Quality Management

> Medicines for Human Use (Clinical Trials) Regulations, 2004 "Systems with procedures that assure the quality of every aspect of the trial shall be implemented"

The CRCTU has a dedicated Quality Management Team to ensure that trials are run in accordance with the applicable regulatory requirements, the NHS Research Governance Framework for Health and Social Care and Good Clinical Practice (GCP).

Team Leader
Mrs Anna Hutton

Role of the Team
The team is responsible for managing a Quality Management System, performing internal audits and conducting on-site monitoring.

The Quality Management System includes Standard Operating Procedures covering all aspects of trials from trial set up to trial closure. It also covers specific processes for all CRCTU teams, from Biostatistics to IT Support.

Internal audits are performed across the different teams to ascertain their adherence to the Quality Management System, regulations and GCP.

The team performs on-site monitoring for the complete CRCTU trial portfolio, thereby covering all trial phases and different disease areas in both the adult and paediatric setting. The extent of on-site monitoring is trial specific, and the team advises the relevant Trial Management Group on appropriate levels of on-site monitoring based on the risks for that specific trial.

Quality Management Resource
Internal Quality Management Procedures (staff only) (http://www.cancertrials.bham.ac.uk/qms/qms.htm)