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THE IMPACT OF COVID-19 ON RARE DISEASE CLINICAL TRIALS

BACKGROUND

The ability to conduct clinical trials has been significantly impacted by the COVID-19 pandemic. Many clinical trials have been halted or delayed and the enrollment of new participants is being postponed. Without important data on the safety and effectiveness of treatments from clinical trials, the arrival of new treatments in the marketplace will ultimately be delayed. In addition, patients fighting serious and life-threatening diseases may not be able to access investigational products because of suspended clinical trials, even though those investigational treatments may be their best hope for health improvement in the absence of other approved drugs.

WHY ARE CLINICAL TRIALS BEING IMPACTED?

- > Patient visits to healthcare facilities or trial sites may not be possible due to risk of COVID-19 infection.
- > Health care providers are busy caring for COVID-19 patients and may be unable to carry out day-to-day clinical trial duties.
- > Many laboratories for scientific research have been closed due to the COVID-19 public health emergency.

FDA GUIDANCE ON THE CONDUCT OF CLINICAL TRIALS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY

The FDA issued a guidance for industry, investigators, and institutional review boards (IRBs) to inform key considerations (such as the decision to continue or suspend a clinical trial) and requirements for sponsors undertaking clinical trials during the COVID-19 outbreak. FDA's guidance provides flexibility to sponsors to continue clinical trials where feasible and appropriate. The following are key points from the guidance:

- > Safety first! The safety and well-being of clinical trial participants is most important and must be the focus for decision-making.

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- > Communication is key! Trial participants should be informed of changes to the study and monitoring plans that could impact them. Sponsors should engage with IRBs about protocol changes and consult with FDA as early as possible regarding protocol changes.
- > Modifications to data collection and safety assessments may be made, but every effort must be made to preserve the integrity of the study.
- > All changes to the study protocol must be documented to explain why the changes were made, what the changes were, and the impact of the changes on the study.

WHAT IS IMPORTANT FOR CLINICAL TRIAL PARTICIPANTS AND THEIR LOVED ONES TO KNOW?

- > There may be unfortunate delays in recruitment, start-up or continuation of some clinical trials.
- > For ongoing trials, there may be changes to the way visits are conducted and how information is collected. For example, visits could be virtual or take place at an alternate site. Data could be collected via home visits. Some laboratory tests may be delayed.
- > You have the right to know about changes to a trial you are enrolled in. Don't hesitate to ask questions and reach out to the trial coordinator.
- > Keep collecting your data, participating in registries, and following your own natural history. This information remains important.
- > Delays are frustrating, at times with enormous consequences. Do your best to stay positive and remain hopeful.

ADDITIONAL RESOURCES

[FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)

[NPR Weekend Edition: Coronavirus Pandemic Brings Hundreds Of U.S. Clinical Trials To A Halt](#)

[Biospace: COVID-19 Slows More than Two-Thirds of Clinical Trials, Report Shows](#)

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