EU Health Union Resilience and Health Emergency Response Authority HERA

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SUMMARY

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Notes on EU Health Union Resilience and Health Emergency Response Authority (HERA)

Background: The EU Vaccine Strategy has secured access to 2.6 billion vaccine doses as part of the broadest global portfolio of safe and secure COVID-19 vaccines. Less than a year since the virus appeared for the first time in Europe, vaccination has started across all Member States.
At the same time, there are challenges to scale-up industrial vaccine production to keep pace. In order to boost production capacity in Europe, a much closer, more integrated and more strategic **public-private cooperation** with industry is needed. In this spirit, the Commission has set-up a Task Force for Industrial Scale-up of COVID-19 vaccines to detect and help respond to issues in real-time.

On November 2020 a press release https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041 was published by EU about a set of proposals to strengthen the EU's health security framework, and to reinforce the crisis preparedness and response role of key EU agencies.
In order to step up the fight against the COVID-19 pandemic and future health emergencies, more coordination at EU level is needed. Drawing lessons from the current crisis, today's proposals will ensure stronger preparedness and response during the current and future health crises.
Main message was that EU agencies need to be equipped with stronger mandates to better protect EU citizens. To fight the COVID-19 pandemic and future health emergencies, more coordination with more efficient tools at EU level is required to be ready to respond collectively.

To this aim, the EU Commission proposed:

- New Regulation on serious cross-border threats to health in order to: Strengthen preparedness, Reinforce surveillance, Improve data reporting, and declaration of an EU emergency situation
- Stronger and more operational EU Agencies, i.e. European Centre for Disease Control and Prevention and the European Medicines Agency whose mandates will be reinforced

Moreover, the Commission also **set out the main elements of the future Health Emergency Response Authority (HERA), to be proposed by the end of 2021.** Such a structure would be an important new element to support a better EU level response to cross-border health threats.

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On February 2021, in a new press release, the EU Commission proposes a new European bio-defence preparedness plan against COVID-19 variants called "HERA Incubator" that will work with researchers, biotech companies, manufacturers and public authorities in the EU and globally to detect new variants, provide incentives to develop new and adapted vaccines, speed up the approval process for these vaccines, and ensure scaling up of manufacturing capacities.

https://ec.europa.eu/commission/presscorner/detail/en/ip_21_641 To this end, it will act immediately and as a matter of urgency on a number of different fronts:

1. Rapid detection of variants. It is essential that Member States have sufficient sequencing capacity in place. HERA Incubator and ECDC will standardise sequencing procedures so that the data is comparable. HERA Incubator and ECDC will support the increased use of specialised tests to detect samples that are likely to contain variants of concern ('RT-PCR tests').

2. Swift adaptation of vaccines. Flexible and diversified approach, including the testing of prime-boost vaccine strategies, the development of multivalent vaccines, as well as testing combinations of different vaccines - the mix and match approach.

3. Setting up a European Clinical Trials Network. As part of this a new EU-wide and EU-funded vaccine trial net work called VACCELERATE is being launched.

4. Fast-tracking regulatory approval of updated vaccines and new or repurposed manufacturing infrastructures;

5. Enable upscaling of production of existing, adapted or novel COVID-19 vaccines. The Commission will also continue to address potential bottlenecks in production and supply of raw materials and other essential input required for vaccines manufacturing. Creation of an "EU Fab" project, a network of 'ever-warm', single and/or multi-user, single and/or multi-technology production capacities for vaccine and medicine manufacturing at European level, thus becoming over time an asset of the future HERA.

This emergency plan will tackle the short to medium-term threat and simultaneously prepare for the future. It will serve as the vanguard for the European Health Emergency Preparedness and Response Authority (HERA).

Given the race against time, sufficient funding will need to be made quickly available, and the Commission is ready to mobilise all means at its disposal, including through the Emergency Support Instrument. The HERA Incubator will start rolling out its activities immediately.

The Commission invited the European Heads of State and Government meeting on 25 February to endorse and properly mandate the HERA Incubator and to mobilise the relevant national actors and capacities in this coordinated effort.

https://www.linkedin.com/posts/european-commission_healthunion-safevaccines-europeanunion-activity-6768201054912950273-_Ewe

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Vaccines & therapeutic clinical trials to boost COVID-19 prevention and treatment

HORIZON-HLTH-2021-CORONA-01-01

Types of action: Research and Innovation action

Programme: Horizon Europe Framework Programme (HORIZON)

Forthcoming

Opening date: 15 April 2021

Deadline model: single-stage

Deadline date: 06 May 2021 17:00:00 Brussels time

Indicative Budget: 3-10M €

Expected Outcome:

This topic aims at supporting activities that enable the conduct of vaccine & therapeutic trials to boost prevention and further inform public health policy and clinical management. To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to two of the three expected outcomes listed below:

- Enrichment of the current portfolio of SARS-CoV-2 /COVID-19 prophylactics and therapeutics with clinical testing of promising candidates.
- Further development of new, or adjustment of existing, vaccine candidates to be effective against the current SARS-CoV-2 variants and potentially protect against new emerging ones.
- Development of new effective therapies against SARS-CoV-2 for the clinical management of COVID-19 disease, including for the prevention of disease progression to severe illness and hospitalisation.

