

European Commission



Third EU Health Programme (2014-2020) Mono-Beneficiary European Reference Networks' Grants (ERN Grants) (HP-ERN-2016) Framework Partnership Agreements (FPA)

Guide for Applicants

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Disclaimer

This document is aimed at informing potential applicants for 3rd EU Health Programme funding. It serves only as an example. The actual Web forms and templates, provided in the online proposal submission system under the Participant Portal, might differ from this example. Proposals must be prepared and submitted via the Electronic Submission System under the Participant Portal.



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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) (<u>the Programme</u>), European Commission Implementation Decision C (2016) 1158 of 01 March 2016.

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 Agriculture programme and the Better Training for Safer Food initiative.

A beneficiary is the ERN coordinator (the coordinator) that has received EU co-funding following successful application and the signature of the related grant agreement (The "ERN Assessment Manual for Applicants" refers to the coordinator as "Coordinating Member").

A mono-beneficiary grant agreement (MGA) is a binding written agreement signed by two parties: Chafea (acting under powers delegated to it by the European Commission) and the ERN coordinator, i.e. the recipient of the EU co-funding. By signing the agreement, the beneficiary organisation accepts the grant and agrees to implement the action under its 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.

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

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

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

The LEAR (Legal Entity Appointed Representative) is the appointed representative within the beneficiary organisation. He/she is authorized to sign the grant agreement and action's documents on behalf of the organisation.

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.

Dear Applicant,

Welcome to the Guide for Applicants for ERN Grants (the 'Guide) which is intended to help you in preparing and submitting a grant proposal under the Call for proposals for ERN grants 2016 ('the call') of the Third Programme of the Union's action in the field of health (2014-2020).

The applicants will be able to submit their proposals via the Electronic Submission System (an IT platform including an online submission tool). This will make the monitoring phases for submission, evaluation and, for those recommended for funding, quicker, simpler and more efficient.

For the (potential) applicants, here are several important points worth observing.

What is an ERN Grant ?

This is an EU financial support to ERNs which aims at co-funding coordination, management and non-clinical activities of approved ERN for a period of 12 months.

What is NEW in terms of ERN grants?

For each coordinator of the applying ERN under this call it is compulsory to apply as well for FPA. Following this call, a call for proposals for Specific Grant Agreements (SGA) will be opened for successful ERN-FPA applicants.

In order to respond to the needs of the European reference networks, it was decided to award ERN grants under the framework of long-term cooperation between Chafea and the potential beneficiaries. There are three reasons for doing so. Firstly, this type of agreement will help establish a partnership procedure for important actors at EU level; secondly, it will offer a clearer financial perspective for the ERNs; and thirdly, it will provide more stability and efficiency gains for all involved.

THE CONCEPT of two types of agreements: FPA and SGA

If awarded, the cooperation between Chafea and the beneficiary will last five years (from 2017 to 2021) and will be based on the signing of a so-called Framework Partnership Agreement (FPA). This FPA will spell out the applicant's strategic pursuits and objectives for the period between 2017 and 2021.

The annual co-funding will be ensured through the signature of a so-called Specific Grant Agreement (SGA) and will be awarded on the basis of the already signed FPA and invitation (by Chafea to the FPA signatory) to submit a proposal for the ERN grant for 12 months. Namely, an SGA spells out the applicant's 12 calendar months coordination, management and non-clinical activities as an ERN.

What is an FPA?

The FPA proposal will present an action plan covering the period from 2017 to 2021 (5 years). This plan will include only those activities that are to be co-funded by the EU. Following an evaluation process, the successful applicants will be invited to sign the FPA covering that period. At that stage, signing an FPA will not result in a grant providing funding to the applicant's selected FPA proposal; it will be a legal commitment, serving as a basis for the partnership established between the successful applicant and Chafea for the next 5 years. Once the FPA is signed, it will make the signatory ERN eligible for receiving EU funding on the basis of an SGA proposal.

Work plan for the first year of FPA implementation

The proposal under this call will need to include the detailed action plan for the first year of the partnership including the request for EU financial contribution. The proposal will be evaluated for its quality and alignment with their respective FPA action plan.

The process of the annual work programme submission is going to be repeated each year covered with the FPA, in the framework of a call for Specific grant agreements (SGAs).

What does it mean in practice for the 2016 Call for proposals?

The applying ERN coordinator is called to submit a single application including two proposals: one for ERN and one for FPA. After the submission deadline, and in compliance with the provisions of Commission Delegated Decision (2014/286/EU) and in the Commission Implementing Decision (2014/287/EU) the ERN Board of Member States will decide on the approval of each candidate network previously assessed by Independent Assessment Bodies contracted by the European Commission. Only approved ERNs will be considered eligible for grant (FPA and SGA). The evaluation committee will draw up a list of successful proposals for FPA 2017-2021. Then the successful applicants will be invited to submit a proposal for SGA.

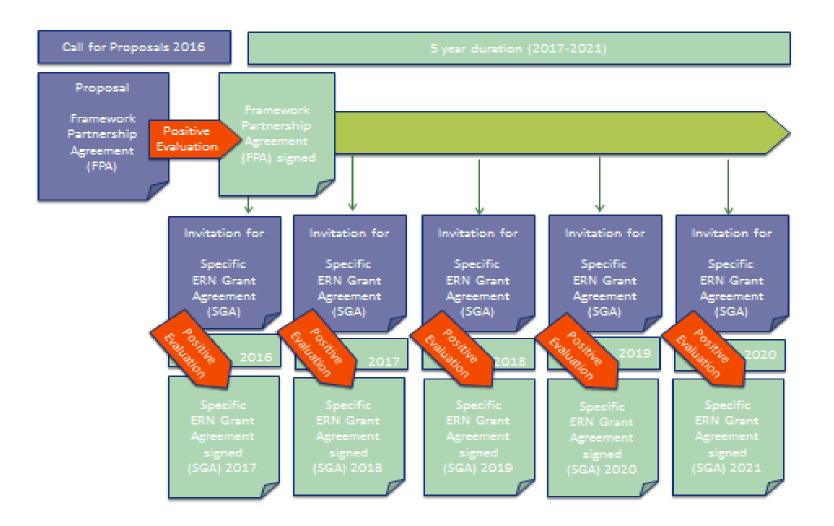
This means that, under call for proposals 2016 your network will need to put more effort and submit two proposals within one application. On the other hand, this will substantially reduce the time to grant the successful ERNs in future.

What does it mean in practice for the next Calls?

In 2017, the FPA signatories (meaning those coordinators of approved ERNs that have signed the FPA 2017-2021) <u>will be invited</u> to submit their proposals for the 2^{nd} year of action. The successful proposals will be awarded a Specific Grant Agreement (SGA) for the 2^{nd} year of implementation of FPA. The same procedure will be repeated in 2018, 2019 and 2020. In other words, there will be no open calls, which will simplify the SGA submission process.

