Tender Specifications

for

assessing the impact of vaccination with conjugate vaccines on the epidemiology of invasive pneumococcal disease in the EU/EEA

Framework service contract

Publication Reference: OJ/15/06/2015-PROC/2015/020

June 2015

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Introduction to ECDC

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.

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 directives **92/50/EEC, 93/36/EEC and 93/37/EEC**, 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. An offer which does not contain all the required information and documentation may be rejected.

1.2 Timetable

Activity	Date	Comments
Launching of tender	16/06/2015	Dispatch of contract notice to the OJ
Site visit or clarification meeting (if any)	-	Not applicable to this tender
Deadline for request of clarifications	11/08/2015	
Deadline for submission of offers	**19/08/2015**	At 16:30 local time if hand delivered
Interviews (if any)	-	Not applicable to this tender
Opening session	27/08/2015	At 10:00 local time
Date for evaluation of offers	Opening date plus 1 week	Estimated
Notification of award to the selected Tenderer	Evaluation date plus 3 weeks	Estimated
Contract signature	Notification date plus 2 weeks	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 EU, EEA and SAA countries.

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.

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 provide the required evidence for the exclusion and selection criteria (see section 3 of these tender specifications). Concerning the selection criteria 'technical and professional capacity', 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 person will result in the automatic exclusion of that person. In particular, if that ineligible person belongs to a consortium, 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. The total value of the subcontracted part of the services cannot represent the total value of the contract value.

Subcontractors must satisfy the eligibility criteria applicable to the award of the contract.

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 comply with the following conditions:

1.6.1 Double envelope system

Offers must be submitted in two sealed envelopes. The inner envelope contains 3 separate inner envelopes clearly marked Envelopes A, B and C (see Invitation to tender).:

The content of each of these envelopes shall be as follows:

1. Envelope A – Administrative documents
   One original and one copy of:
   - The signed, dated and duly completed **Tender Submission Checklist** using the template in **Annex IX**;
   - The duly filled in, signed and dated **Exclusion Criteria and Non-Conflict of Interest Declaration**(s) as requested in section 3.1 and using the standard template in **Annex II**;
   - The duly filled in, signed and dated **Legal Entity Form**(s) as requested in section 3.2.1 and using the standard template in **Annex III** as well as the requested accompanying documents;

- The duly filled in, signed and dated **Financial Identification Form**[1] using the template in **Annex IV**;
- Financial and economic capacity documents as requested in section 3.2.2;
- The technical and professional capacity documents as requested in section 3.2.3;
- A statement containing the name and position of the tenderer's **authorised signatory**; and
- In case of consortia, a **consortium agreement** duly signed and dated by each of the consortium members specifying the company or person heading the project and authorised to submit a tender on behalf of the consortium (please see section 1.4 of these tender specifications)**.**

2. Envelope B – Technical proposal
   - One original (unbound, signed and clearly marked as "Original") and four copies (bound and each marked as "Copy") of the Technical Proposal, providing all information requested in section 4.1.

3. Envelope C – Financial proposal
   - One signed original and four copies of the Financial Proposal, based on the format in found in **Annex VII**.

Tenderers are welcome to submit in an environmentally friendly way, e.g., by choosing a simple and clear structure (list of contents and consecutive page numbering), double-sided printing, limiting attachments to what is required in the technical specifications (no additional material) and avoiding plastic folders or binders. This will not affect the evaluation of the tender.

1.6.2 Language

Offers 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 Confirmation of offer submission

In order to keep track of offers due to arrive, tenderers who do not hand deliver their offers are requested to complete and return the form found **Annex VIII**.

1.8 Contacts between ECDC and the tenderers

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

1.8.1 Written clarification before the deadline for submission of offers

Requests for clarification regarding this procurement procedure or the nature of the contract should be done **in writing only** and should be sent by mail, fax or email to:

[1] In the case of a consortium, only **one** Financial Identification Form for the whole consortium shall be submitted, nominating the bank account into which payments are to be made under the contract in the event that the respective tender is successful.

