



EU4Health Programme (EU4H)

Call for proposals

**EU4Health-Action Grants 2023
(EU4H-2023-PJ-2)**

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EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

HaDEA.A – Health and Food
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CALL FOR PROPOSALS

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0. 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 2018/1046 ([EU Financial Regulation](#)¹)
- the basic act (EU4H Programme Regulation [2021/522](#)²).

The call is launched in accordance with the 2023 Work Programme³ and will be managed by the **European Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topic**:

- **EU4H-2023-PJ–2-1 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiota transplants**

We invite you to read the **call documentation** carefully, and in particular this Call Document, the [Model Grant Agreement](#), the [EU Funding & Tenders Portal Online Manual](#) 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 and the expected results (sections 1 and 2)
 - timetable 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)
 - legal and financial set-up of the Grant Agreements (section 10)
 - how to submit an application (section 11)

¹ [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

² [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).

³ [Commission Implementing Decision C\(2022\) 8510 final](#) of 21/11/2022 concerning the adoption of the work programme for 2023 and the financing decision for the implementation of the EU4Health programme.

- the [Online Manual](#) 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 website](#) to consult the list of projects funded previously.

1. Background

The 2019 evaluation of the Union legislation on blood, tissues and cells identified a legal gap in terms of Regulation for some therapies made from substances of human origin (SoHO) that cannot necessarily be defined as blood, tissues, cells or organs. It concerns in particular therapies like human Faecal Microbiota Transplants (FMT) whose use entails the need to avoid transmission of diseases from donors, a key concern for all SoHO therapies. The revision of the Union legislative frameworks (blood and tissues and cells) aims to cover this gap and it plans to address safety and quality requirements for these therapies.

Dedicated guidelines on safety and quality will therefore have to be implemented by a new group of actors with expertise on these therapies, and supervised by the SoHO authorities. It is estimated that around 200 new entities or establishments, working with BM or FMT, will be regulated under the new SoHO legislation.

This action will help actors and establishments for the preparation of the implementation of these new legal requirements.

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

EU4H-2023-PJ—2-1 — Call for proposals: action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants) (b) HS-g-23-50.02 Faecal microbiota transplants

[Objectives \(linked to general and specific objectives of the programme\)](#)

This action implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (c) and (h), of Regulation (EU) 2021/522.

This action aims to bring together sector professionals, for FMT, and to facilitate the implementation of new SoHO Regulation (guidelines and legislative requirements as

well as the compliance with oversight tasks), in order to allow the safe, effective and qualitative preparation and use of these SoHO-based therapies.

Strand (scope)

This action is part of the “Health Systems and Healthcare Workforce” strand, and it will contribute to “strengthening the implementation of the legislation on blood, tissues and cells and organs”. More specifically, this action will support harmonisation across national competent authorities in the field of organs.

Activities that can be funded (scope)

The activities are:

- 1) building an expert forum on faecal microbiota transplants;
- 2) developing, for each SoHO-based therapy, a common set of draft guidelines on the basis of the expert forum and existing initiatives (e.g. professional societies’ work, work in research actions);
- 3) possible future updating of the guidelines, taking account of the new EU legislative framework;
- 4) providing an implementation plan for establishments/entities in order to implement SoHO requirements, which will also consider the compliance with technical guidelines as well as with oversight provisions (entity and establishment authorisations, preparation process authorisations, inspections, vigilance and traceability); and
- 5) training and dissemination programme.

These activities are to be developed taking account the commonalities and specificities of SoHO-based therapies, i.e. FMT.

Specific mandatory deliverables and/or milestones

The mandatory deliverables are:

- Set-up of an expert forum including mandate, rules of procedure and proposed membership.
- Set of draft guidelines for entities to implement technical standards, agreed amongst professionals and authorities where possible, and indicating points with divergent views
- Set of draft guidelines for entities to comply with oversight requirements, agreed amongst professionals and authorities where possible, and indicating points with divergent views
- A proposed approach for future updating of guidelines
- Gap analyses, recommended actions and implementation plan for entities to implement guidelines on technical standards and on oversight.
- Agreed training programme including necessary tools (manuals, surveys)

Expected impact (including EU added value, expected outputs and results)

The topic should provide up-to-date guidelines on:

- a) technical safety and quality aspects for FMT;

b) implementation of the legal requirements by establishments preparing these substances and applying therapies based on them.

They will also create a forum where key experts including Member States authorities can be engaged also in the future whenever the guidelines need to be updated, or when further advice is needed on their implementation.

This topic will support the implementation of the new Union legislative framework on SoHO for entities preparing FMT.

The result of the topic on faecal microbiota will consider the coherence with pharmaceutical actors/legislation, so that actors from both sectors (SoHO and Pharmaceuticals) can look into technical rules for faecal microbiota collected under SOHO and later to be used for manufacturing of pharmaceuticals.

