Research Audits Guidance
For Auditees

Contents

Purpose

This document outlines how audits are conducted by the JRMO, with the aim of outlining expectations for auditees should their study, organisation, or department be selected for an audit. Please see JRMO SOP 22 Audits for the process explaining how JRMO audits are conducted, or JRMO SOP 22 Associated Document 2 for information regarding expectations for auditors performing audits on behalf of the JRMO.

Audits are conducted in order to:

- Improve data quality,
- Protect the reputation of the researcher, Barts Health, and Queen Mary,
- Protect current and future funding opportunities,
- Measure compliance with regulatory requirements, Barts Health, and Queen Mary policies,
- Improve research performance,
- Prepare potential auditees for external audits and inspections.

Audits can be of (but are not restricted to):

- Study essential documentation,
- Sites,
- Clinical facilities,
- Sponsors,
- Laboratories,

- Databases,
- Investigational Medicinal Products (IMPs),
- Studies,
- Systems,
- External vendors.

Audit notification and plan

Following notification of an audit the lead auditee (typically the Chief Investigator (CI), Principal Investigator (PI), or Study Manager) liaises with the auditor to arrange a suitable time and location for the audit to take place. Once a time and date is agreed, the auditor provides an audit plan.

The plan includes:

- Details regarding when and where the audit will take place,
- The outline of scope and objectives of the audit,
- The requirements and standards against which the research will be audited,
- Notification of whether the auditor will be accompanied by an observer,
- A proposed schedule for the audit interviews, visits, tours, and document review,
- A list of groups and areas to be audited,
- A list of documents and records to be reviewed,
- A list of people whose functions will be audited.

The auditees are responsible for arranging meetings and suitable spaces for the auditor (usually meeting rooms for interviews and meetings, and either desk space or a room for document review). They are also responsible for arranging electronic access to documentation; access should be confirmed in advance of any portions of the audit being conducted remotely. Auditees should notify the auditor of a preference to hold some or all of the audit remotely as early as possible.

While preparing for the audit it is recommended that the study team:

- Notifies everyone who may be affected by the audit,
- Reviews all documents and data to be assessed by the auditor,
- Confirms timings early on, particularly for interviews and meetings,
- Reserves required rooms,
- Ensures the auditor has access to everything they may wish to review (particularly databases and other electronic systems) and key individuals they may wish to meet,
- Determines physical access arrangements for the auditor (access to the audit location, bathrooms, and if applicable refreshments).

The audit plan is an indication of how the auditor intends to spend their time during the audit, and is subject to change as the audit progresses (particularly if the auditor identifies specific areas of concern).

In general, audits last between half a day and five days. The length of time allocated to the audit may be increased or decreased depending on pertinent factors (e.g. additional areas for review, concerns, the complexity of the research, the length of time the research has been conducted for, how many participants have been recruited, etc.).

Opening meeting

Once the auditor starts the audit, an opening meeting takes place to introduce the auditor to the auditees and areas to be audited. During this meeting the auditor:

- Defines scope, objectives, and schedule,
- Explains how the audit will be carried out,
- Confirms that the team are ready to support the audit process.

During the audit

This is the main part of any audit process as it is the period where information is assessed and recorded. This is done by the auditor by:

- Reviewing documents,
- Reviewing data capture methods (e.g. databases),
- Observing study activities,
- Examining physical conditions and facilities,
- Documenting observations,
- Meeting key individuals for interviews,
- Developing conclusions.

Once the review has been completed by the auditor, they process the collected evidence to determine preliminary conclusions and recommendations. The auditor lists the findings (non-compliances with the specified requirements) supported by the observed evidence (or lack thereof).

If deemed necessary, the auditor may extend the audit. In such instances, the auditor would inform the lead auditee as soon as possible and would return to finish the audit as soon as reasonably possible.

Discussing results and conclusions

At the end of the audit, the auditor chairs a closing meeting between the primary stakeholders to discuss the main findings. This can be used as a discussion, but auditees should bear in mind that whilst the auditor will try to feedback fully, some items may need review and consideration after the audit. As such, this should not be viewed as the final result of the audit.

Grading definitions for findings

Findings are categorised as critical, major, or other. These categories and definitions are based on the Medicines and Healthcare products Regulatory Agency (MHRA) inspection categories and definitions and are used for all audits.

Critical

- Where evidence exists that significant and unjustified departure(s) from applicable requirements have occurred with evidence that:
    - The rights, safety, or well-being or confidentiality of research participants either has been or has significant potential to be jeopardised, and/or
    - The research data are unreliable, and/or
    - There are a number of Major non-compliances across areas of responsibility, indicating a systematic QA failure, and/or

- Where inappropriate, insufficient, or untimely corrective action has taken place regarding previously reported Major non-compliances
- Where provision of the study documentation is not readily available or accessible, or incomplete to such an extent that it cannot form the basis of an audit and therefore impedes or obstructs the auditor(s) in verifying compliance.

Major

- A non-critical finding where evidence exists that a significant and unjustified departure from applicable requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or
- Where evidence exists that a number of departures from applicable requirements have occurred within a single area of responsibility, indicating a systematic QA failure.

Other

- Where evidence exists that a departure from applicable requirements has occurred, but it is neither Critical nor Major.

Audit report

Once the auditor has completed the on-site visit, they will write a formal report to document their observations, conclusions, findings, and recommendations. The Audit report will be sent to the individual listed as per SOP.

