EU4Health Programme (EU4H)

Call for proposals

EU4Health - Action Grants 2024 (HERA)
(EU4H-2024-PJ-01)

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EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

HaDEA.A – Health and Food
HaDEA.A.1 – EU4HEALTH I

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)
- the basic act (EU4H Programme Regulation 2021/522[1], Strategic Technologies for Europe Platform (STEP) Regulation 2024/795[2]).

The call is launched in accordance with the 2024 Work Programme[3] and will be managed by the **European Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topics**:

- **EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)**
- **EU4H-2024-PJ-01-2 (CP-g-24-11) - Call for proposals for next-generation respiratory protection (HERA)**
- **EU4H-2024-PJ-01-3 (CP-g-24-12) - Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)**
- **EU4H-2024-PJ-01-4 (CP-g-24-105) Call for proposals to support the development of novel antivirals (HERA)**

Each project application under the call must address only one of these topics. Applicants wishing to apply for more than one topic, must submit a separate proposal under each topic.

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)

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

[2] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241 (OJ L, 2024/795, 29.2.2024).

[3] Commission Implementing Decision C (2023) 8524 final of 5.12.2023 concerning the adoption of the work programme for 2024 and the financing decision for the implementation of the EU4Health Programme.

- 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)

- 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

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

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

- improve public health in the Union through disease prevention and health promotion, as well as international health initiatives and cooperation;

- protect people from serious cross-border health threats through prevention, preparedness and response to cross-border health threats; complementing national stockpiling of essential crisis-relevant products; and establishing a reserve of medical, healthcare and support staff;

- improve access to medicinal products, medical devices and crisis-relevant products by encouraging sustainable production and supply chains and innovation in the Union and efficient use of medicinal products;

- strengthen the national health systems through improved health data use and re-use, development of digital tools and services, digital transformation of healthcare; enhancing access to healthcare; developing and implementing EU health legislation and evidence-based decision making; and integrated work among Member States' health systems.

The following topics contribute to the objectives of the Strategic Technologies for Europe Platform (STEP):

- **EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)**
- **EU4H-2024-PJ-01-3 (CP-g-24-12) - Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)**
- **EU4H-2024-PJ-01-4 (CP-g-24-105) - Call for proposals to support the development of novel antivirals (HERA)**

1.1. EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)

Following the European Health Union proposals of 11 November 2020, the Commission established HERA through a Commission Decision on 16 September 2021. Overall, HERA will contribute to the development, manufacturing, procurement and distribution of medical countermeasures in the Union to allow for a better preparedness for and response to serious cross-border threats to health and emergencies – whether of natural or deliberate origin. One of HERA's core missions is to support the development, access and uptake of medical countermeasures, including medicinal products, medical devices, in vitro diagnostic devices, Personal Protective Equipment ('PPE') and other health technologies, necessary to improve preparedness and response to serious cross-border health threats.

The COVID-19 crisis and many other epidemics and health emergencies before have illustrated the need to support technologies that can be used to ensure a rapid response in case of emergency. Among these, the development and access to prototype vaccines are an important cornerstone of pandemic preparedness and can be achieved by bundling existing excellence and expertise in the field at Union level and interlink it with wider international initiatives. A decentralised European hub for vaccine development, will bundle critical knowledge and experience in critical steps of vaccine development and combine it with capacities for clinical trials. Vaccine prototypes, based on most effective technologies would significantly speed up bringing innovative medical countermeasures to the market and would contribute to scaling of production and equal distribution of vaccines in case of need.

1.2. EU4H-2024-PJ-01-2 (CP-g-24-11) – Call for proposals for next-generation respiratory protection (HERA)

HERA is responsible for improving preparedness and response to serious cross-border health threats through ensuring the availability and accessibility of relevant Medical Counter Measures (MCM). Notably, by promoting research and development of MCM, as well as of the related technologies and potential solutions to market challenges. Personal Protective Equipment (PPE), and especially respiratory protection, plays a fundamental role in saving lives in the context of public health emergencies. PPE is particularly critical in the early stages of pandemics and epidemics, before vaccines and therapeutics are developed.

At the same time, respiratory protection widely used in the COVID-19 pandemic like medical facemasks or FFP2 respirators has drawbacks. For example, it did not offer

adequate protection against highly transmissible pathogens like SARS-CoV-2[4] and it did not allow for comfortable multi-hour use, resulting in low adherence to protocols. Crucially, FFP2 respirators require expensive 'fit testing' to ensure filtration efficiency across population groups (particularly women, children, and other groups) and their indicated level of protection, which is not feasible to provide to the general public before a public health emergency.[5] Even if FFP2 respirators are fit-tested and worn correctly, their level of protection decreases significantly over time.[6] These shortcomings are widely recognised to have exacerbated the health impact of the COVID-19 pandemic and hamper the response to future pandemics.

