The partner will identify the areas where an EQA scheme exists or should be developed in the area of TB diagnostic services (e.g. microscopy, culture, drug susceptibility testing, molecular diagnostic assays) and molecular typing (e.g. WGS), following the recommendations in international guidelines and existing standards.

The requested results are:

R2.2.1 Description of the existing EQA system in diagnostic and molecular typing techniques and additional techniques to be included into the EQA.

R2.2.2 EQA work plan on implementation of regular EQA rounds.

R2.2.3 Work plan with a proficiency testing scheme for new methods (based on R2.1.1) that helps to establish a performance baseline for ERLTB-Net members.

R2.2.4 Report on training needs to support improvements in performance in order to meet EQA standards (refer to A3 on training for improving EQA performance).

A2.3 Implementation of regular EQA rounds and data analysis

Following the EQA work plan (see R2.2.2 and R.2.2.3), the partner will perform annual EQA rounds, collection and analysis of EQA results. The non-anonymised EQA results by country will be shared with ECDC for internal use only. The non-anonymised EQA results by country will not be published by ECDC but used to ensure tailored technical support to laboratories with suboptimal performance for specific tests.

The requested results are:

R2.3.1 EQA system described in R2.2.1 is implemented as part of EQA rounds.

R2.3.2 The laboratory certification (after every EQA round) based on the EQA results.

R2.3.3 An annual summary EQA report* with anonymised data is produced.

*The report should follow the ECDC content template for EQA reports[10] and include at least the following chapters: credits, table of contents, list of abbreviations, executive summary, introduction/background, detailed description of methodology/study design, results, discussion on results including lessons learned, conclusions/next steps including the training areas identified, references and annexes. The report should provide results separately for EU/EEA, non-EU/EEA countries, and all countries. The report should be written using British English grammar and spelling. The report should be consistently formatted throughout the document. ECDC will provide a template for the report in advance.

A3. TRAINING IS PREPARED AND IMPLEMENTED

Based on the identified needs, the partner will develop a training programme including large and small capacity building workshops, staff exchange visits and targeted country support with the overall aim to strengthen Member States capacity in laboratory diagnosis of TB (i.e. demonstration, isolation and characterisation of *Mycobacteria*), in supporting public health activities (e.g. molecular typing) and in coordination of national TB laboratory networks.

A3.1 Identification of training needs and development of training curricula

Under each SGA the partner will identify training needs in addition to those identified in R2.2.4 and develop the appropriate curricula for laboratory capacity building workshops, staff exchange visits and targeted country support to:

- strengthen performance in traditional diagnostic methods, DST, molecular typing, and other specialised analytical techniques for TB as well as other more general topics such as biosafety, laboratory management and quality control in the context of working with TB;
- improve EQA performance;
- support the establishment and coordination of national TB laboratory networks.

[10] ECDC internal document. Relevant section will be provided to the partner.

The requested results are:

R3.1.1 Report* on identified training needs in laboratory methods, including molecular typing methods, diagnostics, organisation / coordination of the national TB laboratory network and other areas of TB laboratory reference services in EU/EEA Member States.

R3.1.2 Detailed training curricula on the topics identified in R3.1.1.

* The report should include at least the following chapters: table of contents, list of abbreviations, executive summary, introduction/background, detailed description of methodology, results, discussion on results. The report should be written using British English grammar and spelling. The report should be consistent formatted throughout the document.

A3.2 Implementation of training activities

Preferred types of training, but not exhaustive:

- Small and large capacity building workshops: their goal is to disseminate methods, identify challenges and provide solutions for overcoming them. The training must be provided by a training organiser delegated by the partner or by the partner themselves. The topics, agenda, invitation list, location and the trainers will be agreed with ECDC.

- The preferred format for both small and large capacity building workshops is hybrid. However, it can be carried out as an online event, as long as the topic and the set up allow it. In addition, if the training cannot be performed in hybrid format, then face-to-face meeting is organised. Whenever is possible, face-to-face trainings sessions will be video recorded and made available as online training material for the entire network through ECDC extranet.

- It is encouraged to provide small capacity workshops in webinar format.

- TB laboratory staff exchange visits or targeted country support: short visits to improve on specific methods based on the results of the EQA, provide training in specific methods to improve characterisation of pathogens and/or specialised reference techniques, to enhance coordination of national TB laboratory networks, and to promote collaboration between ERLTB-Net members.

The training activities will be coordinated by the partner and implemented by the partner or a third party specialised in the specific area.

