

GUIDE FOR APPLICANTS

GRANT FOR PROJECT

PILOT PROJECT ON Establishing a registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations

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GLOSSARY

The Pilot Project on Establishing a Registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations is the Pilot project "Registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations " as described in the Commission Decision C(2016) 5651final of 08 September 2016.

A beneficiary is an organisation that receives EU co-funding following successful application in one of the EU's funding programmes and the signature of the related grant agreement (during the application process reference is made to the "applicant(s)").

A multi-beneficiary grant agreement (MGA) is a binding written agreement signed by the parties European Commission and the beneficiary organisations, i.e. the recipients of the EU co-funding. By signing the agreement, the beneficiary organisations accept the grant and agree to implement the action under their responsibility and in accordance with the agreement with all the obligations and conditions that the latter sets out.

The **Consumers, Health, Agriculture and Food Executive Agency (Chafea)** manages the technical and financial implementation of the EU Health Programme, the Consumer Programme, the Better Training for Safer Food initiative and the Agri promotion actions provided for in Regulation. In the frame of the current Pilot Project, it will assist the Commission with the on-line submission of proposals.

The **Participant Portal (PP)** is the website hosting the information about funding for this Pilot Project

The ECAS account is the European Commission's Authentication Service. It is the system for logging on to a whole range of websites and online services run by the Commission.

The Beneficiary Register is the European Commission's online register of the beneficiaries participating in the Health and Consumers Programmes and in Horizon 2020 programmes. This allows consistent handling of the beneficiaries' official data and avoids multiple requests for the same information.

The Participant Identification Code (PIC number) is a 9-digit participant identification code, received upon completing the registration of the entity online.

The LEAR (Legal Entity Appointed Representative) is the appointed representative within the beneficiary organisation. He/she is authorized to manage all the organisation-related data on the Participant Portal and appoints representatives within their organisation to electronically sign grant agreements or financial statements for project costs.

PREFACE

Dear Applicant,

Welcome to the Guide for Applicants (the Guide) which is intended to help you in preparing and submitting a project proposals for the Pilot Project on Establishing a Registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations.

Applicants must submit their proposals via the Electronic Submission System. This will make the submission, evaluation and, for those recommended for funding, granting, monitoring and reporting quicker, simpler and more efficient.

The present Guide for Applicants – Projects ('the Guide') is designed as the main reference document to help you prepare the proposal. It provides all the necessary information for preparing and submitting your application and answer questions you may have in this process. Please note that this Guide does not supersede the rules and conditions laid out in the following documents which should be consulted in case of doubt:

- Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) no 1605/2002, hereafter referred to in this document as the [Financial Regulation](#);
- Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, hereafter referred to in this document as the [Rules of Application of the Financial Regulation](#);
- Commission Decision C(2016) 5651 final of 08 September 2016 on the adoption of a financing decision for 2016 on the pilot project " Establishing a registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations ", hereafter referred to in this document as Pilot Project on registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations;
- Call for proposals for the Pilot Project on Registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations, hereafter referred to in this document as the [Call for proposals](#);
- The multi-beneficiary action model grant agreement, hereafter referred to in this Guide as the *Model grant agreement*.

VERY IMPORTANT: This guide was prepared for multi-beneficiary applications. In case of a single entity application, the provisions of the guide will apply *mutatis mutandis*. If successful, a single beneficiary grant agreement will be signed.

This Guide consists of three main parts (Part A, Part B, and Part C)

Part A: Legal framework and participants

This section describes the legal terms and general conditions for participation.

Part B: Submission of proposals

This section describes the entire process of submission of proposals and has two sub-sections:

The first sub-section refers to the necessary preparatory steps. This includes: (1) reference to the background documents that you need to consult prior to preparing a project proposal; (2) instructions on the process for creating a user account or an ECAS account (more on the ECAS account is presented in Chapter B, paragraph 1.2) and (3) the registration of the applicant organisation at the European Commission's Beneficiary Register (more on the Beneficiary Register is presented under paragraph 1.3); and (4) general recommendations on how to best prepare your proposal.

The second sub-section guides you through the different steps of the application process itself: it covers the registration process for the participating legal entities; and the actual submission process itself, namely completing the so-called Part A (administrative information and budget of the proposal) and Part B (technical and financial content) of the Electronic Submission System.

Part C: Evaluation process of the applications

This section describes the evaluation process and criteria when reviewing and evaluating the submitted proposals. It also provides information on the evaluation outcomes issues, as well as the process following a recommendation for funding.

In case of further questions the following options are at your disposal:

- For information on how to register or related enquiries please look on the [Participant Portal](#):
- IT helpdesk – you can contact the Participant Portal IT helpdesk for questions only related to the online submission tool such as forgotten passwords, access rights and roles, technical aspects of submission of proposals, etc. Requests must be submitted via the [Research Enquiry Service](#), by completing the form
- For non-IT related questions, please contact DG SANTE helpdesk at the European Commission email: SANTE-PP-CALLS@ec.europa.eu

Finally, please be aware that submitting your proposal can take some time even if you have all the necessary information ready at hand. Do not wait until the deadline to start the online submission process. We strongly advise you to complete your proposal sufficiently in advance so as to avoid any last minute problems.

Good luck!

A. LEGAL FRAMEWORK AND PARTICIPANTS

1 OBJECTIVES OF THE PILOT PROJECT ON ESTABLISHING A REGISTRY OF RARE CONGENITAL MALFORMATIONS (AS PART OF THE RARE DISEASE REGISTRY), DRAWING ON THE STRUCTURE, ORGANISATION AND EXPERIENCE OF THE REGISTRY OF CONGENITAL MALFORMATIONS

The Financing Decision for the pilot project "Establishing a registry of rare congenital malformations (as part of the Rare Disease Registry), drawing on the structure, organisation and experience of the Registry of Congenital Malformations" was adopted on 08 September 2016. Its Annex sets out the main priority areas for this pilot project on to be implemented through the present call:

- The key objective of this pilot project is to set up a registry of rare congenital malformations as a part of rare diseases national registers. The project should be implemented at a national level.
- The secondary aim of the project is to provide an example of how to extend an existing birth defects registration and surveillance system to a rare diseases registration system.
- The birth defects registration system has already been set up in several MSs as part of the EUROCAT surveillance network. The pilot project provides a model for exploring whether a birth defects registry can be extended to form a rare diseases registry.
- The pilot project should contribute to the development of an EU Platform on Rare Diseases Registration to provide a common access point to data collections on rare diseases across Europe and to be compatible with platform tools.

2 EU FINANCIAL CONTRIBUTION

EU co-financing for projects is calculated on the basis of eligible costs actually incurred. The maximum rate of EU co-financing is 80%.

Given the complementary and motivational nature of EU grants, projects are financed under the co-financing principle⁽¹⁾. If the amount granted is lower than the funding sought by the applicant, it is up to the latter to find supplementary financing or to cut down on the total cost of the project without diluting either the objectives or the content.

3 ADMISSIBILITY REQUIREMENTS

- Applications must be submitted online via the [participant portal](#).
- Applications must be drafted in one of the EU official languages.

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

In principle, project proposal applications may be submitted in any official language of the European Union. However, if the technical part (part B) of the application is written

¹ Art. 125 of the Financial Regulation and Art. 183 of the Rules of Application.

in another EU official language, it should also include an English translation in order to facilitate assessment by the evaluators.

Proposals received after the deadline for submission laid down in the call for proposals will not be considered for funding.

4 ELIGIBLE APPLICANTS

The eligibility criteria are laid down in the text of the Calls for proposals.

The following main elements are especially drawn to the attention of applicants:

- Only legal persons or entities which have legal personality under the applicable national law (provided that their representatives have the capacity to undertake legal obligations on behalf of the entity and offer guarantees for the protection of the Union's financial interests equivalent to those offered by legal persons) are eligible as applicants. The application shall state the legal status of the applicant.
- Only applications from entities established in one the following countries are eligible:
 - One of the 28 EU Member States;

5 ROLE AND RESPONSIBILITY OF BENEFICIARIES

Roles and responsibilities towards the Commission

If a proposal is successful and a grant agreement is signed between the applicants and the Commission, the terminology is changed from "applicant" to "beneficiary".

The beneficiaries have full responsibility for implementing the action and complying with the Multi-Beneficiary Grant Agreement (MGA).

The beneficiaries are jointly and severally liable for the technical implementation of the action as described in the proposal, which will become Annex 1 to the grant agreement, if the project is selected for co-funding.

If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the Commission expressly relieves them of this obligation.

The financial responsibility of each beneficiary is governed by Articles 28, 29 and 30 of the MGA.

Different entities can be involved in a project. These categories are as follows:

- Coordinator;

The coordinator must:

- Monitor that the action is implemented properly (see Article 7 of MGA);

- Act as the intermediary for all communications between the beneficiaries and the Commission (in particular, providing the Commission with the information described in Article 12 of MGA), unless the MGA specifies otherwise;
- Request and review any documents or information required by the Commission and verify their completeness and correctness before passing them on to the Commission;
- Submit the deliverables and reports to the Commission (see Articles 14 and 15 of MGA);
- Ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 16 of MGA);
- Inform the Commission of the amounts paid to each beneficiary, when required in the MGA (see Articles 28 and 34) or requested by the Commission.

Note:

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

- Other beneficiaries;

Each beneficiary must:

- Keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 12 of MGA);
- Inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 12 of MGA);
- Submit to the coordinator in good time:
 - Individual financial statements for itself and its affiliated entities (if applicable) and, if required, certificates on the financial statements (see Article 15 of MGA);
 - The data needed to draw up the technical reports (see Article 15 of MGA);
 - If applicable, ethics committee opinions and notifications or authorisations for activities raising ethical issues ;
 - Any other document(s) or information required by the Commission under the MGA, unless the MGA requires the beneficiary to submit this information directly to the Commission.

- Subcontractor(s);

- Subcontractors are not parties to the grant agreement. They do not have a contractual relationship with the Commission.
- If necessary to implement the action, the beneficiaries may award contracts covering the implementation of certain tasks of the co- financed action as

described in the proposal (the latter will become Annex 1 to the grant agreement if the project is selected for co-funding).

Note:
subcontracting may only cover a limited part of the action.

- Collaborating stakeholders;
 - The collaborating stakeholders may significantly increase the technical and scientific content of the project, as well as its relevance for different users in the Union.
 - They have no contractual relationship with the Commission, nor do they receive any EU funding.
 - Note that it is not mandatory to involve collaborating stakeholders entities in your project.
- Affiliated entities.
- Affiliated entities have to comply with the exclusion and eligibility criteria. While they do not sign the grant agreement, they can actively contribute to the implementation of the action. The names of the affiliated entities participating in the implementation of the action should be listed in the grant agreement (Article 11) and tasks attributed to them described in Annex I. They may declare as eligible the costs they incur in accordance of Article 6.3.

