

# Supporting and coordinating the development of COVID-19 therapies

## Building a clinical research network to treat COVID-19 and emerging infectious diseases

The European Commission is providing a €15.7 million, through its Horizon 2020 research and innovation programme, to the **EU-RESPONSE** project, to establish and co-ordinate a European adaptive platform trials network for COVID-19 and emerging infectious diseases.

### **EU-RESPONSE - European REsearch and Preparedness network for pandemics and emerging infectious diseaSEs**



The **EU-RESPONSE** consortium, led by the **Institut national de la santé et de la recherche médicale (INSERM)** brings together 21 partners with world-class clinical research capabilities from 13 Member States (Austria, Belgium, Czech Republic, France, Greece, Hungary, Italy, Ireland, Luxembourg, Poland, Portugal, Slovakia and Spain) together with Norway, Switzerland and Turkey.

EU-RESPONSE represents an important addition to the portfolio of EU-funded research actions and complements the public health policy and activities that the European Commission is coordinating with the Member States. It implements the European ERAvsCORONA Action Plan<sup>1</sup> by extending and supporting large EU wide clinical trials for clinical management of COVID-19 patients.

EU-RESPONSE builds on the DisCoVeRy trial originally initiated in France, in coordination with the WHO Solidarity trial, at the peak of the COVID-19 pandemic and will allow to take such trials to the next level. EU-RESPONSE will initially focus on the evaluation of repurposed medicines to treat COVID-19, and the EU funding will ensure that large-scale, multi-centric clinical trials across Europe can be implemented to generate data that will allow solid scientific results. EU-RESPONSE will use the acquired knowledge and develop emerging hypotheses in order to include new experimental treatments in a flexible manner, quickly supporting clinical development of the most promising treatment options. Its geographical expansion and evolution of research activities will initiate the establishment of a European adaptive platform trials network for COVID-19 that could also deal with future emerging infectious diseases. It will test and develop safe and effective medicines for the European market and beyond.

<sup>1</sup> [https://ec.europa.eu/info/sites/info/files/covid-firsteravscorona\\_actions.pdf](https://ec.europa.eu/info/sites/info/files/covid-firsteravscorona_actions.pdf)

Adaptive platform trials (APTs) that are at the core of the project represent an innovative trial design, which is able to simultaneously study multiple interventions in a disease or condition, including infectious diseases, in a continuous manner, with therapeutic candidates entering and leaving the platform based on a predefined decisional mechanism. In particular, this mechanism allows for quickly eliminating interventions that emerge as being unsafe or not effective, assuring the best use of resources in a timely manner.

A lesson learned from the early stages of the COVID-19 crisis is that the uncoordinated myriad of study initiatives have generated data that did not have enough breath and dimension, leading to inconclusive results. In order to avoid this in the future, and to ensure complementarity, harmonization, and synergies with European and international initiatives in the field, EU-RESPONSE will develop a joint coordination mechanism with the RECOVER project (Rapid European COVID-19 Emergency research Response), previously funded by the European Commission. These two projects, working in close coordination, will deliver a comprehensive development strategy for COVID-19 platform trials in Europe, providing a streamlined access for new COVID-19 therapeutic interventions to be tested and to offer technical and methodological support for the establishment and the management of adaptive platform trials. This high-level coordination strategy could also inform strategic choices regarding COVID-19 vaccine development and testing.

**The aims of EU-RESPONSE are:**

- To implement large-scale, multi-centric clinical trials across Europe to evaluate the safety and efficacy of repurposed medicinal products and new therapeutic options to treat COVID-19
- To build a European COVID-19 and emerging infectious diseases adaptive platform trials network with a single, coherent strategic mechanism to ensure the best scientific outcomes and use of resources
- To strengthen the EU clinical research capacity and preparedness to tackle future pandemics

**Partners in the EU-RESPONSE consortium**

Institut National de la Santé et de la Recherche Médicale (U1137 IAME, U1111 CIRI, U1136, PRC) (FR)

Inserm Transfer (FR)

European Clinical Research Infrastructure Network (ECRIN-ERIC)

Norwegian Institute of Public Health (NO)

Oslo University Hospital (NO)

Università degli Studi di Verona (IT)

Centro Hospitalar Universitário Sao Joao (PT)

Universita Pavla Josefa Safarika V Kosiciach (SK)

Université Libre de Bruxelles (BE)

University of Szeged (HU)

University College Cork (IE)

Swiss Clinical Trial Organisation (CH)

Hacettepe University Faculty of Medicine (TR)

Centre Hospitalier de Luxembourg (LU)

Arbeitsgemeinschaft medikamentöse Tumortherapie gemeinnützige GmbH (AT)

Assistance Publique - Hôpitaux de Paris (FR)

Hospices Civils de Lyon (FR)

Servicio Madrileño De Salud (ES)

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