European Commission

3rd EU Health Programme

Call for project proposals under the Annual Work Programme 2019

HP-PJ-2019

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EUROPEAN COMMISSION
CONSUMERS, HEALTH, AGRICULTURE AND FOOD EXECUTIVE AGENCY

Health and Food Safety Unit

3rd EU Health Programme

Call for project proposals under the Annual Work Programme 2019

(HP-PJ-2019)

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0. Introduction

This is a call for grants in the area of health under the Third Programme for the Union's action in the field of health (2014-2020)[1].

Grant agreements will be concluded in relation to the following specific topics:

- Rare disease registries for the European Reference Networks (PJ-01-2019)
- Stakeholder actions to implement the EU guidelines on prudent use of antimicrobials in human health (PJ-02-2019)

The Consumers, Health, Agriculture and Food Executive Agency (hereafter Chafea) is entrusted by the European Commission with the implementation of parts of the third EU Health programme and will be in charge of this Call for proposals.

The Agency invites you to read the call documentation carefully, i.e. this call for proposals and the guide for applicants. These documents provide clarifications and answers to questions you may have when preparing your application:

The call for proposals outlines the:

  - objectives, themes and priorities, types of activities that can be financed and the expected results of the call
  - timetable and available budget
  - eligibility, exclusion, selection and award criteria
  - evaluation procedure.

- The guide for applicants outlines the:
  - procedures to register and submit proposals online (via the EU Participant Portal)
  - recommendations for the preparation of the proposal
  - explanation on the application form (Proposal Template (Part A and B)), which describes the project
  - overview of the cost eligibility criteria.
- The Proposal Template Part B:
  - recommendations for the preparation of the technical part of the proposal
  - recommendations on planning and managing your project.

You also are encouraged to visit the Chafea website[2] to consult the list of projects funded previously under the 1st, 2nd and 3rd EU Health Programme.[3]

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/;jsessionid=5Qj3TvyCyBqbhfLZzzBttjDGh3gyXkQWYrjhrt36mChMJJlp02XX!2060916514?uri=uriserv:OJ.L_.2014.086.01.0001.01.ENG

[2] http://ec.europa.eu/chafea/index_en.htm

[3] https://webgate.ec.europa.eu/chafea_pdb/health/

1. Background to the call

The Annual Work Programme 2019 (AWP 2019) under the 3rd EU Health Programme was adopted on 29 March 2019[4].

This work programme sets out the priorities and actions to be undertaken for the year 2019, including the allocation of resources, to implement the Third Programme of the Union's action in the field of health (2014-2020) established under Regulation (EU) No 282/2014 ('the Programme Regulation')[5].

The main lines of the annual work programme 2019 are built around the following priority areas, while addressing the dimension of health inequalities as a cross-cutting issue:

(1) Country specific and cross country knowledge;

(2) Cross border health threats, preparedness and response, including antimicrobial resistance and vaccination;

(3) Structural support to health systems and link to digital single market;

(4) Promotion of health and prevention of non-communicable diseases.

The Commission encourages non-governmental bodies to work with the European Solidarity Corps, where appropriate. Actions are related in general to EU Member States and countries participating in the Health Programme.

Heading 2 of the Annex of the work programme outlines actions to be co-funded as project grants. Under the global budgetary envelope reserved for grants, EUR 5 800 000 will be reserved for projects.

Project grants are calculated on the basis of eligible costs incurred. The maximum rate for EU co-financing is 60%. However, the rate may rise to 80 % if a proposal meets the criteria for exceptional utility.

The budget line is 17 03 01.

The target groups are legally established organisations, public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments established in EU Member States and in countries participating in the Health Programme[6]

[4] https://ec.europa.eu/health/funding/adoption_workplan_2019_en

[5] https://ec.europa.eu/health/sites/health/files/funding/docs/wp2019_annex_en.pdf

[6] An updated list of countries is available on the Commission/Chafea website at http://ec.europa.eu/chafea/health/funding/projects-grants/index_en.htm

2. Objectives — Themes & priorities — Activities that can be funded — Expected impact

Themes & priorities

The Annual Work Programme 2019 outlines two priorities to be co-funded under this Call for proposals:

- Rare disease registries for the European Reference Networks (Heading 2.1 of the AWP 2019, Topic Code PJ-01-2019).
- Stakeholder actions to implement the EU guidelines on prudent use of antimicrobials in human health (Heading 2.2 of the AWP 2019, Topic Code PJ-01-2019).

Topic PJ-01-2019: Rare disease registries for the European Reference Networks (Heading 2.1 of the AWP 2019):

Background and purpose of the call:

The proposed action aims to support the development of rare disease (RD) registries for the European Reference Networks (ERNs).

