

## EU Supports Clinical Trials During COVID-19



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The European Commission has [published](#) 'Guidance on the Management of Clinical Trials During the Covid-19 (Coronavirus) Pandemic' to ensure continuation of clinical trials in the EU during the pandemic.

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The recommendations are part of the EU efforts to find treatments and a vaccine for the coronavirus. Currently there are over 200 COVID-19-related clinical trials registered in the European Union Drug Regulating Authorities Clinical Trials Database ([EudraCT](#)).

The document is aimed at mitigating the disruption of clinical research in Europe by the COVID-19 pandemic. It provides a set of recommendations to ensure the safety of trial participants and consistent quality of the data generated by the trials – in relation not only to COVID-19 research, but also clinical trials for other treatments, eg for rare diseases and serious or life-threatening medical conditions with no satisfactory treatment options.

The recommendations cover the following aspects: new and ongoing trials (including ones on COVID-19), safety reporting, risk assessment, communication (authorities, sponsors/sites/participants), informed consent, distribution of the investigational medicinal products and in vitro diagnostic and medical devices, monitoring, auditing as well as protocol deviations and reimbursement.

Commissioner Stella Kyriakides, in charge of Health and Food Safety, underscored the importance of allowing flexibility in the existing rules to maintain research on critical treatments 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," she said in a statement.

It is noted that the simplification measures proposed in the guidance will only last during the current public health crisis, and will be revoked once the current health crisis in the EU/EEA has been surpassed.

The full text of the guidance is available [here](#).

Source: [EU Commission](#)

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