



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION
Directorate E - People
The Director

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NOTE FOR THE ATTENTION OF [REDACTED]

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Subject: EU-wide network for COVID-19 therapeutic trials

Please find attached a short note that provides details on the EU-wide network for COVID-19 therapeutic trials, which is now fully operational, supported by Horizon 2020 funds.

We would like to ask kindly to share this information with the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP) and the Health Security Committee (HSC). This will ensure that the Member State health authorities are fully aware of this initiative, while emphasising the importance of joining European forces for implementing large-scale multi-centre clinical trials to generate the robust evidence on COVID-19 treatments.

We like to take the opportunity to thank you for the support of your teams in the past months to develop this network of therapeutic trials. We look forward to continuing this fruitful collaboration, in particular also for launching in the near future a similar initiative of an EU-wide network for COVID-19 vaccine trials.

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Update on EU-wide network for COVID-19 therapeutic trials

Priority action two of the ERAvsCORONA action plan¹ refers to the EU commitment of extending and supporting large EU-wide clinical trials for the clinical management of COVID-19 patients. We hereby provide an update on the progress made to implement this action, through the establishment of an EU-wide network for COVID-19 therapeutic trials.

The EU-wide network for COVID-19 therapeutic trials is based on two large-scale adaptive platform trials, i.e. the DisCoVeRy trial and the REMAP-CAP for COVID trial – details on both of these trials are provided in the Annex. In line with the European Medicines Agency's call² to pool research resources into large-scale clinical trials, Horizon 2020 funding supports the expansion of these two running trials to ensure an inclusive geographic scope in Europe, as well as operational readiness of all participating sites for conducting large-scale trials on COVID-19. A coordination mechanism between the two trials, a common Trial Coordination Board, was established to promote complementarities, avoid redundancies, and facilitate cooperation in order to maximise the robustness of trial outcomes and speed-up discoveries of much-needed therapeutics to treat COVID-19.

Both the DisCoVeRy trial and the REMAP-CAP for COVID trial are complex high-quality trials, fully capitalising on and further extending the high-level expertise and trial capacity present in Europe. The trials collect the necessary data to allow for marketing authorisation of new molecules, and are in close coordination with Regulatory Bodies for this purpose.

Furthermore, the SUPPORT-E project supports and coordinates efforts to determine if COVID-19 convalescent plasma transfusion – using plasma from patients who recovered from the disease - is an effective and safe treatment.

More information on these three abovementioned Horizon 2020 funded projects is provided in the Annex. Trial sites interested in more information and/or collaboration are invited to contact us using the following e-mail address: 5.1.2e@ec.europa.eu

We take this opportunity to inform you that efforts are underway to establish a similar initiative of an EU-wide network for COVID-19 vaccine trials. More details will be provided at a later stage.

¹ https://ec.europa.eu/info/sites/info/files/covid-firsteravscorona_actions.pdf

² <https://www.ema.europa.eu/en/news/call-pool-research-resources-large-multi-centre-multi-arm-clinical-trials-generate-solid-evidence>

Annex. Projects contributing to the EU-wide network for COVID-19 therapeutic trials

1. EU-RESPONSE project, covering the DisCoVeRy trial

The EU-RESPONSE project³ incorporates the ongoing DisCoVeRy⁴ trial, a multi-centre, adaptive, randomized, open clinical trial assessing the safety and efficacy of potential COVID-19 treatments in hospitalized adults. The trial is sponsored by the French National Institute of Health and Medical Research (Inserm), and is currently recruiting patients in France, Luxemburg, Austria, Belgium, and Portugal; more EU countries are expected to join shortly.

Through the EU-RESPONSE project, the expansion of the DisCoVeRy trial will further contribute to the EU-wide therapeutic trial network, and lead to a European independent multi-centre, multi-arm COVID-19 adaptive platform trial.

2. RECOVER project, covering the REMAP-CAP for COVID trial

The RECOVER project⁵ received Horizon 2020 funding following its successful application to the first expression of interest of 31 January 2020⁶ and builds on a previous EU funded research project called “PREPARE”⁷. The latter developed harmonized large-scale clinical research studies on infectious diseases to be prepared to rapidly respond to any severe outbreak through providing real-time evidence for the clinical management of patients and for informing the public health response. One of the trials developed and conducted under the PREPARE project is the REMAP-CAP trial⁸, a response-adaptive trial for intensive care patients with community-acquired pneumonia. The RECOVER project is coordinated by the Antwerp University in Belgium, and the REMAP-CAP trial in Europe is sponsored by the Utrecht University Medical Centre in the Netherlands.

Through the RECOVER project, the REMAP-CAP trial has now extended its treatment domains to fully integrated therapeutic approaches for COVID-19 patients, both in intensive care and in hospital wards, to also include moderately-ill COVID-19 patients. Moreover, to cover well the geographic distribution of the COVID-19 pandemic, REMPA-CAP for COVID is further expanding to more hospitals in more Member States.

3. SUPPORT-E project

The SUPPORT-E project⁹ brings together major European Blood Establishments with world-leading research capabilities, to support the high-quality clinical and scientific

³ https://ec.europa.eu/info/news/commission-supports-international-clinical-research-network-treat-covid-19-2020-sep-18_en

⁴ <https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000936-23/FR>

⁵ <https://www.recover-europe.eu/>

⁶ https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_cv-projects.pdf

⁷ <https://www.prepare-europe.eu/>

⁸ <https://www.remapcap.org/>

⁹ https://ec.europa.eu/info/news/commission-supports-crucial-research-convalescent-plasma-treat-covid-19-2020-sep-11_en

evaluation of COVID-19 convalescent plasma (CCP). The project intends thereby to achieve a consensus on the appropriate use of CCP in the treatment of COVID-19 across EU member states and to promote best practises regarding CCP use in the pandemic.

The project is coordinated by the European Blood Alliance, and brings together a consortium involving Blood Establishments of eight countries.