Exceptional measures applicable to tests clinicians to manage problems arising from COVID-19 emergency

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The Spanish Agency for Medicines and Health Products (AEMPS), as authority national competent in the authorization of clinical trials, proposes a series of recommendations for exceptional application during the period of the COVID crisis-19 in Spain. These measures are intended to preserve trial activities in the as much as possible, guaranteeing the healthcare of patients, protecting their safety and well-being and preserving the traceability of the actions implemented in this health emergency situation.

It is essential to maintain the maximum capacity of the health system by reducing the risk of infection for the population. In addition, the measures applied must be taken into account in the different autonomous communities after the declaration of the state of alert by the Government.

In this context, scheduled follow-up visits could be compromised, the access of external personnel to the centers and monitoring of the trial on site. In some cases, it may be necessary to transfer a patient from one center to another to facilitate their healthcare. On the other hand, there may be a decrease in the staff of the promoter responsible for monitoring the trial.

It is important that the promoter together with the researcher make a risk analysis and prioritize activities that are critical and how they should be carried out. Both should evaluate the application of these measures in a proportionate manner for each clinical trial considering their particularities, the organization of each center and the characteristics epidemiological studies of COVID-19 in it. These measures may be updated to adapt to epidemiological evolution as determined by the Ministry of Health.

Any of these exceptional measures that are adopted must be duly documented in the trial file. However, your application does not require approval prior case by case as a substantial modification by AEMPS or by the Ethics Committee of Research with medication (CEIm) and also the individual notification of serious breaches of the protocol, except when expressly required in point 2.

In the four months following the date on which the COVID-19 crisis is considered to have finished in Spain, the promoter must communicate for each trial a report on the Exceptional measures taken to be sent to the Agency and the CEIm.

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1. Scheduled face-to-face visits of patients in a clinical trial

The promoter together with the researcher must consider the advisability of postponing said visits, or transform them into telephone visits, reprogramming them in the visit calendar of the clinical trial. Critical scheduled on-site visits should be ensured are carried out. In the case of rescheduling visits, these deviations from the protocol are not will consider serious breaches unless they jeopardize the safety of the patient.

2. Recruitment of new patients

Prospective deviations from the protocol are not acceptable and are expected that all subjects included in a clinical trial will meet all Selection criteria. The promoter together with the researcher, based on an assessment benefit / risk that considers the characteristics of the trial and the circumstances of the Participating centers may interrupt recruitment and even interrupt treatment of trial patients in order to avoid unnecessary risks and ensure best possible healthcare for patients. This analysis is especially pertinent in clinical trials involving treatment with immunosuppressants and therefore a increased risk of infection, with no expectation of benefit to participants.

In the event of an interruption of the trial leading to the cessation of treatment in part of the patients, the promoter would have to report these measures as “measures security issues ”explaining the measures taken to guarantee the treatment alternative of patients sending an Ad Hoc report to both AEMPS and the Committee of Research Ethics with medicines. (CEIm) in the 15 days following the interruption or termination.

3. Access to trial treatment

Patient access to trial medication must be guaranteed in the same conditions in which it was occurring. It is recommended that the researcher assess the possibility and convenience that, when the patient comes to a scheduled visit, he receives a quantity of medicine that allows covering a longer period of treatment.

The Pharmacy Services of the hospitals may take the measures they consider necessary, for example, dispensing to a person authorized by the trial patient of a treatment that must be taken at home or sent from the Pharmacy Service of the treatment at the patient's home when their circumstances make it advisable. In

In relation to the latter, the conservation of the treatment during the transportation and communication with the patient that allows reception and adequate administration of the same. Section 10 of the document " Q&A: Good clinicalpractice (GCP) "- GCP Matters". The situation must be assessed in each particular case, by the promoter, the main researcher and the Pharmacy Service.

4. Monitoring visits

Sponsor recommended to update trial monitoring plans for all four next months prioritizing centralized monitoring and remote monitoring of

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participating centers that do not entail overloading the center's staff with tasks or review of source data and postponing data verification as much as possible source until you can access the medical history in person. The promoter will agree with the participating centers and teams the conditions for such monitoring.

5. Transfer of patients from one center to another

If it is necessary to transfer a patient from one trial center to another, this may be carry out whenever: a) a transfer agreement is signed between centers, b) the new center have access to the data collection notebook and the patient's medical history (or in your default the original center send you a copy of it); c) the original center send a transfer report summarizing the most relevant medical data of the patient in relationship with the trial to facilitate its follow-up to the new center; d) the transfer of patient is documented in the trial file of the two centers.

6. Clinical trials aimed at investigating new medications against coronavirus

The AEMPS is prioritizing together with the CEIm the evaluation of clinical trials intended to treat or prevent coronavirus disease. The promoters o researchers who have a research project of this type must send a message to the Clinical Trials Area indicating in the subject: URGENT new EC COVID19. I know will give an answer the same day.

For any other query to AEMPS related to these recommendations you can contact:

- or Department of Medicines for Human Use: Clinical Trials Area
- or Department of Inspection and Control of Medicines: Area of BPC and BPFV

In both cases, URGENT COVID19 must be indicated and priority will be given to the answer.

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