There are two options how entities can be affiliated to each other:

1. Several entities together form one entity, possibly specifically established for the purpose of implementing the action. They will be treated as one entity.
2. A beneficiary has entities with legal or capital links. These links are not limited to the action nor established just to implement it.

Please also refer to Article 122 of the Financial Regulation.

Note:
in respect to equal treatment, the partnership cannot change after the submission of a project proposal.

Number of participants and dimension of the proposal

A proposal should involve one or more independent legal entities established in an EU Member States. On the one hand, the number of beneficiaries in a given proposal should reflect a European dimension of the proposed action and should make sense.

On the other hand, the management of projects with a very large number of beneficiaries has proven to be administratively difficult. The number of beneficiaries need to be considered carefully.

6 FINANCIAL ASPECTS

Applicants need to conform to the principles and rules as set out by the EU Financial Regulation, i.e. the financial rules applicable to the general budget of the Union and the related rules of application of the financial regulation and most importantly provisions under Title VI (Grants).

This section provides information on the general aspects of financial management of a grant in order to have a better understanding of the applicable principles and rules that need to be taken into account within the context of preparing and submitting your application.

6.1 General principles applicable to grants providing EU co-funding

Grants awarded must comply with the following principles:

- Principle of non-cumulative award

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

In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, applicants shall indicate the sources and amounts of Union funding received or applied for the same action or part of the action or for their functioning during the same financial year as well as any other funding received or applied for the same action.

- Principle of non-retroactivity

No grant may be awarded retrospectively for actions already completed.

A grant may be awarded for an action, which has already begun only where the applicant can demonstrate the need to start the action before the grant agreement is signed.

In such cases, costs eligible for financing may not have been incurred prior to the date of submission of the grant application.

- Principle of co-financing

Co-financing means that the resources, which are necessary to carry out the action, may not be entirely provided by the EU budget.

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

- the beneficiary's own resources,
- income generated by the action,
- financial contributions from third parties.

- No-profit principle

Grants shall not have the purpose or effect of producing profit. Profit is defined as surplus of the receipts over eligible costs incurred by the beneficiary at the time of payment request.

6.2 Planning the budget of the action

6.2.1 Form of the grant

The grant is a partial *reimbursement* of the action's total *eligible costs* at the reimbursement rate defined under point 2 of the present guide ("EU Financial Contribution"). The grant is expressed both as a maximum amount and also as a pre-defined percentage of the eligible costs.

In other words, the *grant has a double ceiling*: the maximum amount and the reimbursement rate is applied on the total eligible cost. These key data will be set in the grant agreement, please refer to article 5 of the model grant agreement.

6.2.2 Definition of eligible costs

Eligible costs must meet the following *cumulative* criteria:

- they must be *actually incurred by the beneficiary*;
- they must be *incurred within the period of the action* set in the grant agreement, with the exception of costs relating to the submission of the final report.;
- they must be *indicated in the estimated budget*;
- they must be *incurred in connection with the action* and necessary for its implementation;
- they must be *identifiable and verifiable*, in particular *recorded in the beneficiary's accounts* in accordance with the accounting standards applicable in the country where the beneficiary is established and *with the beneficiary's usual cost accounting practices*;
- they must *comply with the applicable national law* on taxes, labour and social security, and
- they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

Please refer to article 6 of the model grant agreement.

6.2.3 Description of cost types

Costs of the action must be established in the following cost categories – please consult with article 6.2 of the grant agreement for a detailed description.

Note: Costs of affiliated entities must be also estimated by the applicant they are linked to. Please also refer to article 6.3. of the grant agreement.

Personnel costs

Personnel costs are eligible if they are related to personnel working for the beneficiary under an *employment contract* (or equivalent appointing act) and *assigned to the implementation of the action*.

In addition, the following costs can also be recognised as personnel cost:

- The *costs for natural persons* working under a *direct contract with the beneficiary other than an employment contract*, if certain conditions apply;
- Cost of *personnel seconded by a third party against payment* if costs are incurred by the beneficiary.

Please refer to art. 6.2. of the model grant agreement for a detailed presentation of the conditions that need to be fulfilled.

In line with the Financial Regulation the salary costs of **public officials** will be considered as direct cost of the beneficiary to the extent that they relate to the cost of activities which the relevant public authority as beneficiary would not carry out if the project concerned was not undertaken.

Cost of Subcontracting

Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT)) paid by the beneficiaries that are not public bodies acting as public authority are eligible if the conditions of Article 10.1.1 are met:

Subcontracting costs:

- Must be justified having regard to the nature of the action and what is necessary for its implementation;
- Must be clearly stated in the proposal and be listed in the budgetary annex (please also see article 10 of the MGA).
- The beneficiaries must award the subcontracts ensuring the *best value for money* or, if appropriate, the lowest price. In doing so, they must *avoid any conflict of interests*.

For public bodies: entities acting in their capacity of contracting authorities in the meaning of Directive 2004/18/EC or contracting entities in the meaning of Directive 2004/17/EC shall abide by the applicable national public procurement rules.

Other direct costs

The following cost types may also be included in eligible costs:

a) Travel costs and related subsistence allowances are eligible if they are *in line with the beneficiary's usual practices on travel*.

b) Equipment - portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

c) Costs of other goods and services are eligible, if they are purchased specifically for the action.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests.

Indirect costs

Indirect costs are eligible if they are declared *on the basis of the flat-rate of 7%* of the total eligible direct costs.

Beneficiaries receiving an operating grant financed by the EU or Euratom can declare indirect costs for the period covered by the operating grant only if the following conditions have been fulfilled:

1. The operating grant covers only part of the usual annual activities of the beneficiary and part of its annual operating budget (partial operating grant).

If the operating grant covers the entire activity and budget of the beneficiary, the latter is not entitled to receive any indirect costs under the action grant. Indeed, in that case the operating grant covers the entire overheads needed for the functioning of the beneficiary. Paying indirect costs under the action grant would therefore lead to double financing in breach of the last subparagraph of Article 129 (1) FR.

2. The beneficiary is able to demonstrate clearly that the operating grant does not cover any costs (including overheads) that may be claimed under the action grant.

To demonstrate this the beneficiary must:

- a) use analytical cost accounting that allows to separate all costs (including overheads) attributable to the operating grant and the action grant. For that purpose the beneficiary must, according to its usual cost accounting practices, use reliable accounting codes and allocation keys ensuring that the allocation of the costs is done in a fair, objective and realistic way.*
- b) record separately:*
 - all costs incurred for the operating grants (i.e. personnel, general running costs and other operating costs linked to the part of its usual annual activities), and
 - all costs incurred for the action grants (including the actual indirect costs linked to the action)

The obligation to record the actual indirect costs of the action does not prevent the use of a flat rate for the reimbursement of such costs. The flat rate remains the determining factor for the *amount* of indirect costs that can be charged under the action grant.

6.2.4 Exchange rate

The Budget of the grant agreement and financial statements must be drafted in euro.

Beneficiaries with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the Official Journal of the European Union, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the Official Journal of the European Union for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

6.2.5 VAT

The Financial Regulation, applicable as from 1 January 2013, provides for the full eligibility of the cost of VAT when attributable to exempt activities or activities out of the scope, except activities carried out as a public authority of a Member State. In other words, non-deductible VAT is eligible as expenditure, save for those activities matching the concept of sovereign powers exercised by Member States.

6.2.6 Definition of non-eligible costs

‘Ineligible costs’ are:

- Costs that do not comply with the conditions set out in articles 6.1 to 6.3 of the model grant agreement and in particular:
 - costs related to return on capital;
 - debt and debt service charges;
 - provisions for future losses or debts;
 - interest owed;
 - doubtful debts;
 - currency exchange losses;
 - bank costs charged by the beneficiary’s bank for transfers from the Agency;
 - excessive or reckless expenditure;
 - deductible VAT;
 - costs incurred during suspension of the implementation of the action;
 - in kind contributions provided by third parties free of charge.
- Costs declared under another EU grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission for the purpose of implementing the EU budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU budget in the same period.

6.3 Determination of the grant and payment arrangements

6.3.1 Calculation the grant amount

The ‘final grant amount’ depends on the actual extent to which the action is implemented and costs related to the implementation of the action.

The final grant amount will be calculated by the Commission when the payment of the balance is made in the following steps:

Step 1 The Commission evaluates the implementation of the action and verifies the actual costs related to the implementation declared by the beneficiaries. The reimbursement rate of the grant agreement is applied to the total eligible costs approved by the Commission.

Step 2 Application of the double ceiling: the amount obtained following Step 1 is compared to the maximum grant amount set out in the grant agreement. The final grant amount will be limited to the lower amount

Step 3 – Application of no-profit principle. ‘Profit’ is generated when the sum of the amount obtained following Steps 2 and the action’s total receipts is higher than the action’s total eligible costs. If there is a profit, it will be deducted in proportion to the final rate of reimbursement of the eligible actual costs approved by the Commission.

Step 4 – Reduction of the grant amount due to improper implementation or breach of other obligations.

For further details please also consult with article 5.3 of the model grant agreement.

6.3.2 *Type of receipts*

The following are considered receipts:

- Income generated by the action;
- Financial contributions given by third parties to the beneficiary specifically to be used to cover the action's eligible costs

Please consult with article 5.3.3. of the model grant agreement

6.4 Payment Scheme

Payments will be made to the coordinator. The coordinator must distribute the payments between the beneficiaries without unjustified delay.

The following payments will be made to the coordinator:

- ***One pre-financing payment:***

The aim of the pre-financing is to provide the beneficiaries with a float. It remains the property of the EU until the payment of the balance.

Note:

Pre-financing payments will only be distributed by the coordinator when 90% of the beneficiaries signed the accession form and only to those beneficiaries who signed the form! Please refer to article 16.7 of the grant agreement

- ***One or more interim payments, on the basis of the request(s) for interim payment:***

Interim payments *reimburse the actual eligible costs* incurred and declared by the beneficiaries for the implementation of the action during the corresponding reporting periods.

The number of interim payments will be set in the grant agreement. Interim payments are subject to the approval of the periodic report with the corresponding deliverables and the declaration of actual costs incurred by the beneficiaries.

The maximum amount of the interim payments (including the amount of pre-financing) is limited to the 90% of the maximum grant amount as set out in article 5.1 of the grant agreement.

- *One payment of the balance, on the basis of the request for payment of the balance.*

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action. The amount due as the balance is calculated by the Commission by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount.

If the total amount of earlier payments is greater than the final grant amount, the payment of the balance takes the form of a recovery.

If the total amount of earlier payments is lower than the final grant amount, the Commission will pay the balance.

Payment is subject to the approval of the final report.

Please consult with article 16 of the model grant agreement.

