



**Tender Specifications**

**for**

***Coordination of the European Reference  
Laboratory Network for Pertussis  
(ERLNPert-Net)***

***Framework service contract***

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## Introduction to ECDC

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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. Its purpose is to identify, assess and communicate current and emerging threats to human health from communicable disease. Within this broad mission statement, the main technical tasks of the Centre fall into the following four categories:

- The publication of independent scientific opinions, bringing together technical expertise in specific fields through its various EU-wide networks and via ad hoc scientific panels;
- The provision of technical assistance to EU member states, communication of the Centre's activities and results and dissemination of information tailored to different audiences;
- The development of epidemiological surveillance at the European level and the maintenance of networks of reference laboratories; and
- Early Warning and Response based on 'round the clock' availability of specialists in communicable diseases.

Further information about the Centre can be found on the ECDC website [www.ecdc.europa.eu](http://www.ecdc.europa.eu).

### The tender process

The purpose of competitive tendering for awarding contracts is two-fold:

- to ensure the transparency of operations;
- to obtain the desired quality of services, supplies and works at the best possible price.

The applicable regulations, namely Directive 2014/24/EU and Regulation 966/2012, oblige the ECDC to guarantee the widest possible participation, on equal terms in tender procedures and contracts.

# 1 Overview of this tender

## 1.1 Description of the contract

The services required by ECDC are described in the terms of reference in **section 2** of the present tender specifications.

In drawing up a tender, tenderers should bear in mind the provisions of the draft contract in **Annex I**. In particular, the draft contract indicates the method and the conditions for payments to the contractor.

Tenderers are expected to examine carefully and respect all instructions and standard formats contained in these specifications and the invitation to tender. A tender which does not contain all the required information and documentation may be rejected.

## 1.2 Timetable

| Activity                                     | Date                             | Comments  |
|--|----------------------------------|---|
| Launching                                    | 29/11/2018                       | Estimated dispatch of contract notice to the OJ |
| Site visit or clarification meeting (if any) | -                                | Not applicable to this tender                   |
| Deadline for request of clarifications       | 23/01/2019                       | Six working days before deadline                |
| Deadline for submission of tenders           | <b>31/01/2019</b>                | At 16:00 local time Sweden                      |
| Interviews (if any)                          | -                                | Not applicable to this tender                   |
| Opening session                              | 04/02/2019                       |   |
| Date for evaluation of tenders               | Opening session date plus 1 week | Estimated                                       |
| Notification of award to the tenderers       | Evaluation date plus 1 month     | Estimated                                       |
| Contract signature                           | Notification date plus 1 month   | Estimated                                       |

## 1.3 Participation in the tender procedure

This procurement procedure is open to the natural or legal person wishing to bid for the assignment and established in the European Union, European Economic Area and Stabilisation and Association Agreements countries.

It is also open to international organisations defined as international public-sector organisations set up by international agreements and specialised agencies set up by such organisations.

Tenderers must not be in any situation of exclusion under the exclusion criteria indicated in section 3.1 of these tender specifications and must have the legal capacity to allow them to participate in this tender procedure (see section 3.2.1).

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.

For tenderers established in the United Kingdom (UK): please be aware that after the UK's withdrawal from the EU, the rules of access to EU procurement procedures of economic operators established in third countries will apply to tenderers from the UK depending on the outcome of the negotiations. In case such access is not provided by legal provisions in force tenderers from the UK could be rejected from the procurement procedure.

#### **1.4 Participation of consortia**

A consortium may submit a tender on condition that it complies with the rules of competition.

A consortium may be a permanent, legally-established grouping or a grouping which has been constituted informally for a specific tender procedure. Such grouping (or consortium) must specify the company or person heading the project (the leader) and must also submit a copy of the document authorising this company or person to submit a tender. All members of a consortium (i.e., the leader and all other members) are jointly and severally liable to ECDC.

In addition, each member of the consortium must have access to ECDC's procurement procedures as stated in section 1.3, and provide the required evidence for the exclusion and selection criteria (see section 3). Concerning the selection criteria, the evidence provided by each member of the consortium will be checked to ensure that the consortium **as a whole** fulfils the criteria.

The participation of an ineligible member of the consortium will result in the automatic exclusion of that member, and the whole consortium will be excluded.

#### **1.5 Subcontracting**

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

If the identity of the subcontractor is not known at the time of submitting the tender, the tenderer who is awarded the contract will have to seek ECDC's prior written authorisation before entering into a subcontract.

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

#### **1.6 Presentation of the tender**

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.

##### **1.6.1 Language**

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.

## **1.7 Contacts between ECDC and the tenderers**

Contacts between ECDC and tenderers are prohibited throughout the procedure, except in the following circumstances:

### **1.7.1 Written clarification before the deadline for submission of tenders**

Requests for clarification regarding this procurement procedure or the nature of the contract should be done **in writing only** through the eTendering website at <https://etendering.ted.europa.eu> in the "questions and answers" tab, by clicking "create a question".

Each request for clarification sent to ECDC should indicate the publication reference and the title of the tender.

The deadline for clarification requests is indicated in the timetable under section 1.2. Requests for clarification received after the deadline will not be processed.

At the request of the tenderer, ECDC may provide any additional information or clarification resulting from the request for a clarification on the eTendering website (see above).

ECDC may, on its own initiative, inform interested parties of any error, inaccuracy, omission or other clerical error in the text of the contract notice or in the tender specifications by publishing a corrigendum.

