Call for proposals

VACCINE SAFETY IN EUROPE: IMPROVING SYSTEMS FOR REPORTING AND EVALUATING POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) IN EU/EEA/EFTA COUNTRIES GRANT/2009/003

1. OVERVIEW .............................................................................................................................2
1.1. Title ........................................................................................................................................2
1.2. Introduction ...........................................................................................................................2
1.3. Background ...........................................................................................................................2

2. IMPLEMENTATION OBJECT OF THE CALL FOR PROPOSALS .................................................................................5
2.1. Objectives of the call for proposals ......................................................................................5
2.2. Main actors of the management and communication ..........................................................5
2.3. Characteristics of the agreement object of the call of proposals ..........................................6
2.4. Deliverables ............................................................................................................................6
2.5. Description of work packages and related tasks of the successful applicant .............................7
2.6. Meetings: ................................................................................................................................10
2.7. Amount available for financial support and provisions about the results ............................11
2.8. Reporting requirements ..........................................................................................................11
2.9. Payments ................................................................................................................................12
2.10. Profile of the expected applicants .......................................................................................12
2.11. Indicative time frame 1st year .............................................................................................13
2.12. Implementation of the Work Packages in years 2 to 4 ...................................................14

3. CONTENT OF THE APPLICATION .......................................................................................................14
3.1. THE DEADLINE FOR APPLICATION IS 24 APRIL 2009 ......................................................14
3.2. The proposal to submit to ECDC should include: .....................................................................14
3.3. Management and Communication Plan ..................................................................................15

4. EVALUATION OF THE PROPOSALS .................................................................15
4.1. Verification of submission requirements ..................................................................................16
4.2. Eligibility criteria ......................................................................................................................16
4.3. Exclusion criteria ......................................................................................................................17
4.4. Selection criteria ......................................................................................................................18
4.5. Award criteria ........................................................................................................................19

5. ANNEXES ..............................................................................................................................20
1. **OVERVIEW**

1.1. **Title**

VACCINE SAFETY IN EUROPE: IMPROVING SYSTEMS FOR REPORTING AND EVALUATING POTENTIAL ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) IN EU/EEA/EFTA COUNTRIES

1.2. **Introduction**

The European Centre for Disease prevention and Control (ECDC) was established by the European Parliament and Council Regulation 851/2004 of 21 April 2004 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:

1. Scientific opinions, bringing together technical expertise in specific fields through its various EU-wide networks and via ad hoc scientific panels.
2. Technical assistance and communication about its activities and results, and disseminating information tailored to meet the needs of its different audiences.
3. Epidemiological surveillance and networking of laboratories, i.e. the development of epidemiological surveillance at European level and the maintenance of networks of reference laboratories.
4. Early Warning and Response, based on ‘round the clock’ availability of specialists in communicable diseases.

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 collection, validation, analysis and dissemination of data at Community level, including on vaccination strategies”.

Details of the Centre’s mandate and functions are set out in the above referenced Regulation, accessible through the ECDC web site [http://www.ecdc.europa.eu](http://www.ecdc.europa.eu)

1.3. **Background**

Introduction of vaccines against infectious diseases, previously resulting in death or long-term sequelae, has been a success and development of new vaccines is likely to continue.

Robust vaccine safety systems with the goal of minimizing occurrence of serious adverse events from routinely administered vaccines and detecting them in a timely manner when they do occur are needed more than ever. Adverse events following immunization (AEFI) may differ in terms of severity, causality and public health consequences. The large number of doses of vaccines administered creates the conditions for reporting of post-vaccination events which are temporally associated with vaccination and can either
be real or coincidental. Enhancing the current vaccine safety systems is important for a number of reasons; an increasing number of vaccines are used in all age groups, combination vaccines or a combination of vaccines administered at the same time are used increasingly to reduce the number of visits to the vaccine provider, a number of new adjuvants with the goal of being antigen sparing and providing longer immunologic memory are being included in the new vaccines, a better understanding of the human biology is needed, especially the human immune system and host genetics and finally expansion of healthcare databases that can be linked to AEFI surveillance are becoming available. To maintain public confidence in the immunization programs vaccine safety must be a focus for all stakeholders in the vaccine and immunization enterprise including governments, manufacturers and vaccine providers.

Dealing adequately with AEFI implies at least the existence of sensitive and timely systems for rapid detection of AEFI and AEFI clusters and technical capacity to carry out valid and reliable investigations at individual and population level;

While common adverse events are likely to be detected during the clinical trials (Phase I/III), rare events are more likely to occur after marketing of vaccine products (Phase IV). Other unexpected events may be due to programme errors and can occur at any stage of the vaccination programme. Therefore post-marketing surveillance of vaccine products and their implementation are essential.

