



EUROPEAN COMMISSION
CONSUMER, HEALTH AND FOOD EXECUTIVE AGENCY

Health Unit

Luxembourg

**THIRD PROGRAMME OF COMMUNITY ACTION
IN THE FIELD OF HEALTH (2014-2020)**

2016 CALL FOR PROPOSALS:

APPLICATION FOR

APPROVED EUROPEAN REFERENCE NETWORK (ERN)

&

FRAMEWORK PARTNERSHIP AGREEMENT

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1. INTRODUCTION - BACKGROUND

This Call for proposals is conducted in the framework of the Third Programme for the Union's action in the field of Health (2014-2020) adopted by the European Parliament and the Council¹ on 11 March 2014. The programme entered into force retroactively from 1 January 2014 onwards.

The general objectives of the Programme are to complement, support and add value to the policies of the Member States aimed at improving the health of Union citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

The Consumer, Health, Agriculture and Food Executive Agency (CHAFEA) is entrusted with the implementation of the third Health Programme².

2. OBJECTIVES

The present call for proposals relates to the Third Health Programme specific objective 4:

"In order to facilitate access to better and safer healthcare for Union citizens: increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to the improvement of health literacy.

This objective shall be measured, in particular, through the increase in the number of European reference networks established in accordance with Directive 2011/24/EU of the European Parliament and of the Council³ ("European reference networks"), the increase in the number of healthcare providers and centres of expertise joining European reference networks, and the increase in the number of Member States using the tools developed."

Furthermore, one of the Programme thematic priorities aims to "support the establishment of a system of European reference networks for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, as in the case of rare diseases, on the basis of criteria to be established under Directive 2011/24/EU."

The objective of this call is to provide financial support to approved ERNs, once established.

¹ Regulation 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. OJ L86, volume 57; 21 March 2014.

² COMMISSION IMPLEMENTING DECISION of 17 December 2013 establishing the Consumers, Health and Food Executive Agency and repealing Decision 2004/858/EC (2013/770/EU)

³ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

Co-funding will be provided in the form of mono-beneficiary grants to the ERN Coordinator to run the ERN and implement all actions in order to fulfil the goals as provided for in the legal basis on ERNs

The present Call for proposals aims at concluding

- a five-year Framework Partnership Agreements (FPAs) with an approved ERN, covering the years 2017 – 2021
- the ERNs awarded an FPA will be invited to a subsequent call for proposals with a purpose to conclude a Specific Grant Agreements (SGA) covering the operating the first year action.

3. PROCEDURE

Application are invited to be submitted via the [Participant Portal](#):

Submission Deadline

The deadline for the submission of proposals is as indicated in the [call announcement](#) on the Participants Portal.

4. INDICATIVE TIMETABLE

<u>STAGES</u>	<u>INDICATIVE TIMELINE</u>
<u>Submission of applications</u>	<u>June 2016</u>
<u>ERN</u>	
<u>Evaluation of applications</u>	<u>June – October 2016</u>
<u>FPA</u>	
<u>Evaluation of applications</u>	<u>≤ November 2016</u>
<u>Ranking of applications</u>	<u>November 2016</u>

5. BUDGET AVAILABLE FOR ERN GRANTS 2016

The total budget earmarked for the co-financing in 2017 is estimated at € 2.500.000.

The Budgetary ceiling per grant awarded in 2017 is € 200.000

Proposals requesting more than 60% co-funding (up to 80%) will need to comply with the criteria of exceptional utility:

Criteria for the exceptional utility of mono beneficiary ERN grants

1. At least 25 % of the members of the ERN come from Member States whose gross national income (GNI) per inhabitant is less than 90 % of the Union average. This criterion intends to promote the participation of highly specialized healthcare providers from Member States with a low GNI.
2. The mission and the annual programme of the ERN include activities aiming at foster capacity building such as organising training activities, contributing to the pooling of knowledge and collaborating closely with other centres of expertise and networks.