1.3. EU4H-2024-PJ-01-3 (CP-g-24-12) – Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)

HERA contributes to the improvement of the Union's development, manufacturing, procurement, and distribution of key medical countermeasures within the Union so to best prepare and respond to serious cross-border threats and emergencies – whether of natural or deliberate origin. In the EU4Health 2021 work programme, HERA launched an action to assess how flexible (multi-technology) manufacturing and process innovation capacities can be implemented to facilitate surge manufacturing capacity and improve the Union's access to medical countermeasures. This study[7], amongst others, indicated that it is recommended to invest in mechanisms to stimulate innovation for manufacturing landscape technologies that may lead to greater flexibility in the manufacturing of medical countermeasures in the Union in the longer term.

This action is a follow-up to these recommendations, specifically focusing on medicines' production, and aims at addressing some of the challenges identified in the Commission Communication 'Addressing medicine shortages in the EU', especially to boost Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients[8] and noting that some of these critical medicines will not address cross-border health threats but rather non-communicable diseases. The EU has been confronted with critical shortages, including of critical medicines, whose absence can threaten the life of patients. Many of these medicines are off patent.

Contextually, the scope of this action focuses on innovative manufacturing for the production of Active Pharmaceutical Ingredients (APIs), their intermediates and excipients of generic medicines. It shall address relevant technological vulnerabilities and dependencies such as nitration, cyanation, fluorination or iodination[9], and enhance the use of technologies that boost economic and supply security while possibly enabling the substitution of chemical processes by biomanufacturing processes.

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[4] Empirical studies are unclear about whether masks provide adequate protection (see Jefferson et al., 2023 for Cochrane library for an overview). Even if empirical data is ambiguous, there are strong theoretical reasons to suspect FFP2 respirators do not offer sufficient protection – see e.g., results of a parametric analysis by Gryphon Scientific suggesting exposure to SARS-CoV-2-infected individuals for less than one hour results in 50% infection risk, even if a tight-fitting N95 respirator is worn.

[5] Ciotti et al., 2012; Ng et al., 2022.

[6] Mahdavi et al., 2015.

[7] A study assessing scientific, engineering, legal and economic considerations of flexible EU manufacturing and innovation of medical countermeasures for serious cross-border threats to health - Publications Office of the EU (europa.eu)

[8] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing medicine shortages in the EU. COM (2023)672 final.

[9] Commission Staff Working Document - Vulnerabilities of the global supply chains of medicines

1.4. EU4H-2024-PJ-01-4 (CP-g-24-105) Call for proposals to support the development of novel antivirals (HERA)

Certain viral infections represent considerable pandemic threats, and consistently pose a substantial economic and public health burden due to their ability to cross species barriers and cause unpredictable outbreaks of viral diseases in humans. Antiviral development remains a crucial aspect of epidemic and pandemic preparedness to ensure timely and effective treatment of infected individuals and to reduce virus transmission of needed. Further, the continuous evolution of new variants of Sars-CoV2 underpinned that more tools are needed in the public health armamentarium to fight a pandemic.

The development of broad-spectrum antivirals (BSA), and BSA-containing drug combinations (BCC) can be a crucial key tool for pandemic preparedness when targeting HERA's defined viral families of concern as they target many viruses of the same family (pan-family inhibitors), or viruses belonging to different viral families (cross-family inhibitors). An important direction in the development of BSAs is to expand their antiviral activity, that is to find new targets, or optimise combinations of antivirals, amongst others. BSAs are a class of molecules or compounds, which inhibit replication of multiple viruses from the same or different viral families, thus reducing virus transmission from human to human, while BCCs can mitigate the development of antiviral drug resistance. Moreover, synergistic BCCs contain lower concentrations of antivirals which decrease their toxicity and reduce side effects.

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

2.1. EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)

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

This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures, with a focus on priority pathogens with pandemic potential. It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of crisis-relevant products (Article 3, point (c)) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Strand (scope)

Crisis preparedness

Activities that can be funded (scope)

This action aims to create a European Hub for public health relevant vaccine development, combining excellence in vaccine development with clinical trials and activities for scaling manufacturing. This call targets consortia of developers of vaccines covering expertise in development including publicly funded and industrial organisations.

The Hub will develop a strategic vaccines plan for Europe, and subsequently deliver on creating vaccine prototypes in particular for priority pathogens with epidemic and pandemic potential, further developing of state-of-the-art technologies that can be rapidly adapted, preparing relevant master clinical trial protocols, combining its

activities to reach out to clinical trial capacities/networks and at scale production initiatives at national and European levels. The Hub should establish connections with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01) and private manufacturers including through specific manufacturing agreements such as EUFAB or comparable national models.

Specific mandatory deliverables and/or milestones

Vaccines are central to get infectious disease outbreaks also of epidemic and pandemic dimensions under control, hence investments into research and development remains core to health security and preparedness. Recent regional outbreaks, epidemics and pandemics have shown that timely and large amounts of vaccines save millions of lives and ensure the recovery of economies and social life.