ECDC
Attn: Procurement Back Office

Granits väg, 8

171 65 Solna, Sweden Fax: +46 8 5860 1001

email: procurement@ecdc.europa.eu

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 ECDC Procurement webpage:
http://www.ecdc.europa.eu/en/aboutus/calls/Pages/ProcurementsandGrants.aspx.

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 on its website.

Tenderers should regularly check the ECDC website for updates.

1.8.2 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.

1.8.3 Visits to ECDC premises

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

1.8.4 Interviews

The Evaluation Committee will not conduct interviews for this procedure.

1.9 Division into Lots

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

1.10 Variants

Not applicable.

1.11 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:

- 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. 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

1.12 Contractual details

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

ECDC wishes to conclude a framework contract (FWC) to assess the impact of vaccination with conjugate vaccines on the epidemiology of the invasive pneumococcal disease in Europe, for a period of one year, renewable automatically three times,, as indicated in the article I.2.5 of the framework contract (Annex I).

A framework contract will establish the terms governing specific contracts to be awarded during a given period; in particular with regard to the services and the price.

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.

1.13 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. Other applications currently under development may be implemented on a voluntary basis during the contract execution.

1.14 Additional information

By virtue of article 134(1)(f) and article 134(3) 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.

2 Terms of reference

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

1.1 Introduction: Background to the invitation to tender

According to its mandate and in the specific field of vaccines and immunization, the ECDC "should foster the exchange of best practices and experience with regard to vaccination programmes" and "shall coordinate the collection, validation, analysis and dissemination of surveillance data at Community level".

Globally, *S. pneumoniae* is the most common cause of bacterial meningitis and mortality in children below five years of age. In March 2007, the WHO issued a position paper to highlight the need for introducing and implementing pneumococcal conjugate vaccination in all countries of the world. The first conjugate vaccine against *S. pneumonia*, the 7-valent pneumococcal conjugate vaccine (PCV7), became available on the market in 2000 in the USA and 2001 in the EU/EEA, The vaccine was introduced into the routine vaccine schedule for children below the age of five years in many countries and targeted the seven most common serotypes causing invasive pneumococcal disease (IPD). However, there are more than 90 different serotypes of *S. pneumoniae*, and the bacteria have an impressive ability to adapt to changes in their environment. Following the introduction of the PCV7 vaccine, other serotypes have since become more prevalent causes of IPD, therefore, in 2009 and 2010 respectively, 10-valent (PCV10) and 13-valent (PCV13) vaccines were released onto the market.

Currently 25 out of 31 Member States have pneumococcal vaccination with conjugate vaccines in their primary immunisation schedule. It is essential to assess the impact of these vaccines on the epidemiology of pneumococcal disease in Member States; to compare the effectiveness of different vaccination schedules; to identify risk factors for vaccine failure; and to collect evidence of serotype replacement following the introduction of the vaccines.

High quality surveillance systems for IPD are essential to allow the assessment of the effectiveness and impact of new vaccines' on disease epidemiology. In the EU/EEA, enhanced surveillance of IPD has been ongoing since 2010, however surveillance systems are heterogeneous between member states, while many report data from passive national surveillance systems that are prone to underreporting. Active, population based-surveillance is considered the gold standard of surveillance as it theoretically captures 100% of diagnosed cases in a defined population allowing the burden of a disease to be accurately estimated and ensuring the effectiveness of public health interventions. Passive systems with proven high sensitivity may also provide equally sufficient surveillance data for this purpose.

In response to the above situation, in 2012 the ECDC embarked on a pilot project (SpIDnet) aimed at establishing an enhanced population based surveillance system for IPDs in the EU/EEA with the ultimate goal of assessing the impact of vaccination with pneumococcal conjugate vaccines on the epidemiology of IPD in the EU/EEA. The outcome and results of SpIDnet and the consequently established surveillance system for IPD, provide a basis and support for informed vaccination strategy and policy development. Initially only children aged below 5 years of age were included; however, in 2014 SpIDnet was expanded to include all age groups in order to ensure accurate assessment of the effectiveness and impact of conjugate vaccines in all age groups, and in light of the potential future introduction of PCV13 into the routine vaccination schedule among older age groups.