Tenderers should regularly check the eTendering website for updates.

### **1.7.2 After the closing date for submission of tenders**

If, after the tenders have been opened, some clarification is required in connection with a tender, or if obvious clerical errors in the submitted tender must be corrected, the ECDC may contact the tenderer, although such contact may not lead to any alteration of the terms of the submitted tender.

### **1.7.3 Visits to ECDC premises**

No site visits at ECDC's premises are deemed necessary for this procedure.

### **1.7.4 Interviews**

The Evaluation Committee will not conduct interviews for this procedure.

## **1.8 Division into Lots**

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

## **1.9 Variants**

Not applicable.

## **1.10 Confidentiality and public access to documents**

All documents presented by the tenderer become the property of the ECDC and are deemed confidential.

In the general implementation of its activities and for the processing of tendering procedures in particular, ECDC observes the following EU regulations:

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- Council Regulation (EC) No. 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents; and
- Council Regulation (EC) No. 45/2001 of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

The tender process will involve the recording and processing of personal data (such as a tenderer's name, address and CV). Such data will be processed pursuant to Regulation (EC) No. 45/2001.

Unless indicated otherwise, a tenderer's replies to questions and any personal data requested by ECDC are required to evaluate the tender in accordance with the tender specifications and will be processed solely for that purpose by ECDC. A tenderer is entitled to obtain access to their personal data on request and to rectify any such data that is inaccurate or incomplete.

If you have any queries concerning the processing of your personal data, you may address them to the ECDC Data Protection Officer [dpo@ecdc.europa.eu](mailto:dpo@ecdc.europa.eu). You also have the right of recourse at any time to the European Data Protection Supervisor for matters relating to the processing of your personal data.

### **1.11 Contractual details**

A draft contract is attached to these technical specifications as **Annex I**.

Signature of the framework contract imposes no obligation on the Centre 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.

### **1.12 Electronic exchange of documents**

Please refer to the draft contract attached to these technical specifications as Annex I. The related documentation can be found at: [http://ec.europa.eu/dgs/informatics/supplier\\_portal/index\\_en.htm](http://ec.europa.eu/dgs/informatics/supplier_portal/index_en.htm). Other applications currently under development may be implemented on a voluntary basis during the contract execution.

### **1.13 Additional information**

By virtue of article 134(1)(e) and article 134(4) of the Rules of Application of the Financial Regulation, ECDC reserves the option to launch further negotiated procedure, with the contractor chosen as a result of the present call for tender, for new services consisting in the repetition of similar services during the three years following the signature of the original contract.

### **1.14 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: <https://ecdc.europa.eu/en/about-us/procurement-and-grants>.

## 2 Terms of reference

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The terms of reference will become an integral part of the contract that may be awarded as a result of this tender procedure.

### 2.1 Introduction: Background to the invitation to tender

The European Centre for Disease Prevention and Control (ECDC) is a European Union (EU) agency with a mandate to identify, assess, and communicate current and emerging threats to human health from communicable diseases. To fulfil its mandate, ECDC operates several disease networks. Within its mission, ECDC shall 'foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health.

Whooping cough (pertussis) is an acute respiratory infection most commonly caused by the bacterium *Bordetella pertussis* and to a lesser extent *Bordetella parapertussis*. Pertussis remains endemic worldwide and is an important public health issue. Infants are the most vulnerable group to pertussis infection; but older children and adults can display milder symptoms and are also responsible for transmission. In recent years, there has been a marked increase in the number of cases in areas with high vaccination coverage, such as the EU and North America<sup>1234</sup>.

In 2016, 48 446 (42 974; 88.7% confirmed) cases of pertussis were reported by 30 EU and European Economic Area (EEA) countries leading to the notification rate of 10.8 per 100 000 population, that is the highest rate reported since 2012. Compared to the 2015, the notification rate has increased in 20 Member States and decreased in seven<sup>5</sup>.

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1 Gabutti G, Rota MC. Pertussis: A review of disease epidemiology worldwide and in Italy. Int J Environ Res Public Health. 2012 Dec;9(12):4626-38.

