Risk Based Quality Management

Working Group Scope
With a wider remit focused on RBQM, this Working Group will identify innovative approaches in the planning (Quality by Design, Critical to Quality, Risk Identification and Characterisation), conduct (Risk Control), and continuous improvement (Risk Review, Risk Communication) elements of RBQM that support proactive management data reliability and participant well-being. The Working Group will support the pharmaceutical industry with change management strategies related to embracing risk-based approaches.

Current Projects
Centralised Monitoring Capabilities
OpenRBQM: Pre-Competitive Collaboration on Open-Source Software for RBQM
Quality Tolerance Limits
Quality Tolerance Limits – Threshold Setting Methodologies

Resources		Recording
The Risk Based Monitoring Feedback Loop Community Forum	Vera Pomerantseva, *ZS Associates*	Recording

jeremy.howells@roche.com

Jeremy Howells is a People & Product Leader in the Data Strategy & Delivery, Data Sciences group at Roche. Jeremy has a BSc in Maths from Cardiff University and 15+ years' experience as a stats programmer. His career in pharmaceutical biometrics began at GlaxoSmithKline in 2006 as a placement statistician. He joined Roche in 2012 as a statistical programmer, working for about seven years across the lifecycle of drug development. In 2019 he made the move into clinical data management as a People Manager, evolving into his current role in 2021. It was here he began his current involvement in risk-based quality management as the Product Operational Expert for QTLs at Roche. Jeremy is a member of the PHUSE QTL Working Group project.

michael.walega@bms.com

Michael Walega is the Head of Centralized Monitoring at BMS. He is responsible for providing protocol teams with actionable insights to achieve higher quality, ensuring centralised monitoring processes are aligned to relevant regulatory requirements, and championing risk-based quality management approaches to clinical trial monitoring activities.

He was previously at LabCorp/Covance, where he led the team responsible for development and growth of Covance's Risk-Based Monitoring (RBM) solutions, processes and operational delivery. He also led the Late-Stage Biostatistics and Programming groups, as well as the Process Excellence team. Michael is a qualified biostatistician and a Six Sigma Master Black Belt.