The flowchart in Figure 1 provides an overview of the procedure of the ERN proposal.

Figure 1: Flowchart of the grant process under FPA



This Guide is designed as the main reference document to help you prepare the submission of your FPA proposal. The Guide for the call for interest for ERNs is available as a separate document.

The ERNs grants Guide provides the necessary information for preparing and submitting your application and answer questions you may have in this process. Please note that this Guide does not supersede the rules and conditions laid out in the following documents which should be consulted in case of doubt:

- Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) no 1605/2002, hereafter referred to in this document as the *Financial Regulation* and <u>Regulation</u> (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 <u>Rules of Application of the Financial Regulation</u>; and <u>Commission Delegated Regulation</u> (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 01 March 2016 on the adopting the 2016 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 <u>Work</u> <u>Programme 2016</u>;
- Call for proposals for ERNs grants 2016 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 ERNs grants;
- The mono-beneficiary FPA model, hereafter referred to in this document as the *model FPA /model grant agreement*;

The Guide consists of three main parts:

A. Legal framework and participants

This section describes the legal terms and general conditions for participating in the Health Programme, in particular through the Call for proposals for ERNs grants.

B. Submission of proposals – preparing the application

"Submission of proposals" describes the entire process of the submission of proposals and has two sub-sections:

The first sub-section refers to the necessary preparatory steps. This includes: (1) reference to the background documents that you need to consult prior to preparing a proposal; (2) instructions on the process for creating a user account or an ECAS account for the ERN coordinator (more on the ECAS account is presented in the IT Help Guide for the submission of proposals, Chapter 2) and (3) the registration of the applicant ERN coordinator 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 preparation of the FPA proposal and the 1st-implementation year work plan. Thus, after completing the general common form of Part A (Proposal submission form), you can proceed to the technical content of your proposal, Part B (Proposal template).

Part B, in turn, is split into three parts: *ERN application (minimum 10 Health Care Providers per 1 ERN)*, part B.1: "Template proposal B.1: 5-year Work Programme 2017-2021 for the Framework Partnership Agreement for an ERN Grant (HP-FPA-ERNG)" for the submission of the FPA proposal and part B.2 – "Template proposal B.2: 1-year Work Programme which would later become the SGA proposal.

Details as to what information you are expected to provide are noted under the respective sections in the Guide under:

- <u>Section 2.2</u>: Part B.1 "Template proposal B.1: 5-year Work Programme 2017-2021 for the Framework Partnership Agreement", and
- <u>Section 2.3</u>: Part B.2 "Template proposal B.2: 1-year Work Programme".

C. Evaluation process of the applications

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

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

- The <u>Frequently Asked Questions (FAQ)</u>
- National Focal Points (NFP) <u>you can contact your NFP for further assistance</u>

- For information on how to register or related enquiries please look on the <u>Participant Portal</u>.
- IT helpdesk you can contact the Participant Portal IT helpdesk for questions only related to the online submission tool. Requests must be submitted via the <u>Research</u> <u>Enquiry Service</u>
- For non-IT related questions, the Chafea Helpdesk is available via email: and telephone: +352-4301-37707. This helpdesk is open on weekdays between 9:30 12:00 and 14:00 17:00. The helpdesk is unavailable on weekends and public holidays.

Please do not contact the 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 Helpdesk.

This Guide is to be updated on the basis of suggestions to make it as user-friendly as possible. Should you have any suggestions or comments on how to improve this Guide for next year's call, please send us an <u>email</u> to the Helpdesk.

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

Good luck!

Your Chafea Health Unit Team

A. LEGAL FRAMEWORK AND PARTICIPATION

1 OBJECTIVES OF THE HEALTH PROGRAMME AND 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 linked 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. Taken 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 EU, 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 annual Work Programme are set out in detail in 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 <u>Commission Staff Working Document Investing in Health. SWD(2013)43 final</u>. 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 FINANCIAL CONTRIBUTION TO THE FUNCTIONING OF AN ERN (ERN GRANT)

Grants (FPAs and SGAs) may be awarded to ERNs active in areas corresponding to the fourth objective of the Health Programme. Work under ERNs grants should contribute to achieving the priorities of the European Union as set out in <u>Commission Communication</u> <u>COM (2010) 2020 of 3 March 2010 EUROPE 2020 — A Strategy for smart, sustainable and inclusive growth</u>.

3 WHO CAN APPLY?

Only Networks applying also for the call for interest for ERN can apply for FPA. Only Networks approved as ERNs can be awarded EU co-funding.

4 HOW ARE ERN GRANTS AWARDED

This Call for proposals aims at establishing multiannual framework partnerships by means of FPAs for a duration of 5 years (2017 to 2021), in view to provide financial contributions through subsequent specific grant agreements (SGAs) to ERNs. Signing an FPA does not guarantee annual co-funding.

The applicant is invited to submit an application with a proposal for an FPA including all the requested parts and documents.

The awarded EU grant to the ERN can cover up to **60**% of the total estimated costs of the action. In cases of **exceptional utility**, for activities offering significant added value to the EU, the EU contribution can be increased up to **80%** of the total cost. The criteria for exceptional utility are defined in <u>Annex VII</u> of the Work Programme 2016.

Each FPA signatory will be invited to submit SGA proposal again in years 2017, 2018, 2019 and 2020 and will be subject to evaluation.

The eligibility criteria are laid down in the Call for proposals 2016, as well as in the Work Programme 2016 where <u>Annex V</u> contains the exclusion, eligibility, selection and award criteria for ERN grants.

5 ROLE AND RESPONSIBILITY OF THE BENEFICIARY

As mentioned above the successful ERN applicants can be awarded EU co-funding through a **Specific Grant Agreement (SGA)** with Chafea and will be referred to as "beneficiary ERN". In consequence, all sections of the present Guide referring to the contractual relations between Chafea and the ERN grant beneficiary (the ERN coordinator) will be using the term "beneficiary":

- The beneficiary has the full responsibility to ensure that the Work Plan proposed by the ERN is implemented according to the grant agreement. The beneficiary is responsible for the technical and financial management of the Work Plan and the administrative management of the Work Plan by providing Chafea with all required documents and information, particularly in relation to payment requests (i.e. original accounting documents, signed copies of sub-contracts etc.);
- The beneficiary shall inform Chafea immediately of any change likely to affect or delay the implementation of the action of which the beneficiary is aware;
- Any claims Chafea may have addressed to the beneficiary regarding the grant

agreement shall be immediately answered by the beneficiary;

- The beneficiary bears the responsibility for providing all the necessary documents in the event of checks and audits initiated before the payment of the balance, and in the event of evaluation in accordance with Article II.27 of the grant agreement;
- During the entire duration of the FPA, the beneficiary shall inform Chafea on any changes concerning the structure, composition and legal status of the ERN that could affect its eligibility for receiving an ERN grant.

