

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Disease Programmes Unit

CALL FOR TENDERS

OJ/2023/DPR/26040

Estimating the burden of tuberculosis infection in the EU/EEA

Framework service contract

TENDER SPECIFICATIONS

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1. INFORMATION ON TENDERING

The European Centre for Disease Prevention and Control (ECDC) is an agency of the European Union, established by the European Parliament and Council Regulation 851/2004 of 21 April 2004. Further information about ECDC can be found on the ECDC <u>website</u>.

This tender process is governed by Directive 2014/24/EU and Regulation 2018/1046.

1.1. Participation

Participation in this procurement procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties, as well as to international organisations, established in the European Union, European Economic Area and Stabilisation and Association Agreements countries.

Please note that any attempt by a tenderer to obtain confidential information, enter into unlawful agreements with competitors or influence the evaluation committee or ECDC during the process of examining, clarifying, evaluating and comparing tenders will lead to the rejection of his tender and may result in administrative penalties.

1.2. Contractual conditions

The tenderer should take note of the provisions of the draft contract (see section 4. Annexes) which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, intellectual property rights and checks and audits.

Signature of the single framework contract imposes no obligation on ECDC to order services. Only the implementation of the framework contract through specific contracts/order forms is binding for ECDC.

Each specific contract/order form will contain details of deliverables and timelines for particular services to be provided.

1.3. Compliance with applicable law

The tender must comply with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU¹.

1.4. Joint tenders

A joint tender (such as a consortium) is a situation where a tender is submitted by a group of economic operators (natural or legal persons). Joint tenders may include subcontractors in addition to the members of the group.

¹ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

In case of joint tender, all members of the group assume joint and several liability towards ECDC for the performance of the contract as a whole, i.e., both financial and operational liability. Nevertheless, tenderers must designate one of the economic operators as a single point of contact (the leader) for ECDC for administrative and financial aspects as well as operational management of the contract.

After the award, ECDC will sign the contract either with all members of the group, or with the leader on behalf of all members of the group, authorised by the other members via powers of attorney.

Any change in the composition of the group during the procurement procedure may lead to the rejection of the tender. Any change in the composition of the group after the signature of the contract may lead to the termination of the contract.

1.5. Subcontracting

Subcontracting is permitted but the contractor will retain full liability towards ECDC for performance of the contract as a whole.

If subcontracting is envisaged, the tenderer must clearly indicate in the tender which parts of the work will be subcontracted.

If the tenderer relies on the subcontractors to fulfil the selection criteria (see section 3.2 Selection criteria), these subcontractors must provide a statement declaring their undertaking to collaborate with the tenderer in case of award, and the resources that they will put at the tenderer's disposal for the performance of the contract.

If the tenderer relies on the capacity of a subcontractor for economic and financial capacity, ECDC may require the third party to be jointly liable for the performance of the contract.

Tenderers are required to identify all subcontractors whose share of the contract is above 20% and whose capacity is necessary to fulfil the selection criteria.

During contract performance, the change of any subcontractor identified in the tender or additional subcontracting will be subject to prior written approval of ECDC.

Where no subcontractor is given, the work will be assumed to be carried out directly by the tenderer.

1.6. Division into lots

This contract is not divided into lots. The tenderer must be in a position to provide all the services requested.

1.7. <u>Structure and content of the tender</u>

The tenders must include the following:

- Part A: Identification of the tenderer
- Part B: Non-exclusion (see section 3.1 Verification of non-exclusion)
- Part C: Selection (see section 3.2 Selection criteria)

- Part D: Technical tender (see section 3.3 Award)
- Part E: Financial tender

All tenders must contain a financial tender to be submitted **<u>according to the form in</u>** section 4. Annexes.

The tenderer's attention is drawn to the following points:

The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

The quoted price must be a fixed amount which includes all charges (including travel and subsistence). Travel and subsistence expenses are not refundable separately.

Tenders must be submitted through the electronic submission system (see point 1 in the Invitation to tender for further information).

Make sure you submit your tender on time: you are advised to start completing your tender early. To avoid any complications with regard to late receipt/non receipt of tenders within the deadline, please ensure that you submit your tender several hours before the deadline. A tender received after the deadline indicated in the procurement documents will be rejected.

1.8. Identification of the tenderer

The tender must include a **cover letter** signed by an authorised representative presenting the name of the tenderer (including all entities in case of joint tender) and identified subcontractors if applicable, and the name of the single contact point (leader) in relation to this procedure.

In case of joint tender, the cover letter must be signed either by an authorised representative for each member, or by the leader authorised by the other members with powers of attorney. The signed powers of attorney must be included in the tender as well. Subcontractors that are identified in the tender must provide a letter of intent signed by an authorised representative stating their willingness to provide the services presented in the tender and in line with the present tender specifications.

All tenderers (including all members of the group in case of joint tender) must provide a signed Legal Entity Form with its supporting evidence. The form is available on: http://ec.europa.eu/budget/contracts grants/info contracts/legal entities/legal entities en.cfm

Tenderers that are already registered in ECDC's accounting system (i.e., they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.

The tenderer (or the leader in case of joint tender) must provide a Financial Identification Form with its supporting documents. Only one form per tender should be submitted. No form is needed

for subcontractors and other members of the group in case of joint tender. The form is available on: <u>http://ec.europa.eu/budget/contracts_grants/info_contracts/index_en.cfm</u>

The tenderer (and each member of the group in case of joint tender) must declare whether it is a Small or Medium Size Enterprise in accordance with <u>Commission Recommendation 2003/361/EC</u>. This information is used for statistical purposes only.

