Ref. Ares(2025)6926640 - 27/08/2025

EU4Health Programme (EU4H)

Call for proposals

EU4H HERA Action Grants 2025
EU4H-2025-HERA-PJ

Version 1.0
4 September 2025

EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

HaDEA.A – Health and Food
HaDEA.A.1 – EU4Health

CALL FOR PROPOSALS

TABLE OF CONTENTS

0. Introduction

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

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

- Regulation 2024/2509 (EU Financial Regulation)[1]
- the basic act (EU4H Programme Regulation 2021/522[2]; STEP Regulation 2024/795[3]).

[1] Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) ('EU Financial Regulation') (OJ L, 2024/2509, 26.9.2024).

The call is launched in accordance with the 2025 Work Programme[4] and will be managed by the **European Health and Digital Executive Agency, (HaDEA)** ('Agency').

The call covers the following **topics**:

- **EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products**
- **EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits**
- **EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis**
- **EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (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)
  - 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)

---

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

[3] 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).

[4] Commission Implementing Decision C(2025) 5148 final of 23.7.2025 concerning the adoption of the work programme for 2025 and the financing decision for the implementation of the EU4Health Programme.

  - 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)*.

1. Background

- **EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products**
- **EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits**
- **EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis**

HERA is responsible for improving preparedness and response to serious cross-border health threats through ensuring the availability and accessibility of relevant medical countermeasures. In the current geopolitical context, the use of chemical, biological or radio nuclear ('CBRN') agents poses a risk that authorities and healthcare providers need to prepare for. The threat landscape in the field of chemical and biological agents is evolving rapidly, facilitated by developments in biotechnology and artificial intelligence. While their probability is low, the impact of CBRN attacks can be high. One of the key pillars of preparedness, as for other health emergencies, are medical countermeasures.

With the synthesis of novel toxins and pathogens as a possibility, and many currently known chemical and biological threats, threat-agnostic and platform approaches are especially relevant. These can be leveraged for agents against which no or no specific medical countermeasures are available. While there are few new radio nuclear threats, the current range of medical countermeasures against them is overall very limited, meaning that a broader arsenal would help to better protect European residents.

This action supports the policy priority to enhance the availability and accessibility of medical countermeasures, to support innovation and access regarding such products and to ultimately enhance preparedness for future health emergencies with a focus on civilian capabilities. This action will complement the defence industry focused Counteract and Resilience projects financed under the European Defence Fund and

thereby contribute to deeper civil-military cooperation and whole-of-society preparedness.

It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices and 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.

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(b).

- **EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)**

The emergence and re-emergence of vector-borne diseases ('VBDs') present a growing public health challenge within the Union. As vectors expand their geographical reach due in part to climate change and global travel, the Union faces increased threat from several VBDs, particularly mosquito-borne diseases such as Dengue, Zika, Chikungunya and West Nile fever. Furthermore, many VBDs are characterised not only by a lengthy incubation period but also by non-specific symptoms. Current diagnostic methods for these diseases often lack the necessary sensitivity and specificity, leading to significant rates of underdiagnosis and, consequently, delayed treatments and medical complications. This underdiagnosis not only affects the health outcomes of individuals but also impedes the effective epidemiological tracking and management of these diseases.

Developing cost-effective diagnostics for resource-limited settings is a priority for HERA, to facilitate timely diagnosis without central laboratory testing. There is therefore a critical need to develop new point of care diagnostic tests that are both more sensitive and more specific, cost-effective and capable of accurately detecting these diseases early in their onset. Additionally, the ability to rapidly diagnose VBDs is essential for initiating timely treatment and controlling outbreaks. Rapid diagnostic tests can significantly enhance response efforts by healthcare providers and public health officials, reducing the spread and impact of infections.

This call for proposals aims to support the development of innovative diagnostic technologies that address these needs. By fostering advancements in diagnostics, the Union seeks to improve health surveillance, enhance disease prevention, and ensure better health outcomes for its citizens, thereby strengthening the overall resilience of its health systems against VBDs.

This action contributes to the horizontal policy priority aimed at fighting climate change.

It implements the EU4Health Programme's general objective of improving the availability, accessibility and affordability of medicinal products and medical devices and crisis-relevant products (Article 3, point (c), of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a), (b) and (c), of Regulation (EU) 2021/522.

This action contributes to the STEP objectives as defined in the STEP Regulation, in particular to the objective referred to in Article 2(1)(a)(iii) of the STEP Regulation and meets the condition under Article 2(2)(a).

STEP

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

- EU4H-2025-HERA-PJ-1-a
- EU4H-2025-HERA-PJ-1-b
- EU4H-2025-HERA-PJ-1-c
- EU4H-2025-HERA-PJ-2

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

- **EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products**

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

This action will focus on supporting advanced research on threat-agnostic medical countermeasures against CBRN agents and platform approaches to treat injuries from CBRN agents.