6.5 Pre-financing guarantee

In the event that the applicant's financial capacity is not satisfactory, measures may be taken in order to limit the financial risks linked to the pre-financing payment. These may include a financial guarantee for an amount up to that of the pre-financing payment or the inclusion of several reporting periods, leading to interim payments, subject to the approval of the periodic report.

If requested, the financial guarantee, in euro, shall be provided by an approved bank or financial institution established in one of the Member State of the European Union. When the beneficiary is established in a third country, the authorising officer responsible may agree that a bank or financial institution established in that third country may provide the guarantee if he considers that the bank or financial institution offers equivalent security and characteristics as those offered by a bank or financial institution established in a Member State. Amounts blocked in bank accounts shall not be accepted as financial guarantees.

The guarantee may be replaced by a joint and several guarantee by a third party or by a joint guarantee of the beneficiaries of an action who are parties to the same grant agreement.

The guarantee shall be released as the pre-financing is gradually cleared against interim payments or payments of the balance to the beneficiary, in accordance with the conditions laid down in the grant agreement.

No financial guarantee will be requested for a beneficiary receiving an EU contribution of EUR ≤60. 000 (low value grants).

B. SUBMISSION OF PROPOSALS

The Call for proposals under the Pilot project for "Establishing a registry of rare congenital malformations" will benefit from the use of the Electronic Submission System originally developed for the Horizon 2020 Research programmes.

Submitting an application **is only possible online** via the Electronic Submission Service of the [Participant Portal](#) and before the call deadline.

This appears to be highly beneficial for the applicants, as it will simplify their work.

However, the fact that the whole process is now done through an online system, requires a better level of preparation from the potential applicants before embarking on submitting the application itself. Even though the online system enables you to save successive versions of your application, the Commission strongly encourages you to have fully prepared the proposal before starting the online submission process and not view it as a "do-it-as-you-go" process.

Also note that the online submission system is composed of a two-step process:

- a) Registration of the applicant organisation through a specific procedure;
- b) Submission of the proposal itself, also broken down into three parts, as follows:
 - **Part A** includes administrative information of the applicant organisations (future coordinator and co-beneficiaries) and the summarized budget of the proposal. It is to be completed directly online. It comprises of fields of information, checklists and declarations to be filled in by the coordinator.

Note:

In order to complete part A:

- all other co-beneficiaries (i.e. not subcontractors, collaborating stakeholders and affiliated entities) must be registered in the [Beneficiary Register](#) and communicate the PIC to the coordinator
- all other beneficiaries must have performed a [financial viability self-check](#)
- the coordinator must have the project budget per co-beneficiary

- **Part B** includes the technical content of the proposal. This part must be written by the coordinator, following the template provided and in collaboration with the co-applicants and, when completed, uploaded directly as a PDF file into the Electronic Submission System.

- **Annex:** an annex is a necessary document to support evidence for checking the applicant organisation's compliance with the selection criteria. The annex must be uploaded directly into the electronic submission system.

There is an annex that may need to be uploaded for the submission of project proposals for those applicant organizations that demand more than €750 000 EU co-funding (and only those!): an audit report produced by an approved external auditor certifying the accounts for the last financial year available. This provision shall not apply to public bodies.

1 PREPARING FOR THE SUBMISSION OF YOUR APPLICATION

There are several stages to observe when preparing for the submission of your application, such as documents to consult (see below); sign up to your possibly already existing ECAS account for registered users or create a new ECAS account for new users; and register your organisation in the Beneficiary Register.

1.1 Documents to consult

Prior to taking the decision of submitting a proposal and filling in the different application forms, please verify whether your organisation complies with the eligibility criteria.

For this, the very first step is to go through the relevant documentation in detail. In this respect, the key documents to consult are the following:

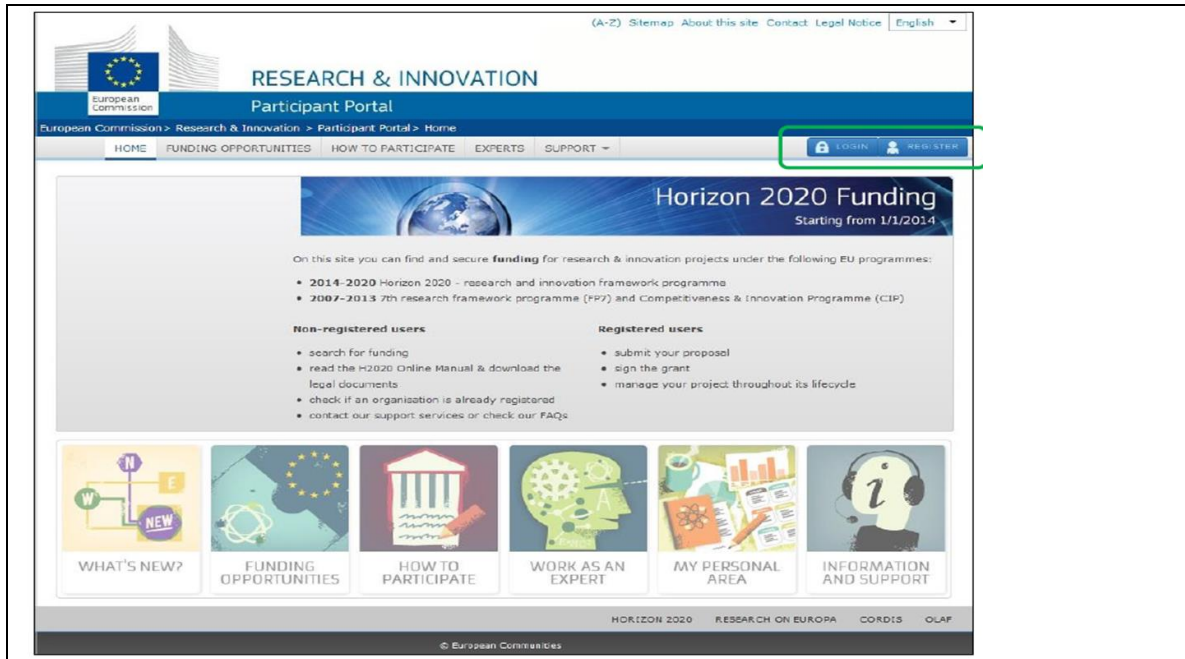
- The Financing Decision for the pilot project "Establishing a registry of rare congenital malformations"
- The Call for proposals;
- The multi-beneficiary grant agreement.

1.2 Create a user account on the Participant Portal – your ECAS Account

Remember, applications in response to this call are only possible via the Electronic Submission System. In order to use this system you first need to create a user account, the so-called ECAS account.

To do so, you simply need to access the [Participant Portal](#)

Figure 1: Screen shot of the Participant Portal homepage



You can see in the screen shot above that the homepage refers to registered and non-registered users.

- If you do not already have a user account for the Participant Portal, you simply click on 'REGISTER' (in the upper right corner next to 'LOGIN') and register online.
- If you already have a user account for the Participant Portal, you can log in (click on 'LOGIN' in the upper right corner) and start entering the required information.

1.3 Register your organisation - Beneficiary Register

With the ECAS account at hand, you can proceed to the next step, which is to register your organisation; this is done through the European Commission's Beneficiary Register.

- The European Commission has an online register of the organisations participating in various EU programmes called the [Beneficiary Register](#). This allows consistent handling of different organisations' official data and avoids multiple requests of the same information. However, check first on the Beneficiary Register page if your organisation is already registered at the [Organisation search](#).

Figure 2: Screen shot of the Beneficiary Register

The screenshot shows the 'Beneficiary Register' page on the European Commission's Participant Portal. The page is titled 'RESEARCH & INNOVATION Participant Portal' and includes a navigation menu with options like 'MY AREA', 'HOME', 'FUNDING OPPORTUNITIES', 'HOW TO PARTICIPATE', 'EXPERTS', and 'SUPPORT'. A sidebar on the left contains 'My Organisation(s)', 'My Proposal(s)', 'My Project(s)', 'My Notification(s)', and 'My Expert Area'. The main content area features a 'SEARCH' button and a 'REGISTER ORGANISATION' button. Two green callout boxes provide instructions: one for the 'SEARCH' button and one for the 'REGISTER ORGANISATION' button.

- If you do not find your organisation there, and only in this case, you should start the registration process by clicking on 'Register your organisation'.
- To complete this registration process, you will need to provide information about your entity legal status and its finances.
- You do not need to complete the registration process in a single session. You can enter some information, save it and continue later on the **My Organisations** page of the "My Area" section. Incomplete draft registrations are automatically deleted after one year.
- Once your registration is finalised, you will receive a **9-digit Participant Identification Code (PIC number)**. You will need the PIC numbers of the coordinator and all other beneficiaries (i.e. not for subcontractors, collaborating stakeholders and affiliated entities) in order to complete part A of the application.
- The person who registers the organisation, called 'self-registrant', can submit updates and corrections (with corresponding supporting documents) on the **My Organisations** page of the My Area section.
- Please note that in case if the registered organisation receives EU funding, the 'self-registrant' will be replaced by the appointed representative LEAR (Legal Entity

Appointed Representative). This person will then be will be the only person able to provide further updates.

1.4 Deadline, acknowledgement of receipt, rejection of a proposal and complaints

- **Submission deadline**

The proposals **must** be submitted via the Electronic Submission System.

The deadline for submission is **31 January 2017**.

The Electronic Submission system enables you to replace/ update the proposal at any time. **It is very important that you do not wait until the very last day of the deadline for submitting your proposal. This will significantly increase the risk of a last minute problem blocking your submission.**

You do not need to send your proposal by post / e-mail to the CommissionChafea! Please use only the Electronic Submission System!

- **Acknowledgement of receipt**

The date and time of the submission of the application will be automatically recorded and an acknowledgement of receipt email will be sent to the applicant organisation. **If you do not receive an email with the acknowledgement of receipt, it is because the proposal has not been submitted. If you miss the call deadline, your proposal will be disregarded by the system and cannot and will not be considered as submitted. After the deadline for the call for proposal, changes or additions are no longer possible.**

The Electronic Submission System will carry out basic verification checks for completeness of the proposal, internal data consistency, virus infection file types, size limitations etc. The system will also check page limits in specific parts of the proposal and, if necessary, suggest that you shorten it. After the deadline, any excess pages will be overprinted with a 'watermark' indicating to the evaluators that these pages must be disregarded.

- **Rejection of proposals**

IMPORTANT TO NOTE: it is extremely important that you upload the proper document (in PDF) under the corresponding heading. Errors in this process that result in an incomplete proposal may jeopardize your entire application as inadmissible!

Hence, before closing the application procedure or logging-of, double-check if the content of your PDF documents matches the given headings in the online submission tool.

It is your responsibility to have uploaded to proper documents.