Patient registries and databases constitute key instruments to develop clinical research in the field of rare diseases, to improve patient care and healthcare planning. They are the best way of pooling data to achieve a sufficient sample size for epidemiological and/or clinical research. Registries serve as a recruitment tool for the launch of studies focusing on disease etiology, pathogenesis, diagnosis or therapy.

The Council of the European Union recommended[7] that, in the field of rare diseases, Member States consider supporting at all appropriate levels, including the EU level, for epidemiological purposes, registries and databases, whilst being aware of independent governance. In order to support this process and, in particular, the interoperability of data in rare diseases registries, the Commission decided to set up a European Platform on Rare Disease Registration (EU RD Platform[8]) and to develop specific standards for the interoperability of such rare disease registries ("JRC standards" developed by the Commission's Joint Research Centre).

As foreseen in Article 12 of the Directive on the application of patients' rights in cross-border healthcare[9], 24 European Reference Networks (ERNs) were kicked-off in 2017 and since 2018 they are developing their research capabilities. Patient registries belong to this development, enabling to build patients cohorts at European level to follow up the natural course of diseases with sufficient patients data.

Five ERNs already received financial support from the Health Programme (Annual Work Plan 2016) and are currently developing a comprehensive approach for rare disease registries covering their entire ERN, following JRC standards and tools.

The remaining 19 ERNs are preparing their strategy in terms of research and

[7] Council Recommendation of 8 June 2009 on an action in the field of rare diseases, title II, point 5, OJ C 151 of 3.7.2009, p. 7.

[8] https://eu-rd-platform.jrc.ec.europa.eu/

[9] 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 of 4.4.2011, p. 45.

registries and need to be financially supported, too.

As laid down in the Directive, research in general and registries in particular are one of the objectives of the ERNs[10]. Since five ERNs are already supported for this purpose, only approved ERNs not yet receiving grants for registries are eligible to be co-funded through the present call.

Objectives pursued and expected results:

The main objectives of the present Call for projects for RD registries for ERNs are:

- to enable building, upgrading, linking and making interoperable registries covering the diseases and conditions of each ERN, thus linking and making visible patients cohorts at European level in order to follow up the natural course of diseases with sufficient patients data, also by registering all individual RD registries of the ERNs on the EU RD Platform;

- based on the above registration, to develop a comprehensive approach for rare disease registries covering the respective ERNs following the standards and tools provided by the EU RD Platform.

Patient registries will also contribute to the ERNs evaluation process foreseen in the ERN implementing decision and to the continuous monitoring and quality improvement system of the networks.

Proposals for upgrading already established registries are acceptable, as long as the proposal is in line with the objectives and registry policy of the specific ERN and covering the diseases and conditions of that ERN. The Coordinator or the Board of the ERN should approve the proposal and nominate the healthcare provider (a member of the ERN) to be responsible to carry out the action on its behalf and coordinate the project to be implemented with partners, in particular other members of the same ERN.

Description of the activities to be funded under this topic:

The activities to be carried out concern the building and development of rare disease patient registries for ERNs and further development and quality-control of existing registries.

In doing so, the following principles should be followed:

(i) strengthen coordination and cooperation and develop synergies among the networks and their registries;

(ii) build on existing tools and avoid doubling similar actions or activities;

(iiI) avoid the development of a variety of diverse, non-interoperable solutions.

Registries should, in particular, be built using the infrastructure and following the standards of the EU RD Platform and provide it with all the necessary data, and comply with the relevant data protection rules. For developing the registries, the ERNs commit to ensure, as a first step, that all individual registries used by the respective ERNs are registered on the EU RD Platform and in particular on its "European Rare Disease Registry Infrastructure" (ERDRI) that renders rare disease registries' data searchable and findable. Thus, the proposals to be funded will have to work with JRC, making sure that all ERNs will benefit from harmonised tools and standards following coordinated efforts around the EU RD Platform.

[10] Objective (e): "to reinforce research, epidemiological surveillance like registries and provide training for health professionals"

The projects must end with fully operational, interoperable and visible registries. The co-funded projects shall use JRC common data elements and shall be enrolled in the EU RD Platform / ERDRI. These registries should acknowledge the link with their ERNs.

Cooperation with the European Medicines Agency (EMA) can also be envisaged, but there are no specific requirements on how the ERN registries projects should cooperate with EMA.

The Clinical Patient Management System (CPMS), the online tool currently used for the clinical work of the ERNs, shall also be considered in this context if it serves the specific needs of the ERNs. Thus, if the consortium so wishes, an interaction with the ERN IT Advisory Group and/or with DG SANTE IT specialists for information and advice can be foreseen.

