Academic and Clinical Central Office for Research and Development

RISK ASSESSMENT

The MHRA established Risk-adapted Approaches to the Management of CTIMPS to facilitate a risk-proportionate approach to applying the principles of GCP to clinical trials.

ACCORD has developed a **risk assessment tool** with the MHRA to identify potential risks associated with research projects and agree on methods to mitigate those risks.

What is Risk Assessment?

ACCORD representatives, collaborating with Investigators, Trial Managers, and other stakeholders, meet to discuss UoE/NHS Lothian sponsored research, identify risks, considering the likelihood of occurrence and impact of the risk (low, moderate, high), and agree on methods to mitigate those risks.

Risks may relate to the safety of the participant or the integrity/reliability of results.

During the Meeting

You will be invited to the meeting to provide input into the process. During the discussion, the risk assessment tool is completed, which is shared with the trial team to agree on mitigation of risks.

Possible risk-adapted approaches to the management of the study are discussed, allowing for methods to be adapted, become less onerous and more efficient, while still maintaining applicable standards.

After the Meeting

Monitoring procedures are determined based on the Risk Assessment. Research perceived to be high risk will be subject to more frequent and more intense monitoring than lower risk research.

The process is complete when the ACCORD QA Manager finalises a document describing the risks and agreed mitigations. After the Risk Assessment is finalised and signed by the relevant parties, a submission to the Competent Authority/REC can be authorised by your Sponsor Representative.

What Projects need Risk Assessment?

All Clinical Trials of Investigational Medicinal Products (CTIMPs) and Clinical Investigations of Medical Devices (CIMDs) are risk assessed.

Research projects with a complex design, higher risk or novel intervention, or involving a vulnerable population may be risk assessed. Your Sponsor Representative will discuss this with you if necessary.

It's useful to receive the following documents to facilitate discussion at the Risk Assessment meeting, at least 2 weeks before the scheduled meeting:

- Research protocol
- Participant Information Sheet(s)
- Participant questionnaires
- IMP/device labels
- A site feasibility may also be requested and any other documents particular to your project.
- IRAS form
- Consent Form(s)
- GP letters
- Investigator Brochure and documents covering details of manufacture, e.g. a Summary of Product Characteristics or IMP dossier.

How long does the process take?

Research projects present a variety of risks and challenges, and it is difficult to indicate a representative length of time from the Risk Assessment meeting to sign off. This can be a few weeks for some projects while others can take longer.

When a project is submitted to ACCORD, a Risk Assessment meeting date is scheduled.

Before the meeting, your Sponsor Representative will complete an initial review and provide comments, suggestions, any necessary changes, and common Risk Assessment findings.

You should respond to the initial review as quickly as possible, returning revised documents at least 2 weeks before the scheduled Risk Assessment meeting.

After the meeting, written feedback is provided, typically within 10 days. The time to finalisation of the Risk Assessment then depends on how quickly you can adapt or create documents/processes/arrangements in response to the Risk Assessment outcomes. Your Sponsor Representative and other relevant ACCORD personnel will help and guide you through this process.

If you have any questions or want to seek advice about Risk Assessment, please contact us by emailing resgov@accord.scot
For a detailed overview of the Risk Assessment process, read ACCORD SOP GS002 (Combined Risk Assessment) on www.accord.scot

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