A considerable number of vaccine developments, driven by private entities and/or by public efforts, are underway. However, the COVID-19 pandemic again reminded that pandemic vaccines are challenging to design and develop, but support to research into better understanding of immunity, identification of antigens, library constructions, prototype development and technology advancement, including for at scale manufacturing must be enforced for a fast and meaningful response to future health events. The COVID-19 pandemic has shown that substantial public investments over decades into RNA based vaccines eventually helped us to contain this pandemic and to recover relatively quickly.

However, future outbreaks, also more severe in terms of transmissibility, disease impact and mortality as COVID-19, are unavoidable. Scarce resources, along the whole value chain of vaccine design, development down to manufacturing, might very likely again cause a global run in case of future emergencies. Despite a multitude of regional, national and global political and operational efforts to allow equal access to vaccines and other medical countermeasures, and despite spontaneous or pre-fixed arrangements and agreements with partners, a safety net for domestic vaccine development, production and fast regulatory approval is important. Strategic autonomy as the decisive factor: managing dependencies is key, substantial manufacturing capacities in the EU need to be paired with the best possible research and development capacities for vaccines, and with swift clinical trials and regulatory processes. Linking these elements is a core public interest reflected by a European Vaccines Hub (EVH).

A European Vaccine Hub will be an excellence based - Public Health focused - infrastructure that develops vaccine prototypes of selected pathogens to phase 2, and prepares processes that guarantee at scale production by industry partners under outbreak conditions. In addition, the Hub will be at the origin of technology spin-offs contributing to the development of vaccines against other high-impact, also non-pandemic pathogens.

The Hub will contribute to the coordination of different pandemic vaccine development programmes and projects by reviewing and advising on progression along all phases of the product development cycle. The Hub will ensure an appropriate pre-regulatory pipeline for selected vaccines in public interest.

These capacities culminate in a consortium that ensures all preparatory work for the development of vaccine-based countermeasures at the necessary scale. The Hub aligns its different bodies´ activities from discovery research to the development and production of trials vaccines, design and development of relevant clinical and biological assays as well as contracting manufacturers for production at scale. The Hub should link strongly innovative teams working on designated pathogens, on different vaccine technologies, while expanding work also to improving the value chain for antibodies. The Hub should establish functional links with relevant international partners and with like-minded organisations undertaking similar activities, to seek for synergies and

acceleration of processes. This should be described as part of the governance structure of the proposal.

All activities carried out by the EVH should contribute to the development of an agreed set of public health-relevant prototype vaccines and scalable technologies through a consortium of major EU Vaccine R&D institutions and manufacturers (including effective coordination of national vaccine programmes). The EVH will coordinate robust vaccine development from prototype design to clinics, to accelerating innovations, and clinical evaluation capacities, will work on the coordination with manufacturers, and digitalisation of design and development processes and distribution solutions. The EVH should:

a) Develop and implement a pandemic vaccines readiness plan: In the context of an epidemic or pandemic, the consortium integrates dispersed efforts into one single targeted workstream to design, develop, and enable manufacturing of candidate vaccines (or antibodies) for preventive or therapeutic purposes. This should be done in coordination with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01).

b) Develop pandemic vaccines candidates for agreed pathogens along all phases up to phase 2, including through relevant in vitro, in vivo and animal models. Collaboration with European Research Infrastructures, e.g. through ISIDORe, should be sought.

c) Ensure rapid delivery of vaccine candidates for trial and mass production to manufacturing partners, including those covered by EU FAB or similar national contracts or other relevant capacities.

d) Optimise digitalisation of discovery, development and production technologies of vaccines.

e) Organise and optimise the clinical evaluation of candidate vaccines among its constituents including in Phases I and II and the appropriate use of controlled infection facilities in close collaboration with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01). Contribute to the Partnership's "ever-warm" clinical trials system for vaccines (and antibodies) ready, audited and tested. Provide trainings for all aspects around optimisation of clinical trials organisation.

f) Implement a system of study laboratories in coordination with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01) able to develop and implement relevant biological, pre-clinical and clinical assays, in full respect of industrial standards.

g) Set up shared, ready-to-use and scalable state of the art technology platforms covering all phases of vaccine development with a focus on of high-yield and rapidly adaptable production systems.

h) Prepare and support technology transfers among EU partners and other eligible entities while developing a centre of shared knowledge for public health-relevant vaccine development. Implement a capacity to audit processes and functions among partners to ensure a state-of the art preparedness level.

i) Perform stress tests of pandemic vaccine production, including critical supply chains. Develop standard, enforceable contractual agreements relevant for vaccine readiness and access for crisis situations.

j) Develop a system for inclusive and safe data sharing within the consortium and

with external entities executing downstream operations.

k) Develop strong links with leading international partners

Specific deliverables:

- ad-hoc reports, studies (related to data analysis) and advice on relevant aspects linked to the project (e.g. vaccine design, development, production and deployment in preparedness and crisis times).
- An EU epidemic and pandemic vaccines readiness plan, implementation plan and progress reports on implementation.
- List of priority pathogens for development of epidemic and pandemic vaccine prototypes to be agreed by HERA.
- Processes and procedures to ensure rapid development and delivery of vaccine candidates for trial and mass production. Including written agreements with respective trial and manufacturing partners.
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- Development plan for epidemic and pandemic vaccines for agreed pathogens along all phases up to phase 2b. Progress reports on implementation of such a plan. Written agreements with relevant partners.
- Plan and processes for optimising digitalisation of discovery, development and manufacturing of vaccines. Implementation plan and progress reports.
- Plan and procedures to improve pre-clinical and clinical evaluation of candidate vaccines among its constituents including in Phases I and II in collaboration with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01). Conduct of trials and progress reports including relevant results.
- Plan and procedures to ensure the appropriate use of controlled infection facilities.
- Plan to ensure a contribution to the above-mentioned Partnership's "ever-warm" clinical trials system for vaccines and antibodies ready, audited and tested. Implementation of this system with progress reports on dry-runs and actual runs including compounds using such capacities.
- Training plan and implementation for optimisation of clinical trials conduct.
- In coordination with the future Horizon Europe-funded European Partnership on Pandemic Preparedness (HORIZON-HLTH-2024-DISEASE-12-01) developing a system of study laboratories able to develop and implement relevant biological, pre-clinical and clinical assays for vaccines, in full respect of industrial standards. Implementation plan for this system and progress reports on the implementation.
- Innovative technology platforms covering all phases and all relevant state of the art technologies of vaccine manufacturing, including implementation plan.
- Technology transfers plan and implementation among EU partners and other eligible entities.
- A concept and implementation of a centre of shared knowledge for public health-relevant vaccine development.

- Capacities to audit processes and critical functions of vaccine development among partners.
- Plan and implementation of stress tests of pandemic vaccine production.
- Standard, enforceable contractual templates relevant for vaccine readiness and access that can be deployed in crisis situations.
- A system for technical advice on vaccine design, development, production and deployment issues, to the European Commission and other EU institutions.

A plan concerning the sustainable establishment of the Hub and achievement of long-term impacts after the end of the project, including tangible non-high level policy recommendations. These should include reflections on the need for scope extension or reduction and lessons learned from the implementation to be delivered at least 3 months ahead of the end of the final reporting period of the project duration.

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

This action is expected:

a) to contribute to better preparedness and early response to health emergencies;

b) to increase the availability and uptake of public health relevant vaccines and antibodies;

c) to contribute to the availability of preventive measures to slow the spread of selected pathogens;

d) to reduce strategic dependencies, expand Europe's competitiveness and strategic autonomy.

Specific action-level indicators for reporting purposes

- Number of plans and implementation according to work plan, delivered on time
- Number of written agreements and contracts developed and signed to facilitate the activities of the hub
- Number of vaccine prototypes or candidates subject to studies and trials
- Number of optimally digitalised processes
- Number of improved clinical and preclinical evaluations
- Number of ever-warm capacities after auditing and testing
- Number of trainings delivered and number of participants
- Satisfaction and efficiency of trainings tested
- Number of laboratories implementing the system for standardized and innovative assays
- Number of technology platforms developed optimised or adapted
- Number of users of the centre of shared knowledge
- Number of stress tests carried out
- Number of contractual agreements developed
- Number of pieces of advice provided

Special requirements

Applicants – specific eligibility criteria	Vaccine developers including publicly funded and industrial organisations.

Specific eligibility criteria applicable to the 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 consortium is expected to bring together European organisations involved in vaccines' development and manufacturing, with proven experience in the field (i.e. at least one member of the organisations should have a proven history of successful vaccine development demonstrated by having participated in bringing at least one vaccine to the market), and complementarity of technical competences across the numerous fields of vaccine development. The consortium should have the possibility to mobilise additional resources under pandemic or emergency conditions. For this to be assessed, the consortium should provide past evidence of such mobilisation (e.g. reaction to and management of a major health crisis in the past 5 years). Proven expertise relevant to the tasks to be performed in the project, demonstrated by involvement in successful programs in this area, in particular one or several aspects of vaccine research, development and manufacturing, along with solid knowledge in regulatory aspects of bio-pharmaceutical production and all steps of clinical development.

2.2. EU4H-2024-PJ-01-2 (CP-g-24-11) – Call for proposals for next-generation respiratory protection (HERA)

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

Through this action, HERA will support the development of next-generation respiratory PPE that addresses and/or mitigates the above-mentioned issues (see section 1.2), ending a 30-year period of no significant innovation in the field and ultimately ensuring a more effective response to future cross-border health threats, with an all-threats approach. In this context, it implements the EU4Health general objective of improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supports the innovation of such products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c) of Regulation (EU) 2021/522.

The objective of this action is to foster innovation and support development of next-generation respiratory PPE that overcomes the limitations outlined above and result in increased availability of enhanced medical countermeasures for pandemic preparedness and response.

Strand (scope)

Crisis Preparedness.

Activities that can be funded (scope)

Applicants might develop completely new technologies or rely on reformulated designs and novel applications of existing materials and technologies. Applicants need to propose a detailed plan to design, prototype, validate, and CE-mark innovative, cost-effective, and sustainable next-generation respirators. To overcome the limitations outlined above, they need to offer higher levels of protection than FFP2 respirators while being universally fitting, enabling comfortable multi-hour use.

