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La science pour la santé
From science to health

Clinical Research Department

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Subject: Open call to join the DisCoVeRy trial

The COVID-19 pandemic

The fast evolving nature of the COVID-19 pandemic and the significant unknowns coming with a new virus, and the disease it causes, have led to unprecedented challenges for health care systems all over the European Union and the world at large. It has already claimed hundred thousands of lives and will continue to put health care systems under significant strain. The depth and the breadth of this global health crisis require a response of unprecedented scale, speed and solidarity. This is why, more than ever, coordination and collaboration at European level are necessary for exchanging data and knowledge about COVID-19 and for clinical trials to achieve critical mass to ensure complementarity of efforts and to avoid wasting precious resources.

Trial of potential Treatments for COVID-19 in Hospitalized Adults - the DisCoVeRy trial

In response to the COVID-19 pandemic, the French National Institute of Health and Medical Research (Inserm) established a trans-disciplinary team that led to the elaboration of the DisCoVeRy[1,2] trial as a multi-centre, adaptive, randomized, open clinical trial of the safety and efficacy of potential treatments[3] of COVID-19 in hospitalized adults. The DisCoVeRy protocol was submitted to the French health regulatory and ethical authorities in early March 2020, resulting in the first patient being enrolled on 22 March 2020. DisCoVeRy has become an add-on trial of the WHO Solidarity soon after. As of today, 750 patients have been enrolled across 35 clinical centers in France and 2 centers in Luxembourg. The sponsor of DisCoVeRy is Inserm , monetary support is given by the Direction Générale de l'Offre de Soins (DGOS) from the French Ministry of Health and Solidarities (via a grant of the French national program for funding national hospital clinical research - PHRC-N) and the Ile de France region. Four pharmaceutical companies (Sanofi, Gilead, AbbVie and Merck) collaborate with DisCoVeRy by providing the investigational medicinal products free of charge.

[1] https://clinicaltrials.gov/ct2/show/NCT04315948?term=DisCoVery+inserm&cond=COVID&draw=2&rank=1
[2] https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-000936-23/FR
[3] Currently Remdesivir, Lopinavir/Ritonavir, Interferon Beta-1A, Hydroxychloroquine

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How to join DisCoVeRy

Investigators operating in the European Union, or an associated country, who are interested in joining the DisCoVeRy protocol should send an e-mail expressing their interest to:

- Juliette Saillard, Project leader (10)(2e) @inserm.fr

with in copy:

- (10)(2e) Coordinating Investigator (10)(2e) @chu-lyon.fr
- (10)(2e) (10)(2e), Chair of the Steering Committee (10)(2e) @aphp.fr

A non-disclosure agreement and the DisCoVeRy protocol will then be sent for review, together with a concise document to assist with implementing it. This document explains the main features of the protocol and the standard of care, and it also clarifies the compulsory and optional exploratory objectives of the trial. The contact details for the pharmacology and virology studies leaders are also shared.

Inserm can assume sponsorship within the EU/EEA[4], and all aspects concerning the different requirements (insurance, research documentation, SOP, investigational medicinal product supply, data, samples, pharmacovigilance) will be detailed by Inserm.

Interested investigators, before committing to the trial participation, must identify:

- a national institution representative that will act as coordinator;
- a physician who will act as Coordinating Investigator;
- local contacts that will act as the application in their country for obtaining regulatory authorisations (both at the level of the national competent authority and the ethics committee);
- a virologist and a pharmacologist who will act as referents;
- a central hospital pharmacy for the medicines provided by Inserm, if possible;
- a local safety officer who will act as contact with the Inserm pharmacovigilance team.

Inserm provides funding for the DisCoVeRy trial in France. Importantly, Inserm is committed to obtain additional funding from the European Commission to build a large European network to scale up the DisCoVeRy trial and implement it in additional European countries. Any favorable outcome towards this end will be promptly communicated and acted upon. Notably, the investigational medicinal products used in the trial will be provided free of charge by Inserm.

Pr (10)(2e) Coordinating Investigator
Pr (10)(2e) (10)(2e), Chair of the Discovery Steering Committee

[4] European Economic Area (EEA)