The objective is to improve the Union's readiness to respond to intentional health threats, including cross-border ones, by supporting the development of medical countermeasures to biological, chemical and radio-nuclear agents for which there currently are no or only limited treatment options.

The focus of sub-topic a) is on medicinal products, i.e. vaccines and therapeutics against biological, chemical and radio-nuclear threats.

Activities that can be funded (scope)

The range of activities include an end-to-end approach to bridge the gap between advanced research, innovation, market access and deployment by supporting:

- Advanced research and development ('R&D') to support the development of medical countermeasures;
- Involving end users and security practitioners to bring the research products closer to market readiness; and
- Support research into market readiness or facilitate tech and entrepreneurial skills development.

This will be done in synergy with relevant Horizon Europe[5] and European Defence Fund[6] actions.

[5] Cluster 3: "Civil security for society", Destinations: "Better protect the EU and its citizens against Crime and Terrorism"; "Resilient Infrastructure"; "Disaster-Resilient Society for Europe" and "Strengthened Security Research and Innovation".

[6] European Strategic alliance for research, development and innovation on medical countermeasures against CBRN threats (RESILIENCE).

Specific action-level indicators for reporting purposes

- Number of threats against which the proposed solution(s) was(were) validated against (see under 'Milestones and deliverables' section).
- Number of threats against which the proposed solution(s) was(were) regulatory approved against.
- Number of prototypes or candidates to be developed against threats up to trials stage.
- Number of patent applications filled (if applicable).
- Number of clinical studies performed and stage (phase I or phase II, where possible).
- Number of animal models used in preclinical studies.
- Number of enrolled and completed follow-up participants (per clinical study).

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

This action is expected to increase the preparedness of the Union to respond to CBRN threats and improve the availability of medical countermeasures against these threats. It should advance one or more medical countermeasures against CBRN threats along the steps towards regulatory approval and market readiness. In particular:

- For countermeasures against biological threats, this includes vaccines, therapeutics (such as antivirals, small molecules, antimicrobials, monoclonals and polyclonals).
- For countermeasures against chemical agents, this includes antidotes, supportive treatments, and innovation in application devices or techniques.
- For countermeasures against radio-nuclear agents, treatments against acute radiation syndrome, against bone marrow suppression, and decorporation agents after exposure to radioactive substances.

Type of applicants targeted: Secondary or higher education establishments, research organisations, hospitals, expert networks including ERNs, security practitioners, end users, other private entities or public bodies and public authorities.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

– **EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits**

Objectives

This action will focus on supporting advanced research on threat-agnostic medical countermeasures against CBRN agents and platform approaches to treat injuries from CBRN agents.

The objective is to improve the Union's readiness to respond to intentional health threats, including cross-border ones, by supporting the development of medical

countermeasures to biological, chemical and radio-nuclear agents for which there currently are no or only limited treatment options.

The focus of sub-topic b) is on reusable respiratory personal protective equipment (PPE) and protection suits.

Activities that can be funded (scope)

The range of activities include an end-to-end approach to bridge the gap between advanced research, innovation, market access and deployment by supporting:

- Advanced research and development ('R&D') to support the development of medical countermeasures;
- Involving end users and security practitioners to bring the research products closer to market readiness; and
- Support research into market readiness or facilitate tech and entrepreneurial skills development.

This will be done in synergy with relevant Horizon Europe[7] and European Defence Fund[8] actions.

Specific action-level indicators for reporting purposes

- Number of threats against which the proposed solution(s) was(were) validated against.
- Number of threats against which the proposed solution(s) was(were) regulatory approved against.
- Number of patent applications filled (if applicable).

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

This action is expected to increase the preparedness of the Union to respond to CBRN threats and improve the availability of medical countermeasures against these threats. It should advance one or more medical countermeasures against CBRN threats along the steps towards regulatory approval and market readiness. In particular:

- For Personal Protective Equipment ('PPE'), the focus is on reusable respiratory PPE and protection suits.

Type of applicants targeted: Secondary or higher education establishments, research organisations, hospitals, expert networks including ERNs, security practitioners, end users, other private entities or public bodies and public authorities.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

[7] Cluster 3: "Civil security for society", Destinations: "Better protect the EU and its citizens against Crime and Terrorism"; "Resilient Infrastructure"; "Disaster-Resilient Society for Europe" and "Strengthened Security Research and Innovation".

[8] European Strategic alliance for research, development and innovation on medical countermeasures against CBRN threats (RESILIENCE).

- **EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis**

Objectives

This action will focus on supporting advanced research on threat-agnostic medical countermeasures against CBRN agents and platform approaches to treat injuries from CBRN agents.

