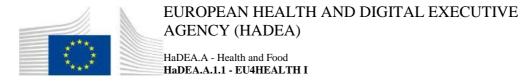


EU4Health Programme (EU4H)

Call for action grants under the Annual Work Programme 2021

EU4H-2021-PJ-03

Version 1.0 18 11 2021



CALL FOR PROPOSALS

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Introduction

This is a call for proposals for EU action grants in the field of health under the **EU4Health Programme (EU4H)**.

The regulatory framework for this EU Funding Programme is set out in:

- Regulation 2021/522 (EU4Health Regulation)¹
- Regulation 2018/1046 (EU Financial Regulation)²

The call is launched in accordance with the 2021 EU4Health Work Programme³ and will be managed by the European **Health and Digital Executive Agency**, (HaDEA) ('Agency').

The call covers the following **topic**:

EU4H-2021-PJ-19 (DP/C-g-09.1.2) Action grants to support accreditation and certification of quality assurance schemes for breast, colorectal and cervical cancer screening programmes

We invite you to read the **call documentation** carefully, in particular this Call Document, as well as the EU4Health Model Grant Agreement, the <u>EU Funding & Tenders Online Manual</u> and the EU Grants AGA — Annotated Grant Agreement.

These documents provide clarifications and answers to questions you may have when preparing your application:

- the Call Document outlines the:
 - background, objectives, scope, activities that can be funded, expected results, expected impact, mandatory specific milestones and deliverables, and the indicators (sections 1 and 2);
 - timetable, project duration and available budget (sections 3 and 4);
 - admissibility and eligibility conditions (including mandatory documents; sections 5 and 6);
 - criteria for financial and operational capacity and exclusion (section 7);
 - evaluation and award procedure (section 8);
 - award criteria (section 9);

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¹ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027 (OJ L107 of 26 March 2021, p.1).

² Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012

³ Commission Implementing Decision C(2021) 4793: final of 24/06/2021 on the financing of the Programme for the Union's action in the field of health (EU4Helath Programme) and the adoption of the work programme for 2021.

- legal and financial set-up of the Grant Agreements (section 10);
- how to submit an application (section 11).
- the <u>Online Manual</u> outlines the:
 - procedures to register and submit proposals online via the EU Funding & Tenders Portal ('Portal');
 - recommendations for the preparation of the application;
- the AGA Annotated Grant Agreement contains:
 - detailed annotations on all the provisions in the Grant Agreement you will have to sign in order to obtain the grant (including cost eligibility, payment schedule, accessory obligations, etc.).

You are also encouraged to visit the DG SANTE website⁴ to consult the list of projects funded previously.

1. Background

On 24 March 2021, the EU4Health Regulation was adopted as part of the EU Multiannual Financial Framework for the 2021-2027 period. The EU4Health Regulation established 'the EU4Health Programme'. This marks an important step towards making available instruments and solutions to support Member States in building stronger, more resilient and accessible health systems.

The EU4Health Programme represents an unprecedented level of financial commitment for the EU in health in comparison with previous health programmes. The Programme is EU's response to the current public health emergency that will make a significant contribution to the post-COVID-19 recovery aiming to:

- improve public health in the Union through disease prevention and health promotion, as well as international health initiatives and cooperation;
- protect people from serious cross-border health threats through prevention, preparedness and response to cross-border health threats; complementing national stockpiling of essential crisis-relevant products; and establishing a reserve of medical, healthcare and support staff;
- improve access to medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union and efficient use of medicinal products;
- strengthen the national health systems through improved health data use and re-use, development of digital tools and services, digital transformation of healthcare; enhancing access to healthcare; developing and implementing EU health legislation and evidence-based decision making; and integrated work among Member States' health systems.

⁴ Public Health Europe - European Commission - EU | Public Health (europa.eu)

Cancer is the second leading cause of mortality in the Member States after cardiovascular disease. The prevention and control of cancer would benefit the majority of citizens since it shares common risk factors with other non-communicable diseases. Europe's Beating Cancer Plan, which is a key pillar of a stronger European Health Union, tackles the entire cancer disease pathway by means of flagship initiatives, such as launching a Cancer Inequalities Registry, and supporting actions, such as establishing an EU Network of Youth Cancer Survivors. The EU4Health programme will provide the financial support to implement these initiatives that are important to mitigate the impact of the COVID-19 pandemic on cancer control and care.

Policy context

Cancer screening is necessary for disease risk reduction as it allows the detection of the disease at an early stage of invasiveness or even before the cancer becomes invasive. Screening therefore is an important tool in limiting morbidity and improving survival rates of those who have developed cancer.

In the Union, countries have adopted significant measures to deliver cancer screening services to their populations as recommended in the Council Recommendation of 2 December 2003 on cancer screening⁵. Screening methodologies are subject to ongoing development and therefore the application of recommended screening approaches and methodologies should be accompanied by simultaneous assessments of the quality, applicability and cost-effectiveness of new methods.

Quality assurance at all levels of population-based screening programmes can only be ensured if good information about benefits and risks, adequate resources, follow-up with complementary diagnostic procedures and treatment of those with a positive screening test are available.