Specific action-level indicators for reporting purposes for both topics

Applicants will include the following specific action-level indicators and related reporting activities in their proposals:

- Numbers of entities/establishments involved
- Number of FMT prepared by these entities/establishments
- Numbers of guidelines drafted and agreed with professionals and SoHO authorities



For more information about EU health policies, see [Health and Food Safety](#).

3. Available budget

The estimated available call budget is **EUR 400.000**.

We expect to sign 1 grant agreement.

We reserve the right not to award all available funds or to redistribute them between the call priorities, depending on the proposals received and the results of the evaluation.

4. Timetable and deadlines

Timetable and deadlines (indicative)	
Call opening:	9 April 2024
<u>Deadline for submission:</u>	<u>11 June 2024 – 17:00:00 CET</u> <u>(Brussels)</u>
Evaluation:	June - July 2024
Information on evaluation results:	Mid-July 2024
GA signature:	November 2024

5. Admissibility and documents

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

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 — they 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** (*templates available to be downloaded from the Portal Submission System, completed, assembled and re-uploaded*):
 - detailed budget table/calculator
 - CVs (standard) of core project team
 - list of previous projects (key projects for the last 4 years) (*template available in Part B*)


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 **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 [Online Manual](#).

6. Eligibility

Applications will only be considered eligible if their content corresponds wholly (or at least in part) to the topic description for which it is submitted.

Eligible participants (eligible countries)

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

- be legal entities (public or private bodies)
- be established in one of the eligible countries, i.e.:
 - EU Member States (including overseas countries and territories (OCTs))
 - eligible non-EU countries:
 - listed EEA countries and countries associated to the EU4Health Programme (list of participating countries)
- other eligibility conditions:

Type of applicants targeted	Civil society organisations (professional associations, foundations, NGOs and similar entities) with expertise in the field of gastroenterology.
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Beneficiaries and affiliated entities must register in the [Participant Register](#) — 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, third parties giving in-kind contributions, etc (*see section 13*).

Specific cases

Natural persons — Natural persons are NOT eligible (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 persons⁴.

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'⁵. ⚠ Please note that if the action will be implemented by the members, they should also participate (either as beneficiaries or as affiliated entities, otherwise their costs will NOT be eligible).

⁴ See Article 197(2)(c) EU Financial Regulation [2018/1046](#).

⁵ For the definitions, see Articles 187(2) and 197(2)(c) EU Financial Regulation [2018/1046](#).

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 — Beneficiaries from countries with ongoing negotiations for participation in the programme (*see list of participating countries above*) may participate in the call and can sign grants if the negotiations are concluded before grant signature and if the association covers the call (i.e. is retroactive and covers both the part of the programme and the year when the call was launched).

EU restrictive measures — Special rules apply for certain entities (*e.g. entities subject to [EU restrictive measures](#) under Article 29 of the Treaty on the European Union (TEU) and Article 215 of the Treaty on the Functioning of the EU (TFEU)*⁶ and entities covered by Commission Guidelines No [2013/C 205/05](#)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).

Following the [Council Implementing Decision \(EU\) 2022/2506](#), as of 16th December 2022, no legal commitments (including the grant agreement itself as well as subcontracts, purchase contracts, financial support to third parties etc.) can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain.

Affected entities may continue to apply to calls for proposals. However, in case the Council measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties).

In this case, co-applicants will be invited to remove or replace that entity and/or to change its status into associated partner. Tasks and budget may be redistributed accordingly.

 For more information, see [Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment](#).

[Consortium composition](#)

Applications may be either by a single applicant or a consortium (no minimum requirement)

[Eligible activities](#)

Eligible activities are the ones set out in section 2 above.

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

Projects must comply with EU policy interests and priorities (*such as environment, social, security, industrial and trade policy, etc*).

Financial support to third parties is not allowed

⁶ Please note that the EU Official Journal contains the official list and, in case of conflict, its content prevails over that of the [EU Sanctions Map](#).

⁷ Commission guidelines No [2013/C 205/05](#) on the eligibility of Israeli entities and their activities in the territories occupied by Israel since June 1967 for grants, prizes and financial instruments funded by the EU from 2014 onwards (OJEU C 205 of 19.07.2013, pp. 9-11).

Geographic location (target countries)

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

Duration

Projects should normally be maximum 18 months.

Extensions are possible, if duly justified and through an amendment.

Project budget

Project budgets (maximum grant amount) are expected to be around EUR 400.000 per project.

This does not however preclude the submission/selection of proposals requesting other amounts. The grant awarded may be lower than the amount requested.

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 [Participant Register](#) 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.