6. ADMISSIBILITY REQUIREMENTS

- Applications must be sent no later than the deadline for submitting applications referred to in section 3.
- Applications must be submitted in writing via the [participant portal](#).
- Both applications for ERN and FPA must be submitted simultaneously, under this call for proposals
- Applications may be submitted in any official language of the European Union. However, in order to facilitate assessment by the evaluators, an English translation of the technical part should accompany that written in another EU official language.

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

7. CRITERIA

7.1. ERN

Please refer to ERN Assessment Manual for Applicants.

7.2. FPA

7.2.1. *Eligible applicants*⁴

Only the network coordinator can apply. The applicant (the ERN network coordinator) must satisfy the following criterion:

The applicant, on behalf of a network, must have applied to be approved as a 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).

7.2.2. *Exclusion from participation:*

Applicants will be excluded from participating in the call for proposals procedure if they are in any of the following situations:

- (a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- (b) they or persons having powers of representation, decision making or control over them have been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State which has the force of res judicata;
- (c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify including by decisions of the EIB and international organisations;
- (d) they are not in compliance with their obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the grant agreement is to be performed;
- (e) they or persons having powers of representation, decision making or control over them have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation, money laundering or any other

⁴ Refer to FPA applications FR Art. 131, regulation 2015/1929 Art. 120 FR, 201 RAP

illegal activity, where such an illegal activity is detrimental to the Union's financial interests;

- (f) they are currently subject to an administrative penalty referred to in FR Article 109(1).

7.2.3. Exclusion from award:

FPAAs can be concluded only with those applicants whose network and membership applications, to become an official European Reference Network in the meaning of Directive 2011/24/EU have been positively assessed and approved.

Applicants will not be granted financial assistance if, in the course of the grant award procedure, they:

- (a) are subject to a conflict of interest;
- (b) are guilty of misrepresenting the information required by the contracting authority as a condition of participation in the grant award procedure or fail to supply this information;
- (c) find themselves in one of the situations of exclusion, referred to in section 7.1.

In order demonstrate compliance with the exclusion criteria, the applicant has to check the relevant box in the electronic submission system certifying that it not in one of the situations referred to in articles 106, 107 and 108 of the Financial Regulation^{5, 6}. The applicant should follow the instructions in the participant portal and the guide for applicants.

7.2.4. Selection criteria

The selection criteria make it possible to assess the applicant organisation's financial and operational capacity to complete the proposed work programme for the 5 years of duration of the Framework Partnership Agreement.

Financial viability

Applicants must have the financial resources necessary to ensure their functioning through the 5-year duration of the Framework Partnership Agreement.

The applicant's financial viability has to be certified by ticking the relevant box in the electronic submission system, after having carried out the financial self-assessment. In case co-funding is accepted to be awarded, the financial viability will be assessed, except:

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

⁶ [COMMISSION DELEGATED REGULATION \(EU\) on the rules of application of Regulation \(EU\) No.../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 is \leq EUR 60 000:

b) the beneficiary is a public body

Checklist of the documents that will be needed when assessing the financial viability:

Document	check box
The profit and loss account, the balance sheet for the last three financial years for which the accounts were closed; For newly created entities, the business plan for five coming years might replace the above documents.	<input checked="" type="checkbox"/>
Forward multi-annual budget plan for the organisation, balanced in terms of income and expenditure, covering the 5 years of duration of the Framework Partnership Agreement	<input checked="" type="checkbox"/> (clearly specifying the network related part)

On the basis of the documents submitted, if the assessment considers that financial capacity is not satisfactory, they may:

- request further information;
- propose a grant agreement without pre-financing;
- propose a grant agreement with a pre-financing paid in instalments;
- propose a grant agreement with a pre-financing covered by a bank guarantee (see section 11.4 below);
- where applicable, require the joint and several financial liability of all the co-beneficiaries;
- reject the application.

