EU4Health Programme (EU4H)

Call for proposals under the Annual Work Programme 2021

Action grant to support a HERA laboratory network
(EU4H-2021-PJ4)

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EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

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CALL FOR PROPOSALS

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Introduction

This is a call for proposals for a EU action grant in the field of Crisis Preparedness 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 invitation is launched in accordance with the EU4Health 2021 Annual Work Programme[3] and will be managed by the **European Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topic**:

- **EU4H-2021-PJ-20[4] — Action grant to support a HERA laboratory network**

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)

[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).

[3] Commission Implementing Decision amending Commission Implementing Decision C(2021) 4793 final of 24 June 2021 and Commission Implementing Decision C(2022) 317 final of 14 January 2022 on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programmes for 2021 and 2022 respectively.

[4] (CP-g-06.5)

  - how to submit an application (section 11)

- 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

Following the EU Health Union proposals of 11 November 2020, the Commission established the European Health Emergency preparedness and Response Authority (HERA) on 16 September 2021. HERA will contribute to improving the Union's development, manufacturing, procurement and distribution of key medical countermeasures within the Union so as to contribute for improving preparedness and response to serious cross-border threats and emergencies – whether of natural, accidental or deliberate origin. With the view of ensuring development and supply of medical countermeasures, one of HERA's tasks is strengthening health security coordination within the Union during preparedness and crisis response times, and bringing together Member States, the industry and the relevant stakeholders in a common effort. HERA will do so, among others through the assessment of health threats and intelligence gathering relevant to medical countermeasures.

The COVID-19 crisis has illustrated certain limits to the ability to have informed decision-making in terms of preparedness and response to serious cross-border threats. This included, for example: the difficulty to, at an early stage, detect and warn on emerging health threats, in particular those from outside the Union; fragmented involvement in global surveillance, and the access to surveillance results and relevant biological samples from third countries; the paucity and lack of comparability of scientific data; the translation of scientific data (e.g. biological characterisation) into operational recommendations on medical countermeasures for prevention and treatment.

A stable long-term network of laboratories and research institutes could address these challenges and provide scientific data and analysis necessary for HERA's operations in the area of medical countermeasures.

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

EU4H-2021-PJ-20 (CP-g-06.5) — Action grant to support a HERA laboratory network

Objectives (linked to general and specific objectives of the programme)

This action supports the policy priority to respond to the COVID-19 crisis and to enhance preparedness for future health emergencies with the particular emphasis on intelligence gathering to support the timely provision of medical countermeasures. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b)) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

This action aims to establish a pilot network of top-class laboratories and research institutes that have the critical expertise and capacities to provide the information needed in the shortest possible timeframe and to support HERA in identifying emergent pathogens and ensuring the availability of medical countermeasures for improved health preparedness and response.

Activities that can be funded (scope)

In preparedness time, the network will provide data, information and knowledge for HERA's threat assessments and intelligence gathering function relevant to medical countermeasures. Its activities will focus on the health threats arising at global level including those that have not been included in the priority list developed by HERA. The tasks will include at least: operating and maintaining the network of participating laboratories and research institutes, supporting HERA's assessment of health threats and intelligence gathering in the area of medical countermeasures, pro-actively running the detection and biological characterisation of emerging pathogens, rapid identification of relevant medical countermeasures and enhancing global cooperation.

Activities should draw on relevant intelligence from animal, environmental and public health (One Health) surveillance and other relevant areas.

In times of emergency, the network will inform HERA's decision making with respect to medical countermeasures by providing a timely, targeted, and tailored input on the identified health threat. This will include: collecting global intelligence including through biological samples; carrying out specific emergency studies mandated by HERA, including biological characterisation, providing specific medical countermeasures, options for diagnosis, prevention and treatment and provide ad-hoc in-country response support. The network will also activate critical surge capacities at Union and global level to allow rapid and effective response during crisis times.

All these activities will be defined and carried out taking into account of the EU reference laboratories to be established under Article 15 of the Proposal for a Regulation of the European Parliament and of the Council on serious cross border health threats[5], and in close collaboration with ECDC, in particular its activities under Article 5 (surveillance network), Article 8 (early warning and response system) and 10 (identification of emerging health threats) of Regulation (EC) No 851/2004 (ECDC

[5] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on serious cross-border threats to health and repealing Decision No 1082/2013/EU

Regulation)[6], and the planned future network of EU reference laboratories and activities under other relevant EU policy areas (e.g. One Health) to ensure complementarities and avoid overlap and duplication.