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 of 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 / Work Programme

6.2.1 Form of the grant

The grant is a partial *reimbursement* of the Work Programme's *eligible costs* at the reimbursement rate defined in the EU Health Programme. The grant is therefore expressed both as a maximum amount and also as a pre-defined percentage of the total eligible costs.

In other words, the *grant has double ceiling*: the maximum amount and the reimbursement rate applied on the total eligible cost. These key data will be set in the grant agreement.

6.2.2 Definition of eligible costs

Eligible costs must meet the following *cumulative* criteria:

- they must be *actually incurred by the beneficiary*;
- they must be *incurred within the period of the action* set in the grant agreement.;
- 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 ERN actions (coordination, management and non-clinical activities) must be established in the following cost categories

Personnel costs

Personnel costs are related to personnel working for the applicant under an *employment contract* (or equivalent appointing act).

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.

General administrative expenditure

This category contains all the costs that are necessary for the daily operation of the applicant, like:

- Costs related to the building / office / office equipment and supply
- Telecommunications / administration costs
- Financial charges and financial services (accounting, audit)

Expenditure linked to the beneficiary's normal operation related to the coordination and networking activities of the ERN

This cost category contains all the costs of the core and / or re-current activities of the applicant, like:

- Basic networking services such as coordination, management and non-clinical activities of an approved ERN (human resources, administrative and logistic support).
- Training activities: e-training and short stays of healthcare professionals. These stays should focus on strengthening professional relations, coordination and common practices, for monitoring purposes and the development of clinical guidelines. Professionals from Members or affiliated partners with less experience or casuistic should be the priority.

Other activities and actions such as:

- Meetings and conferences organisation: organisation, preparation and follow up of the meetings of the Network Board and its advisory committees and working groups (periodical virtual meetings, teleconferences, preparation of physical meetings, documentation management, minutes, etc.).
- Logistics: support for travel and accommodation.
- Analysis: preparation and dissemination of reports, technical documents.
- Data gathering/sharing: support to the maintenance of activity data and information system of the Network Dissemination: liaison and coordination with the European Commission incl.Chafea, periodical update and upload of the information and documents (related with the work of the Network) to the central ERN IT platform.
- Sharing of best practices.

6.2.4 Exchange rate

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

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

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

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

6.2.5 VAT

VAT is accepted as eligible costs if it is not recoverable. VAT is considered as not recoverable, if according to national law it is attributable to any of the following activities:

- Exempt activities without the right of deduction;
- Activities which fall outside the scope of VAT.

6.2.6 Definition of non-eligible costs

'Ineligible costs' are:

- Costs that do not comply with the conditions set out above 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 Chafea;
 - 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 Chafea 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 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 the actual costs related to the implementation declared by the beneficiary. The reimbursement rate of the grant agreement is applied to the approved 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

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.

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

- 6.3.2 If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.
- 6.3.3 *Type of receipts*

The following are considered receipts:

- income generated by the applicant; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;
- financial contributions given by third parties to the beneficiary

6.4 Payment Scheme

The following payments will be made to the beneficiary:

- 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.

- 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 beneficiary for the implementation of the action.

Payment is subject to the approval of the final report and the corresponding deliverables.

The amount due as the balance is calculated by Chafea by deducting the total amount of pre-financing 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, Chafea will pay the balance.

6.5 Pre-financing guarantee

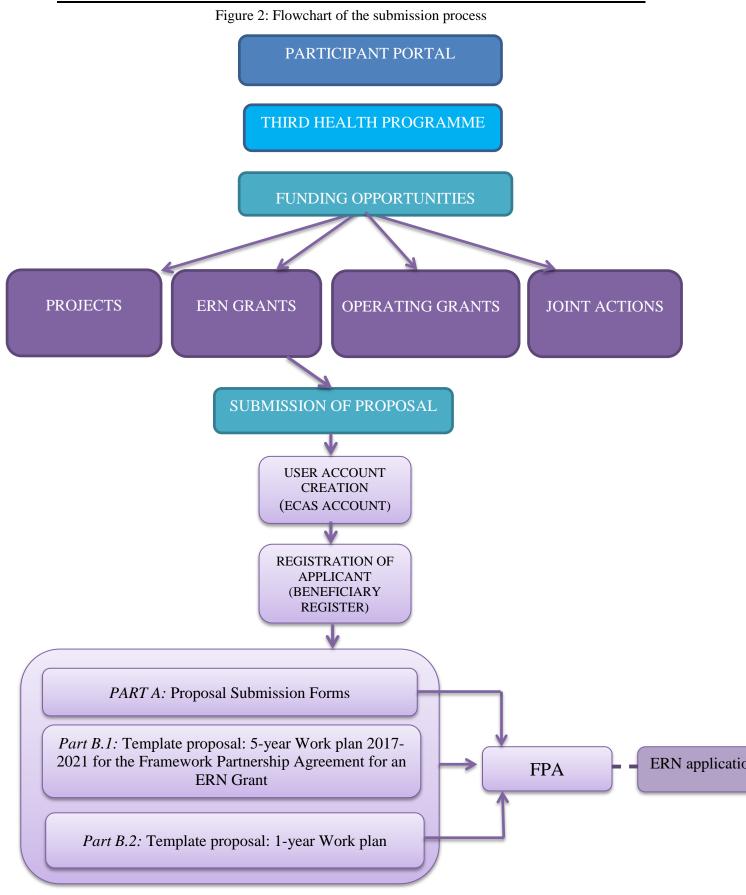
In the event that the applicant's financial capacity is not satisfactory, a pre-financing guarantee for up to the same amount as the pre-financing may be requested in order to limit the financial risks linked to the pre-financing payment.

The financial guarantee, in EUR, shall be provided by an approved bank or financial institution or any other third party whose financial capacity is verified by Chafea - established in one of the Member State of the European Union. Amounts blocked in bank accounts shall not be accepted as financial guarantees.

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

No financial guarantee will be requested if the EU contribution is EUR $\leq 60\ 000$.

B. SUBMISSION OF PROPOSALS – PREPARING THE APPLICATION



The beginning of the submission process is related to general information about this Call for proposals, as well as the description of the necessary preparatory steps that need to be taken into consideration. Here are some steps you may want to follow:

- Documents to consult: Reference to the documents that you need to consult prior to submitting an application;
- A description of the process for the creation of a user account <u>ECAS account</u> (⁴);
- A description of the process for the registration of an applicant network (i.e. Beneficiary Register);
- Call deadline, acknowledgment of receipt and language of the application;
- Data protection issues; and
- Certain general recommendations on how to best prepare your proposals in view of the competitive nature of the present call.

Please note, that proposals must be submitted **only online** via the Electronic Submission Service of the Participant Portal and before the call deadline.

The application consists three parts:

Part A: Proposal Submission Forms

The Proposal Submission Forms consist of two sections: (1) General information and (2) Participants & contacts. It concerns the administrative information of the applicant network. It comprises of fields of requested information, tables and checklists and declarations to be filled by your network via the Electronic Submission System.

