



3rd Health Programme

Guide for Applicants

Project grants (PJ)

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Disclaimer

This guide aims to facilitate potential applicants. It is provided for information purposes only and is not intended to replace consultation of any applicable legal sources. Neither the European Commission nor the Consumers, Health, Agriculture and Food Executive Agency - CHAFEA (or any person acting on their behalf) can be held responsible for the use made of this guidance document.

Table of Contents

A.	LEG	AL FRA	MEWORK AND PARTICIPANTS	8			
1			S OF THE HEALTH PROGRAMME AND THE 2016 WORK ME	8			
2	EU I	FINANC	IAL CONTRIBUTION	9			
3	ADMISSIBILITY REQUIREMENTS						
4			APPLICANTS				
5	ROL	E AND	RESPONSIBILITY OF BENEFICIARIES	10			
6			ASPECTS				
Ü	6.1		al principles applicable to grants providing EU co-funding				
	6.2		ng the budget of the action				
	0.2	6.2.1	Form of the grant				
		6.2.2	Definition of eligible costs				
		6.2.3	Description of cost types				
		6.2.4	Exchange rate				
		6.2.5	VAT				
		6.2.6	Definition of non-eligible costs				
	6.3		nination of the grant and payment arrangements				
		6.3.1	Calculation the grant amount				
		6.3.2	Type of receipts				
	6.4	Payme	nt Scheme and Payment Arrangements (Art. 16)				
	6.5		ancing guarantee				
B. S	SUBM	IISSION	OF PROPOSALS	20			
1	PRE	PARINO	G FOR THE SUBMISSION OF YOUR APPLICATION	20			
	1.1	Docum	nents to consult	21			
	1.2		a user account on the Participant Portal – your EU Login	21			
	1.3		er your organisation - Beneficiary Register				
	1.4	Deadli	ne, acknowledgement of receipt, rejection of a proposal and mints				
	1.5	-	rotection				
	1.6	1	d guidance before drafting your proposal				
2			ON FOR A PROJECT				
	2.1		application form: Part A – Administrative part of the applicant				
		U	sation	26			
	2.2	Project	application form: Part B - Technical content	31			
		2.2.1	Problem analysis including evidence base	33			
		2.2.2	Aims and objectives of the project	33			
		2.2.3	Target groups	34			
		2.2.4	Political Relevance				
		2.2.5	Methods and means	36			

2.2.6 Expected outcomes	36
2.2.7 Work packages	36
2.2.8 Milestones and deliverables	39
2.2.9 Project management structure	41
2.2.10 Budget	44
2.2.11 Previous and current grants relevant to the programme	49
2.2.12 Current applications relevant to the programme	49
2.2.13 Exceptional Utility	49
C. EVALUATION	51
1 EVALUATION PROCESS OVERVIEW AND OUTCOMES	51
1.1 Eligibility criteria	51
1.2 Exclusion criteria	52
1.3 Selection criteria: operational and financial capacity	54
1.4 Award criteria	55
1.5 Result of the evaluation	58

GLOSSARY

The Work Programme is the annual work programme drafted by the European Commission to implement the third Programme of the Union's action in the field of health (2014-2020) ('the Programme'), European Commission Implementation Decision C (2017) 316 of 26/01/2017.

The Consumers, Health, Agriculture and Food Executive Agency (Chafea), formerly EAHC, 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 the Regulation.

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 model grant agreement (MGA) is a binding written agreement signed by the parties: Chafea (acting under powers delegated to it by the 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 Participant Portal (PP) is the website hosting the information about funding for the third Health Programme (2014-2020) and Horizon 2020 programmes. Submitting an application for funding is only possible online via the Participant Portal. Participant Portal must also be used for grant preparation. PP also enables the beneficiaries to access all their EU projects that have been selected and approved for funding. Depending on the beneficiaries' roles, they can view or manage the following project-related tasks:

- •Prepare and sign their grant agreements
- •Submit amendments to the grant agreements
- •Manage scientific and financial reports linked to the grant agreements
- •View or manage roles and access rights in their projects consortia

Detailed information on how to perform the actions listed above can be found on PP (https://ec.europa.eu/research/participants/portal/desktop/en/projects/index.html).

The EU Login 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 Programme, and Consumers Programme, in other non-Horizon 2020 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.

The National Focal Point (NFP) is a contact person nominated by the government of the Member State for sharing and disseminating the information on health programmes of the Union's actions.

PREFACE

Dear Applicant,

Welcome to the Guide for Applicants (the Guide) which is intended to help you in preparing and submitting a project proposals to the third Programme of the Union's action in the field of health (2014-2020).

This is a call under the Third Health Programme covering the period from 2014 to 2020. The Third Health Programme contains 4 major objectives and several thematic priorities all contributing to improve the health of EU citizens.

Applicants must submit their proposals via the Electronic Submission Sytem (the Participant Portal).