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

This action is expected to result in the following outcomes:

a) in the short-term, a sustainable, efficient and high capacity laboratory network (consisting in one or more existing EU laboratories with a structure allowing the widest possible geographical and global coverage e.g. having branches or associated members in several countries and continents) that addresses HERA's needs notably in terms of intelligence gathering;

b) in the short/medium-term, established and optimised procedures and means such as key infrastructure, resources, policies and procedures for the network preparedness operations and rapid response in crisis times, to work in emergency mode for a readily available network in case a public health emergency is declared;

c) in the medium/long-term, dedicated assessments of health threats and related countermeasures and intelligence gathering supporting HERA's tasks during preparedness times including biological characterisation.

d) in the medium/long-term, contribution to extend and reinforce the global outreach of the pilot network by sharing of relevant data and analysis, and providing advice, reports, country support missions, etc;

e) in the long-term, contribution to enhanced medical countermeasures preparedness to timely and efficiently respond to future cross-border health threats.

This action will provide the Commission with information to support the decision making as regards the extension (geographical and pathogens prioritisation) and options for potential institutionalisation of the HERA laboratory network in the medium/long term.

Specific mandatory deliverables and/or milestones

This action is expected to strengthen and enhance the overall capacity of the EU to react quickly and in a coordinated manner in particular in the case of emerging biological health threats and other relevant high-priority biological public health emergency by fostering an integrated national and international network of laboratories. Work carried out by the HERA laboratory network will support Member States and Commission's decision making as regards medical countermeasures response options.

The action will contribute to HERA's intelligence gathering and analysis function by providing real time data as well as early signals of the potential emergence or spread of biological health threats. This action will contribute to a more rapid, comprehensive and effective testing, identification and enhanced characterisation of pathogens, and resulting notification to decision-makers, with the view to inform the identification, development and purchase of appropriate medical countermeasures. It

[6] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 april 2004 establishing a European Centre for disease prevention and control

will further allow HERA to continuously develop and adapt the EU portfolio of medical countermeasures (e.g. vaccines, drugs) as well as necessary diagnostics and medical devices in order to better and faster respond to a health emergency.

The applicants will have notably to plan the following -not- exhaustive - tasks in preparedness times:

- Operating and maintaining the network of participating laboratories and research institutes (a governance and sustainability plan should be included as a deliverable), establishing clear procedures for the network to work together in preparedness times, while ensuring rapid response in crisis time, herein establishing and maintaining a clear interoperable IT infrastructure, including machine learning/AI tools, allowing for secure messaging and timely notification of – inter alia – decision-makers as regards laboratory results

- Providing continuous training to the HERA laboratory network members, thus expanding the core capacities relevant to the network at EU level and provide surge capacities in times of crisis. This should be in cooperation with the established laboratory networks run by ECDC and the EU Reference Laboratory network that will be established under the new Regulation on cross-border health threats (to be adopted).

- Enabling and establishing mechanisms for privacy-compliant rapid data sharing, integration and comparability within the network, herein ensuring interoperability at national and international level, especially including with the HERA IT platform and other IT systems at Union level, thus fostering actively technical discussions with the relevant national and international stakeholders.

- Contributing to the assessment of health threats and intelligence gathering especially, but not limited to, the area of medical countermeasures by complementing biological evidence, aligned with HERA's mission and related ongoing activities.

- Ensuring rapid access to biological samples globally, and pro-actively running biological characterisation of emerging pathogens (virulence, pathogenicity, immunological features, severity of infection), including:

  o Isolation and biological analysis of pathogens/ health threats arising at global level including also those prioritised by HERA.

  o Support the establishment of individual modelling scenarios of the spread and impact of such pathogens.

  o Conducting serology and immunological studies to understand population immunity working closely with ECDC/WHO EURO seroepidemiological surveillance networks.

  o Use the results of biological characterisation for forecasting (e.g. predicting risks of an emerging variant to become prevalent etc.).