Part B: Template proposals – technical content of the proposals

Part B comprises three parts:

- Complete Network Application: ERN application form & self-assessment; HCP application form + self-assessment+ endorsement certificate (minimum 10 HCPs):
- Part B.1: Template proposal B.1: 5-year Work Plan 2017-2021 for the Framework Partnership Agreement for an ERN Grant (hereafter, referred to as *Template proposal B.1*);
- Part B.2: Template proposal B.2: 1-year Work Plan (hereafter, referred to as *Template proposal B.2*).

Part B concerns the technical content of the FPA and the 1-year Work Plan proposal. *Template proposal B.1* is your technical content of the FPA's proposal where you will need to open a **new blank Word document** (the page limit is set to 30 pages) and write the proposals in line with the provided *Template proposal B.1* structure or outline. Once

⁴ ECAS stands for the European Commission Authentication Service

you have prepared your proposal in the Word document format, save it as a PDF and then uploaded directly into the Electronic Submission System. Similarly, you will also need to open a new blank Word document (the page limit is set to 20 pages) and prepare your 1-year Work Plan proposal in accordance with the structure set in *Template proposal B.2* and then upload it in PDF.

1 PREPARING FOR THE SUBMISSION PROCESS

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 <u>ECAS</u> account for registered users or create a new <u>ECAS</u> account for new users; and register the applicant ERN (the ERN coordinator) in the Beneficiary Register.

1.1 Documents to consult

Prior to taking the decision of submitting an FPA proposal and filling in the application form, please verify whether your organisation complies with the eligibility criteria. You should also check whether your planned activities are in line with specific objective 4 of the <u>Third Health Programme</u> and the priorities listed in the <u>Work Programme 2016</u>. 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 <u>Third Health Programme</u> and its <u>Work Programme 2016</u> with the <u>annexes</u>.

In addition, you can also consult the <u>H2020 Online Manual</u> for the submission of proposals with comprehensive instructions on HOW TO USE the Electronic Submission System.

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

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

To do so, you need to access the Participant Portal .

Figure 3: Screen shot of the Participant Portal homepage

		(A-Z)	Sitemap About this site Cont	act Legal Notice ???header.top	p.menu.search???
	RESEARCH	& INNOV			
European Commission	Participant Po	ortal			
	th & Innovation > Participant Pr	PARTICIPATE EXPERT	S SUPPORT -	P	
	a or or out and the	CARINET ALE LATERI	a arron e	Lall	
		R		Horizon 20	20 Funding Starting from 1/1/2014
	• 2014-20	20 Horizon 2020 - resear	nding for research & innovat ch and innovation framework rik programme (FP7) and Cor	programme	
	Non-regist	ered users	Register	ed users	
	 search for read the l 	funding (2020 Online Manual & do		t your proposal he grant	
	legal doci	iments n organisation is already i	• mana	ge your project throughout its	i îlfecycle
		ir support services or che			
	Ø				i
WHAT'S NEW?	FUNDING OPPORTUNITIES	HOW TO PARTICIPATE	WORK AS AN EXPERT	MY PERSONAL AREA	INFORMATION AND SUPPORT
				HORIZON 2020 RESEAR	ICH ON SURDPA CORDIS C
		© Europei	an Communities		

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. For further details please consult the IT Help Guide for the submission of proposals, chapter 2;
- If you already have a user account for the Participant Portal, you can log in (click on 'LOGIN' in the upper right corner) and start entering the required information.

1.3 Register your organisation - Beneficiary Register

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

- The European Commission has an online register of the organisations participating in various EU programmes called the <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.

Figure 4: 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). This PIC number will need to be quoted in your proposal and in any correspondence with Chafea.
- 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 the only person able to provide further updates.

1.4 Submission process overview

Once you have completed Part A - Proposal Submission Forms and validated it, you will be transferred to Part B and Annexes where you will find the *Template B1 5yr WorkPlan* 2017-2021 and *Template B2 1yr WorkPlan* to download. At this point you can then move on to working and preparing the content of your proposals on a blank Word document following the provided structure in the *two templates*. Remember to upload the proposals and annexes in the PDF format. Details of the submission are described under Section 2.2 and Section 2.3 of the present guide.

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

There are several aspects that need to be observed such as the deadline, acknowledgement of receipt; when a proposal may be rejected even after submission and / or when Chafea would get in touch with the applicant.

• Submission deadline

The entire application must be submitted via the Electronic Submission System.

The deadline for submission is 21 June 2016.

• Acknowledgement of receipt

Before the call for proposals deadline, the applicants may replace or update their proposals. You will receive a confirmation email of the submitted application by the deadline. After the call for proposals deadline, changes or additions are no longer possible.

The Electronic Submission System carries out basic verification checks for completeness of the proposal, internal data consistency, virus infection file types, size limitations etc. This system will also check for number of pages of the proposals and, if necessary, suggest that you shorten it. Any excess pages will be overprinted with a 'watermark' indicating to the evaluators that these pages must be disregarded.

The date and time of the submission of the application with the proposals 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 properly submitted. If you miss the call deadline, your proposal will be disregarded by the system and will not be considered as submitted.

• Rejection of proposals

IMPORTANT TO NOTE: It is extremely important you upload the proper document (in PDF) under the corresponding heading as you may jeopardize your entire application and will be considered as inadmissible!

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

It is your responsibility to have uploaded to proper documents.

Once the application is submitted, the applicant will not hear from Chafea until the applications are 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.

• Languages

In principle, 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, the applicant 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.

1.6 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 <u>Agency's Data Protection Officer</u>. 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 <u>this website</u> at regular intervals so as to be duly informed on possible updates that may occur by the deadline for submission of their proposals.

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

1.7 General guidance before drafting your proposal

The present Call for proposals 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 or selected for EU funding.

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

Relevance: check that your intended proposal does indeed address specific objective 4 of the third Programme for the Union's action in the field of health. Proposals falling out of the scope of the Programme will be excluded.

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.1 and Part B.2 and ensure that all the requested information is inserted and the requested documents are 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. As already mentioned, the page limits for Part B.1 - *Template proposal B.1* (FPA) is 30 pages and Part B.2 - *Template proposal B.2* (1st Year work programme) is 20 pages.

Management quality: clearly indicate the ability for high-quality management adapted to the scope of the intended activities of the ERN. 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.

SUBMISSION OF THE APPLICATION

2 APPLICATION FOR AN ERN GRANT: SUBMISSION OF THE FRAMEWORK PARTNERSHIP AGREEMENT (FPA) 2017 – 2021 PROPOSAL

As already mentioned, the ERN grant (HP-ERN-2016) application is composed as follows:

- Part A Proposal Submission Forms: General information, Participants & contacts;
- ERN application since this call for grants is a joint call together with the call for interest for ERN, all application forms and related documents of this call for ERN should be uploaded in this section
- Part B.1 *Template proposal B.1:* Technical content of the FPA and
- Part B.2 *Template proposal B.2:* Technical content of the 1st Year of implementation; and

2.1 Part A – Proposal Submission Forms

In this part, you will have to provide general information related to your FPA proposal and information related to the coordinator and its contacts.

