

Risk Based Quality Management

Project Leads:
Ann Fleenor & Shawntel
Swannack

Proposed Project End Date:
Q1 2026

Project Scope:
Provide community forums for presentation and discussion of RBQM-related topics to support industry education. Topics considered include: What are CtQs?, RBQM and Technology, Risk Assessments, Central Monitoring Analytics, QTLs, AI/ML, and RBQM-related change management.

Deliverable:
Webinar series

End to End RBQM Education

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Planning for October webinar
- SDR in China survey

Deliverables & Targets Planned for the Next Quarter:

- October webinar
- Completion of China survey and article on results

Project Leads:
Agnes Verhoeven &
Alicja Budek Mark

Proposed Project End Date:
Ongoing

Project Scope:
To discuss and focus on a robust strategy/process and best practices for:

- Identifying critical items
- Risk-based data review approaches
- Risk-based monitoring approach strategy (tSDV/tSDR)
- Using analytical tools and methods for data review and central monitoring, including limitations on (statistical) methodologies
- Identifying thresholds or equivalent on limited patient data
- Targeted medical review
- Adequately anticipating on highly dynamic data
- Establishing links with the other work streams on FIH/small studies focus

Deliverable:
White paper or guidance document
TBD: webinar

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

Project Status:
Green

*Project Accepting New
Members: No*

*Key Achievements
This Quarter:*

Consolidated
guidance sent to
broader team for
review

*Deliverables & Targets
Planned for the Next
Quarter:*

Editing/finalising for
PHUSE internal review

Project Leads:
Kristin Stallcup &
Rachael Geedey

Proposed Project End Date:
Q1 2026

Project Scope:
Process that begins with identifying CtQ factors through a risk assessment (characterising risk, including assessment and mitigation/risk reduction strategies) and the ongoing management of risks and mitigation throughout the trial (living process).

Deliverable:
Guidance document

Enhancing the Clinical Trial Risk Assessment Process

Project Status:
Green

*Project Accepting New
Members: No*

*Key Achievements
This Quarter:*

- Paper being drafted
- Webinar planning with CluePoints

*Deliverables & Targets
Planned for the Next
Quarter:*

- Determine if two papers are needed due to length
- October webinar

Project Leads:
Jeremy Howells & Jeremy
Wildfire

Proposed Project End Date:
Ongoing

Project Scope:

Open-Source RBQM Working Group:
Discuss open-source projects related to RBQM. This will be a cross-functional team, which will consider how open-source solutions can be developed using RBQM best practices. Monthly meetings will include discussion of RBQM software best practices, design discussions for development team deliverables, and demos of RBQM tools developed.

RBQM Development Team:
Focus on pre-competitive co-development of RBQM centralised monitoring tools and R package development. The team will create reports and interactive graphics related to centralised statistical monitoring (e.g. digit preference charts, missing data analysis, fraud detection). All development will be done using GitHub.

Deliverable:

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

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

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Open-source QTL meeting
- Planning CM in small clinical trials webinar for October

Deliverables & Targets Planned for the Next Quarter:

October webinar on CM in small clinical trials (collaborate with small trials project team)

Project Leads:
Nathalie Van Borrendam &
Annett Keller

Deliverable:
White paper
TBD: webinar

*Key Achievements This
Quarter:*

Drafting white paper

Proposed Project End Date:
Q4 2025

QTLs - Threshold Setting Methodologies

*Deliverables & Targets
Planned for the Next
Quarter:*

Finalise draft white
paper

Project Scope:

The Working Group has successfully completed the first step of clarifying the definitions and labels linked to QTL monitoring. Recommendations on how to derive thresholds for QTL monitoring have been developed.

The next stage is to:

- Share this acquired knowledge and common understanding within the industry.
- Continue the discussion on further refining the (statistical) methodology regarding threshold derivation for QTL monitoring.

Closely follow ICH (R3) developments regarding risk-based monitoring and discuss whether this has impacted on the guidance provided so far (QTL vs. acceptable range).

Project Status:
Green

*Project Accepting New
Members: No*