

# Genomics-based support activities implemented by ECDC under HERA Incubator action area 1: Rapid detection of SARS-CoV-2 variants

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# The EU Health Emergency Preparedness and Response Authority (HERA)



- As part of the EU Health Union proposals of 11 November 2020, the European Commission proposed to set up a EU Health Emergency Preparedness and Response Authority (HERA)
  - Goal: to enable the EU and its Member States to rapidly deploy the most advanced medical and other counter measures, to ensure capacity and readiness to respond to cross-border threats and emergencies
  - Address gaps revealed by COVID-19 and previous serious cross-border threats to health, such as the flu pandemic H1N1 in 2009
  - Complement and create synergies with the work of existing EU Agencies, in particular ECDC and EMA
- On 16 September 2021, the European Commission put forward a legislative proposal for HERA

# HERA Incubator and Action Area 1

- In preparation of the formal establishment of HERA, several preparatory actions were launched in 2021 to serve as a blueprint for the EU's long term preparedness for health emergencies, and to pilot some of the aspects that will be covered by the new Authority
- On 17 February, the Commission launched 'HERA Incubator', a new EU bio-defence preparedness plan against SARS-CoV-2 variants
- HERA Incubator focuses on five specific action areas:
  1. Rapid detection of SARS-CoV-2 variants
  2. Swift adaptation of COVID-19 vaccines (investments in research and innovation)
  3. Setting up a European Clinical Trials Network (VACCELERATE)
  4. Fast tracking the regulatory approval process
  5. Ramping up industrial production of COVID-19 vaccines against variants of concern
- On 25 February, President Ursula von der Leyen announced that the EU would provide EUR 200 M to strengthen detection of variants and improve knowledge on how they are developing and spreading, under Action Area 1. More specifically, this funding would be used to invest in:
  - Whole genome sequencing (WGS), both shorter-term support for access to high-capacity WGS services, and longer-term support for national investments into WGS infrastructure for the public health laboratories as well as cross-border networking activities such as bioinformatics, standardisations, and training
  - In case of need, ensuring the swift development and deployment of specialised RT-PCR assays that are able to detect VOCs
  - Wastewater surveillance as a complementary data tool

# WGS and RT-PCR support activities in 2021 under HERA Incubator action area 1



- *Shorter-term support:* **Access to high-capacity WGS services** in a commercial laboratory (external contractor)
- *Medium-term support:* Cross-border capacity-building support programme for **bioinformatics training, twinning and WGS and RT-PCR standardisation**
- *Medium-to-longer term support:* Infrastructure support programme to **develop and/or enhance national WGS and RT-PCR infrastructure**

# Outsourced WGS support



- Immediate sequencing capacity is provided to EU/EEA countries and Western Balkans through access to a WGS service contract with an external contractor
- Services include shipping of RNA samples, cDNA synthesis, sequencing and basic bioinformatics

# Cross-border capacity-building support programme



- Capacity-building activities should include:
  - Laboratory support activities
  - Laboratory and bioinformatics training activities, including support to twinning
  - WGS and RT-PCR quality assurance and standardisation activities
  - RT-PCR assay development and validation

# National infrastructure support programme



- Aim: Supporting activities via the award of grants for action that directly lead to enhanced and/or improved national public health WGS and/or RT-PCR capacity
  - Implemented as call for proposals to enable a bottoms-up approach where countries specify their needs and the proposed solutions at the national level
  - Reimbursement rate 90% of the eligible costs, i.e. each country needs to finance 10% of the included activities
  - Equipment purchase costs: Not normally eligible for reimbursement under such grants, but costs exceptionally fully eligible due the nature of the programme
- On 3 September 2021, ECDC allocated 77.1 M to 24 national projects

# Overview of ECDC-led activities under HERA Incubator action area 1 (2021-2024)



Access to high-capacity, rapid turn-around time WGS services

National WGS and RT-PCR infrastructure projects

Cross-border capacity-building support programme

2021

2022

2023

2024



# Wastewater surveillance



- Also part of HERA Incubator Action Area 1, but responsibilities for activities delegated to Joint Research Centre (JRC) instead of ECDC
- JRC is coordinating network of national initiatives on wastewater surveillance
- Agreement to support collaboration between initiatives, initially by sharing contact information between national HERA Incubator WGS grants and national wastewater surveillance initiatives

# Questions?