FDA Issues Guidance for Conducting Clinical Trials During COVID-19

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On March 18, 2020, the FDA issued Guidance for Industry, investigators, and institutional review boards (IRBs) conducting clinical trials during the COVID-19 pandemic. The FDA recognized that certain challenges may arise in connection with COVID-19 that may create difficulty for clinical trials, such as quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected. Protocol modifications may be required, and there may be unavoidable protocol deviations. In its guidance, the FDA outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practices (GCPs), and minimizing risks to trial integrity. Noted considerations include, among others, the following:

- Since trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary, feasible, and sufficient to assure the safety of trial participants. Sponsors should determine if in-person visits are necessary to fully assure the safety of trial participants (e.g., to carry out procedures necessary to assess safety or the safe use of the investigational product appropriately). In making the decision to continue use or administration of the investigational product, the sponsor should consider whether the safety of trial participants can be assured with the implementation of the altered monitoring approach.

- In some cases, trial participants who no longer have access to the investigational product or site may need additional safety monitoring (e.g. withdrawal of an active investigational treatment).

- Changes in a protocol are typically not implemented before review and approval by the IRB, and in some cases, by FDA. Sponsors and clinical investigators are encouraged to engage with IRBs as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. ***Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval and before filing an amendment to the IND or IDE but be reported (and/or amendments must be submitted) afterwards***. FDA encourages

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sponsors and investigators to work with their IRBs to prospectively define procedures to prioritize reporting of deviations that may impact the safety of trial participants.

- If scheduled visits at clinical sites will be significantly impacted, certain investigational products, such as those that are typically distributed for self-administration, may be amenable to alternative secure delivery methods. For other investigational products that are normally administered in a healthcare setting, consulting FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel) is recommended. In all cases, existing regulatory requirements for maintaining investigational product accountability remain and should be addressed and documented.

- With respect to efficacy assessments, FDA recommends consultation with the appropriate review division regarding protocol modifications to gather data in relation to efficacy endpoints, such as use of virtual assessments, delays in assessments, and alternative collection of research-specific specimens, if feasible. For individual instances where efficacy-endpoint data is not collected, the reasons for failing to obtain the efficacy assessment should be documented (e.g., identifying the specific limitation imposed by COVID-19 leading to the inability to perform the protocol-specified assessment).

- Sponsors, clinical investigators, and IRBs should consider establishing and implementing, or revising, policies and procedures to describe approaches that may be used to protect trial participants and manage study conduct during any COVID-19-related disruptions to the study. Changes to policies and procedures could address (among other things) changes relating to the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and study personnel (e.g., investigators, site staff, and/or monitors), secondary to travel restrictions, quarantine measures, or the illness, itself. Policies and procedures should be compliant with applicable (regional or national) policies for the management and control of COVID-19. And, as mentioned above, depending upon the nature of the changes described above, a protocol (and/or IDE/IND) amendment may be required under the applicable regulations.

For all trials impacted by COVID-19, sponsors should include in the appropriate sections of the clinical study report (or in a separate study-specific document):

- Contingency measures implemented to manage study conduct during any disruption(s) to the study.

- A list of all study participants affected by the disruption, identifying such participants by their unique subject-number identifiers and by investigational site, along with a description of how the individual's participation was altered.

- Analyses and corresponding commentary addressing the impact of implemented contingency measures on the safety and efficacy results reported for the study.

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