Scope:

Proposals submitted under this expression of interest should aim to further develop promising therapeutic or prophylactic candidates against SARS-CoV-2/COVID-19. The vaccine/treatment candidates should have completed preclinical development, including animal studies, and be ready to enter clinical evaluation in Phase I or II studies. Applicants should have addressed the current viral variants of concern in their pre-clinical work, and/or anticipated the emergence of new variants. Proposals should include a summary of results obtained in the concluded studies (pre-clinical and/or Phase I).

Proposals are also expected to include assurances on sufficient and timely access to GMP production of the compound(s) to be trialled (the costs of which can be included in the proposal). In addition, options to upscale production for subsequent development beyond the activities for which funding is requested, should be indicated as appropriate.

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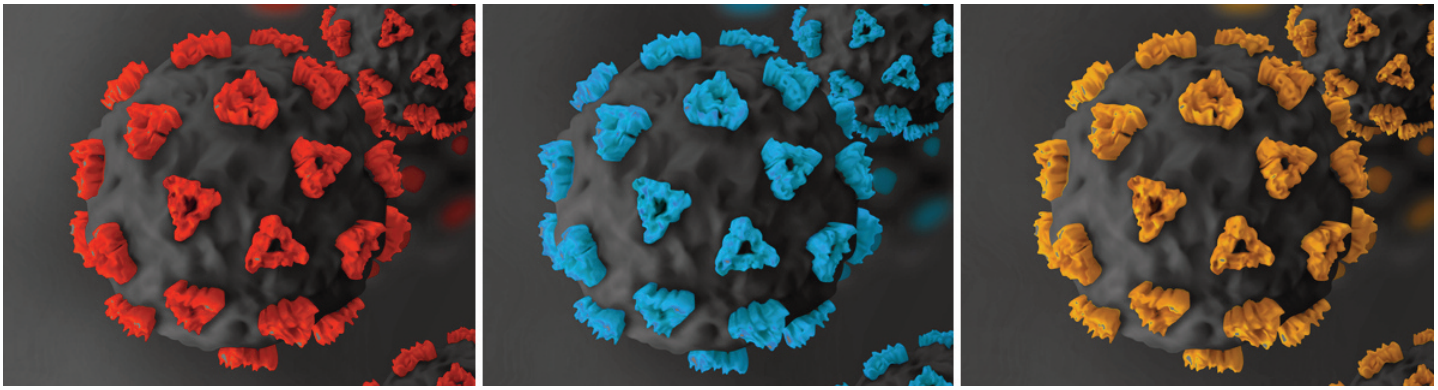

Cohorts united against COVID-19 variants of concern

HORIZON-HLTH-2021-CORONA-01-02

Types of action: Research and Innovation action

Programme: Horizon Europe Framework Programme (HORIZON)

Forthcoming

Opening date: 15 April 2021

Deadline model: single-stage

Deadline date: 06 May 2021 17:00:00 Brussels time

Indicative Budget: 7-10M €

Expected Outcome:

This topic aims at supporting activities that are enabling or contributing to the development of large scale, COVID-19 cohorts and networks worldwide, including beyond Europe's borders, forging links with European initiatives as a global response to the pandemic. To that end, proposals under this topic should aim at delivering results that are directed, tailored towards and contributing to all of the following expected outcomes:

- In the short-term, contribution to a better understanding of the global circulation of the current and emerging SARS-CoV-2 variants of concern and their characteristics, delivering recommendations on the best strategies to control viral spread, as well as on optimized clinical management and treatment of COVID-19 patients.
- In the short-term, contribution to the evaluation of the impact of the variants of concern on the different vaccines and vaccination strategies and information on best vaccine and treatment options.
- In the short/medium/long-term, monitoring the emergence of new variants of concern, elucidating the impact of different variants on transmissibility and severity of COVID-19 disease, including long-term post-infection sequelae (long COVID).
- In the long term, establishment of regional and internationally linked strategic cohorts that can be pivoted rapidly to research on emerging infectious diseases.
- In the long-term, contribution to regional and international pandemic preparedness networks to rapidly address pandemics in the future on a global scale.

Scope:

Proposals submitted under this expression of interest are expected to build on existing large-scale, multi-centre, regional or international cohorts worldwide and/or establish new ones linked to those. These cohorts should aim to rapidly advance the knowledge on SARS-CoV-2 and its emerging variants of concern, with the aim of developing evidence-based strategic and robust recommendations for the effective control and prevention of COVID-19 infection. The regional or international cohort(s) should allow to rapidly and consistently provide estimations on the occurrence and spread of emerging variants of concern in different parts of the world. They should contribute to a better understanding of their transmissibility, virulence and pathogenicity.