Once the proposal is submitted, the applicant will not hear from the Commission until the proposal is evaluated, unless:

- The Commission needs to contact the applicant to clarify matters such as eligibility or to request additional information;
- More information or supporting documents are needed to establish the legal entity or to perform the financial viability check²; and / or
- The applicant made a complaint regarding the submission procedure.

- **Languages**

In principle, project proposals may be submitted in any official language of the European Union. However, in order to facilitate the evaluation process, an English translation of the proposal should be provided. The English version should be at the beginning of the proposal, followed by the other language version.

- **How to file a complaint**

If you believe that submission failed due to a fault in the Electronic Submission System, you should immediately file a complaint via the Helpdesk on the Participant Portal, explaining the circumstances and attaching a copy of the proposal. The method of filing a complaint over other aspects of submission is explained in the information you receive via the electronic exchange system (see 'My Area' section of the Participant Portal).

Note:

The Commission does not manage the submission process via the Electronic Submission System. Hence, please contact the Helpdesk of the Participant Portal and not the Commission for submission related questions.

1.5 Data protection

All personal data that will be included in the applications submitted via the electronic submission system will be processed by the Commission and Chafea under Regulation No 45/2001 and according to the procedure announced with the relevant notifications submitted to the Data Protection Officer. A privacy statement informs all data subjects whose data are to be processed in the context of the proposal evaluation and ensuing grant agreement preparation, implementation and follow up.

In this respect, please check the information available on [Legal notices](#)

as well as the information available on [Data protection](#)

Applicants are invited to check this website at regular intervals so as to be duly informed on possible updates that may occur by the deadline for submission of their proposals.

² Note: this is not performed by the Commission. The system may contact you about this, if needed, not the Commission.

1.6 General guidance before drafting your proposal

A call for proposal is part of a competitive process. A weak element in an otherwise good proposal may lead to a negative evaluation, resulting in the applicant not being recommended for EU funding.

With this in mind we would advise you, in addition to the above-mentioned considerations and suggestions, to consider the following aspects before embarking in the drafting of a proposal:

Relevance: check that your intended proposal does indeed address the objectives of the Pilot Project. Proposals falling out of the scope will be scored low.

Completeness: check that your intended proposal includes all relevant information, as it will be evaluated only on the basis of the submitted content (such as information, documents etc.). Follow closely the format of the template of Part B and ensure that all the requested information is uploaded. However, avoid mixing quality with quantity: good proposals are clearly drafted and are easy to understand and follow; they are precise and concise, focusing on substance, and it is not about the number of pages. The page limit for Part B of your proposal is 50 pages for the technical part and 30 pages for the budget (1 page per partner for a maximum of 30 partners) i.e. in total 80 pages. Any text after page 80 will be watermarked and evaluators will not take those pages into consideration.

Note:

Even if you have less than 30 partners, we recommend that you keep the technical description of your project to 50 pages. Evaluators do not score the quantity but the quality of the project description. Any page above the 50th should be used for the budget. Hence, 80 pages is a maximum in order to allow for large consortia and not the target!

Management quality: clearly indicate the ability for high-quality management adapted to the scope of the intended activities of the organisation. Good financial management is a key component of management quality and adequacy between activities and requested budget is important.

Orientation towards results and impact: good proposals clearly show the results that will be achieved, and how the participants intend to disseminate and/or use these results. In addition, good proposals include a sound and credible evaluation plan, not only focusing on process evaluation, but looking in particular at outcomes.

The above points are central to drafting a proposal with a chance of being recommended for funding.

2 APPLICATION FOR A PROJECT

As noted above, the project application is composed of three parts:

- Part A, which includes the administrative information;
- Part B, which comprises of the technical content of the proposal; and
- Annexes. This only concerns applicants requesting EU co-funding of 750 000€ or higher per applicant. In such cases an audit report must be attached for the applicant concerned.

2.1 Project application form: Part A – Administrative part of the applicant organisation

Part A comprises of fields of required information, checklists and declarations to be filled and must be completed directly via the online submission tool; it is structured in three sections, as follows:

- Section 1: General information
- Section 2: Administrative data of the organisation
- Section 3: Budget

Please note that Part A follows a common template and is applicable to all funding programmes and all financial instruments, regardless of the specificities of each.

Figure 3: Screen shot of the Table of Contents of Part A

<i>Section</i>	<i>Title</i>	<i>Action</i>
1	<i>General Information</i>	
2	<i>Participants and Contacts</i>	
3	<i>Budget</i>	

Section 1: General information

In this section, you should provide the Acronym, Proposal Title, Duration (in months), Free Keywords and an Abstract (max. 2000 characters) explaining the objectives of the proposal, how these will be achieved, and their relevance to the Pilot Project.

The abstract will be used as a short description of the proposal. Therefore, do not include any confidential information, use plain typed text, avoiding formulae and other special characters.

In the "Declarations" section, there are also a number of self-declarations to be made by coordinator by clicking the corresponding boxes. These declarations about about the following topics. We recommend that the coordinator checks with all the partners before clicking the boxes.

The coordinator declares:

- a) to have explicit consent of all applicants on their participation and on the content of the proposal.

b) that the information in the proposal is correct and complete.

c) that the proposal complies with ethical principles. The next statements concern the exclusion, eligibility and selection criteria.

The coordinator must make the following declarations:

For the exclusion and eligibility criteria:

- each applicant is fully compliant with the exclusion and eligibility criteria set out in the specific call for proposals

Note:

If the proposal is retained for EU funding, the applicants will be required to present a more formal declaration of honour on the exclusion criteria during the grant agreement preparation process.

For the selection criteria:

Financial capacity:

- the coordinator's organisation as well as each other applicants for its own organisation has performed the [self-check of the financial capacity](#) of the organisation (or are exempt as they are public bodies)
- each applicant has confirmed that if it is receiving an operating grant from any EU programme, it will not claim indirect costs for this action for the specific year covered by operating grant
- applicants have stable and sufficient sources of funding to maintain their activity throughout the period during which the activity is being carried out and to participate in its co-financing

Note:

the only reason you are requested to run a self-check on your financial capacity and tick the box is to warn you that in the case you are awarded the project and your financial standing may be weak, the EC may need to take specific measures e.g. may ask you to provide a bank guarantee.

By no means should it discourage you from submitting a project proposal.

Operational capacity:

- the applicants have the professional resources, competences and qualifications required to complete the proposed action.

If you do not click on each appropriate box, you may prevent application from being submitted.

Section 2: Participants and contacts

The coordinator will encode the PIC code of his/her organisation and of every other applicant (see B 1.3 in this guide). Part of the administrative data will be filled in automatically after encoding the PIC code. Then, the coordinator will be required to fill in the contact details for every participant. Hence, it is recommended to have this information at hand when completing the part A.

Section 3: Budget

Here, you must fill a budget overview table in this section. Please refer to the screen shot below.

The co-funding rate for the Pilot project is 80% of the total eligible cost.

The coordinator must fill in the budget table as presented below.

Explanation:												
White cells: to be filled by the coordinator												
Grey cells: automatically calculated												
Black cells: cannot be filled in – not applicable at the level of each applicant.												

Figure 4: The Budget Overview Table in part A

No	Participant	Country	Direct personnel costs/€	Direct costs of subcontracting	Other direct costs	Indirect costs (max 7% on a, b and c) ³	Total estimated eligible costs	Reimbursement rate (%)	Maximum EU contribution	Requested Grant ^{1, 2}	Income generated by the action	Financial contributions given by third parties to the beneficiary	Action's total receipts
			(a)	(b)	(c)	(d) = 0.07 * ((a)+(b)+(c))	(e) = (a)+(b)+(c) + (d)	(f)	(g) = (e)*(f)	(h)	(k)	(l)	(m) = (k) + (l)
1	TestNGO	LU	200 000	0	50 000	17500,00	287500,00			0	0	0	0
Total			200 000	0	50 000	17500,00	287500,00	80	180500,00	0,00	0	0	0

^{*1)} The requested Grant per beneficiary can be up to the total eligible cost of this beneficiary. In total at project level, the EU funding shall not be higher than the Maximum Reimbursement Rate (60% or 80% in cases of exceptional utility).

^{*2)} If a particular beneficiary is requesting more than 750.000 Euro EU contribution, an audit report produced by an approved external auditor shall be submitted. That report shall certify the accounts for the last financial year available.

^{*3)} If an organisation is receiving an Operating Grant under any EU programme, it is not eligible for indirect costs in the respective year covered by the Operating Grant. In this case, please deduct the respective portion in this proposal.

Each row of the budget table represents the total estimated expenditure and total receipts for each applicant.

Eligible costs are: direct personnel cost (column a), direct cost of subcontracting (column b) and other direct costs (column c), including costs for travel, equipment and other goods and services. Please refer to Article 6 of the Model Grant Agreement for a detailed description as well as calculation methods of these eligible cost items. Costs need to be explained in detail in the individual detailed budget under Part B of the application, heading 10.4

NOTE: Please make sure that the amount of each cost category and totals in Part A must be equal to the corresponding amounts given in the individual detailed budget under Part B of the application, heading 10.4.

The maximum grant amount in column (g) is only calculated at the level of the action and not at the level of each applicant.

The requested grant amount needs to be entered into the table by the applicant. Overall, the total amount in column (h) should be equal to or less than the total amount of column (g).

The applicants must also estimate if:

- there is any income of the project foreseen (e.g. sale of an equipment used by a project, sale of publications, conference fees, etc.). Such amount should be given in column (k).
- there is any third party contribution. The sponsorship means actual money inflow to any of the applicants. The amount should be dedicated to cover the eligible cost of the action. Such amount should be given in column (l).

NOTE: Please note that for reasons of simplification of the budget table, the Applicant's contribution as well as the total income does not need to be stated for proposals since 2015.

Instead, the applicants must state the total receipts (column m), which is composed of Income generated by the action (column k) and Financial contributions given by third parties to the beneficiary (column l). The sum of total receipts (column m) plus the Requested Grant (column h) must not be higher than the total estimated costs (column e; Non-profit rule).

Any amount in difference of Total estimated eligible costs (column e) minus the Requested Grant (column h) minus the total receipts (column m) are implicitly considered as "Applicant's contribution".

An additional important point concerns financial contributions given by third parties to the beneficiary. These shall be described in detail in the Part B of the application, heading 10.2. In case of a potential conflict of interest, please also describe the necessary measures to prevent any situation where the impartial and objective implementation of the project is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest.

2.2 Project application form: Part B - Technical content

Part B concerns the technical content of the proposal. This should be limited to 50 pages. Then, up to 30 pages can be added for the budget tables (one page per beneficiary) Applicants must write the proposal following the template provided. You can write your proposal in any word processing tool. However, once completed, the up-loading into the Electronic Submission System is only possible in PDF format.