The present Guide for Applicants – Projects ('the Guide') is designed as the main reference document to help you prepare the proposal. It provides the necessary information for preparing and submitting your application and answers 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* and *Regulation* (EU, Euratom) 2015/1929 of the European Parliament and of the Council of 28 October 2015 amending Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union;
- 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*; and Commission Delegated Regulation (EU) 2015/2462 of 30 October 2015 amending Delegated Regulation (EU) No 1268/2012 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
- Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC, hereafter referred to in this document as <u>Decision No 282/2014</u>;
- Commission Implementing Decision published on 26 January 2017 on the adopting the 2017 annual Work Programme for implementation of the programme of Union's action in the field of health (2014-2020), including budgetary implications and funding criteria for grant, hereafter referred to in this document as the Work Programme 2017;
- Call for proposals for project grants 2017 Third Programme of the Union's action in the field of health (2014-2020), hereafter referred to in this document as the Call for proposals for projects;;

 The multi-beneficiary action model grant agreement, hereafter referred to in this Guide as the *Model grant agreement*.

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 participating in the Third Health Programme, in particular through the call for proposals for projects.

Part B: Submission of proposals

This section describes the entire process of submission of proposals and has two subsections:

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 EU LOGIN account (more on the EU LOGIN 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 overview of the proposal budget) 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:

- The Frequently Asked Questions (FAQ)
- National Focal Points (NFP) you can contact your NFP for further assistance
- For information on how to register or related enquiries please look on the <u>Participant Portal</u>.

<u>IT helpdesk</u> – you can contact the Participant Portal IT helpdesk for questions related to IT matters, e.g. the online submission tool. General research programme related requests can be submitted via the <u>Research Enquiry Service</u>.

For non-IT related questions the Chafea Helpdesk is available via email: CHAFEA-HP-CALLS@ec.europa.eu on weekdays at 9.30-12.00 and 14.00-16.30. The helpdesk is not available on weekends and EC public holidays (13-17 April 2017, 09,25,26 May 2017, 5 June 2017).

Please do not contact the Chafea Helpdesk before having tried to find the information in the documentation that is provided to you. Please ensure you have exhausted all the options before contacting the Chafea Helpdesk.

Please be aware that submitting your proposal can take some time even if you have all the necessary information ready at hand. Please 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.

This is the applicant's responsibility to have the entire proposal placed in and accepted by the electronic submission system before the call closure date and time.

We wish you Good Luck!

Your Chafea Health Unit Team

A. LEGAL FRAMEWORK AND PARTICIPANTS

1 OBJECTIVES OF THE HEALTH PROGRAMME AND THE 2016 WORK PROGRAMME

On 11 March 2014, the European Parliament and the Council adopted the Regulation establishing the third Programme for the Union's action in the field of health for the period 2014-2020 (1).

It is based on Article 168 of the Treaty on the Functioning of the European Union (TFEU) and ensuing legal obligations and policy commitments. Article 168 of the TFEU sets out the scope of EU action in the area of public health which is to carry out actions to support, coordinate or supplement the actions of the Member States.

The EU Health Strategy (²) provides a policy framework for all the areas covered by this Work Programme. The 'Investing in health' Staff Working Document (³) adopted in February 2013 links this policy framework more closely to the broader Europe 2020 strategy. More specifically, it stresses the necessity to invest in sustainable healthcare systems, invest in people's health and reducing health inequalities. Together, these three strands demonstrate that a healthy population and sustainable healthcare systems are decisive for smart, sustainable and inclusive growth.

The third Programme of the Union's action in the field of health (2014-2020) supports and adds value to the policies of Member States aimed at improving people's health and reducing health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of healthcare systems and protecting Union citizens from serious cross-border health threats.

Focusing on the key issues in terms of bringing added value and making a positive impact on delivering mutual benefits across the European Union, the EU Health Programme is built around the following four objectives:

- 1. Promoting health, preventing diseases and fostering supportive environments for healthy lifestyles taking into account the 'health in all policies' principle;
- 2. Protecting Union citizens from serious cross-border health threats;
- 3. Contributing to innovative, efficient and sustainable health systems, and
- 4. Facilitating access to better and safer healthcare for Union citizens.

The EU Health Programme is implemented through annual Work Programmes which set out the priorities for actions to implement its objectives.

The priorities for action under the 2016 Work Programme are set out in detail in its Annex I.

¹ OJ L 86, Volume 57, 21.3.2014, p. 1.

² Commission White Paper Together for Health: A strategic approach for the EU 2008-2013 (COM(2007) 630 final.

³ Commission Staff Working Document Investing in Health. SWD(2013)43 final. Brussels; 20 February 2013. Accompanying the Communication: Towards Social Investment for Growth and Cohesion – including implementing the European Social Fund 2014-2020. COM(2013)83 final

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 60%. However, this may go up to 80% in cases of actions meeting the criteria of exceptional utility. Assessment of exceptional utility will be carried out according to the criteria indicated in Annex VII of the Work Programme 2016. Chafea will determine in each individual case the maximum percentage to be awarded.

The total indicative amount of the present call is EUR.250.000.

Given the complementary and motivational nature of EU grants, projects are financed under the co-financing principle(⁴). 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.

Chapter 2.1 of Annex I of the Work Programme sets out the priority areas for projects to be implemented through (a) call(s) for proposals for projects. Only project proposals which directly correspond to the topic described therein will be considered for funding.

3 ADMISSIBILITY REQUIREMENTS

- Applications must be submitted online via the Participant Portal.
- Applications must be fully submitted before the closing date and time (see part B, point 1.4 hereafter. The closure date and time "Deadline" is indicated on PP and the call submission page). Any application which the electronic submission system records as belatedly submitted will be considered as non-admissible.
- 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 in another EU official language, it should also include translation into English in order to facilitate assessment by the evaluators.