1.9. <u>Language</u>

Tenders must be submitted in one of the official languages of the European Union. ECDC prefers, however, to receive documentation in English. Nonetheless, the choice of language will be not play any role in the consideration of the tender.

1.10. Additional information

By virtue of Point 11.1(e) of Annex 1 FR (Financial Regulation 2018/1046), ECDC reserves the option to launch further negotiated procedure, with the contractor(s) chosen as a result of the present call for tender, for new services consisting in the repetition of similar services for up to 50% of the contractual amount during the three years following the signature of the original contract.

1.11. Use of Electronic Procurement Tools (e-Procurement)

The successful tenderer(s) shall take the appropriate measures to be compliant with e-invoicing and submit invoices through the system. The successful tenderer(s), whose tender was submitted as a joint tender, may be required to acquire a Global Location Number (GLN), at no additional cost for ECDC.

For additional information on ECDC's e-procurement tools, please refer to: <u>https://ecdc.europa.eu/en/about-us/procurement-and-grants</u>.

1.12. Public access to documents

In the general implementation of its activities and for the processing of tendering procedures in particular, ECDC observes Regulation (EC) No. 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

2. TECHNICAL SPECIFICATIONS

2.1. General background

Approximately one-fourth of the world's population is infected with tuberculosis (TB)². In Europe, the prevalence of TB infection has been estimated to be between 11 and $15\%^{2,3}$. However, country-specific estimates are not available for Member States of the European Union /European

² Houben RMGJ, Dodd PJ. <u>The global burden of latent tuberculosis infection: a re-estimation using mathematical</u> <u>modelling</u>. PLoS Med. 2016;13 (10):e1002152.

³ Cohen A, *et al.* <u>The global prevalence of latent tuberculosis: a systematic review and meta-analysis</u>. Eur Respir J. 2019; 54 (3):1900655.

Economic Area (EU/EEA). Furthermore, most EU/EEA countries have a fragmented picture of the TB infection prevalence in at-risk populations.

Systematic screening of TB infection in at-risk populations and provision of TB preventive treatment are key components of the global TB elimination strategy ^{4,5,6}. Availability of estimates of the number of people qualifying for TB preventive treatment contributes to the implementation of timely and cost-effective interventions to prevent progression to active TB.

Various statistical methods have been used to estimate TB infection prevalence and TB reactivation rates in non-EU/EEA countries with low TB incidence ^{7,8,9,10}. These methods could be applied in the EU/EEA to provide scientifically sound evidence on the burden of TB infection in the region.

Through this tender, ECDC would like to support EU/EEA Member States in the evidence-based implementation of targeted interventions for management of TB infection.

2.2. <u>Scope and objectives</u>

The **scope** of this call is to generate country-specific estimates of TB infection prevalence and estimates on progression to active TB in at-risk populations of selected EU/EEA countries. The specific at-risk populations will be identified in collaboration with national stakeholders from the selected EU/EAA countries.

The overall **<u>objectives</u>** of this call for tender are to:

- 1. assess the feasibility of generating country-specific estimates of TB infection prevalence and progression to active TB, using data sources already available in EU/EEA countries;
- conduct country-specific analyses using statistical methods appropriate for the data available on specific at-risk populations, in order to generate estimates of TB infection prevalence and progression to active TB;
- 3. provide an overview of the estimated prevalence of TB infection across selected at-risk populations and their risk of progression to active TB at national level;
- 4. identify key challenges related to the management of TB infection in the EU/EEA and recommend potential action points for future ECDC work.

⁴ World Health Organization. <u>The end TB Strategy</u>.Geneva:WHO;2015

⁵ European Centre for Disease Prevention and Control. <u>Programmatic management of latent tuberculosis infection in</u> <u>the European Union</u>. Stockholm: ECDC;2018.

⁶ World Health Organization. <u>WHO consolidated guidelines on tuberculosis: module 1: prevention: tuberculosis</u> preventive treatment. Geneva: WHO;2020

⁷ Haddad MB *et al.* <u>Simple estimates for local prevalence of latent tuberculosis infection, United States, 2011-2015</u>. Emerg Infect Dis. 2018; (24)10:1930-1933.

⁸ Dale KD *et al.* Estimating the prevalence of latent tuberculosis in a low-incidence setting: Australia</u>. Eur Respir J. 2018; 52 (6): 1801218

⁹ Dale KD *et al.* Estimating long-term tuberculosis reactivation rates in Australian migrants. Clin Infect Dis. 2020; 70 (10):2011-2118

¹⁰ Mirzazadeh A *et al.* <u>State-level prevalence estimates of latent tuberculosis infection in the United States by medical</u> <u>risk factors, demographic characteristics and nativity</u>. PLoS One. 2021;16(4):e0249012.

2.3. Tasks, deliverables, quality requirements and timelines

The work to be conducted is described in five work packages, each including specific tasks and deliverables that may be requested more than once through specific contracts. The request for services of each specific contract will describe the timeline for delivery of the specific assignment. Over the whole duration of this service framework contract the contractor is expected to work with all EU/EEA countries in work package 2 and with six to nine EU/EEA countries in all other work packages.