In addition, the ERN Research Working Group (formed of ERN representatives and of representatives of the ERN Board of Member States) can also play a facilitating role to create synergies for the registries developed for ERNs.

Expected output and impact:

The expected outputs are:

- Setting up new or improving the existing rare disease registries;
- Better coordination and cooperation among rare disease registries;
- Increased interoperability between rare disease registries;
- Cost-effective building of registries by avoiding fragmentation and duplication of work;
- Better visibility of rare disease registries and, in particular, of those used and enhanced by ERNs.

For more information about European Reference Networks, *see the website of the Directorate General for Health and Food Safety on European Reference Networks*[11].

Topic PJ-02-2019: Stakeholder actions to implement the EU guidelines on prudent use of antimicrobials in human health (Heading 2.2 of the AWP 2019).

Target groups of this topic are professional organisations and other stakeholders, such as healthcare systems and institutions

Background and purpose of the call:

The proposed action should consider activities focused on the implementation of the EU guidelines on the prudent use of antimicrobials in human health, which were published by the Commission in June 2017[12]. These Guidelines aim to support a variety of key stakeholders and public health authorities in Member States in reducing unnecessary antibiotic use and combatting AMR. While the Guidelines have been well

[11] https://ec.europa.eu/health/ern_en

[12] https://ec.europa.eu/health/amr/sites/amr/files/amr_guidelines_prudent_use_en.pdf

received further action is needed to facilitate and encourage stakeholders to take them forward and implement them.

The European One-health Action Plan against Antimicrobial Resistance COM(2017)339 commits the Commission to engage with and support collaboration among key stakeholders in the human health, animal health, food, water and environmental sectors to encourage the responsible use of antimicrobials in the healthcare sector.

The levels and trends of resistant infections in the EU are still not yet improving. This action is thus urgent to engage stakeholders more actively as one of the contributions to reducing the spread of AMR, namely the need to ensure more prudent use of antibiotics and foster antibiotic stewardship.

Three out of the four key priorities of the Third EU Health Programme (2014-2020) are directly related to this action. The most relevant is the fourth priority on facilitating access to better and safer healthcare for citizens, which calls for 'Measures to prevent antimicrobial resistance and control healthcare-associated infections'. Also relevant is the Programme priorities to 'Contribute to innovative, efficient and sustainable health systems' and 'Protect citizens from serious cross-border health threats'.

The project(s) aims to involve European level stakeholders to promote, disseminate and directly apply the EU guidelines on the prudent use of antimicrobials in human health among the target groups identified in the guidelines, i.e., prescribers (e.g. doctors and hospital clinicians), pharmacists, nurses, infectious disease specialists and those responsible for the management of health systems.

This proposal is for incentive measures to combat serious cross border threats to health as set out in TFEU Article 168 and enabled via the EU Health Programme Regulation.

This project(s) will support chiefly the implementation of EU legislation, namely Decision (EU) 1082/2013, which includes actions to support and coordinate response on serious cross-border health threats including AMR.

The project(s) will contribute towards the key performance indicators of Directorate-General health and Food Safety, as set out in its Strategic Plan, namely to reduce antibiotic consumption in human health in the EU by 30% by 2020.

Objectives pursued and expected results:

The main objectives of the present call for projects (stakeholders actions) are focused on the implementation of the EU guidelines on prudent use of antimicrobials in human health:

- to raise awareness and foster the direct application of the EU guidelines on the prudent use of antimicrobials by healthcare practitioners and members of the stakeholder organisations;

- to change practices on antimicrobial prescription and dispensing amongst members of the stakeholder organisations involved (in the project) in the direction of compliance with the guidelines;

- to reduce of inappropriate use of antimicrobials in human health.

Description of the activities to be funded under the call for proposals:

The activities should enable stakeholder organisations to take further action on AMR within the framework of the EU guidelines on prudent use of antimicrobials in human health. The action will engage with professional groups and settings which require specific attention and develop and implement packages of interventions to implement

the guidelines adapted to the needs of the job roles and settings (e.g. hospital, primary care long term care) involved. Deliverables are expected to include adaptations of the guidelines to the local situation, training packages, clinical audit tools, evaluation tools, methods for assessing outcome indicators, tools and methods for providing positive and negative feedback to practitioners and incentive schemes.

The organisations intending to participate in a project should include, but are not restricted to professional associations and scientific societies relevant for the target groups identified in the guidelines – including prescribers (e.g. doctors and other clinicians), pharmacists, nurses, infectious disease specialists and those responsible for the management of health systems.