4 ELIGIBLE APPLICANTS

The eligibility criteria are laid down in the 2017 Work Programme (its Annex II contains the exclusion, eligibility, selection and award criteria for projects);

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.

⁴ Art. 125 of the Financial Regulation and Art. 183 of the Rules of Application.

• Applicants participating in a project proposal have to be different legal entities (i.e. independent from each other) from at least 3 countries. Proposals which involve fewer applicants will be rejected.

In accordance with recital 23 of the Health Programme, collaboration should be facilitated with third countries not participating in the programme. This should not involve funding from the programme. Nevertheless, travel and subsistence expenses for experts invited from or travelling to such countries can be considered eligible costs in duly justified, exceptional cases, where this directly contributes to the objectives of the programme.

5 ROLE AND RESPONSIBILITY OF BENEFICIARIES

Roles and responsibilities towards the Agency

If a proposal is successful and a grant agreement is signed between the applicants and the Agency, 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 Annex B of the proposal, which will become Annex I 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 Agency 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 Agency (in particular, providing the Agency with the information described in Article 12 of MGA), unless the MGA specifies otherwise;
- Request and review any documents or information required by the Agency and verify their completeness and correctness before passing them on to the Agency;
- Submit the deliverables and reports to the Agency (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 Agency of the amounts paid to each beneficiary, when required in the MGA (see Articles 28 and 34) or requested by the Agency.

Note:

The coordinator may not subcontract the above-mentioned tasks.

- 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);
 - o The data needed to draw up the technical reports (see Article 15 of MGA);
 - Any other document(s) or information required by the Agency or the Commission under the MGA, unless the MGA requires the beneficiary to submit this information directly to the Agency or the Commission.

Subcontractor(s);

- Subcontractors are not parties to the grant agreement. They do not have a contractual relationship with the Agency.
- 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).
- 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 (see Article 20 of MGA).

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 Executive Agency, nor do they receive any EU funding.
- Note that it is not mandatory to involve collaborating stakeholders entities in your project.

Affiliated entities.

Entities affiliated to the beneficiary are:

- (a) entities that form a 'sole beneficiary' (i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant);
- (b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 131(4) of the Financial Regulation and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.
- 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.

Please refer also 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

As stated above under section 4, a proposal must involve at least three independent legal entities (one coordinator and two beneficiaries) established in three different eligible countries. However, the number of beneficiaries in a given proposal should reflect a **European dimension** of the proposed action and should make sense both technically and politically.

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 to be appropriate for each particular project.

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 oder 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 under the EU Health programme 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 isexpressed both as a maximum amount and also as a predefined 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 (Please refer also to Article 6 of the MGA):

- 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.

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 affilitied entities must be also estimated by the applicant they are linked to. Please consult Article 6.3. of the Model 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 technical part of Annex B of the proposal and be listed in the budgetary part of the same 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 2014/24/EU or contracting entities in the meaning of Directive 2014/23/EU 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 and in accordance with Article 9.1.1.

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 budget cannot declare indirect costs for the period covered by the operating grant.

6.2.4 Exchange rate

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

Beneficiaries (and affiliated entities) with accounting established in a currency other than the euro must convert costs recorded in their accounts 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, they must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries (and affiliated entities) 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 new Financial Regulation, applicable as from 1 January 2013, provides for the full eligibility of the cost of VAT when attributable to exempted 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 or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the Agency for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom 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 in accordance with the Agreement's terms and conditions and costs related to the implementation of the action.

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

- **Step 1** The Agency evaluates the implementation of the action and verifies the actual costs related to the implementation declared by the beneficiaries (and affiliated entities). The reimbursement rate of the grant agreement is applied to the total eligible costs approved by the Agency (Application of the reimbursement rate to the eligible costs).
- **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 (limit to the maximum grant 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 Agency (Reduction due to the no-profit rule).
- **Step 4** Reduction of the grant amount due to substantial errors, irregularities or fraud or serious breach of obligations (reduction due to improper implementation or breach of other obligations).

For further details please also consult 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 (or to an affiliated entity) 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 and Payment Arrangements (Art. 21)

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 be only distributed by the coordinator when 90% of the beneficiaries have signed the accession form and only to those beneficiaries who signed the form! Please refer to Article 21.2 of the Model 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 Agency 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 Agency will pay the balance.

Payment is subject to the approval of the final report.

Pease consult with Article 21 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 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 (s)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 explicitly remains in force until the payment of the balance and, if payment of the balance takes the form of recovery, until three months after the debit note is notified to a beneficiary. (Aarticle 21 of MGA).

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

B. SUBMISSION OF PROPOSALS

The Calls for proposals under the third EU Health Programme use the Electronic Submission System originally developed for the Horizon-2020 Research programmes.

Submitting an application is only possible **online** via the Electronic Submission System of the Participant Portal and **before** the call **deadline**.

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

Also note that the online submission system comprises a two-step process:

- a) Registration of the applicant organisation through a specific procedure;
- b) Submission of the proposal, 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 consists of fields of information, checklists and declarations to be filled in by the coordinator.