The objective is to improve the Union's readiness to respond to intentional health threats, including cross-border ones, by supporting the development of medical countermeasures to biological, chemical and radio-nuclear agents for which there currently are no or only limited treatment options.

The focus of sub-topic c) is on detection and diagnosis.

Activities that can be funded (scope)

The range of activities include an end-to-end approach to bridge the gap between advanced research, innovation, market access and deployment by supporting:

- Advanced research and development ('R&D') to support the development of medical countermeasures;
- Involving end users and security practitioners to bring the research products closer to market readiness; and
- Support research into market readiness or facilitate tech and entrepreneurial skills development.

This will be done in synergy with relevant Horizon Europe[9] and European Defence Fund[10] actions.

Specific action-level indicators for reporting purposes

- Number of diagnostic tools developed against CBRN threats in this topic's scope (see under 'Milestones and deliverables' section).
- Number of CBRN threats that the tool can detect.
- Number of patent applications filled (if applicable).
- Number of conformity assessment procedures undertaken.

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

This action is expected to increase the preparedness of the Union to respond to CBRN threats and improve the availability of medical countermeasures against these threats. It should advance one or more medical countermeasures against CBRN threats along the steps towards regulatory approval and market readiness. In particular:

[9] Cluster 3: "Civil security for society", Destinations: "Better protect the EU and its citizens against Crime and Terrorism"; "Resilient Infrastructure"; "Disaster-Resilient Society for Europe" and "Strengthened Security Research and Innovation".

[10] European Strategic alliance for research, development and innovation on medical countermeasures against CBRN threats (RESILIENCE).

- For detection and diagnostics, a special focus is on tests that can rapidly detect individual or broad range of chemical and biological agents, including biotoxins.

Type of applicants targeted: secondary or higher education establishments, research organisations, hospitals, expert networks including ERNs, security practitioners, end users, other private entities or public bodies and public authorities.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

– **EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)**

Objectives

This action aims to:

- enhance disease detection, reduce misdiagnoses, and improve patient outcomes by broadening the diagnostic toolkit, with a focus on rapid tests.
- advance early detection of VBDs through the development of novel diagnostic tests that identify these diseases at an early stage, enabling timely treatment and control.
- increasing the accuracy and specificity of existing diagnostic assays to better identify VBD pathogens, thus minimising misdiagnoses.

Activities that can be funded (scope)

The activities conducted under this action will focus on supporting late-stage development of medical devices, bringing them to (near-) market; improvement of existing products in terms of accessibility, affordability, or accuracy; or, in case of unmet needs, aid the creation of innovative solutions. Supported actions will need to advance beyond the current R&I status and, where applicable, must also take into account ongoing Union projects, such as under Horizon Europe, guaranteeing complementarity. This will expand diagnostic capabilities to address emerging and re-emerging pathogens in the Union, by providing advanced tools to monitor and respond to outbreaks.

Updating diagnostic technologies to improve accuracy, speed, and accessibility and the optimisation of diagnostic technologies such as molecular assays and serological tests, should be supported by evidence on novel antigens or genetic sequences, including clinical testing.

Specific action-level indicators for reporting purposes

- Number of patents filed and/or granted relating to the activities under the grant.
- Performance metrics of the developed diagnostic tests, such as analytical and clinical sensitivity and specificity, and time to result, benchmarked against established gold-standard methods.
- Number of pathogens against which the developed tests were validated and/or received regulatory approval.
- Number of prototypes or tests manufactured.

- Number of new diagnostic tests / molecular assays validated.
- Number of new diagnostic tests that contribute to the earlier detection of vector borne diseases.
- Number of improved existing products in terms of accessibility, affordability and/or accuracy.

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

This action is expected to:

a) improve diagnostic capabilities that will lead to earlier detection of VBDs, enabling prompt treatment initiation and reducing disease transmission.

b) develop new diagnostic tests to stimulate research and innovation in the field of VBDs.

c) support global health initiatives focused on attaining goals for international health security.

Type of applicants targeted: Secondary or higher education establishments, research organisations, hospitals and other healthcare institutions, NGOs, developers and other private entities or public bodies with expertise in diagnostics development.

Proposals under this action that are eligible and exceed the evaluation thresholds will be awarded a STEP Seal, aimed at increasing their visibility and helping them attract alternative or additional public and private investments.

3. Available budget

The estimated available call budget is **EUR 30 000 000**.