As a reminder, financial contributions by the EU may be awarded to actions of ERNs. Only the ERN coordinator can apply for a grant and not the members of the network. Please note that in the following, for simplification sake, we may interchange the terms ERN or the coordination of an ERN with the term 'organisation'.

Part A comprises of fields of required information, checklists and declarations to be filled and must be completed directly via the Electronic Submission System.

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.

Section 1: General information

Please note that the first page of "General Information" section refers specifically to the FPA proposal:

You must provide the Acronym, Proposal Title, Duration (in months - 60), Free Keywords and an Abstract (max. 2000 characters) explaining the objectives of the proposal, how these will be achieved, their relevance to the annual Work Programme 2016 of the third Health Programme. The abstract is the overall abstract of the FPA proposal and is very important that in its content it covers the multiannual Work Plan of the organisation (2017-2021).

The abstract will be used as a short description of the FPA 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 formulas and other special characters.

<u>The second page of this section</u> contains a certain number of self-declarations to be made by the ERN coordinator by clicking in the corresponding boxes. The information contained here ONLY applies to the ERN coordinator and not to any of the possible applicants to the ERN call for interest. The "plural" should not be taken into account here.

Figure 5: Print screen of the Declarations

Declarations	
1) The coordinator declares to have explicit consent of all applicants on their participation and on the content of this proposal.*	
2) The information contained in this proposal is correct and complete.	
3) The coordinator confirms that:	
-he/she carried out for the coordinator's organisation the financial capacity self-check and has received confirmation from each participant that they have carried out the same at https://ec.europa.eu/research/participant that they have carried out the same at https://ec.europa.eu/research/participant that they have carried out the same at https://ec.europa.eu/research/participants/portal/desktop/en/organisations/lfv.html unless the coordinator or any participant is exempt from the check being a public body.	
4) The coordinator hereby declares that 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 the Operating Grant.	
5) The coordinator hereby declares that:	
 - all applicants are fully compliant with the exclusion and eligibility criteria set out in the specific call for proposals; and 	
 - all 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; and 	
 - all applicants have the professional resources, competences and qualifications required to complete the proposed action. 	
The coordinator is only responsible for the correctness of the information relating to his/her own organisation. Eac remains responsible for the correctness of the information related to him/her and declared above. If the proposal retained for EU funding, the coordinator and each beneficiary will be required to present a formal declaration in th	to be
* According to Article 131 of the Financial Regulation of 25 October 2012 on the financial rules applicable to the general budg (Official Journal L 298 of 26.10.2012, p. 1) and Article 145 of its Rules of Application (Official Journal L 362, 31.12.2012, p. 1) found guilty of misrepresentation may be subject to administrative and financial penalties under certain conditions.	
Personal data protection	
Your reply to the grant application will involve the recording and processing of personal data (such as name, address and CV) will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of per the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, the questions and data requested are required to evaluate the application in accordance with the specifications of the call for proposal will be pro for that purpose by the Executive Agency / the Commission. Details concerning the processing of personal data are available	rsonal data by any personal ocessed solely

Please note: the only reason you are requested to run a on <u>financial viability selfcheck</u> and tick the box under " 3) the applicant confirms that: he/she has carried out for its organisation a financial capacity self-check at " is to warn you that in the case you are awarded the ERN grant and your financial standing is weak, the EC may need to take specific measures and may ask you to provide a bank guarantee. By no means this should discourage you from submitting an application.

Also, please note: If the ERN applicant does not click on each appropriate box, this may prevent the submission of the application!

Section 2: Participants & contacts

The first page of the section "Participants & contacts" refers to the administrative data of the coordinator of the applying ERN.

It concerns the administrative data of the coordinator. Part of that administrative data will be automatically filled in after encoding of the relevant PIC code of the coordinator of the applying ERN. The remaining set of administrative data will need to be inputted directly by the applicant.

In the second and third page you need to provide administrative information concerning the specific department(s) of the applicant organisation carrying out the proposed work, as well as those of the person in charge of the proposal.

2.2 Part B.1 – Template proposal B.1 - Technical content of the FPA proposal

Part B.1 concerns the technical content of the FPA proposal. Applicants will work on a blank Word document following the *Template proposal B.1 (Template B1 5yr Work Plan 2017-2021)* structure for the FPA proposal. Once the FPA proposal is prepared, you need to save it in PDF and upload it directly into the Electronic Submission System.

The technical content of the FPA proposal should present the ERN applicant's Work Plan for the next five years in a way that will enable the evaluators to make a proper assessment against the award criteria.

Your FPA proposal must cover the following:

2.2.1 Goals and activities for the work plan:

The five year Work plan should only include activities that are to be co-funded by the Health Programme. Applicants must assure compliance between the goals and activities described in the ERN proposal and the five year Work plan.

2.2.2 Applicant ERN's contribution to public health at EU level

Strategic relevance and contribution of the applicant ERN activities to the implementation of the forth objective of the third Health Programme and other relevant EU policies

For this section, the analysis should be done at the strategic level (the proposal should provide descriptions in the following areas:

- A description of the applicant ERN's key strategic objectives for the period 2017-2021 and their relevance for the 3rd Health Programme.
- EU added value and expected impact of the ERN's activities. The ERN's activities are expected to bring added value to the existing health knowledge allowing for the practical use of that knowledge on the field. The ERNs are also expected to contribute and to add value to EU policies formulated or in the process of being so. The ERN's activities are also expected to have a positive implication for the health of the citizens and the proposal must demonstrate this.
- <u>Structure, membership and working methods of the ERN</u>, with a view to demonstrate its effective outreach across the EU.

What is more important is to demonstrate the effective outreach of the all healthcare providers-members of the ERN, as well as to show that the ERN's members contribute regularly and actively to its work e.g. via consultation mechanisms, regular data gathering, training and research, patients empowerment, development, sharing and dissemination of information, knowledge and best practices etc.

2.2.3 Applicant organisation's Multiannual Work Plan for 2017-2021

This section should provide a detailed description of the objectives, means and expected outputs of the ERN's multiannual Work Plan. The applicants should provide descriptions in the following areas:

• Objectives, means and methods as well as expected outputs of the applicant ERN's multiannual Work Plan 2017-2021

General and specific objectives of the ERN for the five coming years, as well as of the methods to be employed in order to achieve these objectives. The specific objectives are concrete statements describing what the ERN 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 at a level which allows them to be evaluated at the conclusion of the action. They should also be 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. The methods should be explicitly linked to the objectives, in the sense that for each objective at least one intervention method/ action area of the Health Programme is specified.