Work package 1: Project management

Deliverable	Task	Estimated timeline	Minimum requirement
Deliverable DL1 Inception meeting	Task T1.1: Organisation and implementation of an inception meeting between ECDC and the contractor to discuss the methodological and logistic approach to the tasks requested	Estimated timeline Planned to take place at the beginning of each specific contract, within one month after contract signature.	The inception meeting at the start of the first specific contract will be a one-day face-to- face meeting at ECDC premises in Stockholm. At least two team members (one of them being the project manager), but not more than four people are expected to attend the meeting. If necessary, this first meeting may be held online following ECDC approval. The contractor is required to cover all costs associated with travel, accommodation and
DL1.1a Inception meeting agenda	T1.1a: Preparation of the draft agenda for the inception	Following approval by ECDC, the contractor will send out the final agenda and support documents, at least one week before the meeting.	 subsistence allowance (if any) for its staff. The inception meetings of subsequent specific contracts will be held online with a duration of at least half a day, using a technical platform approved by ECDC. The agenda should include: List of participants. Topics for discussion. Description of supporting documents, e.g., updated work plan (draft) or
DL1.1b Inception meeting report	meeting T1.1b: Preparation of the inception meeting report on the discussions and conclusions of the inception meeting.	Within two weeks after the inception meeting the inception meeting report should be submitted for ECDC approval. ECDC will provide written feedback within 10 working days after the initial submission of the draft report. The contractor is expected to submit a revised version of the document within 10 working days after receiving ECDC's comments.	 other relevant technical documents. The inception meeting report should include: Cover page (project title, contract number, deliverable number and title, authors, place and date). Introduction. List of participants. Description of the key issues discussed, and decisions made during the meeting. Annexes Annexes Annexes Annexes; methodological approach, timeline and expected outputs. The synopsis will be used to inform ECDC's internal and external stakeholders.
DL1.2 Project work plan	T1.2: Preparation of a project work plan for each specific contract, considering the discussions and	Within two weeks after the approval of the inception meeting report of each specific contract, the draft project work plan should be submitted for ECDC approval.	 The project work plan should include the following elements: Cover page (project title, contract number, deliverable number and title, authors, place and date). Table of contents. List of abbreviations.

	decisions made in the inception meeting.	ECDC will provide written feedback within 10 working days after the initial submission of the draft work plan. The contractor is expected to submit a revised version of the document within 10 working days after receiving ECDC's comments. Implementation of the proposed activities shall be initiated after ECDC's approval of the (updated) work plan.	 Introduction. Aim and specific objectives. Description of methodological approach. Timeline, including a Gantt chart. Organisation of the work (team structure, roles and responsibilities). Risk management and mitigation measures. Quality assurance processes. Annexes (if necessary).
DL1.3 Monthly meeting minutes	T1.3: Organisation of monthly briefing videoconferences with ECDC and preparation of meeting minutes.	The exact schedule for the videoconferences and the online platform to be used will be proposed by the contractor and approved by ECDC for each specific contract. The contractor will finalise the minutes within one week after each videoconference and submit them to ECDC for approval. The tasks and deliverable 1.3 will be ordered for each specific contract as a single annual project management service. The price of the service may be adjusted for a period of implementation of a specific contract shorter than 12 months. In such cases the value of the service ordered will be calculated on pro-rata monthly basis with respect to	 The meeting minutes shall: be a brief document (1-2 pages), listing meeting participants and main action points. document the feedback provided and the revisions requested by ECDC; include annexes, when needed, to document ongoing activities or mid- point outputs
DL1.4 Activity report	T1.4: Preparation of a report summarising the activities implemented under a specific contract	 pro-rata monthly basis with respect to the duration and will be based on the financial offer of 12 months. Up to five activity reports will be requested during the duration of the framework service contract. Before the end of each specific contract, and as agreed in the approved workplan, the contractor is expected to submit an activity report for ECDC approval. ECDC will provide written feedback within 10 working days after the initial submission of the activity report. The contractor is expected to submit a revised version of the document within 10 working days after receiving ECDC's comments. 	 The activity report should include: Cover page (project title, specific contract number, deliverable number and title, authors, place and date). Introduction. Table of contents. List of abbreviations. Specific objectives. Description of planned activities. Progress to date, including interim results. Description of obstacles encountered. Updated risk management and mitigation measures. Discussion on preliminary findings (if applicable). Annexes (if applicable).

Work package 2: Feasibility assessment

In close collaboration with ECDC, the contractor will conduct a feasibility assessment with the purpose of identifying and prioritising countries with suitable data to perform the intended

analyses. All EU/EEA countries should be invited to participate in the feasibility assessment. The feasibility assessment will occur once over the duration of the framework service contract.