The report on the implementation of the Council Recommendation on cancer screening (2017)⁶ demonstrated barriers to access to screening services by the population and also to deliver quality-assured services. These barriers introduce serious inequities at the Union level and the delivery of quality-assured services in a population-based approach still has to be assessed and addressed through pragmatic public health initiatives in many countries. This action supports the implementation of a Europe's Beating Cancer Plan flagship initiative and implements the EU4Health Programme's general objective of improving and fostering health in the Union (Article 3, point (a)) through the specific objectives defined in Article 4, points (a) and (j) of Regulation (EU) 2021/522.

Grants shall involve co-financing. Grants paid by the Union shall not exceed 60 % of eligible costs for an action relating to an objective of the Programme. In cases of exceptional utility, the contribution by the Union may be up to 80 % of eligible costs.⁷

⁵ OJ L 327, 16.12.2003, p.34-38.

Cancer Screening in the European Union (2017). Report on the implementation of the Council Recommendation on cancer screening, International Agency for Research on Cancer.

⁷ Actions with a clear Union added value shall be considered to have exceptional utility, inter alia, where:
(a) at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; or

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

2.1 Topic EU4H-2021-PJ-19 (DP/C-g-09.1.2)

Action grants to support accreditation and certification of quality assurance schemes for breast, colorectal and cervical cancer screening programmes

Objectives pursued

The action aims at supporting Member States in the implementation of accredited certification schemes for cancer screening programmes and follow-up and subsequent diagnosis and care in agreement with the Union (EU) guidelines and quality assurance schemes for population-based screening programmes.

Description of the activities to be funded under this topic

Activities will include the organisation, implementation and running of accreditation and certification activities making use of guidelines for breast, colorectal and cervical cancer screening, diagnosis and care.

Expected results and impact

The expected result is the implementation at national and/or regional level of accreditation and certification quality assurance schemes for the entire pathway of breast cancer screening, including diagnosis and care.

This action will improve the quality and performance of the entire pathway of population-based screening for breast cancer and is expected to pave the way to address cervical and colorectal cancers in subsequent open calls. The action furthermore aims to reduce the disparity among and within the Member States associated with an unequal access to quality-assured screening programmes.

Specific mandatory deliverables and/or milestones

(in addition to those listed in sections C and D above)

The successful applicant(s) shall take into consideration the developed European Quality Assurance scheme for breast cancer and support the implementation of ECIBC⁸, *via* accredited certification (ISO/IEC 17065).

During the second half of 2022 (July-September) a pilot accreditation certification run will be implemented in real settings to test the auditing mechanism of the European QA scheme for Breast Cancer Services with the aim to enhance its feasibility across the EU.

The activities of the successful applicant / consortium are expected to be as follows:

• Preparatory phase (6 - 9 months) – Set-up the *modus operandi* of the project and its internal structure, and the rules to ensure the best coordinated approach of the project, including the protocols to run the future activities of

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⁽b) bodies from at least 14 participating Member States participate in the action, of which at least four are Member States whose GNI per inhabitant is less than 90 % of the Union average.

^{8 &}lt;u>https://healthcare-quality.jrc.ec.europa.eu/ecibc/breast-quality-assurance-scheme</u>

accreditation/certification, which will be tested through the pilot run in the second phase of the project (e.g. 'Proof of concept' of the pilot). The activities will take advantage of the steering support provided by the Commission's Knowledge Centre on Cancer. In particular the beneficiary(es) will define the entitiesand the Breast Cancer Services which will participate to the pilot phase, taking into consideration the need to include at least 30% services originating from underrepresented territorial/geographical areas⁹, and/or those Breast Cancer Services which still do not have an accreditation certification process for the entire breast cancer care pathway. In addition, the beneficiary(es)should ensure, where possible, the participation in the pilot run of the Conformity Assessment Bodies.

Pilot Phase (after the first phase until the end of the project) – Organisation, coordination, implementation, monitoring and collection of outcomes, evaluation and proposal for improvement of the scheme piloted, to allow the feasibility and implementability of the accreditation certification in different EU settings, which will foster the subsequent rollout of the final scheme¹⁰.

Specific action-level indicators for reporting purposes

Applicants must include data on the following indicators in their regular reporting activities in case of award, and must be prepared to include additional specific indicators where needed:"

- Number of Breast Cancer Centres, which will be part of the proposal's consortium.
- Number of EU/EEA Member States represented in the proposal's consortium.
- Number of Conformity Assessment Bodies in the proposal's consortium.
- Number of Breast Cancer Centres participating in the pilot.
- Number of EU/EEA Member States participating in the pilot.
- Number of Conformity Assessment Bodies participating in the pilot.
- Number of Meetings done in the first phase.

Satisfaction rate of participants to the project.