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

Topic	Topic budget
EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products	**EUR 18 000 000**
EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits	**EUR 1 000 000**
EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis	**EUR 1 000 000**
EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)	**EUR 10 000 000**

We expect to sign this number of grant agreements per topic:

Topic	Expected number of grant agreements to be signed
EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products	**2-3**
EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits	**1**
EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis	**1**
EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)	**2-3**

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:	4 September 2025
Deadline for submission:	4 December 2025 – 17:00:00 CET (Brussels)
Evaluation:	January - February 2026
Information on evaluation results:	March - April 2026
GA signature:	August 2026

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 Calls for proposals 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 *(template to be downloaded from the Portal Submission System, completed, assembled and re-uploaded)*

- **mandatory annexes and supporting documents** *(templates 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)*
  - Other annexes:
    - For topics:**EU4H-2025-HERA-PJ-1-a**, **EU4H-2025-HERA-PJ-1-b**, **EU4H-2025-HERA-PJ-1-c**: **A Security Issues Table** with three sub-tables on 1) EU classified information (EUCI) and participation of non-EU countries; 2) Misuse; and 3) Other security issues (see the guide How to handle security-sensitive projects for guidance and models). Where appropriate, this annex should include a proposed plan to mitigate potential misuse risks, including proposed oversight mechanisms and compliance with relevant security frameworks. For additional information, see the Guidance note on potential misuse of research. **Please note that proposals must NOT contain classified information.**
    - In addition to the previous mentioned mandatory annexes and supporting documents:

      For topic **EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products,** the following are required, if applicable:

      - List of previously submitted patents.
      - Previous development activities of proposed solution(s) and relevant technical or scientific (preliminary) data that supports the feasibility of the solution(s).
      - (Self-)Declaration of GMP (Good Manufacturing Practice) compliance by applicants and/or subcontractors.

      For topic **EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits,** the following are required, if applicable:

      - List of previously submitted patents.

- Previous development activities of proposed solution(s) and relevant technical or scientific (preliminary) data that supports the feasibility of the solution(s).
- Portfolio of products (personal protective equipment), specifying regulatory status in the EU.
- (Self-)Declaration of GMP (Good Manufacturing Practice) compliance by applicants and/or subcontractors.

For topic **EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis,** the following are required, if applicable:

- List of previously submitted patents.
- Previous development activities of proposed solution(s) and relevant technical or scientific (preliminary) data that supports the feasibility of the solution(s).
- Portfolio of products (in vitro medical devices), specifying regulatory status (CE-marked, past CE-marked, not approved in the EU, etc).
- (Self-)Declaration of GMP (Good Manufacturing Practice) compliance by applicants and/or subcontractors.

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 all 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** (please check carefully the layout of the documents uploaded).

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

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

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

6. Eligibility

Eligible participants (eligible countries)

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

– be legal entities (public or private bodies)

- be established in one of the eligible countries, i.e.:
  - EU Member States (including overseas countries and territories (OCTs))
  - eligible non-EU countries:
    - listed EEA countries and countries associated to the EU4Health Programme (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)*.

For the participation of associated partners, the rules on eligible countries apply as laid down in the present section, subsection 'eligible participants' of this call.

Specific cases and definitions

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[11].

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'[12]. ⚠ 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 entities subject to EU restrictive measures under Article 29 of the Treaty on the European Union (TEU) and Article 215

[11] See Article 200(2)(c) EU Financial Regulation 2024/2509.
[12] For the definitions, see Articles 190(2) and 200(2)(c) EU Financial Regulation 2024/2509.

of the Treaty on the Functioning of the EU (TFEU)[13]. 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).

EU conditionality measures — Special rules apply for entities subject to measures adopted on the basis of EU Regulation 2020/2092[14]. Such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties, etc). Currently such measures are in place for Hungarian public interest trusts established under the Hungarian Act IX of 2021 or any entity they maintain (see Council Implementing Decision (EU) 2022/2506, as of 16 December 2022).

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

Consortium composition

Proposals can be submitted either by a single applicant or a consortium (no minimum requirement).

Eligible activities

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 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)*. Projects must also respect EU values and European Commission policy regarding reputational matters (*e.g. activities involving capacity building, policy support, awareness raising, communication, dissemination, etc*)[15].

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

- **EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products:** Projects should range between 24 months and 48 months.
- **EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits:**

[13] 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.

[14] Regulation (EU, Euratom) 2020/2092 of the European Parliament and of the Council of 16 December 2020 on a general regime of conditionality for the protection of the Union budget (OJ L 325, 20.12.2022, p. 94).

[15] See, for instance, Guidance on funding for activities related to the development, implementation, monitoring and enforcement of Union legislation and policy.

Projects should be maximum 24 months. Projects of longer duration (up to a maximum of 48 months) are possible, if duly justified by the nature and expected duration of the proposed activities.

- **EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis:** Projects should be maximum 24 months. Projects of longer duration (up to a maximum of 48 months) are possible, if duly justified by the nature and expected duration of the proposed activities.
- **EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA):** Projects should range between 36 months and 48 months.