Different solutions may target different populations (e.g., clinicians, critical workers, the public, etc.). Proposals should include a dissemination and market readiness plan that ensures a market for the product in preparedness times – e.g., through stockpiling or active use. This plan should generate sufficient demand to set up production.

Importantly, developers also need to demonstrate feasibility for a rapid production scale-up once a public health emergency materialises, possibly relying on distributed manufacturing solutions and use of accessible raw materials. Products should demonstrate the potential to be at a cost that will allow for a switch from the currently used PPE. To encourage sustainability, products should be reusable, less harmful for the environment and ideally foster environmentally friendly production. Proposals need to take into consideration that next generation respiratory devices should be easy to store (e.g., occupying minimum space in stockpiles and having long expiry dates) and simple to use by the target population.

Specific mandatory deliverables and/or milestones

Proposals need to outline in detail, including detailed and realistic timeline and cost overview, how the applicant will:

- Develop,
- Certify compliance with the PPE Regulation[10] and also with the Medical Devices Regulation[11], when applicable,
- Facilitate uptake (use in healthcare settings/by other critical workers, stockpiling or, when addressing manufacturing innovation, possibility for rapid scale-up in emergencies),

of one of the following products:

- Long-term reusable air-purifying half-masks ("elastomerics")
    - Stress-test for 100 cycles of hospital-grade hygienic reprocessing
    - Filter lifecycle of at least 100 8h-shifts
    - Either of the following:
        - Simple, scalable production with ad hoc supply chains in mainland Europe
        - Optimised for long-term storage (long shelf life, minimal space requirements)
- Accessible powered filtering respiratory protective devices:
    - Unit price EUR 200 or less when produced at scale and overall low lifecycle cost (e.g. through reusable and durable hoods, filters and components)

[10] Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC, OJ L 81, 31.3.2016, p. 51–98

[11] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175

    - Any of the following properties are desired, but not mandatory:
        - Lower communication barriers (e.g., by reducing fan noise)
        - Source control
        - Disinfection and reprocessing protocol with standard hospital equipment
        - Compatible with UV-disinfection
        - Increased comfort (e.g., by reducing weight and preventing heat buildup)
        - Compatibility with standard rechargeable batteries
        - Either of the following:
            - Simple, scalable production with ad hoc supply chains in mainland Europe
            - Optimised for long-term storage (long shelf life, minimal space requirements)
- Other reusable respiratory protective equipment, at least as protective as FFP2- masks, addressing or integrating any of the following:
    - Enhanced communication
    - Improved aesthetic appeal, leading to higher desirability of reusable respiratory protective devices
    - Better breathability or thermal comfort, e.g. through the use of advanced materials
    - Possibility for manufacturing innovation:
        - Innovative manufacturing processes that allow rapid scale-up in emergencies, e.g. novel automation technology to minimise need for human labour or best practices for stockpiling raw materials
        - Distributed manufacturing solutions
    - Sensors for real-time fit assurance or leakage detection (e.g. using dual-channel condensation particle counters)
    - Low risk of self-contamination during doffing
    - Universal fit (95% of adult population) without fit-testing
    - Maintain fit and user compliance during extended periods of use
    - Long shelf lives (12 years or more)

Proposals need to clearly and credibly outline how the uptake (including education and training) of the developed product will be ensured in preparedness times, either through use in healthcare settings and for other critical workers or through stockpiling. A significant percentage of the budget should fund testing and general distribution of the product in such settings, e.g. through developing a user-managed inventory protocol[12]. Alternatively, when focusing on manufacturing innovation, proposals need to credibly outline how production could be more rapidly scaled up in emergencies.

Successful applicants shall also consider registering in HERA's Dynamic Purchasing System[13] for more effective joint procurement of PPE, allowing the EU to procure the developed products more rapidly in times of emergency.

Deliverables will include details of the development activities, studies and tests supported as well as:

[12] Supply bubbles of respiratory protective devices stored directly at or close to medical facilities to meet the demand surge in emergencies.

[13] https://s2c.mercell.com/today/18783

- results of the consultations with user base (essential workers in- and outside of healthcare) across all stages of the development phase
- Detailed analysis of costs (material, personnel, manufacturing etc) and resale price
- Testing and trial results in clinical settings or other critical workers relevant for pandemic preparedness
- and documentation resulting from engagement with notified bodies and regulatory authorities: including defining the pathway to conformity assessment and submission of applications.

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

This action will support bringing next generation PPE to the market to provide sustainable, universal and effective choices for the personal protection of healthcare and other essential workers, patients and the public. Superior respiratory protection will be available for stockpiling, scale-up and uptake by healthcare systems and the public in response to future pandemics or epidemics. The reduction of the use of single-use products will make the EU less vulnerable to supply chain disruptions.