Note:

In order to complete part A:

- all other beneficiaries incl. affiliated entities (i.e. not subcontractors or collaborating stakeholders) must be registered in the <u>Beneficiary Register</u> and communicate their PIC to the coordinator
- all beneficiaries must have performed a financial viability self-check
- the coordinator must have the project budget per beneficiary
- Part B includes the technical content of the proposal. This part must be written by the coordinator, following the template provided by Chafea and in collaboration with the co- applicants and, when completed, uploaded directly as a PDF file into the Electronic Submission System.

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 EU Login account for registered users or create a new EU Login 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. You should also check whether your planned activities are in line with the objectives of the third Health Programme and the priorities listed in the Work Programme.

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 Third Health Programme 2014-2020;
- The Commission Implementing decision of 26/01/2017 adopting the 2017 Work Programme for the implementation of the Programme of Union's action in the field of health (2014-2020) The Annual Work Programme 2017;
- The 2017 Call for proposals for projects;
- The multi-beneficiary Model Grant Agreement.

1.2 Create a user account on the Participant Portal – your EU Login 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 an user account, the so-called EU Login 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 EU LOGIN account at hand, you can proceed to the next step, which is to register your organisation; this is done through the European Commision's Beneficiary Register.

The European Commission has an online register of the organisations participating in various EU programmes called the <u>Beneficiary Register</u>. This allows consistent handling of different organisations' official data and avoids multiple requests of the same information. However, check first on the <u>Beneficiary Register</u>page if your organisation is already registered.

RESEARCH & INNOVATION Participant Portal FUNDING OPPORTUNITIES HOW TO PARTICIPATE EXPERTS SUPPORT * HZ020 DNLINE MANUAL Beneficiary Register My Proposal(s) My Project(s) My Notification(s) The Commission has an online register of the beneficiaries participating in the EU research and in My Expert Area or education, audiovisual and cultural programmes. This allows consistent handling of the beneficiaries' efficial data and avoids multiple requests for the same information. If you want to participate in a project proposal, your organisation needs to be registered and have a 9-digit Participant Identification Code (PIC) that is the unique identifier of your organisation and will be used as a Reference Documents reference by the Commission in any interactions Beneficiary Register Financial Capacity Self-Check Is your organisation already registered? Search PIC SME Participation As you have to register your organisation only once, please see first if it has also Click to organisation Search page and check if your organisation and/or your Partners' organisations are If you did not find your organisation in the register, you can start its registration already registered Register your organisation Please note that you need to have a valid ECAS account to start registering your organisation or update its data. Login for the registration in the user manual. To start registration, click on the button below. Click to initiate the organisation registration process - this action will You can guit the registration process at any time; the data entered can be saved as a draft and you may continue open in a new window the Registration Wizard in the your registration at a later time. Save the already entered data by clicking on the Save draft button at the bottom Unique Registraton Facility. After providing all the necessary details, click on the Confirm button to submit your registration. You will receive a If you did not finalise the registration, you can continue it later on My Organisations of the My Area section. You can modify your organisation data also on the My Organisations page of the My Area section. Once your data has been validated by the Validation Service team, only the Legal Entity "Account Administrative" role for this organisation) will be able to AR) (or the persons with an request the modification of the data and provide the corresponding supporting documents on the **My Organisations** page of the Participant Portal.

Figure 2: Screen shot of the Beneficiary Register

- 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 15 June 2017, 17:00 h Luxembourg time.

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.

The only submission mode is the on-line submission. <u>Please use only the Electronic Submission System!</u>

• 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 the proper documents entirely.

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

- Chafea 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 check⁵; 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:

Chafea does not manage the submission process via the Electronic Submission System. Hence, please contact the Helpdesk of the Participant Portal and not Chafea 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 Agency under Regulation No 45/2001 and according to the procedure announced with the relevant notifications submitted to the Agency's 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.

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.

1.6 General guidance before drafting your proposal

The present call for proposal is expected to be highly competitive. 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:

⁵ Note: this is not performed by Chafea. The system may contact you about this, if needed, not Chafea.

Relevance: check that your intended proposal does indeed address a topic indicated in chapter 2.1. of the Work Programme i.e. responds directly to the call for proposals for new rare diseases registires. Proposals falling out of the scope of the Work Programme 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. However in case of more then 30 partners the number of pages for the budget can be exceeded.

Note:

Even if you have more 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 its budget; 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 $\mathbf{A} - \mathbf{Administrative}$ 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 summary

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

Section	Title	Action
1	General Information	
2	Participants and Contacts	
3	Budget	

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 Work Programme of the Third EU Health Programme.

The abstract will be used as a short description of the proposal in the evaluation process and in communication with the programme management committee and other interested parties. 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 are 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, exligibility and selection criteria as set-out in the Work Programme.

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 <u>self-check of the financial capacity</u> 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. In addition you must indicate which co-funding rate you apply for.

The usual co-funding rate for project under the EU Health Programme is 60% of the total eligible costs. However, this may increase to up to 80% of the total eligible costs, if the project application is deemed to be of exceptional utility towards achieving the objectives of the Programme. **Importantly, the same co-funding rate (60% or 80% in case of**

exceptional utility) shall be used by each participant in the proposal to calculate their requested grant.