The ECDC now looks to maintain and further develop the enhanced EU population based surveillance system established in SpIDnet to continue the assessment of the effectiveness and impact of pneumococcal conjugate vaccines on the epidemiology of the disease in the EU/EEA.

1.2 Description of the services & scope of the contract

1.2.1 Contract objectives and scope

The scope of the framework contract / project is to maintain and further develop an enhanced, population-based IPD surveillance system and subsequently sustain IPD surveillance and vaccination impact assessment in the EU/EEA. This continued development of enhanced IPD surveillance and vaccine impact assessment should build upon and use the system developed in SpIDnet performed under the procedure "OJ/04/04/2012-PROC/2012/031" (http://ecdc.europa.eu/en/aboutus/calls/_layouts/forms/Call_DispForm.aspx?List=02511b7b-3a16-4c4b-9304-54cfc08a1647&ID=624).

The specific objectives of the framework contract are:

- To maintain and further develop a coordination infrastructure and a network of reporting sites for enhanced, population-based IPD surveillance in the EU/EEA
- To estimate the incidence rate and mortality due to IPD in children and adults;
- To provide systematic monitoring of circulating *S. pneumoniae* serotypes in order to detect emerging strains and serotype replacement;
- To calculate the vaccine effectiveness of the pneumococcal conjugate vaccines
- To evaluate the impact of pneumococcal conjugate vaccines in terms of the disease burden of vaccine and non-vaccine strains;
- To monitor antimicrobial non-susceptibility in pneumococcal isolates;

1.2.2 Description of the tasks

The contractor will perform the study according to the design, specifications and scope as discussed and agreed with ECDC. The overall description applies to all deliverables listed in the section above. The contractor needs to include all necessary tasks to achieve the requested deliverables. Regular contact between the contractor and ECDC is required.

Inclusion of study sites that are geographically representative if the EU/EEA

As previously, a minimum sample of six study sites that are geographically representative of the EU/EEA is required and should be included in the tenderers offer. Pending budget availability in the sequential specific contracts to the framework, an increase in the number of study sites might be considered.

For the requirement of European geographical representativeness, the following country grouping should be taken into account:

- Group 1: Cyprus, Greece, Italy, Malta, Portugal, Spain
- Group 2: Denmark, Finland, Iceland, Ireland, The Netherlands, Norway, Sweden, United Kingdom
- Group 3: Bulgaria, Estonia, Latvia, Lithuania, Romania
- Group 4: Austria, Belgium, France, Germany, Liechtenstein, Luxembourg
- Group 5: Czech Republic, Hungary, Poland, Slovak Republic, Slovenia

The contractor must ensure that at least one study site from a Member State in group 1, 3 or 5 will be included in the study.

Included Member States should preferably already have a national IPD surveillance system in place that is based on the formal IPD case-definition, and the included study sites should already be involved in the national IPD surveillance system in their country. Further, the site should be in a Member State where pneumococcal conjugate vaccines are part of the

routine vaccinations schedule. To allow for continuity, the tenderer should strongly consider including existing study sites having taken part in SpIDnet under previous procedure "OJ/04/04/2012-PROC/2012/031" (http://ecdc.europa.eu/en/aboutus/calls/_layouts/forms/Call_DispForm.aspx?List=02511b7b-3a16-4c4b-9304-54cfc08a1647&ID=624) .

For new study sites joining the project, deliverables may be newly requested, while for the existing study sites updates can be requested during the foreseen four year period of the project's implementation. Modifications to the protocol initially developed and methodology used can also be requested to the team of experts coordinating the project.

