INFORMATIVE NOTE

Actions by AEMPS [Spanish Agency for Medicines and Medical Devices] to speed up and promote clinical trials and observational studies about COVID-19

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Category: drugs for human use, COVID-19
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- **Researchers must consider the possibility of joining clinical trials already in progress rather than proposing their own study**
- **Priority is given to the assessment of clinical trials about COVID-19**
- **The not-for-profit prospective observational follow-up studies shall be classified as EPA-AS**

Clinical trials are an essential tool to be able to identify the manner to prevent and treat the disease COVID-19. For this reason, from the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), measures have been established to facilitate and speed up the process of authorisation of clinical trials and classification of observational studies.

Clinical trials aimed at researching new drugs against coronavirus

The situation resulting from the COVID-19 crisis is evolving towards a new stage in which the number of patients is reducing day-by-day. However, cases have not disappeared. Infected patients continue evolving at hospitals, and it is necessary to be prepared for a potential upturn during the de-escalation phase or in the autumn/winter of this year.

In this less demanding healthcare context, it is important to work together on big clinical trials with statistical power to complete recruitment and obtain results that help the taking of clinical and necessary decisions in order to be prepared if faced with a potential increase in cases. Researchers must assess the value of joining clinical trials already in progress (consult the Spanish Register of Clinical Trials [REec] https://reec.aemps.es/reec/public/web.html) before proposing the setting up of new trials.

The AEMPS, together with the CEIms, has prioritised the assessment of clinical trials aimed at treating or preventing disease due to coronavirus. It is also necessary to maintain usual activity in clinical trials devoted to other diseases which, as healthcare activity returns to normal, will go back to their usual number. However, COVID-19 applications still get priority and are assessed as quickly as possible within fifteen days maximum.

Sponsors or researchers who have a clinical trial project of this type must send the request to both the CEIM and the AEMPS through the ECM Portal (see Instructions for the carrying out of clinical trials in Spain), warning about the presentation by means of a message to aecaem@aemps.es with the subject “URGENT COVID-19” and identifying the trials with the

EudraCT number. The trial title must include the term COVID-19.

To consult only specific aspects of the trial design before formal application, it is necessary to indicate the specific questions, attaching a summary of the trial and the data justifying the biological plausibility of the effect sought in the conditions of use of the drug in the trial to Clinical Trials Area, preferably copying in the CEIm and indicating in the subject: URGENT new CT COVID-19 and the name of the investigational drug. A response will be given as soon as possible, within a maximum of fifteen days.

We kindly remind you that for the obtaining of answers about more global aspects of the development of a drug, you must contact Asesorias Científicas Nacionales [National Scientific Consultants] (aecaem@aemps.es) or Oficina de Apoyo a la Innovación [Innovation Support Office] (innov_spain@aemps.es).

Clinical trials from not-for-profit sponsors are exempt from paying the fee[12]. In addition, with the aim of facilitating their start-up, it is recommended to make them exempt from fees and to simplify the contracts between the sponsor and the site. In the sponsor's not-for-profit clinical trials, the contract can be replaced with a document of compliance from the site management.

It is essential to speed up the analysis of the clinical trial results as much as possible and to present them to the AEMPS as soon as they are available.

Prospective observational follow-up studies with drugs related to coronavirus.

In the classification request email for prospective observational studies with drugs related to coronavirus, the subject line shall include URGENT COVID-19.

Classification resolutions from these studies shall be sent to the applicant by email and shall be settled as soon as possible, normally on the same day as the request, and within a maximum of two working days.

The prospective observational follow-up studies in which the not-for-profit sponsor is an investigator belonging to an independent organisation (research groups, scientific associations) shall be considered of health interest and classified as EPA-AS. The AEMPS offers itself to provide methodological support to those investigators who request it.

For the evaluation/authorisation of the EPA-AS of COVID-19, the AEMPS shall only request, in addition to the protocol, the favourable opinion of the CEIm and the authorisation resolution shall be issued within a maximum period of 7 calendar days from the receipt of the opinion of the CEIm. With the aim of contributing to the improvement in quality and efficiency of the observational investigation regarding COVID-19, the AEMPS shall try to facilitate collaboration between investigators from different sites who propose studies with shared objectives. To do so, we are putting said investigators in touch, in case it might be feasible that between them they can come up with some kind of collaboration and, where applicable, the carrying out of multicentre studies.

For any consultation to the AEMPS related to these recommendations, please write to:

- Department of Drugs for Human Use: Clinical Trials Area; farmacoepi@aemps.es

In all cases, the subject line should read URGENT COVID-19 name of the drug(s) and researcher(s) and priority will be given to the response.