- Rapid identification and assessment of relevant diagnostic, preventive, protective and therapeutic medical countermeasures, existing and under development, including:

  o Assessment of medical countermeasures effectiveness to treat, prevent and detect a given pathogen and suggesting necessary modifications on the existing technologies for better effectiveness.

  o Cross protection, sensitivity to available biological treatment options.

o Assessment of the need as regards diagnostics medical countermeasures in view of proposing updates to the current detection tools or supporting further targeted development of diagnostics in the pipeline.

• Enhancing global cooperation e.g. by strengthening third countries' epidemic intelligence and laboratory capacities by collecting and sharing relevant surveillance data, information and samples from third countries through the promotion of a global network of laboratories and relevant entities.

• Cooperate with other relevant laboratory networks such as e.g. the existing national public health laboratory networks and EURLs to be created.

In emergency mode, in addition to the tasks outlined for preparedness time, applicants have to enhance the following tasks:

• Ensure rapid testing, timely notification, and secure messaging of laboratory results to relevant decision-makers by collecting threat-specific epidemic intelligence on the ongoing threat.

• Collect further threat-specific biological samples, carry out specific emergency studies on the concerned pathogen, including biological characterisation (see above).

• Provide or advise on specific medical countermeasures options for diagnosis, prevention and treatment and launch emergency studies and develop actions on the relevant MCM identified where needed (including medical countermeasures effectiveness assessment).

• Provide ad-hoc in-country response support (under the wider umbrella of the EU's health response, e.g. the 'EU's Health Task Force' as per the proposal to extend the mandate of the ECDC).

Considering the potential of the project to provide direct support to HERA's activities, the applicants are invited to actively include HERA in its governance structure, inter alia by nominating HERA as member of the steering board of related relevant projects. In addition, in order to ensure complementarity with on-going activities in the field, the applicants are invited to nominate ECDC as an observer on the board.

It is expected that the laboratory network will carry out activities including:

• List of processes and procedures developed and implemented to ensure the establishment and smooth, sustainable operation of the HERA laboratory network, including the operationalisation of the aforementioned tasks. These will take into account activities carried out by existing networks and EU and international organisations in order to avoid duplication.

• List of processes and procedures established and implemented to ensure continuous and rapid and sharing of data, knowledge and other means with HERA's IT platform and other Commission and EU Agencies relevant IT tools, ensuring interoperability.

• Simulation-based activities to ensure that procedures and processes implemented can effectively cover the tasks to be carried out during preparedness and crisis times.

• Communication activities informing on the objectives and results of the project to the general public.

• Bi-annual reports, herein describing main findings regarding health threat assessment and intelligence gathering in relation to medical countermeasures,

especially related to HERA's prioritized health threats. These reports should include information on collaboration with other laboratory networks to avoid duplications.

- ad-hoc reports, studies (related to data analysis) and advice on relevant aspects linked to the project and to HERA's mission in general (e.g. when detecting early signals of a given threat, or when a need for rapid response is identified on the basis of data analysed).

- Developing a blueprint concerning the sustainable establishment of the network and achievement of long-term impacts described in the annual work planned after the end of the project, including tangible non-high level policy recommendations. These should include reflections on the need for scope extension (geographical and pathogens prioritisation) and options for potential institutionalisation of the HERA laboratory network, to be delivered at least 6 months ahead of the end of the final reporting period of the project duration

Specific action-level indicators for reporting purposes

- Laboratory capacity across the EU with global reach in several continents in support of preparedness to cross border health threats

- Effective procedures and processes allowing for rapid sharing of information between the network and with relevant public health authorities, including HERA and ECDC, and other existing EU networks.

- Accurate biological characterisation of health threats carried out at EU and global level

- Medical countermeasures effectively identified and assessed in connection with an existing or new pathogen

- Number of reports, studies and advice provided as part of the regular or ad-hoc activities

- Global samples adequately made accessible by the network

- Average time of response and sharing of information

3. Available budget

The available call budget is **EUR 25 000 000**. This budget might be increased depending on further budget availability.

We expect to sign 1 grant agreement.

We reserve the right not to award all available funds depending on the proposals received and the results of the evaluation.