Operational capacity

Only organisations with the necessary operational resources, skills and professional experience may be awarded a Framework Partnership Agreement.

7.2.5. Award criteria

Only proposals submitted by applicants meeting the eligibility, exclusion and selection criteria will be evaluated against the award criteria.

The award criteria make it possible to select actions that can assure compliance with the applicable objectives of the European Reference Networks and EU objectives and priorities and can guarantee proper dissemination and high visibility of the EU co-funding granted.

Award criteria evaluation scores:

Criterion	Maximum score (nr of points)	Threshold (pass-mark)
<p>1. Policy and contextual relevance of the operation of the approved ERN</p> <p>The following sub-criteria are taken into account in the assessment:</p> <ul style="list-style-type: none"> • 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 ⁽⁷⁾ value of the proposed goals and activities has to be shown in the multiannual work programme of the approved ERN. • Pertinence of the mission, vision and overall purpose of the ERN and contribution of the multi annual work programme of the approved ERN to achieve the specific objective 4 of the 3rd Health Programme. • Contribution of the approved ERN to help MSs 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 ⁽⁸⁾. 	10	7
2. Technical quality of the multi-annual work	10	7

⁽⁷⁾ Commission Implementing Decision (2014/287/EU):
 (5) In order to guarantee that the Network has genuine **European Union added value** and is big enough to enable the sharing of expertise and to improve access to care for patients across the Union, only applications from the minimum required numbers of healthcare providers and Member States, submitted in line with the call of interest, should be approved. If an insufficient number of healthcare providers apply or applications cover an insufficient number of Member States, the Commission should ask Member States to encourage their healthcare providers to join the proposed Network.

(11) Using a common evaluation manual, an independent evaluation body appointed by the Commission should periodically evaluate Networks and their Members. The evaluation should conclude with a technical evaluation report detailing the extent to which the objectives set out in Article 12(2) of Directive 2011/24/EU have been achieved and the criteria and conditions set out in Delegated Decision 2014/286/EU fulfilled. It should also describe the outcomes and performance of the Network and the contribution of its Members. A negative evaluation report should generally prompt Member States to approve the termination of a Network. Compliance with the requirement to have a minimum number of healthcare providers and Member States should be monitored after the evaluation so that the European Union added value of the Network can be maintained.

⁽⁸⁾ Directive 2011/24/EU article 12, 2 (h)

<p>programme proposed (10 points, threshold: 7 points)</p> <p>The following sub-criteria are taken into account in the assessment:</p> <ul style="list-style-type: none"> • Quality of the operational framework. • Pertinence of the proposed goals and activities of the multiannual work programme of the approved ERN. • Quality of the evaluation strategy of the ERN. • 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. 		
<p>3. Management Quality</p> <p>The following sub-criteria are taken into account in the assessment:</p> <ul style="list-style-type: none"> • 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. 	10	7
TOTAL	30	21

Only the proposals reaching all thresholds will be put onto the ranking list.

8. LEGAL COMMITMENT

To conclude the FPA, formalising a long-term cooperation mechanism, the beneficiary is invited to enter in an so called adaptation period via the electronic grant preparation system. In this period all comments made by the external evaluators should be taken into consideration by the applicant and the FPA proposals should be amended accordingly.

This FPA shall be signed electronically by the FPA beneficiary and by Chafea.

There is no financial commitment from the side of Chafea when signing an FPA. Hence, **the conclusion of a FPA does not guarantee receiving co-funding.**

9. FINANCIAL PROVISIONS

9.1. General Principles

The Financial Regulation and the Rules of Application are the reference documents for the implementation of the third Health Programme.

Grants must comply with the following principles:

a) Non-cumulative award

An action may receive only one grant per financial year from the budget of the European Union.

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 its functioning during the same financial year as well as any other funding received or applied for the same action.

b) 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 or the grant decision is notified.

