

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



Problem Statement

Risk-based quality management (RBQM) is a regulatory-recommended approach to detect and effectively manage risk in a clinical trial. While there is a significant body of literature describing RBQM implementation and best practices (1, 2), there are few publicly available open-source tools for RBQM available. Instead, commercial tools and custom company-specific RBQM implementations currently serve as the industry standard for RBQM implementation.

Project Scope

We propose forming an Open-Source RBQM Working Group and an associated development sub-team.

Open-Source RBQM Working Group – A Working group that will discuss open-source projects related to RBQM. This will be a cross-functional team that 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 – This team will focus on pre-competitive co-development of RBQM centralised monitoring tools. The primary focus will be on R package development, though other technologies may be considered. The team will start with a focus on creating 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. The team will meet every other week in 2024.

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Objectives & Deliverables	Timelines
<ul style="list-style-type: none">Working Group<ul style="list-style-type: none">Establish membership.Host kick-off meeting.Development Team<ul style="list-style-type: none">Identify team members with capacity for several hours a week.Establish Agile development best practices.Create mock-ups and technical specification for initial CSM module.	Q1 2024
<ul style="list-style-type: none">WG Meeting – Monthly meeting series with demos focused on innovative open-source RBQM technology. Possible presenters include:<ul style="list-style-type: none">Gilead – GSM framework improvementsRoche – CSM tools including NLP frameworkZS – AI in RBQM.Development Team<ul style="list-style-type: none">Agile development cycles.Release functional prototype of first CSM module and solicit feedback.	Q2 – Q3 2024

<ul style="list-style-type: none"> • Working Group <ul style="list-style-type: none"> ◦ Develop publication/presentation strategy for 2025. ◦ Series of discussions to develop a roadmap for a robust set of open-source RBQM tools – a “Qualityverse”. • Development Team <ul style="list-style-type: none"> ◦ Release v1 of first CSM module with full QC documentation and framework. ◦ Identify next development priorities. 	Q4 2024
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