• Planning of the applicant ERN's activities for the five year period 2017-2021

Your proposal must describe the activities for the five-year period, including a detailed:

- Timetable with milestones: a timetable can be used to show the planning of the ERN's activities during the five year period and the link between activities and deliverables. The template includes a timetable for you to fill. Milestones mean control points in the implementation of the ERN's programme that help to chart progress. Milestones may correspond to the completion of a key deliverable, 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;
- <u>List of deliverables</u> deliverable means a distinct and tangible output of the project, meaningful in terms of the project's overall objectives, generally related to a specific objective or a set of activities and constituted by a report, guideline, publication, newsletter, tool, website etc.

The **Template B1 5yr WorkP Plan 2017-2021** includes a timetable; it also includes a table to be completed with all planned deliverables with a short description of the content, the link with the person/team responsible and expected delivery month. This list does not include technical reports. For each deliverable a dissemination level (public or confidential) will need to be added. <u>Please be aware that only in dully substantiated cases the dissemination level could be confidential.</u>

• Dissemination and evaluation of the applicant ERN's multiannual work plan

Dissemination and evaluation strategies are employed by the ERN in order to disseminate the results of its activities, as well as measure their potential impact. This section should include:

- A detailed description of the <u>ERN's dissemination plan and strategy;</u>
- A detailed description of the <u>ERN's evaluation strategy;</u>

Taking into account the multiannual nature of the plan, it should be possible to also include an evaluation of the uptake of the results of the ERN's activities.

2.2.4 Management and implementation of the applicant organisation's Multiannual Work Plan 2017-2021

In this section, applicants must lay out in detail the way that the applicant ERN is planning to implement its multiannual plan for the next five years, 2017-2021, including: the applicant ERN's overall structure and processes regarding responsibility, internal communication, decision-making, monitoring and supervision; skills and competencies of staff in implementing and monitoring the multiannual Work Plan; risk analysis and risk mitigation capacity; financial management, controls and reporting mechanisms.

- The ERN's overall structure and processes regarding the planning, execution and monitoring of the multiannual Work Plan
 - The organisational structure and the decision-making processes within the ERN, including the organisational chart;
- Role of the Board and Executive Director or equivalent in setting strategy, as well as the internal communication processes in the ERN to ensure information flow, transparent decision making, coordination and conflict management;
- A risk analysis will help to predict the events that could prevent the ERN from implementing part(s) of the multiannual Work Plan on time or even failing to implement them. Describe critical risks, relating to the implementation of the multiannual Work Plan and provide adequate risk mitigation measures.
- The applicant ERN's operational capacity

In this section you are called to provide the following descriptions:

- Describe the applicant ERN's capacity, in terms of the skills of the staff members, concrete contribution(s) by the applicant ERN's members.
- The capacity of the applicant ERN to actually deliver the expected outputs included in its multiannual programme has to be demonstrated. For this, please provide an organisational chart, together with a description of the tasks and responsibilities of the different staff members. In addition, provide a description of the skills and experience of the team entrusted with the implementation of the multiannual programme.
- If certain, necessary skills are not to be found within the ERN coordinator itself, which can happen for a variety of reasons, please argue alternative ways of accessing them –this could be ensured, for example, through concrete

contribution(s) of a member of the ERN. If this is the case, please provide a clear description of how this is practically done.

- Describe the financial resources of the applicant ERN, of the budget required for the implementation of the multiannual work plan, as well as of the financial circuits. The ability to build and monitor a budget has to be clearly demonstrated as well as the tools used for that purpose. Therefore, please provide all necessary references to the way the budget is presented for approval, the terms of the discussion at the board or executive level, how it is monitored after its approval. Please also refer to all relevant documents, such as certification and validation process of annual accounts, IT or other tools used to monitor budget execution, financial controls and external audits.
- Budget overview in support of the applicant ERN's multiannual work plan 2017-2021

Even though the FPA proposal does not include a co-funding request, it is necessary to provide a budget overview in support of the applicant ERN's multiannual Work Plan for 2017-2021.

The present section requires a descriptive part on the relevance of the budget in relation to the activities included in the multiannual plan– so you should describe in detail how you have built the budget for the period 2017-2021 and the rationale for doing so.

2.2.5 Exceptional Utility

With regards to exceptional utility, describe how you comply with the criteria of the 2016 Work Programme of the EC as indicated in **Template B1 5yr WorkPlan 2017-2021.**

2.3 Part B.2 – Work Plan of the 1st Year of implementation

This Part of the proposal should present the detailed action plan of the network (ERN) for the 1st Year of implementation. The proposed annual detailed work plan will be then evaluated for its quality and its alignment with their respective FPA action plan presented in the applicant's FPA proposal.

At a later stage the SGA proposal will be invited through a specific call procedure.

Through the next years, the SGA proposal will be **simplified** in the sense that the ERN that have signed an FPA for the period 2017 - 2021 will not be required to resubmit the same documents in support of compliance with the eligibility, exclusion and selection criteria each year. In other words, FPA holders will be invited in 2017 to submit their proposal and Work Plan for the 2nd year of implementation, and so on.

Part B.2 - *Template proposal B.2* Similarly as with the FPA, applicants will work in a blank Word document. Once completed, you need to save it as a PDF and upload directly into the Electronic Submission System.

Below you can find the main sections that your proposal will need to contain.

2.3.1 Content of the annual Work Plan for the 1st Year of implementation

In this section, applicants must lay out the coherence of their annual Work Plan for the 1st year with regards to the multiannual plan included in the FPA proposal of the application. To do so, they must provide a detailed description of the operational objectives of the ERN's annual Work Plan, including:

• Problem analysis and evidence base for the activities proposed in Year 1

This description should focus less so in the analysis of the health problem or the analysis of the factors underlying the problem, as these elements should have been adequately covered in the FPA proposal.

It should focus more on the pertinence of the targets for Year 1 and how these support the achievement of the ERN strategic objectives set in the multiannual work plan.

• The applicant ERN's key objectives for Year 1

These objectives are concrete statements describing what the ERN 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 at a level which allows them to be evaluated at the conclusion of the action.

They should also be 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.

The methods underlying the applicant ERN's activities must be explicitly linked to the objectives for Year 1.

• Target groups of the applicant ERN's main activities for Year 1

A section requiring a description of the target groups of the ERN's main activities has been included in the multiannual work plan submitted in the framework of the FPA proposal. It is possible that in any given year, the activities of the ERN may focus more particularly on some of the target groups. It is this specific element that we would like the applicant to focus on in the proposal.

This section, therefore, is not about repeating but about consistency between the multiannual framework of activities and the specific operational objectives fixed for every year of operations.

• EU added value and expected impact of the activities projected to take place in Year 1

The ERN's activities planned for 2017 are expected to bring added value to the existing health knowledge allowing for the practical use of that knowledge on the field. They are also expected to contribute and to add value to EU policies formulated or in the process of being so. Finally, they are also expected to have a positive implication for the health of the citizens and the application must demonstrate this.

