



## Meeting of Member States representatives on the HorizonEurope Partnership on pandemic preparedness

### Please:

- **Keep your microphone muted and your camera off during the meeting**
- **How to ask questions or the floor?**
  - **Use the chat function**
  - **Unmute your micro only when the chair invites you to take the floor**
  - **Do not use the chat function to start discussions**



# Draft agenda



10:00

## 1. Welcome and Introduction

- [REDACTED] 5.1.2e [REDACTED] 5.1.2e [REDACTED] 5.1.2e

10:30

## 2. the COVID19 Pandemic – HERA and HERA Incubator

- [REDACTED] 5.1.2e [REDACTED] 5.1.2e
- [REDACTED] 5.1.2e [REDACTED] 5.1.2e [REDACTED] 5.1.2e

10:45

## 3. Towards the proposed partnership on pandemic preparedness

- [REDACTED] 5.1.2e
- [REDACTED] 5.1.2e

12:00

## 4. Discussion

12.30

## 5. End of the meeting





# 1. Welcome and Introduction





## **2. COVID-19 Pandemic – HERA and HERA Incubator**





# Health Emergency Preparedness and Response Authority

# HERA

5.1.2e

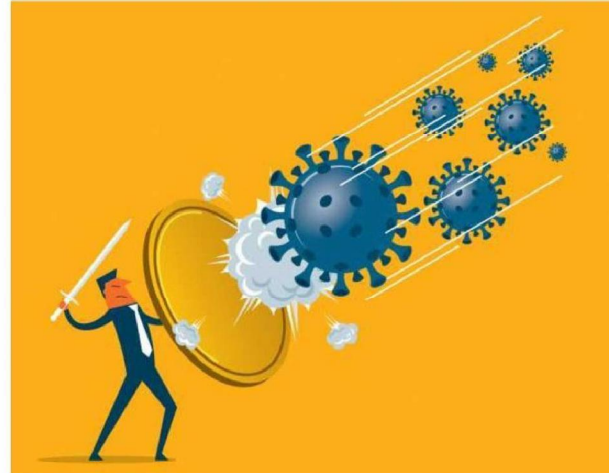
5.1.2e

C.3



## SOTEU 2020 – President von der Leyen

- We need to build a **stronger European Health Union**
- Opportunities for **strengthening EU preparedness and response** to serious cross-border health threats
- Set up a “**European BARDA**” – an agency for biomedical advanced R&D to support capacities and readiness for response



<https://www.eppgroup.eu/newsroom/publications/a-european-solidarity-pact-against-the-coronavirus-pandemic>





## 11 Nov 2020 – Building a European Health Union

- Pandemic has revealed **structural weaknesses**, such as:
  - Weak or suboptimal preparedness plans and modelling
  - Fragmentation of efforts in the EU
  - Market failures and lack of medical countermeasures
  - Vulnerabilities in global supply chains
  - Insufficient oversight of manufacturing capacities and research priorities
- A comprehensive **EU Health Security Framework** is in place (e.g. Decision 1082, EWRS, HSC, ECDC, EMA, Joint Procurement)
- But there is need for strengthened **EU coordination** to improve **preparedness and response** capability





## EU Health Emergency Preparedness & Response Authority (HERA)

- **Mission:** Enable the EU and its MS to rapidly deploy the most advanced medical and other measures in the event of a health emergency
- Assembly of **ecosystems of public and private capabilities**
- This will be done by covering the **whole value chain** and by providing **end-to-end solutions**

*Flexible and resourced financing & procurement capacities*



**Knowledge generation:** horizon scanning, market intelligence, foresight

**Development:** late stage research, innovation and development

**Production:** flexible and scalable manufacturing capacities

**Deployment:** EU level stockpiling and distribution

**Use:** training programmes





## R&D as part of HERA

- Research and Development needs across the whole value chain
- For example:
  - Horizon scanning and foresight to anticipate specific threats and enable technologies
  - Identifying promising potential countermeasures and underpinning competencies
  - Development of specific counter measures (e.g. through clinical trials and data infrastructures)
  - Development of cross-cutting technologies and solutions (e.g. application of AI or digital tools)
  - Identifying innovative ways of pooling production capacity and development facilities
  - Providing solutions for supply chain vulnerabilities
  - ...