Requirements to ensure representative data for calculating rates of IPD

The contractor will have to identify study sites, for which an estimate of the population in the area is available and/or the catchment area of the hospital is known. An essential aspect is the accurate description and matching of both the denominator and numerator data regarding the population under surveillance. Both the number of IPD cases (numerator) and the surveillance population (denominator) should be resident of the predefined surveillance area. The numerator data should capture IPD cases from all age groups.. In settings where clinical specimens are sent outside the surveillance area for testing at the reference national laboratory, it is important to ensure these cases are captured and reported.

The established surveillance system should allow for the integration of data from multiple sources, including laboratories and hospitals and allow access for the public health workers active in the study areas as well as those actively involved in the case notification and investigation. Such an integrated system allows for the control for underreporting and provides reliable information, not only on the isolated strains, but also on the clinical and epidemiological characteristics of IPD cases, including cases' vaccination status. Finally, the collection of the agreed set of variables is essential for the calculation of EU/EEA IPD incidence rates and the impact-assessment of vaccination.

For the purpose of this Framework contract, the EU 2012 case definition should be applied in all settings for case-identification and reporting. Thus, only laboratory-confirmed isolates should be included and only blood, CSF pleural fluid or other sterile-site isolates should be considered.

Ensuring clear plan and directives for procedures in the study sites

To achieve the required task, the contractor will conduct case-ascertainment coordinated in each study site at the national and/or subnational PH level. Laboratories, hospitals and public health experts in the study areas will all be involved in the development of the procedures and the implementation of the project. The contractor will clearly identify and present the personnel involved in the project in each study site, explicitly listing those working in the public health institutions, the laboratory-based individuals and/or the hospitals and its personnel in the identified surveillance areas.

Epidemiological and laboratory requirements for ensuring complete, high-quality data on reported cases

It is desirable that during the implementation of the project, strong collaboration between laboratory experts and epidemiologists involved at the study sites is secured. Laboratory information often needs to be complemented with data from additional sources (medical records, vaccination registries and death certificates) to provide complete data about a case. The contractor will develop a minimal dataset to be collected in all study sites. The proposal, which will need to be agreed with ECDC experts before complementation, should ensure the collection of variables such as demographic characteristics, clinical presentation,

outcome, underlying conditions, vaccination status, and laboratory tests. These data have to be collected on a regular basis. The feasibility of providing data available in each study site before the introduction of Pneumococcal conjugate vaccines (to be used as baseline data) is crucial in order to assess the impact of vaccination.

The included *S. pneumoniae* isolates should be isolated by the laboratories of the surveillance area, and, if needed, sent to the National Reference Laboratory for further characterisation, serotyping and antimicrobial susceptibility testing. All the expenses generated by the shipping and identification and characterisation of the strains should be budgeted as part of the project; no expenses incurred in the performance of these services will be reimbursed separately by ECDC. The contractor will contact the National Reference Laboratories and agree on a protocol for confirming identification, serotyping and antimicrobial susceptibility testing of submitted isolates. For this task the tenderer may consider the experience, quality assessment and harmonisation of methods undertaken during the previous project (IPD laboratory passive surveillance project, *S. pneumoniae* EQA scheme)

Taking into account that variability in blood culture practices greatly influences the estimate of IPD, the contractor is also requested to collect data on blood culturing in the study sites, in order to assess how this factor may impact on differences in IPD incidence in the different study sites.

Planning, coordination and conducting meetings

Travel and subsistence costs for the meetings organized during the framework contract for experts and other stakeholders will be covered by the contractor.

Meetings will not be organized at ECDC premises; the estimated number of participants for each meeting is 45 people, including ECDC staff. Cost for travel, subsistence and accommodation for ECDC staff are not covered by this contract. Other costs, such as catering and venue, cover all participants.