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

Project budget

Project budgets (requested grant amount) are expected to be as described in the table below:

Topic	Project budgets (requested grant amount)
EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products	**Between EUR 5 500 000 and EUR 9 000 000**
EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits	**EUR 1 000 000**
EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis	**EUR 1 000 000**
EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)	**Between EUR 3 300 000 and EUR 5 000 000**

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

Ethics

Projects must comply with:

- highest ethical standards and
- applicable EU, international and national law (including Directive 2005/28 on investigational medicinal products for human use[16] and Regulation 536/2014

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

on clinical trials on medicinal products for human use[17]).

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

Security

Projects involving EU classified information must undergo security scrutiny to authorise funding and may be made subject to specific security rules (detailed in a security aspects letter (SAL) which is annexed to the Grant Agreement).

These rules (governed by Decision 2015/444[18] and its implementing rules and/or national rules) provide for instance that:

- projects involving information classified TRES SECRET UE/EU TOP SECRET (or equivalent) can NOT be funded
- classified information must be marked in accordance with the applicable security instructions in the SAL
- information with classification levels CONFIDENTIEL UE/EU CONFIDENTIAL or above (and RESTREINT UE/ EU RESTRICTED, if required by national rules) may be:
  - created or accessed only on premises with facility security clearance (FSC) from the competent national security authority (NSA), in accordance with the national rules
  - handled only in a secured area accredited by the competent NSA
  - accessed and handled only by persons with valid personnel security clearance (PSC) and a need-to-know
- at the end of the grant, the classified information must either be returned or continue to be protected in accordance with the applicable rules
- action tasks involving EU classified information (EUCI) may be subcontracted only with prior written approval from the granting authority and only to entities established in an EU Member State or in a non-EU country with a security of information agreement with the EU (or an administrative arrangement with the Commission)
- disclosure of EUCI to third parties is subject to prior written approval from the granting authority.

Please note that, depending on the type of activity, facility security clearance may have to be provided before grant signature. The granting authority will assess the need for clearance in each case and will establish their delivery date during grant preparation. Please note that in no circumstances can we sign any grant agreement until at least one of the beneficiaries in a consortium has facility security clearance.

Further security recommendations may be added to the Grant Agreement in the form of security deliverables *(e.g. create security advisory group, limit level of detail, use fake scenario, exclude use of classified information, etc)*.

[17] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

[18] See Commission Decision 2015/444/EU,Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

Beneficiaries must ensure that their projects are not subject to national/third-country security requirements that could affect implementation or put into question the award of the grant *(e.g. technology restrictions, national security classification, etc)*. The granting authority must be notified immediately of any potential security issues.

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 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.

Where the application concerns a grant for which the amount exceeds EUR 750 000 per beneficiary, an audit report that is 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 the last two available financial years, must be part of the application. In all other cases, the applicant shall provide a self-declaration signed by its authorised representative certifying the validity of its accounts for the last two available financial years.

The check will normally be done for all beneficiaries, except:

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

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

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

- further information
- an enhanced financial responsibility regime, i.e. joint and several responsibility for all beneficiaries or joint and several liability of affiliated entities *(see below, section* 10)
- prefinancing paid in instalments
- (one or more) prefinancing guarantees (see below, section 10)

or

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

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) *(template available in Part B)*.

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[19]:

- 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[20] (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)

[19] See Articles 138 and 143 of EU Financial Regulation 2024/2509.

[20] 'Professional misconduct' includes, in particular, the following: violation of ethical standards of the profession; wrongful conduct with impact on professional credibility; breach of generally accepted professional ethical standards; false declarations/misrepresentation of information; participation in a cartel or other agreement distorting competition; violation of IPR; attempting to influence decision-making processes by taking advantage, through misrepresentation, of a conflict of interests, or to obtain confidential information from public authorities to gain an advantage; incitement to discrimination, hatred or violence or similar activities contrary to the EU values where negatively affecting or risking to affect the performance of a legal commitment.

- shown significant deficiencies in complying with main obligations under an EU procurement contract, grant agreement, prize, expert contract, or similar (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- guilty of irregularities within the meaning of Article 1(2) of EU Regulation 2988/95 (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin or created another entity with this purpose (including if done by persons having powers of representation, decision-making or control, beneficial owners or persons who are essential for the award/implementation of the grant)
- intentionally and without proper justification resisted[21] an investigation, check or audit carried out by an EU authorising officer (or their representative or auditor), OLAF, the EPPO, or the European Court of Auditors.

Applicants will also be rejected if it turns out that[22]:

- 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) 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 — Project design and implementation' and then for the criterion 'Quality — Project team and cooperation arrangements'.

[21] 'Resisting an investigation, check or audit' means carrying out actions with the goal or effect of preventing, hindering or delaying the conduct of any of the activities needed to perform the investigation, check or audit, such as refusing to grant the necessary access to its premises or any other areas used for business purposes, concealing or refusing to disclose information or providing false information.

[22] See Article 143 EU Financial Regulation 2024/2509.

