ACCORD Sponsor Position Statement: Quality by Design and Risk-Based Quality Management

The Academic and Clinical Central Office for Research and Development (ACCORD), acting on behalf of NHS Lothian and the University of Edinburgh as Sponsor of clinical research, is committed to promoting a proactive and proportionate approach to trial quality through the application of **Quality by Design (QbD)** and **Risk-Based Quality Management (RBQM)** principles throughout the clinical trial lifecycle.

High-quality clinical research is achieved not through retrospective checking alone, but by building quality into study design from the earliest stages of development. ACCORD therefore encourages all Chief Investigators, researchers and trial teams to consider QbD principles during study conception, grant applications and protocol development. Early consideration of the factors that are critical to participant safety, trial integrity and reliable study outcomes helps ensure that studies are scientifically robust, operationally feasible and proportionate in their demands on participants and research sites.

This position aligns with the expectations of ICH-GCP E6(R3) and the UK Clinical Trials Regulations, which emphasise the importance of identifying Critical-to-Quality (CTQ) factors, applying Quality by Design principles and implementing proportionate risk-based oversight throughout the conduct of a clinical trial.

Our Expectations

As Sponsor, ACCORD encourages research teams to:

- Consider QbD principles as early as possible in study development.
- Identify Critical-to-Quality (CTQ) factors relating to participant safety, trial endpoints and data integrity before and during protocol development.
- Design protocols, procedures and operational processes that focus effort on what matters most to trial quality.
- Undertake proportionate risk assessments that evaluate risks to CTQ factors and inform monitoring, oversight and quality management activities.
- Review risks and quality measures throughout the study lifecycle and adapt controls when new information emerges.

We recognise that the approach taken should be proportionate to the complexity and risk profile of the study. However, documented consideration of quality and risk at an early stage is strongly encouraged for all ACCORD-sponsored regulated clinical trials and medical device investigations.

Further Guidance and Resources

Researchers seeking practical guidance on implementing QbD and RBQM are encouraged to review:

- MHRA Guidance: *Clinical Trials for Medicines – Guidance on Quality and Risk Proportionality*, which explains regulatory expectations for QbD, RBQM and proportionate oversight in UK clinical trials.

- *TransCelerate Risk-Based Quality Management Framework.* This practical resource describes industry-recognised approaches to identifying Critical-to-Quality factors, conducting risk assessments, defining risk indicators and implementing risk-based oversight throughout the trial lifecycle. It may be a useful companion resource when planning and conducting ACCORD-sponsored studies.

These resources complement ACCORD's sponsorship processes and provide useful practical examples for study teams designing and delivering clinical trials.

Continuous Improvement

The publication of revised UK Clinical Trials Regulations, ICH-GCP E6(R3) and MHRA guidance presents an opportunity to continue enhancing how quality and risk management are embedded within ACCORD-sponsored studies.

A review of ACCORD's Sponsor risk assessment framework, tools and supporting processes is planned following the QA Manager's return from maternity leave in 2027. This review will ensure continued alignment with regulatory expectations, evolving RBQM methodologies and recognised best practice, while identifying opportunities to improve the usability, consistency and effectiveness of risk assessment across ACCORD-sponsored studies.

Be Involved

ACCORD recognises that effective quality and risk management is best achieved through collaboration with the research community. We welcome input from Chief Investigators, trial managers, statisticians, data managers and other stakeholders who use Sponsor risk assessment processes in practice.

If you are interested in contributing to the review and redesign of ACCORD's risk assessment process, or would like to share your experience of applying QbD or RBQM within sponsored studies, please contact the ACCORD Quality Assurance Team: QA@ACCORD.scot. Your feedback will help shape future Sponsor processes and ensure they remain practical, proportionate and supportive of high-quality clinical research.