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

c) Co-financing

Co-financing means that the resources which are necessary to carry out the action or the work programme may not be entirely provided by the EU grant.

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

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

d) Balanced budget

The estimated budget of the action is to be attached to the application form. It must have revenue and expenditure in balance.

The budget must be drawn up in euros.

e) Implementation contracts/subcontracting

Where the implementation of the work programme requires the award of procurement contracts (implementation contracts), the beneficiary must award the contract to the bid offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests and retain the documentation for the event of an audit.

For public bodies: Entities acting in their capacity of contracting authorities in the meaning of Directive 2014/24/EC⁹ or contracting entities in the meaning of Directive 2014/25/EC¹⁰ shall abide by the applicable national public procurement rules.

⁹ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC.

Sub-contracting, i.e. the externalisation of specific tasks or activities which form part of the action as described in the proposal must satisfy the conditions applicable to any implementation contract (as specified above) and in addition to them the following conditions:

- it may only cover the implementation of a limited part of the work programme
- it must be justified having regard to the nature of the work programme and what is necessary for its implementation;
- it must be clearly stated in the proposal.

9.2. In regard to SGAs under FPA

9.2.1. *Funding form: mixed financing*

Mixed financing grants are calculated on the basis of an estimated budget indicating clearly the costs that are eligible for EU funding. The grant amount may neither exceed the eligible costs nor the amount requested. Amounts are indicated in euros.

Maximum amount requested

The EU grant is limited to a maximum co-funding rate of 60% of **eligible costs**. In case of exceptional utility up to 80% can be requested (see. section 4)

Consequently, part of the total eligible expenses entered in the estimative budget must be financed from sources other than the EU grant (see section 11.1c).

Eligible costs

Eligible costs are actually incurred by the beneficiary of a grant and meet all the criteria indicated in the grant agreement.

- Eligible (direct and indirect) costs are specified in Article 6 of the grant agreement;
- Ineligible costs are specified in Article 6.4 of the grant agreement.

Please note that contributions in kind are not considered as eligible cost.

Calculation of the final grant amount

The final amount of the grant to be awarded to the beneficiary is established after completion of the work programme, upon approval of the request for payment containing the documents indicated in the grant agreement.

EU grants may not have the purpose or effect of producing a profit within the framework of the work programme of the beneficiary. **Profit shall be defined as a surplus of the receipts over the eligible costs incurred by the beneficiary**, when the request is made for payment

¹⁰ Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC.

of the balance. In this respect, where a profit is made, the Chafea shall be entitled to recover the percentage of the profit corresponding to the Union contribution to the eligible costs actually incurred by the beneficiary to carry out the action or work programme. A beneficiary requesting an EU-contribution of EUR \leq 60 000, is exempted from this provision.

9.2.2. *Payment arrangements*

The payments generally consist of the following:

A pre-financing payment will be transferred to the beneficiary within 30 days either of the date when the last of the two parties electronically signs the SGA agreement, provided all requested guarantees have been received. 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

A final payment will be calculated at the end of the SGA. The Chafea will establish the amount of the final payment to be made to the beneficiary on the basis of the calculation of the final grant amount (see section 9.2.1). If the total of earlier payments is higher than the final grant amount, the beneficiary will be required to reimburse the amount paid in excess by the Chafea through a recovery order.

If the applicant's financial viability is not satisfactory, one more reporting period (e.g. at the end of month 6) may be introduced. An interim payment will be executed to cover the eligible expenses of the first period of the SGA. This interim payment is subject to the approval of a periodic report.

For more details, please see Article 16 of the model grant agreement.

9.2.3. *Pre-financing guarantee*

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

The guarantee shall be released as the pre-financing is gradually cleared against interim payments or 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.

10. PUBLICITY

10.1. By the beneficiaries

Beneficiaries must clearly acknowledge the European Union's contribution in all publications or in conjunction with activities for which the grant is used in line with Article 22 of the grant agreement.