The report includes:

- A review of the evidence observed by the auditor,
- Any conclusions drawn from the audit,
- An assessment of how well requirements have been met,
- A list of all identified findings identified by the auditor,
- Recommendations for changes in practice to conform to all requirements,
- A timescale for corrective and preventative actions (CAPAs) to be proposed by the auditees to address the findings.

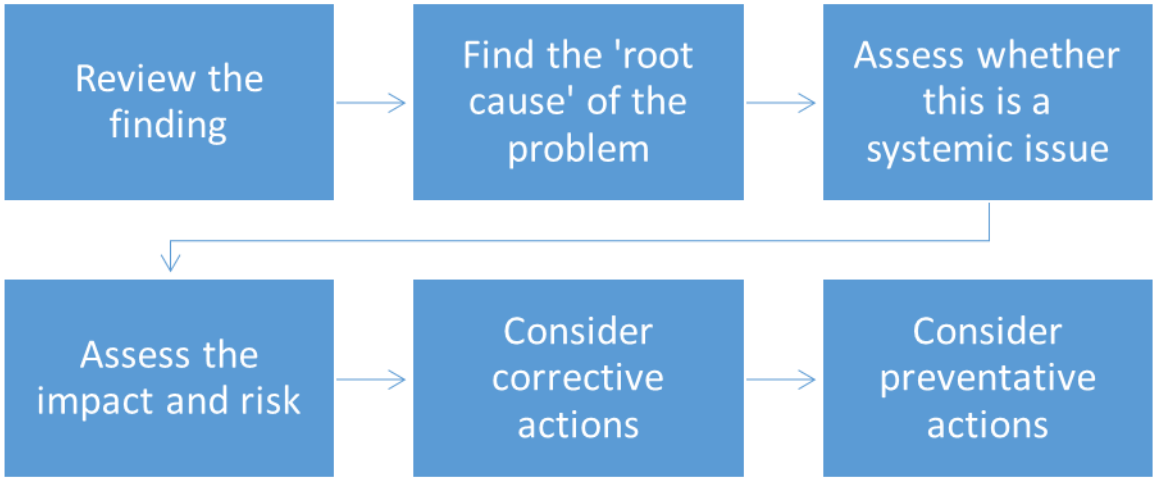
Common findings

- Not completing activities which are required by the protocol,
- Completing extra activities not specified in the protocol,
- Lack of documentation (particularly relating to databases and laboratories),
- Missing deadlines for annual progress reports,
- Using online service providers without a formal review of their terms and conditions,
- Removing required statements from template informed consent forms,
- Poor version control,
- Lack of evidence of suitable training,
- Poor delegation log completion,
- Errors on completed consent forms,
- Lack of a suitable end of trial definition, or continuing after the definition is met,
- Insufficient documentation of eligibility (e.g. tickboxes for criteria),
- Case Report Forms held alongside participant identifiable data (i.e. not pseudonymised).

Auditees response to the report

The auditee should review the report with care, and it is their responsibility to identify actions to correct and prevent recurrence of findings. Timelines for completion should also be assigned to each action.

Corrective Action Preventative Action (CAPA) Plan process



CAPA Plan Writing Tips

- Be clear and succinct, and write in full sentences,
- Focus on answering the finding, but provide brief background information if helpful,
- Answer each part of the finding,
- Propose actions which are clear and achievable,
- Provide realistic completion dates for each action.

Common issues with CAPA Plans

- Proposed actions only address the immediate problem, when there is a larger systemic issue to address,
- Response focuses on justifying or explaining the cause of the finding rather than proposing ways to fix it,
- Response acknowledges the finding but does not propose actions to correct or prevent it,
- Responses are too detailed (think about the big picture),
- Findings are “missed” (corrective and/or preventative actions are not proposed to address a finding, without any explanation as to why actions have not been suggested),
- Timelines for completing actions are unrealistic – either too short to be completed, or too long to address the issue in a timely manner.

Support with CAPA planning

It is strongly recommended that auditees take time to discuss both findings and CAPA with the JRMO GCP and Governance Managers. This means that any CAPA will be in line with JRMO expectations and procedures and therefore more likely to be accepted by the auditor.

The CAPA plan proposed by the auditees is then submitted and reviewed by the auditor to ensure the actions fully address the findings. Once these actions have been agreed and

completed, the auditor issues an audit certificate (which documents that an audit has taken place and what it covered).

Confidentiality

To preserve the independence of the audit, regulatory authorities do not routinely request copies of audit reports. Regulatory authorities may seek access to an audit report on a case-by-case basis when evidence of serious non-compliance exists, or in the course of legal proceedings. The JRMO retains records for all of the audits they conduct. Auditees are advised to retain the audit certificate only in their records, in case of inspection.

More information

The R&D Forum has also produced information regarding preparing for MHRA inspections: http://www.rdforum.nhs.uk/content/wp-content/uploads/2014/05/RDFguidance-MHRA.pdf. Most JRMO audits follow a similar format to MHRA (competent authority) inspections. The MHRA has produced guidance related to their inspections: https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials

For more information and questions about the audit process, please contact the JRMO's Clinical Research Auditor, GCP and Governance Managers, and / or Research Governance Operations Manager (contact details for these individuals can be found on the JRMO's website).