COSMOS
Navigate the Compliance Universe

Report on Research Compliance Volume 20, Number 7. June 22, 2023
RRC E-Alerts: June 8, 2023

By Theresa Defino

FDA Issues Final, Draft Guidance Documents

Sponsors of clinical trials under Food and Drug Administration (FDA) regulations should develop a risk-based monitoring program that begins with protocol creation and extends throughout the course of a study, with the aim of "eliminating or mitigating important risks to both human subject protection and data integrity." According to FDA's recently issued guidance, which finalizes a 2019 draft, "the risk assessment should include an evaluation of the potential causes, likelihood of detection, and severity of the consequences of risks to critical data or human subject protections." The guidance, which includes eight FAQS, stresses that the "risk assessment and monitoring plan should be reviewed and revised, as needed, to help ensure the risk of recurrence is decreased, or if possible, eliminated. In instances in which corrective actions modify study processes, the protocol and/or associated investigational plans should be amended to reflect changed processes. Related systemic issues should be identified and resolved promptly to help ensure that investigation quality, including the rights, safety, and welfare of investigation participants and data integrity, is maintained," FDA said.

FDA also issued draft guidance on decentralized clinical trials (DCTs), which is open for comment until Aug. 1. FDA defined DCTs as studies where "some or all of the trial-related activities occur at locations other than traditional clinical trial sites," such as the research participants' homes "or in local health care facilities that are convenient for trial participants." The agency noted that, "in general, investigators can consider telehealth visits instead of in-person visits with trial participants if no in-person interaction is needed." FDA also said, "there should be a physical location where all clinical trial-related records for participants under the investigator's care are accessible and where trial personnel can be interviewed." Sponsors must take steps to "help reduce variability, including regular review by investigators of participant data entered by local [health care providers] HCPs, to assess consistency and completeness of the required procedures. The type and scope of quality control measures should be tailored to the criticality of the data and the complexity of procedures done by the local HCPs," the draft guidance states.

Link to final guidance

Link to draft guidance