Budget

Available budget for this topic: EUR 2 000 000

Proposals to be awarded under this topic: One single proposal

Expected duration of project

Given the complexity of the activities to be funded under this topic, the recommended maximum duration of a project is 24 months where up to 9 months will be dedicated to the preparatory phase (see section 6 of the call document).

https://healthcare-quality.jrc.ec.europa.eu/

The next EC Initiative will start in early 2022 to develop a European Quality Assurance Scheme for Colorectal Cancer services (ECICC), followed by the EC Initiative on Cervical Cancer (ECICvC). Similar actions for these two initiatives will be initiated after their completion and covered in future calls by the Commission.

Part B – Special requirements to be included in the call document

Applicants – specific eligibility criteria	Civil society organisations (associations, foundations, NGOs and similar entities); academia and education establishments, research institutes, hospitals, expert networks and Member States' authorities - cancer centres The activities to be funded under this topic will be implemented by the successful applicant/consortium of Breast Cancer Services (BCS), and Conformity Assessment Bodies ¹¹ .		
Specific eligibility criteria applicable to the consortium composition	Applications by either a single sole applicant or by a consortium are acceptable		
Selection criteria	The successful applicant (at least the applicant leading the consortium, in case of multiple partners) must have experience in certification of healthcare activities and must follow the EC's accredited certification approach. The written acceptance to follow the certification approach (free format) must be attached to the proposal.		
Place of implementation	EU/EEA countries		
Ethics/Security measures	None in addition to the ethics rules already applicable in relation to clinical activities, including diagnosis and treatment, and the GDPR legislation. See "Ethics" section under paragraph 6 below.		

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The European Quality Assurance Scheme for Breast Cancer Services (the European QA scheme) has been established under the auspices of the first European Commission Initiative on Breast Cancer (ECIBC) and defines a common set of quality and safety requirements for breast cancer services (BCSs) in Europe that should be followed by any entity providing BCSs to women (a 'BCS entity'). It covers all the relevant areas of healthcare provision for breast cancer including screening. The requirements are defined, where possible, by considering evidence-based recommendations from high-quality guidelines, best professional practices and relevant legislation. The owner of the European QA scheme is the European Commission (the 'the European QA scheme owner').

3. Available budget

The available call budget is **EUR 2 000 000**.

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

Topic	Topic budget	Proposals to be awarded	Recommended project duration
EU4H-2021-PJ- 19 Action grants to support accreditation and certification of quality assurance schemes for breast, colorectal and cervical cancer screening programmes	2.000.000	One single proposal	Given the complexity of the activities to be funded under this topic the recommended maximum duration of the action is 24 months, where up to 9 months will be dedicated to the preparatory phase (see section 6 of the call document).

4. Timetable and deadlines

Timetable and deadline (indicative)			
Call publication:	18 November 2021		
Proposal submission opening:	16 December 2021		
Deadline for submission of proposals:	<u>17 February 2022 - 17:00:00 CET</u> (Brussels)		
Evaluation:	March – end May 2022		
Information on evaluation results:	June 2022		
GA signature:	October 2022		

5. Admissibility and documents

Proposals must be submitted before the call deadline (see section 4 above).

Proposals must be submitted **electronically** via the Funding & Tenders Portal Electronic Submission System (accessible via the Topic page in the Search Funding & Tenders section). Paper submissions are NOT possible.

Proposals (including annexes and supporting documents) must be submitted using the forms

provided *inside* the Submission System (NOT the documents available on the Topic page — these are only for information).

Proposals must be **complete** and contain all the requested information and all required annexes and supporting documents:

- Application Form Part A contains administrative information about the participants (future coordinator, beneficiaries and affiliated entities) and the summarised budget for the project (to be filled in directly online)
- Application Form Part B contains the technical description of the project (to be downloaded from the Portal Submission System, completed and then assembled and re-uploaded)
- mandatory annexes and supporting documents (to be uploaded):
 - detailed budget table (template available in the Submission System)
 - CVs (standard) of core project team
 - activity reports of last year: see operational capacity below
 - list of previous projects (key projects for the last 4 years) (template available in Part B)
 - other annexes: not applicable

Please note that the amounts entered into the summarised budget table (filled in directly online) must correspond to the amounts calculated in the detailed budget table. In case of discrepancies, the amounts in the online summarised budget table will prevail.

At proposal submission, you will have to confirm that you have the **mandate to act** for all applicants. Moreover you will have to confirm that the information in the application is correct and complete and that the participants comply with the conditions for receiving EU funding (especially eligibility, financial and operational capacity, exclusion, etc.). Before signing the grant, each beneficiary and affiliated entity will have to confirm this again by signing a declaration of honour (DoH). Proposals without full support will be rejected.

Your application must be **readable**, **accessible and printable**.

Proposals are limited to maximum of 70 pages (Part B). Evaluators will not consider any additional pages.

You may be asked at a later stage for further documents (for legal entity validation, financial capacity check, bank account validation, etc.).