4. Timetable and deadlines

Timetable and deadlines (indicative)	
Call opening:	12 May 2022
Deadline for submission:	18 August 2022 – 17:00:00 CET (Brussels)
Evaluation:	August-September 2022
Information on evaluation results:	October 2022
GA signature:	November-December 2022

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** *(to be uploaded)*:
  - detailed budget table *(template available in the Submission System)*
  - CVs (free format) 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

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 or countries which are in ongoing negotiations for an association agreement and where the agreement enters into force before grant signature (list of participating countries)*Specific eligibility conditions*

In addition to the above, applicants must be public or non-profit or profit private laboratories or research institutes.

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 persons[7].

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'[8]. 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).

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 *(see list above)* may participate in the call and can sign grants 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 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)[9] and entities covered by Commission Guidelines No 2013/C 205/05[10])*. 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 Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment*.

Consortium composition

Proposals must be submitted by a consortium of at least 3 applicants (beneficiaries; not affiliated entities) which complies with the following conditions:

– The members of the consortium should be established in at least three different countries eligible for the EU4Health Programme.

– The structure of the consortium should allow the widest possible geographical coverage at EU level and global level. For this purpose, at least one of the laboratories/research institutes should have e.g. branches or associated members to allow the network to have widespread global coverage ideally in all continents.

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

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

9 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.

10 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).

The consortium should consist of top-internationally leading laboratories or research institutes.

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:

—Actions and activities not specified in section 2 above.

Projects should take into account the results of projects supported by other EU funding programmes and avoiding overlap and duplications. 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

Geographic location (target countries)

Proposals must relate to activities taking place in the eligible countries (see above) ensuring global reach at least in terms of biological characterisation and access to samples.

Duration

The recommended duration of proposals should be 48 months (extensions are possible, if duly justified and through an amendment).

Project budget

The project budget (maximum grant amount) is expected to be around EUR 25.000.000 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 use[11] and Regulation 536/2014

[11] 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).

on clinical trials on medicinal products for human use[12]).

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 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, for a beneficiary requesting an EU-contribution of ≥ EUR 750 000 EUR, 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 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 for the last two available financial 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 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.

[12] 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 (OJ L 158, 27.5.2014, p. 1).

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.

Specific selection criteria

– The consortium shall have specific competence and experience in global epidemic intelligence, biological characterisation of emerging pathogens including SARS-CoV-2 variants (having been actively performing these tasks during the COVID-19 pandemic). The consortium should have experience in and knowledge on the identification and assessment of medical countermeasures.

– The consortium should also have a proven track-record in data provision to EU institutions and/or national authorities, preferably proven during health emergencies like the ongoing COVID-19 pandemic, solid competence in the management of large health databases, and the provision of recommendations and guidance to key stakeholders on relevant public health response matters during emergencies.

– The consortium need to prove high technical competence and relevant laboratory capacities with a high degree of specialisation on a broad range of threats, including zoonotic threats while respecting an overall One Health approach.

– The overall structure of the consortium should allow to access samples globally at short notice and carry out the specific activities in case of a rapid response needed.

– The consortium should have research publications or similar related to the understanding of biological threats virulence and pathogenicity, including the immunological features, including for instance SARS-CoV-2.

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 participate[13]:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct[14] (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 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, decisionmaking- 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, decisionmaking- 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, decisionmaking- or control, beneficial owners or persons who are essential for the award/implementation of the grant.

Applicants will also be refused if it turns out that[15]:

- 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)

[13] See Articles 136 and 141 of EU Financial Regulation 2018/1046.

[14] 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.

[15] See Article 141 EU Financial Regulation 2018/1046.

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'.

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.

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 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.

The proposals that passes the individual thresholds AND the overall threshold will be considered for funding — within the limits of the available call budget. Other proposals will be rejected. We expect to sign 1 grant agreement.

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. Retroactive application can be granted exceptionally for duly justified reasons but never earlier than the proposal submission date

The recommended project duration is 48 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
- 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 (**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 inhabitant 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
- 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 cost[16] Yes
- travel and subsistence unit cost[17]: 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 eligible cost
  - 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

[16] 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).

[17] 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).

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
- other ineligible costs: No

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 **30%** 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 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.

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 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 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.

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):*

- 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 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 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.