To receive up to 80% of co-funding, the proposals must comply with the criteria (see also Annex VII of the Work Programme):

- At least 60 % of the total budget of the action is used to fund staff (rational: this criterion intends to promote capacity building for development and implementation of effective health policies)
- At least 30% of the budget of the proposed action is allocated to Member States whose gross national income (<u>GNI</u>, as published by <u>EUROSTAT</u>) per inhabitant is less than 90 % of the Union average. (*rational: this criterion intends to promote the participation from Member States with a low GNI*).
- The proposal demonstrates excellence in furthering public health in Europe.

Note:

if you want to apply for exceptional utitily, it is your duty to ensure that your proposal complies with the first two criteria. The third one will be assessed by the external evaluators, as part of the award criteria.

Please be aware that if your proposal does not meet the criteria for exceptional utility, the final EU contribution will only be up to 60% and additional applicant's contribution will become necessary.

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

Explanation:

White cells: to be filled by the coordinator

Grey cells: automatically calculated

Crossed out 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	Indirect costs (max 7% on a, b and c) ³	Total estimated eligible costs	Reimbursem ent rate (%)	Maximum EU contribution	Requested Grant ^{1, 2}	Income generated by the action	Financial contributions given by third parties to the beneficiary	total
			(a)	(b)	(c)	(d) = 0.07 *((a)+(b)+(c))	(e) = (a)+(b)+(c) +(d)	(f)	(g) = (e)*(f)	(h)	(k)	(1)	(m) = (k) + (l)
1			0	0	0	0,00	0,00	\times	\times	0	0	0	0
Total		0	0	0	0,00	0,00		0	0	0	0	0	

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 is equal to the corresponding amounts given in the individual detailed budget under Part B of the application, heading 10.4.

The reimbursement rate is identical for each participant and corresponds to the rate of the total (e.g. in the case reimbursement of 60% of the total eligible costs of the action is requested, the only option for reimbursment request per each participants shall be 60%).

For a project grant this reimbursement rate is 60%. However, in case of exceptional utility, that reimbursement rate can be up to 80%

The maximum EU contribution in column (g) corresponds to the total eligible cost in column (e) multiplied by the reimbursement rate in column (f). The same ratio of 60% (or 80%) also applies for each partner for its own maximum EU contribution.

The Requested Grant amount (by participant or in total) in column (h) can be up to maximum EU contribution (for each participant and for the total). At the proposal stage, we recommend to each participant to have the requested grant amount (h) to be equal to the maximum EU Contribution amount (g).

Important:

When completing the budget table please also bear in mind that for your budget request being valid:

- it is obligatory to input in column (h) the amounts of requested grants.
- at the proposal stage it is highly recommended to have the amount of the **requested grant equal** to the amount of the **maximum EU contribution** you apply for (comments valid for each participant).

Please make careful calculations before inputting figures into the table and make a careful check before submitting the application

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 (1).

The applicants must state the total receipts (column (m)), which is composed of the 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)), as per the 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".

Another important point concerns financial contributions given to the beneficiary by third parties. These shall be described in detail in 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 by the Chafea. You can write your proposal in any word processing tool. However, once completed, the uploading 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 and priorities defined in the annual work programme
- 4.2 Added value at EU level in the field of public health
- 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)

12. CURRENT APPLICATIONS RELEVANT TO THE PROGRAMME

13. EXCEPTIONAL UTILITY

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: as mentione above, 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 descrtion 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. 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 rare diseases 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 revelance of action co-funded under the Third Health Programme is important. Hence, please describe it in detail in your proposal, guided by the four points below.

Contribution to meeting the objectives and priorities defined in the annual work programme:

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 which is open for call for proposals for new registries (section 2.1, point 2.1.4.2. of the Work Programme) 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.

The project must be innovative and also sufficiently compatible with existing actions. In this context, participation in networks and coordination meetings between different actions co-funded under the EU Health Programmes is important.

Added value at EU level in the field of public health:

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

- 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 and EU Member States policies and programmes including compatibility with the European Platform on RD registration and the EC European reference Networks' platform.

Ways - how to achieve EU-added value

- Implementing EU legislation
- Achieving economies of scale
- Promoting best practice
- Benchmarking for decision making,
- Reducing cross border threats
- Strengthening free movement of persons
- Strengthening networking activities

As mentioned under the topic description in the 2016 work programme, the registries should be built with the support and according to the standarts set up by the European Platform on rare diseases registration and provide all necessary data to the Platform. They should also be compatable with the European Commission ERNs' platform which is currently under preparation.

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. As the Third Health Programme is not expected to fund recurrent actions, the proposal should also address its sustainability.

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 within the EU Third Health

Programme 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, including by the Executive Agency.

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 (note: the kick-off meeting should be held in Luxemburg) 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.

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

Figure 5: Sample table of a WP

Timetable or Gantt Chart⁶

-

⁶ 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.

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 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:

Chafea 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). Chafea 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 indicated in a table below. Please copy them into your proposal and complete with data specific to 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 Executive Agency i.e. confidential (CO, see also conditions in the Model 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 Chafea).

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

6 newsletters are produced throughout the project, they should be listed a one deliverable and not as 6 individual ones (even if in different languages). Indicate the different months when the newsletters would be produced (e.g M6, M12, M18, M24, M30, M36).