Many of the surveillance systems in place for AEFI detection are based on spontaneous reporting, however new methods are being developed to increase sensitivity, specificity and timeliness of reporting. In addition, new statistical methods are being developed and used to detect reported signals and may be used to distinguish them from the background incidence of the condition.

However, once a signal is detected, the assessment of causality between the event and the administration of a vaccine remains a difficult process. High sensitivity of signal detection systems may generate many alerts out of which, only a few are of real significance. Thus, the implementation of proper controlled epidemiological studies become of crucial importance and one of the few tools available for investigators to confirm or rule out causality and to quantify possible risk.

The existence of integrated systems for detection and management of AEFI is particularly important in the implementation phase of newly marketed vaccines or new combination of vaccines.

In the EU new vaccines are introduced according to common European Union (EU) regulatory procedures, which imply that they often are licensed with common indications for their use across the European countries. Although many countries use similar childhood vaccination schedules and also the same commercial products, they may concurrently administer different vaccines, measure vaccine coverage in different ways or in different age groups and have different systems for monitoring adverse events following immunisation (AEFI).

While the World Health Organization (WHO) has produced extensive guidelines on reporting and investigation of AEFI, the level of compliance to these guidelines and the feasibility of their application in EU remain to be investigated in a systematic way.

Many initiatives are currently ongoing at the EU level to optimize the different phases of the process of evaluating AEFI. The European Medicines Agency (EMEA) has set up an electronic database for the reporting of adverse reactions during the development and following the marketing authorization of medicinal products, including vaccines, in the
European Economic Area (EEA). Guidelines for the use of statistical signal detection methods in the Eudravigilance data analysis system have also recently been produced. The reporting obligations of the various stakeholders are defined in the Community legislation, in particular Regulation (EC) No 726/2004, Directive 2001/83/EC as amended and Directive 2001/20/EC. In addition on 25 January 2006, the European Commission published the Final Report of the Assessment of the European Community System of Pharmacovigilance contracted to the Fraunhofer Institute for System and Innovation Research, Karlsruhe. This report was based on a comprehensive audit of Member States’ systematic capabilities for data collection, data management, signal detection, safety issue assessment, decision-making and communication and action in the field of Pharmacovigilance.

The Vaccine European New Integrated Collaboration Effort (VENICE) project (http://venice.cineca.org), a European Commission DG-SANCO funded project, has collected information on systems in place in EU for monitoring of AEFI (Zanoni et al Vaccine adverse event monitoring systems across the European Union countries: Time for unifying efforts Vaccine (2009), doi:10.1016/j.vaccine.2009.01.059). The project aimed to deliver recommendations on common case definitions and study protocols for investigating aetiology in use and report on case studies focused on AEFI prevention and management.

Another DG-SANCO funded project, VACSATC - Vaccine Safety - Attitudes, Training and Communication (http://www.vacsatc.eu) – is currently working on the conduction of a feasibility study on the possibilities on linking large database systems to evaluate real or perceived vaccine safety issues.

The Brighton Collaboration (http://www.brightoncollaboration.org) has initiated development of case definitions for reporting of AEFI that are intended to enhance data comparability within and across clinical trials, surveillance systems, and retrospective epidemiologic studies. They have until now published case definitions for 21 AEFIs.

Although there are published recommended study protocols to carry out investigation of AEFIs, the feasibility of implementation of such protocols in individual EU countries has not been investigated. A Self-assessment tool, consisting of a serious of questions, has recently been developed by the VAESCO-project (http://vaesco.net), financed by ECDC, with the aim to offer a tool to Member States to evaluate the robustness of their reporting system: Protocol for evaluation of Detection, Reporting and Investigation Systems for Adverse Events Following Immunisation (AEFIs) in EU Member States (called Self-assessment tool hereafter). The same project has also established a Guidance document for evaluation of causal associations between immunizations and adverse events following immunization (AEFI) (called Guidance document hereafter).

The two documents, Self-assessment tool and Guidance document, are currently under revision at ECDC but available confidentially upon request to all applicants. Please forward your request in writing and signed, scanned via email to kari.johansen@ecdc.europa.eu. The request should clarify that the applicant undertakes to treat in the strictest confidence and not make use of or ever divulge to third parties this information/documents.

With the present tender the ECDC aims to continue its efforts to facilitate for the Member States to provide robust vaccine safety surveillance systems through sharing best practices for management of AEFI.
2. IMPLEMENTATION OBJECT OF THE CALL FOR PROPOSALS

2.1. Objectives of the call for proposals

The work to be carried out under the agreement to be awarded is organised in three main Work Packages (WPs) and the related objectives:

WP 1. Evaluation of AEFI reporting systems in EU Member States following a common Self-assessment tool provided by the ECDC.