For more information about the submission process (including IT aspects), consult the <u>Online Manual.</u>

6. Eligibility

Eligible participants (eligible countries)

In order to be eligible for funding, the applicants (beneficiaries and affiliated entities) must:

- be legal entities (public or private bodies) created under Union law or an international organisation, or
- be established in one of the eligible countries, i.e.:
 - EU Member States (including overseas countries and territories linked to it (OCTs))
 - eligible non-EU countries:

EEA countries and countries associated to the EU4Health Programme (third countries, candidate countries and potential candidate countries, neighbourhood countries) <u>or</u> countries which are in ongoing negotiations for an association agreement and where the agreement enters into force before grant signature.

Beneficiaries and affiliated entities must register in the <u>Participant Register</u> — before submitting the proposal — and will have to be validated by the Central Validation Service (REA Validation). For the validation, they will be requested to upload documents showing legal status and origin.

Other entities may participate in other consortium roles, such as associated partners, subcontractors, etc. (see section 13).

Specific cases

Natural persons — Natural persons are NOT eligible for grants (with the exception of self-employed persons, i.e. sole traders, where the company does not have legal personality separate from that of the natural person).

International organisations — International organisations are eligible. The rules on eligible countries do not apply to them.

Entities without legal personality — Entities which do not have legal personality under their national law may exceptionally participate, provided that their representatives have the capacity to undertake legal obligations on their behalf, and offer guarantees for the protection of the EU financial interests equivalent to that offered by legal persons¹².

EU bodies — EU bodies (with the exception of the European Commission Joint Research Centre) can NOT be part of the consortium.

Associations and interest groupings — Entities composed of members may participate as 'sole beneficiaries' or 'beneficiaries without legal personality.¹³

Please note that if the action will be implemented by the members, they should also

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¹³ See Article 197(2)(c) EU Financial Regulation 2018/1046.

participate (either as beneficiaries or as affiliated entities, otherwise their costs will NOT be eligible).

European Reference Networks (ERNs) — These cover networks between healthcare providers and centres of expertise in the Member States to reinforce healthcare cooperation, in particular in the area of rare diseases, in line with the objectives set out in Article 12 of Directive 2011/24.

Countries currently negotiating association agreements — Participants from countries with ongoing negotiations (see above) may participate in the call and can sign grants as beneficiaries eligible for funding if the negotiations are concluded before grant signature (with retroactive effect, if provided in the agreement).

EU restrictive measures — Special rules apply for certain entities (e.g. entities subject to <u>EU restrictive measures</u> under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU) and entities covered by Commission Guidelines No <u>2013/C 205/05</u>7). Such entities are not eligible to participate in any capacity, including as beneficiaries, affiliated entities, associated partners, subcontractors or recipients of financial support to third parties (if any).

For more information, see <u>Rules for Legal Entity Validation, LEAR Appointment and Financial</u> <u>Capacity Assessment.</u>

Consortium composition

Unless stated otherwise in section 2 above (Call topics) proposals must be submitted by either a single applicant or a consortium of at least 3 applicants (beneficiaries; not affiliated entities), which complies with the following conditions:

Minimum 3 entities from 3 different eligible countries.

Eligible activities

Eligible activities are the ones set out in section 2 above. The following activities are not considered as eligible for funding under this call:

Those which do not implement the objectives listed in Articles 3 and 4, (as referenced in article 12 of the EU4Health Regulation).

Projects should take into account the results of projects supported by other EU funding programmes. The synergies and complementarities must be described in the project proposals (Part B of the Application Form).

Financial support to third parties is not allowed.

Geographic location (target countries)

Proposals must relate to activities taking place in the eligible countries (see above).

Duration

Projects should normally range between 12 and 24 months (extensions are possible, if duly

justified and introduced through an amendment). Indications of the recommended duration are given in section 2 above (call topics).

Project budget

Project budgets (maximum grant amount) are expected to be around EUR 2 000 000, 00 EUR but this does not preclude the submission/selection of proposals requesting other amounts.

Ethics

Projects must comply with highest ethical standards and applicable EU, international and national law (including Directive 2005/28 on investigational medicinal products for human use¹⁴ and Regulation 536/2014 on clinical trials on medicinal products for human use¹⁵).

Projects involving ethics issues may be made subject to specific ethics rules.

7. Financial and operational capacity and exclusion

Financial capacity

Applicants must have **stable and sufficient resources** to successfully implement the projects and contribute their share. Organisations participating in several projects must have sufficient capacity to implement all these projects.

The financial capacity check will be carried out on the basis of the documents you will be requested to upload in the <u>Participant Register</u> during grant preparation (e.g. profit and loss account and balance sheet, business plan, audit report produced by an approved external auditor, certifying the accounts for the last closed financial year, etc.). The analysis will be based on neutral financial indicators, but will also take into account other aspects, such as dependency on EU funding and deficit and revenue in previous years.

The check will normally be done for all beneficiaries, 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.

If needed, it may also be done for affiliated entities.

If we consider that your financial capacity is not satisfactory, we may require:

- further information
- an enhanced financial responsibility regime, i.e. joint and several responsibility for all

¹⁴ Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

¹⁵ REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

beneficiaries or joint and several liability of affiliated entities (see below, section 10)

- pre-financing paid in instalments
- (one or more) pre-financing guarantees (see below, section 10)

or

- propose no pre-financing
- request that you are replaced or, if needed, reject the entire proposal.

