

Risk Based Quality Management

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End to End RBQM Education

Description

This initiative will provide Community Forums to present and discuss RBQM-related topics, supporting broader industry education. Planned topics include CtQs, RBQM and technology, risk assessments, central monitoring analytics, QTLs, AI/ML, and change management.

There remains a significant need for foundational RBQM education across the industry, including its core components and effective implementation. In addition, limited regulatory feedback, particularly from the FDA, has contributed to uncertainty, highlighting an opportunity for collaborative educational efforts.

Misconceptions and lack of understanding have delayed adoption within many organisations. Although RBQM approaches can improve data quality and operational efficiency across functions such as data management, medical monitoring and clinical operations, these benefits are not fully realised due to hesitancy in applying risk-based methods. These forums aim to address knowledge gaps, encourage engagement and support more consistent adoption of RBQM practices.

Ongoing

Proposed
End Date

Webinar series

Deliverable

Webinars 2026:

- 23 June - Quality Tolerance Limits: Setting the Threshold
- 01 Sep - Action Limits as an Early Warning System within a QTL Monitoring Strategy

Key Achievements
This Quarter:

Webinar series
continues from
November 2026 and
planned into 2027.

Deliverables &
Targets Planned for
the Next Quarter:

Ann Fleenor &
Shawntel Swannack

Leads



Project Status: Green
Accepting New Members

- On track

Project Status

Enhanced Risk-Based Quality Management (RBQM) Approaches for First-in-Human and/or Small Clinical Trials

Description

Early development (ED), including first-in-human (FIH) and small clinical trials (e.g. rare diseases), involves complex, adaptive study designs that can be fast-paced or data-limited. Determining the appropriate balance for applying risk-based approaches and timing their implementation can be challenging, particularly when ensuring meaningful, value-added oversight.

In FIH studies, participant safety is paramount, often leading to conservative approaches where many elements are considered critical, limiting effective risk prioritisation. Rare disease studies present additional challenges due to limited data, which restricts the ability to identify and assess emerging risks.

This project will focus on defining robust strategies, processes, and best practices for identifying critical data and processes; implementing risk-based data review and monitoring approaches (including tSDV/tSDR); and applying analytical tools for central monitoring, with consideration of methodological limitations. It will also address threshold setting with limited patient data, targeted medical review, and proactive management of highly dynamic data, while aligning with related FIH and small study workstreams.

Project closed

Proposed End Date

White paper or guidance document

Deliverable

Agnes Verhoeven & Alicja Budek Mark

Leads

White paper published: PHUSE Risk Based Quality Management (RBQM) Working Group Recommendations: RBQM in First-in-Human and/or Small Clinical Trials, 19 June 2026 [\(link\)](#)

Key Achievements This Quarter:

N/A

Deliverables & Targets Planned for the Next Quarter:



Project Status: Green

Project Status

Enhancing the Clinical Trial Risk Assessment Process

Description

This project will begin by identifying critical to quality (CtQ) factors through a structured risk assessment process, including risk characterisation, evaluation, and mitigation strategies, alongside defining trial-level quality tolerance limits (QTLs) aligned with these CtQs.

Risk assessment in clinical trials is often time-intensive and may not consistently prioritise the most relevant CtQ risks. Establishing enhanced approaches and best practices can improve both the efficiency and the effectiveness of this process. Refining the methodology to better integrate CtQs with intercurrent events/estimands (ICEs), and to clearly define QTLs, will help ensure the scientific objectives are met and that collected data is reliable and suitable for analysis.

This approach is expected to strengthen stakeholder engagement, enable more focused and meaningful risk assessments, and support the reuse of risk assessment outputs in downstream activities, and improve overall study efficiency.

Q4 2026

Proposed
End Date

White paper

Deliverable

Practical guidance for risk assessment has been developed, including a six-step framework with accompanying pro tips. Final review and publication preparations are underway.

Key Achievements
This Quarter:

Guidance publication is expected by the end of 2026 and with that, the project is anticipated to conclude.

Deliverables &
Targets Planned for
the Next Quarter:

**Kristin Stallcup &
Rachael Geedey**

Leads



Project Status: Green

- On track

Project Status

OpenRBQM: Pre-Competitive Collaboration on Open-Source Software for RBQM

Description

Risk-based quality management (RBQM) is a regulatory-recommended approach for identifying and managing clinical trial risks. While extensive literature describes RBQM best practices, there are limited publicly available open-source tools; most implementations rely on commercial or organisation-specific solutions.

This project proposes establishing an Open-Source RBQM Working Group alongside a dedicated development team.

The Working Group will provide a cross-functional forum to explore and guide open-source RBQM initiatives. Activities will include discussions on software best practices, design input for development outputs, and demonstrations of emerging tools.

The RBQM Development Team will focus on pre-competitive co-development of centralised monitoring tools, primarily using R, with flexibility to explore additional technologies. Initial work will centre on reports and interactive visualisations for statistical monitoring, such as digit preference, missing data, and fraud detection analyses. Development will be managed via GitHub, with regular collaborative meetings.

Ongoing

Proposed End Date

- 1. Series of discussions to develop a roadmap for a robust set of open-source RBQM tools - a 'Qualityverse'
- 2. Release v1 of first CSM module with full QC documentation and framework. Identify next development priorities

Deliverable

Continued open-source tool development (AI-enabled workflows, new metrics) and quarterly releases. IMPALA connections and collaborations for a limited number of modules.

Key Achievements This Quarter:

Continuing to grow community and industry engagement

Deliverables & Targets Planned for the Next Quarter:

Jeremy Howells & Jeremy Wildfire

Leads



Project Status: Green
Accepting New Members

- On track

Project Status

Quality Tolerance Limits - Threshold Setting Methodologies

Description

The project has successfully completed an initial phase focused on clarifying definitions and standardising labels associated with QTL monitoring. In addition, recommendations have been established to support the derivation of thresholds for QTL monitoring.

The next phase will focus on sharing this knowledge and building a consistent understanding across the wider industry. It will also involve continuing discussions to further refine the statistical methodologies used for threshold derivation. In parallel, the group will closely monitor developments in ICH (R3) guidance on risk-based monitoring and assess any potential implications for the current recommendations, particularly in relation to QTLs and acceptable ranges.

Q4 2026

**Proposed
End Date**

- White paper
- TBD: webinar

Deliverable

Webinars 2026:

- 23 June - Quality Tolerance Limits: Setting the Threshold
- 01 Sep - Action Limits as an Early Warning System within a QTL Monitoring Strategy
- White paper published: Understanding the Added Value of Action Limits for QTL Monitoring. TIRS, 2 July 2026 ([link](#))

**Key Achievements
This Quarter:**

EU Connect 2026: Early Signals, Better Decisions: Action Limits as an Early Warning. 18 Nov 2026. The project is anticipated to conclude at the end of 2026.

**Deliverables &
Targets Planned for
the Next Quarter:**

**Annett Keller &
Nathalie van Borrendam**

Leads



Project Status: Green

- On track

Project Status