2 Clark TA. Changing pertussis epidemiology: everything old is new again. J Infect Dis 2014;209:978-81.

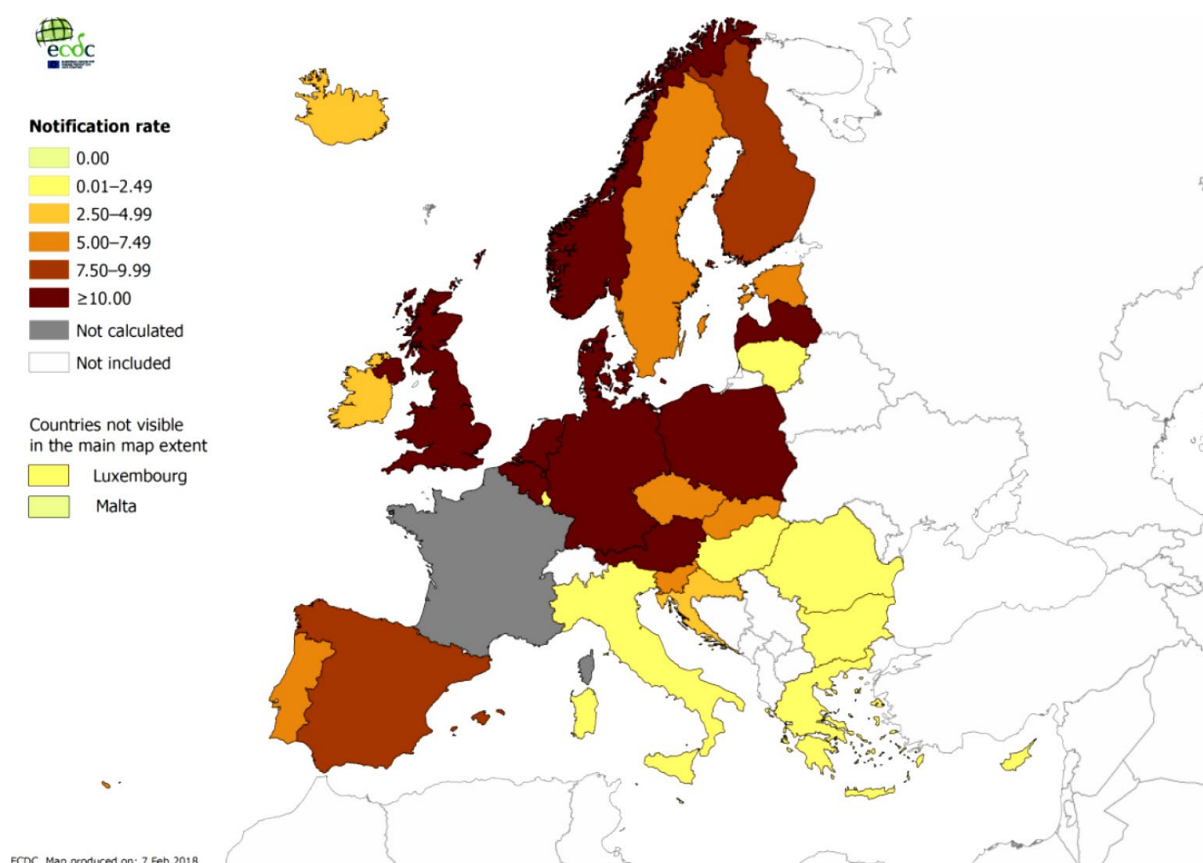
3 Barkoff AM, Gröndahl-Yli-Hannuksela K, He Q. Seroprevalence studies of pertussis: what we learned in different immunized populations. Pathog Dis 2015;73(7). pii: ftv050.

4 Esposito S, Principi N; European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Vaccine Study Group (EVASG). Immunization against pertussis in adolescents and adults. Clin Microbiol Infect. 2016 Dec 1;22 Suppl 5:S89-S95. doi: 10.1016/j.cmi.2016.01.003. Epub 2016 Apr 26.

5 European Centre for Disease Prevention and Control. Pertussis. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2018.



Table 1. Number of reported pertussis cases per 100 000 population by country, EU/EEA, 2016



Source: European Centre for Disease Prevention and Control. Pertussis. In: ECDC. Annual epidemiological report for 2016. Stockholm: ECDC; 2017.

Laboratory diagnosis of pertussis infection plays a crucial role in timely initiation of adequate treatment, prevention and control measures as well as in supporting surveillance activities. Surveillance systems as well as the proportion of laboratory-confirmed cases in EU/EEA Member States are heterogeneous, and direct comparisons between countries should be made with caution. The Member States reporting the highest notification rates were also those with the highest proportion of laboratory-confirmed cases. This highlights the importance of harmonisation and standardisation of diagnostic methods and diagnostic algorithms in order to strengthen the laboratory capacity for diagnosis of pertussis and the laboratory-based surveillance at the national and EU/EEA level<sup>6</sup>.

## 2.2 Description of the services

### 2.2.1 Contract scope and objectives

With this project, ECDC aims to strengthen the EU/EEA Member States' capacity for laboratory diagnosis and characterisation of toxigenic *Bordetella* species that would permit wider bacteriological confirmation of suspected pertussis cases, adequate monitoring of vaccine-antigen match among circulating strains, as well as better-targeted prevention and control activities supported by the enhanced surveillance activities.

The scope of this call is to design and implement the support activities for laboratory diagnosis of pertussis in close collaboration with the ECDC, the reference laboratories / laboratories with reference functions and pertussis laboratory experts in the Member States.

<sup>6</sup> <https://ecdc.europa.eu/en/pertussis>

The overall **objectives** of this call for tender are:

1. To coordinate, in collaboration with ECDC, the reference laboratory network for pertussis.
2. To assess laboratory performance in diagnosis of pertussis and characterisation of toxigenic *Bordetella* species against international standards.
3. To identify training needs of the network members.
4. To strengthen expert capacity through training in laboratory diagnosis and characterisation of toxigenic *Bordetella* species.
5. To identify the new tools in laboratory diagnosis and characterisation of toxigenic *Bordetella* species, as well as to assess the feasibility of those for introduction into the diagnostic and surveillance algorithms.

### **2.2.2 Tasks, deliverables and project schedule**

The task of the contractor will be to ensure functional coordination of the ERLNPert-Net network, regular communication to ECDC and implementation of the tasks described below. All the tasks should be implemented in agreement with and upon approval of the ECDC.

The nomination of the ERLNPert-Net network members will be done by ECDC. The ERLNPert-Net network will consist of one national reference laboratory for Pertussis or the laboratory for Pertussis with reference functions from each EU/EEA Member State.