Cost-effective and user-friendly next generation respirators will slowly replace regular respirators and be deployed at national, regional, and local levels, ensuring better preparedness for future pandemics and other cross-border health threats. Widely incorporating improved respirators into clinical practice will also lead to better protection for healthcare workers and patients already in preparedness times, and overall improved health outcomes.

Specific action-level indicators for reporting purposes

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

- Resale price and lifetime cost of RPD
- Number of distributed units of RPD (projection in offer)
    - Alternatively, when targeting manufacturing innovation, potential for rapid scaleup within first months of emergency
- Projected shelf life
- Number of consultations with user base (essential workers in- and outside of healthcare) across all stages of the development phase
- Number of individuals evaluated for fit
- Quantitative user satisfaction levels
- Number of prototypes produced and tested

Special requirements

Applicants – specific eligibility criteria	Legal entities active in the field of innovation and with adequate expertise in PPE, proven by

	experience in the sector (e.g. past development activities, academic research). Hospitals, other employers of critical workers or stockpiling entities might be part of a consortium to ensure validation, testing and uptake of developed products.
Specific eligibility criteria applicable to the consortium composition	Proposals must be submitted by either a single applicant or a consortium of at least **3 applicants** (beneficiaries; not affiliated entities), which complies with the following conditions: Single applicants (or at least one of the members of a consortium) must have expertise (proven by relevant past projects) in at least one of the following areas: - respiratory protective equipment, - hospital management, - medical device engineering, or - stockpiling. Expertise needs to be clearly highlighted in the proposal.

2.3. EU4H-2024-PJ-01-3 (CP-g-24-12) – Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)

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

This action aims at supporting improved manufacturing technologies and processes that allow for a more effective, less expensive, easier to scale-up, more sustainable and cleaner production of medicines in the Union. Innovations developed under this action should be designed to enable rapid scale-up of Union pharmaceutical production in the context of a health emergency or to prevent critical shortages of critical medicines. This action supports the Union's pharmaceutical industry to be better able to respond to public health need s in the context of health emergencies and critical medicines' shortages.

It does so by enabling the development of tools that contribute to the improvement and optimisation of manufacturing of medicines, with the objective of reducing production costs (e.g., related to labour and energy consumption), and facilitating compliance with the Union's environmental occupational and social requirements, as well as the Union's current and future needs to scale-up pharmaceutical production. This action supports the policy priority to enhance crisis preparedness and response for future health emergencies in relation to medical countermeasures with an all-threats approach, as well as preventing critical shortages of critical medicines, especially those in a situation of technological vulnerability with regards to the EU market. It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of crisis-relevant products (Article 3, point (c) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Strand (scope)

Crisis preparedness

Activities that can be funded (scope)

This action covers activities aimed at developing support for or innovations targeting manufacturing of APIs, their intermediates and/or excipients, namely by developing:

a) novel manufacturing processes and technologies, e.g., additive manufacturing, continuous manufacturing and flow chemistry, and biomanufacturing technologies; combined or not with activities covering:

b) novel industrial manufacturing and facility designs, e.g., modular manufacturing, smart manufacturing execution systems, including automation and robotics, advanced analytics, smart sensors, among other.

Overall, the action should contribute to increasingly sophisticated enhancements to chemical and/or biological processes or decreasing the production of polluting agents. This action is limited to manufacturing technologies and processes and does not cover innovation exclusively targeting the field of quality control.

Specific mandatory deliverables and/or milestones

Having in mind the specific focus of the grant for developing new manufacturing technologies for the production of APIs, intermediates, finished products and/or excipients, and the expected impact, projects awarded under this grant shall address one or more of the following challenges:

- Optimizing existing manufacturing processes to improve efficiency, reduce costs, and/or improve product quality.
- Developing technologies to enable rapid scale-up of production of medicines.
- Developing new technologies for manufacturing medicines in real-time.
- Developing new technologies for manufacturing medicines in remote or resource-constrained settings.
- Designing manufacturing processes that are resilient to climate change and other environmental threats.
- Developing new manufacturing technologies for the production of high-potency APIs, which are difficult to produce using traditional/resource limited methods.
- Optimizing/developing new manufacturing processes for personalized medicines, which require individualized dosing and formulation.
- Developing new manufacturing technologies that can be used to produce medicines in extreme environments.
- Developing new technologies for recycling or upcycling waste generated during medicines' production.

The grant supports the design and development of manufacturing technologies, processes and facilities that adhere to Good Manufacturing Practices principles. At the same time, and with the understanding of the challenges regarding the adoption of new technologies in the pharmaceutical sectors, this grant also supports relevant work developed in the context of regulatory affairs in order to ensure the future successful implementation of manufacturing processes and technologies in the EU. For example,

to allow early communication with competent authorities to understand their regulatory expectations and identify potential challenges.