For cost estimation of training initiatives, please use the following scenarios as a guide:

- One large capacity building workshop (based on 50 participants) and/or no more than 3 smaller laboratory training workshops (8-10 participants to cover topic-specific needs) may be requested by ECDC per 12 months. The large capacity building workshop should be held back-to-back with the annual meeting. The partner will cover the travel, accommodation and relevant subsistence expenses within EU/EEA for all the participants in the workshop (maximum 3 days per workshop), for face-to-face meetings, when justified. The partner will also cover their own expenses and expenses of trainers/experts which will be included in the budget proposal together with the costs of participants. Travel, accommodation and subsistence expenses of ECDC staff will be covered by ECDC.

- Based on the scenario, 3 "country support" visits should be included per 12 months (anticipated should be no more than 2 visitors for a period of time between two to five days), unless otherwise justified by the results of A2. The partner will cover the travel, accommodation and relevant subsistence expenses for all the experts involved. The partner will also cover their own expenses which will be included in the budget estimation together with the costs of participants.

- Based on the scenario, 2 staff exchanges for a period of time between two to five days per 12 months should be budgeted for. Each such staff exchange would have to be justified and approved by ECDC. The partner will cover the travel, accommodation and relevant subsistence expenses for the participants for up to one week. The partner will cover their own expenses which will be included in the budget estimation together with the costs of participants.

The requested results are:

R3.2.1 Detailed implementation plan[#] of training curricula described in R3.1.2.

R3.2.2 Training materials and training initiatives are developed and implemented during annual meetings, laboratory capacity building workshops, and in laboratory exchanges and country support visits and made available through the dedicated ECDC platform (e.g. extranet). The copy of all developed materials will be provided to ECDC latest one month before the expiring of the FPA.

R3.2.3 Individual reports[*] on each implemented training activity

[#] The implementation plan should include at least the following chapters: table of contents, list of abbreviations, executive summary,

introduction/background, detailed description of implementation steps, risks and mitigation. The report should be written using British English grammar and spelling. The implementation plan should be consistently formatted throughout the document.

* The report should include at least the following chapters: table of contents, list of abbreviations, executive summary, introduction/background, detailed description of activities, results of activities, discussion on results/lessons learned, and conclusions/next steps. The report should be written using British English grammar and spelling. The report should be consistently formatted throughout the document.

A4. REFERENCE AND SUPPORT ACTIVITIES

A4.1 Methods harmonisation

- The partner will propose an implementation plan for harmonisation of new TB laboratory methods in needed areas, taking into account ongoing projects at the EU/EEA and global level.

- Maintain the European "handbook"[11] (technical guidance) of harmonised methods as the ultimate output of the network to be used as a shared tool amongst the network members and all interested TB laboratories in the EU/EEA. The "handbook" will be made available on the ECDC public web portal.

The requested results are:

R4.1.1 Maintained and updated "handbook" of TB diagnostic methods.

R4.1.2 Developments in laboratory methodologies and techniques are followed up and new developments are to be reported to the network members and ECDC at the annual meetings and through the ECDC platform (e.g. extranet).

R4.1.3 A work plan for the introduction of new methodologies and techniques into routine TB diagnosis for the National TB Reference Laboratories.

A4.2 Reference services

Provide a reference service catalogue and promote access to these laboratory services to network members.

The requested results are:

R4.2.1 The list of reference services provided by the network

[11] https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/tuberculosis-laboratory- diagnostic-methods-eu.pdf

members and the costs per service are maintained and made available to the network members in a "bio-book" format. The exact format will be agreed with ECDC.

R4.2.2 Feedback on acting collaborations and on the use of these reference services should be provided for periods between 6 to 12 months.

A4.3 Alert and response

Involve the ERLTB-Net members (knowledgeable in epidemiology, microbiology, WGS) in contributing to the ECDC's alert and response activities, including the analysis of WGS data (e.g. on EpiPulse platform) collected in TESSy, in accordance to ECDC data access rules and the General Data Protection Regulation[12] (GDPR).

Involve sufficient number of ERLTB-Net experts, based on the number and frequency of sequences submitted, in the molecular typing and WGS-based typing data analysis, review and assessment of public health importance of identified molecular clusters.

The requested results are:

R4.3.1 Upon ECDC request, ERLTB-Net supports ECDC's alert and response activities, including public health actions triggered by cluster notifications coming from ECDC's TB molecular surveillance system (estimated number of requests is 4 per year).

A4.4 Scientific support and excellence

The partner will participate in relevant ECDC scientific activities and will promote these on relevant national and international meetings and conferences.

