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# Impact of COVID-19 legislative changes: Exceptional measures applicable to clinical trials for managing problems arising from COVID-19 emergency

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**In the throes of the health emergency caused by COVID-19, the Spanish Agency of Medicinal Products and Medical Devices (AEMPS) published Informative Note MUH 4/2020, *of March 16, 2020*, establishing exceptional measures to guarantee the performance of clinical trials, patient safety and traceability of the implemented measures.**

The AEMPS provides for several exceptional measures that sponsors and/or investigators may implement in clinical trials currently underway, without having to obtain prior authorization from the AEMPS or the Spanish Ethics Committee for Research with Medicinal Products (CEIm). However, they must submit a report of their actions, in the four months following the end of the COVID-19 crisis in Spain.

To summarize, sponsors and/or investigators of clinical trials are authorized to take the following measures at their discretion:

- Postpone scheduled face-to-face visits with patients or change them to telephone visits.
- Interrupt the recruitment of patients and their treatment to avoid unnecessary risks, particularly in clinical trials involving treatment with immunosuppressant drugs. However, they must submit an *ad hoc* report to both the AEMPS and the CEIm to notify them of the standstill of treatment.
- In scheduled visits, provide patients with enough medicinal products to cover a longer period of treatment.
- Update the trial monitoring plans, prioritizing centralized and remote monitoring.
- Move patients from the trial center to another center, provided that certain requirements listed in the note are observed.

If a sponsor or investigator begins or is developing a research project to treat or prevent COVID-19, it must send an email to aecaem@aemps.es, with the subject "URGENTE nuevo EC COVID19."

For additional information on the contents of this document, please contact Cuatrecasas.