Mandatory deliverables

1. **Communication plan:** to disseminate information about the project's achievements and outcomes to stakeholders interested in such technological developments.
2. **Regulatory interaction plan (if applicable):** plan to allow to effectively navigate the regulatory landscape and bring innovative manufacturing technologies to market in a timely and compliant manner.
3. **Pilot trial results:** report on the completion of pilot lab/plant trials to validate the performance and feasibility of the innovative technologies.
4. **Commercialisation roadmap:** detailed roadmap outlining the strategy for commercialising the developed technologies and processes.
5. **Technical documentation:** detailed documentation product of the developed innovative manufacturing technologies and processes, including technical specifications, design drawings, and user manuals.
6. **Training materials:** development of training materials for internal staff and potential licensees on the use and implementation of the innovative technologies.
7. **Patent application(s):** patent application(s) filed for the developed technologies and processes and other relevant registrations related to the technology.
8. **Final project report:** comprehensive report summarizing the project's objectives, methodology, findings, conclusions, and recommendations.

Milestones

1. Communication plan implementation.
2. Technology design/development completed.
3. Prototype fabrication completed.
4. Pilot trial completed.

Patent application filed.

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

This action is expected to result in:

a) more agile, simplified scale-up, sustainable and resilient manufacturing of APIs, their intermediates, finished products and/or excipients, allowing for better capacity to respond to demand surges and prevent critical shortages of critical medicines.

b) improved competitiveness of the Union's manufacturing industry, improved Union's strategic autonomy and more resilient Union's industry in the field of medical countermeasures/medicines.

Specific action-level indicators for reporting purposes

1. Number of new patented manufacturing technologies developed.
2. Number of webinars or presentations given on innovative manufacturing technologies.
3. Percentage increase in production capacity using innovative technologies.
4. Reduction in manufacturing costs per unit using innovative technologies.
5. Number of medicines or formulations that could potentially use the innovative technologies.
6. Percentage reduction in waste generated during manufacturing using the innovative technologies.
7. Number of publications in peer-reviewed journals on innovative manufacturing technologies.
8. Number of articles in trade publications or industry magazines on innovative manufacturing technologies.
9. Number of collaborations with academic institutions or research organisations on innovative manufacturing technologies.
10. Number of new industrial partnerships formed to commercialise innovative manufacturing technologies.
11. Number of patents licensed to other companies using innovative manufacturing technologies.
12. Number of jobs created or sustained by the development and implementation of innovative manufacturing technologies.
13. Number of awards or recognition received for the development of innovative manufacturing technologies.

Special requirements

Applicants – specific eligibility criteria	• Industrial economic operators, technology developers and applied research stakeholders capable of developing the mentioned manufacturing technologies and processes. • Established legal entities with a clear track record of industrial innovation development. • Technical expertise in the area of manufacturing technologies and/or processes relevant to the call.
Specific eligibility criteria applicable to the consortium composition	Applications may be submitted either by a single applicant or a consortium of at least **3 applicants** (beneficiaries; not affiliated entities). In both cases (single applicants or consortium) the proposal must include one eligible applicant with expertise (proven by relevant past projects) in manufacturing technologies or processes.

2.4. EU4H-2024-PJ-01-4 (CP-g-24-105) Call for proposals to support the

development of novel antivirals (HERA)

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

This action supports the policy priority to be better prepared to respond to serious cross-border health threats. It contributes to the achievement of 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), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (b) and (c), of Regulation (EU) 2021/522.

Strand (scope)

Crisis preparedness

Activities that can be funded (scope)

This action aims to diversify and advance the pipeline of BSA candidates. More specifically, it will support the development and further characterisation of broad-spectrum antivirals targeting identified HERA priority viral families, which largely can be divided among respiratory RNA viral families, such as Paramyxo-, Orthomyxo and Coronaviridae, as well as those targeting viral families known for causing viral haemorrhagic fever (VHF), such as Arena-, Bunya-, Flavi-, Filoviridae. The action aims to identify a potent BSA candidate, in order to advance its clinical development. A robust pipeline should contain multiple BSA candidates for each viral family that are developed in parallel. When selecting the BSA candidate, attention will be paid to the complementarity with existing Horizon Europe projects. Synergies with projects funded under the topic HORIZON-HLTH-2023-DISEASE-03-04 should be sought.

The proposal would need to cover early safety and efficacy trials for testing new or improved anti-viral therapeutics, with a clear regulatory and clinical pathway, including first in humans.

Innovative delivery systems and suitable safety profiles for broad use should be considered when possible as well as application of novel approaches and widely applicable workflows (e.g. artificial intelligence) for rapid and reliable identification of broad-spectrum anti-viral therapeutics.

Specific mandatory deliverables and/or milestones

Applicants should provide details of the studies and tests supported (including efficacy testing in animal and/or human challenge models) as well as:

- Ethical approvals for testing and/or clinical protocols.
- When applicable, patient enrolment plan and implementation, ensuring that those trials are preferably carried out in the EU.
- Testing and trial results including those towards the establishment of maximum tolerated dose, dose ranging, adverse effects, pharmacokinetics and pharmacodynamics.
- and documentation resulting from engagement with regulatory bodies: applicants are expected to engage with regulatory bodies in a timely manner to ensure adequacy of the actions from a regulatory point of view.

