How should a trial manager prepare for an MHRA inspection?
The plan for today

- Inspection experience?
- Inspectors & Inspection process
- Preparing for the Inspection
- Experience of an inspection
Inspection experience
Inspectors & Inspection process
What does an inspection involve?

http://www.mhra.gov.uk/CON2024532

A “preliminary notification to organisation of statutory inspection” is sent to the organisation which requests the pre-inspection dossier.

Organisation supplies the pre-inspection dossier.

The inspection dates are confirmed with the Organisation.

The inspection plan is developed with the organisation and finalised.

After organisation inspection, the inspection of any other sites takes place as applicable [e.g. Investigator(s) sponsored by commercial organisation, Laboratories etc.]

Main inspection takes place of the organisation (Commercial Sponsor, Host Organisation).

After the last site inspection, a report of the findings is issued to organisation.

The organisation responds, and the Corrective Action Preventative Action (CAPA) plan is reviewed for acceptability.

Once CAPA acceptable, an inspection closing letter and GCP statement are issued.

Where critical issues are found, these may be referred to the Clinical Trial Inspection Action Group (CTIAG).
Pre-Inspection Dossier

1. Organisational charts
2. List of Clinical Trial Processes
3. Adverse Event Reporting Systems and Procedures
4. List of all computer systems & validation status
5. Overview of any joint sponsorship or close collaborations
6. Clinical Trials Spreadsheet/Table listing trials
7. One page summary for each of 16 areas of trial management.
Any activity involved in the running of Clinical trials at your institution

- Contracts
- Trial Monitoring
- IMPs
- Archiving
- Quality System
- PV
- Data Management & Statistics
- Clinical Facilities
- Clinical Quality Assurance
- Regulatory Affairs
- Clinical Trial Reporting
- Laboratories
- Project Management
- Computer Systems
- Trial Master File
- Equipment Maintenance
What happens during the visit?

• Change in focus?
• Emphasis on document review with impromptu interviews?

2009 Cardiff University Inspection
• Document review
  • SOPs
  • Trial master files
• Interviews
  • CI
  • Sponsor
  • IT
  • Archiving
  • Stats
Inspection preparation
Is inspection a one off event?

…..Trials should always be inspection ready

….. In theory trials documentation should fit together to tell the story of the trial

In reality you may feel that the trial looks more like this…..
Pieces of the jigsaw (1)

Inspectors
Pieces of the jigsaw (2)

Inspection experience
Pieces of the jigsaw (3)

Sponsor
Pieces of the jigsaw (4)

Trial Master File
Pieces of the jigsaw (5)

Training
Pieces of the jigsaw (6)

Roles & Responsibilities
Pieces of the jigsaw (7)

SOPs
Audit/ Monitoring Actions
Trial Manager.....
How can Research Groups/Units prepare?

- GAP analysis
- Trial Master File (including security)
  - Approvals
  - Document Control
  - IMP management
  - Delegation Logs
  - TMGs
  - SOPs
  - Pharmacovigilance
  - Data management
  - Labs
  - Equipment
- Roles and Responsibilities (Contracts)
Cardiff University preparations

- Clinical Trial Governance Group
  - Gap Analysis Working Group
  - Information Technology and Information Management Working Group
- Sponsor TMF
- SOP review
- Review of previous inspection findings
- Trial monitoring review
- Training records
- Sponsor Oversight policy document
Summary

• Cycle of preparation
  – Pre-inspection dossier
  – Gap analysis and action plan

• Sponsor can not review everything

• Dialogue
Further information

Good Clinical Practice: The inspection process
http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Theinspectionprocess/index.htm

Good Clinical Practice: Risk-based inspections
http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/Riskbasedinspections/index.htm

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