For meetings, the successful applicant shall carry out the following tasks:

- Develop the agenda for the meetings or workshops in close collaboration with ECDC experts.
- Distribute and collect declarations of interest (DoI) from all invited experts using the ECDC DoI forms. DoIs in original should be forwarded to ECDC for archiving.
- Propose the list of participants and seek ECDC input and approval prior to the meeting. Provide a final list of participants, including their affiliation and contact details, at the meeting. Make it available to ECDC in an electronic copy.
- Ensure the delivery of the full meeting, including a) Organize travel for all participants (economy class) to come to the meeting, meals and accommodation for all participants. It is responsibility of the awarded contractor to cover these costs, and to set reasonable cancellation terms and conditions for the participants. (In case of cancellation of participation or rebooking due to illness, the contractor is requested to cover the costs of cancellation and rebooking needed).
- Provide the meeting venue as appropriate, ensuring smooth implementation and ideal working conditions; including all relevant material such as personal computer, video projector, power point and beamer, screens, flip charts (with paper and pens), easy access to printer, photocopier (with sorter and stapler function); and including coffee breaks and water on the table during meetings.
- The meetings shall be held in English.
- Ensure the relevant support to allow for the smooth organisation and implementation of the meeting.

- Ensure that all participants sign the participants list for each day of the meeting and submit the originals to ECDC for archiving.
- Collect and make participant presentations available to ECDC and other meeting participants.
- Write comprehensive meeting reports. These should include: Background to the meeting; meeting documents; participant list; summarize the main discussion points of the meeting, including the recommendations and action points. Write a shorter summary meeting reports for publication on the ECDC website after approval by ECDC project manager and respective line manager or Head of Disease Programme and if desirable on the project website.
- Provide the meeting material and report.

1.2.3 Deliverables, reporting and project schedule

The following are deliverables requested by ECDC through specific contracts within this framework contract.

1. An updated generic surveillance protocol for guiding the establishment of the surveillance system in the selected study sites, based on the previous protocol from SpIDnet;
2. Updated site specific study/surveillance protocols;
3. An updated list of minimum required variables to be collected by all surveillance sites concerned in the format of a metadata set compatible with The European Surveillance System (TESSy);
4. Further development of analysis plans and reproducible scripts as necessary;
5. Annual meeting involving relevant stakeholders and the study participants. At this meeting, the results of the project will be presented;
6. One (or more if necessary) restricted meetings with the study participants each year of the contractual service. The deliverables, will be the meeting minutes or report;
7. Statistical analysis of the surveillance data in each study site (estimated at once update every 6 months);
8. Periodical reports combining data from all study sites on the epidemiology of IPD with interpretive commentary (estimated at one per year);
9. Two draft manuscripts that provide estimates on vaccine effectiveness combining the data from all study sites;
10. A draft manuscript on the impact of different PCV immunisation strategies on the epidemiology of the disease combining the data from all study sites;
11. A draft manuscript on antimicrobial resistance in pneumococcal isolates combining the data from all study sites;
12. A draft manuscript on the impact of PCV vaccination on the clinical presentation of cases of IPD combining the data from all study sites;
13. A surveillance evaluation protocol to be used for evaluating surveillance sites during site visits or for their self-evaluation.

For deliverables 9 – 12, the manuscripts will be prepared for publication in a relevant peer-reviewed journal.

The reporting requirements are defined in the contract (see article I.4, Annex I). The contractor should provide all deliverables to ECDC written in English language, except when

explicitly mentioned. Each specific contract will have an interim and final activity and financial reports. These reports are in addition to the technical deliverables presented in such paragraph

Interim activities reports

The interim activity reports about the progresses achieved on the deliverables in accordance with the relevant specific contract, and financial report will contain a detailed description of the activities implemented following the completion of each contract.

Final activities report

The final activity and financial report will contain the detailed description of the activities implemented in the whole contractual period.

The final reports should be submitted to ECDC on the completion of the assignment.

1.2.4 Duration of the contract

The overall duration of the framework contract is expected to be for a period of one year, renewable automatically three times, as indicated in the article I.2.5 of the framework contract (Annex I). Thus, the overall duration of the project is foreseen to be four years.