The amount is intended to either support either 1 large project with 20-30 partners or 2 or more smaller projects with 5-19 partners.

Project teams should include at least one European umbrella organisation covering a significant part of the health workforce. Ideally partner organisations should include several such organisations and also include partners in individual EU Member States and other countries participating in the EU 3rd Health Programme.

Expected impact:

The expected outputs are

- Adaptation of guidelines to the local situation;
- Trainings,
- Workshops,
- Clinical audit tools,
- Evaluation tools,
- Tools and methods for providing feedback to practitioners and incentive schemes.

The projects(s)' activities should complement and be synergistic with the Joint Action on Antimicrobial Resistance and Healthcare Associated Infection (JAMRAI) (2017-2020)[13].

For more information about European Reference Networks, *see the website of the Directorate General for Health and Food Safety on Anitmicrobial Resistance*[14].

[13] https://eu-jamrai.eu/

[14] https://ec.europa.eu/health/amr/antimicrobial-resistance_en

3. Timetable & available call budget

Time-table

Timing (planned)	
Call publication:	14 May 2019
Opening of submission	21 May 2019
Deadline for applications:	10 September – 17:00 CET
Evaluation:	September - October 2019
Information on evaluation result:	October to November 2019
Grant agreement signature:	January to February 2020
Starting date:	March 2020

Call budget

The available call budget is **EUR 5 800 000.**

Specific budget information per topic can be found in the table below.

Topic	Topic budget	Range of project budgets
Topic PJ-01-2019: Rare disease registries for the European Reference Networks (Heading 2.1 of the AWP 2019)	**EUR 3 800 000**	Indicative amount of EU contribution: Maximum 200 000 €/ERN, totalling maximum EUR 3 800 000
Topic PJ-02-2019: Stakeholder actions to implement the EU guidelines on prudent use of antimicrobials in human health (Heading 2.2 of the AWP 2019).	**EUR 2 000 000**	Maximum EUR 2 000 000

Criteria for the exceptional utility of projects

1. At least 60 % of the total budget of the action must be used to fund staff. This criterion intends to promote capacity building to develop and implement effective health policies

and

2. At least 30 % of the budget of the proposed action must be allocated to at least five different Member States whose gross national income (GNI) per inhabitant is less than 90 % of the EU average. This criterion is intended to promote the participation of stakeholders in the field of health from Member States with a low GNI.

The Agency reserves the right not to award all available funds or to redistribute them between the call priorities, depending on the applications received and the evaluation results.

4. Admissibility conditions

Admissibility

Applications must be submitted before the call deadline *(*see time-table section 3).

Applications must be submitted electronically via the Participant Portal Electronic Submission System (accessible via the Call Topic page in the Funding Opportunities section). Paper submissions are no longer possible.

Applications (including annexes and supporting documents) must be submitted using the forms provided inside the Electronic Submission System (not the documents available on the Call Topic page — they are only for information).

Your application must be readable, accessible and printable and contain all the requested information and all required annexes and supporting documents *(see section 10)*.

5. Eligibility conditions

Participants

In order to be eligible for a grant, the applicants must be:

- legal persons
- belong to one of the following categories: public, non-governmental or private bodies
- be established in one of the eligible countries, i.e.:
    - EU Member State (including overseas countries and territories (OCTs))
    - eligible non-EU countries:
        - Iceland and Norway,
        - countries which have a bilateral agreement with the EU, in accordance with Article 6 of Regulation (EU) No 282/2014 (the 'Programme Regulation'): currently Serbia, Moldova and Bosnia-Herzegovina.
- be directly responsible for the preparation and management of the project with the other applicants, i.e. not acting as an intermediary.

Natural persons are NOT eligible. International organisations are not eligible under this call.

To prove eligibility, all applicants must register in the Participant Register — before the call deadline — and upload the necessary documents showing legal status and origin.

Additional eligibility criterion:
For topic Topic PJ-01-2019: Rare disease registries for the European Reference Networks (Heading 2.1 of the AWP 2019):

Only approved ERNs not having received grants for registries under the related call of the AWP 2016 are eligible for co-funding.

Applications by single applicants are allowed.

Applicants participating in a project proposal must have different legal entities (i.e. be independent from each other) and may be from less than three countries participating in the Health Programme.

For Topic PJ-02-2019: Stakeholder actions to implement the EU guidelines on prudent use of antimicrobials in human health (Heading 2.2 of the AWP 2019):

In order to be eligible for a grant, the applications must be submitted by a consortium complying with the following conditions:

- Applicants participating in a project proposal must have different legal entities (i.e. be independent from each other) and be from at least three countries participating in the Health Programme. Proposals which involve fewer applicants and/or cover fewer countries will be rejected.