Deliverable	Task	Estimated timeline	Minimum requirement
DL2.1 List of assessment criteria	T2.1a: Definition of assessment criteria	Within one month after the approval of the work plan for the corresponding specific contract, the contractor should submit a list of assessment criteria. The list shall be submitted as background document for one of the monthly meetings. ECDC will provide oral feedback during the corresponding monthly meeting, complemented by written comments if necessary. The meeting minutes shall document the feedback provided and the revisions requested by ECDC (DL1.3). The contractor shall submit a revised list for ECDC approval, within 10 working days after approval of the meeting minutes.	 The list of assessment criteria should include: Cover page (project title, specific contract number, deliverable number and title, authors, place and date). List of abbreviations. Glossary (if necessary). Rationale: the contractor is expected to elaborate on the rationale for the proposed set of assessment criteria by: Cleary describing the methodological approach used to define the criteria, including identification of all relevant information sources; Describing how the proposed criteria will enable the prioritisation and selection of EU/EEA countries for inclusion in work package 3. List of assessment criteria, clearly describing: The characteristic being assessed; The weighing factor assigned to each criterion in relation to its relevance for the overall assessment.
DL2.2 Feasibility assessment report	T2.2a Collection of relevant information to assess the feasibility of conducting data analyses in EU/EEA Member States.	Data collection and analysis shall be initiated as agreed in the approved workplan, and after ECDC's approval of the assessment criteria. The estimated time frame for implementation of this task is approximately two months	ECDC will facilitate interactions with stakeholders from EU/EEA countries (i.e. ECDC National Focal Points for TB, Operational Contact Points for TB Microbiology and Operational Contact Points for TB Epidemiology). The contractor shall perform all activities in close collaboration with the designated ECDC staff and is expected to collect reliable and relevant data for the final assessment in a time-efficient manner.
	T2.2b: Preparation of a report summarising the results of the feasibility assessment.	Approximately eight months after the inception meeting, the contractor is expected to submit a feasibility assessment report for ECDC approval. ECDC will provide written feedback within 15 working days after the initial submission of the draft activity report. The contractor is expected to submit a revised version of the document within 15 working days after receiving ECDC's comments.	 The feasibility assessment report should include: Cover page (project title, contract number, deliverable number and title, authors, place and date). Introduction. Table of contents. List of abbreviations. Specific objectives. Description of methodological approach. Description of the assessment process. Priority list of countries to be considered for inclusion in work package 3. Summary of key challenges related to the management of TB infection in the EU/EEA, identified through the

	 assessment process. If possible, practical recommendations on how to tackle such challenges shall be included in the report. Conclusions. Next steps. Annexes (if necessary).
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Work package 3: Implementation of technical activities

Six to nine EU/EEA countries will be selected by ECDC to participate in the activities included in this work package based on the list of priority countries identified in the feasibility assessment report (DL2.2).

This work package will be ordered two to three times during the framework contract through different specific contracts that may overlap if necessary. For each specific contract the contractor should have the capacity to conduct the tasks in two to three countries simultaneously. Therefore, tasks under this work package are estimated to be executed up to 9 times during the FWC, one per country.

Deliverable	Task	Estimated timeline	Minimum requirement
DL3.1 Country specific study protocol	 T3.1a: Organisation of local study teams in the selected EU/EEA countries and provision of a secretariat for their activities. Each local study team will include the contractor's staff and national experts identified as contact points for the implementation of the project. 	Within two months after the approval of the work plan for the corresponding specific contract, the contractor should have established the local study teams in the selected EU/EEA countries.	 ECDC will identify national contact points with whom the contractor can coordinate the establishment of local study teams (T3.1a). At least one member of the contractor's staff shall meet face-to-face with the national contact points, in the respective EU/EEA country, with the purpose of establishing the local study teams. A brief summary of each onsite meeting shall be included as annex of the monthly meeting minutes (DL1.3). It should include: date and duration of the on-site meeting a list of people met during the visit; the final list including the names of team members in each local study team. Action points agreed with the local study team. Action points agreed with the local study team.

	T3.1b: Development of a study protocol for each EU/EEA country selected to participate in the project.	Approximately four months after approval of the work plan the contractor shall submit the country-specific study protocol for ECDC approval. ECDC will provide written feedback within 10 working days after the initial submission of the study protocol. The contractor is expected to submit a revised version of the document within 10 working days after receiving ECDC's comments.	 The contractor is expected to identify a methodological approach tailored to data already available in each selected country. Prospective data collection is excluded from the scope of this tender. The country-specific study protocol should include: Cover page (project title, specific contract number, deliverable number and title, authors, place and date). Table of contents. List of abbreviations. Introduction. Specific objectives. Description of methodological approach, including ethical considerations, data protection and data management measures, data analysis plan. Timeline. Personal data concerning health shall be processed in a pseudonymised manner in line with the provisions in the FWC.
	T3.2a: Implementation of the country-specific study protocol approved by ECDC.	Implementation of the proposed activities shall be initiated in accordance with the approved work plan and after ECDC's approval of each country-specific study protocol. This this task is expected to be finalised within eight months	
DL3.2 Country specific technical report	T3.2b: Preparation of a report summarising the activities performed and results obtained in each country. Individual country reports shall be prepared to facilitate dissemination of results with national stakeholders.	after approval of the work plan.The contractor shall submit atechnical report for eachcountry for ECDC approval,approximately nine monthsafter approval of the workplan.The timeline final will beagreed in the approved workplan of the correspondingspecific contract.ECDC will provide writtenfeedback within 15 workingdays after the initial submissionof the country-specifictechnical report. The contractoris expected to submit a revisedversion of the document within15 working days after receivingECDC's comments, withpossibility for a 5-day extensionif agreed in advance withECDC.	 The country-specific technical report should include: Cover page (project title, specific contract number, deliverable number and title, authors, place and date). Table of contents. List of abbreviations. Introduction. Specific objectives. Description of the methodological approach. Results. Discussion. Conclusions. Recommendations. Annexes.

Work package 4: Ad hoc expert services

In addition to the above deliverables the contractor could be asked to provide ECDC with expertise to address specific needs related to the activities described in work package 3. These services will be

requested as specific tasks, they will be ordered on daily consultancy rate basis and are expected to be performed by professionals with the expert profiles described in section 3.2.4 B3 (criteria related to the team delivering the service). Thus, the contractor is expected to provide daily rates for consultancy service for each level of expertise, i.e., junior (DL4.1), medium (DL4.2) and senior level (DL4.3). The estimated number of days of support requested will be 15 days during the framework contract. These services will not exceed 10% of the total value of the framework contract.