The structure of the template is as follow:

1. PROBLEM ANALYSIS INCLUDING EVIDENCE BASE

2. AIMS AND OBJECTIVES OF THE PROJECT

2.1 General objective of the project

2.2 Specific objective(s) of the project

3. TARGET GROUPS

4. POLITICAL RELEVANCE

4.1 Contribution to meeting the objectives defined

4.2 Added value at EU level

4.3 Pertinence of geographical coverage

4.4 Consideration of the social, cultural and political context

5. METHODS AND MEANS

6. EXPECTED OUTCOMES

7. WORK PACKAGES

7.1 Overview on work packages

7.2 Work package descriptions

7.3 Timetable or Gantt Chart

8. MILESTONES AND DELIVERABLES

9. PROJECT MANAGEMENT STRUCTURE

9.1 Quality of the partnership

9.2 Capacity of the staff

9.3 External and internal risk analysis and contingency planning

9.4 Financial management

10. BUDGET

10.1 Content description and justification

10.2 Summary of staff effort

10.3 Detailed budget

11. PREVIOUS AND CURRENT GRANTS RELEVANT TO THE PROGRAMME (LIMITED TO THE LAST 3 YEARS) (Not Applicable)

12. CURRENT APPLICATIONS RELEVANT TO THE PROGRAMME (Not Applicable)

13. EXCEPTIONAL UTILITY (Not Applicable)

14. COLLABORATING STAKEHOLDERS

Note:

the proposal must follow the structure of the template. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the experts to make an effective assessment against the award criteria.

Page limit: again, the proposal must not be longer than 80 pages, that is 50 for the technical description plus a maximum of 30 pages for the budget. Hence, all tables need to be included within this limit. The minimum font size allowed is 11 points. The page size is A4, and all margins (top, bottom, left, right) should be at least 15 mm (not including footers or headers). If you attempt to upload a proposal longer than the specified limit, before the deadline you will receive an automatic warning, and will be advised to shorten and re-upload the proposal. After the deadline, any excess pages will be overprinted with a 'watermark' and disregarded. **Please do not consider the page limit as a target!** It is in your interest to keep your text as concise as possible, since evaluation experts rarely view unnecessarily long proposals in a positive light.

Note:

if you submit a proposal in a language other than English, please make sure that the pages available for the technical description include both the proposal in its original language, as well as an English version.

2.2.1 Problem analysis including evidence base

Applicants must include a problem analysis and clearly describe the factors, the impact, the effectiveness and applicability of the proposed measures and present the relevant evidence on which the project is based. For instance, it may concern the analysis of the health problem and its impact on quality of life and on society (incidence, prevalence, distribution in the population, evolution over time, seriousness...), the analysis of the factors underlying the problem (factors regarding human biology, quality of health care, lifestyle, physical and social environment, risk factors, protective factors), the effectiveness of the proposed measures, or the applicability in the proposed context. This context analysis should also look at elements in the environment which may facilitate or hinder the project implementation process.

2.2.2 Aims and objectives of the project

General objective(s) of the project:

Applicants must define a general objective. This is a general indication of the project's contribution to society in terms of its longer-term benefits (e.g., contribute to the reduction of cancer mortality; reduce social inequality in population's health). The general objective has to correlate with the different specific objectives.

Specific objective(s) of the project:

Applicants must include specific objectives. These are concrete statements describing what the project is trying to achieve in order to reach its general objective. They should be matched to the problem determinants identified in the problem analysis, and should be written in a way that they can be evaluated at the end of the Project. Hence, formulate them "SMART": Specific, Measurable, Acceptable for the target group, Realistic, and Time-bound (containing an indication of the time within which it must be reached). Objectives can be hierarchically and temporally structured, so that the achievement of some objectives is a precondition for another.

For each specific objective, please formulate pertinent indicators – process, output and outcome/impact. Indicators are variables measuring the performance of an action and the level to which the set objectives are reached. This is why the indicators should be directly linked to the specific objectives. For each specific objective, at least one indicator should be formulated. If possible, the indicators should also specify target values. The indicators must be adequate for the project and, like the objectives, formulated "SMART".

Specific Objective Number		
Specific Objective		
Process Indicator(s)		Target
(repeat line as needed)		
Output Indicator(s)		Target
(repeat line as needed)		
Outcome/Impact Indicator(s)		Target
(repeat line as needed)		

2.2.3 Target groups

Applicants must specify the target group(s) in the proposal. These are persons or entities who will be positively affected by the action. A proper target group specification provides a clear definition including information about the demographic characteristics, the needs and social norms with regard to the health problem(s) of interest, the size (i.e., the numbers that will be reached by the action), and the method to reach these people. For certain types of interventions it is also useful to segment the target group into subgroups based on relevant characteristics and adapt the communication strategy to reach them.

2.2.4 Political Relevance

The political relevance of the action co-funded under the Pilot Project is important. Hence, please describe it in detail in your proposal, guided by the four points below.

Contribution to meeting the objectives of the Pilot Project:

Applicants must address the topic to which their proposal corresponds and explain how the proposal addresses the specific challenge and scope of it. Proposals which do not clearly address the topic will be scored low.

In addition, the applicants must describe the way the project brings added value to the existing public health knowledge allowing the practical use of that knowledge on the field. It is also expected to contribute and add value to EU policies formulated or in the process of being so.

Added value at EU level:

Applicants must describe how the project has EU added value. EU added value can be achieved in different areas and in different ways, as depicted in the table below.

Areas – where to achieve EU added value	Ways - how to achieve EU-added value
<ul style="list-style-type: none">- Impact on target groups	<ul style="list-style-type: none">- Implementing EU legislation
<ul style="list-style-type: none">- Long-term effect and potential multiplier effect, such as replicable, transferable and sustainable activities,	<ul style="list-style-type: none">- Achieving economies of scale
<ul style="list-style-type: none">- Contribution to complementarity, synergy and compatibility with relevant EU and EU Member States policies and programmes.	<ul style="list-style-type: none">- Promoting best practice- Benchmarking for decision making,- Reducing cross border threats- Strengthening free movement of persons- Strengthening networking activities

Applicants should demonstrate in the proposal that the expected impact of coordinating the work at European level is greater than the sum of the impacts of national activities. Moreover, the proposal should include planning for reproducing and transferring the actions, so to cover the whole concerned population in the future.

Pertinence of geographical coverage

Applicants must ensure that the geographical coverage of the project is adequate to its objectives, and explain the role of the eligible countries as partners and the relevance of project resources or the target populations they represent. As public health practices and policies differ between EU Member States, actions funded should take account of this geographical, cultural and social diversity. A sufficient number of organisations from different EU Member States and other eligible countries should be involved in the Project depending on the scope, objectives and target group of the project.

Consideration of the social, cultural and political context

Applicants must explain how the project relates to the situation of the countries or specific areas involved, and ensure the compatibility of envisaged actions with the culture and views of the target groups. The project should demonstrate its compatibility with the culture, knowledge, views, customs and roles of the target group, and with the local policy context in which it will be implemented. This compatibility should take account of the information deriving from the context analysis identifying the trends, opportunities and threats in the broader social and policy context.

Also, applicants must discuss ethical aspects, confidentiality and protection of personal data if the proposal includes studies involving human beings.

2.2.5 *Methods and means*

Applicants must describe the methods and means that will be used to implement the project. These should be explicitly linked to the objectives, in the sense that for each specific objective at least one intervention method is specified.

The methods and means should be described using scientific methods. The methods and means should describe how the specific objectives will be reached, what are the essential tasks to be carried out, e.g., study protocol, survey methods, panel of experts, training development, etc.

2.2.6 *Expected outcomes*

The application includes a description of the anticipated outcomes and deliverables. Project outcomes are the changes that are expected to occur as a result of the project when the objectives are reached. They can be distinguished from a specific type of output, the deliverables presented in 3.2.8

2.2.7 *Work packages*

Applicants must organize their project in work packages (WP). A WP is a major subdivision of the proposed action and contains a set of coherent tasks grouped together in order to facilitate the project management.

Applicants must include a work package overview table as well as one detailed table per work package (work package description).

There are two types of WP: *horizontal* and *core*.

The horizontal WP are mandatory and include three groups of tasks: management (WP1), evaluation (WP2) and dissemination (WP3) and are linked to deliverables.

Each core WP is linked with one or several specific objectives of the project and produces one or several deliverables. It is not possible to find the same specific objective or the same deliverable in different work packages.

Give full details. Base your account on the logical structure of the project and the stages in which it is to be carried out. Include details of the resources, person/days and financial means, to be allocated to each WP. The number of core WP should be proportionate to

the scale and complexity of the project. You should give details in each WP to justify the proposed resources to be allocated and also quantified information so that progress can be monitored.

The WP must be presented in a table format, following the template below.

For the three mandatory WP, the following content must be covered:

WP 1 – Management of the project

Applicants must clearly describe the actions undertaken to manage the project and to make sure that it is implemented as planned.

Project management requires the systematic monitoring of the activities to check whether they are implemented according to the plan, whether results and deliverables are attained at the milestones, if there are obstacles or difficulties which may prevent the project from delivering, and to assure the overall quality of the project implementation. Many of these tasks are typically performed by the project manager with input from other participants (e.g. via a management and/or steering committee).

Also describe how information will be exchanged among participants, how potential conflicts between participants will be coped with and the planned meetings among the participants etc.

WP 2 – Dissemination

Dissemination refers to the process of making the results and deliverables of the project available to the stakeholders and a wider audience.

Applicants must describe all actions planned to ensure that the results and deliverables will be made available to the stakeholders and can be used by them. Hence, a stakeholder analysis could be performed before developing the dissemination strategy. Applicants must describe the dissemination strategy in terms of planning, target groups, adequacy of channels used, and visibility of European Union co-funding.

Although a project is by definition limited in time, the purpose is to make the results and outcomes sustainable. The dissemination strategy should therefore pay attention to the transfer of knowledge and to the processes needed for embedding and future take-up. The sustainability of the dissemination actions must also be addressed.

A dissemination plan should be elaborated, explaining how the project plans to share outcomes with stakeholders, including public authorities. A dissemination plan should be included, which illustrates the following:

- what will be disseminated (key message),
- to whom (audience),
- why (purpose),
- how (method), and
- when (timing).

WP 3 – Evaluation

Applicants must evaluate the project activities. This includes all actions undertaken to verify if the project is being implemented as planned and reaches the objectives. Applicants should develop an evaluation strategy that includes a clear description of the methods for the evaluation, indicators and measures of verification. This must take-up the indicators listed before with the specific objectives and explain how they will be measured.

Applicants must explain the project's own internal evaluation, i.e. a systematic appraisal of the quality of the action (e.g., whether the project outcomes are useful and meet the user needs), and its effects (e.g., whether the project achieved its objectives and had an impact on the target group). The evaluation methodology should be adequate (formulation of specific evaluation questions and for each evaluation question, methods to collect data), inferred from an evaluation plan, specifying purpose, questions, study design, method, measurement instruments, and the task, responsibilities and timing of the evaluation. External evaluation can be opted for.