For UK applicants: Please note that until the United Kingdom leaves the EU, nothing changes with regard to the participation in EU programmes. Please be aware however that the eligibility criteria must be complied with for the *entire* duration of our framework partnerships/grants. If the United Kingdom withdraws from the EU during that period (without an agreement ensuring eligibility for UK beneficiaries), you will cease to receive EU funding or be required to leave the project on the basis of the contractual provisions on termination.

Activities

Eligible activities are set out in section 2 above.

Financial support to third parties is not allowed.

Duration

Projects may not be longer than 36 months.

6. Award criteria

Admissible and eligible applications will be evaluated and ranked against of the following award criteria:

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

Sub-criteria taken into account in the assessment:

- relevance of the project for meeting the objectives and priorities set out in the annual work plan of the third Health Programme, under which the call for proposals is published;
- added value at EU level in the field of public health;
- pertinence of the geographical coverage of the proposal;
- consideration of the social, cultural and political context.

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

Sub-criteria taken into account in the assessment:

- quality of the evidence base;
- quality of the content;
- innovative nature, technical complementarity and avoidance of duplication of other existing actions at EU level;
- quality of the evaluation strategy;
- quality of the dissemination strategy and action plan.

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

Sub-criteria that are taken into account in the assessment:

- quality of the planning and appropriate task distribution to implement the project,
- relevance of the organisational arrangements, including financial management;
- quality and complementarity of the partnership.

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

Sub-criteria taken into account in the assessment:

- realistic estimation of person days per deliverable and per work package;
- appropriate budget allocated for evaluation and dissemination activities.

Maximum points: 40 points.

Individual thresholds: See above.

Overall threshold: 25 points.

Applications that pass the individual thresholds AND the overall threshold will be considered for funding and ranked according to the number of points received. The grant agreement(s) will then be awarded to those ranking highest, up to the available budget allocated for project grants.

The proposals meeting all thresholds but which are ranked beyond the budget ceiling will be put on a reserve list, in case additional budget is available.

Applications that do not pass all individual thresholds OR do not pass the overall threshold will be rejected.

7. Other conditions

Financial capacity

All project participants must have stable and sufficient resources to successfully implement the project and contribute their share. Organisations participating in several projects must have sufficient capacity to implement several projects.

The financial capacity check will be done by the European Commission and the Agency on the basis of the documents that applicants will be requested to upload in the Participant Register (profit and loss account and balance sheet for the last two closed financial years, or for newly created entities possibly the business plan; for applicants requesting more than EUR 750 000: audit report produced by an approved external auditor, certifying the accounts for the last closed financial year).

The analysis will take into account elements such as dependency on EU funding and deficit and revenue in previous years.

It will normally be done for all applicants, except:

- public bodies (entities established as public body under national law, including local, regional or national authorities) or international organisations
- if the individual requested grant amount is not more than EUR 60 000 (low-value grant).

If needed, it may also be done for linked third parties.

If the Agency considers that an applicant's financial capacity is not satisfactory, the Agency may require:

- further information
- an enhanced financial responsibility regime, i.e. full joint and several responsibility for all applicants (see below, section 9)
- pre-financing paid in instalments
- (one or more) pre-financing guarantees (see below, section 9)

or

- propose no pre-financing
- reject your participation or, if needed, the entire application.

For more information, *see* *Rules on Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment*[15].

Operational capacity

All participants must have the know-how and qualifications to successfully implement the project (including sufficient experience in EU/trans-national projects of comparable size).

This capacity will be assessed on the basis of the experience of the applicants and their staff.

Applicants will have to show this via the following information in the Proposal Template (Part B):

- a description of the consortium participants
- a list of EU funded actions/projects for the last 4 years.

Additional supporting documents may be requested, if needed to confirm the operational capacity of any applicant.

Public bodies are exempted from the operational capacity check.

Exclusion

Applicants that are subject to an EU administrative sanction (i.e. exclusion or financial penalty decision)[16] or in one of the following situations[17] are excluded from receiving EU grants and will automatically be rejected:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct[18] (including if done by persons having powers of representation, decision-making or control, beneficial owners or natural persons who are essential for the award/implementation of the grant)
- committed fraud, corruption, links to a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decision-making or control, beneficial owners or natural persons who are essential for the award/implementation of the grant)
- shown significant deficiencies in complying with main obligations under an EU procurement contract, grant agreement or grant decision (including if done by persons having powers of representation, decision-making or control, beneficial owners or natural persons who are essential for the award/implementation of the grant)
- guilty of irregularities within the meaning of Article 1(2) of Regulation No 2988/95 (including if done by persons having powers of representation,

[15] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/lev/h2020-rules-lev-lear-fvc_en.pdf

[16] See Article 136(1) EU Financial Regulation 2018/1046.