For more information, see <u>Rules for Legal Entity Validation</u>, <u>LEAR Appointment and Financial</u> Capacity Assessment, Financial Regulation article 196(d).

Operational capacity

Applicants must have the **know-how, qualifications** and **resources** to successfully implement the projects and contribute their share (including sufficient experience in projects of comparable size and nature).

This capacity will be assessed together with the 'Quality' award criterion, on the basis of the competence and experience of the applicants and their project teams, including operational resources (human, technical and other) or, exceptionally, the measures proposed to obtain it by the time the task implementation starts.

If the evaluation of the award criterion is positive, the applicants are considered to have sufficient operational capacity.

Applicants will have to show their capacity via the following information:

- general profiles (qualifications and experiences) of the staff responsible for managing and implementing the project
- description of the consortium participants
- applicants' activity reports of last year
- list of previous projects (key projects for the last 4 years).

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

Public bodies, Member State organisations and international organisations are exempted from the operational capacity check.

Exclusion

Applicants which are subject to an **EU exclusion decision** or in one of the following **exclusion situations** that bar them from receiving EU funding can NOT participate¹⁶:

- 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

See Articles 136 and 141 of EU <u>Financial Regulation 2018/1046</u>.

unlimited liability for the applicant's debts)

- guilty of grave professional misconduct¹⁷ (including if done by persons having powers
 of representation, decision-making or control, beneficial owners or persons who are
 essential for the award/implementation of the grant)
- committed fraud, corruption, links to a criminal organisation, money laundering, terrorism-related crime (including terrorism financing), child labour or human trafficking (including if done by persons having powers of representation, decisionmaking or control, beneficial owners or 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, prize, expert contract, or similar (including if done by persons having powers of representation, decision making or control, beneficial owners or 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, decision making or
 control, beneficial owners or 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 persons who are essential for the award/implementation of the grant).

Applicants will also be refused from participation if it turns out that 18:

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

8. Evaluation and award procedure

The proposals will have to follow the **standard submission and evaluation procedure** (one-stage submission + one-step evaluation).

An **evaluation committee** (potentially assisted by independent outside experts) will assess all applications. Proposals will first be checked for formal requirements (admissibility, and

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.

¹⁸ See Article 141 EU <u>Financial Regulation 2018/1046</u>.

eligibility, see sections 5 and 6). Proposals found admissible and eligible will be evaluated (for each topic) against the operational capacity and award criteria (see sections 7 and 9) and then ranked according to their scores.

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

Successively for every group of *ex aequo*¹⁹ proposals, starting with the highest scored group, and continuing in descending order:

- 1) Projects focusing on a theme that is not otherwise covered by higher ranked projects will be considered to have the highest priority.
- 2) The *ex aequo* proposals within the same topic will be prioritised according to the scores they have been awarded for the award criterion 'Relevance'. When these scores are equal, priority will be based on their scores for the criterion 'Impact'. When these scores are equal, priority will be based on their scores for the criterion 'Quality'.
- 3) If this does not allow to determine the priority, a further prioritisation can be done by considering the overall project portfolio and the creation of positive synergies and complementarity between projects, or other factors related to the objectives of the call. These factors will be documented in the panel report.

All proposals will be informed about the evaluation result (evaluation result letter). Successful proposals will be invited for grant preparation; the other ones will be put on the reserve list or rejected.

⚠ 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. It may also include adjustments to the proposal to address recommendations of the evaluation committee or other concerns. Compliance will be a pre-condition for signing the grant.

If you believe that the evaluation procedure was flawed, you can submit a **complaint** (following the deadlines and procedures set out in the evaluation result letter). Please note that notifications which have not been opened within 10 days after sending are considered to have been accessed and that deadlines will be counted from opening/access (see also Funding & Tenders Portal Terms and Conditions). Please also be aware that for complaints submitted electronically, there may be character limitations.

9. Award criteria

The **award criteria** for this call are as follows:

• Relevance: clarity and consistency of project, objectives and planning; extent to which they match the themes and priorities and objectives of the call; contribution

¹⁹ Proposals with the same score.

to the EU strategic and legislative context; European/trans- national dimension; impact/interest for a number of countries (EU or eligible non-EU countries); possibility to use the results in other countries; potential to develop mutual trust/cross-border cooperation (30 points)

• Quality:

- Project design and implementation: technical quality; logical links between the identified problems, needs and solutions proposed (logical frame concept); methodology for implementing the project (concept and methodology, management, procedures, timetable, risks and risk management, monitoring and evaluation); feasibility of the project within the proposed time frame; cost effectiveness (sufficient/appropriate budget for proper implementation; best value for money) (30 points)
- Project team and cooperation arrangements: quality of the consortium and project teams; appropriate procedures and problem solving mechanisms for cooperating within the project teams and consortium (30 points)
- - Impact: ambition and expected long-term impact of results on target groups/general public; appropriate dissemination strategy for ensuring sustainability and long-term impact; sustainability of results after EU funding ends (10 points).