After these mandatory WP, the applicant should add as many WP as needed to carry out the project. Please do not split the tasks in too small units. A suggested number of additional WP is 3-7. Each WP must be lead by one of the applicants. Please assign the WP to the partners according to their knowledge and skills.

For each work package, please create a table as the model below and fill it in.

Figure 5: Sample table of a WP

Work package number												
Work package title												
Starting month						Ending month						
Leading participant												
Participants Nr												
Participants Acronym												
Person month per participant												
Objectives												
Description of work	where appropriate, broken down into tasks, specifying the role of the WP leader and those of others											
Deliverables linked to this work package	brief description, month of delivery, reference to the list of deliverables											
Milestones to be reached by this WP												

Timetable or Gantt Chart³

A timetable must be included. It must comprise the work packages, milestones and delivery month of deliverables, including the name/acronym of the responsible participant. Applicant can choose to use a graphical form, such as a Gantt chart. In addition, you can also opt for a graphical presentation of the components showing how

³ This type of chart is named after its developer Henry Gantt. It is a specific type of bar chart used to illustrates a project schedule. Such a chart includes start and end dates and indicates milestones (e.g. meetings) and deliverables.

they inter-relate (Pert chart or similar). The time to reach objectives of the project and thus the activities comprised in each of the WP must be realistic, taking into account the available resources (person/days) and capacities.

2.2.8 Milestones and deliverables

Milestones

Milestones mean control points in the project that help to monitor progress. Milestones may correspond to the completion of a key deliverable (see below), allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems have arisen, corrective measures can be taken. A milestone may be a critical decision point in the project where, for example, the consortium must decide which of several technologies to adopt for further development

Deliverables

Applicants must specify the deliverables of the project. A deliverable is a physical output related to a specific objective of the action, e.g. a report, publication, newsletter, tool, software, handbook, training guide, website, or conference. In your proposal, please create a table, guided by the model below, to list all the deliverables.

Note:

The Commission will make a payment to the beneficiaries at about half-way through the project. This payment must be based on deliverables which have been produced in the first half of the project (besides the interim report). Thus it is important that some deliverables are available at the point of the payment (usually month 18 for a 36 months long project). The Commission cannot make an interim payment without receiving deliverables at that point in time (e.g. drafts of reports to be finalized at the end of the project). Please take this into account.

Note that there are several mandatory deliverables. These are already included in below table. Please copy them into your proposal.

The table should have the following columns:

1. The running number of the deliverable.

Note:

Please give deliverable numbers in order of delivery dates. Use the numbering convention <WPnumber>.<number of deliverable within that WP>. For example, deliverable 4.2 would be the second deliverable from work package 4.

2. Name of the deliverable, e.g. training manual for health care workers, report on literature review, final conference etc.
3. Number of the work package which will produce this deliverable
4. Acronym of the partner that is responsible for / leading the production of this deliverable
5. Short description of the content of the deliverable
6. Dissemination level: indicate if this deliverables is public (PU) or its distribution is limited to the partnership and the Commission i.e. confidential (CO, see also conditions in the grant agreement, Articles 21 and 22)._

If a deliverable is labelled confidential, please describe the reasons for the confidentiality.
The objective is to make the results of all actions as widely accessible as possible,

therefore confidential deliverables will only be accepted in duly justified and exceptional cases.

7. The deadline of the deliverable (the month when the deliverable will be ready and submitted to the Commission). Several months can be indicated here e.g. a draft report in M18 and the final report in M36 (together makes one deliverable).

Figure 6: An example of a table with the list of deliverables

Deliverable Number	Deliverable Name	Work package number	Leading participant acronym	Content specification	Dissemination level	Delivery month

Please add lines to the table as needed. While there is no limitation to the number of deliverables, it is strongly suggested to keep the number reasonable, especially since deliverables are directly linked to the payments, as mentioned previously.

For example:

- draft version are not different deliverables from the final product, but please indicate the month when the draft will be ready (e.g. M16) and when the final report will be ready (e.g. M24)
- translations into other languages are also not different deliverables from the original version

Obligatory deliverables:

Mandatory Deliverable Number	Deliverable name	Work package number	Leading participant acronym	Content specification	Dissemination level	Delivery month
MD.1	Periodic report(s)	1	The coordinator	This report describes the activities carried out, milestones and results achieved in the first half of the project. Deliverables can be attached as annexes.		
MD.2	Final report	1	The coordinator	This report describes the project implementation and the results achieved. The deliverables are annexed.		End of project
MD.3	Leaflet	2		A leaflet to promote the project must be produced at the beginning	P	M3

MD.4	Layman version of the final report	2		This is a short (e.g. 10 pages) version of the final report, written for the interested public as a target group.	P	End of project
MD.5	Web-site	2		Each project must have a dedicated web-site / web-pages. This can have a public part and another one accessible only to the participants.	P (and C)	M3

MD = "mandatory deliverable"

2.2.9 Project management structure

Applicants must describe the organisational structure and the decision-making and explain why these are appropriate to the complexity and scale of the project.

Consider an appropriate governance structure possibly to include a management or steering committee, (scientific) advisory committee etc.

Appropriate mechanisms for monitoring and supervision should be planned.

Also, as the management of a project implies the coordination of several participants located in different countries, it is thus important to have a good communication strategy and plan. This should include details how information will be communicated between the project participants, how decisions will be taken, by whom, and what the procedure will be in case of conflict.

Finally, also note that a consortium agreement, which will formalize the project management structure and the rights and obligations of partners within the consortium is now mandatory.

Quality of the partnership

Applicants must describe the consortium. The description will provide answers to these questions:

- How will the participants' expertise match the project's objectives and tasks?
- How do the participants complement one another?
- In what way does each of them contribute to the project?
- How will they be able to work effectively together?

Highlight previous working experiences and existing collaboration. All proposals should be built on a sound partnership. The quality of the partnership would rest on:

- Its extensiveness (stakeholders' identification based on the project topic determinants),
- Sharing common goals and objectives,
- The synergy (added value),
- Commitment (interest of the various participants to be involved in the project), and a solid network structure.

This point could refer to the internal network logic which explains why certain participants are involved and not others. For example, the network's rationale could be based on previous links, or built after a search of adequate participants in the geographical area of interest. Describe the roles and responsibilities of the different participants. Public–private partnerships may be relevant in some cases. Here, the different roles should be made clear as well as the overall rationale.

Capacity of the staff

Applicants must clearly but concisely describe the competence of staff related to the scientific, technical and managerial implementation of the project.

- *Coordinator institution, description of competence, experience, leadership and authority in the action area*

Demonstrate the capacity of the coordinator to realise the work in relation to the project. The leadership and authority refers both to the organisational and personal aspects of leadership.

On the organisational level, there should be a clear division of responsibilities and tasks between the project manager and other decision makers. On the personal level, the project manager must have the necessary skills, expertise and authority to lead a team and to achieve the action objectives. He or she should also be capable of using the resources in a flexible way.

- *Key staff of the coordinator – description of competence (leadership and authority) and experience in the action area.*

Present the profile of the key staff members (recommendation: a half page for all staff together) illustrating their (academic) qualifications, professional experience, competence, expertise, leadership quality and authority required by the action tasks.

Note:

Applicants are requested to include staff profiles into the proposals and not summary CVs. A staff profile is a generic description of the minimum (academic) training and professional experience needed in order to perform specific tasks to implement the project. For example, an epidemiologist with a university degree in medicine and at least 5 years of professional experience in infectious disease epidemiology or a project manager with a relevant university degree and at least 3 years of experience in managing projects at EU level, having also a high command of English.

- *Participants' institutions, description of competence, experience, leadership and authority in the action area*

Demonstrate the capacity of the participants to realise the work in relation to the specific objectives.

- *Key staff of the participants – description of competence (leadership and authority) and experience in the action area*

Present profiles (please see above, do not add CVs, specify names etc) of the key staff members (recommendation: a half page for all staff together), illustrating their (academic) qualifications, professional experience competence and expertise required by the action tasks.

External and internal risk analysis and contingency planning

Even in the best-planned actions there are uncertainties, and unexpected events can occur. Therefore applicants must provide a risk analysis at the start of the project. This will help to predict the risks that could prevent the action from delivering on time or even failing. A risk is an uncertainty of outcome of an action or event. A risk analysis addresses the questions what could possibly go wrong, what is the likelihood of it happening, how it may affect the project, and what can be done about it. The risk analysis should identify internal risks, like a low performance of one of the participants, a withdrawal of one of the participants, and external ones e.g. target group is harder to reach than foreseen, response rate to a survey is lower than expected, translation of documents is delayed due to sickness of translator, collaboration with external stakeholders is not as smooth as anticipated.

Please provide the risk analysis in form of a table, using the template below.

- Identified risk: describe any critical risks, relating to action implementation, which might hamper the achievement of the project's objectives;
- Likelihood: include the probability or likelihood (high, medium and low) of the risks identified;
- Impact: rate the impact (high, medium and low) and what would be affected;
- Contingency planning: detail all risk mitigation measures.

Figure 7: Template table for risk analysis

Identified Risk	Likelihood	Impact	Contingency planning

Financial management

Applicants must describe the financial management of the project. They must be able to build and monitor the project budget. The important amount of money involved and its distribution among participants, in function of the work achieved, demands a strong financial management capacity. This capacity has to be demonstrated with all relevant elements such as the competency of financial officers , tools used to monitor the action, including reporting (e.g. collection of financial documents from the participants), procedures (e.g. preparation of financial reports, distribution of co-funding) and quality controls.

2.2.10 Budget

As mentioned previously, the Budget Overview Table will be included in the Administrative Form of the application.

In this part of the application you must provide a description of the way the budget was built in support of the implementation of the action– in short, its relevance with the activities planned during the year and the rationale for doing so. Please remember that the budget is one of the award criterion and will be evaluated as the other parts of the application.

It is highly recommended that the consortium members work closely together and with the coordinator in the preparation phase.

The Budget of the Technical Proposal has three parts:

1. Content description and justification

This is a free space for the applicants to explain how the budget is build.

2. Table of "Summary of staff effort"

This table summarises the personnel need of the action, estimated as personmonth at applicant level with an allocation to each work package the applicant participates in. Please make sure that all personnel of the affiliated entities are also included.

Each row of the table represents one applicant of the consortium.

The amount of "Total personmonth per applicant " must be equal to the sum of total personmonth given in the table of "Detailed budget" for the applicant and its affiliated entities.

Figure 8: Table: Summary of Staff Effort

	WP n	WP n+1	WP n+2	Total Person/ Months per Applicant
Applicant Number/ Short Name				
Applicant Number/ Short Name				
Applicant Number/ Short Name				
Total Person/Months				

3. The "Detailed budget" Table

This table summarises all the estimated costs with a breakdown for each cost category for each applicant with its justification.