[17] See Articles 136(1) and 141(1) EU Financial Regulation 2018/1046.

[18] Professional misconduct includes: violation of ethical standards of the profession, wrongful conduct with impact on professional credibility, false declarations/misrepresentation of information, participation in a cartel or other agreement distorting competition, violation of IPR, attempting to influence decision-making processes or obtain confidential information from public authorities to gain advantage.

decision-making or control, beneficial owners or natural persons who are essential for the award/implementation of the grant)

- created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin or created another entity with this purpose (including if done by persons having powers of representation, decision-making or control, beneficial owners or natural persons who are essential for the award/implementation of the grant).

Applicants will also be rejected if it turns out during the grant award procedure that they[19]:

- misrepresented information required as a condition for participating in the grant award procedure or failed to supply that information
- were previously involved in the preparation of grant award documents where this entails a distortion of competition that cannot be remedied otherwise (conflict of interest).

[19] See Article 141(1) EU Financial Regulation 2018/1046.

IMPORTANT

- **Coordinator & consortium —** The coordinator represents the consortium towards the EU. You must have agreement of the other members and their mandate to act on their behalf and will have to confirm this in your application. Moreover you will have to declare that the information in the proposal is correct and complete and that all participants comply with the conditions for receiving funding (especially, eligibility, financial and operational capacity, no exclusion, etc.) and have agreed to participate. Before signing the grant agreement, each participant will have to confirm this again by signing a declaration of honour (DoH). Proposals without full support will be rejected.

- **Linked third parties** — Applicants may participate with linked third parties (i.e. affiliated entities) that receive funding. Linked third parties must comply with all the conditions set out in this call (just like applicants), but they do not sign the grant agreement and do not count towards the minimum eligibility criteria for consortium composition.

- **Subcontractors —** Subcontracting is allowed, but subject to strict limits *(see section 9)*.

- **Registration —** All applicants must register in the Participant Register — before the call deadline — and upload the necessary documents showing legal status and origin. Linked third parties can register later (during grant preparation).

- **Completed/ongoing projects —** Applications for projects that have already been completed will be rejected; applications for projects that have already started will be assessed on a case-by-case basis (in this case, no costs can be reimbursed for activities that took place before proposal submission).

- **Balanced project budget —** Applicants must ensure a balanced project budget and sufficient other resources to implement the project successfully *(e.g. own contributions, income generated by the action, financial contributions from third parties)*. You may be requested to lower the estimated costs in the detailed budget table, if they are ineligible or excessive.

- **No profit rule —** Grants may NOT give a profit (i.e. surplus of receipts + EU grant over costs). This will be checked by us at the end of the projects.

- **No double funding** — Any given action may receive only one grant from the EU budget. The project must therefore NOT receive any financial support under any other EU funding programme (including EU funding managed by authorities in EU Member States or other funding bodies, e.g. Regional Funds, Agricultural Funds, EIB loans, etc.). Cost items may NOT be declared twice under different EU actions.

- **Combination with EU operating grants —** Combination with EU operating grants is possible if the specific project grant remains outside the operating grant work programme and you make sure that cost items are clearly separated in your accounting and NOT declared twice.

- **Multiple applications —** Applicants may submit more than one application for *different* projects under the same call (and be awarded a grant for them).

  Organisations may participate in several applications.

  BUT: if are several applications for the *same/very similar* project, only one application will be accepted and evaluated; the applicants will be asked to withdraw one of them (or it will be rejected).

- **Language —** You can submit your proposal in any official EU language. However, for reasons of efficiency, we strongly advise you to use English. In order to facilitate assessment by the evaluators, an English translation of the technical part should accompany that written in another EU official language. If you need the call document in another official EU language, please submit a request within 10 days after call publication (for the contact information, *see section 10*).

8. Evaluation & award procedure

This call is subject to the standard submission and evaluation procedure (one-stage submission + one-step evaluation).

Applications will be checked by the Agency for formal requirements (admissibility and eligibility) and will be evaluated for each topic separately by an evaluation committee (assisted by independent outside experts) against the operational capacity and award criteria and then listed in a ranked list according to their quality score.