The following tasks and deliverables can be requested through specific contracts within this framework contract. Some of these tasks and deliverables can be repeated. The exact time schedule and delivery deadlines will be specified in each specific contract.

#### **Task 1 - Coordination of activities and communication**

##### **Task 1.1 - Project inception**

- The contractor (max. 5 persons) will participate in a one-day kick-off meeting with ECDC staff at ECDC premises within one month after signature of the first specific contract. Issues to be discussed include methodological approaches, timelines, expected outputs, etc. The contractor will develop the meeting agenda in close collaboration with and upon approval of the ECDC.
- The contractor will prepare a report of the meeting within two weeks following the kick-off meeting, including the key issues discussed and decisions made.
- Two weeks after the kick-off meeting, the contractor will produce a two/three-page synopsis of the project. The purpose of this synopsis is to outline the general scope and purpose of the project. This synopsis will be shared with relevant stakeholders for information about the ongoing project.
- ECDC will share the synopsis of the project with the stakeholders.
- The contractor will produce a project work plan within one month following the kick-off meeting, including general methodological approach, milestones and timelines in accordance with the objectives of the ERLNPert-Net and the decisions of the kick-off meeting.

- DL 1.1.1: Contractor's participation (max. 5 persons) at the kick-off meeting at ECDC premises and the detailed report on the discussions and conclusion of the kick-off meeting, including the key issues discussed and decisions made (to be delivered two weeks after the kick-off meeting).
- DL 1.1.2: The updated project work plan for the entire duration of the contract, including general methodological approach, milestones and timelines in accordance with the objectives of the project and decisions of the kick-off meeting (to be delivered one month after the kick-off meeting).
- DL 1.1.3: The two/three-page synopsis of the project outlining the general scope and purpose of the project to the relevant stakeholders for their information about the project (to be delivered two weeks after the kick-off meeting).

### **Task 1.2 - Communication**

- The contractor will organise regular monthly teleconferences with ECDC and provide minutes from these teleconferences.
- The contractor will follow the ECDC rules in communication to the National Focal Points for Vaccine-preventable Diseases, and Operational Contact Points in the Member States as instructed by ECDC.

DL 1.2.1: Project coordination and minutes of the monthly teleconferences (one week after the monthly teleconference).

### **Task 1.3 - Coordination**

- The contractor will be responsible for the implementation of activities described in this tender. Monthly reports on the progress should be produced and submitted to ECDC. The monthly reports can be included within the minutes of monthly teleconferences.
- Coordination should be performed in close collaboration with ECDC. The implementation steps and coordination issues will be discussed on regular monthly teleconferences and pending ECDC approval.
- A final summary report on the whole project should be produced by the end of the last specific contract.

DL 1.3.1: Report on the activities performed under the Specific Contract. A separate report should be produced for each Specific Contract. The report should be submitted to ECDC within one month after the end of the Specific Contract. At least the following chapters should be included: table of content, list of abbreviations, executive summary, introduction/background, detailed description of activities, results, discussion on results/lessons learned, and conclusions/next steps. The report should be written by using British English grammar and spelling rules. The report should have consistent formatting.

DL 1.3.2: Final summary report on the whole project should be submitted to ECDC within one month from the end of the last Specific Contract. At least the following chapters should be included: table of content, list of abbreviations, executive summary, introduction/background, detailed description of activities, results, discussion on results/lessons learned, and conclusions/next steps. The report should be written by using British English grammar and spelling rules. The report should have consistent formatting.

### **Task 2 - Assessment of laboratory performance in laboratory diagnosis and characterisation of toxigenic *Bordetella* species**

The contractor will, in accordance with the ECDC External Quality Assessment (EQA) strategy (to be provided by ECDC), develop the EQA schemes for methods routinely used by the reference laboratories in the EU/EEA for diagnosis of pertussis and characterisation of toxigenic *Bordetella* species. Every year one EQA round for the ERLNPert-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 ERLNPert-Net EQA activities interact with global initiatives supported by the WHO to build synergies and avoid duplication of efforts.

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

- The contractor will prepare an approach on how to provide EQA schemes to national reference laboratories and promote their participation. The EQA schemes are to cover diagnostic methods routinely used by the reference laboratories in the EU/EEA (e.g. culture, biochemical, serological

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and molecular identification assays), antimicrobial susceptibility testing (e.g. phenotypic, molecular assays) and molecular typing methods to ensure that the ERLNPert-Net members produce valid and comparable data.

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

### Task 2.1 - Establishment of the current performance

Using experiences from existing EQA initiatives and previous EQA rounds, the contractor will design a proficiency round in agreed areas of pertussis laboratory diagnostic services to confirm or establish a new baseline of performance for ERLNPert-Net members and to help identify future needs for collaboration and training.

- After every EQA round, the contractor will provide a summary report on EQA performance for all methods included in the ERLNPert-Net EQA. For methods that were also included in the past EQA exercises, a comparison with results in previous years should be made. This summary report establishes the baseline EQA performance.

DL 2.1.1: Strategy and implementation plan for providing EQA for toxicogenic *Bordetella* species.

### Task 2.2 - Development of EQA schemes

Following the recommendations in international guidelines and existing standards, the contractor will identify the areas of pertussis laboratory diagnostic services and molecular typing for which an EQA scheme exists, or should be developed. The contractor might purchase the already existing EQA schemes or develop its own according to the recommendations in international guidelines and existing standards.