ERLTB-Net members and/or the partner will produce at least one peer-reviewed article per year based on network activities. The partner will encourage the network members to engage in scientific collaborations with ECDC (e.g. tuberculosis surveillance, HIV surveillance). The partner, or the lead partner if a consortium, will appoint a qualified ERLTB-Net member to produce the article. Co-authorship will be offered to network members and relevant ECDC staff meeting the authorship requirements described by the International Committee of Medical Journal Editors[13]. All scientific

[12] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

[13] http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

publications should be Open Access. Cost for Open Access publishing is covered by the FPA.

The requested results are:

R4.4.1 The partner participates in and promotes ECDC's scientific activities to TB colleagues/community of experts (e.g. meetings, conferences).

R4.4.2 At least one peer-reviewed article per year is produced based on ERLTB- Net activities.

A4.5 Support to national laboratory networks for tuberculosis

The partner will provide technical support to ERLTB-Net member laboratories in building, managing and assessment of national TB laboratory networks. The partner will maintain the existing tool for self-assessment of national TB laboratory networks, and if needed, further develop it. Member laboratories will be encouraged to use the tool and to share the results with the partner. The partner will use the results of the self-assessment for prioritising countries for support applying a predefined algorithm for prioritization. When requested in the SGA, the partner will explore the interest of the ERLTB-Net members for receiving the support, and after the ECDC approval, provide the support.

The requested results are:

R4.5.1 Tool for the self-assessment of national TB laboratory networks.

R4.5.2 Performed self-assessments of national TB laboratory networks.

R4.5.3 Report* on the performed self-assessments of national TB laboratory networks, including proposed priority list based on self-assessment results.

R4.5.4 Action plan for targeted country support in selected countries according to the identified needs in R4.5.3.

R4.5.5 Implemented action plan for targeted country support in selected countries according to the R4.5.4.

R4.5.6 Report* on the implemented targeted country support activities in selected countries.

* The report should include at least the following chapters: table of contents, list of abbreviations, executive summary, introduction/background, detailed description of activities, results of activities, discussion on results and conclusions/next steps. The report

should be written using British English grammar and spelling. The report should be consistently formatted throughout the document.

2.5. Meetings

Meetings should be organised according to the general principles described in Annex V, Travel and Logistic standards, by taking into account the specific requirements described below.

For all face-to-face meetings (including laboratory capacity building workshops), the following tasks will be carried out by the partner, (or the lead partner if in a consortium):

- Propose the list of participants, provide the scope and purpose of the meeting and seek ECDC input and approval prior to sending invitations to the identified meeting participants. The scope and purpose document should describe the background, objectives, expected outcomes, and working methods of the meeting.

- Organise travel and accommodation for all participants, including the invited speakers. Travel and accommodation for ECDC staff will be organised by ECDC according to its internal procedures. Self-funded participants should organise their travel and accommodation themselves.

- Ensure that all participants sign the attendance list for each day of the meeting.

- The partner will cover their costs and the costs of the participants (excl. self- funded participants) including the invited speakers at the country-specific fixed rate as indicated in 11.19 - Eligible Costs of the Model FPA, Annex IV(a). Participant costs will be reimbursed after conclusion of the meeting/workshop and upon proof of participation by an attendance list signed by the participant for each meeting day.

- Provide an appropriate meeting venue, ensuring appropriate working conditions, including all relevant equipment, such as overhead projector / video projector with connection to MS PowerPoint software, beamer, screens (if needed), flip charts (with paper and pens), easy access to printer, photocopier (with sorter and stapler function).

- Plenary room will be 1 large room for lectures accommodating all the participants. Participants will have own laptops and will need access to outlets. There will be a dedicated presentation computer/laptop hooked up to the projector. Each participant will have enough table space for the laptop, paper notes and small (0.5 litre) bottle of refreshment (e.g. mineral water).

- Breakout room (optional) will be a smaller discussion room for group work accommodating half of the participants. Presentation screen, projector, and flipchart with pens are needed in each room.

- Free of charge Wi-Fi internet access will be provided to each participant in the meeting spaces (e.g. plenary room, breakout rooms).

- Provide catering during the event. The catering should consist of healthy food, taking into account possible restrictions due to allergies or health conditions, fast-food is excluded. Provide 2 coffee breaks per day and water on the table during meeting sessions.

- The working language at the meetings is English.

- Provide to the participants the printed and/or electronic version of background and working documentation related to the meeting in English language at least 2 weeks before the meeting.