For proposals with the same score (within a topic) a priority order will be determined according to the following approach:

Successively for every group of *ex aequo* proposals, starting with the highest scored group, and continuing in descending order:

(1) Higher score in Award Criteria 1 (*Policy and contextual relevance*);
(2) Higher score in Award Criteria 2 (*Technical quality*);
(3) Higher score in Award Criteria 3 (*Management quality)* given higher priority;
(4) If a distinction still cannot be made, the panel may decide to further prioritise by considering how to enhance the quality of the project portfolio through synergies between projects, or other factors related to the objectives of the call. These factors will be agreed upon by voting and documented in the report of the Panel.

Unsuccessful applications will be informed about their evaluation result *(see time-table section 3)*.

Successful applications will be invited for grant preparation.

IMPORTANT

- **No commitment for funding —** Invitation to grant preparation does NOT constitute a formal commitment for funding. We will still need to make various legal checks before grant award: legal entity validation, financial capacity, exclusion check etc.
- Grant preparation will involve a **dialogue** in order to fine-tune technical or financial aspects of the project and may require extra information from your side.

9. Legal & financial set-up of the grants

If a project is selected for funding, the applicant will be asked to sign a grant agreement with the Agency.

This grant agreement will set the framework for your grant and its terms and conditions, in particular provisions on deliverables, reporting and payments.

Starting date & project duration

The project **starting date and duration** will be fixed in your grant agreement (art. 3). Normally the starting date will be after grant signature. Retroactive application can be granted exceptionally for duly justified reasons — but never earlier than the proposal submission date.

Project duration: 36 months (extensions will be possible only exceptionally, for duly justified reasons and with the Agency's agreement)

Maximum grant amount, reimbursement of eligible costs & funding rate

All grant parameters (maximum grant amount, funding rate, total eligible costs etc.) will be fixed in your grant agreement (art. 5).

Project budget: see section 3 above. The grant awarded may be lower than the amount requested.

The grant will be a reimbursement of actual costs grant. This means that it will reimburse ONLY certain types of costs (eligible costs) and ONLY those costs you *actually* incurred for your project (NOT the *budgeted* costs).

The costs will be reimbursed at the funding rate fixed in the grant agreement (60% rising to 80% if a proposal meets the criteria of exceptional utility).

EU grants may NOT produce a profit. If there is a profit (i.e. surplus of receipts + EU grant over costs), we will deduct it from your final grant amount.

The final grant amount you will receive will therefore depend on a variety of criteria *(actual costs incurred and project income; eligibility; compliance with all the rules under the grant agreement, etc)*.

Cost eligibility rules

For the **cost eligibility rules**, see the model grant agreement (art. 6) and the Guide for applicants.

Special cost eligibility rules for this call:

- Max. 7% flat-rate for indirect costs determined at project level during grant preparation
- depreciation costs for equipment
- project activities must take place in one of the eligible countries
- financial support to third parties is not allowed
- subcontracting[20] of action tasks is subject to special rules and must be approved by us (either as part of your proposal or in a periodic/final report)

[20] For more details see the guide for applicants

- VAT — please note that there are new rules in place since 2013 for public entities (VAT paid by beneficiaries that are public bodies acting as public authority is NOT eligible)

Reporting & payment arrangements

The **reporting and payment** arrangements will be fixed in the grant agreement (art. 15 and 16).

After grant signature, the Agency will normally provide you with a float to start working on the project (pre-financing of normally 50% of the maximum grant amount; exceptionally less or no pre-financing).

There will be 1 or 2 interim payments linked to a periodic report.

At the end of the project, you will be invited to submit a report and the Agency will calculate your final grant amount. If the total of earlier payments is higher than the final grant amount, the Agency will ask you (your coordinator) to pay back the difference (recovery).

Deliverables

Standard **deliverables** will be listed the grant agreement (art. 14). The project-specific deliverables will be listed in Annex 1.

Standard deliverables for this call: none.

Pre-financing guarantee

If the Agency requires a pre-financing guarantee, it will be fixed in your grant agreement (art 16.2). The amount will be fixed by us during grant preparation, and will be equal or lower than the pre-financing for your grant.

The guarantee should be in euro and issued by an approved bank/financial institution established in an EU Member State.

If you are established in a non-EU country and would like to provide a guarantee from a bank/financial institution in that country, please contact us (this may be exceptionally accepted, if it offers equivalent security).

Amounts blocked in bank accounts will NOT be accepted as financial guarantees.

The guarantee is NOT linked to individual consortium members. You are free to organise how the guarantee amount should be provided (by one or several beneficiaries, for the overall amount or several guarantees for partial amounts). The only thing that is important is that the amount the Agency requests is covered and the guarantee(s) are sent by the coordinator before the pre-financing (by PP Communication to the Project Officer or Formal Notification).

