Apertura de Expresiones de Interés de los Programas de Trabajo de Salud y de Infraestructuras de Investigación de Horizonte Europa en nuevas variantes del SARS-CoV-2

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Topics en el Clúster de Horizonte Europa

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Dos topics en el Clúster Salud

Topic ID: **HORIZON-HLTH-2021-CORONA-01-01**

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

Type of Action: Research and Innovation Action (RIA) **- Single stage**

Budget: 3-10 Mio. €/Project **Total Budget:** 60 Mio. Euros

The EC expects to select at least one proposal on a vaccine and one on a therapeutic candidate for funding

Topic ID: **HORIZON-HLTH-2021-CORONA-01-02**

Name: **Cohorts united against COVID-19 variants of concern**

Type of Action: Research and Innovation Action (RIA) **- Single stage**

Budget: 7-10 Mio. €/Project **Total Budget:** 30 Mio. Euros

Call Identifier: **HORIZON-HLTH-2021-CORONA-01-01**

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

Type of Action: Research and Innovation Action (RIA)

Call: CORONA (01 - 2021)

Budget: 3-10 Mio. €/Project
The EC expects to select at least one proposal on a vaccine and one on a therapeutic candidate for funding

Aim:

To support activities that enable the conduct of vaccine & therapeutic trials to boost prevention and further inform public health policy and clinical management.

Expected outcomes (2 or 3):

1. Enrichment of the current portfolio of SARS-CoV-2 /COVID-19 prophylactics and therapeutics with clinical testing of promising candidates.
2. 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.
3. 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.

Call Identifier: **HORIZON-HLTH-2021-CORONA-01-01**

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

Type of Action: Research and Innovation Action (RIA)

Call: CORONA (01 - 2021)

Budget: 3-10 Mio. €/Project
The EC expects to select at least one proposal on a vaccine and one on a therapeutic candidate for funding

Scope (part 1):

- 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 trialed (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.
- **Address and assess different age population groups** including children and pregnant women, and target specific groups of interest such as immunocompromised, patients with co-morbidities or other groups with higher risk to develop severe disease, and patients suffering from long-term health consequences of COVID-19.

Call Identifier: **HORIZON-HLTH-2021-CORONA-01-01**

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

Type of Action: Research and Innovation Action (RIA)

Call: CORONA (01 - 2021)

Budget: 3-10 Mio. €/Project
The EC expects to select at least one proposal on a vaccine and one on a therapeutic candidate for funding

Scope (part 2):

- The therapeutic interventions to be developed should aim at treating **mild to moderate illness** (e.g. antivirals, antibodies, immunomodulators). **Therapeutic interventions targeting severe to critical illness** resulting from the infection **are excluded**.
- Thermostability, innovative delivery systems, affordability and the flexibility of the platforms to speedily adjust the candidates to emerging variants, should be also considered **when possible.**
- Applicants are expected to **engage early on with the European Medicines Agency (EMA)** to ensure adequacy of the proposals from a regulatory point of view.
- **Collaboration with one of the large European trial networks** VACCELERATE, RECOVER or EU-RESPONSE projects is expected and applicants are encouraged to describe their plans for such collaboration in the proposal[1].
- Proposals should envisage an appropriate level of **collaboration with existing European research infrastructures,** and should **link to the COVID-19 data portal** for the timely sharing of relevant data.
- **Gender-related issues** are an important crosscutting priority of this Expression of Interest. All data should be sex- and gender-disaggregated, and attention should be paid to critical social factors intersecting with sex/gender, such as age, social origin, ethnicity/migration, and disability.

Topic ID: HORIZON-HLTH-2021-CORONA-01-02

Name: Cohorts united against COVID-19 variants of concern

Type of Action: Research and Innovation Action (RIA)

Call: CORONA (02 - 2021)

Budget: 7-10 Mio. €/Project

Aim:

To support activities 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.

Expected outcomes (all):

In the short-term:

1. 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.
2. 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:

1. **Establishment of regional and internationally linked strategic cohorts** that can be pivoted rapidly to research on emerging infectious diseases.
2. **Contribution to regional and international pandemic preparedness networks** to rapidly address pandemics in the future on a global scale.

Call Identifier: **HORIZON-HLTH-2021-CORONA-01-02**

Name: **Cohorts united against COVID-19 variants of concern**

Type of Action: Research and Innovation Action (RIA)

Call: CORONA (02 - 2021)

Budget: 7-10 Mio. €/Project

Scope (part 1):

- **Build on existing** large-scale, multi-centre, regional or international cohorts worldwide and/or establish new ones linked to those.
- 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.
- **Risk and protective factors to infection**, and clinical manifestation including long-term post-infection sequelae (long COVID) should be **investigated for different variants and different (risk) groups** (e.g. children, elderly) to potentially identify biomarkers for vulnerable populations and inform treatment options.
- **The cohort(s) should also contribute to elucidating the effectiveness of the various first-generation vaccines and the risk of reinfection** in previously infected individuals in the different cohort populations, including risk groups, to inform on optimal vaccine strategies. The effectiveness of second-generation or adjusted vaccines should be considered as soon as they become available.
- **Clinical studies, carried out within the cohort(s),** might also help to inform best treatment options and vaccine strategies.