- Ensure the necessary administrative support (including continuous on-site support) in order to allow smooth organisation and implementation of the meeting.

- Seek speakers' agreement for sharing their meeting presentations with the meeting participants and including them in the meeting report.

- Provide a detailed meeting report[#].

[#] The report should include at least the following chapters: table of contents, list of abbreviations, executive summary, introduction/background, detailed description of activities, results of activities, discussion on results/lessons learned, and conclusions/next steps. As part of the meeting report, a final list of participants (including their affiliation and contact details), will be provided to ECDC in electronic (e.g. xlsx, pdf) format. The report should be written using British English grammar and spelling. The report should be consistently formatted throughout the document.

For all online meetings, the following tasks will be carried out by the partner, (or the lead partner if in a consortium):

- Propose the list of participants, provide the scope and purpose of the meeting, and seek ECDC input and approval prior to sending invitations to the identified meeting participants. The scope and purpose document should describe the background, objectives, expected outcomes, and working methods of the meeting.

- Provide a link to an online platform meeting GDPR regulations that allows all participants to attend the event, such as WebEx, Zoom or MS Teams. Ensure a reliable and fast internet connection with sufficient bandwidth for a high-resolution video call for the

participants connecting with their own equipment (e.g. computer, headset, camera) of sufficient quality for conducting such a video call. The hardware and software requirements shall be communicated in advanced.

- Provide a help desk to support participants in solving any issues regarding joining and participation in the meeting.
- Ensure and conclude the registration of participants at least one week before the meeting as well as provide an ICS file and login details (e.g. link, password) for each day of the meeting.
- Reminders and necessary updates should be provided in timely manner.
- Provide to the participants an electronic version of background and working documentation related to the meeting in English language at least 2 weeks before the meeting.
- Define the roles and responsibilities of each member of the organisation group, such as the coordinator, assistant responsible of creating breakout rooms, handling breaks and wrap-up sessions, checking regularly the chat for questions and comments, ensure that all questions are answered, etc.
- During the event, facilitate discussions among the participants in smaller groups making use of breakout rooms.
- Ensure recording of the meeting session for minutes purpose. Prepare and provide minutes for comments and approval by ECDC.
- In close collaboration with ECDC representatives, wrap up the sessions and, once the meeting is coming to an end, develop and deliver take home messages.
- The working language of the events is English.

For hybrid meetings, the tasks carried out by the partner (or the lead partner if in a consortium) should include the relevant points of both face-to-face meetings and online meetings described above.

3. TIMETABLE

	Stages	Date and time or indicative period
a)	Publication of the call	07/06/2022
b)	Deadline for submitting applications	**02/09/2022** – 16:00 CEST
c)	Evaluation period	12/09/2022 – 22/09/2022
d)	Information to applicants	10/10/2022
e)	Signature of grant agreement	30/11/2022

4. BUDGET AVAILABLE

The total budget earmarked for the co-financing of projects is estimated at 800,000 EUR for a maximum duration of the framework partnership agreement of four years. ECDC reserves the right not to distribute all the funds available.

This amount is subject to the availability of the appropriations provided for in the draft budget for the specific year after the adoption of the budget for the respective year by the budgetary authority.

The maximum grant will be 90% of the total eligible costs, and the partner will co-finance the remaining (minimum 10%) of the total eligible costs. Such distribution will apply to every specific grant agreement within the framework partnership.

ECDC expects to sign one framework partnership agreement with one successful applicant (a consortium made up of a collective group of applicants is also considered an applicant).

5. ADMISSIBILITY REQUIREMENTS

In order to be admissible, applications must be:

- sent no later than the deadline for submitting applications referred to in section 3.
- dated, readable, accessible and printable and contain all the requested information and all the required annexes and supporting documents.
- submitted electronically (see section 14), using the forms available at https://www.ecdc.europa.eu/en/about-us/procurement-and-grants?f%5B0%5D=deadline_date%3A1[14].

[14] Article 196 Financial Regulation (FR).

- drafted in one of the EU official languages. ECDC prefers to receive documentation in English. Nonetheless, the choice of language will not play any role in the consideration of the application.

Failure to comply with these requirements will lead to the rejection of the application.

The documents to be completed and submitted are:

- Application Form and Checklist of documents to be provided (Annex I).
- Estimated Budget Form (Annex II).
- Declaration on Honour Form.
- Authorised Signatory Form (Annex III).
- "Financial Identification Form" and "Legal Entity Form" duly signed by the person authorised to sign the framework partnership agreement. Financial Identification Form and Legal Entity Forms should be submitted in scanned format. The forms are available through links in the List of Annexes below.

