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FDA Guidance on Conducting Clinical Trials During the COVID-19 Pandemic

By James C. Shehan

Recognizing the impact of the COVID-19 pandemic on the conduct of clinical trials for drugs and medical devices, on March 18, the Food and Drug Administration (FDA) issued a guidance without prior public comment that is effective immediately. The intent of the *Guidance on Conduct of Clinical Trials of Medical Products* is to assure the safety of trial participants, help maintain compliance with good clinical practice, and minimize risks to trial integrity during the pandemic. Highlights include:

- Sponsors, investigators, and institutional review boards (IRBs) that have not already adopted policies and procedures to protect participants and manage study conduct during the pandemic should do so now.
- In the interest of safety, sponsors should consider whether they should (1) continue patient recruitment, (2) continue use of investigational products for patients already in a trial, and (3) change how patients are monitored.
- Sponsors should carefully document all actions taken in response to the pandemic.

FDA recognizes that a clinical trial participant's safety, welfare, and rights may be best served by continuing in the trial as per the protocol, by discontinuing the administration or use of the investigational product, or by discontinuing participation in the trial. Decisions should be made by sponsors, in consultation with investigators and IRBs, based on specific circumstances, including the nature of the investigational product, the ability to conduct appropriate safety monitoring, the potential impact on the investigational product supply chain, and the nature of the disease under study in the trial.

Guidance on Specific Points

Some of the specific points covered by the guidance include:

- Sponsors should consider policies and procedures addressing changes to the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigators, site staff, and clinical monitors because of travel restrictions, quarantine measures, or COVID-19 illness.
- If a trial, as designed, cannot be properly conducted, consider whether it is possible to delay some assessments, whether recruitment should be stopped, and/or whether participants should be discontinued.
- Patients should be kept informed about changes to the study or monitoring plans that could affect them.
- If patients can't make clinical site visits, consider alternative methods such as phone calls and alternative locations.
- If live visits by clinical trial monitors can't be conducted, consider use of central and remote monitoring programs.
- COVID-19 screening procedures mandated by the health care system in which a clinical trial is being conducted do not need to be reported to FDA as a protocol amendment even if done during clinical study visits, unless the sponsor is incorporating the data collected as part of a new research objective.
- If COVID-19-driven protocol or informed consent changes are made to protect the lives and well-being of participants, these changes may be implemented without IRB approval or before filing an amendment to the IND or IDE. Early engagement with IRBs is encouraged, however, and changes must be reported to FDA later.

- The implementation of alternative processes should be consistent with the protocol to the extent possible.
- If use of an investigational product is discontinued, consider whether the withdrawal requires additional safety monitoring.
- Sponsors as well as clinical investigators should document (1) how restrictions related to COVID-19 led to changes in study conduct, (2) the duration of those changes, and (3) which trial participants were affected and how.
- Sponsors should consult with their review division, if feasible, regarding possible modifications to efficacy endpoints or possible changes to the statistical analysis plan, such as virtual assessments, delays in assessments, and alternative collection of research-specific specimens.
- Questions about clinical trial conduct during the COVID-19 pandemic can be sent to this FDA email address: Clinicaltrialconduct-COVID19@fda.hhs.gov.

Recommendations

Clearly, all clinical sponsors should be assessing the impact of the pandemic on their clinical trials **now**. Sponsors should be adopting specific policies and procedures covering changes to their clinical trials, and such policies and procedures should be flexible enough to address rapidly changing circumstances. Sponsors should also make sure that they are appropriately documenting all the COVID-19-driven steps they are taking. And sponsors should be engaging with investigators, other study personnel, and IRBs to ensure that they understand the FDA guidance and any changes the sponsors are implementing. Finally, sponsors should be considering whether they need to engage with FDA regarding any of these steps.

Contacts

Please contact the listed attorneys for further information on the matters discussed herein.

JAMES C. SHEHAN
Senior Counsel
Chair, FDA Regulatory
T: 646.414.6897
jshehan@lowenstein.com

MICHAEL J. LERNER
Partner
Chair, Life Sciences
T: 973.597.6394
mlerner@lowenstein.com