



HERA HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY

#HealthUnion

EUROPEAN HUB FOR VACCINE DEVELOPMENT

CALL FOR PROPOSALS EU4H 2024

HERA



- **Past pandemics:** vaccines and other MCMs short, long lead times – global race
- Covid19 → **HERA creation** 2021: contribute to the development, manufacturing, procurement and distribution of medical countermeasures: medicinal products Vx, Tx, medical devices, in vitro diagnostic devices, Personal Protective Equipment ('PPE') and other health technologies
- **Consequence:**
 - * support technologies to ensure a rapid response in case of emergency - incl **prototype vaccines**
 - * bundle existing **excellence** and expertise at Union level and link it with international initiatives.
- A **decentralised** European **hub** for vaccine development to bundle critical knowledge, expertise and experience in vaccine development and combine it with capacities for clinical trials.
- **Vaccine prototypes** to speed up bringing innovative medical countermeasures to the market and contribute to scaling of production and equal distribution of vaccines in case of need.

- Budget EU: 102 M euro
- Grants: 1
- Duration: 48 months
- 60/80%

- enhance crisis preparedness and response for future health emergencies with a focus on **priority pathogens** with pandemic potential
- improving the **availability, accessibility and affordability** of crisis relevant products - VACCINES

- **Create a European Hub for public health relevant vaccine development, combining excellence in vaccine development with clinical trials and activities for scaling manufacturing**
- **Consortium** of developers of vaccines with **expertise** in product development (publicly funded and industrial organisations targeted)
- The EVH will
 - Draft a **strategic vaccines plan** for Europe
 - Create **vaccine prototypes** in particular for priority pathogens with epidemic and pandemic potential
 - Develop **state-of-the-art technologies** (adaptation, speed, ...)
 - prepare relevant master **clinical trial protocols**
 - reach out to clinical trial capacities/networks and at **scale production initiatives** at national and European levels (synergies, alignment)

- The EVH should:
 - a) Develop and implement a pandemic vaccines readiness plan (in coordination with the future European Partnership on Pandemic Preparedness).
 - b) Develop pandemic vaccines candidates for agreed pathogens up to phase 2. Collaboration with European Research Infrastructures expected.
 - c) Ensure rapid delivery of vaccine candidates for trial and mass production to manufacturing partners, including those covered by EU FAB or similar national contracts or other relevant capacities.
 - d) Optimise digitalisation of discovery, development and production technologies of vaccines.
 - e) Organise clinical evaluation of candidate vaccines including in Phases I and II and the appropriate use of controlled infection facilities. Contribute to the EPPartnership's "ever-warm" clinical trials system for vaccines (and antibodies) ready, audited and tested. Provide trainings for all aspects around optimisation of clinical trials organisation.
 - f) Implement a system of study laboratories to develop and implement relevant biological, pre-clinical and clinical assays, in full respect of industrial standards.
 - g) Set up shared, ready-to-use and scalable state of the art technology platforms covering all phases of vaccine development
 - h) Prepare and support technology transfers among EU partners and other eligible entities. Implement a capacity to audit processes and functions among partners to ensure a state-of the art preparedness level.
 - i) Perform stress tests of pandemic vaccine production, including critical supply chains. Develop standard, enforceable contractual agreements relevant for vaccine readiness and access for crisis situations.
 - j) Develop a system for inclusive and safe data sharing within the consortium and with external entities.
 - k) Develop strong links with leading international partners

- a) improve preparedness and early response to health emergencies;
- b) to increase the availability and uptake of public health relevant MCMs (vaccines and antibodies);
- c) to contribute to the availability of preventive measures to slow the spread of selected pathogens;
- d) to reduce strategic dependencies, expand Europe's competitiveness and strategic autonomy in the field of vaccine research and development.

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Thank you!