Risk Based Quality Management

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End to End RBQM Education

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.

Proposed End Date

Q2 2027

Deliverable Type

Webinar series

Key Achievements This Quarter:

- Fourth webinar ‘Decoding AI in Clinical Trials: Practical Applications, Regulatory Reality, and the Road Ahead’ completed 26 February 2026
- Continue survey development regarding SDR/SDV across industry

Deliverables & Targets Planned for the Next Quarter:

- Finalise a comprehensive webinar schedule for 2026 and early 2027. There is a strong pipeline of potential topics, including two sessions on QTL, a proposed session covering medical writing and RBQM, and a possible presentation from the Risk Assessment Working Group project.
- Continue development of the SDR/SDV survey, with the potential to establish a related sub-project leading to a subsequent white paper

Leads

Ann Fleenor & Shawntel Swannack

Project Status

Project Status: Green
Accepting New Members

- Preparing for a webinar(s)

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

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 Working Group projects on FIH/small studies

Proposed End Date

Q2/Q3 2026

Deliverable Type

- White paper or guidance document
- TBD: Webinar

Key Achievements This Quarter:

- The consolidated guidance was shared with the broader team for review, then released for public consultation
- Public review comments are being reviewed and incorporated

Deliverables & Targets Planned for the Next Quarter:

- Edit and consolidate public feedback, followed by formatting and stylistic refinements to finalise the document. Resubmit to the PHUSE Committee for review
- Once publication-ready, hold a final alignment meeting with the team prior to release

Leads

Agnes Verhoeven & Alicja Budek Mark

Project Status

Project Status: Green

- Reviewing public review comments

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Enhancing the Clinical Trial Risk Assessment Process

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).

Proposed End Date

Q2/Q3 2026

Deliverable Type

- White paper or guidance document
- TBD: Webinar

Leads

Kristin Stallcup & Rachael Geedey

Key Achievements This Quarter:

- Presenting and discussing related topics during the March 2026 Community Meeting.
- Developing the white paper

Deliverables & Targets Planned for the Next Quarter:

Finalise the white paper, submit for peer review, and progress to publication

Project Status

Project Status: Green

- Final draft under review with authors

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

Scope

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 relating to centralised statistical monitoring (e.g. digit preference charts, missing data analysis, fraud detection). All development will be done using GitHub.

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 Type

- 3 PHUSE US Connect presentations in March
- Quarterly releases planned at least through 2026

Q1:

- Key user-facing improvements include:
- Expanded QTL and KRI reporting, including new eligibility and inclusion/exclusion metrics, and improved ongoing monitoring outputs
- Enhanced Site Risk Score (SRS) functionality, supporting cross-study comparisons and richer visualisations
- Improved reporting accuracy and consistency across retention, patient disposition, and action tracking workflows
- New and refined visualisations, including time series, bar charts and cross-study risk displays
- Stronger quality controls supporting report generation and validation, improving confidence in reported results.
- Developer-Facing Updates
- Substantial CI/CD and workflow enhancements, particularly through gsm.utils, establishing standardised GitHub Actions, example frameworks, and released automation across GSM packages.
- Introduction of a reusable QC framework via qcthat, enabling automated, traceable quality control reporting tied to issues, pull requests, milestones and releases.
- Expanded and modernised examples and vignette infrastructure, with HTML output and pkgdown integration.
- Improved test coverage and quality validation, including adoption of the {qcthat} framework and comprehensive unit tests for KRI and cross-study functionality.
- Data model extensions and harmonisation, enabling new IE-based KRIs, study-level QTL metrics, and improved compatibility across packages.
- Refactoring and cleanup of package dependencies, reducing coupling, and improving long-term maintainability.

Key Achievements This Quarter:

- Continue quarterly releases through 2026
- Open Source QTL Workshop
- ShinyConf, SCDM, PHUSE CSS and UseR presentations

Deliverables & Targets Planned for the Next Quarter:

Jeremy Howells & Jeremy Wildfire

Leads

Project Status: Green
Accepting New Members

- Ongoing efforts to support quarterly releases

Project Status

Quality Tolerance Limits – Threshold Setting Methodologies

Scope

The Working Group project 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.

We will 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).

Proposed End Date

Q1 2027

Deliverable Type

- White paper
- TBD: webinar

Key Achievements This Quarter:

- White paper submitted, in review process at TIRS
- White paper for PHUSE is in preparation
- Dates for webinars in June and September are confirmed, with work on presentation underway

Deliverables & Targets Planned for the Next Quarter:

- Prepare webinar regarding QTL Monitoring (our PHUSE deliverable)
- Prepare abstracts and presentation for the PHUSE EU Connect 2026 and the PHUSE US Connect 2027
- For the webinar (regarding CtQ Factors to QTL monitoring: Need to discuss approach with Risk Assessment Project Team)

Leads

Annett Keller &
Nathalie van Borrendam

Project Status

Project Status: Green

- White paper follow-up activities