Call Identifier: **HORIZON-HLTH-2021-CORONA-01-02**

Name: **Cohorts united against COVID-19 variants of concern**

Type of Action: Research and Innovation Action (RIA)

Call: CORONA (02 - 2021)

Budget: 7-10 Mio. €/Project

Scope (part 2):

- The cohort(s) should **cover different regions of the world** to capture the various variants and vaccine and treatment strategies.
- A strong **collaboration with the EU-funded projects ORCHESTRA and RECODID**, as well as the EU COVID-19 data portal is expected. **Applicants should describe their plans for such collaborations** in the proposal.
- Applicant consortia are expected to **collaborate with other relevant initiatives** already existing or under development at national, regional, and international level, in order to maximise synergy and complementarity and avoid duplication of the research efforts.
- Strong **collaboration with regional public health and regulatory authorities** is strongly encouraged.
- Proposals should include a **plan on maintaining the established cohort(s)** to strengthen regional or international research preparedness for a future epidemic or pandemic.
- **If more than one proposal is successful**, **proposals should collaborate** and this should be foreseen in the proposal.
- **Gender-related issues are an important crosscutting priority** of this Expression of Interest. All data should be sex- and gender-disaggregated, and attention should be paid to critical social factors intersecting with sex/gender, such as age, social origin, ethnicity/migration, and disability.

Requerimientos para ambos topics

- 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

- Applicants should indicate in their proposal which networks/projects would be relevant for their proposed work. If their application is successful, the Commission will facilitate the connection between the coordinator/project and the relevant network/project(s) at the time the grant preparation will start.
- Applicants should not contact these projects before they submit the proposal

Novedades en el formulario para la inclusión de Ensayos Clínicos en Horizonte Europa

The below **3 mandatory deliverables** apply to each clinical study included in the proposal:

1. **Study initiation package** (before enrolment of the first study participant) including:
2. **Midterm recruitment report**
3. **Report on the status of posting results**

Irrespective of the successful completion of the clinical study, **summary results must be posted in the applicable registry/ies** (where the study was registered) even if the timing of posting of results falls outside of the grant period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/essential-information-for-clinical-studies_horizon_en.pdf

Novedades en el formulario para la inclusión de Ensayos Clínicos en Horizonte Europa

1 Description of the clinical study

1.1 Title, acronym, unique identifier (e.g. EudraCT Number5, or identifier from ISCRTN6, ClinicalTrials.gov7 if available) of the clinical study

1.2 Study rationale

1.3 Objective(s) of the clinical study

1.4 Characteristics of the study population (size, age group, inclusion and exclusion criteria; all items with justification!)]

1.5 Design of the clinical study (controlled / uncontrolled; randomised; open / blinded; parallel group / cross over / other; please justify the appropriateness of the selected design)

1.6 Type of intervention (medicinal product / advanced therapy medicinal product / medical device / in vitro diagnostic medical device / surgical or other invasive procedure / other medical intervention, including, e.g., counselling)

1.7 Description and timing of study procedures

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/essential-information-for-clinical-studies_horizon_en.pdf

Novedades en el formulario para la inclusión de Ensayos Clínicos en Horizonte Europa

2 Preparedness status

2.1 Development of the clinical study protocol

3 Operational feasibility

3.1 Please describe how the **availability of the intervention(s) (including comparators) is secured** throughout the entire implementation phase (give details on manufacturing, packaging / labelling operations, storage, logistical, import/export issues, etc.)

3.2 Please describe **how the study population will be recruited**

3.3 Please **describe what additional supply** (e.g. an electronic device for remote data capture, a specific instrument for administering the investigational product, etc.) is necessary to carry out the required study procedures and how this supply will be made available to the clinical sites

3.4 Please provide **plans on data management aspects** (data standards, type of data capture, verification of data, central data collection, cleaning, analysis, reporting, security)

3.5 Please give **details on** how **reporting obligations** (regarding study initiation, safety of study participants, ethical concerns, quality issues, integrity of data, study results) to regulatory bodies and ethics committees will be met.

3.6 List of all items of the **sponsor's responsibilities** (e.g. monitoring clinical sites, meeting regulatory obligations, data management, etc.) that will be supported by entities that are not part of the sponsor's organisation. Please describe **how the sponsor will ensure oversight** of these activities.

3.7 What are the **plans for major study milestones** and what evidence supports its feasibility?

¡Muchas gracias por su atención!

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