2) 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.

3) 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. Proposals under topics EU4H-2025-HERA-PJ-1-a, EU4H-2025-HERA-PJ-1-b, EU4H-2025-HERA-PJ-1-c and EU4H-2025-HERA-PJ-2 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. Full 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 activities; extent to which the proposal matches the priorities and objectives of the call/topic; contribution to the EU strategic and legislative context; European/trans-national dimension; 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, timetable, risks' identification and mitigation, monitoring and evaluation); feasibility of the project within the proposed time frame; cost effectiveness and financial management (sufficient/appropriate budget for proper implementation;) (30 points)

   - **Project team and cooperation arrangements:** quality and complementarity of the consortium and project teams; appropriate

management procedures and problem-solving mechanisms for cooperating within the project teams and consortium (30 points)

3. **Impact:** ambition and expected impact of results on target groups/general public; appropriate communication and dissemination strategy for ensuring sustainability and maximise 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

Specific mandatory deliverables and/or milestones per topic:

EU4H-2025-HERA-PJ-1-a — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Medicinal products

Deliverables:

- (Platform and/or Therapeutic) Development Plan
  - Building upon the submitted proposal, this report should outline the following:
    - Initial use case of the proposed solution, which should focus on one or several CBRN threat(s) targeted by this call[23].
    - General overview of the platform expected characteristics, with a focus on its versatility and threat-agnostic design and/or expected therapeutic properties, including its potential adaptability/reconfigurability for threats other than the initial use case. Additionally, this report should also compare the product's characteristics/properties against current standard treatment option(s).
    - The solution's innovative aspects or its potential to enhance access and accessibility and accessibility to treatment, for instance through enhanced formulation, easier-to-use delivery systems, fewer specific storage conditions, clear pathway to market or other attributes.

[23] For this topic, the applicants should focus on the following CBRN threats, based on the Commission's current gap analysis and factoring the topics covered by past and current calls:

Chemical agents:

- Ricin
- Abrin
- *Clostridium perfrigens* epsilson toxin
- Shigatoxins
- Saxitoxins
- Tetrodotoxins
- Trichothecenes
- *Clostridium botulinum* toxin
- Other emerging chemical threats understood as newly developed or recently identified substances, naturally occurring or synthetic, that can cause harm to human health due to acute or short-term exposure will be equally considered. For the purpose of this topic, this category includes novel synthetic chemicals with toxic effects and industrial compounds repurposed for harmful uses, with clearly documented potential for misuse or weaponisation.

Biological agents:

- Poxviruses
- Bacillus anthracis
- Francisella tularensis
- Yersinia pestis
- Other emerging biological threats referring to infectious diseases caused by pathogens that are newly identified, have recently evolved new characteristics, or have gained the ability to cause greater harm to humans will be equally considered. Specifically, under this topic, this includes only pathogens where direct human intervention has led to these changes in characteristics and ability, or where there is clearly documented potential for weaponisation or malicious use.

Radionuclear agents requiring either treatments against acute radiation syndrome or decorporation agents after exposure.

        - Technology Readiness Level (TRL)[24] of the proposed solution at project inception, and TRL expected at the end of the project. It is to note that at least TRL 3 must be reached before the project inception. The report should outline how the project's activities will result in TRL advancement from the initial level (ranking from 3 to 6) to a minimum of one level higher, preferable two or more levels.
    - This report should be submitted during the initial stages of the project and updated upon completion to detail the progress achieved throughout its implementation.

- Prototype Validation and Characteristics Report
    - This report should outline the functionality of the prototype against the targeted threat(s) following the development activities. Where applicable, and based on preliminary data, a draft report may be submitted at mid-implementation.
    - If clinical study(ies)/trial(s) are not foreseen, this report must also include any relevant scientific data and outputs resulting from the project's activities.

- Versatility, Adaptability, and Scalability Plan
    - This report should detail the platform or therapeutic's mechanism for adaptation to threats other than the initial use case and underlying technology, such as genetic sequence input, antigen modularity, toxin structures, or others.
    - Moreover, this report should also include an assessment of the manufacturing scalability of the proposed solution, including (where relevant) quality control processes and GMP-readiness.
    - Characteristics/properties relevant for market access and availability, whether achieved or predicated, must also be included. These can include, for instance, formulation, dosage form, delivery method, shelf-life, storage conditions, including special logistic requirements, such as the need for cold chain.

- Security and Safety Report
    - Short report detailing how biosecurity risks and dual use concerns of the developed solution have been addressed and mitigated, and how these biosecurity risks, dual use concerns, and any ethical implications of the research will be addressed moving forward.

