Risk Based Quality Management

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End to End RBQM Education

Scope

The cSDRG and ADRG apply to a single study. Sponsors have used these templates when creating reviewer's guides for integrated study data and integrated analysis data. The template has to be changed to document the information for multiple studies. There is an opportunity to create a template for integrated study data and integrated analysis data. The project team will determine if this can be accomplished in one reviewer's guide or two separate reviewer's guides. Deliverables include a template, completion guidelines and example documents.

Q1 2026

Proposed End Date

Webinar series

Deliverable Type

Ann Fleenor & Shawntel Swannack

Leads

Key Achievements This Quarter:

- Fourth webinar: 'Leveraging AI/ML for Enhanced Central Monitoring Analytics' on 15 October 2025
- Drafting and publication of SDR/SDV in China survey. Data collected.

Deliverables & Targets Planned for the Next Quarter:

Continue with webinar series
Collate SDR/SDV in China results and organise webinar to share results

Project Status: Green
Accepting New Members

- Activities to support the delivery of the webinar content

Project Status

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

Scope

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

- Identifying critical items
- Risk-based data review approaches
- A 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 focus.

Q1 2026

Proposed End Date

White paper or guidance document
TBD: Webinar

Deliverable Type

- The Consolidated Guidance was stablised in terms of editing, formatting, and stylistic refinements
- White paper drafted and sent to PHUSE for peer review
- Paper submitted for the EU Connect - Analytics & Statistics (AS) Stream
- Presented at the EU Connect - 17 November 2025 (AS01)

Key Achievements This Quarter:

- Submit a draft of the white paper to the PHUSE leadership committee for review and feedback
- Finalise and publish white paper

Deliverables & Targets Planned for the Next Quarter:

Agnes Verhoeven & Alicja Budek Mark

Leads

Project Status: Green

- White paper development is in progress

Project Status

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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).

Q1 2026

Proposed End Date

Guidance document

Deliverable Type

Kristin Stallcup & Rachael Geedey

Leads

- The initial draft of the white paper is under review with the Working Group project
- Webinar 'Risk Assessment Best Practices' on 23 October 2025

Key Achievements This Quarter:

- Continue developing the white paper
- Finalise and publish the white paper

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green

- White paper development is in progress

Project Status

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

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.

Proposed End Date

Ongoing

Deliverable Type

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.

Key Achievements This Quarter:

- PHUSE EU Connect workshop and presentation (November 2025)
- {simaerep} gsm plugin
- Modularised {gsm} v2.4 release

Deliverables & Targets Planned for the Next Quarter:

- Open-Source QTL Workshop
- ShinyConf, SCDM, PHUSE CSS and UseR Presentations
- Possibly support the US Connect

Leads

Jeremy Howells & Jeremy Wildfire

Project Status

Project Status: Green
Accepting New Members

- Continuing with development activities

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).

Q4 2025, but promotional and phase-out activities will take till Q1 2027

Proposed End Date

White paper & companion webinar

Deliverable Type

Final draft of the white paper is in company review
Submission to PHUSE will follow immediately after

Key Achievements This Quarter:

- Finalise white paper and prepare webinar regarding QTL monitoring (our PHUSE deliverable)
- Internal discussion about whether there are still pain points on the topic of QTL monitoring --> if so, discuss how to proceed with the team
- Prepare abstracts and presentation for PHUSE EU 2026 and PHUSE US 2027

Deliverables & Targets Planned for the Next Quarter:

Nathalie van Borrendam & Annett Keller

Leads

Project Status: Green

- White paper development is in progress

Project Status