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Short Communication

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Enhancing Audit Readiness in Clinical Trial Sites: Practical Insights from Monitoring Experience in India

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Abstract

Audit readiness is critical, ensuring patient safety and regulatory compliance in clinical trials. Site Monitoring activities play a key role in identifying operational risks and strengthening site preparedness for sponsor audits and regulatory inspections. This article presents practical insights from monitoring experiences across multicenter clinical trial sites in India, demonstrating how operational issues identified were managed through structured corrective and preventive actions.

Two real-world monitoring scenarios involving laboratory report misfiling and damaged investigational product shipments are described to illustrate practical implementation approaches at the site level.

In the first scenario, laboratory reports filed under an incorrect participant record were identified during monitoring review and addressed through source document reconciliation, verification of investigator oversight, implementation of two-step filing checks, and monitoring verification checkpoints.

In the second scenario, a damaged investigational product vial identified upon receipt of the shipment was managed through immediate segregation, inventory reconciliation, sponsor notification, and strengthened receipt-verification procedures before integration into active inventory.

These experiences highlight that practical controls such as real-time documentation, role-based verification, structured review steps, and standardized monitoring checks can strengthen traceability, reduce operational errors, and improve site preparedness for audits and inspections.

Keywords: Clinical trials; Audit readiness; Site monitoring; Corrective And Preventive Action (CAPA); Good Clinical Practice; Investigational Product Management; Clinical Research Compliance

1. Introduction and Problem Statement

Audit readiness is an essential aspect of clinical trial management, reflecting a site's ability to demonstrate compliance with regulatory requirements, protocol specifications, and Good Clinical Practice (GCP) standards. Sponsors and regulatory authorities rely on documented evidence to confirm that clinical trials are conducted in a manner that protects participant safety and ensures data integrity.

Although audit readiness is well-defined in regulatory guidance, most existing literature focuses on theoretical frameworks and checklist-based compliance rather than on real-world operational issues identified during routine monitoring and their translation into corrective and preventive actions (CAPA).

Clinical research sites operate through complex workflows involving patient visits, investigational product (IP) management, documentation, and sponsor communication. In practice, even when clinical activities are performed correctly, gaps such as documentation inconsistencies, delayed issue detection, or unclear process ownership can compromise audit readiness and become evident only during monitoring visits.

This article presents practical monitoring experiences from multicenter sites in India, linking real operational findings with practical improvement measures to enhance audit preparedness. The novelty of this work lies in its practice-based, CAPA-focused approach, directly connecting monitoring observations with compliance improvement actions while providing India-specific operational insights from multicenter trials.

2. Scenarios

2.1. Scenario 1: Misplacement of Laboratory Reports and Impact on Oversight Documentation

During a routine monitoring visit, it was identified that laboratory reports for study participant ABC had been filed in participant XYZ's source document file. Although investigator review of laboratory results had occurred prior to investigational product (IP) administration and the participant was safely dosed, the filing error created a documentation gap, as source records did not clearly demonstrate traceability of PI review prior to dosing. The issue was managed through document reconciliation, verification of investigator oversight, implementation of corrective actions, and preventive process improvements to maintain an accurate audit trail.

2.1.1. Identification and Initial Assessment

The issue was identified during the monitor's source document review, which revealed a mismatch between laboratory report identifiers and participant files. The study coordinator and monitor jointly verified laboratory reports, dosing records, and investigator signatures to confirm that laboratory review had occurred prior to IP administration and that no participant safety impact was present.

2.1.2. Root Cause Evaluation

The review determined that the misfiling occurred during routine document-filing activities on a high-volume clinic day when multiple laboratory reports were printed and filed simultaneously. The absence of a secondary verification step before filing contributed to the error remaining undetected until the monitoring review.

2.1.3. Corrective Actions Implemented

The study coordinator immediately reconciled all laboratory reports filed during the monitoring period by verifying subject identifiers, visit dates, and the corresponding source documents. The incorrectly filed reports were corrected and placed in the appropriate participant file. The investigator reviewed the corrected records to confirm alignment with dosing decisions and safety documentation.