WP 2. Conduction of pilot studies to assess possible causality of one or more AEFIs in EU Member States using the Guidance document, provided by ECDC.

WP 3. Establishment of AEFI monitoring and evaluation, using data linkage of databases in several EU Member States, on vaccination and clinical outcome in e.g. hospitalization registries/ death registries. Use the system to estimate background incidence rates of several clinical outcomes of interest in vaccine safety studies (details to be agreed with ECDC).

2.2. Main actors of the management and communication

Here below are outlined some details regarding the main actors of the project:

Coordinator – the Lead Institute - the host organisation with overall responsibility for the project. It consists of the Project Leader, who will be the chairman of the team, the Project Manager (see below), senior representatives from the host organisation and other relevant project staff. The Project Leader is the key contact person for liaising with ECDC and with Associate Partners.

Project Manager - the individual with overall responsibility for day-to-day project coordination and management. The Project Leader and Project Manager should both be employed by the Coordinator.

Associate Partners are the consortium members. They are responsible for coordinating and conducting part of the work plan at a regional or national level, are expected to contribute technical expertise, and play a key role in obtaining relevant data for the project as appropriate.

Management Team – consists of 3-5 people including the Project Leader and selected representatives from Associated Partners. The Management Team is expected to meet with the Steering Committee regularly throughout the project duration and not less than once every 6 months.

Steering Committee – will be established to oversee project activities and to ensure the quality and relevance for the European added value of the project. The Steering Committee will be formed by the ECDC, in consultation with the beneficiary of the partnership agreement. The Steering Committee will include the successful Applicant, ECDC and representatives from other Agencies that ECDC finds appropriate.

The successful Applicant shall collect input and exchange advice with the group of the ECDC Horizontal Project on Vaccine Preventable Diseases and proceed after agreement by the Head of the Scientific Advice Unit.
2.3. Characteristics of the agreement object of the call of proposals

ECDC wishes to conclude a framework partnership agreement with one applicant or a consortium of partners. The duration of this agreement is planned to be four years. The framework partnership agreement establishes the framework of the deliverables and requires an additional step to make the actual implementation. This is in the form of a specific grant agreement specifying the details for each particular implementation, based on the previously signed framework partnership agreement, and specifying the resources used. Due to calendar planning and in order to group processes, the submission of the first specific grant agreement is already requested with this application (see Section 3.1 concerning year 1).

The successful Applicant shall organize a consortium with other Institutions in at least other two selected countries in order to facilitate the project. The successful Applicant must submit the details of institutions involved.

The signature of the agreements shall be by one Lead Institute. Partner institutions give mandate to the Lead Institute for the performance of the agreement. A consortium arrangement between partners will ensure pooling of existing European knowledge and expertise in this area.

The coordinator shall ensure that consortium partners complete the formalities for them to accede to the contract. (see Article I.2 of the model Framework Grant Agreement in Annex II), including the duly completed and signed originals of Form A (set out in Annex III).

Under each item of the description of the work packages below it is specified what should be done during the first year specific grant agreement.

2.4. Deliverables

WP 1. Evaluation of AEFI reporting systems in EU Member States following a common Self-assessment tool provided by the ECDC.

- The evaluation of AEFI reporting systems is organised and overseen in EU Member States using the Self-assessment tool.

- Strengths and weaknesses in the Self-assessment tool are identified and the Self-assessment tool is updated.

WP 2. Conduction of pilot studies to assess causality of one or more AEFIs in EU Member States using the Guidance document, provided by ECDC.

- Pilot studies are organised and overseen in collaboration with EU Member States and the causal relationship is evaluated.

WP 3. Establishment of AEFI monitoring and evaluation using data linkage of databases in several EU Member States
• An AEFI monitoring and evaluation system is established using data linkage of databases in several EU Member States on vaccination AND clinical outcomes in eg. hospitalisation registries/death registries.

• The system is used to estimate background incidence rates of several clinical outcomes of interest in vaccine safety studies (details to be agreed with ECDC).

2.5. Description of work packages and related tasks of the successful applicant

For the various tasks of all three Work packages described in this proposal, the successful Applicant shall take into account and be complementary to the work carried out by the World Health Organization (WHO) on criteria of causality, the EMEA on regulations and requirements for AEFI reporting in EU, the VENICE project on the inventory of AEFI systems in EU, and the Brighton collaboration on AEFI case definitions.

The tasks of the successful applicant include:

Organize a start-up meeting for the project Vaccine Safety in Europe: Improving systems for reporting and evaluating potential Adverse events following immunization (AEFI) inviting representatives from the Consortium and ECDC (see section 3.3 on meetings).