## Timeline and next steps

### • Inception Impact Assessment

- Feedback period 27 Jan 2021 – 24 Feb 2021 (midnight Brussels time)
- Presentation of several policy options
- Feedback will be taken into account for further development and fine tuning of the initiative



### • Legislative proposal: 2021

### • Preparatory actions: launch in 2021

- Piloting HERA
- E.g. HERA Incubator, AMR, vaccine and drug R&D, climate change and (re)emerging diseases

### • HERA to be operational: 2023





## HERA Incubator

- 17 Feb – Commission Communication
- Launch of a new EU bio-defence preparedness plan against COVID-19 variants
- Key actions to boost preparedness, develop vaccines for the variants and increase industrial production
- The HERA Incubator will also serve as a blueprint for the EU's long-term preparedness for health emergencies





## HERA Incubator – Focus on 5 key action areas

### Rapid detection of new variants

- Sequencing capacities
- Exploring use of detection assays
- Data sharing and exchange
- Wastewater monitoring
- Support to low income countries

### Swift adaptation of vaccines

- Bringing together research and evidence on VOC
- Aligning research with existing/new vaccines and their technologies
- Vaccine development for children and adolescents

### Setting up a EU Clinical Trials network

- Launch of VACCELERATE
- Ensure MS involvement
- Streamline the process between clinical trials and the regulatory approval process

### Fast tracking of regulatory vaccine approval process

- Amending the regulatory procedure to accelerate vaccine approval
- Amending EU pharmaceuticals legislation
- Ensuring support to manufacturers

### Upscaling of vaccine production and swift delivery

- Creating the "EU-FAB" project
- Mapping of potential bottlenecks of vaccine production
- Exploring use of flexible production models
- Providing capacity support
- Facilitate technology transfer
- APAs





## HERA Incubator – launched on 17 February

- Plans include important new research investments, mobilising
  - an additional €30 million from Horizon 2020
  - further €120 million from HorizonEurope.





## HERA Incubator – launched on 17 February

Horizon 2020 funding will support:

- the rapid establishment of a new EU-wide vaccine trial network called [VACCELERATE](#)
- boost capacities to track and analyse virus variants and to share data by reinforcing the [European COVID-19 Data Platform](#) and other existing research infrastructure projects and networks.
- Horizon Europe funding will complement this action by providing further support for open data sharing, cohorts studies and for clinical trials





## VACCELERATE

### Key objectives

- Single entry point for European stakeholders in vaccine development
- Contribute to public health knowledge in vaccine development for vaccination strategies
- Capacity mapping of clinical trial and laboratory sites, for individual phase 2 & 3 vaccine trials  
<https://www.euvap.eu/index.html>
- Capacity building to ensure high quality data output in sites across Europe
- Volunteer registries to facilitate recruitment of trial participants
- Access to laboratories, comprehensive standardised methods essential for Phase 2 & 3 trials
- Harmonised data collection, open data sharing and pooling of data for stronger analysis



## Vaccine clinical network – VACCELERATE

- Grant signed
- 26 partners in consortium, from 16 MS and 5 Associated Countries

DE	PL	TR
SK	AT	RS
PT	IE	IL
EL	DK	CH
FR	BE	NO
CY	NL	
ES	IT	
SE	LT	





### **3. Towards the proposed partnership on pandemic preparedness**





## European R&I Partnership on Pandemic Preparedness

- **Responds to request for better coordination from the ERAvsCorona Action Plan**
- **Objectives:**
  - improve the EU's preparedness to prevent, predict and respond to emerging infectious health threats
  - develop a Strategic Research and Innovation pandemic preparedness agenda with common objectives
  - Build a coherent European Research Area (ERA) in pandemic preparedness
- **Was discussed in:**
  - Shadow Health Cluster 1 meeting of 27 November 2020 and
  - HorizonEurope SPC meeting of 4 December 2020
- **Scope was limited to health threats** (focus can be revised or broadened later).
- **16 MS and 1 AC nominated representatives for the development of the partnership**





## Proposed activities of the partnership

### 1. Generate new scientific knowledge

- to better understand the pathogens (virus, bacteria, etc.), their characteristics and transmission, and their interaction with hosts and the environment;

### 2. Design and develop countermeasures, such as vaccines, diagnostics or therapeutics, personal protective equipment;

### 3. Improve evidence generation for public health policy decisions

- more agile public health response with scientific evidence, thus improving their quality and increasing trust
- developing tools & digital solutions to better monitor the spread of outbreaks and better model the impact of public health measures;

### 4. Support for setting up EU-wide infrastructures for improved

- data collection, timely translation of research findings into emergency response actions;
- increasing operational readiness of clinical trial sites across Europe.





## Process

### How:

- Quickly operational; co-programmed Partnership,
- supported by a CSA in Cluster 1 - 2021 and R&I actions in Cluster 1 - 2022
- Links with proposed Health Emergency Response Authority (HERA), ECDC and EMA, EU Health Security Committee, etc.

### Next steps:

- Refine list of participating Member States, identify possible leads
- Continue discussions in a further meeting





# 4. Discussion





## Questions for discussion

- What could you contribute to this partnership, what are the strengths that you could bring to further develop and/or build upon?
- What are your thoughts on the 4 areas of proposed activities?
- Would you be interested in taking an active leading role in the preparation of the partnership?
- Consider the synergies with the current Covid-19 response, the HERA incubator and HERA itself, and the need to align timelines.





# 5. End of the meeting