  Where the applicant has already signed another agreement or contract with ECDC, please submit a copy of a previously submitted Legal Entity and Financial identification, unless a change has occurred in the meantime.

  In order to assess the applicants' eligibility, the following supporting documents are also requested to be submitted with the Legal Entity Form:
  • **Beneficiary - private entity:** extract from the national official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical, only one of these documents is required);
  • **Beneficiary - public entity:** copy of the resolution, decision or other official document establishing the public-law entity.

6. ELIGIBILITY CRITERIA[15]

6.1. Eligible applicants

- non-profit organisation (private or public);
- public authorities (national, regional, local);
- international organisations;
- universities;
- educational institutions;

[15] Article 197 FR

- research centres.

Legal entities having a legal or capital link with applicants, which is neither limited to the action nor established for the sole purpose of its implementation, may take part in the action as consortium members, and may declare eligible costs as specified in section 12.1.

For that purpose, applicants shall identify such consortium members in the application form.

Only applications from legal entities established in the following countries are eligible:

- EU Member States;
- EEA countries: Iceland, Liechtenstein, Norway.

For the purpose of declaring eligible costs as specified under section 12.1, the entities composing the applicant shall be treated as consortium members.

In order to assess the applicants' eligibility, the following supporting documents are requested:

- **private entity:** extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical, only one of these documents is required);
- **public entity**: copy of the resolution, decision or other official document establishing the public-law entity;
- **natural persons**: photocopy of identity card and/or passport; certificate of liability to VAT, if applicable (e.g. some self-employed persons)
- **entities without legal personality:** documents providing evidence that their representative(s) have the capacity to undertake legal obligations on their behalf.

6.2. Eligible activities

Types of activities eligible under this call for proposals.

- cooperation projects;
- conferences, seminars;
- training activities;
- awareness and dissemination actions;
- actions aiming at the creation and improvement of networks, exchanges of good practices;
- studies, analyses, mapping projects;
- research activities.

7. IMPLEMENTATION PERIOD

Activities may not start before February 2023 and the date of signature of the framework partnership agreement.

Activities are to be completed by the date indicated in the respective specific grant agreement.

The maximum duration of the framework partnership agreement is four years.

Applications for projects scheduled to run for a longer period than that specified in this call for proposals will not be accepted.

8. EXCLUSION CRITERIA

8.1. Exclusion

The authorising officer shall exclude an applicant from participating in call for proposals procedures where:

(a) the applicant is bankrupt, subject to insolvency or winding-up procedures, where its assets are being administered by a liquidator or by a court, where it is in an arrangement with creditors, where its business activities are suspended, or where it is in any analogous situation arising from a similar procedure provided for under national laws or regulations;

(b) it has been established by a final judgment or a final administrative decision that the applicant is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the authorising officer is located or those of the country of the performance of the agreement;

(c) it has been established by a final judgment or a final administrative decision that the applicant is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the applicant belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:

(i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract, a grant agreement or a grant decision;

(ii) entering into agreement with other applicants with the aim of distorting competition;

(iii) violating intellectual property rights;

(iv) attempting to influence the decision-making process of the ECDC during the award procedure;

(v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;

(d) it has been established by a final judgment that the applicant is guilty of any of the following:

(i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 of the European Parliament and of the Council and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;

(ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA, or corruption as defined in the applicable law;

(iii) conduct related to a criminal organisation, as referred to in Article 2 of Council Framework Decision 2008/841/JHA;

(iv) money laundering or terrorist financing within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council;

(v) v. terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;

(vi) vi. child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;

(e) the applicant or affiliated entity has shown significant deficiencies in complying with main obligations in the performance of a contract, a grant agreement or a grant decision financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an authorising officer, OLAF or the Court of Auditors;

(f) it has been established by a final judgment or final administrative decision that the applicant or affiliated entity has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95.

(g) it has been established by a final judgement or final administrative decision that the applicant or affiliated entity has created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations of mandatory application in the jurisdiction of its registered office, central administration or principal place of business;

h) it has been established by a final judgement or final administrative decision that an entity has been created with the intent referred to in point (g);

i) for the situations referred to in points (c) to (h) above, the applicant or affiliated entity is subject to:

(i) facts established in the context of audits or investigations carried out by European Public Prosecutor's Office after its establishment, the Court of Auditors, the European Anti-Fraud Office or the internal auditor, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;

(ii) non-final judgments or non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;

(iii) facts referred to in decisions of persons or entities being entrusted with EU budget implementation tasks;

(iv) information transmitted by Member States implementing Union funds;

(v) decisions of the Commission relating to the infringement of Union competition law or of a national competent authority relating to the infringement of Union or national competition law; or

(vi) decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.