Organize a meeting towards the end of Year 1 to evaluate the outcomes from WP 1-3 and plan for further activities (see section 3.3 on meetings).

WP 1. Evaluation of AEFI reporting systems in EU countries following a common Self-assessment tool provided by the ECDC.

Year 1

• Invite 4-5 Member States that voluntarily wish to evaluate their Reporting system for AEFI through the Self-assessment tool.

• If necessary, subcontract personnel in the relevant Institution in the country evaluating their Reporting system for AEFI.

• Encourage Member States with different Pharmacovigilance systems to participate.

• Instruct the participating Member States how to utilize the Self-assessment tool.

• Perform a country visit to each participating Member State and discuss the outcome of the Self-assessment. Experts from ECDC and other Agencies appointed by ECDC should participate in as many country visits as judged by ECDC fit. Confidentiality agreements must prior to the country visits be developed and signed by experts participating.
• Write a report on the outcome of the Self-assessment in the individual countries, to be confidentially shared with ECDC and other Agencies that ECDC finds appropriate.

• Write an evaluation report/scientific article on general strengths and weaknesses in the Self-assessment tool aiming for a report on best shared practices after visiting the 4-5 Member States.

• Based on the results update the Self-assessment tool.

Year 2-4

The implementation of this phase is subject to budget availability and the satisfactory outcome of the previous phase.

• Invite new Member States that voluntarily wish to evaluate their Reporting system for AEFI through the Self-assessment tool.

• Perform a country visit to each participating Member State and discuss the outcome of the Self-assessment. Experts from ECDC and other Agencies appointed by ECDC should participate in as many country visits as judged by ECDC fit. Confidentiality agreements must prior to the country visits be developed and signed by experts participating.

• Write a report on the outcome of the Self-assessment in the individual countries, to be confidentially shared with ECDC and other Agencies that ECDC finds appropriate.

WP 2. Conduction of pilot studies to assess possible causality of one or more AEFIs in EU Member States using the Guidance document provided by ECDC.

Year 1

• Invite 2-3 Member States that voluntarily wish to assess causality of one or more AEFIs using the Guidance document.

• If necessary, subcontract personnel in the relevant Institution in the country evaluating their Reporting system for AEFI.

• Encourage Member States with different Pharmacovigilance systems to participate.

• Instruct the Member State how to utilize the Guidance document.

• Perform a country visit to each participating Member State and discuss the outcome. Experts from ECDC and other Agencies appointed by ECDC should participate in as many country visits as judged by ECDC fit.
• Write an evaluation report/scientific article on the studies performed and on the general strengths and weaknesses in the Guidance document aiming for a scientific article on best shared practices after performing pilot epidemiological causality assessment studies in 2-3 countries.

• Based on the results update the Guidance document.

Year 2-4
The implementation of this phase is subject to budget availability and the satisfactory outcome of the previous phase.

• Invite for further causality assessments in Member States that voluntarily wish to assess causality of one or more AEFIs using the Guidance document in as many EU Member states as possible.

• Write an evaluation report on best shared practices for epidemiological causality assessment studies.

WP 3. Establishment of AEFI monitoring and evaluation using data linkage of databases in several EU Member States, on vaccination and clinical outcome in e.g. hospitalisation registries/ death registries.

The implementation and especially the work within this work package must comply with data protection requirements (EU Directives 95/46/EC).

Year 1
• Arrange a workshop in collaboration with ECDC on database linked AEFI monitoring and evaluation studies. If possible arrange this workshop back to back with the start-up meeting of the project. The successful Applicant shall, in doing this, explore interest in and possibilities for networking between interested organisations with access to medical databases related to childhood and adult vaccination and clinical outcomes in various member states and on the international level and determine the optimal way to proceed. When preparing budget for this workshop allocate budget for 2-3 invited international speakers.

• Identify several countries (4-5 recommended) able to do studies on AEFI using linkage of different databases (eg databases on AEFIs and hospitalisation registries/death registries), linking individual level data on childhood and adult vaccination status with data on clinical outcomes.

• Perform a pilot study coordinating information from data linkages in Member States initially using a known association between an adverse event and a certain vaccination as a positive control before continuing with testing a new hypothesis.

• Use the system to estimate background incidence rates of several clinical outcomes of interest in vaccine safety studies (details to be agreed with ECDC).

• Write an Evaluation report and a Scientific report for a peer reviewed journal on possibilities and obstacles for developing a Vaccine Safety Data linkage system in Europe including a plan for sharing best practices in data linkage studies.
Year 2-4

The implementation of this phase is subject to budget availability and the satisfactory outcome of the previous phase.

