

# 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 CtOs, 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.

Q2 2027

Proposed  
End Date

Webinar series

Deliverable

Webinars continue to be successful. The last session was held in March 2026. The programme resumed in June following a pause for the US Connect.

Key Achievements  
This Quarter:

The webinar programme is planned to restart on 23 June 2026 with QTL Thresholds (#1). QTL Thresholds (#2) will follow in September 2026, AI and Medical Writing in October 2026, and SDR/SDV in China is also planned.

Deliverables &  
Targets Planned for  
the Next Quarter:

Ann Fleenor &  
Shawntel Swannack

Leads



Project Status: Green  
Accepting New Members

- Topics may be refined based on survey data and industry feedback expected in February 2027. Sessions are currently mapped through to June 2027.

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.

Q3 2026

Proposed  
End Date

White paper or  
guidance document

Deliverable

Agnes Verhoeven &  
Alicja Budek Mark

Leads

White paper has been  
finalised and sent for  
publication.

Key Achievements  
This Quarter:

Complete publication of the  
white paper and conduct a  
team close-out meeting.

Deliverables &  
Targets Planned for  
the Next Quarter:



Project Status: Green

- On track to publish before end Sep 2026.

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.

Q3 2026

Proposed  
End Date

White paper

Deliverable

Final draft of white paper  
is in formal review  
process.

Key Achievements  
This Quarter:

Complete peer review  
and publish the white  
paper; conduct a team  
close-out meeting.

Deliverables &  
Targets Planned for  
the Next Quarter:

Kristin Stallcup &  
Rachael Geedey

Leads



Project Status: Green

- On track to publish before end Sep 2026.

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

Jeremy Howells & Jeremy Wildfire

### Leads

Continued technical development (GSM releases, AI workflows); increasing external collaboration.

### Key Achievements This Quarter:

Continued technical development (GSM releases, AI workflows); increasing external collaboration.

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



Project Status: Green  
Accepting New Members

- Work continues but is impacted by the availability of team members.

### 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.

**Q1 2027**

**Proposed End Date**

- White paper
- TBD: webinar

**Deliverable**

- **Webinars: Session #1** (23 June) in final stages of preparation.
- **TIRS Publication:** Feedback received and addressed; currently awaiting final approval.
- **PHUSE EU Connect:** Abstract submitted; awaiting approval.

**Key Achievements This Quarter:**

- **Webinars: Session #2** (1 September) in preparation.
- **White Paper:** Continue development.

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

**Annett Keller & Nathalie van Borrendam**

**Leads**



**Project Status: Green**

- All activities are on track. Aiming to have all development activities completed by end of Sep 2026.

**Project Status**