Award criteria	Minimum pass score	Maximum score
Relevance	21	30
Quality — Project design and implementation	21	30
Quality — Project team and cooperation arrangements	21	30
Impact	7	10
Overall (pass) scores	70	100

Maximum points: 100 points.

Individual thresholds per criterion: 21/30, 21/30, 21/30 and 7/10 points.

Overall threshold: 70 points.

If the proposal passes the individual thresholds AND the overall threshold, it will be considered for funding — within the limits of the available call budget. Only one proposal is funded under this call.

10. Legal and financial set-up of the Grant Agreements

If you pass evaluation and you are the first ranked, your project will be invited for grant preparation, where you will be asked to prepare the Grant Agreement together with the EU Project Officer.

This Grant Agreement will set the framework for your grant and its terms and conditions, in

particular concerning deliverables, reporting and payments.

The Model Grant Agreement that will be used (and all other relevant templates and guidance documents) can be found on Portal Reference Documents.

Starting date and project duration

The project starting date and duration will be fixed in the Grant Agreement (*Data Sheet, point 1*). 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: between 12 and 24 months (extensions are possible, if duly justified and through an amendment).

Milestones and deliverables

The milestones and deliverables for each project will be managed through the Portal Grant Management System and will be reflected in Annex 1 of the Grant Agreement.

The following deliverables will be mandatory for all projects:

- Project websites (presentation of the project on the participants' websites, informing on the objectives and results of the project)
- Project leaflet (informing on the objectives and results of the project)
- Dissemination Report (including the dissemination strategy)
- Evaluation Report.

Form of grant, funding rate and maximum grant amount

The grant parameters (maximum grant amount, funding rate, total eligible costs, etc) will be fixed in the Grant Agreement (Data Sheet, point 3 and art 5).

Project budget (maximum grant amount): see section 6 above. The grant awarded may be lower than the amount requested.

The grant will be a budget-based mixed actual cost grant (actual costs, with unit cost and flat-rate elements). This means that it will reimburse ONLY certain types of costs (eligible costs) and costs that were actually incurred for your project (NOT the budgeted costs). For unit costs and flat-rates, you can charge the amounts calculated as explained in the Grant Agreement (see art 6 and Annex 2 and 2a).

The costs will be reimbursed at the funding rate fixed in the Grant Agreement (maximum **60%**). You can apply for a higher project funding rate (maximum **80%**) if your project is of 'exceptional utility'.

Actions with a clear Union added value shall be considered to have exceptional utility, inter alia, where:

(a) at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average; or

(b) bodies from at least 14 participating Member States participate in the action, of which at least four are Member States whose GNI per inhabitant is less than 90 % of the Union average.

Grants may NOT produce a profit (i.e. surplus of revenues + EU grant over costs). For-profit organisations must declare their revenues and, if there is a profit, we will deduct it from the final grant amount (see art 22.3).

Moreover, please be aware that the final grant amount may be reduced in case of non-compliance with the Grant Agreement (e.g. improper implementation, breach of obligations, etc.).

Budget categories and cost eligibility rules

The budget categories and cost eligibility rules are fixed in the Grant Agreement (Data Sheet, point 3, art 6 and Annex 2).

Budget categories for this call:

- A. Personnel costs
 - A.1 Employees, A.2 Natural persons under direct contract, A.3 Seconded persons
 - A.4 SME owners and natural person beneficiaries
- B. Subcontracting costs
- C. Purchase costs
 - C.1 Travel and subsistence
 - C.2 Equipment
 - C.3 Other goods, works and services
- D. Other cost categories: n/a
- E. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
 - SME owner/natural person unit cost²⁰: Yes
- travel and subsistence unit cost²¹: Yes
- equipment costs: depreciation
- other cost categories:
 - costs for financial support to third parties: not allowed

²⁰ Commission Decision of 20 October 2020 authorising the use of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary for the work carried out by themselves under an action or work programme (C(2020)7715).

²¹ Commission Decision of 12 January 2021 authorising the use of unit costs for travel, accommodation and subsistence costs under an action or work programme under the 2021-2027 multi-annual financial framework (C(2021)35).

- indirect cost flat-rate: 7% of the eligible direct costs (categories A-D, except volunteers costs and exempted specific cost categories, if any)
- VAT: non-deductible VAT is eligible (but please note that since 2013 VAT paid by beneficiaries that are public bodies acting as public authority is NOT eligible)
- other:
 - in-kind contributions for free are allowed, but cost-neutral, i.e. they cannot be declared as cost
 - in-kind contributions by 3rd parties' is 'not applicable'
 - kick off meeting: costs for kick-off meeting organised by the granting authority are eligible (travel costs for maximum 2 persons, return ticket to Brussels and accommodation for one night) only if the meeting takes place after the project starting date set out in the Grant Agreement; the starting date can be changed through an amendment, if needed
 - project websites: communication costs for presenting the project on the participants' websites or social media accounts are eligible; costs for *separate* project websites are not eligible

Reporting and payment arrangements

The reporting and payment arrangements are fixed in the Grant Agreement (Data Sheet, point 4 and art 21 and 22).