8.2. Remedial measures

If an applicant declares one of the situations of exclusion listed above (see section 8.1), it should indicate the measures it has taken to remedy the exclusion situation, thus demonstrating its reliability. This may include e.g. technical, organisational and personnel measures to prevent further occurrence, compensation of damage or payment of fines. The relevant documentary evidence which illustrates the remedial measures taken must be provided in annex to the declaration. This does not apply for situations referred in point (d) of section 8.1.

8.3. Rejection from the call for proposals

The authorising officer shall not award a grant to an applicant who:

a. is in an exclusion situation established in accordance with section 8.1[16];

b. has misrepresented the information required as a condition for participating in the procedure or has failed to supply that information;

c. was previously involved in the preparation of calls for proposal documents where this entails a distortion of competition that cannot be remedied otherwise.

The same exclusion criteria apply to consortium members.

Administrative and financial penalties may be imposed on applicants, or consortium members where applicable, who are guilty of misrepresentation.

8.4. Supporting documents

Applicants and consortium members must provide a completed declaration on their honour: Declaration on honour (grant); certifying that they are not in one of the situations referred to in articles 136(1) and 141 FR.

This obligation may be fulfilled in one of the following ways:

(i) the applicant signs a declaration in its name and on behalf of the consortium members

OR

[16] Article 136 FR

(ii) the applicant and the consortium members sign each a separate declaration in their own name.

9. SELECTION CRITERIA[17]

Only applications that meet the exclusion and eligibility criteria will be assessed on the basis of the selection criteria.

An evaluation of the quality of the applications and of the capacity of the grant applicant and its partners, will be subsequently carried out in accordance with the evaluation criteria set out in the Evaluation Grid included below. There are two types of evaluation criteria: selection and award criteria.

9.1. Financial capacity[18]

Applicants must have stable and sufficient sources of funding to maintain their activity throughout the duration of the grant and to participate in its funding. The applicants' financial capacity will be assessed on the basis of the following supporting documents to be submitted with the application:

- a declaration on their honour;
- **an audit report** produced by an approved external auditor certifying the accounts for the two last financial years.
  In the case of legal entities forming **one** applicant (the "sole applicant"), as specified in section 6.1, the above requirements apply to each one of those entities.

and

EITHER

- the profit and loss account as well as the balance sheet for the last financial year for which the accounts were closed;
- for newly created entities: the business plan might replace the above documents;

OR

- the table provided for in the application form, filled in with the relevant statutory accounting figures, in order to calculate the ratios as detailed in the form.

On the basis of the documents submitted, if the ECDC considers that financial capacity is weak, ECDC may:

- request further information;
- decide not to give pre-financing;
- decide to give pre-financing paid in instalments;
- decide to give pre-financing covered by a bank guarantee (see section 12.6 below);

[17] Article 198 FR
[18] Article 198 FR

- where applicable, require the joint and several financial liability of all the co-beneficiaries.

If ECDC considers that the financial capacity is insufficient ECDC will reject the application.

Please note that verification of financial capacity does not apply to public bodies[19]

9.2. Operational capacity[20]

Applicants must have the appropriate qualifications as well as the professional competencies necessary to complete the proposed actions:

- Have the management capacity, professional competencies and qualifications required to successfully complete the proposed actions. This also applies to any partner of the grant applicant;

- Proofs of relevant expertise and experience by documenting activities of the applicant in the areas of actions described in paragraphs 2.3, 2.4 and 2.5.

In this respect, applicants have to submit a declaration on their honour, and the following supporting documents:

- curriculum vitae or description of the profile of the people primarily responsible for managing and implementing the action (accompanied where appropriate, like in the field of research and education, by a list of relevant peer-reviewed publications);
- the organisation's activity reports, i.e. introduction of the organisation's work areas relevant to this action in last 3 years;
- an exhaustive list of previous projects and activities performed that are connected to the actions to be carried out;
- a description of the technical equipment, tools or facilities and patents at the disposal of the applicant;
- an inventory of economic resources involved in the project.

In the case of legal entities forming **one** applicant (the "sole" applicant), as specified in section 6.1, the above requirements apply to each one of those entities.

[19] Article 198(5) (c) FR.

[20] Article 198 FR.