- Regulatory and Market Access Plan
    - Depending on the final stage of development reached during the project, this report must include an overview of the regulatory steps taken or planned towards achieving EU approval of the developed prototype.
    - Moreover, the report must also include an overview of the EU market availability of the developed solution. It should address the specific business challenges associated with the development of this (these) niche product(s) and present a market viability plan, including any potential challenges for market sustainability of the solution in the EU, such as (but not limited to):

[24] For the purpose of this call, TRL definitions for Horizon 2020/Europe apply.

- support with market authorisation fees,
- need for regular purchases by authorities,
- need for further investment, and
- medium-term planning for procurements of the solution.

Milestones:

- Minimum viable product (MVP) achieved or Product validated in a clinical study/trial (e.g. safety and efficacy)

If the project includes clinical study(ies) or trial(s), the following milestones deliverables must also be submitted (per clinical trial/study):

Deliverables:

- Ethical/Regulatory Submission Package
  - Including registration of the clinical study preferably in CTIS, or in another WHO-compliant registry, final version of the study protocol, and regulatory and ethics approval for the enrolment of the first study participant.
- Mid-term recruitment
  - Report when 50% of volunteers have been recruited for the clinical study/trial.
- Clinical Study/Trial Results
  - Contingent on the development plan, preliminary data should be present at mid-term reporting and subsequently updated by the final reporting period.

Milestones:

- First participant enrolled
- Midterm recruitment achieved
- Final follow-up completed

EU4H-2025-HERA-PJ-1-b — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Reusable respiratory personal protective equipment (PPE) and protection suits

Deliverables:

- Attributes & Development Plan
  - This document should outline how the expected product to be developed addresses one or more of the desirable attributes, including the following:
    - For reusable respiratory PPE – UV- and/or disinfection and reprocessing protocols compatible with standard hospital equipment; increased comfort wear compared to current solutions (e.g. use of lightweight or heat-dissipating materials), better breathability, universal fit without need for fit-testing (≥ 95% adult population), and fit maintenance during extended usage.
    - For protection suits – ability to be used in environments with temperatures up to 40.º Celsius, use for up to 50 6-hour shifts without affecting performance, easy use in healthcare settings and/or by other essential workers (e.g. first responders), better breathability and

thermal comfort, with incorporated leakage detection and/or fit assurance technologies (e.g. sensor integration), with low risk of self-contamination during doffing, availability in sizes that can cover ≥ 95% adult population without fit-testing, and fit maintenance during extended usage.
    - For both – easily scalable, EU-based production and suppliers, including for components and raw materials (supply chains), long shelf-life, simple storage requirements (both on technical and space requirements), and innovative manufacturing processes (e.g. automation-based)
  - Furthermore, this document should also outline any plan regarding development of protocols for the use of developed solution in real-world environments.
  - Finally, this plan must include an outline of the proposed solution validation plan, including eventual performance testing, both in controlled or real-world environments, and/or clinical studies.

- Development & Validation Study(ies) Results
  - This document must outline the outputs of any clinical studies or equivalent development and/or validation activities, such as performance testing, stress tests, fit testing, among others.

- Manufacturing, Stockpiling, and Market Report
  - Informed by the "Attributes & Development Plan", this report should include an overview of manufacturing and stockpiling requirements at the end of development, including expected production and storage costs, and pricing.

- Regulatory Compliance Report
  - This report should include any taken or envisioned regulatory steps towards CE certification of developed prototype by the end of the project, including an overview of relevant applicable legislation, a conformity assessment plan, costs for certification and certification maintenance in medium and long-term, and expected challenges and mitigation measures proposed.

EU4H-2025-HERA-PJ-1-c — Call for proposals to support the development of innovative medical countermeasures for chemical, biological, radiological and nuclear threats (HERA) - Detection and diagnosis

- Development Plan
  - This document should include an overview of the initial stage and expected final stage of development and detail expected analytical and/or clinical studies to be conducted, including any testing protocols.
  - This plan should also include a list of expected use-case CBRN threats[25] to be targeted by proposed solution and development activities performed

[25] For this topic, the applicants should focus on the following CBRN threats, based on the Commission's current gap analysis and factoring the topics covered by past and current calls:
Chemical agents:
- Ricin
- Abrin
- *Clostridium perfrigens* epsilson toxin
- Shigatoxins

prior to the project start and resulting and/or expected characteristics to be achieved following the project's implementation (e.g. sensitivity, specificity, number of targeted agents, time-to-result, etc).
    - A highlight of innovative features compared to existing solutions should also be included, especially on desirable attributes, such as ability to be deployed in the field for the prompt and accurate clinical identification of threats, time-to-result ≤ 6 hours, use of next-generation biosensors (such as antigen test-based platforms), user-friendly testing workflows and reporting tools, ability to be used by non-healthcare workers, and optimized to be used in mobile laboratory environments.

- Prototype/Device Specification Report
    - An overview of the technical specifications of developed prototype/device should be provided at the end of the project. Furthermore, it should also inform on relevant design and manufacturing information.