- Invite new Member States to do studies on AEFI using linkage of different databases (eg databases on AEFIs and eg hospitalisation registries/death registries), linking individual level data on childhood and adult vaccination status with data on clinical outcomes.
- Write an evaluation report on sharing best practices in data linkage studies.

2.6. Meetings:

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

- Propose the list of participants and seek ECDC input and approval prior to the meeting and provide the scope and purpose of 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
  - Organize travel for all participants: Cover all costs related to the travel of experts (2nd class) – public transport only – to come to the meeting. Organize meals and accommodation for all participants. The successful applicant will be paid, for covering the costs of the participants, the country-specific fixed rate indicated in Annex VI Rules on Eligibility of Costs of the draft agreement per participant and per day, after conclusion of the module, upon proof of participation by a participants’ list signed by each participant for each meeting day.
  - Provide the meeting venue as appropriate, ensuring smooth implementation and ideal working conditions; including all relevant material such as personal computer, overhead projector, 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 are held in English.
- Provide printed material related to the meeting.
- 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.
- Collect presentations.
- Write a short report of the main discussion points of the meeting, including the recommendations and action points.
- Provide the meeting material and report.
2.7. **Amount available for financial support and provisions about the results**

The estimated grant for the two year period of the project (covering all activities in WP1-WP4) is 450,000 EUR. This is however subject to budget availability. The maximum grant amount will be determined time by time, contingent on the available budget and on the work plan of ECDC.

For the activities expected to commence in 2009, estimated funding available from ECDC is 230,000 EUR.

The ECDC will contribute 90% of the total eligible costs and the successful applicant will co-finance the remaining 10% of the total eligible costs.

Applicants must apply the Rules on eligibility of costs (see Annex VI of this Call).

The ultimate aim is an active cooperation between ECDC and the successful Applicant/Consortium for the duration of the project.

Ownership of the results of the project (action, work packages), including industrial and intellectual property rights, and of the reports and other documents relating to it shall be vested in the ECDC.

Without prejudice to the previous paragraph, the ECDC grants the partner the right to make free use subject to prior written consent of ECDC of the results of the project (action) as it deems fit, provided it does not thereby breach its confidentiality obligations or existing industrial and intellectual property rights.

ECDC should be acknowledged / mentioned as provider of funding on all communications meaning the ECDC logo and a disclaimer will be put on all reports, website, bulletins, etc.

All activities and products will be transferred to ECDC after the completion of the agreement. During the project period, a detailed transition plan will be developed in close collaboration with the Coordinator so that at the end of this agreement subsequent activities will be coordinated by ECDC.

2.8. **Reporting requirements**

The following reports are requested to be submitted:

The reports related to the deliverables of the call for proposal, in particular those indicated at:

- The last three tasks (bullet points) for WP1 year 1
- The last two tasks (bullet points) for WP2 year 1
- The last task (bullet point) for WP3 year1
- The last task (bullet point) for WP1 years 2 to 4
• The last task (bullet point) for WP2 years 2 to 4

• The last task (bullet point) for WP3 year 2 to 4

The reports related to the financial management of the implementation:

• A financial statement supporting the request for payment: The costs here declared by the partner shall be real, accurately recorded and eligible, in accordance with the framework agreement and the specific agreement. The supporting documents are not requested to be submitted and are kept by the partners, according to their accounting and internal auditing procedures. They must permit direct reconciliation of the costs and revenue declared for the implementation with the corresponding accounting statements and supporting documents, in compliance with Article II.22 - Checks and Audits of the agreement.

• A comprehensive condensed technical report on the implementation

• Relevant written correspondence, including ECDC’s approval on any item mentioned above

2.9. Payments

Payments for the year 1 Specific Grant Agreement will be performed as follows:

• 40% pre-financing upon receipt of a request for pre-financing that can also be submitted together with the agreement for signature.

• 75% interim payment upon receipt of a draft a report on the outcome of the Self-assessment in the individual countries and a draft evaluation report/scientific article on the studies performed and on the general strengths and weaknesses in the Guidance document.

• 25% final payment upon receipt and approval of a final invoice, final financial and technical report, the related supporting documents, all the deliverables and scientific paper ready for submission.

For specific grants agreements for the successive years, the payment schedule will be established when there is the request for resources allocation and budget.

2.10. Profile of the expected applicants

Applicants can be a public or a private entity, including a consortium of institutions from different countries, with the following requirements:

Essential requirements for Work Packages 1-3 are

1. Extensive involvement in Public Health activities and/ or Pharmacovigilance either at local, national or international level.