The monitor independently verified the completeness of the correction by reviewing source documents, confirming that all laboratory reports were correctly refiled, and assessing whether any additional subjects were affected. The monitor documented the findings in the monitoring report and confirmed resolution with the site. The investigator provided oversight confirmation that laboratory review had been appropriately completed prior to dosing.

A note-to-file was generated to document the issue, corrective actions, and confirmation of PI oversight.

2.1.4. Preventive Actions Implemented

To prevent recurrence, the site implemented a mandatory two-step filing process in which laboratory reports are first verified by the study coordinator against subject identifiers and visit dates, then independently cross-checked by a second trained staff member prior to final filing. Staff were retrained on source documentation practices with emphasis on real-time, traceable filing linked to investigator review activities.

An example of the monitoring checklist used during source document review is presented below (Table 1):

Table 1: Monitoring checklist used during source document review

Monitoring Check Point	Records Reviewed	Monitoring Actions
Laboratory report accuracy	Subject File / Laboratory reports	Verify the correct subject identifier and visit date match
PI review prior to dosing	Signed lab reports/visit notes	Confirm PI review is documented before IP administration
Source filing completeness	Subject file	Check that all laboratory reports are correctly filed and traceable within the visit window

2.1.5. Audit Readiness Outcome

The availability of reconciled laboratory records, documented corrective actions, and supporting note-to-file documentation enabled clear reconstruction of the event during review. The incident reinforced the importance of accurate source document filing and strengthened processes supporting investigator oversight, audit traceability, and inspection readiness.

2.2. Scenario 2: Investigational Product Receipt and Audit Readiness in Handling Damaged Shipment

During receipt of an investigational product (IP) shipment, the study coordinator performed routine inventory verification and inspection activities in accordance with site procedures. During this verification, one vial was identified as damaged, likely

due to transit conditions. Since a participant visit requiring investigational product administration was scheduled for the same day, the issue required immediate assessment to ensure continued protocol compliance and uninterrupted dosing.
The issue was managed through shipment assessment, inventory verification, corrective action implementation, and preventive controls to support compliant investigational product management.

2.2.1. Identification and Initial Assessment

The study coordinator identified the damaged vial during shipment unpacking and immediately verified shipment contents against the packing list. Temperature logs were reviewed to confirm storage conditions were maintained, and available inventory was assessed to ensure sufficient undamaged vials for the scheduled participant visit. The investigator and sponsor/CRO were promptly informed for guidance on handling the affected vial.

2.2.2. Root Cause Evaluation

The damage was assessed as most likely related to transit handling during shipment. No storage or site handling issues were identified, as temperature monitoring records and receipt conditions confirmed appropriate handling upon arrival.

2.2.3. Corrective Actions Implemented

The study coordinator immediately segregated the damaged vial, labeled it as unusable, and documented the finding in the IP accountability log. A reconciliation of received versus usable inventory was performed to confirm adequate stock for the scheduled participant visit. The investigator reviewed the available inventory and confirmed that dosing could proceed using an intact vial.
The sponsor/CRO provided confirmation regarding the disposition of the damaged vial.
The monitor reviewed receipt documentation, temperature logs, and accountability records to ensure completeness and compliance with IP management requirements. All communications and documentation updates were completed contemporaneously.

