European Commission - Press release

Coronavirus: Commission issues guidance to mitigate clinical trial disruption in the EU

Brussels, 28 April 2020

Today, the Commission has published guidance to ensure that clinical trials can continue taking place in the EU during the COVID-19 pandemic. The aim is to mitigate the disruption of clinical research in Europe and therefore the negative effects of the pandemic, without compromising on quality and safety. These recommendations are an important part of the overall strategy in finding treatments and a vaccine to protect citizens against the coronavirus.

With more than 200 coronavirus clinical trials now registered in the EU database (EudraCT), the guidance offers recommendations for simple and flexible measures to respond to the current situation, and to ensure that patients participating in clinical trials across the EU can continue receiving their medicines.

Commissioner Stella **Kyriakides**, in charge of Health and Food Safety, said: *"We are in the midst of the worst pandemic in recent memory and it is absolutely crucial that we show flexibility in our rules to maintain research on critical treatments, including chronic and rare diseases, through clinical trials. Developing and deploying effective diagnostics, treatments and a vaccine will also undoubtedly be the most important breakthrough to stop the coronavirus. On 4 May, our international pledging conference will kick-start global cooperation and support for this work, with the aim to raise €7.5 billion in funding to the benefit of the global community.* Together in solidarity, we will prevail."

Key recommendations of the guidance cover:

- Distribution of medicines to patients in clinical trials: the purpose is to protect the safety and well-being of trial participants and the integrity of the clinical trials. This recommendation takes into account social distancing measures and possible limitations in trial site/hospital resources.
- Remote source data verification (SDV): the verification of the raw data in hospitals can become extremely difficult during the pandemic due to safety measures, such as social distancing. Remote SDV to conclude a trial could facilitate the marketing authorisation of coronavirus and life-saving medicines.
- Communication to authorities: urgent actions to protect trial participants against any immediate hazard or other changes with an effect on patient safety or data robustness might become necessary to mitigate disruptions during the ongoing public health crisis. The guidance clarifies the classification and notification of these actions.

These measures will be used exclusively during the coronavirus pandemic, and will be revoked once the current health crisis in the EU/EEA has been surpassed.

Background

Elaborated under the supervision of the European Commission, a first guidance document was published in late March by the Clinical Trials Expert Group (CTEG) of the European Commission, supported by EMA (European Medicines Agency), the Clinical Trials Facilitation and Coordination Group (CTFG) of the Heads of Medicines Agency (HMA) and the GCP (good clinical practice) Inspectors' Working Group of EMA.

The objective of the document is to provide a harmonised set of recommendations, to ensure the utmost safety and well-being of trial participants across the EU while preserving the quality of the data generated by the trials. The guidance also aims to make sure that clinical trials for other treatments than coronavirus, notably for rare diseases and serious or life-threatening medical conditions with no satisfactory treatment options, are not disrupted by the current crisis.

For more information

Guidance

Commission's dedicated coronavirus response webpage

Coronavirus Global Response pledging conference

Commission's website

European Medicines Agency

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