2. Extensive experience in surveillance activities including setting up of new surveillance systems, evaluation of surveillance systems, surveillance of vaccine preventable diseases.
3. Extensive expertise in vaccine programme management at national or local level.
4. Expertise in AEFI detection, management and reporting.
5. Have skills for the coordination of a multinational network of public health institutes.
6. Expertise in data management and setting up of large linked databases. Expertise in database linked studies
7. Experience in setting up a risk management plan.
8. Experience of data reporting to international organizations (EMEA, WHO, European surveillance networks).
9. Experience in setting up epidemiological studies for the assessment of causality of AEFI.
11. Expertise in database linked studies related to adverse events following medication.
12. Expertise and experience in pharmacoepidemiological analysis.
13. Experience in coordinating data analysis across various databases in different formats in a common analysis.

For all the above, please provide documents supporting relevant experience.

#### 2.11. Indicative time frame 1st year

<table>
<thead>
<tr>
<th>Tasks</th>
<th>WP 1 Agreement signature and kick off meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Field evaluation country 1</td>
</tr>
<tr>
<td>1.2</td>
<td>Field evaluation country 2</td>
</tr>
<tr>
<td>1.2</td>
<td>Field evaluation country 3</td>
</tr>
<tr>
<td></td>
<td>Field evaluation country 4</td>
</tr>
<tr>
<td></td>
<td>Field evaluation country 5</td>
</tr>
<tr>
<td>1.2</td>
<td>Draft report</td>
</tr>
<tr>
<td>1.2</td>
<td>Post field evaluation meeting</td>
</tr>
<tr>
<td>1.2</td>
<td>Final report year 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tasks</th>
<th>WP 2 Agreement signature and kick off meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Pilot epidemiological study in country 1</td>
</tr>
<tr>
<td>2.2</td>
<td>Pilot epidemiological study in country 2</td>
</tr>
<tr>
<td>2.3</td>
<td>Pilot epidemiological study in country 3</td>
</tr>
</tbody>
</table>
### 2.4 Draft report

### 2.5 Post pilot epidemiological study meeting

### 2.6 Final report year 1

<table>
<thead>
<tr>
<th>Tasks</th>
<th>WP 3 Agreement signature and kick off meeting/workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Inventory of EU countries capacity</td>
</tr>
<tr>
<td>3.2</td>
<td>Performing pilot study using in 3-4 countries</td>
</tr>
<tr>
<td>3.3</td>
<td>Draft report</td>
</tr>
<tr>
<td>3.4</td>
<td>Post pilot study using data linkages meeting</td>
</tr>
<tr>
<td>3.5</td>
<td>Final report year 1</td>
</tr>
</tbody>
</table>

### 2.12. Implementation of the Work Packages in years 2 to 4

By the end of October, the successful applicant is requested to present a detailed description of each of the three Work Packages, including meetings, for the deliverables concerning each year from 2 to 4, including the relative budgets and workplan, with timeline, approach and list of milestones and deliverables.

### 3. CONTENT OF THE APPLICATION

#### 3.1. THE DEADLINE FOR APPLICATION IS 24 APRIL 2009

#### 3.2. The proposal to submit to ECDC should include:

- An outline of the whole project.

- A detailed description of each of the three Work Packages (WP) including meetings, for the deliverables concerning year 1, together with a detailed list of the countries/institutions that will be potentially part of the consortium (EU and EEA/EFTA wide coverage has to be ensured). A detailed workplan with timeline, approach and list of milestones and deliverables for the work shall be presented.

- An outline of further activities, including meetings, to be conducted under the three work packages, for the successive years.

The offer from an Applicant should include a technical and financial proposal per Work Package including country visits, meetings, and workshop.

For the evaluation using the **Self-assessment tool**, a sum per country evaluated should be mentioned and for the pilot studies using the **Guidance Document**, a sum per study conducted should be mentioned.
The detailed description of activities and deliverables for these subsequent activities will only be discussed and negotiated afterwards, based on an invitation by ECDC to submit a proposal in accordance with Article I.4 of the framework partnership agreement and taking into account the budgetary context at that time.

The framework partnership agreement will be signed by the Coordinator of the consortium.

3.3. Management and Communication Plan

A preliminary project Management plan should be designed and submitted as part of the proposal for this grant.

The Management plan should clearly describe members of this consortium (Associate Partners) and delineate responsibilities. It should describe the project organisation i.e. a Coordinator, Project Leader, Project Manager, Associate Partners. The Management Plan should also include a Communication Plan (see below). Description of project organisation should also include the interaction with the Steering Committee. A project organigram showing links between participating partners should be included.

The Communication Plan should outline both internal and external communication.