10. AWARD CRITERIA[21]

The award criteria allow the quality of the applications submitted to be evaluated in relation to the set objectives and priorities. They enable the selection of applications which ECDC can be confident will meet its needs and preferences. The following award criteria will be used:

Evaluation Grid

Criteria	Maximum Score
The quality of the proposal to meet the objectives as demonstrated by: 1) the extent to which the proposed implementation plan and milestones credibly responds to this call for proposals (20 points); 2) the extent to which the application addresses the needs of the coordination of the ERLTB-Net (15 points); 3) the quality of the proposed methods for carrying out the actions and the envisaged impact of the disseminated results (20 points); 4) the extent to which the application identifies the possible risks to the project implementation and the quality of proposed mitigation actions (15 points).	**70**
Composition of the team: The degree to which the applicant demonstrates logically, and soundly, that the structure and organization of the team will allow the partner to mobilize experts and assign them to the activities.	**30**
Maximum total score	**100**

Scoring:

Only applications scoring **75 points** or more (of a maximum of 100) points will be awarded a grant.

Applications scoring less than **60%** for any individual award criterion will be deemed to be of insufficient quality and eliminated from further consideration.

11. LEGAL COMMITMENTS[22]

In the event the application for framework partnership is selected, a framework partnership agreement detailing the conditions of cooperation will be sent to the applicant, as well as information on the procedure to formalise the agreement of the parties. See the Model FPA, Annex IV(a).

[21] Article 199 FR
[22] Article 201 FR.

12. FINANCIAL PROVISIONS

12.1. Eligible costs

Eligible costs shall meet all the criteria stated in the Model FPA, Article II.191, Annex IV(a).

Eligible costs may be direct or indirect.

12.1.1. Eligible direct costs

The eligible direct costs are defined in Article II.19.2 of the Model FPA, Annex IV(a).

12.1.2. Eligible indirect costs (overheads)

See Article II.19.3 of the Model FPA for details of the indirect costs.

A flat-rate amount of 7% of the total eligible direct costs of the action, is eligible as indirect costs, representing the partner's general administrative costs which can be regarded as chargeable to the action/project.

12.2. Ineligible costs

Please refer to the Model FPA, Article II.19.4 for the list of ineligible costs.

12.3. Form of the grant

12.3.1. Reimbursement of costs actually incurred[23]

The grant will be defined by applying a maximum co-financing rate of 90% to the eligible costs actually incurred and declared by the partner (see Article II.20.1 of the Model FPA, Annex IV(a)).

12.4. Balanced budget[24]

The estimated budget of the action must be attached to the application form. It must have revenue and expenditure in balance.

The budget must be drawn up in euros.

The applicant must ensure that the resources which are necessary to carry out the action are not be entirely provided by the EU grant.

Co-financing of the action may take the form of:

- the partner's own resources,

[23] Article 186 FR
[24] Article 196 (1) (e) FR

- income generated by the action or work programme,
- financial contributions from third parties.

12.5. Calculation of the final grant amount

The final amount of the grant is calculated by ECDC at the time of the payment of the balance. The calculation involves the following steps:

Step 1 — Application of the reimbursement rate to the eligible costs

The amount under step 1 is obtained by application of the reimbursement rate specified in section 12.3.1 to the eligible costs accepted by the ECDC, to which the co-financing rate applies in accordance with section 12.3.

Step 2 — Limit to the maximum amount of the grant

The total amount paid to the beneficiaries by the ECDC may in no circumstances exceed the maximum amount of the grant as indicated in the grant agreement. If the amount obtained following Step 1 is higher than this maximum amount, the final amount of the grant is limited to the latter.

Step 3 — Reduction due to improper implementation or breach of other obligations.

ECDC may reduce the maximum amount of the grant if the action has not been implemented properly (i.e. if it has not been implemented or has been implemented poorly, partially or late), or if another obligation under the Agreement has been breached.

The amount of the reduction will be proportionate to the degree to which the action has been implemented improperly or to the seriousness of the breach.

12.6. Reporting and payment arrangements[25]

The partner may request payment as per the provisions of the Model SGA, Article 4 (Annex IV(b)):

	Reporting requirements	Payment request
1)	Non-applicable.	A **pre-financing payment**[26] corresponding to 70% of the grant amount
2)	Interim technical report, an overview of expenditure highlighting any deviations from the original estimated budget.	**Non applicable**
3)	(a) final technical report; (b) final financial statement; (c) summary financial statement aggregating the financial statements already submitted previously and indicating the receipts (d) a certificate on the financial statements and underlying accounts (i.e. external audit report).	**Payment of the balance** ECDC will establish the amount of this payment on the basis of the calculation of the final grant amount (see section 12.5 above). If the total of earlier payments is higher than the final grant amount, the partner will be required to reimburse the amount paid in excess by the ECDC through a recovery order[27].