If agreed with us, the bank guarantee may be replaced by a joint and several guarantee from a third party.

The guarantee will be released at the end of the grant, in accordance with the conditions laid down in the grant agreement.

Special provisions

Intellectual Property Rights rules: see model grant agreement (art. 19)

Promotion & visibility of EU funding: see model grant agreement (art. 22)

Cost rejection, grant reduction, recovery, suspension & termination

The grant agreement (chapter 6) provides for the measures the Agency may take in case of **breach of contract** (and other violations of law).

Liability regime for recoveries

The liability regime for recoveries will be set out in your grant agreement (art. 28), i.e. either:

- limited joint and several liability with individual ceilings — each beneficiary up to *its* maximum grant amount
- unconditional joint and several liability — each beneficiary up to the maximum grant amount for the *action*

or

- individual financial responsibility — each beneficiary only for its debt.

10. How to submit an application?

All applications must be submitted electronically via the Participant Portal Electronic Submission System (accessible via the Call Topic page in the Funding Opportunities section). Paper submissions are no longer possible.

The **submission process** is explained in the Funding and Tenders Portal Online Manual (together with detailed instructions for the IT tool).

Mandatory **annexes & supporting documents** (directly available in the Submission System) for this call:

- detailed budget table as part of the Proposal Template Part B.

Contact

For questions on the Participant Portal Submission System, please contact the IT Helpdesk.

For non-IT related questions a helpdesk at the Chafea is available via: CHAFEA-HP-CALLS@ec.europa.eu . The deadline to submit questions is 6 calendar days before the deadline. Answers to relevant questions will be published on the Funding and Tenders Portal FAQ section[21], latest 14 calendar days after receipt.

Frequently asked questions are published on the Funding and Tenders Portal FAQ section[22]

Please note that any replies from the help desk provided in the frame of the current procedure can by no means be regarded as CHAFEA' s binding opinion producing any legal effect. All aspects of the proposals to be submitted in response of the call (including the eligibility, selection and award criteria) will be formally evaluated by the evaluation committee(s) that will be set up on the basis of the applicable rules.

Please indicate clearly the reference of the call for proposals and the topic to which your question relates *(see call document cover page)*.

[21] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/faq;programme=3HP;

[22] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/faq;programme=3HP;

IMPORTANT

- **Consult** the Participant Portal Call Topic page regularly. We will use it to publish updates and additional information on the call (call updates).
- **Don't wait** until the end.

  Questions received later than 6 days before the call deadline cannot be answered.

  We strongly advise you to complete your proposal sufficiently in advance of the deadline, to avoid any last minute technical problems. Any problems due to last minute submissions *(e.g. congestion, etc.)* will be at your risk. The call deadline will NOT be extended.
- Before submitting a proposal, all applicants must be **registered** in the Participant Register and obtain a participant identification code (PIC) (one for each applicant).
- By submitting their proposal, all applicants **accept**:
  - the terms and conditions of this call (as described in this call document and the documents it refers to)
  - to use the electronic exchange system in accordance with the Participant Portal Terms & Conditions.
- After the call deadline, the proposal is locked and can no longer be changed.
- You may be contacted later on if there is a need to **clarify** certain aspects of your **proposal** or for the correction of clerical mistakes.
- You may be asked to submit **additional documents** later on *(e.g. for the legal entity validation, LEAR appointment and financial capacity check)*.
- We intend to organise an **Kickoff - meeting** for successful applicants after signature of the grant to discuss project management, administrative and financial aspects and reporting obligations. Participation by the coordinator (persons in charge of project coordination and financial matters) will be mandatory.
- We are committed to **transparency**. Each year, information about EU grants awarded is published on the Europa website**.** This includes:
  - the beneficiaries' names
  - the beneficiaries' addresses
  - the purpose for which the grant was awarded
  - the maximum amount awarded.

  The publication can exceptionally be waived (on reasoned and duly substantiated request), if there is a risk that the disclosure could jeopardise the rights and freedoms under the EU Charter of Fundamental Rights or harm your commercial interests.
- **Data privacy —** The submission of an application under this call involves the collection, use and processing of personal data (such as name, address and CV). This data will be processed in accordance with Regulation No 2018/1725. It will be processed solely for the purpose of evaluating your proposal (and subsequent management of your grant and, if needed, programme monitoring, evaluation and communication). Details are available in the Participant Portal Privacy Statement.
- **Cancellation —** There may be circumstances which may require the cancellation of the call. In this case, you will be informed via a call update. Please note that cancellations are without entitlement to compensation.