Timeline: The above services would be requested on an ad hoc and/or as needed basis and would be short term support. The timing will be agreed for each specific contract.

Work package 5: Dissemination of scientific findings

In close collaboration with ECDC and the local study teams, the contractor is expected to produce written outputs to summarise the main findings from the project i.e., the execution of the framework contract.

Deliverable	Task	Estimated timeline	Minimum requirement
DL5.1 Final summary report	T5.1: Preparation of a report summarising all the activities performed and results obtained during the project.	The task will be ordered once over the duration of the framework contract during the last specific contract. The contractor shall submit a summary report for ECDC approval as agreed in the approved work plan of the corresponding specific contract. ECDC will provide written feedback within 15 working days after the initial submission of the summary report. The contractor is expected to submit a revised version of the document within 15 working days after receiving ECDC's comments, with possibility for a 5-day extension if agreed in advance with ECDC.	 The final summary report should include: Cover page (project title, specific contract number, deliverable number and title, authors, place and date). Table of contents. List of abbreviations. Executive summary Introduction. Specific objectives. Description of the methodological approach. Results. Key challenges related to the management of TB infection in the EU/EEA, identified during the project implementation. Discussion. Conclusions. Recommendations. Annexes.
DL5.2 Draft scientific manuscript	T5.2 Preparation of a draft scientific manuscript describing main findings from the project. The scope of all scientific publications derived from the project will be discussed and jointly agreed with ECDC during the monthly meetings.	The task will be ordered one or two times over the duration of the framework contract. The contractor shall submit a draft scientific manuscript for ECDC approval, as agreed in the approved work plan of the corresponding specific contract. The contractor is expected to submit a revised version of the document within 15 working days after receiving ECDC's comments, with possibility for a 5-day extension if agreed in advance with ECDC.	Preferably, the draft manuscript shall be formatted following the instructions for authors of a pre-selected peer-reviewed, open access biomedical journal. Alternatively, the draft manuscript should comply with the general IMRAD structure (i.e. introduction, methods, results and discussion) and references should be listed using Vancouver style. In addition, all references cited in the draft manuscript should be provided as a separate file using a reference management software approved by ECDC.

2.4. Horizontal aspects related to all deliverables

Quality requirements: All written deliverables shall:

- Be of a high standard of English (C1 equivalent¹¹) by using British English grammar and spelling rules.
- Have consistent formatting (in MS Word format) and contain all required elements, according to agreed templates, when indicated, and which will be provided by ECDC.
- Be complete, i.e., including all minimum requirements described in section 2.3.

Deliverables planned for publication shall:

- Include reliable data, i.e., report data relevant to the objectives of the deliverable and which are free from factual and logical errors. Information sources and analytical tools used should be described, discussing and explaining the limitations of the data collection.
- Be scientifically sound, i.e., concerning the adequacy of the analysis methods and the correct interpretation of data. Thus, the analysis techniques should be described in sufficient detail to assess their coherence with and appropriateness for the objectives of the deliverable, discussing the limitations and/or exceptions of the analysis.
- Present credible findings, i.e., support findings with evidence originating from sound analysis; ensuring main findings are replicable and discussing limitations with internal/external validity.
- Include valid conclusions, i.e., all relevant conclusions addressing the objective of the deliverable, that are logically connected to the findings and interpreted in relation to the context.

Business continuity: The contractor shall ensure the continuity of the services during the entire duration of the project, in particular proper business continuity shall be guaranteed when a member of the team becomes unavailable. In any case, the services should be provided in a timely manner.

Replacement of team member: At ECDC's request, the contractor must replace a team member who prove incapable of carrying out the specified tasks to the required standards (e.g. due to underperformance, improper conduct in service, prolonged absence). Any departure of a team member not requested by ECDC shall be communicated by the contractor without delay.

It shall be the contractor's responsibility to manage the replacement of their personnel/ subcontractors to ensure that knowledge and information are transferred with minimum interruption of the services and that a high level of service quality is maintained at all times.

Publication policy: Publications using data obtained through funding by ECDC through this contract may be published only after written approval from ECDC, unless the data have entered the public domain or have otherwise been made publicly available by ECDC. Publications of national or sub-national data, that included data collected through this tender should acknowledge that part/ all study was funded through the project. The appropriate wording should be checked with the ECDC project manager before manuscript/publication submission.

¹¹ Common European Framework of Reference for Languages: Learning, Teaching, Assessment (http://www.coe.int/langcefr)

The manuscripts should have shared authorship between ECDC co-authors and the contractor with at least two last ECDC authors (one of whom either second or last), taking into account the ECDC authorship policy (<u>https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-authorship-internal-policy.pdf</u>) and the Internal Policy on open access publication of scientific content, including articles submitted to peer-reviewed journals (<u>https://www.ecdc.europa.eu/en/publications-data/internal-policy-openaccess-publication-scientific-content-including-articles</u>).

ECDC follows a strict open access policy and therefore requires contractors to submit manuscripts for peer-reviewed publication (following ECDC approval) to open access journals. The cost for open access fees must be covered by the contractor and must be included in the financial proposal.

For all manuscripts based on data or information gathered through a task of this tender (commissioned by ECDC or self-initiative from the contractor), ECDC shall be informed and give prior approval. ECDC shall also be invited to contribute as relevant. The draft manuscripts with ECDC authors will need to be of high scientific quality and will need to undergo formal ECDC clearance before being submitted to a journal.