2.3.2 Planning and implementation of the applicant ERN's main activities for Year 1

In this second section, applicants must lay out in detail the ERN's annual plan for the 1st year of implementation, including: planning of activities; related timetable and deliverables; dissemination activities in support of the ERN's operational objectives; and evaluation process and relevant indicators.

More specifically, this section should comprise the following:

• Planning and expected outputs of the ERN's activities for 2017

This section should include a detailed timetable with milestones, as well as a list of deliverables:

Milestones mean control points in the implementation of the ERN's programme that help to chart progress. Milestones may correspond to the completion of a key deliverable, allowing the next phase of the work to begin. They may also be needed at intermediary points so that, if problems arise, corrective measures can be taken.

Deliverable means a distinct and tangible output of the project, meaningful in terms of the project's overall objectives, generally related to a specific objective or a set of activities and constituted by a report, publication, newsletter, tool, website etc.

Template B2 Work Plan Year 1 includes a timetable with the activities, linked deliverables and necessary resources (person/months); it also includes a table to be completed with all planned deliverables with a short description of the content, delivery month and dissemination level. Technical reports should not be included in these tables as deliverables. For each deliverable a dissemination level (public or confidential) needs to be added. Only in dully substantiated cases the dissemination level could be confidential.

• Dissemination and evaluation of the applicant ERN's work plan for Year 1.

The choice of the dissemination activities to be implemented in the 1st year of implementation should reflect the dissemination strategy and plan included in the FPA proposal. It is possible that in any given year, the activities of the network may focus more particularly on some of the target groups. It is this specific element that you need to focus on in the proposal. **Dissemination** refers to the process of making the results and deliverables available to stakeholders and a wider audience.

The description of the related activities must clearly illustrate what will be disseminated (key messages), to whom (audience), why (purpose), how (method), and when (timing). It should include adequate timing and milestones for the dissemination activities over the year. You should also focus on the adequacy of the different tools and channels of dissemination to ensure sustainability of the action results.

This section therefore, is not about repeating but about consistency between the multiannual framework of dissemination and the specific operational targets fixed for the year of operation.

In the **evaluation** section you are expected to describe the internal and external evaluation of the activities to be carried out in the 1^{st} year of implementation, including the indicators to be used in order to verify that the operational objectives of the annual work plan have been achieved.

The evaluation methodology should be adequate, in line with the evaluation strategy included in the FPA proposal and be based on indicators

• Operational management of the applicant ERN for Year 1:

In this section, applicants must lay out in detail the way that the ERN is planning to implement its annual plan for Year 1.

The ERN's overall structure and processes regarding responsibility, internal communication, decision-making, monitoring and supervision will have already been provided for in the FPA proposal.

In the proposal for Year 1 the applicant ERN must describe the concrete operational framework in place to ensure the achievement of the operational targets for the 1^{st} year of implementation.

Annexes

A complete submission application consists of:

- Part A Proposal Submission Forms: this is a form accessible on-line which you need to complete and validate;
- Part B: composed of the proposals for the FPA and Year 1.

You will prepare two separate word files, following the structure and guidance of the provided templates (*Template B.1* and *Template B.2*.).

Once saved as PDF documents they will also be uploaded;

• Annexes of supporting documents required as evidence of compliance with the eligibility, exclusion, selection and award criteria.

Figure 7 below illustrates the templates you can download and the annexes that must be uploaded in the PDF format with the exact titles as provided. Again, please note, that it is your responsibility to upload the proper documents with the proper content as any error may jeopardize your application.

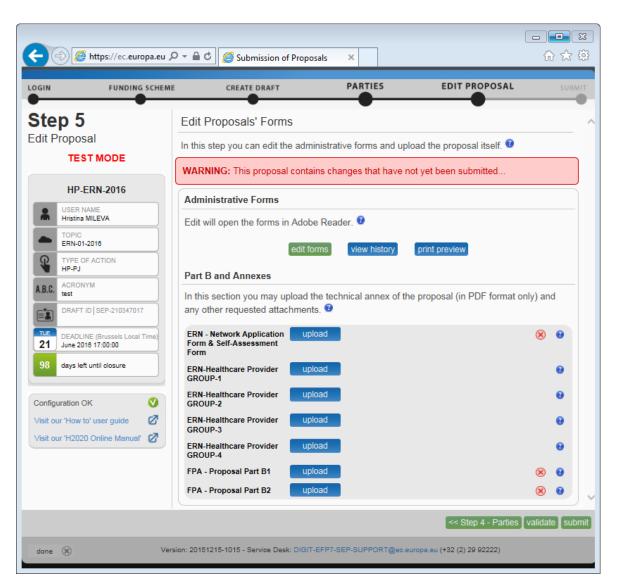


Figure 6: Screen shot of Part B and Annexes

The documents that must be uploaded in PDF in order to complete your application:

1. **ERN application form**, consisting of:

- Complete Network Application:
 - i. ERN application form
 - ii. ERN Self-Assessment
- b. Application Form for Healthcare Provider one per each HCP (minimum 10):
 - i. HCP application form
 - ii. HCP Self-Assessment
 - iii. HCP endorsement certificate



a.

Please be aware that for technical reason you will be requested to merge several HCP applications in one scanned simple PDF document to be uploaded in the system. Further information in the IT technical annex.

- 2. **Part B.1 5yr Work Plan 2017-2021**: the ERN's five-year Work Plan for the period 2017 2021. This document shall contain the technical narrative part of your FPA proposal. Please use the document structure as provided in the template. Please observe the page limit of 30 pages.
- 3. **Part B.2** 1st **year Work Plan**: the ERN's one-year Work Plan for 2017. This document shall contain the technical narrative part of your SGA proposal. Please use the document structure as provided in the template. Please observe the page limit of 20 pages.

Please first download the relevant template – you will then need to complete it, have it signed, scan and save as a PDF before uploading it.

C. EVALUATION

In order to get a favourable decision, recommending the applicant for EU co-funding, proposals go through a multi-level process of evaluation with regards to several categories of criteria: the eligibility, exclusion, selection and award criteria.

This part of the guide on EVALUATION describes the process and details of how the submitted applications are selected for funding, including the criteria and the consecutive phases of the evaluation.

An important element to note is that the eligibility, exclusion and selection criteria are the same both for the FPA and the SGA proposals. However, the award criteria differ between these two.

For this reason, and in order to reduce potential repetition, we have structured this part as follows:

- 1. 'Evaluation process overview and outcomes';
- 2. 'Eligibility, exclusion and selection phases and relevant criteria';
- 3. 'Award criteria'

The criteria and the mandatory supporting documents are specified in the 2016 Work Programme, Annex V.

