

SOP-QA-29 V5

Title: Audit

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Document History

Version	Description of update	Date Effective
4	Updated audit schedule oversight and process at 2 and 3.2 Reference to remote opening/closing meetings and discussion at 3.8	09-08-26
5	Updated reference to electronic Quality Management System. Reference to SOP-QA-43 at 3.12	15-09-26

1. Scope

- 1.1 This SOP applies to all members of staff within University of Aberdeen (UoA) and NHS Grampian (NHSG) who are involved in conducting, supporting or managing clinical trials (sponsored and hosted) and their associated processes and facilities.
- 1.2 The Quality Management System within UoA and NHSG shall be subject to internal audit to ensure it is fit for purpose, and complies with relevant legislation and the principles of Good Clinical Practice (GCP). The same procedure shall also apply to any third party audits conducted on behalf of Sponsor by QA. Internal audits may also be conducted for Health & Safety or Environmental compliance as necessary.

2. Responsibilities

Sponsor	Implement an audit schedule to ensure that clinical trials are conducted and managed safely and effectively and in compliance with relevant SOPs, study protocols and regulations.
QA Manager (QAM)	Conduct audits of clinical trials, facilities and activities as appropriate.
CSOG	Oversight of audit findings.

3. Procedure

Audit plan

- 3.1 The type and frequency of internal audits shall vary, depending on the risk or process being audited. The Quality Assurance Manager (QAM) shall maintain an audit schedule documenting the type and frequency of audits. Additional audits may be undertaken if potential or actual quality issues arise, or as deemed appropriate by Sponsor or QAM.
- 3.2 The QA audit schedule shall be agreed and signed by the R&D Director annually.
- 3.3 The audit schedule may be amended (irrespective of who sponsors the trial) if:
 - Concerns are raised regarding research practice.
 - Other audits/monitoring has highlighted concerns.

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Key to symbols ⓘ = Important point to note ⚠ = Warning

- Information provided to NHSG R&D or UoA is causing concern, or is inconsistent.
- The Medicines and Healthcare products Regulatory Agency (MHRA), or other regulatory/inspection body, have indicated that they are to conduct an inspection.
- Instructions are received from the Clinical Studies Oversight Group (CSOG).

3.4 External companies and/or auditors may be engaged to audits on behalf of UoA/NHSG. Such transfers of responsibilities must be formally agreed with the external party in writing.

Audit process

- 3.5 Prior to an audit being undertaken, the QAM, or delegate, shall contact individuals concerned (auditees) to agree a convenient date and time for the audit. Relevant documents required for the audit may be requested and collated at this time. However, the QAM and CSOG reserve the right for the QAM to perform unannounced audits if deemed appropriate.
- 3.6 Audit templates/checklists may be prepared by the QAM, or delegate, as an aide memoire as appropriate. Consideration shall be given to previous or systematic findings, and these may be included in the scope of the audit.
- 3.7 The QAM, or delegate, shall obtain an audit number when the audit is scheduled in the electronic Ideagen Quality Management System.
- 3.8 The scope of the audit shall be discussed at an opening meeting. Any findings identified during the audit shall be discussed with auditee(s) as part of the audit process. Appropriate Correction, Corrective Actions and Preventive Action (CAPA) shall be discussed and agreed at a closing session. These meetings may be conducted remotely if appropriate.
- 3.9 An audit summary report shall be issued to the auditee (and any other interested parties) within ten days. Any correction and CAPA detailed in the audit summary report shall be as agreed and discussed at the closing session.  Auditees shall have a **maximum of 28 days** from the audit to close out findings and inform the QAM, or delegate. The CAPA template (TMP-QA-80) may be used to detail CAPA to the auditor. A shorter timescale may be implemented for serious findings.
- 3.10 Findings shall be reported as non-conformances if they do not comply with the Principles of GCP, the trial protocol, sponsor SOPs or trial specific SOPs.
- 3.11 If an opportunity for improvement or a potential non-conformance is noted, it shall be reported as an 'Observation'. Any concerns related to Health & Safety or Environmental Management may also be raised as observations and referred to the appropriate department within UoA or NHSG.
- 3.12 A non-conformance that affects (or has the potential to affect) the rights, wellbeing or safety of participants, or affects (or has the potential to affect) the scientific integrity of a clinical trial shall be treated as a serious (red) non-conformance requiring immediate attention. Such findings shall be referred to CSOG and the NHSG R&D Director (or delegate). A finding may also be reported as a Breach (see SOP-QA-25 – Deviations and Breaches and SOP-QA-43 – Suspected Serious Breaches). Less serious non-conformances shall be colour coded as amber. Observations are not colour coded.

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- 3.13 The QAM, or delegate, shall review non-conformances before their due date and also any Correction and CAPA before closing a finding, or referring back to the auditee for further action if necessary.
- 3.14  Failure to complete CAPA within agreed timescales shall result in referral to the Clinical Research Operational Group (CROG) and is itself regarded as a serious non-conformance; which may be reported as such to CSOG (see 3.12).
- 3.15 Trends from findings shall be reported to CROG and CSOG quarterly by the QAM.

Audit report summary

- 3.16 The audit summary report shall be issued electronically by the QAM, or delegate, on behalf of Sponsor (and copied to the Research Governance Manager and R&D Director, or delegate) using Ideagen Quality Management System. Reports shall include the following:
- Audit title and reference number (assigned by Ideagen QMS)
 - Status ('performed' or 'closed')
 - Audit type (internal, external etc)
 - Lead auditor
 - Scope (Principles of GCP, ISO 14155:2020 etc)
 - Scheduled start date, end date and duration
 - Actual start date, end date and duration
 - Closed by and date (if applicable)
- 3.17 The audit summary report shall also include a summary of the audit visit (overview) detailing the scope of the audit and any findings noted.
- 3.18 The report shall detail the number of non-conformances, the number outstanding, and the number of observations. A summary table of findings shall detail their status (ie open, closed or N/A (for Observations)). If no findings are raised, this shall be indicated in the report.
- 3.19 If necessary, a follow-up visit may be conducted to review progress in ensuring previously agreed Corrections and CAPA have been undertaken. The auditor shall confirm with the auditee once all non-conformances, and the audit, are closed by email.

4. Abbreviations and definitions

Correction	Action to correct an identified non-conformance
Corrective Action	Action to prevent recurrence of an identified non-conformance
Preventive Action	Action to prevent occurrence of a potential non-conformance
CAPA	Corrective Action and Preventive Action
CROG	Clinical Research Operational Group
CSOG	Clinical Studies Oversight Group
QAM	Quality Assurance Manager

5. Related documentation and references

SOP-QA-25	Deviations and Breaches
SOP-QA-43	Suspected Serious Breaches
TMP-QA-80	CAPA Template
UG-QA-1	Risk Assessment to determine audit frequency

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