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Conducting Clinical Trials During COVID – FDA Guidance for Industry

By **IVT Staff Jul 8, 2020 7:00 am EDT**

The FDA recently released the temporary, “Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency,” to assist sponsors in assuring the safety of trial participants,1 maintaining compliance with good clinical practice (GCP) and minimizing risks to trial integrity for the duration of the COVID-19 public health emergency.

Great impacts to life science organizations have resulted from the ongoing COVID-19 pandemic, and while many drug makers are moving quickly to find possible vaccines and other treatments, one of the biggest impediments is the access to participants for clinical trials. Employee quarantines, site closures, travel limitations, and interruptions to the supply chain for the investigational products have also been factors and will continue to be for the unforeseeable future. Understanding these limitations will likely require modifications to protocols and procedures for clinical trials, the FDA outlined the following considerations:

1. For ongoing trials
    1. Keeping patients safe and informed is critical
    2. Modification to study activities, such as recruitment, use of investigational products, changes to patient monitoring and other study changes should be considered for safety of trial participants
    3. Sponsors should determine which patients should continue in trials, and which should not, noting ability to safely administer drugs, monitoring of outcomes, supply chain disruptions for investigational products and nature of disease featured in study.
    4. Alternative methods for safety assessments (methods of communication and monitoring) are sufficient in assuring the safety of trial participants
    5. Study quality as changes in study visit schedules, missed visits, or patient discontinuations may lead to missing information, which would then need to be captured in the case report form
    6. If changes in protocol will lead to amending data management and/or statistical analysis plans, the sponsor should consult with the applicable FDA review division
2. If policies and procedures are not already in place for applicable trials:
    1. Establishing policy and procedures to describe approaches to protect trial participants and manage study conduct during possible disruption of the study as a result of COVID-19 control measures at study sites
    2. Policy and procedures should be compliant with applicable (regional or national) policy for the management and control of COVID-19
3. For all trials that are impacted by the COVID-19 public health emergency, descriptions must be made in the appropriate sections of the clinical study report
    1. Contingency measures implemented to manage study conduct during disruption of the study as a result of COVID-19 control measures.

2. A listing of all participants affected by the COVID-19 related study disruption by unique trial participant number identifier and by investigational site, and a description of how the individual's participation was altered.
3. Analysis and corresponding discussions that address the impact of implemented contingency measures (e.g., trial participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

Most importantly, the FDA expects robust efforts by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants. While there may be unavoidable deviations t protocols, efforts to minimize impacts on trial integrity, and to document reasons for deviations will be extremely important.

Download the FDA Guidance Document