12.7. Other financial conditions

a) Non-cumulative award[28]

An action may only receive one grant from the EU budget.

In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, applicants shall indicate in the grant application the sources and amounts of Union funding received or applied for the same action or part of the action or for its (the applicant's) functioning during the same financial year as well as any other funding received or applied for the same action.[29]

b) Non-retroactivity[30]

[25] Article 203 FR
[26] Article 203 FR
[27] Article 100 FR
[28] Article 191 FR
[29] Article 191 FR
[30] Article 193 FR

No grant may be awarded retrospectively for actions already completed.

c) <u>Implementation</u> contracts/subcontracting[31]

Where the implementation of the action requires the award of procurement contracts (implementation contracts), the partner must award the contract to the bid offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests.

Please refer to the Model FPA, Article II.10, Annex IV(a).

d) Financial support to third parties[32]

The applications may not envisage provision of financial support to third parties.

13. PUBLICITY

13.1. By the Partner

The partner, or the consortium members if a consortium, must clearly acknowledge the European Union's contribution in all publications or in conjunction with activities for which the grant is used.

Please refer to the Model FPA, Article II.8, Annex IV(a).

13.2. By ECDC[33]

With the exception of scholarships paid to natural persons and other direct support paid to natural persons in most need, all information relating to grants awarded in the course of a financial year shall be published on an internet site of the European Union institutions no later than the 30 June of the year following the financial year in which the grants were awarded.

ECDC will publish the following information:

- name of the partner;
- address of the partner when the latter is a legal person, region when the partner is a natural person, as defined on NUTS 2 level[34] if he/she is domiciled within EU or equivalent if domiciled outside EU;
- subject of the grant;
- amount awarded.

[31] Article 205 FR
[32] Article 204 FR
[33] Article 38, 253FR.
[34] European Union Official Journal L 39, of 10 February 2007.

Upon a reasoned and duly substantiated request by the partner, the publication shall be waived if such disclosure risks threatening the rights and freedoms of individuals concerned as protected by the Charter of Fundamental Rights of the European Union or harm the commercial interests of the beneficiaries.

14. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

Proposals must be submitted by the deadline set out under section 3.

The documents to be completed and submitted are:

- application form and checklist,
- estimated budget,
- declaration on honour,
- financial identification form*,
- legal entity form*.

*Where the applicant has already signed another agreement or contract with ECDC, please submit a copy of a previously submitted Legal Entity and Financial identification, unless a change has occurred in the meantime. In order to assess the applicants' eligibility, the following supporting documents are also requested to be submitted with the Legal Entity Form:

- Beneficiary - private entity: extract from the national official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical, only one of these documents is required);
- Beneficiary - public entity: copy of the resolution, decision or other official document establishing the public-law entity.

No modification to the application is allowed once the deadline for submission has elapsed. However, if there is a need to clarify certain aspects or to correct clerical mistakes, ECDC may contact the applicant during the evaluation process[35].

Applicants will be informed in writing about the results of the selection process.[36]

Application forms are available at https://www.ecdc.europa.eu/en/about-us/procurement-and-grants?f%5B0%5D=deadline_date%3A1

Applications must be submitted to the dedicated mailbox: GRANT-2022-DPR-13440@ecdc.europa.eu in the correct form, duly completed and dated. They must be signed by the person authorised to enter into legally binding commitments on behalf of the applicant organisation.

Where applicable, all additional information considered necessary by the applicant can be included in the submission.

Applications sent by fax or post will not be accepted.

[35] Article 200 (3) FR
[36] Article 200 (7) FR.

- **Contacts**

For clarifications only (i.e not for submission of proposals) please send an email to: ECDC.procurement@ecdc.europa, with Grant/2022/DPR/13440 in the subject line.

- **Annexes:**

Documents to be completed by the applicant:

- Annex I - Application form and checklist of documents to be provided
- Annex II – Estimated Budget form
- Declaration on honour for grants (Link)
- Legal Entity File (Link)
- Financial Identification Form (Link)
- Annex III – Authorised Signatory Form

Documents for information:

- Annex IV(a) - Model framework partnership agreement
- Annex IV(b) – Model specific grant agreement
- Annex V – Guidelines for organisation of meetings