Hughes Hubbard & Reed

COVID-19 Impact on Clinical Research and New FDA Guidance

Client Advisories

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The public health emergency caused by the COVID-19 pandemic has impacted clinical research globally for all sorts of medical products, and will continue to do so for the foreseeable future. Concerns include (1) the safety of all study participants, including patients, investigators and other healthcare workers; (2) continued access to the study drug; (3) recruitment of study subjects and investigators; (4) study data collection; and (5) continued collection of adverse event data and safety monitoring in general. To address the ongoing crisis, on March 18, 2020, the FDA implemented its Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic, taking the unusual step of doing so without a period of public comment.

FDA offers the following guidance:

- Safety
  - Determine whether changes are needed regarding trial recruitment; use of the investigational product by study participants; study subject safety monitoring if subjects cannot come to the trial site; and continuation of the study itself.
- Access to Study Drug
  - Determine whether alternative methods for delivery would be appropriate for investigational drugs that typically are self-administered.
  - Where administration normally is performed by a healthcare provider, identify sites for alternative administration with trained personnel.
- Data Collection and Monitoring
  - Changes in study visits, missed visits, or discontinuation leading to missing information must be documented with specific information in case report form, including if related to COVID-19.
- Updates to Study Protocol
  - Confer as soon as possible with the study Institutional Review Board ("IRB").
  - Changes made to minimize or eliminate immediate hazards or to protect the life or well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented *without* IRB approval or before filing an IND/IDE amendment.

- Changes should be as consistent with the study protocol as possible.
- All changes should be documented in detail, including the reasons for the change.

- Reporting
  - Clinical trial study reports must include detailed descriptions of the following with regard to disruptions caused by COVID-19:
    - Contingency measures implemented to manage study conduct.
    - A list of all participants affected by such disruption and how the individual's participation was altered.
    - Analysis and discussion of the impact of contingency measures taken to address the disruption on the safety and efficacy results reported (e.g., study subject discontinuation, alternate procedures used to collect critical safety or efficacy data).

Be prepared to document how restrictions related to COVID-19 led to changes in the conduct of the study, the duration of such changes, who was impacted and how. Following these recommendations to thoroughly document and report on these modifications will be critical to maintaining the integrity of study data and findings, and, ultimately, to drug approval.

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