In addition, a beneficiary, requesting an EU-contribution of \geq EUR 750 000 EUR, shall submit an audit report produced by an approved external auditor, where it is available, and always in cases where a statutory audit is required by Union or national law, certifying the annual accounts (profit and loss account and the balance sheet) for to the last two available financial years. In all other cases, the applicant shall provide a self-declaration signed by its authorised representative certifying the validity of its accounts. 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 beneficiaries or joint and several liability of affiliated entities (*see below, section 10*)
- prefinancing paid in instalments
- (one or more) prefinancing guarantees (*see below, section 10*)

or

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

i For more information, see [Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment](#).

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
- 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 participate⁸:

- 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 misconduct⁹ (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 crimes (including terrorism financing), child

⁸ See Articles 136 and 141 of EU Financial Regulation [2018/1046](#).

⁹ 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.

labour or human trafficking (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)

- 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 EU Regulation [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 rejected if it turns out that¹⁰:

- 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 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* 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'.

¹⁰ See Article 141 EU Financial Regulation [2018/1046](#).

- 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 between projects, or other factors related to the objectives of the call. These factors will be documented in the panel report.
- 4) After that, the remainder of the available call budget will be used to fund projects across the different topics in order to ensure a balanced spread of the geographical and thematic coverage and while respecting to the maximum possible extent the order of merit based on the evaluation of the award criteria.

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 will be 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:

1. **Relevance:** clarity and consistency of project, objectives and planning; extent to which they match the themes and priorities and objectives of the call; contribution 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)
2. **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)

- 3. 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.

Proposals that pass the individual thresholds AND the overall threshold will be considered for funding — within the limits of the available budget (i.e. up to the budget ceiling). Other proposals will be rejected.

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

If you pass evaluation, 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. A retroactive starting date can be granted exceptionally for duly justified reasons — but never earlier than the proposal submission date.

Project duration: *see section 6 above*.

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
- Evaluation Report

Additional milestones and deliverables indicated in section 2 for each specific topic.

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 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 (**60%**). You can apply for a higher project funding rate (**80%**) if your project is of 'exceptional utility', i.e. concerns:

- actions where at least 30 % of the budget is allocated to Member States whose GNI per inhabitant¹¹ is less than 90% of the EU average or
- actions with bodies from at least 14 Member States and where at least four are from Member States whose GNI per inhabitant is less than 90% of the EU 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

¹¹ [GNI per Member State.pdf \(europa.eu\)](#)

- B. Subcontracting costs
- C. Purchase costs
 - C.1 Travel and subsistence
 - C.2 Equipment
 - C.3 Other goods, works and services
- E. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
 - SME owner/natural person unit cost¹²: Yes
- travel and subsistence unit cost¹³: Yes
- equipment costs: depreciation
- other cost categories:
 - costs for financial support to third parties: not allowed
- 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
 - 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
 - other ineligible costs: Yes, costs for infrastructure and land purchase

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 **prefinancing** to start working on the project (float of normally **50%** of the maximum grant amount; exceptionally less or no prefinancing). The prefinancing 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 no interim payments.

¹² 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)7115).

¹³ 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); Commission [Decision](#) of 26 July 2023 amending Commission Decision C(2021)35 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

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.

Prefinancing guarantees

If a prefinancing 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 prefinancing 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.

Prefinancing guarantees are normally requested from the coordinator, for the consortium. They must be provided during grant preparation, in time to make the prefinancing (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 (*art 23*).

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).

Provisions concerning the project implementation

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):*

- durability: No
- 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 [create an EU Login user account](#).

Once you have an EULogin account, you can [register your organisation](#) 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 [Search Funding & Tenders](#) 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 section 5*). 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 webform, 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; not applicable for actions by invitation)
- 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 [IT Helpdesk](#).

Non-IT related questions should be sent to the following email address: HADEA-HP-CALLS@ec.europa.eu.

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

13. 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 in-kind 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).
- **Associated partners** — Applicants may participate with associated partners (i.e. partner organisations which participate in the action but without the right to get grant money). They participate without funding and therefore do not need to be validated.
- **Consortium agreement** — For practical and legal reasons it is recommended to set up internal arrangements that allow you to deal with exceptional or unforeseen circumstances (in all cases, even if not mandatory under the Grant Agreement). The consortium agreement also gives you the possibility to redistribute the grant money according to your own consortium-internal principles and parameters (for instance, one beneficiary can reattribute its grant money to another beneficiary). The consortium agreement thus allows you to customise the EU grant to the needs inside your consortium and can also help to protect you in case of disputes.

- **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 cumulation of funding/no double funding** — It is strictly prohibited to cumulate 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 be declared under two EU grants. If you would like to nonetheless benefit from different EU funding opportunities, projects must be designed as different actions, clearly delineated and separated for each grant (without overlaps).
- **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 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 [EU Financial Regulation](#), information about EU grants awarded is published each year on the [Europa website](#).

This includes:

- beneficiary names
- beneficiary 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 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](#).