After grant signature, you will normally receive a **pre-financing** to start working on the project (float of normally **30%** of the maximum grant amount; exceptionally less or no pre-financing). The pre-financing will be paid 30 days from entry into force/10 days before starting date/financial guarantee (if required) — whichever is the latest.

There will be one or more **interim payments** (with detailed cost reporting).

Payment of the balance: At the end of the project, we will calculate your final grant amount. If the total of earlier payments is higher than the final grant amount, we will ask you (your coordinator) to pay back the difference (recovery).

All payments will be made to the coordinator.

Please be aware that payments will be automatically lowered if one of your consortium members has outstanding debts towards the EU (granting authority or other EU bodies). Such debts will be offset by us — in line with the conditions set out in the Grant Agreement (see art 22).

Please also note that you are responsible for keeping records on all the work done and the costs declared.

Pre-financing guarantees

If a pre-financing guarantee is required, it will be fixed in the Grant Agreement (Data Sheet, point 4). The amount will be set during grant preparation and it will normally 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 your 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.

Pre-financing guarantees are formally NOT linked to individual consortium members, which means that you are free to organise how to provide the guarantee amount (by one or several beneficiaries, for the overall amount or several guarantees for partial amounts, by the beneficiary concerned or by another beneficiary, etc.). It is however important that the requested amount is covered and that the guarantee(s) are sent to us in time to make the pre-financing (scanned copy via Portal AND original by post).

If agreed with us, the bank guarantee may be replaced by a 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.

Certificates

Depending on the type of action, size of grant amount and type of beneficiaries, you may be requested to submit different certificates. The types, schedules and thresholds for each certificate are fixed in the Grant Agreement (*Data Sheet, point 4 and art 24*).

Liability regime for recoveries

The liability regime for recoveries will be fixed in the Grant Agreement (Data Sheet point 4.4 and art 22).

For beneficiaries, it is one of the following:

- limited joint and several liability with individual ceilings each beneficiary up to their 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 their own debts.

In addition, the granting authority may require joint and several liability of affiliated entities (with their beneficiary).

<u>Provisions concerning the project implementation</u>

Ethics rules: see Model Grant Agreement (art 14 and Annex 5)

IPR rules: see Model Grant Agreement (art 16 and Annex 5):

list of background: Yes

rights of use on results: Yes

- access to results for policy purposes: Yes
- access rights to ensure continuity and interoperability obligations: Yes

Communication, dissemination and visibility of funding: see Model Grant Agreement (art 17 and Annex 5):

- communication and dissemination plan: Yes
- additional communication and dissemination activities: Yes

Specific rules for carrying out the action: see Model Grant Agreement (art 18 and Annex 5):

- specific rules for blending operations: No

Other specificities

n/a

Non-compliance and breach of contract

The Grant Agreement (chapter 5) provides for the measures we may take in case of breach of contract (and other non-compliance issues).

For more information, see AGA — Annotated Grant Agreement.

11. How to submit an application

All proposals must be submitted directly online via the Funding & Tenders Portal Electronic Submission System. Paper applications are NOT accepted.

Submission is a 2-step process:

a) create a user account and register your organisation

To use the Submission System (the only way to apply), all participants need to <u>create an EU Login user account</u>.

Once you have a EULogin account, you can <u>register your organisation</u> in the Participant Register. When your registration is finalised, you will receive a 9-digit participant identification code (PIC).

b) submit the proposal

Access the Electronic Submission System via the Topic page in the <u>Search Funding & Tenders</u> section (or, for calls sent by invitation to submit a proposal, through the link provided in the invitation letter).

Submit your proposal in 3 parts, as follows:

- Part A includes administrative information about the applicant organisations (future coordinator, beneficiaries, affiliated entities and associated partners) and the summarised budget for the proposal. Fill it in directly online
- Part B (description of the action) covers the technical content of the proposal.
 Download the mandatory word template from the Submission System, fill it in and

upload it as a PDF file

- Annexes (see section5). Upload them as PDF file (single or multiple depending on the slots). Excel upload is sometimes possible, depending on the file type.
- The proposal must keep to the page limits (see section 5); excess pages will be disregarded.

Documents must be uploaded to the **right category** in the Submission System otherwise the proposal might be considered incomplete and thus inadmissible.

The proposal must be submitted **before the call deadline** (see section 4). After this deadline, the system is closed and proposals can no longer be submitted.

Once the proposal is submitted, you will receive a **confirmation e-mail** (with date and time of your application). If you do not receive this confirmation e-mail, it means your proposal has NOT been submitted. If you believe this is due to a fault in the Submission System, you should immediately file a complaint via the IT Helpdesk web-form, explaining the circumstances and attaching a copy of the proposal (and, if possible, screenshots to show what happened).

Details on processes and procedures are described in the Online Manual. The Online Manual also contains the links to FAQs and detailed instructions regarding the Portal Electronic Exchange System.

12. Help

As far as possible, *please try to find the answers you need yourself*, in this and the other documentation (we have limited resources for handling direct enquiries):

- Online Manual
- FAQs on the Topic page (for call-specific questions in open calls)
- Portal FAQ (for general questions).

