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UKCRF NETWORK

CHIEF SCIENTIST OFFICE

UKCRF Network Quality Assurance Theme Group

# Internal Audit Toolkit Guidelines

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## Introduction

Clinical research is a highly regulated environment, with a vast array of regulations, guidelines, policies and procedures that must be complied with. Working within this complex framework is challenging, but while instances of non-compliance are almost inevitable, they should be minimised as far as is practicably possible. It is a regulatory expectation that organisations have oversight of clinical trial activities they are involved in, with quality assurance procedures in place to allow assessment of compliance with all applicable requirements.

> *"There is a requirement to provide assurance that an organisation's clinical-trial activities are conducted in accordance with approved trial documentation and also to identify any deficiencies in supporting clinical trial processes and systems."*
>
> MHRA Good Clinical Practice Guide

MHRA Regulating Medicines and Medical Devices

This includes an effective internal audit programme. Audit is an important quality assurance activity and a key component of a robust quality management system. A definition of audit is given below:

> *"a systematic and independent examination of trial-related activities & documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCP and the applicable regulatory requirement(s)."*
>
> ICH E6(R2) Guideline for Good Clinical Practice

ICH harmonisation for better health

Auditors should be independent of the activities being audited and appropriately qualified and trained to conduct audits effectively. However, this can be difficult in a CRF setting, particularly when dedicated QA resources are limited, have only recently been established, or do not yet exist.

To support CRFs in developing an internal audit function, the UKCRF Network QA Theme Group has developed a set of audit tools and templates covering such aspects as risk assessment, creating an audit schedule, planning, conducting and reporting audits, tracking associated corrective and preventative actions (CAPA) and trend analysis of audit findings.

**Internal Audit Toolkit**

- Internal Audit Risk Assessment Tool
- Internal Audit Schedule Template
- Internal Audit Plan Template
- Internal Audit Checklist Tool
- Internal Audit Report Template
- Internal Audit Findings and CAPA Tracker

These tools are designed to be adaptable, and CRFs are encouraged to adapt and localise them according to their own individual requirements. However, it is requested that the contribution of the UKCRF Network QA Theme Group is acknowledged.

The purpose of this guidance document is to give an overview of the tools within the Audit Toolkit, outline why they are important elements of an internal audit programme and briefly describe how they can be used effectively. **More detailed guidance is provided within each tool.**

## Internal Audit Risk Assessment Tool

It is usually neither practical nor necessary to audit every system and process within a CRF on an annual basis, and a risk-based approach to compiling an audit schedule is encouraged. A Risk Assessment Tool has been designed to help CRF's prioritise their internal audit activity, focussing on the systems that pose the greatest risk in terms of participant safety, data integrity and regulatory compliance.

The tool can be used to perform either a simple or more detailed risk assessment of all systems (or areas, studies, facilities, etc.) identified for audit. The resulting Risk Ratings can then be used to help determine how frequently those systems should be audited.

## Internal Audit Schedule Template

One important aspect of an internal audit programme is to have a clear schedule of audits agreed in advance. This allows both auditor and auditee to plan, prepare and allocate resources, but also helps ensure that audit coverage is sufficient and in line with organisational objectives. An Internal Audit Schedule Template has been created to help auditors and managers to schedule and agree an annual programme.

## Internal Audit Plan Template

An Audit Plan serves the important purpose of ensuring that all parties involved understand the timing and practical arrangements for an audit, as well as the objectives and scope. A clear and sufficiently detailed plan can help the auditee to prepare and to know what to expect, and can facilitate the smooth running of the audit. An Audit Plan Template has been devised which covers the essentials but which can be adapted as required.

## Internal Audit Checklist Tool

The QA Theme Group has previously developed an Audit Checklist Tool, and this has now been updated to improve the format and scope. The tool covers a range of systems and processes that are common topics for internal audit, and guides the auditor by providing prompts for what should be checked. The checklists are adaptable and can be used separately for system-specific audits, or together for a broader study or facility audit.

## Internal Audit Report Template

Once an audit has been conducted, the findings need to be communicated back to the auditee and relevant management in a format that is concise and unambiguous. An Audit Report Template has been designed to ensure that the important elements are included and to give some guidance on how to construct a clear, specific and easily understandable audit finding.

## Internal Audit Findings and CAPA Tracker

Following an audit, it is important to correct any deficiencies identified and to implement measures to prevent them happening again. These corrective and preventative actions (CAPA) are often quick and easy, but may require more extensive action. A tool has been designed to serve the dual functions of allowing CAPA to be tracked until resolution and identifying trends that may require further attention.

# UKCRF Network QA Theme Group Members

The Internal Audit Toolkit was developed by the following members of the UKCRF Network QA Theme Group:

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- All UKCRF Network QA Theme Group members
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