# FDA ISSUES GUIDANCE FOR CLINICAL TRIAL RESEARCHERS AMID COVID-19 PANDEMIC

*March 30, 2020*

## FDA ISSUES "CONDUCT OF CLINICAL TRIALS OF MEDICAL PRODUCTS DURING COVID-19 PANDEMIC"

On March 27, 2020, the U.S. Food and Drug Administration (FDA) issued an updated guidance that includes a question and answer section devoted to guiding industry, investigators and institutional review boards on how best to address research-related challenges posed by the COVID-19 pandemic. In recognition of how these challenges may interrupt and strain the research process for drugs, devices and biological products, including accommodations required due to quarantines, site closures, travel limitations, and interruptions to the supply chain for the investigational product, the FDA provides significant clarity on how to implement, handle and report protocol deviations. General considerations include the safety of trial participants being of paramount concern, as well as compliance with good clinical practice and minimizing risks to trial integrity. The guidance is posted here, and a brief summary of key provisions follows.

## INFORMED CONSENT

In order to prioritize infection control measures, certain "work arounds" to the written consent requirements under 21 CFR § 50.27 will be permitted during the emergency period. If the appropriate technology is available to utilize electronic methods of obtaining informed consent, they should be used. Where not available, sponsors are encouraged to consider the range of options provided (including utilizing home health workers to deliver the consent forms, direct communications with the patient in isolation and three-way telephone calls or video conferences with the patient and a witness) and implement a standard and consistent process where feasible.

## DOCUMENTATION

The FDA indicates that robust efforts must be made by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants and study data integrity; and clear and concise documentation in the medical record will be critically important where protocol amendments are proposed, protocol deviations are made and methodologies of conduct change (e.g., virtual clinical trial visits for monitoring patients and remote informed consent administration). Appropriate sections of the clinical study report should be updated to reflect contingency measures implemented, a list of anonymized participants affected and a description of how each impacted subject's participation was altered.

Evaluations of how the contingency measures should be expected to effect/not effect safety and efficacy results reported for the study must also be included in the report.

## INNOVATIVE SOLUTIONS ENCOURAGED

Direct to Patient study practices are offered as one solution to addressing COVID-19 challenges. These include delivery of certain investigational products (for self-administration) to the subject home/location as well as other alternative administration modalities (for administered drugs). Researchers must bear in mind that all existing regulatory requirements for maintaining investigational product accountability remain and must be addressed and documented. Additionally, where appropriate based upon study design, on-site monitoring visits may be replaced with central and remote monitoring programs to maintain oversight of clinical sites.

## CONCLUSION

The guidance serves as a cogent reminder to the research community that notwithstanding the current COVID-19 challenges, sponsors, clinical investigators, and IRBs should have established policies and procedures in place that describe the mechanism to be implemented for designing and implementing approaches to be used to protect trial participants and manage study conduct during unpredictable disruptions.

If you have any questions about these pharmacy measures, please contact a member of our Life Sciences Team. For any other concerns arising from the pandemic, please contact a member of our COVID-19 Task Force.