Building Quality into the Design and Conduct of Clinical Studies: Integrating Quality by Design (QbD) and Risk-Based Monitoring (RBM) Approaches

Hybrid Public Meeting • National Press Club • Washington, DC
January 31, 2024 | 9:00 am – 4:20 pm ET

Meeting Background and Objective:

Quality by design (QbD) and risk-based monitoring (RBM) approaches facilitate clinical trial modernization by enhancing efficiency without compromising data integrity or participant protections. The U.S. Food and Drug Administration (FDA) has encouraged the use of QbD and RBM through many outreach activities, such as co-hosting a public workshop in 2019 on implementing RBM approaches in clinical investigations. FDA has also recently published several guidance documents on these topics, such as E6(R3) Good Clinical Practice, A Risk-Based Approach to Monitoring of Clinical Investigations – Questions and Answers, and E8(R1) General Considerations for Clinical Studies. Despite the efforts of FDA and other interested parties, QbD and RBM approaches to plan and conduct of clinical investigations have not been fully utilized. Additionally, as the COVID-19 pandemic necessitated changes to clinical trial design and conduct, recent experiences may help to inform the development of best practices for implementing QbD and RBM moving forward. This public workshop, convened by Duke-Margolis Center for Health Policy under a cooperative agreement with the FDA, is an opportunity to facilitate a discussion among the clinical trials community and interested parties about challenges and successes of integrating QbD and RBM into the design and conduct of clinical studies. The objectives of this meeting are to:

- Encourage the incorporation of QbD principles into the design and conduct of clinical studies, including the development of study protocols and workflow processes
- Identify barriers to QbD and RBM implementation by sponsors, clinical research organizations, and clinical trial sites
- Inform best practices for incorporating QbD and RBM approaches into the design and conduct of clinical studies

Workshop Agenda

9:00 am    Welcome
9:10 am    Opening Remarks
9:20 am    Session 1: Risk-Based Approaches to Building Quality into the Design and Conduct of Clinical Investigations - Regulatory Perspectives of QbD and RBM

Objective: Presenters will provide an overview of quality principles in the design and conduct of clinical investigations while integrating QbD and RBM approaches based on recent FDA guidance.

10:35 am    Break
10:45 am  Session 2: Optimizing Study Design and Setting the Stage for Efficient Study Conduct Through QbD: Successes and Challenges

*Objective:* This session will focus on opportunities to prospectively design quality in study protocols, operations, and training, and identifying successes and challenges when implementing QbD approaches.

12:15 pm  Lunch

1:25 pm  Session 3: Translating QbD Outcomes to Risk-Proportionate Oversight Including RBM: Successes and Challenge

*Objective:* This session will focus on identifying successes and challenges with implementing a risk-based approach to sponsor oversight of clinical trial activities including trial monitoring and other clinical trial activities performed by contracted service providers.

2:55 pm  Break

3:10 pm  Session 4: Next Steps for Implementing Quality Management of Clinical Investigations

*Objective:* This panel discussion session will focus on determining what the immediate next steps are for sponsors, CROs and other interested parties to incorporate quality management into clinical studies. Panelists will identify best practices and needs that will facilitate increased adoption of quality management by interested parties now and in the near future.

4:10 pm  Concluding Remarks

4:20 pm  Adjournment