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	to indicate	A leaflet to promote the project must be produced at the beginning	P	M3
MD.4	Layman version of the final report	2	to indicate	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	to indicate	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"

Note: please do not include the periodic and final technical and financial reports in the table of deliverables as far as they are part of the Periodic Reporting section in the Participant Portal. It is in contrary with the rest of the deliverables which are part of the Continuous Reporting section in the Participant Portal (PP) and should appear in the table of Deliverables.

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 ERN and its members participating in the project proposal. 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?

As mentioned previously, project proposals under this call can be submitted by one, two or more ERNs.

Is it not compulsory to have all Healthcare Providers (HCPs) which are members of a given ERN participating in the project as project beneficiaries. Some of them can participate as collaborating stakeholders or not participate at all.

It is also not compulsory to have as project coordinator the ERN coordinator. Anyother HCP-member of the ERN can play the role of the project coordinator. The proposal should be agreed by the Board of the Network according to their adopted rules and procedures. It shall be explained in the project proposal.

A HCP which is not ERN member cannot participate in the project as beneficiary (get EU co-funding).

Quality of the staff

Applicants must clearly but concisely describe the profiles assigned to the scientific, technical and managerial implementation of the project.

• Coordinator institution profile, description of competences, background, leadership and authority in the action area

Demonstrate the way coordinator will 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. The project manager profile must provide for the necessary skills, expertise and authority to lead a team and to achieve the action objectives as well as capacity to use the resources in a flexible way.

• Key staff of the coordinator – description of profile (leadership and authority) and background in the action area.

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

Note:

Applicants are requested to include staff profiles into the proposals (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.

• Beneficiaries' 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 beneficiaries – 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 then 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;

- Contigency 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)						
Tunction category)				Total person month	Total Costs (€) for (A)	
	Justificatio	n				
	Justification	11				
(B) Direct costs of sub-contracting	Costs (€)	Task	(s)/Justi	fication		
(please repeat line for each						
subcontracted task foreseen)						
Total Costs (€) of (B)	T					
	Justification					
(C) Other direct costs						
(C.1) Travel	Costs (€)		Justific	fication		
(C.2) Equipment	Costs (€) Just		Justific	Justification		
(C.2) Other and beautiful	C 4 - (C)		T4'6"	4 •		
(C.3) Other goods and services	Costs (€) Justif		Justific	cation		
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 Administative 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 "purchase of goods, works or services" 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 relevant to the programme

The coordinator should add here a list of previous and current grants relevant to the Third EU Health Programme (limited to the last 3 years) his/her organization is receiving/has received, if any.

2.2.12 Current applications relevant to the programme

The coordinator should add here a list of the current applications relevant to the Third EU Health Programme he/she is involved in, if any.

2.2.13 Exceptional Utility

The coordinator indicated already in the budget overview table in part A, if he/she requests a higher co-funding percentage than 60% or not. If more than 60% is requested i.e. the applicants want to apply for so-called exceptional utility, add here the justification for this. Please focus on how the proposal fulfils the third criterion for exceptional utility i.e. it demonstrates excellence in furthering public health in Europe and has a very high EU added value.

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 Agency;
- 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).

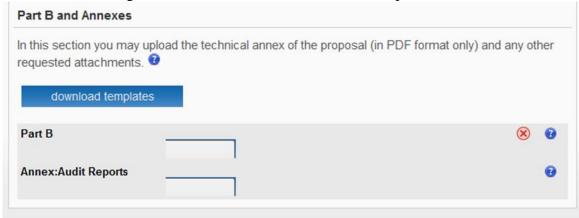
Note that it is not mandatory to involve collaborating stakeholders.

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. Part B and Audit Report Annex



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 by Chafea 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 for new rare diseases registries 2016 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 orgabisations.

Grant applications are eligible if submitted by legal persons. More specifically, the applicants⁷ 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.

In accordance with recital 23 of the Regulation establishing the third health programme, collaboration should be facilitated with third countries not participating in the programme.

This should not involve a financial contribution under the programme. Nevertheless, travel and subsistence expenses for experts invited from or travelling to such countries can be considered eligible costs in duly justified, exceptional cases, where this directly contributes to the objectives of the programme.

- 3. Applicants participating in a project proposal have to be different legal entities (i.e. independent from each other) from at least 3 countries participating in the Health Programme. Proposals which involve fewer applicants will be rejected.
- 4. Only those applicants whose network applications to become an official European Reference Network and membership application within the abovementioned network (in the meaning of Directive 2011/24/EU) have been positively assessed and approved are eligible.

As laid down in Article 12 of the Directive on the application of patients' rights in cross-border healthcare registries will be one of the objectives of the European Reference Networks to be set up.

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

The present call and the proposed EU co-funding is therefore limited to proposals coming from such approved ERNs. More specifically, are eligible under this call, whether as coordinators or associated partners, applicant organisations which are members of official European Reference Networks and which fall under the scope of Directive 2011/24/EU57, i.e. which have been positively assessed and approved by the Board of the Member States.

- 5. The only eligible activities are those listed in section 2.1 "Grants for projects" in the Work Programme 2017.
- 6. Project proposals may be submitted for the priority area presented in the table below. For full descriptions regarding the objectives pursued and expected results please consult the Work Programme 2017.