1 EVALUATION PROCESS OVERVIEW AND OUTCOMES

As discussed, the present call implements a framework of long-term cooperation established between the European Commission and potential beneficiaries.

All proposals for FPAs will be evaluated against the eligibility, exclusion, selection and award criteria (for more information, please refer to Annex V of the 2016 <u>Work</u> <u>Programme</u>). As a result of the evaluation a ranking of the proposals will be drawn up. As mentioned, the positive evaluation of an FPA does not guarantee receiving co-funding.

2 ELIGIBILITY CHECKING, EXCLUSION AND SELECTION PHASES AND RELATED CRITERIA

2.1 ELIGIBILITY CRITERIA

The issues related to the eligibility of applicants are covered under section 7 of the Call for proposals 2016. It is, however, opportune to repeat here that eligibility refers to the following condition:

Applicant, on behalf of a network, havs applied to be approved as an European Reference Network as established in Commission implementing decision (2014/287/EU) in compliance with the criteria and conditions of Commission Delegated Decision (2014/286/EU).

2.2 EXCLUSION CRITERIA

Only proposals that meet the eligibility criterion will be assessed on the basis of the exclusion criteria.

Exclusion from the call occurs if the applicant organisation is under one of the situations mentioned under section 7 of the Call for proposals 2016.

Exclusion from the award occurs if the applicant network has not been approved as European Reference Network.

In order to demonstrate compliance with the exclusion criteria and certify that the applicant is not in one of the situations referred to in articles 106 and 107 of the Financial Regulation(⁶) (⁷), the applicant has to check the related self-declaration which is incorporated in Part A – Proposal Submission Forms of the application.

It may also happen that such exclusion of an applicant may take place later in the course of the grant award procedure. This will be the case if the applicant is identified as:

- (a) being subject to a conflict of interest;
- (b) being guilty of misrepresenting the information required by the contracting authority as a condition of participation in the grant award procedure or fail to supply this information;
- (c) being in one of the situations of exclusion, referred to in section 7 of the Call.
- (d) Network being not approved as European Reference Network.

⁶ 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 <u>REGULATION (EU, EURATOM) NO</u> 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

⁷ 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

2.3 SELECTION CRITERIA

Selection refers to the operational and financial capacity of the applicant organisation to complete the proposed work plan for the 5 years of duration of the framework partnership agreement.

Operational capacity:

Applicants must have the necessary operational resources, skills and professional experience required to complete the proposed action.

Financial capacity:

Applicants are expected to have stable and sufficient sources of funding to maintain their activity for the 5 year duration of the framework partnership agreement and ensure their own share of co-financing while implementing.

If an organisation (the ERN coordinator) is not a public body (which would exempt it from the financial capacity-check) it needs to complete the <u>financial viability self-check</u> and tick the appropriate box.

Evaluation process: award criteria

The submitted FPA proposals are assessed through the award criteria; these make it possible to select Work Plans that are in line with and contribute to EU objectives and priorities; that the Work Plan of the applicant organisation is technically pertinent, well planned and can guarantee proper dissemination; and that it can deliver on their outputs, outcomes and objectives.

2.4 CRITERIA FOR THE AWARD OF AN FPA¹

Please note than only FPA proposals that meet the eligibility, exclusion and selection criteria will be eligible for evaluation against the award criteria.

Criterion	Maximum	Threshold
	points	
1 - *Policy and contextual relevance of the operation of the	10	7
approved ERN		
2 – **Technical quality of the proposed multiannual Work Plan	10	7
3 – ***Management quality	10	7
TOTAL	30	21

Table 1: Evaluation criteria for an FPA award

For each of the criteria in Table 1, the following sub-criteria are taken into account:

*Policy and contextual relevance of the operation of the ERN (10 points, threshold 7 points)

- Pertinence of the mission, vision and overall purpose of the approved ERN in coherence with the scope and services to be provided by the ERN as defined in the delegated (2014/286/EU) and implementing decision (2014/287/EU).
- The European added value of the proposed goals and activities has to be shown in the multiannual work plan of the approved ERN.
- Pertinence of the mission, vision and overall purpose of the ERN and contribution of the multi annual work plan of the approved ERN to achieve the specific objective 4 of the 3rd Health Programme.
- Contribution of the approved ERN to help MS with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality as provided by Directive 2011/24/EU.

******Technical quality of the multiannual Work Plan proposed (10 points, threshold 7 points)

- Quality of the operational framework.
- Pertinence of the proposed goals and activities of the multiannual work plan of the approved ERN.
- Quality of the evaluation strategy of each ERN.

 $\binom{1}{1}$ The outcome of the FPA evaluation and the award does in no way affect the evaluation and approval of ERN applications

• Quality of the internal and external activities and implementation plan regarding the pooling of knowledge, the mobility of expertise, the development, sharing and dissemination of information, knowledge and best practices.

*******Management Quality (10 points, threshold 7 points)

- Quality of the planning of the work;
- Adequacy of the organisational capacity;
- Relevance and appropriateness of the budget plan for the total period of the FPA.

The applicant organisation meeting all threshold values will be awarded an FPA covering the five-year period (2017-2021).

2.5 PROCESS FOLLOWING THE EVALUATION

Applicant ERNs will be notified by the Electronic Submission System, once the evaluation has been finalized. Letters will be sent to all applicants – successful or not.

The successful applicants will be invited to adapt their FPA proposals, based on the evaluators' comments.

Following the completion of the adjustment phase, Chafea will take the award decision to grant Framework Partnership Agreement grant to the successful applicants.

Depending on budget availability, the highest ranked FPA proposals will be awarded FPAs. The remaining proposals that passed the quality threshold will be placed on a reserve list.

Finally, the applicants shall note that during the above procedure Chafea will seek to safeguard the interest of the European Union and may, based on the assessment of the

financial viability, ask for a **bank guarantee** or other suitable measures (only from the contracted beneficiaries).

D. FURTHER STAGES OF FPA IMPLEMENTATION

A call for budgeted SGAs 2016 will be opened for all potential signatories of FPAs, later this year and will be based on the year 1 Work plan included into this call.

During the forthcoming years of implementation, signatories of FPAs will be invited to submit SGA proposals, in 2017, 2018, 2019, 2020.

As already mentioned, signatories of the FPAs, will not be required to re-submit the documents in support on the eligibility, exclusion and selection criteria which will have been submitted under the present Call. In 2017-2020, they will however, be required to submit a declaration that they still comply with these criteria. In addition they are required to inform the Agency at any moment during the period covered by the FPA of any change in their status which may impact these criteria (e.g. change in membership etc.).

Depending on budget availability, the highest ranked applications for SGA proposals (Year 1 Work plan & Budget) will be awarded EU co-funding. The remaining SGA proposals recommended for EU co-funding will be placed on a reserve list.

Note that Chafea may offer a lower contribution for the SGA than the amount requested, or may attach specific conditions before the award decision is taken and will proceed with the signing of the Specific Grant Agreements.