1.2.5 Place of performance of the contract

The tasks are expected to be performed at the contractor's premises and at the study sites when applicable.

1.2.6 Reference documents

Reference documents produced under the two previous Spidnet contracts mentioned above can be made available on request.

1.3 Prices

A ceiling of up to 3.000.000 euro over the four year period is foreseen.

1.3.1 Currency of tender

Prices must be quoted in Euro.

Conversions should use the rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the Website of the European Central Bank at the following URL: http://www.ecb.int/stats/eurofxref

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

1.3.2 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.

1.3.3 Price revision

Prices submitted in response to this tender shall be fixed and not subject to revision.

See the article about "Prices" of the contract for calculation.

1.3.4 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.

1.3.5 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 and must indicate the amount of VAT separately.

1.3.6 Payments

A prefinancing payment of 30% is performed as indicated in the framework contract Article I.4.2 (see draft contract in Annex I).

Interim and balance payments are performed as indicated in the framework contract Articles I.4.3 and I.4.4 (see draft contract in Annex I).

The specific contracts specify the time schedule of payments.

1.3.7 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

1.4 Exclusion criteria

All tenderers shall provide a declaration on their honour (see Annex II), 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 II.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex II 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.

1.5 Selection criteria

Tenderers must submit evidence of their legal, economic, financial, technical and professional capacity to perform the contract.

1.5.1 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 III**) 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.)

1.5.2 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.

Evidence required
Proof of economic and financial capacity shall be furnished by the following documents:

- balance sheets or extracts from balance sheets for at least the last two years for which accounts have been closed (where publication of the balance sheet is required under the company law of the country in which the economic operator is established);

- a statement of overall turnover and turnover concerning services/supplies covered by the contract during the last three financial years.

If, for some exceptional reason which ECDC considers justified, the tenderer is unable to provide the references requested by the contracting authority, he may prove his economic and financial capacity by any other means which ECDC considers appropriate.

The Centre reserves the right to request any additional documentary evidence it deems necessary or useful in order to verify a tenderer's economic and financial standing.

1.5.3 Technical and professional capacity

Requirement(s)
The tenderer's technical and professional capacity will be evaluated using the following criteria:

- Suitability of the organisation and staffing structure available for the activities covered by the contract;
- Relevant qualifications in the fields of epidemiology, surveillance of vaccine preventable disease, vaccinology and laboratory diagnostics of *S. pneumoniae*;
- Research and expertise of key personnel allocated to the project: technical experience, knowledge and capability in the area of the study fields as well as the ability to prepare and present clear and concise reports in the English language to international audience;
- Capability and experience in coordinating a multinational network and participating in multicentre studies either at national or international level;
- Involvement in relevant research activities, particularly for the health sector;

Evidence required
The following documents or information shall be presented as evidence of compliance with the technical and professional capacity criteria:

- Details of the structure of the organisation (including the number of staff) and relevant subcontractors;
- Professional accreditations or references held by the tenderer and relevant subcontractors; CVs of the key experts to carry out the study (preferably using the template in **Annex VI**), covering work experience, education and training, organisational and technical skills as well as an excellent level of English, attesting the drafting and presentation skills;
- A list and description of recent activities (in the last 3 years) in the field of epidemiology, vaccinology and/or laboratory diagnostics of *S. pneumoniae*, including 2 examples of research projects on subjects related to this tender conducted in an international environment.

4 Award of the contract

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

Only the tenders meeting the requirements of the exclusion and selection criteria will be evaluated in terms of quality and price.

1.6 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 tender should indicated the number of study sites involved in the project, ensuring geographical representativeness as indicated in the description of the tasks in section 2.2.3 as well as the criteria used to ensure representative data for calculating rates of IPD;
- A description of the approach proposed and 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 2.2.4 of these tender specifications), including a Gant chart;
- Indicate the specific criteria used to estimate the budget for the meetings included in the list of deliverables in Aneex VII; in more details, please provide examples of venues where meetings can be held, and type of accommodation as well as specifying if possible in which country/ies they will be able to host them;
- 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.

