

# Information session

8 April 2021 - 14.00-16.30

*This information session is by invitation only. It will be recorded and available after the event.*

*Questions can be sent after the session via email [RTD-HEALTH-INFODAY@ec.europa.eu](mailto:RTD-HEALTH-INFODAY@ec.europa.eu)*

*Disclaimer: The information presented in the slides is indicative; applicants must refer to the official call documents on the EC's Funding and Tenders website <https://ec.europa.eu/info/funding-tenders/opportunities/portal>*



# Horizon Europe: Focused actions in ‘Research infrastructures’ and ‘Health’ to target COVID-19 variants



# AGENDA

**Welcome**

**Key messages**

**Presentations of the Health topics**

**Presentations of the Research Infrastructure topics**

**Q&A on the 4 topics**

**Q&A - How to submit a proposal**

**End of the meeting**

# Welcome & key messages



Irene Norstedt, Director,  
Directorate D – People,  
DG Research and  
Innovation (DG R&I),  
European Commission



John Ryan, Director,  
Directorate C – Public  
health, DG Health and  
Food Safety (DG SANTE)  
DG European  
Commission



Anna Panagopoulou,  
Director, Directorate A –  
ERA & Innovation, DG  
Research and Innovation  
(DG R&I), European  
Commission

# Presentation of the topics

1. Cohorts united against COVID-19 variants of concern
2. Vaccines & therapeutic clinical trials to boost COVID-19 prevention and treatment
3. FAIR and open data sharing in support to European preparedness for COVID-19 and other infectious diseases
4. Research infrastructure services for rapid research responses to COVID-19 and other infectious disease epidemics

# 1. Cohorts united against COVID-19 variants of concern (a)

## Expected outcomes

Short term:

- **better understanding** of the global circulation of current and emerging SARS-CoV-2 variants of concern;
- deliver **recommendations on strategies to control** viral spread;
- contribution to the evaluation of the **impact of the variants of concern on the different vaccines** and vaccination strategies and inform on best vaccine and treatment options.

Medium/long term:

- **monitor** the emergence of new variants of concerns;
- **elucidate impact** on transmissibility, severity of COVID-19 disease and treatment options.

Long term:

- regional and internationally **linked strategic cohorts**;
- regional and international **pandemic preparedness networks**.

# 1. Cohorts united against COVID-19 variants of concern (b)

## Scope

- Build on **existing** large-scale, **multi-centre, regional or international cohorts** worldwide and/or establish **new ones linked to those**;
- Proportion of current **SARS-CoV-2 variants**, identify emerging ones;
- **Transmissibility, virulence and immunogenicity** of variants in different cohorts, incl. risk groups;
- **Risk and protective factors** to infection, clinical manifestation;
- Elucidate the **impact of variants on vaccine and treatment options**;
- Collaboration with **ORCHESTRA and RECODID** as well as the **EU COVID-19 data portal => Plans**
- Budget: € 7-10 M
- Selection for funding: geographical distribution of activities taken into account.

## 2. Vaccines & therapeutic clinical trials to boost COVID-19 prevention and treatment (a)

### Expected outcomes

- Enrichment of the current **portfolio of SARS-CoV-2 /COVID-19 prophylactics and therapeutics**
- Clinical testing of promising and innovative **therapeutic candidates**
- New/adjusted existing **vaccines** for SARS-CoV-2 variants



## 2. Vaccines & therapeutic clinical trials to boost COVID-19 prevention and treatment (b)

### Scope

- **preclinical development completed** - ready for Phase I or II studies
- sufficient and timely access to **GMP production**
- **different age groups**, including children, and pregnant women
- specific groups of interest: **immunocompromised, co-morbid patients... ; patients with long Covid**
- for therapies: treat **mild to moderate** illness\*
- **Early engagement with EMA for successful applications**
- strong collaboration with VACCELERATE, RECOVER or EU-RESPONSE
- link **European infrastructures- COVID-19 data platform**
- Budget: € 3-10 M
- Selection for funding: at least one vaccine and one therapeutic candidate

} Plans

\*Ref: WHO WG minimal common outcome measure set for COVID-19 clinical research -

<https://www.who.int/docs/default-source/documents/emergencies/minimalcoreoutcomemeasure.pdf>

# Requirements for both topics (Cohorts and Trials)

- All data should be **sex- and gender-disaggregated**
- Abide by the **public emergency related provisions in the Model Grant Agreement** for the duration of the pandemic:
  - Intellectual Property Rights (**IPR**), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the pandemic;
  - **Open science** and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action
- **First data management plan** at signature of Grant Agreement

