Translated by Jimena BOUZAS and Sarhan YAICHE on 01.04.2021

Application for an initial authorization related to COVID-19 clinical trials

LAST UPDATE 09/12/2020

A system to coordinate the Research related to the management of SARS-Cov2 infection and its complications has been put in place to facilitate the prioritization of high-potential studies in order to accelerate them.

This regulation relies on the definition of a "national research priority" label for a limited number of studies based on:
1) the definition by the scientific council of REACTing (a multidisciplinary consortium, REsearch and ACTion targeting emerging infectious diseases) of the evolving criteria for prioritization.
2) and the attribution by the ad-hoc national steering committee for therapeutic trials and other research on COVID-19 (CAPNET).

More information on the Ministry of Health website:

- National Ad-Hoc Steering Committee on Therapeutic Trials and Other COVID-19 Research (CAPNET) A Prioritization Body for COVID-19 Clinical Research
- And the "national research priority" label
- **If the sponsor requests the national priority label**, the file must be sent first to DGS before any submission to ANSM / CPP via the circuit for COVID19 files (ccs-pole-recherche@sante.gouv.fr). The file will be then sent to REACTing for scientific and methodological examination by its Scientific Council. At this stage, it might be proposed to the Sponsor the possibility of grouping the project with other similar projects, if available. Once the expert report has been transmitted, the project is examined by CAPNET, which decides on its priority status no later than 14 days after submission of the complete file.
- **If the sponsor does not apply for the national priority label** then it has to submit the file to the ANSM and SI RIPH system according to the usual procedures. A random CPP is designated to take into account the sponsor request for opinion. In this case, the sponsor cannot benefit from the accelerated procedure and the file is processed within the usual examination timeframe.

How to submit to ANSM?

Submission to aec-essaiscliniques@ansm.sante.fr

- Following the usual format available here
- The trials that have received the national priority label can be submitted through the Fast Track 2 procedure (Practical Information Guide for Applicants)

Warning: for all trials related to COVID-19, it is mandatory to name the email with the mention: **"AEC-COVID-19 / Type of trial / Trial phase N° / EudraCT N° / Therapeutic area"**

Trials on Medical Devices:

- Use the email address: EC.DM-COS@ansm.sante.fr according to the usual format available in the notice to the sponsor

As requested by the World Health Organization, the sponsor must ensure that the title of the research study includes the mention COVID-19.

Similarly, for the vigilance reports (individual cases, emerging safety issue and Annual Safety Report) related to these trials, the mention "COVID-19_" must be added at the beginning of the e-mail subject.

Submission of a substantial modification for a clinical trial requiring adaptation in relation to COVID-19

The required forms and templates are available on our website

The modifications implemented specifically for the pandemic period can be presented as an attached document, without changing the protocol version.

Substantial modification

Submission to:

- ams-essaiscliniques@ansm.sante.fr

Warning: it is mandatory to name the email with the mention **"MSA-COVID-19 /** Type of trial / Phase of trial / EudraCT number/ Therapeutic area" or **"MSI-COVID-19** / Type of trial / Phase of trial / EudraCT number/ Therapeutic area

Urgent Safety Measures

Submission to:

- vig-essaiscliniques@ansm.sante.fr

Warning: it is mandatory to name the mail following the format: COVID-19_MUS EudraCT_code substanc

Trials on Medical Devices

Use the email adress:

- EC.DM-COS@ansm.sante.fr