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

HERA's threat assessment of 2022 included a vulnerability analysis with regard to the availability or absence of medical countermeasures, in particular the availability of vaccines and treatment options. Given that the large majority of identified virus families lack effective vaccines and/or effective therapeutics at EU and global level, HERA's long-term aim is to, inter alia, support the creation of a diverse portfolio of BSAs and BCCs that can be further developed in clinical by identifying most promising candidates and supporting their characterisation and assessment, including through clinical trials. Actions funded under this topic are therefore expected to either bring innovative, emerging, and cutting-edge elements with significant economic potential to the internal market or to reduce or prevent strategic dependencies of the Union, including by contributing to the Union technological leadership in the innovation and development of BSA and enhancing the access to these products in the EU.

Specific action-level indicators for reporting purposes

- Number of models used and/or of patients/test subjects enrolled
- Number of efficacy/safety trials conducted
- Number of scientific reports and papers published
- Number of ethical and regulatory approvals submitted and authorised
- Number of compounds that were pushed to the next clinical phase
- Demonstrated safety and/or efficacy of the compound

Special requirements

Applicants – specific eligibility criteria	Private, academic and public bodies active and in the field of innovation and with proven expertise in development of antivirals.
Specific eligibility criteria applicable to the consortium composition	Applications may be submitted either by a single applicant or a consortium of at least **3 applicants** (beneficiaries; not affiliated entities).

3. Available budget

The estimated available call budget is **EUR 149 000 000**.

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

Topic	Topic budget	Indicative project budget	Expected number of grant agreements to be signed
1 — EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)	**EUR 102.000.000**	**EUR 102.000.000**	**1**
2 — EU4H-2024-PJ-01-2 (CP-g-24-11) - Call for proposals for next-generation respiratory protection (HERA)	**EUR 20.000.000**	**EUR 5.000.000**	**4**

3. EU4H-2024-PJ-01-3 (CP-g-24-12) - Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)	**EUR 17.000.000**	**EUR 5.600.000**	**3**
4. EU4H-2024-PJ-01-4 (CP-g-24-105) Call for proposals to support the development of novel antivirals (HERA)	**EUR 10.000.000**	**EUR 10.000.000**	**1**

The number of grant agreements expected to be signed is listed in the table above.

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:	23 May 2024
Deadline for submission:	05 September 2024 – 17:00:00 CET (Brussels)
Evaluation:	September-October 2024
Information on evaluation results:	October-November 2024
GA signature:	June 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 they are 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)

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 eligibility criteria, for each of the topics, are mentioned in section 2 above.

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[14].

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'[15]. ⚠ 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 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)[16])*. 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 16 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.

ℹ For more information, *see Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment*.

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

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

16 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.

Consortium composition

See special conditions for each topic under section 2 above.

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.

Geographic location (target countries)

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

Duration

Topic	Expected duration of the project(s) in months
EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)	**48 months**
EU4H-2024-PJ-01-2 (CP-g-24-11) - Call for proposals for next-generation respiratory protection (HERA)	**48 months** 24 months development 24 months to test with end users and ensure widespread uptake
EU4H-2024-PJ-01-3 (CP-g-24-12) - Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)	**24 to 48 months**
EU4H-2024-PJ-01-4 (CP-g-24-105) Call for proposals to support the development of novel antivirals (HERA)	**24 months**

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

Project budget

Project budgets (maximum grant amount) are listed under section 3 "available budget".

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, 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 accounts for up 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.

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 participate[17]:

- bankruptcy, winding up, affairs administered by the courts, arrangement with creditors, suspended business activities or other similar procedures (including procedures for persons with unlimited liability for the applicant's debts)
- in breach of social security or tax obligations (including if done by persons with unlimited liability for the applicant's debts)
- guilty of grave professional misconduct[18] (including if done by persons having powers of representation, decision-making or control, beneficial owners or 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, 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)

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

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

- 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 that[19]:

- 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'.

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.

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

Proposals under topics EU4H-2024-PJ-01-1(CP-g-24-10), EU4H-2024-PJ-01-3 (CP-g-24-12), and EU4H-2024-PJ-01-4 (CP-g-24-105) that are eligible and exceed the evaluation thresholds will be awarded a Sovereignity Seal.

⚠ 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 inhabitant[20] 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[21] Yes

[20] GNI per inhabitant in EU

[21] 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).

- travel and subsistence unit cost[22]: 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.

- **EU4H-2024-PJ-01-1 (CP-g-24-10) - Call for proposals on the European Hub for vaccine development (HERA)**

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

- **EU4H-2024-PJ-01-2 (CP-g-24-11) - Call for proposals for next-generation respiratory protection (HERA)**

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

- **EU4H-2024-PJ-01-3 (CP-g-24-12) - Call for proposals to support innovative manufacturing technologies and processes in the Union for medicines production (HERA)**

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

- **EU4H-2024-PJ-01-4 (CP-g-24-105) Call for proposals to support the development of novel antivirals (HERA)**

There will be no interim payments.

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).

[22] 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).

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).

- **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).

- **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).

- **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 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 the others (or they 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.