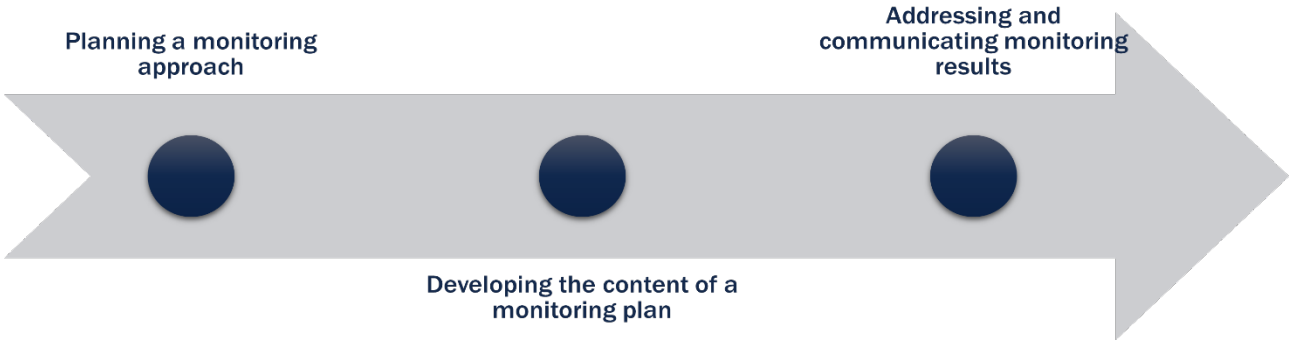
CRSO Insightalyst

April 14, 2023

FDA Publishes Final Question-and-Answer Guidance on a Risk-Based Approach to Monitoring Clinical Investigations

The U.S. Food and Drug Administration (FDA) published a final guidance, "A Risk-Based Approach to Monitoring of Clinical Investigations, Questions and Answers, Guidance for Industry." The guidance provides sponsors with information about implementing a risk-based approach to monitoring clinical studies of human drugs, biologics, medical devices, and combinations of these products. The FDA believes that risk-based monitoring allows for identification and mitigation of issues to safeguard human research participants and ensure data integrity during a clinical study. As the recommendations are intended for sponsors, they apply directly to **UNC investigators** who initiate and conduct clinical investigations (that is, sponsor-investigators).

Although clinical investigations must be monitored, the FDA provides flexibility in how to do so. The guidance provides recommendations on planning a monitoring approach, developing the content of a monitoring plan, and addressing and communicating monitoring results.



To explore the questions and answers in the guidance click here.

The Q&A guidance complements the FDA's 2013 guidance, "Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring," with additional recommendations for implementing risk-based monitoring.

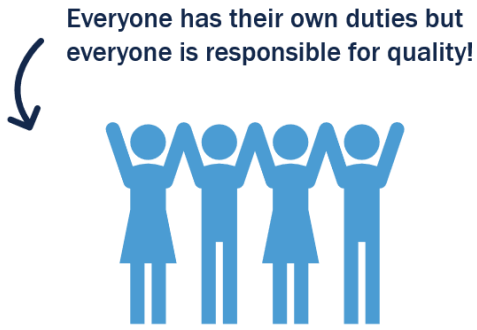
What does it mean for me?

This FDA's Q&A Guidance applies to UNC sponsor-investigators who are initiating and conducting clinical investigations of drugs, biological products, and medical devices as they are required to ensure proper monitoring of the investigation. However, the guidance is more broadly relevant as all clinical research studies should have a monitoring system to help ensure data integrity and protection of the rights, safety, and welfare of participants.

More Available Information

Consider conducting self-assessments as part of your monitoring system to proactively discover strengths and areas for improvement in clinical research activities. Explore the available self-assessments in the CRSO Self-Assessment Toolbox.

If you have questions regarding the guidance or implementing a self-assessment process, please contact the CRSO at crso@med.unc.edu.



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