- Analytical and Clinical Performance Report
    - The report shall summarize the test diagnostic's analytical and clinical performance, including sensitivity, specificity, reproducibility and comparison with different biological matrices (if applicable), and current standard-of-care methods. Interim and final clinical results should be included and stratified by the relevant biological and/or chemical agent.

- Regulatory Compliance Report
    - This report should include any taken or envisioned regulatory steps towards CE certification of developed prototype by the end of the project, including an overview of relevant applicable legislation, a conformity assessment plan, costs for certification and certification maintenance in medium and long-term, and expected challenges and mitigation measures proposed.

Milestones:

- Prototype ready for real-world testing
- Analytical performance testing completed
- Regulatory approval submission dossier started

- Saxitoxins
- Tetrodotoxins
- Trichothecenes
- *Clostridium botulinum* toxin

Biological agents:

- Poxviruses
- Bacillus anthracis
- Francisella tularensis
- Yersinia pestis
- Other emerging biological threats referring to infectious diseases caused by pathogens that are newly identified, have recently evolved new characteristics, or have gained the ability to cause greater harm to humans will be equally considered. Specifically, under this call, this includes only pathogens where direct human intervention has led to these changes in characteristics and ability, or where there is clearly documented potential for weaponization or malicious use.

EU4H-2025-HERA-PJ-2 — Call for proposals for the development of new diagnostic tests for vector-borne diseases (HERA)

Deliverables:

- Initial Assay Design Report. The report shall provide a technical overview of the diagnostic tests concept, including novel features, feasibility data, and intended use context (e.g., multiplex capacity, sample type, turnaround time).
- EU Regulatory Strategy Report. The report shall include an overview of the planned approach towards CE-marking under IVDR; Performance Evaluation Plan, including timelines for consultation or conformity assessment (can be indicative, not binding).
- Clinical study / Trial package (if applicable). Including registration of the clinical study preferably in CTIS, or in other WHO-compliant registry, final version of the study protocol, and regulatory and ethics approval for the enrolment of the first study participant.
- Manufacturing and Scalability Plan. The plan shall address production capacity, quality systems, and potential for rapid scale-up in response to outbreak scenarios.
- Accessibility, Affordability, and Sustainability Strategy. The strategy shall summarise how the developed prototype/product could be made accessible and affordable in low-resource settings within the EU, and how its long-term use and market entry could be supported.
- Analytical and Clinical Performance Report. The report shall summarize the diagnostic test's analytical and clinical performance, including sensitivity, specificity, reproducibility and comparison with current standard-of-care methods. Interim and final clinical results should be included and stratified by disease/pathogen.

Milestones:

- Study protocol(s) submitted to the relevant local regulatory and/or ethics authorities, confirming the initiation of the approval process.
- Prototype design finalised, including the confirmed specifications and core specifications of the diagnostic product.
- Analytical validation studies completed, demonstrating test performance characteristics such as sensitivity, specificity, and reproducibility.
- (If applicable) Midpoint enrolment for clinical performance studies achieved.

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)*.

Requested 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 (or EU4H associated countries) whose GNI per inhabitant is less than 90% of the EU average or

- actions with bodies from at least 14 Member States (or EU4H associated countries) and where at least four are from Member States (or EU4H associated countries) 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
- D. Indirect costs

Specific cost eligibility conditions for this call:

- personnel costs:
  - SME owner/natural person unit cost[26] : Yes
- travel and subsistence unit cost[27]: Yes[28]
- equipment costs: depreciation

[26] 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).

[27] 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).

[28] See EU Grants AGA — Annotated Grant Agreement, art 6 on eligible costs: travel and subsistence costs must be declared using the unit cost according to Annex 2a of the grant agreement. If a particular instance of travel, accommodation or subsistence in the action is not covered by one of the unit costs mentioned in Decision C(2021)35 the actual costs may be used.

- 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/non-refundable 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 *(e.g. acquiring domain name, personal costs for feeding and maintaining the website during the project, etc)*; costs for *separate* project websites are not eligible
  - EU Synergies call: No
  - other ineligible costs: Yes, costs for infrastructure and land purchase.

Reporting and payment arrangements

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

After grant signature, you will normally receive a **prefinancing** to start working on the project (float of normally **50%** of the maximum grant amount; exceptionally less or no prefinancing). The prefinancing will be paid 30 days from entry into force/10 days before starting date/financial guarantee (if required) — whichever is the latest.

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

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

All payments will be made to the coordinator.

⚠ Please be aware that payments will be automatically lowered if you or 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

Consortium agreement: Yes

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 Calls for proposals 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 may 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
- Topic Q&A 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). If affiliated entities participate in your project, please do not forget to provide documents demonstrating their affiliation link to your organisation as part of your application.
- **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; 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.