Date/Version: 08/04/2020
Status of paper: working paper, subject to updates.

Extending and supporting large EU wide clinical trials for clinical management of COVID 19 patients

At this stage of the COVID-19 pandemic, there are no approved medicines to protect from or treat COVID-19. A number of studies have started, to see if treatments that work for other infections would work for COVID-19[1], or if the use of antibody-rich blood plasma or monoclonal antibodies have an effect. The search for new compounds is also actively ongoing. Recent scientific findings seem to indicate fact that an over activation of the immune response could be at the basis of the respiratory complications seen in some patients, requiring them to go into intensive care. These findings open up to new therapeutic approaches. It is also expected that as new scientific discoveries are revealed further treatment options will need to be rapidly tested in the clinical settings.

In order to have enough evidence about what works and what does not, it is essential to avoid fragmentation of study initiatives. Studies need to enrol a sufficient number of patients, and use standardised and agreed upon protocols to reach conclusive results on efficacy.

For these reasons, the European Medicines Agency has asked to prioritise large randomised controlled studies, as the best avenue to generate the conclusive evidence needed to enable rapid development and approval of potential treatments of COVID-19.[2] It also emphasises the need to include all EU countries in these trials.

Two multi-centre and multi-arm clinical trials have already started in Europe, investigating different treatment options for the treatment of COVID-19. The DisCoVery[3] trial, for all COVID19 patients entering hospital, and the REMAP-CAP[4] trial for patients in intensive care units. The DisCoVery trial and the REMAP-CAP trial are complementary and can co-exist in the same sites. This guarantees that a sufficient number of patients are included, the potential for strong and conclusive results is increased, and the evidence base on therapeutic approaches to COVID-19 is supported.

The proposed action aims to harness the Commission's and Member States efforts, joining forces around setting up EU wide clinical trials, such as the DisCoVery and REMAP-CAP trials, to investigate the efficacy and safety of COVID-19 therapeutic approaches including the use of convalescent plasma.

With this action the Commission will provide additional funding so that hospital research sites from all MS can participate in large scale trials throughout Europe, using the same standard protocols and collecting data in a harmonised manner.

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[1] E.g. lopinavir/ritonavir, hydroxychloroquine, or remdesivir (which is still an investigational drug)

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

[3] as an add-on trial to the WHO Solidarity trial

[4] https://www.remapcap.org/coronavirus

In addition to the EU funds, MS are invited to fund complementary research sites, with the aim to further develop **a Europe-wide COVID-19 clinical trials network**.

Having such a network is important also in the context of the support the EIC or InnovFin ID provide to individual companies/SME for developing new approaches. One of the challenges in an outbreak like COVID-19 is to rapidly find the patients to enrol in clinical trials and to identify the clinical sites that are well prepared to run these trials. This is where EU wide networks play an important role, in particular to support SMEs that may have limited capacity to run such trials themselves.

Close collaboration and coordination with the national competent authorities and the European Medicines Agency (EMA), will be sought from the beginning to efficiently and promptly move forward promising therapeutic options through the necessary regulatory pathway.

With time, when plausible vaccine candidates become available, the clinical trial network could also be extended beyond testing of treatments, to also include vaccines.