Clinical drug trials during the coronavirus epidemic (COVID-19)

03/13/2020

Changes in monitoring plan

Due to the coronavirus situation, it may be well justified to reduce on-site monitoring. The need for monitoring visits at the site is assessed and focused only on critical to ensure that monitoring does not expose people to disease and promote the spread of the disease. The sponsor should seek other means of monitoring (e.g. centralized monitoring) so that any reduction in on-site monitoring does not affect the quality of the study and the safety of the subjects. Reasoned deviations from the original monitoring plan shall be documented and, where appropriate, be subject to a relevant substantial protocol change notification.

Provision of investigational medicinal products to the patient

In the event of an epidemic, emergency arrangements may have to be made to deliver the investigational medicinal product to the patient (e.g. home delivery instead of on-site delivery). In this case, an exception scheme must be necessary to ensure the continuity of the trial and the safety of the subjects and the reliability of the study results. The sponsor shall notify Fimea of any exceptional arrangements as soon as practicable and shall make the relevant substantial change to the protocol. Fimea will prioritize the evaluation of such change notices.

Fimea encourages the prevention of the spread of coronavirus and the minimization of potentially drug-related clinical trial related activities that are not necessary for the safety of the subjects.

It is also advisable for operators to follow the European Medicines Agency's website for any further guidance.

More information

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