The contractor will provide:

- Description of the existing EQA system(s) for diagnostic and molecular typing techniques.
- Description of the ERLNPert-Net EQA scheme for methods/additional techniques not included in existing EU or International EQA schemes.
- Develop the EQA scheme for the ERLNPert-Net.
- Work plan on implementation of regular EQA rounds (i.e. 1 round per year) within this scheme.
- Report on participant individual EQA results and performance scoring.
- Draft Questionnaire on participant feedback survey on usefulness of each EQA round.
- Intended format (peer review publication or ECDC technical report) for EQA summary reports and recommendations on actions to support improvements in performance.

DL 2.2.1: Detailed description of the EQA schemes and certification criteria for methods routinely used by the laboratories in the EU/EEA for diagnosis and characterisation of toxicogenic *Bordetella* species.

### Task 2.3 - Implementation of regular EQA rounds, data analysis and reporting

Following the EQA work plan, the contractor will perform free of charge for the ERLNPert-Net members the annual EQA rounds, collection and analysis of EQA results. Each participant will receive an individual performance report with their own results as compared to the overall aggregate results of all participants. The pseudonymised EQA results by country will be shared with ECDC and the network to ensure tailored technical support in case of suboptimal performance for specific tests.

The contractor will provide participation certificates using the ECDC template.

The contractor will:

- Organise one EQA round every year as described in 2.2.
- Provide individual reports with results/performance scores of participants.
- Conduct a post-EQA survey of participants' use of EQA results.

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- Provide participation certificates to the laboratories.
- Provide a summary EQA report\* with anonymised and/or pseudonymised performance data and anonymised data on use of EQA results by participants and recommendations on corrective actions.

\* The report should follow the ECDC guideline on content for EQA reports<sup>7</sup> 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.

- DL 2.3.1: Summary report on EQA performance for all methods included in the ERLNPert-Net EQA. For methods that were also included in the past EQA exercises, a comparison with results in previous years should be made. This summary report establishes the baseline EQA performance.
- DL 2.3.2: Certificates for the laboratories passing the certification criteria.
- DL 2.3.3: Implementation of the EQA scheme; including the shipment of panels.

### **Task 3 - Annual meeting and capacity-building workshop**

#### **Task 3.1 - Annual meeting**

The contractor will organise one meeting for the ERLNPert-Net members every year in one of the EU/EEA Member States. The organisation of these meetings should follow the general rules described in task 3.3.

In addition:

- The meeting will be attended by the ERLNPert-Net members and include nominated persons from all Member States. The EU enlargement countries are welcome to the meeting as observers funded either by other EU project(s) or on their own funding. Other country participants and invited colleagues from relevant organisations (e.g. WHO, European Commission) may attend as observers, but on their own funding.
- By default, one ERLNPert-Net member per EU/EEA Member State should be invited.
- The maximum number of participants, including invited speakers, should not exceed 40 persons, excluding representatives from EU enlargement countries, ECDC employees and invited colleagues from relevant organisations.
- The agenda and the main topics for the meeting will be agreed with and approved by ECDC.
- The format of the meeting will be agreed in advance with ECDC.

The contractor will:

- Organise and facilitate a meeting in duration of maximum 0.5 days.
- Agree with ECDC on participants, invited speakers and self-funded observers. The participants list and draft meeting agenda should be approved by ECDC well in advance.
- 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

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<sup>7</sup> ECDC internal document. Relevant section will be provided to the partner.

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(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.

- DL 3.1.1: Annual meeting organised and facilitated.
- DL 3.1.2: List of annual meeting participants.
- DL 3.1.3: Annual meeting assessment questionnaire.
- DL 3.1.4: Report on the annual meeting. At least the following chapters should be included: table of content, list of abbreviations, executive summary, introduction/background, short summary of the discussions, and conclusions/next steps. The meeting agenda and the list of participants should be attached as annexes.

#### Task 3.2 - Capacity-building workshop

The contractor will identify the training needs in order to organise a capacity-building workshops for ERLNPert-Net members on laboratory diagnosis and molecular typing of toxigenic *Bordetella* species in order to:

- Strengthen performance in traditional diagnostic methods, molecular typing and other specialised analytical techniques for toxigenic *Bordetella* species, as well as other more general topics such as biosafety, laboratory management and quality control in the context of working with toxicogenic *Bordetella* species; and
- Improve EQA performance.

The capacity-building workshop shall be organised back-to-back to the annual meeting and shall follow the general rules described in task 3.3.

The contractor will:

- Perform the needs analysis.
- Develop the workshop agenda based on the needs assessment.
- Provide a draft curriculum and training material for a workshop to ECDC for review and approval, pending potential modifications.
- Provide the training material to all participants in the training workshop, in a train-the-trainers format. In particular, the training material is intended for national coordinating institutes and laboratories to be able to carry on national workshops to educate hospitals and laboratories in their own country.
- Organise, prepare and provide the face-to-face training of maximum 1.5 days.
- The training shall be organised back-to-back to the annual meeting.
- The maximum number of participants, including invited speakers, should not exceed 40 persons, excluding representatives from EU enlargement countries, ECDC employees and invited colleagues from relevant organisations.
- The agenda and the training topics will be agreed with and approved by ECDC.
- The format of the meeting will be agreed in advance with ECDC.
- 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.