Please also consult the Topic page regularly, since we will use it to publish call updates. (For invitations, we will contact you directly in case of a call update).

Contact

For individual questions on the Portal Submission System, please contact the <u>IT Helpdesk</u>. Non-IT related questions should be sent to the following email address: <u>HADEA-HP-CALLS@ec.europa.eu</u>.

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

12.1 Important



IMPORTANT

- **Don't wait until the end** Complete your application sufficiently in advance of the deadline to avoid any last minute technical problems. Problems due to last minute submissions (e.g. congestion, etc) will be entirely at your risk. Call deadlines can NOT be extended.
- Consult the Portal Topic page regularly. We will use it to publish updates and additional information on the call (call and topic updates).
- Funding & Tenders Portal Electronic Exchange System By submitting the application, all participants accept to use the electronic exchange system in accordance with the Portal Terms & Conditions.
- **Registration** Before submitting the application, all beneficiaries, affiliated entities and associated partners must be registered in the Participant Register. The participant identification code (PIC) (one per participant) is mandatory for the Application Form.
- Consortium roles When setting up your consortium, you should think of organisations that help you reach objectives and solve problems.
 - The roles should be attributed according to the level of participation in the project. Main participants should participate as beneficiaries or affiliated entities; other entities can participate as associated partners, subcontractors, third parties giving inkind contributions. Associated partners and third parties giving in-kind contributions should bear their own costs (they will not become formal recipients of EU funding). Subcontracting should normally constitute a limited part and must be performed by third parties (not by one of the beneficiaries/affiliated entities). Subcontracting going beyond 30% of the total eligible costs must be justified in the application.
- **Coordinator** In multi-beneficiary grants, the beneficiaries participate as consortium (group of beneficiaries). They will have to choose a coordinator, who will take care of the project management and coordination and will represent the consortium towards the granting authority. In mono-beneficiary grants, the single beneficiary will automatically be coordinator.
- **Affiliated entities** Applicants may participate with affiliated entities (i.e. entities linked to a beneficiary which participate in the action with similar rights and obligations as the beneficiaries, but do not sign the grant and therefore do not become beneficiaries themselves). They will get a part of the grant money and must therefore comply with all the call conditions and be validated (just like beneficiaries); but they do not count towards the minimum eligibility criteria for consortium composition (if any).

- Balanced project budget Grant applications 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, etc). You may be requested to lower your estimated costs, if they are ineligible (including excessive).
- **No-profit rule** Grants may NOT give a profit (i.e. surplus of revenues + EU grant over costs). This will be checked by us at the end of the project.
- No double funding There is a strict prohibition of double funding from the EU budget (except under EU Synergies actions). Outside such Synergies actions, any given action may receive only ONE grant from the EU budget and cost items may under NO circumstances declared to two different EU actions.
- Completed/ongoing projects Proposals for projects that have already been completed will be rejected; proposals 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 the project starting date/proposal submission).
- Combination with EU operating grants Combination with EU operating grants is possible, if the project remains outside the operating grant work programme and you make sure that cost items are clearly separated in your accounting and NOT declared twice (see AGA Annotated Model Grant Agreement, art 6.2.E).
- **Multiple proposals** Applicants may submit more than one proposal for *different* projects under the same call (and be awarded a funding for them).
 - Organisations may participate in several proposals.
 - BUT: if there are several proposals for *very similar* projects, only one application will be accepted and evaluated; the applicants will be asked to withdraw one of them (or it will be rejected).
- **Resubmission** Proposals may be changed and re-submitted until the deadline for submission.
- **Rejection** By submitting the application, all applicants accept the call conditions set out in this this Call Document (and the documents it refers to). Proposals that do not comply with all the call conditions will be **rejected**. This applies also to applicants: All applicants need to fulfil the criteria; if any one of them doesn't, they must be replaced or the entire proposal will be rejected.
- Cancellation There may be circumstances which may require the cancellation of the call. In this case, you will be informed via a call or topic update. Please note that cancellations are without entitlement to compensation.
- Language You can submit your proposal in any official EU language (project abstract/summary should however always be in English). For reasons of efficiency, we strongly advise you to use English for the entire application. If you need the call documentation in another official EU language, please submit a request within 10 days after call publication (for the contact information, see section 12).

• **Transparency** — In accordance with Article 38 of the <u>EU Financial Regulation</u>, information about EU grants awarded is published each year on the <u>Europa website</u>.

This includes:

- o beneficiary names
- beneficiary addresses
- o the purpose for which the grant was awarded
- o 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 your rights and freedoms under the EU Charter of Fundamental Rights or harm your commercial interests.

• **Data protection** — The submission of a proposal under this call involves the collection, use and processing of personal data. This data will be processed in accordance with the applicable legal framework. It will be processed solely for the purpose of evaluating your proposal, subsequent management of your grant and, if needed, programme monitoring, evaluation and communication. Details are explained in the Funding & Tenders Portal Privacy Statement.