The use of data or the analysis of data obtained as part of the contract shall require written agreement by the data providers and by ECDC as the contracting authority prior to publication, including peer-reviewed manuscripts, and/or disclosure to third parties.

2.5. Place of performance and number of meetings

All tasks are expected to be performed at the contractor's premises with the exception of work packages 3. For these packages work may be performed in the respective EU/EEA countries when required by the tasks described in the work package. The exact place will be defined in the specific contract. Meetings shall be virtual with the exception of the inception meeting of the first specific contract with ECDC which is planned to take place at ECDC premises.

The contractor is expected to cover all costs associated with travel, accommodation and subsistence allowance for its personnel.

2.6. Intellectual property rights

In accordance with Article II.13.1 of the contract (section 4. Annexes) whereby ECDC acquires ownership of the results as defined in the tender specifications, these results may be used for any purpose. In particular, as owner of the results, ECDC has the right to publish and distribute the results in any medium, altering, adapting or modifying the results, reproducing in an unlimited amount of copies and of further transferring of the rights acquired.

2.7. Moral rights of the authors and respect of ethical principles

The contractor is responsible that all contributors and listed authors are taking all necessary precautions to avoid plagiarism, i.e., the contractor ensures correct citation, quotation and attribution, ensures that the deliverable does not contain copied and plagiarised content and that all necessary permissions have been obtained before submission of the deliverable to ECDC.

Where applicable to a specific result, moral rights of the authors will be acknowledged according to the IP on authorship

https://ecdc.europa.eu/sites/portal/files/documents/ECDC%20authorship%20internal%20policy.pdf

3. EVALUATION AND AWARD

The evaluation is based solely on the information provided in the submitted tender. It involves the following:

- Verification of non-exclusion of tenderers on the basis of the exclusion criteria
- Selection of tenderers on the basis of selection criteria
- Verification of compliance with the minimum requirements set out in these tender specifications
- Evaluation of tenders on the basis of the award criteria

ECDC may reject abnormally low tenders, in particular if it established that the tenderer or a subcontractor does not comply with applicable obligations in the fields of environmental, social and labour law.

ECDC will assess these criteria in no particular order. The successful tenderer(s) must pass all criteria to be awarded the contract.

3.1. Verification of non-exclusion

All tenderers must provide a declaration on honour (see section 4. Annexes), signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in that declaration on honour.

In case of joint tender, each member of the group must provide a declaration on honour signed by an authorised representative.

In case of subcontracting, all subcontractors whose capacity is necessary to fulfil the selection criteria must provide a declaration on honour signed by an authorised representative.

ECDC reserves the right to verify whether the successful tenderer(s) is in one of the situations of exclusion by requiring the supporting documents listed in the declaration of honour.

The successful tenderer(s) must provide the documents mentioned as supporting evidence in the declaration on honour before signature of the contract and within a deadline given by ECDC. This requirement applies to each member of the group in case of joint tender and to all subcontractors whose capacity is necessary to fulfil the selection criteria.

The obligation to submit supporting evidence does not apply to international organisations.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by ECDC and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

3.2. Selection criteria

Tenderers must prove their legal, regulatory, economic, financial, technical and professional capacity to carry out the work subject to this procurement procedure.

The tenderer may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to ECDC that it will have at its disposal the resources necessary for performance of the contract, for example by producing an undertaking on the part of those entities to place those resources at its disposal.

The tender must include the proportion of the contract that the tenderer intends to subcontract.

3.2.1. Declaration and evidence

The tenderers (and each member of the group in case of joint tender) and subcontractors whose capacity is necessary to fulfil the selection criteria must provide the declaration on honour (see section 4. Annexes), signed and dated by an authorised representative, stating that they fulfil the selection criteria applicable to them individually. For the criteria applicable to the tenderer as a whole the tenderer (sole tenderer or leader in case of joint tender) must provide the declaration on honour stating that the tenderer, including all members of the group in case of joint tender and including subcontractors if applicable, fulfils the selection criteria for which a consolidated assessment will be carried out.

This declaration is part of the declaration used for exclusion criteria (see section 3.3.2 Award criteria) so only one declaration covering both aspects should be provided by each concerned entity.

The tenderers are also required to provide the evidence mentioned below. This requirement applies to each member of the group in case of joint tender and to subcontractors whose capacity is necessary to fulfil the selection criteria.

A tenderer (or a member of the group in case of joint tender, or a subcontractor) is not required to submit the documentary evidence if it has already been submitted for another procurement procedure and provided the documents were issued not more than one year before the date of their request by ECDC and are still valid at that date. In such cases, the tenderer must declare on its honour that the documentary evidence has already been provided in a previous procurement procedure, indicate the reference of the procedure and confirm that that there has been no change in its situation.

3.2.2. Legal and regulatory capacity

Criteria:

Tenderers must prove that they are allowed to pursue the professional activity necessary to carry out the work subject to this call for tenders. The tenderer (including each member of the group in case of joint tender) must provide the following information in its tender if it has not been provided with the Legal Entity Form: - For legal persons, a legible copy of the notice of appointment of the persons authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation applicable to the legal person requires such publication. Any delegation of this authorisation to another representative not indicated in the official appointment must be evidenced.

- For natural persons, if required under applicable law, a proof of registration on a professional or trade register or any other official document showing the registration number.

Evidence:

The tenderer shall provide a duly filled in and signed Legal Entity Form (see section 4. Annexes) accompanied by the documents requested therein.

(Where the tenderer has already signed another contract with ECDC, they may provide instead of the legal entity file and its supporting documents a copy of the legal entity file provided on that occasion, unless a change in his legal status occurred in the meantime).