Proposals should match the specific description of a given action.

TITLE	INDICATIVE AMOUNT, EUR	Ref. in Work Programme 2017	Grants foreseen
Supporting Member States in mainstreaming health promotion and disease prevention in health and educational settings (Thematic priority 1.3 of Annex I to the Programme Regulation)	250.000	2.1.1.1	one

7. Applications for the action above that have already commenced by the date on which the grant application is registered will be excluded from funding from the Health Programme.

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

1.2 Exclusion criteria

Exclusion from participation:

Applicant will be excluded from participating in the call for proposals procedure if it is in any of the following situations:

- (a) is bankrupt, subject to insolvency or winding-up procedures, where its assets are being administered by a liquidator or by a court, where it is in an arrangement with creditors, where its business activities are suspended, or where it is in any analogous situation arising from a similar procedure provided for under national laws or regulations;
- (b) it has been established by a final judgment or a final administrative decision that the applicant is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the granting authority is located or those of the country of the performance of the grant agreement.;
- (c) it has been established by a final judgment or a final administrative decision that the applicant is guilty of grave professional misconduct by having violated applicable

laws or regulations or ethical standards of the profession to which the applicant belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:

- (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract/grant agreement;
- (ii) entering into agreement with other economic operators with the aim of distorting competition;
- (iii) violating intellectual property rights;
- (iv) attempting to influence the decision-making process of the contracting authority during the procurement / grant award procedure;
- (v) attempting to obtain confidential information that may confer upon it undue advantages in the procurement / grant award procedure;
- (d) it has been established by a final judgment that the applicant is guilty of any of the following:
 - (i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;
 - (ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the law of the country where the contracting authority is located, the country in which the economic operator is established or the country of the performance of the contract;
 - (iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA:
 - (iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
 - (v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
 - (vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;
- (e) the applicant has shown significant deficiencies in complying with main obligations in the performance of a contract / a grant agreement financed by the budget, which has led to its early termination or to the application of liquidated damages or other

contractual penalties, or which has been discovered following checks, audits or investigations by an authorising officer, OLAF or the Court of Auditors;

(f) it has been established by a final judgment or final administrative decision that the applicant has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95.

Exclusion from award:

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

- (a) are in an exclusion situation established in accordance with Article 106 and 107 of the EU Financial Regulation;
- (b) have misrepresented the information required as a condition for participating in the procedure or has failed to supply that information;
- (c) were previously involved in the preparation of documents where this entails a distortion of competition that cannot be remedied otherwise.

In order to demonstrate compliance with the non-exclusion requirements, 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, 107 and 108 of the Financial Regulation^{8,9}. The applicants should follow the instructions in the participant portal.

1.3 Selection criteria: operational and financial capacity

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

Financial viability

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Applicants must have stable and sufficient sources of funding to maintain their activity throughout the period during which the action is being carried out or the year for which the grant is awarded and to participate in its funding.

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:

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 and REGULATION (EU, EURATOM) NO 2015/1929 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 28 October 2015 amending Regulation (EU, Euratom) No 966/2012 on the financial rules applicable to the general budget of the Union

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 and COMMISSION DELEGATED REGULATION (EU) 2015/2462 of 30 October 2015 amending Delegated Regulation (EU) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union

- 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 last 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 proposal (part B, section 2.2.9), as described above. The operational capacity will be judget 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 Committee¹⁰ 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 the award criteria

	Maximum score (points)	Threshold (passmark)
1 – policy and contextual relevance	10	7
2 – technical quality	10	6

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 $^{^{10}}$ The Evaluation Committee is comprised of staff from DG SANCO, DG RTD and Chafea.

3 – management quality	10	6
4 – overall and detailed budget	10	6
TOTAL	40	25

Criterion 1. Policy and contextual relevance (10 points, threshold: 7 points):

Sub-criteria:

Relevance of the contribution to meeting the objectives and priorities defined in the annual work programme of the Third Health Programme, under which the call for proposals is published:

- A detailed description on how the proposal meets these objectives and priorities is provided;
- A clear public health perspective/dimension is demonstrated;
- The proposals contributes to and supports the development of EU policies in the field of health.

Added-value at EU level in the field of public health:

EU added value (¹¹) will be achieved in one or more of the following areas: 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 and EU MS policies and programmes.

Pertinence of geographical coverage of the proposal:

 The geographical coverage of the project is highly commensurate with its objectives. The target population and the reasons for choosing partners in the eligible countries participating are explained.

Consideration of social, cultural and political context:

- The proposals relates well to the situation of the countries or specific areas involved, and ensures the compatibility of envisaged actions with the culture and views of the target groups;
- The proposal contributes, complements and supports MS policies, addressing the demographic challenges, promoting social inclusion of vulnerable groups, promotes gender balance, etc.;

Ethical aspects, confidentiality and protection of personal data are respected for establishing of registries, and performance of studies.

Criterion 2. Technical quality (10 points, threshold: 6 points)

Sub-criteria:

Quality of the evidence base:

EU added value can be achieved in different ways: by implementing EU legislation, economies of scale, promotion of best practice, benchmarking for decision making, reducing cross border threats, strengthening free movement of persons or strengthening networking activities.