(a) The internal component of the Communication Plan should include organising, conducting and chairing meetings of the Management Team via teleconferences and/or face-to-face meetings; expert workshops; and regular meetings with the Steering Committee. Internal communication should also consist of a monthly project status report submitted to ECDC.

(b) The external component of the Communication Plan relates to the dissemination of the final results and should be further detailed. These activities will be coordinated closely with ECDC and will include: (1) presenting results at medical conferences/congresses, (2) publishing study results in peer-reviewed journals, (3) designing and launching a website to display project objectives, methodologies and results, (4) periodic project bulletins, (5), the organisation of project workshops.

4. EVALUATION OF THE PROPOSALS

After having verified the compliance with all the submission requirements (see 4.1), ECDC selects the admissible proposals through a procedure that involves 4 types of evaluation criteria in this order:

(1) eligibility criteria (see 4.2),
(2) exclusion criteria (see 4.3),
(3) selection criteria (see 4.4),
(4) award criteria (see 4.5).

If the submission requirements are not met, the proposal is rejected without looking at the eligibility, selection or award criteria. If the eligibility and non exclusion criteria are not met, the proposal is rejected without looking at the selection or award criteria. If the selection criteria are not met the proposal is rejected without looking at the award

If the submission requirements are not met, the proposal is rejected without looking at the eligibility, selection or award criteria. If the eligibility and non exclusion criteria are not met, the proposal is rejected without looking at the selection or award criteria. If the selection criteria are not met the proposal is rejected without looking at the award
criteria. It is therefore essential to complete the proposal in full and provide all the supporting documents requested.

**An Evaluation Committee** will be established in accordance with article 116 of the Financial Regulation and article 178 of its Implementing Rules in order to evaluate the submitted proposals. ECDC intends to finalise the evaluation of proposals within one month since the final deadline for submission of proposals. In compliance with article 116 (3) of the Financial Regulation, the applicant will be informed in writing of the decision on their proposal. Please note that ECDC has the right not to award a grant and to cancel the procedure at any time before the signature of the agreement without any compensation to be paid to the applicants.

**General principles:**
In compliance with the Financial Regulation and its Implementing Rules, the proposals must comply with the following principles:

- **Co-financing rule:** external co-financing from a source other than EU budget is required as indicated in part 2.7.
- **Non-profit rule:** the grant may not have the purpose or effect of producing a profit for any of the applicants;
- **Non-retroactivity rule:** the costs eligible for financing must be incurred after the starting date stipulated in the agreement;
- **Non-cumulative rule:** only a single EU grant may be awarded for a specific project carried out by a given beneficiary in one financial year.

**4.1. Verification of submission requirements**

The following will be assessed:

- **The final deadline for submission of proposals:** If this deadline has not been respected the proposal will automatically be rejected.
- **The proposal is duly signed** by the duly authorized representative of the consortium. If the proposal is not signed then it may be rejected on that sole basis.
- **The proposal is complete, including all supporting documents and in accordance with the model structure (Annex I).** If any of the requested information/documents is missing or is not complete the proposal may be rejected on that sole basis.

The proposal which meets all the submission requirements will be considered admissible and will pass to the next stage of evaluation process – verification of eligibility criteria.

**4.2. Eligibility criteria**

Consortia consisting of at least two partners (natural/legal persons, private or public), these partners being established in different ECDC member countries (the 27 EU Member States and EEA/EFTA counties which are Iceland, Liechtenstein and Norway), are eligible.

A **LEGAL ENTITY FORM** has to be completed and signed separately by the applicant (each partner of the consortium). This legal entity form should be returned together with a copy of the public legal act establishing the entity in question or failing that, any other official document attesting to the establishment of the entity, clearly indicating it pursues public interest objectives. ECDC provides a template to be used – Annex V.
4.3. Exclusion criteria

Article 114(2) of the Financial Regulation states that “Grants may not be awarded to applicants who are, at the time of a grant award procedure, in one of the situations referred to in Articles 93 and 94”. Accordingly, applicant and possible partners must certify that they are not in one of the following exclusion situations:

(a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

(b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;

(c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;

(d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the implementation is to be performed;

(e) they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;

(f) following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

In addition, grants may not be awarded to applicants who, at the time of the selection procedure:

(a) are subject to a conflict of interest;

(b) are guilty of misrepresentation in supplying the information required by ECDC as a condition of participation in the award procedure or fail to supply this information.

(c) find themselves in one of the situations of exclusion listed above.

Applicants must certify that they are not in one of the situations listed above by signing the attached Declaration on Honour (Annex IV). The Declaration on honour is to be completed and signed separately by each consortium partner.

