



EU4HEALTH 2021 WORK PROGRAMME

Summary of the call for proposals (EU4H-2021-PJ4)
on supporting a HERA laboratory network

*Ana Burgos Gutierrez and Jean-Baptiste Perrin (HERA)
EU4Health 2021 Info Session on action grant
10 June 2022*

HERA – Background information

- 16 September 2021: Decision 2021/C 393 I/02 establishing the **Health Emergency Preparedness and Response Authority** (DG HERA)
- Overarching mission: improve EU preparedness and response to serious cross-border threats in the area of medical countermeasures (MCM)
- Tasks:
 - Assessment of health threats and intelligence gathering on MCM
 - Promoting R&D on MCM and related technologies
 - Addressing market challenges and boosting EU strategic autonomy
 - Procurement, distribution, stockpiling of MCM
 - Knowledge and skills in MCM preparedness and response
- Budget: €6Bn 2022-2027

From existing EU funding programmes: Horizon EUROPE, EU4Health, RescEU

Duration, budget, funding rate, maximum grant amount

CP-g-06.5 Call for proposals: supporting a HERA laboratory network 2021 EU4Health Work Programme - EU4H-2021-PJ4

Project duration:

- Recommended : 48 months (extension possible if duly justified)

Budget:

- EUR 25,000,000

Co-funded by the EU

Policy context

- Challenges in tackling COVID-19 crisis
 - Early detect and warn on emerging health threats from outside the Union;
 - Fragmented involvement in global surveillance, and access to surveillance results and relevant biological samples from third countries;
 - Paucity and lack of comparability of scientific data;
 - Translation of scientific data (e.g. biological characterisation) into operational recommendations on medical countermeasures for prevention and treatment
- Network of laboratories and research institutes to address these challenges, and support HERA intelligence gathering in the area of health threats and related medical countermeasures

Objectives and scope

- Establish a pilot network of laboratories and research institutes that have critical expertise and capacities to support HERA in
 - identifying emergent pathogens and
 - ensuring the availability of medical countermeasures
- One Health approach
 - Gathering information across one health sectors (human, animal & environmental health) to rapidly identify potential threats to health
 - Ensure coordinated preparedness and response accord one health sectors, in term of medical countermeasures

Objectives and scope

- Coordination of activities with existing laboratory networks
 - Laboratory networks under the EU network for epidemiological surveillance
 - Upcoming **EU reference laboratories** to be established under Article 15 of the SCBTH Regulation
 - Close collaboration with ECDC, in accordance with its future extended mandate
- Tasks in both **preparedness** and **emergency time**

Mandatory deliverables – preparedness time

- Establishing the network :
 - governance and sustainability plan
 - procedures (for preparedness and emergency times)
 - interoperable IT infrastructure, including machine learning/AI tools, allowing for secure messaging and timely notification of laboratory results
- Training to network members
- Mechanisms for rapid data sharing, integration and comparability within the network + interoperability with national & international level + HERA IT Platform
- Contribution to assessment of health threats and intelligence gathering relevant to medical countermeasures

Mandatory deliverables – preparedness time

- Global access to biological samples & characterization of emerging pathogens
 - Isolation and biological analysis of biological health threats arising at global level
 - Support individual modelling scenarios of the spread and impact of such pathogens
 - Conduct serology and immunological studies to understand population immunity
 - Use results of biological characterisation for forecasting
- *Close collaboration with ECDC/WHO EURO sero-epidemiological surveillance*
- Rapid identification and assessment of relevant diagnostic, preventive, protective and therapeutic medical countermeasures, existing and under development
 - Assess effectiveness, sensitivity, cross-protection for a given pathogen,
 - Inform development needs for medical countermeasures, including diagnostics

Mandatory deliverables – preparedness time

- Enhance global cooperation, e.g. by promoting global network of laboratories and relevant entities to
 - Strengthen third countries epidemic intelligence and laboratory capacities
 - Exchange relevant surveillance data, information and samples with third countries
- Cooperation with existing laboratory networks
 - Laboratory networks under the EU network for epidemiological surveillance
 - Upcoming EU reference laboratories to be established under Article 15 of the SCBTH Regulation

Mandatory deliverables – emergency time

- Ensure rapid testing, timely notification, and secure messaging of laboratory results to relevant decision-makers by collecting threat-specific epidemic intelligence on the ongoing threat.
- Collect further threat-specific biological samples, carry out specific emergency studies on the concerned pathogen, including biological characterisation (see above).
- Provide or advise on specific medical countermeasures options for diagnosis, prevention and treatment and launch emergency studies and develop actions on the relevant MCM identified where needed (including medical countermeasures effectiveness assessment).
- Provide ad-hoc in-country response support (under the wider umbrella of the EU's health response, e.g. the 'EU's Health Task Force' as per the proposal to extend the mandate of the ECDC)

Mandatory deliverables – expected activities

- List of procedures for network establishment and operation
- List of procedures to ensure data sharing
- Simulation-based activities to test procedures
- Communication activities on objectives and results towards general public
- Bi-annual reports
- Ad-hoc reports, studies and advice

- Developing a **blueprint** concerning the sustainable establishment of the network, including tangible non-high level policy recommendations (scope, option for institutionalisation,) to be delivered 6 months before end of project

Specific action-level indicators for reporting purpose

- EU Laboratory capacity with global reach to support preparedness
- Effective procedures and processes allowing for rapid sharing of information between the network and with relevant public health authorities
- Accurate biological characterisation of health threats at EU and global level
- Medical countermeasures effectively identified and assessed in connection with an existing or new pathogen
- Number of reports, studies and advice provided as part of the regular or ad-hoc activities
- Global samples adequately made accessible by the network
- Average time of response and sharing of information

Expected impact and outcomes

- The projects under this topic should contribute towards the following expected outcomes:

Establishment of a laboratory network of one or more existing EU laboratories with broad global coverage

Extend and reinforce the global outreach of the pilot network by sharing of relevant data and analysis, and providing advice, reports, country support missions

dedicated assessments of health threats and intelligence gathering related to medical countermeasures to support HERA

Established key procedures, infrastructure, resources and policies for preparedness and emergency time

Enhanced medical countermeasures preparedness to timely and efficiently respond to future cross-border health threats

Short-term

Long-term

Thank you for your attention Questions?

HERA-02

Jean-Baptiste Perrin jean-baptiste.perrin@ec.europa.eu

Ana Burgos Gutierrez ana.burgos-gutierrez@ec.europa.eu