In this respect, beneficiaries are required to give prominence to the name and emblem of the European Union on all their publications, posters, programmes and other products realised under the co-financed work programme.

To do this they must use the text, the emblem and the disclaimer available at http://ec.europa.eu/chafea/management/visual_identity.html.

If this requirement is not fully complied with, the beneficiary's grant may be reduced in accordance with the provisions of the grant agreement.

10.2. By the Executive Agency / the Commission

With the exception of scholarships paid to natural persons and other direct support paid to natural persons in most need, all information relating to grants awarded in the course of a financial year shall be published on an internet site of the European Union institutions no later than the 30 June of the year following the financial year in which the grants were awarded.

The following information will be published:

- name of the beneficiary
- address of the beneficiary when the latter is a legal person, region when the beneficiary is a natural person, as defined on NUTS 2 level¹¹ if he/she is domiciled within EU or equivalent if domiciled outside EU,
- subject of the agreement,

Upon a reasoned and duly substantiated request by the beneficiary, the publication shall be waived if such disclosure risks threatening the rights and freedoms of individuals concerned as protected by the Charter of Fundamental Rights of the European Union or harm the commercial interests of the beneficiaries.

11. DATA PROTECTION

The reply to any call for proposals involves the recording and processing of personal data (such as name, address and CV). Such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the call for proposal will be processed solely for that purpose by the Executive Agency / the Commission. Details concerning the processing of personal data are available on the privacy statement at the participants' portal: http://ec.europa.eu/research/participants/portal/desktop/en/support/legal_notices.html

¹¹ European Union Official Journal L 39, of 10 February 2007.

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. Personal data may be registered in the Early Detection and Exclusion System (EDES) established and managed by the European Commission; the new system replaced the Early Warning System and the Central Exclusion Database as of 1 January 2016. The purpose of the EDES is the protection of the Union's financial interests against unreliable economic operators. This is ensured via the following two components:

- Early detection of risks threatening the Union Financial Interests via the inclusion of relevant markings (in case of suspicion or presumption)
- Exclusion of entities/ natural persons, imposition of financial penalties (administrative sanctions) in case of situations provided for by the law

Situations that may give rise to an Early Detection/Exclusion are provided for in article 108 par. 2 and article 106 of the Financial Regulation respectively. an economic operator can only be subject to early detection/exclusion following his/her notification by the responsible service.

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.

12. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

The application must be sent via an electronic submission system and comply with the formal requirements described in the guide for applicants.

All applicants must submit under this call an application for an ERN FPA and for an ERN SGA at the same time. One single deadline applies.

No modification to the application is allowed once the deadline for submission has elapsed. However, if there is a need to clarify certain aspects or for the correction of clerical mistakes, the Executive Agency may contact the applicant for this purpose during the evaluation process.

Applicants will be informed in writing about the results of the selection process.

Proposals must be submitted via the participant portal:

<http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/index.html>

Before submitting a proposal:

1. Create an account to submit a proposal:

<https://webgate.ec.europa.eu/cas/eim/external/register.cgi>

2. Register via the beneficiary registry:

<http://ec.europa.eu/research/participants/portal/desktop/en/organisations/register.html>

To create and submit your proposal please go to:

<https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/index.html>

and select "3rd Health Programme", then select the relevant call.

In submitting a proposal, the applicant accepts the procedures and conditions as described in this Call and in the documents to which it refers. Applications that do not comply with these requirements will be rejected.

Contacts

For problems with the electronic submission system please contact the IT helpdesk set-up for this purpose via the participant portal web-site.

For non-IT related questions a helpdesk at Chafea is available at: e CHAFEA-HP-CALLS@ec.europa.eu on weekdays at 9.30 – 12.00 and 14.00 – 16.30. Note that the helpdesk is not available on EC public holidays.

Frequently asked questions are published on the website of Chafea: <http://ec.europa.eu/chafea/health/faq.html>