# Additional information on projects applicants could collaborate with

## Cohorts

<https://orchestra-cohort.eu/>

<https://recodid.eu/>

## Vaccine trials network

<https://www.vaccelebrate.eu/>

## Therapeutic trial networks

<https://www.recover-europe.eu/>

<https://eu-response.eu/>

## Covid19 data portal

<https://www.covid19dataportal.org/>

# 3. FAIR and open data sharing in support to European preparedness for COVID-19 and other infectious diseases

## Scope

- Respond to the COVID-19 pandemic and prepare Europe for future pandemics
- Enable researchers, health care professionals and society at large to share, access, process and reuse research data and other digital objects across disciplines and national borders
- Integrate data and metadata on SARS-CoV-2 and COVID-19, through the European COVID-19 Data Platform, the Versatile Emerging infectious disease Observatory (VEO) and other relevant initiatives
- Emphasis is placed on identifying and tracking new SARS-CoV-2 variants and creating appropriate links with serology and other host data
- Expand scope to cover other relevant infectious diseases, and incorporate clinical epidemiological and socio-economic data, spanning from molecular biology to other disciplines, including social sciences and humanities
- Domain specific solutions from the project should feed into established international initiatives, paying attention to the harmonisation and management of metadata and sample identifiers to ensure interoperability of national and regional efforts in the EOSC ecosystem

# 3. FAIR and open data sharing in support to European preparedness for COVID-19 and other infectious diseases

## Expected impact

- Catalyse and accelerate research advances to combat the COVID-19 pandemic and prepare for future outbreaks
- Enhanced pandemic and outbreak preparedness, including tracking genomic variations of SARS-CoV-2, linking genomic and clinical data to inform public health action
- Improved timeliness, better quality and better integration of research outputs and public health policy
- Improved trust in science through increased FAIRness, openness and quality of scientific research in Europe

## Additional guidance and conditions

- Coordination with other relevant projects and the EOSC governance structure in the context of the upcoming EOSC Partnership
- Establish synergies with the European Health Data Space as well as relevant initiatives under Digital Europe
- Build on the European COVID-19 Data Platform and support the creation of national and regional structures to further enhance genomic surveillance and rapid-response capabilities

# 4. Research infrastructure services for rapid research responses to COVID-19 and other infectious disease epidemics (a)

## Scope / Outcomes

- Integrated portfolio of pertinent research infrastructure services to support research in response to infectious disease epidemics
- Immediate challenge: target new SARS-Cov-2 variants under current COVID-19 pandemic
- Access to support services towards new/adapted prevention and/or intervention tools and measures (diagnostic procedures, therapies, drugs, vaccines, disease management, vector control, and public health, socio-behavioural & socio-economic research)
- Priority on SARS-Cov2 virus variants but portfolio of relevant services to be available to understand and respond to infectious diseases epidemics in general
- Collaboration with epidemics risk assessment and/or management bodies like ECDC, WHO, others incl. EU-HERA
- Collaboration with relevant data infrastructures like EOSC, European COVID-19 data platform, PHIRI
- Budget: € 21 M

# 4. Research infrastructure services for rapid research responses to COVID-19 and other infectious disease epidemics (b)

## Expected impacts

- enhance EU capacity to identify & characterise/mitigate effects of new SARS-Cov2 variants
- enhance EU capacity for fast research responses to tackle future infectious diseases epidemics
- reinforced EU research infrastructures to support excellent research on societal challenges
- access to the best research infrastructures to enable new discoveries and breakthroughs
- new generation of researchers trained to use advanced research tools and methodologies

## Additional guidance and conditions

- alignment with epidemics assessment/control bodies (ECDC, WHO, national bodies)
- One Health concept
- integration with social sciences
- for specific provisions for access see “Specific features for Research Infrastructures”

# Q&A on the 4 topics



# How to submit a proposal Q&A

Full presentation is available:

<https://ec.europa.eu/research/participants/docs/h2020-funding-guide/other/event210324.htm>



# Eligibility

## Consortium composition (collaborative projects)

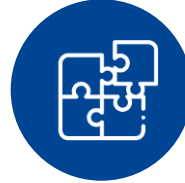
- at least one independent legal entity established in a Member State, and
- at least two other independent legal entities each established either in a different Member State or an Associated Country.

# New features in the Horizon Europe proposal



## NEW FIELDS IN PART A

- Researchers table – needed to follow up researchers careers (HE indicator)
- Role of participating organisation
- Self-declaration on gender equality plan



## FIELDS MOVED FROM PART B TO PART A

- Ethics self-assessment
- Security questionnaire (**NEW!** in all HE proposals)
- Information on participants' previous activities related to the call



## NEW IN PART B

- Glossary of terms.
- Consistency on the use of terminology is ensured in all project phases (from WP to proposal and reporting)
- Extensive explanations on what exactly should be included in each section.

# Policy and horizontal considerations



Open Science across the programme



Gender dimension in R&I content



Pathway to impact



Measures to maximise impact



Do no significant harm principle (DNSH)



Artificial intelligence

**These aspects must normally be considered in all Horizon Europe calls (unless explicitly mentioned in the topic description).**

**Specific calls may include other aspects to take into account.**

# Timelines

All information is available on the participants' portal:

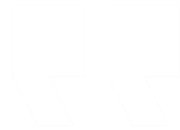
<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-search>

<https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/reference-documents;programCode=HORIZON>

Topics open for submission: 13 April

Deadline for submission: 6 May

Evaluations completed: at the earliest at the beginning of July 2021



# Thank you!

## # HorizonEU

<http://ec.europa.eu/horizon-europe>



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