Clinical Trial and Medical Device Risk Assessment Guidance Document

When undertaking the Risk assessment of a clinical trial or a trial involving an unlicensed medical device which is either sponsored or co-sponsored by NHS GG&C, the following guidance document can be used to serve as a prompt for the questions to be asked at the Risk assessment meeting in order to capture and identify the risks appropriate to the trial.

As the list of potential risks within a trial will be varied and subject to frequent change, a register has been created and maintained under version control within the NHS GG&C R&I Quality Management System, Q-Pulse.

The document can be found in Q-Pulse under the Number “RSK-FACT-1” and will be version controlled as it is updated, all staff assigned to the Risk Assessment SOP, SOP 51.004 will be added as a notified party to this list as potential Risk Factors are updated.

A copy of the most recent list can be requested from the R&I QA Manager at any time or accessed by any member of R&I with a Q-Pulse account.

Document Details

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Document History

Version	Date	Details
1.0	24/05/18	Initial creation
2.0	05/10/2022	Update to move list of questions to Q-Pulse