3.2.3. Economic and financial capacity criteria

Criteria:

The tenderer must have the necessary economic and financial capacity to perform this contract until its end. In order to prove their capacity, the tenderer must comply with the following selection criteria.

The tenderer must be in a stable financial position and have the economic and financial capacity to perform the contract.

The tenderer must have for each of the past two financial years for which accounts have been closed, an average annual turnover of at least € **150,000**. This criterion applies to the tenderer as a whole, i.e. the combined capacity of all members of a group in case of a joint tender.

In the case of tenderers from outside Eurozone, ECDC will calculate amounts of turnovers using exchanges rates for December of the relevant financial year as published in the Official Journal of the European Union.

Evidence:

Duly completed and signed Simplified Financial Statement (see link in section 4. Annexes), and the following depending on the legal form.

For Profit Organisations (whose primary goal is making a profit):

• copy of the profit & loss account and balance sheet for the last two years for which accounts have been closed.

For non-Profit Organisations (formed for the purpose of serving a public or mutual benefit other than the pursuit or accumulation of profits for owners or investors):

• copy of the statement of financial activities and statement of the financial position for the last two years for which accounts have been closed.

For Public sector entities (including public universities and international organizations), which according to the law of the country in which they are established are NOT required to publish balance sheets:

- only complete line 14 (Revenue) of the Simplified Financial Statement (version for nonprofit organisations) available in section 4. Annexes;
- extracts from their last two budgets (including the current one) as evidence of their average budget amounting to at least the value indicated above (under "Criteria").

For Individuals:

- only complete line 14 (Revenue) of the Simplified Financial Statement (version for nonprofit organisations), available in section 4. Annexes;
- provide extracts from any available documents (e.g., income tax returns) as evidence on their average income for the last two financial years amounting to at least the value indicated above (under "Criteria").

If, for some exceptional reason which ECDC considers justified, a tenderer is unable to provide one or other of the above documents, it may prove its economic and financial capacity by any other document which ECDC considers appropriate. In any case, ECDC must at least be notified of the exceptional reason and its justification. ECDC reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

3.2.4. Technical and professional capacity criteria

A. Criteria relating to tenderers

Tenderers (in case of a joint tender the combined capacity of all members of the group and identified subcontractors) must comply with the criteria listed below.

- **Criterion A1**: Minimum of five years of experience in the field of epidemiology of communicable diseases (preferably TB), public health, statistical analysis and mathematical modelling.

Evidence A1: Project references consisting in a list of minimum three references of similar services provided in the past five years, with a description of the projects, the sums, dates and clients, public or private, accompanied by statements issued by the clients.

- **Criterion A2:** Capacity to draft clear and concise reports in English (C1 equivalent¹²) for an international and multidisciplinary audience.

Evidence A2: One document of at least 10 pages (report, study, etc.) in this language that it has drafted and published or delivered to a client in the last two years.

- **Criterion A3:** Capacity to work simultaneously with at least two EU/EEA countries.

¹² Common European Framework of Reference for Languages: Learning, Teaching, Assessment

Evidence A3: References for two projects delivered in the last three years. Each project must have required parallel implementation of planned activities in at least two EU/EEA countries.

B. Criteria relating to the team delivering the service

The team delivering the service should include, as a minimum, the profiles listed below.

Evidence will consist in CVs of the team responsible to deliver the service. Each CV should indicate the intended function in the delivery of the service.

B1 - Project Manager (Minimum 1 CV is required):

- Minimum 3 years of professional experience project management, including overseeing project delivery, quality control of delivered service, client orientation and conflict resolution experience in project of a similar size (at least € 300,000) and coverage (at least two countries covered),
- Experience in management of team of at least two people.
- The project manager must not have any scientific conflict of interest e.g., through private sector funding.

Evidence: CV (preferably in Europass format)

<u>B2 - Language quality check</u>: The project manager and all technical experts (as per profiles described in section B3) should have at least C1 level in English, as defined in the Common European Framework for Reference for Languages¹².

Evidence: a language certificate or past experience in English language, appropriate level of studies or English language as mother tongue.

<u>B3 - Experts in epidemiological and statistical methods:</u> three profiles as described below. The experts must not have any scientific conflict of interest e.g., through private sector funding.

B3.1 – Junior expert (minimum 1 CV is required):

- University degree in statistics, epidemiology, public health or equivalent degree in a field relevant to the tasks requested in this tender.
- Minimum three years of professional experience working full-time (following the award of the diploma), in applying analytical methods to public health, especially for communicable diseases.

Evidence: CV (preferably in Europass format) and Annual declaration of interest (see section 4. Annexes).

B3.2 – Medium-level expert (minimum 1 CV is required):

- University degree in statistics, epidemiology, public health or equivalent degree in a field relevant to the tasks requested in this tender.
- Minimum five years of professional experience working full-time (following the award of the diploma), in applying analytical methods to public health, especially for communicable diseases; including interpretation of epidemiological data and communication of scientific findings demonstrated by list of relevant outputs (e.g., peer-reviewed scientific articles, technical reports and oral presentations in conferences).

Evidence: CV (preferably in Europass format) and Annual declaration of interest (see section 4. Annexes).