DL 3.2.1: Report on the training needs assessment results.

### **Task 3.3 - General rules**

The contractor will:

- Organise travel and accommodation for all participants (excl. self-funded 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.
- The travel arrangements, accommodation and daily allowances shall be in line with the ECDC rules for missions and meetings and will be provided by ECDC. The actual information on the ceilings (i.e. scale of mission allowances) can be downloaded from the following link: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1611&from=EN>
- Provide an appropriate meeting venue, ensuring ideal 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 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.

DL 3.3.1: A maximum two-day training workshop is organised and facilitated.

DL 3.3.2: Curriculum and training material for the training workshop.

DL 3.3.3: List of workshop participants.

DL 3.3.4: Training workshop assessment questionnaire.

DL 3.3.5: Report on the training workshop should be submitted to ECDC within one month from the training workshop. At least the following chapters should be included: table of content, list of abbreviations, executive summary, introduction/background, short summary of the training and training sessions, discussion on results/lessons learned, and conclusions/next steps. The results of the training assessment questionnaire should be an annex to the report on the training workshop. The report should be written by using British English grammar and spelling rules. The report should have consistent formatting.

#### **Task 4 - Reference services**

Following the recommendations in international guidelines and existing standards, the contractor will develop a “Handbook of methods” used for laboratory diagnosis and molecular typing of toxigenic *Bordetella* species.

The contractor will provide:

- A “Handbook of methods used for laboratory diagnosis and molecular typing of toxigenic *Bordetella* species”. In addition to the detailed description and execution of the methods, the Handbook should cover the topics of laboratory/biosafety requirements and procedures, minimum laboratory requirements, disinfection and reporting of the results to clinicians.

DL 4.1.1: A “Handbook of methods used for laboratory diagnosis and molecular typing of toxicogenic *Bordetella* species”. In addition to the detailed description and execution of the methods, the Handbook should cover the topics of laboratory/biosafety requirements and procedures, minimum laboratory requirements, disinfection and reporting of the results to clinicians.

#### **Task 5 - Scientific support to ECDC**

The contractor will:

- Develop a proposal for a WGS-based typing protocol for sentinel surveillance of *B. pertussis* isolates to analyse the clonal diversity, and identify virulence factors associated with severe outcome, antigen shifts and replacement by non-vaccine antigen clones selected by vaccine selective pressure.

DL 5.1.1: The proposal for a WGS-based typing protocol for sentinel surveillance of *B. pertussis* isolates to analyse the clonal diversity, and identify virulence factors associated with severe outcome, antigen shifts and replacement by non-vaccine antigen clones selected by vaccine selective pressure. The proposal should be written by using British English grammar and spelling rules. The report should have consistent formatting.

#### **Task 6 - Targeted country support visit**

Based on the results of each EQA round, the contractor will identify the laboratories with specific needs for strengthening Member State’s capacity in laboratory diagnosis, characterisation and/or molecular typing of Pertussis, and will develop a training programme for targeted country support by staff exchange visits.

The contractor will:

- Based on the results of each EQA round, identify the three ERLNPert-Net members, which would benefit the most from a staff exchange visit.
- The final list of the three identified ERLNPert-Net members shall be approved by ECDC.
- Identify the ERLNPert-Net member most suitable and willing to provide or host the staff exchange visit.
- Develop the agenda of the staff exchange visits.
- Organise the staff exchange visits according to the guidelines described in task 3.3.
- Ensure the development of the report\* on the staff exchange visit and will submit the report to ECDC. Ideally, the report shall be prepared by the beneficiary of the staff exchange visit, but the responsibility for the quality of the report remains by the contractor.

\* 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, 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.

DL 6.1.1: The report on the staff exchange visit (i.e. one report per staff exchange visit).

### **2.2.3 Duration of the contract**

ECDC wishes to conclude a contract for an initial period of 24 months and a maximum total duration of 36 months.

### **2.2.4 Place of performance of the contract**

All tasks are expected to be performed at the contractor's premises. The annual meetings, training workshop and staff exchange visits might be organised outside of contractor's premises upon ECDC agreement.

### **2.2.5 Reference documents**

Not applicable.

## **2.3 Prices**

### **2.3.1 Currency of tender**

The Financial Proposal Form in **Annex II** must be used to submit a tender.

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 assume 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.

### **2.3.2 All-inclusive prices**

Prices submitted in response to this tender must be inclusive of all costs involved in the performance of the contract (e.g. to include delivery, supply and installation, maintenance, travel, subsistence, etc). No expenses incurred in the performance of the services will be reimbursed separately by ECDC.

### **2.3.3 Price revision**

Prices submitted in response to this tender shall be fixed and not subject to revision for Specific Contracts concluded during the first year of performance of the Framework Contract.

From the beginning of the second year of performance of the Framework Contract, prices may be revised upwards or downwards each year, where such revision is requested by one of the contracting parties by notice served no later than three months before the anniversary of the date on which the Framework Contract became effective.

Specific Contracts shall be concluded on the basis of the prices in force on the date on which they are signed. Such prices shall not be subject to revision.

See Article II.20 “Price revision” in Annex I – Draft contract for the formula used for the calculation of the price revision.

#### **2.3.4 Costs involved in preparing and submitting a tender**

ECDC will not reimburse any costs incurred in the preparation and submission of a tender. Any such costs must be paid by the tenderer.

