



Inspection at Investigational Sites

And how to help them run smoothly

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Why does the MHRA inspect sites?

- To verify compliance with UK and EU legislation
- May inspect following routine inspection at sponsor organisation
- A minority may be “triggered” in response to a suspected violation



Scope of Inspection

- Legal and Administrative: Ethics and Regulatory approvals, Contracts, Insurance/Indemnity
- Organisational: How well has the trial been conducted?
- Informed consents
- Trial subject data (includes source files)
- Management of Investigational Medicinal Products



Sponsor and site objectives

- To demonstrate compliance with legislation: make sure that findings are kept to a minimum
- Minimise the disruption on the site
- Minimise stress and ensure that UK sites continue to participate in clinical trial work



Managing the Site Inspection

If the trial has not been conducted in compliance with regulations and guidance, the inspection team will find the problems

Inspection preparation starts when you select sites and investigators



Preparation - Planning

- Manage the communication with site and inspectors
 - Establish the scope of the inspection, and identify areas where the inspectors may wish to focus
 - Select suitable dates , and ensure that the key people are available at the site



Rehearsal

- Go to the site: make sure the team know what to expect during the inspection
- Find out what activity the clinical team have planned for the inspection days, and know when they are free to be interrupted
- Be clear how to contact the team, and the outside world during inspection
- Establish the site geography
- Introduce yourself to the records department, laboratory and pharmacy



Document review

- Check that the Investigator Site File is complete and securely stored
- Check that the Patient Files are accessible: if the notes are electronic make sure the inspectors will have direct, but restricted access
- Make the team aware that other records will be requested during inspection:
 - calibration and maintenance records,
 - temperature records for storage of biological samples and IMP,
 - training records for staff



Practical arrangements

- Ensure the inspectors have a room, with a large desk and preferably a lockable door
- Locate the restaurant, toilets, drinking water
- Access to a fax machine, e-mail, printer and telephone
- Consider who should attend the opening and closing meetings, and timings of staff interviews and tours



During the inspection

- Opening Meeting
- Inspection is a combination of staff interviews, document review and facility visits
- Feedback of general findings at Closing Meeting



Rules for a successful outcome

- Have documentation readily available
- During the inspection, stay calm and answer questions truthfully
- Demonstrate awareness of GCP principles
- Think before you speak, and if necessary go back to the inspectors to correct or clarify information given



After the inspection

- A written report will be sent to the sponsor
- Findings will be classified and each will require a written response
- Response should address the root cause of the problem, as well as the non-compliance observed by the inspector



Thank you for your attention.