Figure 9: Table – Detailed budget: per applicant or affiliated entity

Applicant Number/ Short Name			
(If affiliated entity: Affiliated to which Applicant number/Short name)			
(A) Direct personnel costs			
Staff function	Monthly Cost	Estimated Person-month	Sum Cost (€)
(Please repeat line for each staff function category)			
		Total person month	Total Costs (€) for (A)
	Justification		
(B) Direct costs of sub-contracting	Costs (€)	Task(s)/Justification	
(please repeat line for each subcontracted task foreseen)			
Total Costs (€) of (B)			
	Justification		
(C) Other direct costs			
(C.1) Travel	Costs (€)	Justification	
(C.2) Equipment	Costs (€)	Justification	
(C.3) Other goods and services	Costs (€)	Justification	
Total Costs (€) of (C)			
(D) Indirect Costs	Total Costs (€)		
(Max. 7% on A, B and C)			
Total estimated eligible costs			

Note:

The detailed budget per applicant must be consistent with the Budget Overview Table of the Administrative Form of the application. The online submission system does not provide a reconciliation function among the different budget tables of the application form, it is the consortium responsibility to ensure consistency of the information provided throughout the application.

The table has 4 parts representing the 4 cost categories (A for Direct personnel costs, B for Subcontracting costs, C for Other direct costs and D for Indirect costs.).

If the applicant plans to work with its linked affiliated entities, their costs must be presented in separate tables (one table per one affiliated entity + one table for the applicant).

Note:

There is one single cell provided per cost category. It makes the budget table simple and easy to handle, but it is also easy to over- or underestimate these figures. Even though you may do budget transfers at a later stage it is crucial that the *overall resource need of the action is a fair estimate* as the maximum amount of the EU Contribution is linked to this initial budget estimate.

It is therefore strongly recommended that you have your own templates / spread sheets developed which supports you considering all important factors of a cost category.

A. Direct personnel cost:

Applicants may consider the following costs as eligible under direct personnel costs:

- personnel working for the applicant under an *employment contract* (or equivalent appointing act) and *assigned to the action*

- **Additional remuneration** for personnel assigned to the specific action if it is part of the applicant's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

In addition, the following costs can also be recognised as personnel cost:

- *natural persons* working under a *direct contract with the beneficiary other than an employment contract*, if:

- the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;
- the result of the work carried out belongs to the beneficiary, and
- the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

- *personnel seconded by a third party* if costs are incurred with the beneficiary

Elements of personnel costs:

- Salary;
- Social security contributions, taxes;
- Other costs included in the remuneration, if arise from national law or employment contract.

Please make sure that

- you consult with article 6.2. "A. Direct personnel cost" of the grant agreement;
- you include a separate template for each of your linked affiliated entity;
- cost of a project coordinator / project manager and financial officer are included for the coordinator.
- cost of a coordinator / project manager is included if you are leading a work package;
- you consider all the expertise (=function) that you will contribute to the action.
- you try to consider the level of seniority of a function;
- you consult with human resources department / accounting department of your organisation to support you with salaries, taxes, etc.
- the information is consistent with the table "*Summary of staff efforts*" and the Budget Overview Table of the Administrative Form of the application.

In the cell "**justification**" you should focus on functions and expertise your organisation will contribute.

B. Subcontracting cost:

Conditions describing the possibility to use the subcontracting are described in point 5.2.3 of this Guide and Articles 6.2 and 10.1.1 of the grant agreement).

Please make sure that

- you consult with article 6.2. "B. Subcontracting cost" and article 10 "Implementation of action tasks by subcontractors" of the grant agreement;
- taxes, duties and other charges are included in the estimate
- you include the estimated cost + potential travel and subsistence costs of the subcontractor;
- a separate row added for each activity to be performed by a subcontractor;
- the activity being subcontracted is also described in the Technical Proposal of Part B;
- you consult with your procurement / sourcing department regarding rules you need to comply with;
- you include a separate template for each of your linked affiliated entity;
- the information is consistent with the Budget Overview Table of the Administrative Form of the application.

In the cell "**justification**" you should explain why the activity would be performed by a subcontractor and how the cost is estimated.

C. Other direct cost:

This budget category has three subcategories: C1 Travel; C2 Equipment and C3 Other goods and services.

Please make sure that

- you consult with article 6.2. "C. Other direct cost" and article 9 "Rules for purchasing goods, works or services" of the grant agreement.
- the sum of C1 + C2 + C3 is consistent with Budget Overview Table of the Administrative Form of the application.

C1 Travel and related subsistence allowance

Please pay attention that

- travel and subsistence costs for ALL potential participants whose costs you plan to reimburse (e.g. personnel, collaborating stakeholders, advisors, special speakers, trainers, volunteers, invited experts, conference participants, etc.) are included;
- ALL the events / meetings you plan to participate in (e.g. project meetings, steering committees, advisory boards, dissemination events, conferences, trainings, workshops, study visits, information sessions, coordination visits to other beneficiaries, etc.) are included;
- both travel AND subsistence cost for each participant are estimated;
- you consult with your accounting and / or human resources department regarding your organisation's rules on travel and subsistence;

In the cell "**justification**" you should explain the type of events you plan to participate / plan to organise.

C2 Equipment

Costs related to equipment may take the following forms:

- The depreciation costs of equipment, infrastructure or other assets (new or second-hand) as recorded in the beneficiary's accounts are eligible and written off in accordance with international accounting standards and the beneficiary's usual accounting practices;
- The costs of renting or leasing equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees;

Please pay attention that

- you include only the **depreciation cost** of an equipment within the duration of the action;
- you include **leasing fee** (without financing costs) and **cost of renting** an equipment
- you consider that the equipment in question is shared or not with another project and you calculate only with your share
- you consult with your accounting department on the depreciation rules and calculation method;
- general office equipment and software are part of Indirect costs.

In the cell "**justification**" you should explain the type of equipment you plan to use for the implementation of the action.

C3 Cost of other goods and services:

Please pay attention that

- you include all those activities for the implementation of the action which would not be performed by personnel or subcontractor. Examples:
 - conference and meeting costs (room rental, catering, meeting materials);
 - laboratory materials and tools;
 - costs of certificates on financial statements;
 - postage, delivery of documents, samples, etc;
 - costs of dissemination;
 - translation / printing of periodic reports, etc.
- you consult with your accounting / procurement / sourcing department
- you include taxes, duties and other charges related to the goods and services to be bought

In the cell "**justification**" you should explain the type of other services you plan to use for the implementation of the action.

D. Indirect costs:

This budget category is a flat rate of 7% above the total direct cost (A+B+C).

Please note that operating grants received by beneficiaries have to be considered and indirect costs will be proportionally decreased for those years when beneficiary receives operating grant (non-cumulative principle).

Operating grants awarded after the signature of the grant for an action will be considered at the time of interim or final payment.

2.2.11 Previous and current grants

Not applicable.

2.2.12 Current applications

Not applicable.

2.2.13 Exceptional Utility

Not applicable.

2.2.14 Collaborating stakeholders

- Collaborating stakeholders and/or experts are organisations or individual persons, which:
- may significantly increase the technical and scientific content of the project, as well as its relevance for different users in the Union;
 - have no contractual relationship with the Commission;
 - do not receive any EU funding from this particular grant.

Please list up to 20 collaborating stakeholders or experts that contribute to the project. This should be done in table format (as suggested below).

Note that it is not mandatory to involve collaborating stakeholders.

Figure 11: Sample table of collaborating stakeholders

Institution	Contact person (First and last names)	City & Country

After finalizing the project proposal, according to the above guidelines and based on the template provided, please convert it into a PDF and up-load it into the Electronic Submission System as "part B".

Figure 10:Screen shot of Part B and annex

Part B and Annexes

In this section you may upload the technical annex of the proposal (in PDF format only) and any other requested attachments. ?

[download templates](#)

Part B	<input type="text"/>	<input type="button" value="X"/>	<input type="button" value="?"/>
Annex:Audit Reports	<input type="text"/>		<input type="button" value="?"/>

Note:

You can replace this project proposal which you already up-loaded as often as you wish before the deadline. Please be sure that the final version is up-loaded at the time of the deadline. It is your responsibility to do so!

C. EVALUATION

All proposals received via the Electronic Submission System, go through a multi-level process of evaluation with regards to several categories of criteria: the eligibility, exclusion, selection and award criteria.

The evaluation of proposals is carried out in the **strictest confidence**.

1 EVALUATION PROCESS OVERVIEW AND OUTCOMES

All criteria and the mandatory supporting documents are specified in the Call for proposals document. Please read these criteria carefully. Project proposals failing to meet any of these criteria will be excluded at the given stage of the evaluation chain.

1.1 Eligibility criteria

There are several eligibility criteria, namely:

1. Applicants must be legally established organisations.

Grant applications are eligible if submitted by legal persons. More specifically, the applicants⁴ must be legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments.

The application shall state the legal status of the applicant.

Applicants participating in a project proposal have to be different legal entities (i.e. independent from each other) or a single entity from an EU Member State.

2. Only applications from entities established in one the following countries are eligible:

- One of the 28 EU Member States;

3. The eligible activities are those listed in the financing decision on the Pilot Project on Establishing registry of rare congenital malformations.

4. Project proposals may be submitted for the priorities foreseen in the financing decision on the Pilot Project on Establishing registry of rare congenital malformations.

5. Applications for actions that have already commenced by the date on which the grant application is registered will be excluded from funding from the Pilot Project.

The compliance with the eligibility criteria will be assessed based on the application content.

1.2 Exclusion criteria

Applicants will be excluded from participation in an award procedure if they are in any of the situations of exclusion listed in Articles 106 and 107 of the Financial Regulation.

⁴ Wherever "applicants" is written this means the coordinator and the co-applicants.

Exclusion from participation:

Applicants will be excluded from participating in the call for proposals procedure if they are in any of the following 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 or persons having powers of representation, decision making or control over them have been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State 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 including by decisions of the EIB and international organisations;
- (d) they are not in compliance with their 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 grant agreement is to be performed;
- (e) they or persons having powers of representation, decision making or control over them have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such an illegal activity is detrimental to the Union's financial interests;
- (f) they are currently subject to an administrative penalty referred to in Article 109(1) of the EU Financial Regulation.

Exclusion from award:

Applicants will not be awarded co-funding, in the course of the grant award procedure, they:

- (a) are subject to a conflict of interest;
- (b) are guilty of misrepresenting the information required by the contracting authority as a condition of participation in the grant procedure or fail to supply this information;
- (c) find themselves in one of the situations of exclusion, referred to in the above section.

In order to demonstrate compliance with the exclusion criteria, the coordinator has to check the relevant box in online application. If selected for co-funding, all beneficiaries have to submit a declaration on their honour certifying that they are not in one of the

situations referred to in articles 106(1) and 107 to 109 of the Financial Regulation^{5,6}. The applicants should follow the instructions in the participant portal.