2.2.4. Preventive Actions Implemented

To prevent recurrence, the site reinforced immediate and systematic inspection of all IP shipments at receipt, including verification of vial integrity, quantity, labeling condition, and storage requirements before acceptance into active inventory. Staff were retrained on early detection and documentation of shipment-related discrepancies, with emphasis on immediate escalation and traceable documentation practices.
Additionally, the site implemented a practice of confirming and documenting the condition of all IP shipments before adding the investigational product to the usable site inventory.
An example of the monitoring checklist used during IP verification is presented below (Table 2):

Table 2: Monitoring checklist used during IP verification

Monitoring Check Point	Records Reviewed	Monitoring Actions
Vial integrity	IP shipment	Verify vial integrity, packaging, and labeling at receipt
Temperature compliance	Temperature log	Confirm temperature records are complete and within required limits
IP accountability	IP accountability log	Verify accurate documentation of received and usable IP inventory
Sponsor notification	Site correspondence	Confirm sponsor/CRO notification and documentation of the shipment discrepancy

2.2.5. Audit Readiness Outcome

Shipment receipt records, timely completed temperature logs, IP receipt and accountability documentation, and sponsor communication records collectively ensured full traceability of the event and demonstrated appropriate handling, documentation, and oversight of investigational product receipt activities.

3. Approach

Regular monitoring observations provide valuable opportunities to identify operational risks and implement corrective and preventive actions (CAPA) that support audit readiness. Structured monitoring activities, including document verification, inventory review, and communication with site staff, serve as proactive measures to maintain compliance with protocol requirements and regulatory standards.

Documentation accuracy remains a cornerstone of clinical trial quality management. Incomplete or inconsistent study records can create temporary gaps in the documentation trail, potentially raising concerns during audits even when clinical care has been appropriately delivered. Establishing structured filing systems, site-level documentation checklists, and routine verification steps can significantly reduce the likelihood of documentation discrepancies and improve retrieval efficiency during inspections.

Similarly, investigational product management requires careful attention to accountability, storage, handling procedures, and patient safety considerations. Timely identification of discrepancies, including damaged or non-conforming investigational product vials, along with clear documentation of corrective actions, demonstrates adherence to protocol requirements and reinforces confidence in site operations. Enhanced monitoring checklists and standardized communication processes can support consistent implementation of investigational product handling procedures across study teams (Figure 1 and Table 3).