B3.3 – Senior expert (minimum 1 CV is required):

- University degree in statistics, epidemiology, public health or equivalent degree in a field relevant to the tasks requested in this tender.
- Minimum nine years of professional experience working full-time (following the award of the diploma), in applying analytical methods to public health and interpreting epidemiological data (preferably for TB); including communicating scientific findings (demonstrated by list of relevant outputs e.g., peer-reviewed scientific articles, technical reports and oral presentations in conferences), and coordinating epidemiological studies and/or managing small teams in projects with similar scope as the one described in this tender.

Evidence: CV (preferably in Europass format) and Annual declaration of interest (see section 4. Annexes).

<u>B4 - Data collection assistant</u> (minimum 1 CV is required):

- University degree or non-university degree with at least two years of working experience in the area of public health.
- Minimum one year of proven experience in data collection techniques.

Evidence: CV (preferably in Europass format).

3.3. <u>Award</u>

3.3.1. Technical tender

The technical tender must cover all aspects and tasks required in the technical specifications and provide all the information needed to apply the award criteria (see section 3.3.2 Award criteria). Tenders deviating from the requirements or not covering all requirements may be rejected on the basis of non-compliance with the tender specifications and will not be evaluated.

In particular, the technical tender should have a clear structure, consistent formatting and should not exceed 20 pages in length. The technical tender should include details on:

Proposed methodology:

- A description of the general approach and means to be used to meet the objectives of the tender, including assessment of the main issues, limitations, risks of the analyses to be carried out as well as the proposed mitigation measures;
- A technical proposal for country X (case study described in the table below), including a description of the scientific methods to be applied, work organisation and timeline for requested deliverables;

	"Country X"			
Context	Country X has been selected to participate in the project. The local study team may support the contractor with up to 10 person-days during six months in the implementation of the requested tasks. The following at-risk populations and corresponding data sources have been identified.			

At-risk populations	Close contacts of a person with TB	Asylum seekers	First- generation migrants	Homeless people	People with underlying medical conditions
Data sources	Data available from TB notification register.	Limited data available in some country regions.	Census data available by country of origin, date of entry, age and gender.	Limited data available from surveys or research studies.	Limited facility- based data available.
ECDC request	The contractor within 8 month	•		country specific st	udy protocol (DL3.1)

Organisation of the work and resources

Details on the allocation of time and human resources and the rationale behind the choice of this allocation, in particular resources available to run several tasks in parallel. Description of the involvement of the proposed experts (roles and responsibilities) to execute the planned activities.

Quality control measures:

Details on the arrangements to ensure business continuation and overall high quality of the services delivered; particularly:

- Description of the measures to ensure the relevance, appropriateness, reliability and validity of the project methods and findings;
- Description of the measures for data management and data protection, including ethical considerations.

3.3.2. Award criteria

The contract will be awarded based on the most economically advantageous tender, according to the 'best price-quality ratio' award method. The quality of the tender will be evaluated based on the following criteria. The maximum total quality score is 100 points.

No	Award criteria	Max points
1	 Quality of the proposed methodology This criterion will assess the general approach in relation to: the quality and appropriateness of the proposed methods to cover all the required activities (25); the evaluation of potential difficulties, limitations and risks, together with proposed mitigation strategies (10). For the case study: technical implementation proposed for the case study (the scientific methods to be applied, work organisation and timeline for requested deliverable) (15) 	
2	Organisation of the work and resources This criterion will assess the degree of consistency and logic of the proposed work organisation, the appropriateness of the distribution of the roles and responsibilities of the proposed team (including subcontractors if applicable). It also assesses the global allocation of time and resources to the project, to each task or deliverable (in particular when tasks need to be implemented in parallel in several countries), and whether this allocation is adequate for the work.	30
3	Quality control measures	20

This criterion will assess the quality control system applied to the service foreseen in this tender specification concerning the quality of the deliverables and, the language quality check., and continuity of the service in case of absence of the member of the team A generic quality system will result in a low score.	
TOTAL	100

Tenders must score minimum 60% for each criterion and minimum 70% in total. Tenders that do not reach the minimum quality levels will be rejected and will not be ranked.

3.3.3. Ranking of tenders

The contract will be awarded to the most economically advantageous tender, i.e., the tender offering the best price-quality ratio determined in accordance with the formula below.

A weight of 40/60 is given to price and quality.

		cheapest price*	*		*	0.4		total quality score (out of		0.6
score for tender X		price of tender		100				100) for all award criteria of tender X		
		Х						or tender X		

"Price of tender X" is the "Reference price" in the Financial tender (see section 4. Annexes).

The tender(s) ranked first after applying the formula will be awarded the contract.

<u>Remarks:</u>

Tenderers' attention is drawn to the fact that ECDC will be in a position to make a proper assessment of the tenders on the basis of the above qualitative criteria only if they contain full particulars relating to all aspects of this specification. Lack of detail and vague and perfunctory information will be penalised.

As the tenders will be evaluated on the basis of the quality of the services proposed, they should fully explore all the points included in this specification so as to obtain the best possible mark.

Simply repeating the guidelines given in the specification of this invitation to tender without going into detail or expanding on them will result in a very poor mark.

Furthermore, if any essential points of this specification are not expressly covered by the tender, ECDC may decide to give a zero mark for the relevant quality award criteria.

4. ANNEXES

- Annex I Draft contract
- Annex II Financial tender form
- Annex III Declaration on honour
- Annex IV <u>Authorised signatory form</u>
- Annex V <u>Tender submission checklist</u>
- Annex VI <u>Simplified Financial Statements</u>
- Annex VII Legal entity form

Financial identification form

Curriculum vitae template

Annex VIII - Annual declaration of interest

NB: Please click on the links above to access Annexes III to VIII