The consortium with which the partnership agreement will be signed must provide evidence confirming the declaration referred to in the previous point.
4.4. Selection criteria

Financial capacity:

Evidence of the *consortium’s* economic and financial capacity shall be furnished by the following documents:

- proof of stable and sufficient sources of funding to maintain the *consortium’s* activity throughout the 4 year partnership period;
- for private partners: profit and loss accounts, balance sheet for the last financial year for which the accounts were closed (and audit reports by an approved external auditor certifying the accounts for the last available financial year).

Technical and professional capacity:

Evidence of the *consortium’s* technical and professional capacity to carry out the envisaged project shall be furnished on the basis of the following documents:

1. Detailed CVs (indicating the level of English/other language skills\(^1\)) as well as letters of intent of the core staff and key experts of all consortium partners assigned proposed for the project, proving that the *consortium* as a whole has sufficient technical, scientific and management (including financial) experience to implement the project.

It is preferable that the consortium includes partners from different EU MS and EEA/EFTA countries in order to assure wide EU research collaboration between the countries. It is important to have collaborators from different EU MS and EEA/EFTA countries who could provide data and collaborate on national and regional level to achieve the project objectives.

2. Examples of work done in the areas covered by this call for proposals in the past three years; clearly indicating the role of the contributors.

3. A presentation of the organisation of consortium and its internal organisation. Proposals must specify the role, qualifications and experience of each of the members of the consortium.

Every *consortium* submitting a proposal shall nominate a Coordinator who will alone interface with the Centre.

4. Letters of intent of all consortium partners to participate to the project and to provide co-financing to the project for at least 10 % of the total eligible costs of the work packages\(^2\).

---

1 Languages abilities: statement of the candidate’s language abilities. Most of the work will be performed in English. The core staff/key experts must demonstrate a strong ability to draft and operate in this language and provide examples of previous work

2 The 10%-rule of minimum co-financing is applied towards the *consortium* as a whole. To what extent partners contribute to this co-financing is an internal *consortium* matter. Before awarding any grant through Specific Agreements (SAs) based on Framework Partnership Agreements (FPA(s)), (the) *consortium(a)* must furnish proof of the amount of co-financing to be provided (Article I.6.2 FPA).
4.5. Award criteria

The framework agreement will be awarded to the proposal which will obtain the highest score, taking into account the following criteria; no award criteria and sub criteria others than these will be used to evaluate the proposal.

<table>
<thead>
<tr>
<th>Award criterion 1: Technical implementation</th>
<th>20 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Understanding of the context</td>
<td></td>
</tr>
<tr>
<td>ii) Degree to which the proposed implementation responds in a credible way to the call for proposals</td>
<td></td>
</tr>
<tr>
<td>iii) How the deliverables are apt be disseminated and have an impact</td>
<td></td>
</tr>
<tr>
<td><em>(The above aspects are of the same relative value)</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Award criterion 2: Methodology</th>
<th>35 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Soundness of the proposed analytical basis</td>
<td></td>
</tr>
<tr>
<td>ii) Soundness of the proposed methodology</td>
<td></td>
</tr>
<tr>
<td>iii) Use of the appropriate tools for carrying out the planned tasks</td>
<td></td>
</tr>
<tr>
<td>iv) Sufficient guarantee that all deliverables of the project will be carried out from a multi-disciplinary and pan-EU perspective</td>
<td></td>
</tr>
<tr>
<td><em>(The above aspects are of the same relative value)</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Award criterion 3: Project team and management</th>
<th>25 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Allocation and management of resources and expertise</td>
<td></td>
</tr>
<tr>
<td>ii) Coordination and mobilization of the team and possible subcontractors</td>
<td></td>
</tr>
<tr>
<td>iii) Realistic time deadlines for completion of tasks and work plan</td>
<td></td>
</tr>
<tr>
<td>iv) A group of relevant partners who work together as a multi-disciplinary team</td>
<td></td>
</tr>
<tr>
<td><em>(The above aspects are of the same relative value)</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Award criteria 4: Cost effectiveness</th>
<th>20 points</th>
</tr>
</thead>
<tbody>
<tr>
<td>The extent to which the estimated budget is cost-effective (comparison between estimated cost and anticipated achievement of objectives/results)</td>
<td></td>
</tr>
</tbody>
</table>

Minimum attainment per award criterion

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

Minimum attainment overall

Proposals scoring less than 60% after the evaluation process will be considered to be of insufficient quality and eliminated from the following phase.
5. ANNEXES

I. Model proposal (structure)
II. Model of Framework Partnership agreement
III. Model of Specific grant agreement
IV. Declaration on honour on exclusion criteria
V. Financial identification and legal entity forms
VI. Rules on eligibility of costs
VII. List of previous/current EU grants