Coordination and internal communication

A detailed programme management plan will be submitted as part of the technical proposal. It should describe the project organisation i.e. a Coordinator, Project Manager, Associate Partners (if relevant), and Communication Plan. A project organigram showing links between participating partners should be included. If a consortium is established for the purposes of this FWC (Associate Partners), the management plan should clearly describe members of the consortium and delineate responsibilities. The project organisation plan should include:

- Coordinator: The Lead Institute; the host organisation with overall responsibility for the project;
- Project coordinator: The individual with overall responsibility for day-to-day project coordination and management. The project Coordinator is the key contact person for liaising with ECDC and with Associate Partners and will be supposed to be full-time devoted to the programme;
- Associate Partners (if relevant): These individuals are members of the consortium, if one is established. They are responsible for coordinating and conducting part of the work plan;
- Management Team: Consists of a limited number of people including the Project coordinator and selected representatives from Associated Partners. The Management Team is expected to meet

with the ECDC Steering Committee regularly throughout the project duration and not less than once every 6 months.

The Management Plan should also include an internal Communication Plan, for organising, conducting and chairing meetings of the Management Team via teleconferences and/or face-to-face meetings; expert workshops; internal communication should also consist of a monthly project status report submitted to ECDC.

A web-based communication tool (extranet) should be part of the communication plan and include functionalities like document sharing, forum discussion, messaging, etc.

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

1.7 Technical evaluation

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

No	Criteria	Max points	Awarded score
1	**Technical implementation:** - Quality of the methodology for carrying out the project deliverables - Quality of the approach to integrate the project into other similar European level projects - Degree of geographical representativeness of the study sites - Validity of criteria used to ensure representative data for calculating rates of IPD - Evaluation of the difficulties, limitations and risks as well as the proposed mitigations by the tenderer. (The above aspects are of the same relative value)	**40**	
2	**Allocation of resources and project management:** - Extent of the decentralisation of work to the human resources at the study sites; - Proposal of a realistic workplan and implementation plan; - Verifiable objectives and milestones; - Extent to which the resources are used to meet the objectives and results of the project; - Effective coordination and mobilization of the team. (The above aspects are of the same relative value)	**20**	
3	**Methodology:** - High involvement of the local expertise from the study sites in the methodology used; - Aptitude to foster capacity-building at the study site location; - Quality of the practical and multidisciplinary approach of the implementation; - Scientific validity of the proposal; - Efficiency of the strategy and methods for monitoring the impact of the conjugate vaccines on the IPD at the study sites as well as for calculating the vaccine effectiveness. (The above aspects are of the same relative value)	**40**	
	TOTAL	**100**	

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

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

1.8 Financial proposal

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

1.9 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 offer.

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

$$\text{Score for tender X} = \frac{\text{cheapest price}}{\text{price of tender X}} * 100 * 40\,\% + \frac{\text{Total quality score (out of 100) for all criteria of tender X}}{} * 60\,\%$$

"Price of tender X" is the Overall Total Price Offered OT from the table of Annex VII.

This total price serves only evaluation purposes.

The number of study sites can be changed in consultation with the contractor. This applies also to the number of repetitions (indicated in column I of Annex VII). As indicated in the section 1.12, this occurs at the time the specific contract is signed .

Deliverables may not necessarily be achieved for the first time during the first specific contract; depending on the type of deliverable these may be be achieved for the first time during the second specific contract or later.

1.10 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 offers have not been accepted, nor shall ECDC be liable when deciding not to award the contract.

1.11 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 fax or 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

Annex I — Draft contract

Annex II — Exclusion criteria and non-conflict of interest declaration

Annex III — Legal entity form

Annex IV — Financial identification form

Annex V — Authorised signatory form

Annex VI — Curriculum Vitae template

Annex VII — Financial proposal form

Annex VIII — Confirmation of offer submission

Annex IX — Tender submission checklist