WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Review Article: Conducting of Investigator Site Audit

Dr. Vishal G Jagtap[1], Ms. Neha Baikar[2]

[1] GCP QA Auditor, [2]QA Associate
Mumbai University

ABSTRACT

An investigator site audit is a vital component of clinical trial development, aiming to assure the integrity, compliance, and quality of research undertaken at a specific investigational site. The primary purpose of on-site audits by researchers is to assess and verify a research site's compliance with research protocols, regulatory requirements, and ethical standards.

On-site audits involve a qualified auditor, often from a sponsor or contract research organization (CRO), reviewing a variety of important factors

Keywords – Investigator site audit, CRO, Sponsor, Quality Assurance,

Conducting of Investigator Site Audit

Monitoring and audits are two distinct processes that ensure participant safety, rights protection, and data integrity protection.

Audits of investigator sites are an essential part of making sure clinical trials are high-quality, ethical, and compliant with regulations. To assess how clinical trials are being done at investigational sites, sponsors, contract research organizations (CROs), or regulatory bodies often carry out these audits. In publications about investigator site audits in clinical trials, the following important topics are frequently discussed:

Audit: An audit, on the other hand, is a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and whether the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCP, and the applicable regulatory requirement(s).

Quality Assurance - All those planned and systematic actions that are established to ensure that the trial is implemented and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s)

1. Purpose of Site Audit

- Audit whether the clinical trial is carried out in compliance with protocol, relevant regulations, and Good Clinical Practice (GCP) guidelines is done through investigator site audits.
- The core objective is to examine whether trial subjects' rights, safety, and well-being are being protected with accuracy, reliability, and accuracy.

2. Audit Process:

The audit process entails planning, conducting, and reporting audits, as outlined below.

A) Selection of Site –

i) Risk-based approach - A risk-based strategy is used by many sponsors and regulatory bodies to choose which sites should be audited first. This method takes into account variables like the trial's complexity, the site's previous performance, the investigator's experience, and the possible effects on patient safety and data integrity.

ii) **Random Sampling:** In addition to risk-based selection, random sampling can be used for verification to maintain neutrality and ease misleading information. This ensures that audits are not only targeted at high risk sites.

iii) **Protocol Deviations and Non-Compliance:** Sites with a past history of protocol deviations or noncompliance are always picked for inspection/audit. Such deviations may indicate glitches with GCP compliance.

iv) **Site Performance Metrics:** Sponsors and CROs can maintain effective metrics to identify sites with repeated quality issues. Metrics may include subject enrollment, data quality, and timely reporting.

v) **Phase of the Trial:** Early-phase trials (Phase I & II) could get less frequent audits than later-phase trials (Phase III & IV) due to differences in risk and data importance.

vi) P**revious Audit Findings:** If a site has a previous history of audit findings/observations or regulatory noncompliance, it's more probable to be audited again to verify that CAPA has been taken.

vii) **Geographic Location:** Audit facilities in different geographical locations to ensure global compliance and consistency in worldwide research.

viii) **Specialized Expertise:** For Clinical Studies encompass specialized therapeutic areas or complex procedures, sites with exacting expertise may be targeted for audit.

ix) **Regulatory Requirements:** Regulatory authorities may determine the need for audits of certain types of experiments or facilities, particularly in the case of sensitive or high-risk research.

x) **Data Trends:** A scrutiny of data trends, irregularities, or patterns that could suggest misconduct or fraud or data manipulation may trigger an audit.

xi) **Complaints and Whistle blower Reports:** Complaints from research participants, facility staff, and whistle blowers may result in audits to investigate suspected misconduct and fraud.

xii) **Routine and For-Cause Audits**: Routine audits are usually planned in advance, while "for-cause" audits are triggered by certain events, such as the encounter of significant nonconformities or security problems.

B) Audit Agenda -

An investigator site audit agenda is a structured plan that outlines the topics and accomplishments that will be covered during a clinical trial site audit. This helps auditors and field staff understand the scope and objectives of the audit. Further down is a typical investigator site audit agenda

i) Opening Meeting –Useful for introducing on-site personnel and investigators

ii) Scope of audit – list of documents to be audited and overall scope in brief

iii) Close-out meeting- Discussion on audit findings/observations and Corrective and Preventive Action.

C) Conduct of Audit-

i) Facility Round:

Facility tour the site's facilities and infrastructure, including examination rooms, laboratories, and storage areas. Inspect research-related equipment to ensure proper operation.

ii) Document Review:

Examine key study-related documents such as investigator brochures, protocols, consent forms, case report forms, regulatory documents, and previous audit records. Please ensure that your documentation is complete, accurate and up to date.

iii) Regulatory Compliance Review:

Assess your facility's compliance with regulatory requirements, including Institutional Review Board (IRB) approval, ethics committee documentation, and adherence to applicable regulations.

iv) Process Review:

Examination of the site's processes related to patient recruitment, informed consent, drug accountability, adverse event reporting, and data management.

Assure that these processes are administered as per GCP guidelines.

v) Data Management and Quality Control:

Review data management procedures to ensure data excellence and integrity. Evaluate the site and its quality control measures, as well as data evaluation, query resolution, and data validation procedures.

vi) Source Data Verification (SDV):

Select a sample of patient records and compare the source data with the data recorded on the case report form. Confirm that your data remains accurate, consistent, and compliant with GCP guidelines.

vii) Interview of study staff

Conduct interviews with key site staff such as the principal investigator, co-investigators, research nurses, phlebotomists, and Clinical research coordinators.

Discuss study conduct, protocol compliance, informed consent, and patient safety. Interpret roles and responsibilities

3. Audit Report and Follow-Up:

- Anthologize the audit findings, observations/noncompliance's, and conclusions into a detailed audit report.
- Include recommendations/suggestions and necessary corrective actions.
- Submit the report to the appropriate stakeholders, including the sponsor, regulatory authorities, and the site.
- Follow-up to ensure corrective and preventive actions actions are instigated and monitored as required.

4. Audit Close-Out:

Declare the audit to be officially closed and provide the website feedback regarding the audit's outcome. Through the audit, it's vital to maintain objectives, independence, and competence, and adhere to auditing standards, for instance, Good Clinical Practice (GCP) guidelines. The audit desires to clinch compliance with regulatory requirements, data integrity, and the protection of patient safety in clinical trials.

5. Audit Certificate –

The audit certificate provides information on the audit's scope, date, site number, site address, and meaning, which is that the CAPA has been successfully closed and the audit was carried out. A copy of the audit certificate is kept in the sponsor and investigator site files.

Conclusion-

All over the audit, it's key to maintain objectivity, professionalism, and adherence to audit standards, such as Good Clinical Practice (GCP) guidelines. The goal of the audit is to ensure compliance with regulatory requirements, data integrity, and the protection of patient safety in clinical trials.

References

1) Terry Winchell, "The Investigator Site Audit Process- driven Good Clinical Practice" June 2007 The quality assurance journal 11(2):138-142
2) Integrated addendum to ICH (E6)R1, Guideline for good clinical practice (E6)R2
3) Winchell T. Source documentation: What's the mystery? GCPj 2004; 11(5): 26–29. 2.
4) Winchell T. The heart of GCP. SOCRA Source 2006; February(47): 41.
5) https://chat.openai.com/ (ChatGPT)