1.3 Selection criteria: operational and financial capacity

Only proposals which meet the exclusion and eligibility criteria assessed on the basis of the selection criteria. The following selection criteria have to be met.

The selection criteria are used to assess the financial and operational capacity of the applicants.

Financial viability

Applicants must have stable and sufficient sources of funding to maintain their activity throughout the period during which the activity is being carried out and to participate in its co-financing.

The verification of financial capacity will not apply to public bodies and to international public organisations.

All applicants must certify their financial viability when applying. For this the self-assessment must be carried out (see section 2.1).

The financial viability of all beneficiaries will be assessed, except if:

- a) the EU-contribution for the coordinator / other beneficiary is \leq EUR 60 000:
- b) the beneficiary is a public body

The documents that will be requested when assessing the financial viability include:

- the annual accounts (including the balance sheet and the profit and loss statement) for the past financial year for which the accounts were closed (for newly created entities, the business plan shall be submitted to replace the accounts);

In addition for a coordinator or other beneficiary requesting an EU-contribution of \geq EUR 750 000 (threshold applicable per beneficiary):

- an audit report produced by an approved external auditor certifying the accounts for the last financial year available. This provision shall not apply to public bodies.

Operational capacity

Applicants must have the professional resources, competencies and qualifications necessary to complete the proposed action. The applicants' operational capacity has to be certified by the coordinator by ticking the relevant box in Part A of the online application. To proof the operational capacity, pertinent information has to be provided in the

⁵ [REGULATION \(EU, EURATOM\) NO 966/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation \(EC, Euratom\) No 1605/2002](#)

⁶ [Commission Delegated Regulation \(EU\) No 1268/2012 of 29 October 2012 on the rules of application of Regulation \(EU, Euratom\) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union](#)

proposal (part B, section 2.2.9), as described above. The operational capacity will be judged based on the self-declaration and this information.

As evidence the general profiles (qualifications and experiences) of all relevant staff in all organisations involved in the proposed action must be provided

1.4 Award criteria

Only project proposals which have satisfied the eligibility, exclusion and selection criteria will be evaluated by external experts and the Evaluation Committee⁷ on the basis of the award criteria.

More specifically, each proposal will be assessed according to the points set out in the table below, while a threshold is also set for each of the award criteria blocks.

Any proposal that does not reach all of these thresholds will be rejected.

Figure 12: Points – overview of evaluation criteria

	Maximum points	Threshold	Threshold in % of max. points
1 – policy relevance	40	20	50%
2 – technical quality	30	15	50%
3 – management quality	30	15	50%
TOTAL	100	50	

1. Policy and contextual relevance (40 points, threshold: 20 points) :

(a) Project’s contribution to meeting the objectives and priorities defined in the financing decision (8 points);

(b) Strategic relevance with regard to the EU Health Strategy (COM (2007) 630 final;http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm) and with regard to expected contribution to existing knowledge and implications for health (8 points);

(c) Added value at EU level in the field of public health (8 points):

— impact on target groups, long-term effect and potential multiplier effect, such as replicable, transferable and sustainable activities,

— contribution to complementarity, synergy and compatibility with relevant EU policies and programmes;

(d) Pertinence of geographical coverage (8 points):.

Applicants must ensure that the geographical coverage of the project is commensurate with its objectives, and explain the role of eligible countries as partners and the relevance of project resources or the target populations they represent;

⁷ The Evaluation Committee is foreseen to be comprised of staff from the Commission and Chafea.

(e) Social, cultural and political context (8 points):

Applicants must explain how the project relates to the situation of the countries or specific areas involved, ensuring the compatibility of envisaged actions with the culture and views of the target groups.

2. Technical quality (30 points, threshold: 15 points):

(a) Evidence base (6 points):

Applicants must include a problem analysis and clearly describe the factors, impact, effectiveness and applicability of the proposed measures;

(b) Content specification (6 points):

Applicants must clearly describe aims and objectives, target groups, including relevant geographical factors, methods, anticipated effects and outcomes;

(c) Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level (6 points):

Applicants must clearly identify the progress that is expected to result from the project within a given field in relation to the state of the art and ensure that there will be neither inappropriate duplication nor overlap, whether partial or total, between projects and activities already carried out at EU and international level;

(d) Evaluation strategy (6 points):

Applicants must clearly explain the methods proposed and indicators chosen and their adequacy;

(e) Dissemination strategy (6 points):

Applicants must clearly illustrate the adequacy of the envisaged strategy and methodology to ensure transferability of results and sustainability of dissemination.

3. Management quality and budget (30 points, threshold: 15 points):

(a) Planning and organisation (5 points):

Applicants must clearly describe the activities to be undertaken, timetable and milestones, deliverables, nature and distribution of tasks, and provide a risk analysis;

(b) Organisational capacity (5 points):

Applicants must clearly demonstrate the quality level of the structure of the project by describing its management structure, competence of staff, responsibilities, internal communication, decision-making, monitoring and supervision.

(c) Quality of partnership (5 points):

Applicants must clearly describe the partnerships envisaged in terms of extensiveness, roles and responsibilities, relationships between the partners, and the synergy and complementarity of partners and network structure;

(d) Communication strategy (5 points):

Applicants must clearly describe the communication strategy in terms of planning, target groups, adequacy of channels used, and visibility of EU co-financing;

(e) Overall and detailed budget, including financial management (10 points, threshold: 5 points):

Applicants must ensure that the budget is relevant, appropriate, balanced and consistent in itself, between partners and in relation to the specific objectives of the project. The budget should be distributed between partners at a minimum reasonable level, avoiding excessive fragmentation.

Applicants must clearly describe financial circuits, responsibilities, reporting procedures and controls.

Any proposal which does not reach all the thresholds will be rejected.

Following the evaluation, a list is drawn up containing proposals reaching all the thresholds and ranked according to the total number of points awarded. Only the highest ranked proposal will be awarded co-financing.

1.5 Result of the evaluation

– Ranking lists of proposals

The proposals passing all thresholds will be ranked according to the total number of points awarded. Based on the available budget, two lists may be drawn up:

- A ranking list of proposals recommended for funding, including the highest ranked proposals up to the budgetary availability cut-off point; and
- A reserve list of project proposals in case more appropriations are made available.

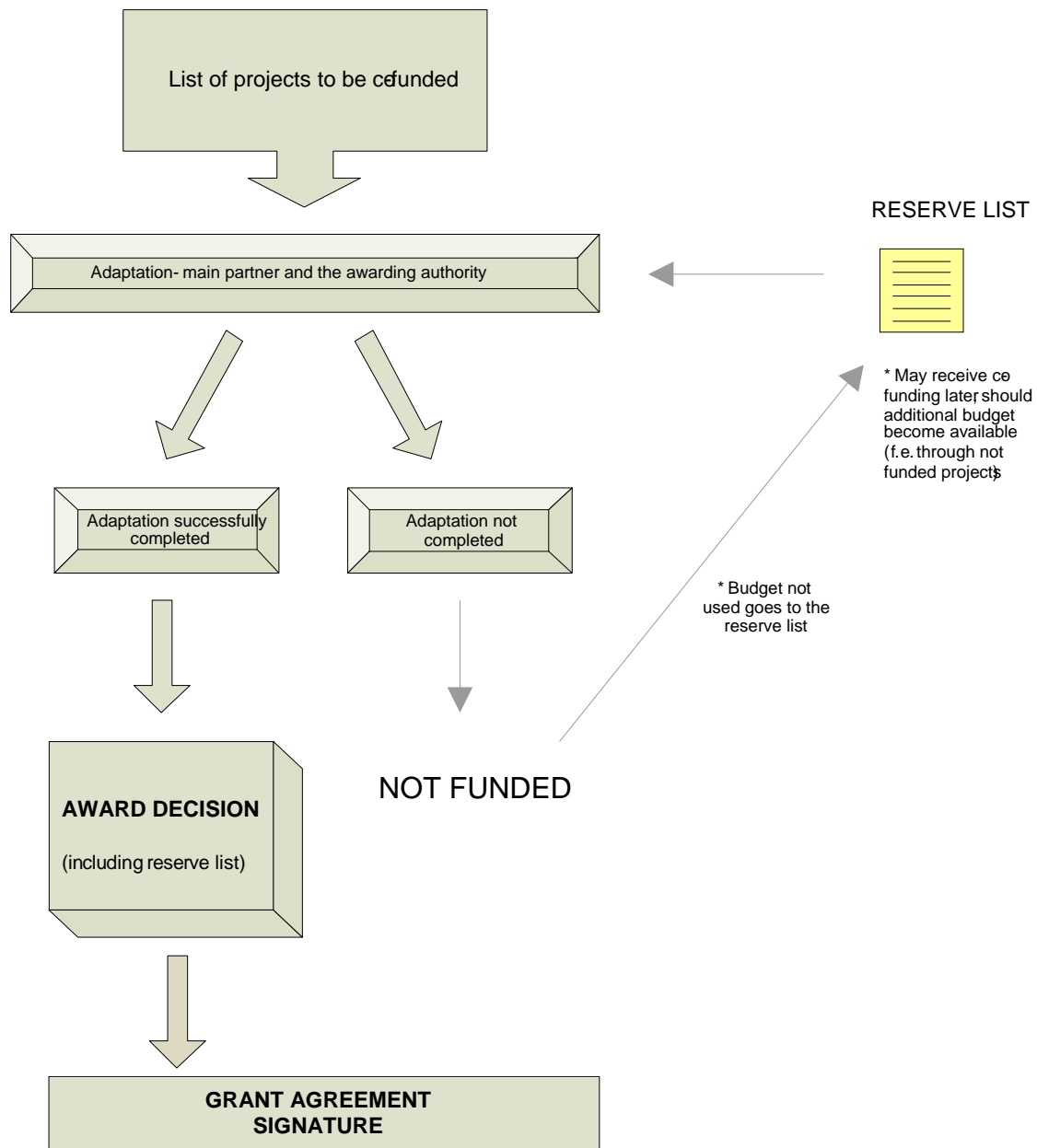
– Adaptation and grant agreement signature

Once the evaluation has been finalized, all applicants – successful or not - will be notified of the results.

The successful applicants will be invited to adapt the proposal, based on the comments of the evaluation committee. Note that the Commission may offer the best ranked applications a lower contribution than the amount requested, or may attach specific conditions before the award decision is taken.

Only if the adaptation phase is positively concluded, will the award decision be taken by the Commission. Subsequently, the grant agreement will be signed. This process is illustrated in the graph below.

Figure 13: Process following the recommendation for EU co-funding.



The Commission trusts that you find this guide for applicants useful. You are welcome to provide feedback and comments in writing to SANTE-PP-CALLS@ec.europa.eu.