

Improving the Implementation of Risk-Based Monitoring Approaches of Clinical Investigations

Marriott Marquis • Washington, DC
July 17, 2019

Agenda

As the time and costs associated with pharmaceutical research and development continue to rise, sponsors, research organizations, and the U.S. Food and Drug Administration (FDA) have explored opportunities for improving the efficiency of traditional approaches to clinical investigations. One such area where potential improvements could be made is in the traditional practice of using on-site monitoring of each clinical site to perform source data verification (SDV) and evaluate study conduct. On-site monitoring, with accompanying 100% source data verification, is resource intensive and by some estimates accounts for up to one-quarter of the total cost of a clinical trial.¹

To help ensure data integrity and human subjects protections, and to improve clinical investigation quality and efficiency, FDA issued final guidance in 2013 that recommends sponsors use risk-based approaches to monitor clinical investigations, rather than relying on traditional monitoring approaches that heavily depend on 100% SDV. Risk-based monitoring (RBM) focuses sponsor oversight on risks to the most critical data elements, procedures, and processes necessary to achieve the objectives of clinical investigations. In 2019, FDA issued additional draft guidance to provide more detailed information to assist sponsors in planning and conducting RBM.

There have been signs, however, that RBM approaches have not yet been widely implemented as part of clinical studies and across development portfolios. FDA is therefore seeking additional feedback from stakeholders on the challenges, barriers, and enablers that might be impacting the adoption of RBM, and related opportunities to improve RBM implementation. This public workshop, held under a cooperative agreement with the U.S. Food and Drug Administration, is an opportunity to capture stakeholder input on:

- The extent to which organizations have implemented risk-based assessment and monitoring, including in conjunction with central monitoring approaches
- Lessons learned from strategies employed to overcome any obstacles to implementation and to continued execution of RBM
- Enablers that support implementation and execution of risk-based monitoring
- How stakeholders assess impact of their RBM program
- Remaining challenges to implementation or execution that need to be addressed

8:30 a.m. Welcome and Overview

- **Gregory Daniel**, Duke-Margolis Center for Health Policy

8:35 a.m. Opening Comments from FDA

- **Jacqueline Corrigan-Curay**, U.S. Food & Drug Administration

8:40 a.m. Session 1: Regulatory Foundation for Risk-Based Monitoring

Moderator: Gregory Daniel

Presenters:

- **Camelia Mihaescu**, European Medicines Agency
- **David Burrow**, U.S. Food and Drug Administration

9:20 a.m. Session 2: Experiences with Implementation of Risk-Based Monitoring Approaches

Moderator: Gregory Daniel

Panelists:

- **Nicole Stansbury**, Syneos Health (Association of Clinical Research Organizations)
- **Tyrus Rorick**, Duke Clinical Research Institute
- **Tim Rolfe**, GlaxoSmithKline (The Pharmaceutical Research and Manufacturers of America)
- **Michele Cameron**, Clearwater Cardiovascular Consultants (Society for Clinical Research Sites)

10:20 a.m. Break

10:30 a.m. Session 3: Analytical Tools and Methods to Support Risk-Based Monitoring

Moderator: Gregory Daniel

Panelists:

- **Ann Meeker-O'Connell**, IQVIA
- **Anne Lindblad**, Emmes
- **Stephanie Clark**, Janssen
- **Jonathan Andrus**, Society for Clinical Data Management
- **Mike Henderson**, SAS Health and Life Sciences

11:30 a.m. Lunch

12:30 p.m. Session 4: Identifying Enablers to Support Implementation of Risk-Based Monitoring Approaches

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Panelists:

- **Rehbar Tayyabkhan**, Regeneron (TransCelerate BioPharma)
- **Rosanne Petros**, Merck
- **Debra Jendrasek**, Premier Research

- **David Burrow**, U.S. Food and Drug Administration
- **Steve Young**, CluePoints

2:00 p.m. Break

2:15 p.m. Session 5: Measuring the Impact of Risk-Based Monitoring Approaches
Moderator: Mark McClellan

Presenter:

- **Justin Stark**, Novartis (TransCelerate BioPharma)

Panelists:

- **Linda Sullivan**, Metrics Champion Consortium
- **Sharon Love**, University College London
- **Brian Barnes**, PPD
- **Michael Walega**, Bristol Myers Squibb

3:15 p.m. Break

3:30 p.m. Session 6: Synthesis and Next Steps
Moderator: Mark McClellan

Panelists:

- **Michele Cameron**, Clearwater Cardiovascular Consultants (Society for Clinical Research Sites)
- **Ann Meeker-O'Connell**, IQVIA
- **Rehbar Tayyabkhan**, Regeneron (TransCelerate BioPharma)
- **Linda Sullivan**, Metrics Champion Consortium
- **Alyson Karesh**, U.S. Food and Drug Administration

4:00 p.m. Closing Remarks and Adjournment

ⁱ Funning S. et al. "Quality Assurance within the scope of good clinical practice (GCP): what is the cost of GCP-related activities? A survey within the Swedish Association of Pharmaceutical Industry (LIF)'s members." Qual Assur J. 2009; 12:3-7.