#### **2.3.5 Protocol on the Privileges and Immunities of the European Union**

The Centre is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred, such as value added tax (VAT), pursuant to the provisions of articles 3 and 4 of the Protocol on Privileges and Immunities of the European Union. Tenderers must therefore quote prices which are exclusive of any taxes and duties.

#### **2.3.6 Payments**

The distribution of payments and the mandatory reporting is detailed in Annex I – Draft Contract.

#### **2.3.7 Financial guarantees**

ECDC may require a pre-financing guarantee or a performance guarantee from the Contractor chosen as a result of this tendering procedure. When such guarantee is requested, the specific conditions related to the provision of a guarantee are included in the draft contract (Annex I). The costs for the guarantee shall be borne by the Contractor.

## 3 Exclusion and selection criteria

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### 3.1 Exclusion criteria

All tenderers shall provide a declaration on their honour (see Annex III), duly signed and dated by an authorised representative of the tenderer, stating that they are not in one of the situations of exclusion listed in the Annex III.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex III before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender.

The contracting authority may waive the obligation for a tenderer to submit documentary evidence if such evidence has already been submitted for another procurement procedure and provided the documents were issued not more than one year earlier and are still valid. In such cases, the candidate or tenderer must declare on his honour that the documentary evidence has already been provided in a previous procurement procedure, provide reference to that procedure, and confirm that there has been no change in the situation.

### 3.2 Selection criteria

All tenderers shall provide the declaration on their honour (see Annex III), duly signed and dated by an authorised representative of the tenderer, stating that they fulfil the selection criteria applicable to them.

#### 3.2.1 Legal capacity

##### **Requirement**

A tenderer is asked to prove that they are authorised to perform the contract under the national law as evidenced by inclusion in a trade or professional register, or a sworn declaration or certificate, membership of a specific organisation, express authorisation or entry in the VAT register.

##### **Evidence required**

The tenderer shall provide a duly filled in and signed Legal Entity Form (see **Annex VII**) 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).

#### 3.2.2 Economic and financial capacity

##### **Requirement**

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 three financial years for which accounts have been closed, an average annual turnover of **at least €100,000**.

## **Evidence required**

**For-Profit Organisations** (whose primary goal is making a profit) shall provide, as part of their tenders:

- duly completed and signed Simplified Financial Statement, available in Annex VI
- copy of the profit & loss account and balance sheet for the last three years for which accounts have been closed.

**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) shall provide, as part of their tenders:

- duly completed and signed Simplified Financial Statement, available in Annex VI,
- copy of the statement of financial activities and statement of the financial position for the last three years for which accounts have been closed.

**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, shall:

- complete line 14 (Revenue) of the Simplified Financial Statement only (version for non-profit organisations) available in Annex VI,
- provide extracts from their last three budgets (including the current one) as evidence of their average budget amounting to at least **€100,000** which satisfy the requirements under the Simplified Financial Statement.

### **Individuals shall:**

- only complete line 14 (Revenue) of the Simplified Financial Statement (version for non-profit organisations), available in Annex VI
- provide extracts from any available documents (e.g. income tax returns) as evidence on their average income for the last three financial years amounting to at least **€100,000** which satisfy the requirements under the Simplified Financial Statement.

When completing the Simplified Financial Statement tenderers are requested to observe the following:

1. It must be signed by the authorised representative of the tenderer or tendering entity.
2. In the case of a consortium submitting a tender, or in cases of subcontracting (if the tenderer relies on the capacities of subcontractor(s) to fulfil economic and financial requirement), the Simplified Financial Statement must be included in the tender for all consortium partners and subcontractors.
3. ECDC reserves the right during the tendering process and before award of contract to request further evidence of the tenderer's compliance with the economic & financial capacity requirement. In this instance copies of official financial statements (e.g. balance sheets and profit & loss accounts or financial position and financial activities statements) for up to three financial years may be requested or any other document enabling ECDC to verify the tenderer's economic and financial capacity.
4. If additional evidence is not provided in response to ECDC's request within the deadline specified, or if the information provided is proved false, ECDC reserves the right to reject the tender as non-compliant with selection criteria.

### **3.2.3 Technical and professional capacity**

The tenderer's technical and professional capacity will be evaluated using the below criteria. The documents or information to be presented as evidence of compliance with the criteria are also listed below.

Criterion A: The tenderer should be accredited for the laboratory diagnosis of *Bordetella pertussis*.

Evidence A: Documentation on accreditation for number and type of methods accredited.

Criterion B: The tenderer should have relevant national or international qualifications, held for at least the last two years in the laboratory diagnosis of *Bordetella pertussis*. The technical experience, knowledge and capability in the area of the study field as well as the ability to prepare and present clear and concise reports in the English language to an international audience shall be proven for each of key experts allocated to the project. The person in charge of writing the reports should have at least C1 level in English following the Common European Framework for Reference for Languages<sup>8</sup>.

Evidence B: The tenderer must provide professional certifications/diplomas or references held by the tenderer and relevant subcontractors; CVs of the key staff to carry out the study (preferably using the template in **Annex VIII**), covering work experience, education and training, organisational and technical skills, English language skills, attesting the drafting and presentation skills.

Criterion C: The Project Manager should have at least five years of experience in financial, human resources and contract management as well as quality management and reporting. He/she should have at least C1 level in English following the Common European Framework for Reference for Languages.