 A relevant problem analysis using scientific evidence is included. It clearly describes the health determinants, factors, impact, effectiveness and applicability of the proposed actions.

Quality of the content:

- Aims and SMART objectives, ensuring a clear public health orientation focus on the implementation of effective measures are clearly stated;
- The methodology on how to carry out the planned activities to achieve the objectives, is well described and adequate;
- The transferability and sustainability of these activities, the target groups, deliverables, milestones, main outputs as well as anticipated effects and outcomes are well described and pertinent;
- Quality of the deliverables: the deliverables are well defined and quantifiable. The
 deliverables correspond to the objectives and are prepared using a defined amount of
 time and person days.

Please note that a strong research focus, including clinical research, is not considered as advantageous. A public health knowledge translational approach (12) will be an advantage.

Innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level:

- The progress the project intends to make within a given field in relation to the state of the art is identified;
- There will not be inappropriate duplication or overlap, whether partial or total, between projects and activities already carried out at EU and international level.
 Applicants demonstrate how the proposal complements EU initiatives and/or EU MS policies.

Quality of the evaluation strategy:

- The methods proposed are adequate, this should include using a logic framework method, with "SMART" indicators (process, output and outcomes/impact) chosen per specific objective, including target values. Specific indicators regarding dissemination and project management are included.
- An external and independent evaluation of the project outcomes is an advantage.

Quality of the dissemination strategy and plan:

- A pertinent stakeholders analysis (including representatives from the Ministries of Health and Public Health institutes) is provided;
- It is well described what will be disseminated to whom, when and why;
- The methodology clearly illustrates the adequacy of the different tools and channels
 of dissemination to ensure sustainability of the project results and the reaching of the
 target group/stakeholders;
- A dissemination plan is provided which includes adequate timing and milestones for the dissemination activities;
- A dissemination report is foreseen that will clearly show the results (with qualitative and quantitative indicators);
- The visibility of EU co-financing is ensured.

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¹² An approach to increase the use of evidence within policy and practice decision-making contexts.

Criterion 3. Management quality (10 points, threshold: 6 points):

Sub-criteria:

Quality of the planning and appropriate task distribution to implement the project,

- The activities to be undertaken are clearly described;
- The project timetable and milestones are logic and harmonized with the objectives;
- The nature and distribution of tasks among the partnership follows the relevant expertise and is balanced;
- A risk analysis and remediation plan is provided and both are adequate;
- The planning is visualized through a GANTT chart.

Relevance of the organisational arrangements, including financial management:

- The management structure and competences of staff are clearly described;
- An internal communication strategy in terms of managing the project consortium, including collaborating partners, decision-making, and monitoring and supervision is set-up and adequate;
- The financial processes (e.g. validation of payments, collection of financial documents etc.) and responsibilities, technical and financial reporting procedures and quality controls are well described and adequate.

Quality of the partnership:

 the partnerships envisaged in terms of extensiveness, roles and responsibilities, relationships between the partners and the planned activities, as well as the synergy and complementarity of partners and the network structure are well described.

Criterion 4. Overall and detailed budget (10 points, threshold: 6 points):

Sub-criteria:

- The budget is relevant, appropriate, balanced and consistent with itself, between partners and in relation to the activities and work-packages defined the project proposal;
- A realistic, planned estimation person months per workpackage is included;
- The budget is consistent in terms of of the estimated cost per applicant and the corresponding activities i.e. it reflects task distribution / role of each partner;
- An adequate proportion of the budget is allocated to ensure the dissemination and evaluation of the action.

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 will be drawn up:

- o 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.

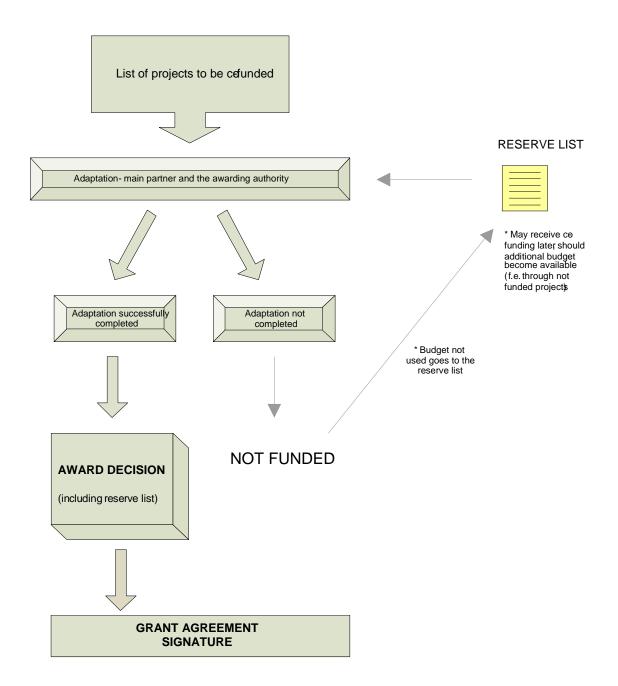
Adaptation and grant agreement signature

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

The successful applicants will be invited to adapt the proposal, based on the comments of the evaluation committee. Note that Chafea 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 Chafea. 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.



Chafea trusts that you find this guide for applicants useful. You are welcome to provide feedback and comments by writing to <u>this email.</u>