Published on *The National Law Review* https://natlawreview.com

# FDA Issues Guidance for Ongoing Clinical Trials During COVID-19 Pandemic

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On Wednesday, March 18, 2020, the Food and Drug Administration ("FDA") issued a guidance document titled, "FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic" (the "Guidance"). FDA's stated purpose in issuing the guidance is to help sponsors to assure the safety of trial participants, maintain compliance with good clinical practice ("GCP"), and minimize risk to the integrity of trials during the ongoing Coronavirus Disease 2019 ("COVID-19") pandemic.

The Guidance recognizes the impact COVID-19 may have on the conduct of ongoing clinical trials, including quarantines, site closures, travel limitations, interruptions to the supply chain, and other considerations should individuals involved in the studies become infected with COVID-19. FDA acknowledges that these factors may impact a sponsor's ability to meet protocol-specified procedures, and that protocol modifications may be necessary and deviations unavoidable.

As noted by the FDA, the Guidance does not establish new legally enforceable responsibilities; rather, the considerations provided should be viewed as recommendations. However, based on our review of the Guidance, we identify the following key takeaways and recommended action items for sponsors and research institutions:

## Sponsors

- Communications with investigators to understand and address local conditions and restrictions will be critical. Sponsors should consider modifying the study drug administration procedures and study evaluations, if possible, to enable safe continuation of the study. For example, a sponsor may consider use of telehealth options (e.g., phone calls or a virtual visit) or home visits instead of a site visit; whether the investigational product could be delivered to the participant while maintaining the safety of the participant; and other remote monitoring options.

- Protocol modifications may be necessary for the success of the study. Sponsors should evaluate the extent to which a study can continue under the existing protocol in light of current conditions, with the safety of participants as the primary consideration. This may include changes to the informed consent used for the study. If emergent or urgent changes are made to the protocol or informed consent, they should be communicated to the IRB in advance, where possible, or must be reported promptly thereafter. Concurrently, sponsors should consider whether any such changes required to ensure participant safety and the well-being of researchers will enable the collection of valid, useful safety and efficacy data.

- Documentation is key. Sponsors must ensure any changes to study conduct arising from the COVID-19 pandemic are clearly documented, including both a description of the change and the reason for the change. Examples may include, among others, a written summary of COVID-19-induced changes to the protocol, including both modifications and deviations; any resulting impact on the performance of the study protocol; changes to study visits or patient discontinuations; and any contingency measures implemented to manage study conduct during the pandemic. Of note, the Guidance provides that any screening procedures implemented as a result of a mandate by the health care system in which the study is conducted do not need to be reported as an amendment to the protocol unless the sponsor is incorporating the data collected during the screening as part of a new research initiative.

- FDA expects sponsors to work with investigators and IRBs to ensure policies and procedures effectively protect study participants and manage study conduct in the context of COVID-19. Sponsors should review and, if needed, update policies and procedures to address COVID-19 considerations.

## Research Institutions

To promote collaborative implementation of the measures described above, research institutions should consider the following recommendations:

- Investigators should consult with sponsors to evaluate whether a study participant's safety, welfare and rights are best served by continuing in the study under the existing protocol, under a modified version, or by discontinuing participation based on the specific circumstances.

- The safety of the study participants, as well as the persons involved in conducting the study at the research institution, is paramount during the COVID-19 pandemic. Investigators should consult with sponsors to provide information regarding local conditions and restrictions to facilitate an informed consideration of alternative procedures for study drug administration and study evaluations in an effort to minimize risks to study participants and research institution staff. Examples of alternative procedures include the telehealth and alternative product administration and/or delivery methods described above. Any changes implemented must be communicated to study participants as necessary.

- Protocol deviations and informed consent modifications may be necessary in urgent or emergent circumstances. Maintaining open and consistent contact with the IRB will be necessary in order to communicate deviations and modifications. These should be reported to the IRB in advance, where possible, or must be reported promptly thereafter. The Guidance notes specifically that changes intended to minimize or eliminate immediate hazards or to

protect the life and well-being of research participants, including from COVID-19, may be implemented without IRB approval, but must be reported after implementation.

- Detailed documentation at the research institution will be important to allow the sponsor to track changes made related to the study and preserve data integrity, particularly for a multi-site study. Research institutions should clearly document all changes and protocol deviations on a subject-by-subject basis, including the reason for the change or deviation.



National Law Review, Volume X, Number 79