Evidence C: Same evidence as in B.

Criterion D: Within the last three years, the tenderer should have been engaged in research activities relevant to this tender in an international environment.

Evidence D: The tenderer must provide references for research activities in the last three years, including at least two examples of research projects on subjects related to this tender conducted in an international environment.

Criterion E: The tenderer should have proven experience in running EQA schemes for laboratory diagnostic/typing methods either at EU or national level in the last five years.

Evidence E: The tenderer must provide references for organisation of at least two EQA schemes at EU or national level in the last five years.

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<sup>8</sup> See [http://www.coe.int/t/dg4/linguistic/Cadre1\\_en.asp](http://www.coe.int/t/dg4/linguistic/Cadre1_en.asp)

## 4 Award of the contract

Tenders are opened and evaluated by a committee, possessing the technical and administrative capacities necessary to give an informed opinion on the tenders. The committee members are nominated on a personal basis by ECDC under guarantee of impartiality and confidentiality. Each of them has equal voting rights.

### 4.1 Technical proposal

The assessment of technical quality will be based on the ability of the tenderer to meet the purpose of the contract as described in the terms of reference. To this end, the technical proposal shall contain the following information to allow evaluation of the tender according to the technical criteria mentioned in section 4.2:

- The project's aims and goals, a description of the proposed methods to be applied; means to be used to meet the objectives of the terms of reference and assessment of the main issues, limitations, risks of the analyses to be carried out as well as the proposed mitigation measures;
- Work organisation and planning (including major milestones and dates for meetings with ECDC to report on progress, as requested in section 2.2.3 of these tender specifications);
- Description of the involvement of the proposed key experts (roles and responsibilities) to execute the planned activities, in particular to cover the key analyses and investigations of the study.

The information in the technical proposal must be consistent with the terms of reference and must be signed by the tenderer.

### 4.2 Technical evaluation

The quality of technical tenders will be evaluated in accordance with the award criteria and the associated weighting as detailed in the evaluation grid below.

| No           | Criteria   | Max points |
|--------------|--|------------|
| 1            | Rationale, strategy, methods and means:  | 30         |
|              | <ul style="list-style-type: none"> <li>• Quality and appropriateness of the proposed methods to cover all the required activities (20)</li> </ul>  |            |
|              | <ul style="list-style-type: none"> <li>• Evaluation of the difficulties, limitations and risks as well the proposed mitigations by the tenderer (10)</li> </ul>  |            |
| 2            | Work organisation and planning:  | 40         |
|              | <ul style="list-style-type: none"> <li>• Relevance of proposed activities and implementation, indicating that the work is structured and organised appropriately and relating inputs and outputs (20)</li> </ul> |            |
|              | <ul style="list-style-type: none"> <li>• Appropriateness of sequence, timing of major milestones in execution of the contract (20)</li> </ul>  |            |
| 3            | Project management:  | 30         |
|              | <ul style="list-style-type: none"> <li>• Appropriateness of the organisation of roles and responsibilities with respect to what each expert contributes best to the implementation (30)</li> </ul>               |            |
| <b>TOTAL</b> |  | <b>100</b> |

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Only tenders scoring **70 points** or more (of a maximum of 100) points against the technical award criteria will have their financial proposal evaluated.

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

### **4.3 Financial proposal**

The financial proposal should be presented in the format found in **Annex II**.

### **4.4 Choice of the selected tender**

The contract will be awarded to the tenderer offering the best value for money, taking into account the awarding criteria listed above. No award criteria and sub-criteria other than those detailed above will be used to evaluate the tender.

The weighting of quality and price will be applied as follows:

|                    |   |  |   |     |   |                       |   |   |   |                                  |
|--------------------|---|--|---|-----|---|-----------------------|---|---|---|----------------------------------|
| Score for tender X | = | $\frac{\text{cheapest price}}{\text{price of tender X}}$ | * | 100 | * | price weighting (30%) | + | Total quality score (out of 100) for all criteria of tender X | * | quality criteria weighting (70%) |
|--------------------|---|--|---|-----|---|-----------------------|---|---|---|----------------------------------|

**“Price of tender X” is the “total price of the tender” in accordance with the financial proposal in Annex II.**

### **4.5 No obligation to award**

Completing the procedure of the call for tenders in no way imposes on the ECDC an obligation to award the contract. ECDC shall not be liable for any compensation with respect to tenderers whose tenders have not been accepted, nor shall ECDC be liable when deciding not to award the contract.

### **4.6 Notification of outcome**

Each tenderer will be informed in writing about the outcome of the call for tender.

If tenderers are notified that a tender has not been successful, tenderers may request additional information by mail. At the discretion of ECDC, this information can be given in a follow-up letter providing further details in writing, such as the name of the tenderer to whom the contract is awarded and a summary of the characteristics and relative advantages of the successful tender. However, ECDC would like to stress that it is not free to disclose any information affecting the commercial interests of other tenderers.

## List of Annexes

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Annex I — Draft contract

Annex II — Financial proposal form

Annex III — [Declaration of honour on exclusion criteria and selection criteria](#)

Annex IV — [Authorised signatory form](#)

Annex V — [Tender submission checklist](#)

Annex VI — [Simplified Financial Statements \(for profit and non-profit organisations\)](#)

Annex VII — [Legal entity form](#)

Annex VII — [Financial identification form](#)

Annex VII — [Curriculum vitae template](#)