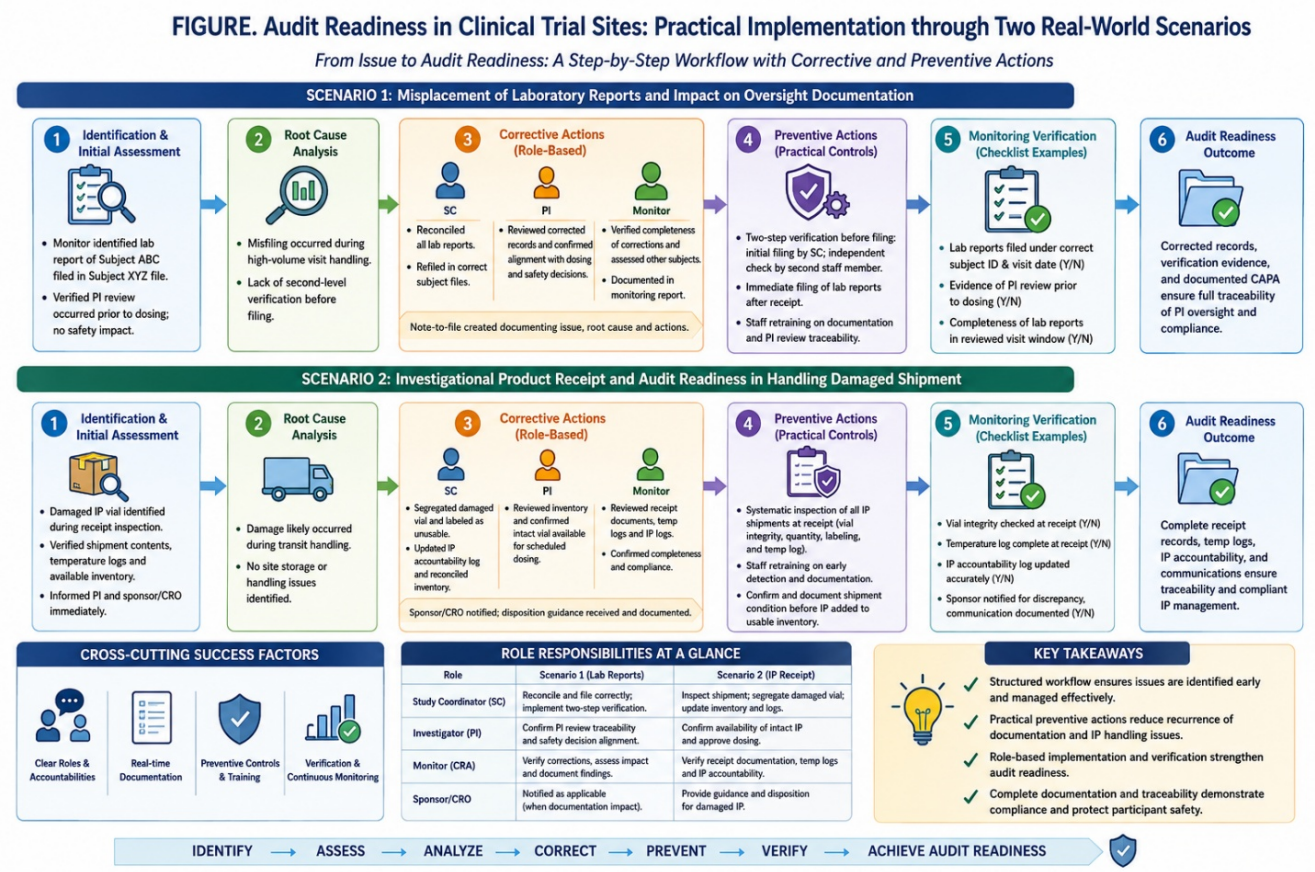

Figure 1: ***Workflow for Maintaining Audit Readiness in Clinical Trial Monitoring.*** *The figure illustrates the structured audit readiness workflow derived from the two real-world monitoring scenarios presented in this article. The workflow begins with the identification and initial assessment of operational findings during routine monitoring activities, followed by root cause analysis to determine the underlying factors contributing to the observed issue. Based on this assessment, role-specific corrective actions are implemented by the study coordinator, investigator, monitor and sponsor/CRO as appropriate to ensure timely resolution and maintenance of participant safety, data integrity and regulatory compliance. Preventive actions, including process improvements, staff retraining and standardized verification procedures, are then introduced to reduce the likelihood of recurrence and strengthen ongoing compliance.*

4. Lessons Learned

The monitoring scenarios presented in this article highlight several practical insights and resulting process improvements that strengthened site-level compliance and audit preparedness.

Key practical improvements and their impact are summarized below:

- Improved investigational product (IP) receipt and inspection documentation, including reinforcement of detection and recording of damaged or non-conforming vials during receipt - Ensured complete accountability and strengthened audit trail for IP handling deviations.
- Strengthened IP inventory reconciliation and temperature log verification processes - Reduced documentation gaps and improved traceability during monitoring reviews and audits.

- Implementation of site-level documentation checklists and enhanced monitoring checklists during routine monitoring activities - Supported systematic review of essential documents, improved consistency of monitoring practices, and enabled early identification of discrepancies before escalation into audit findings.
- Staff retraining on Documentation practices and IP handling responsibilities following identified issues - Improved adherence to procedures and reduced recurrence of documentation-related errors.

Table 3: Common Operational Challenges Observed During Clinical Trial Monitoring

Operational Issue	Potential Impact on Audit Readiness	Recommended Monitoring Action
Incomplete or outdated delegation log	Unclear staff responsibilities during the audit	Verify staff roles against training records and obtain the investigator's signature to update the delegation log immediately
Incomplete informed consent documentation	Ethical and regulatory non-compliance	Conduct document review with site staff and arrange re-consenting process if required. Verify the usage of the correct versions
Protocol visits windows were not adhered to	Risk of protocol deviation	Document deviation, notify the sponsor and investigator, and ensure corrective action documentation in the deviation log
Inadequate temperature log documentation for investigational product storage	Risk to product integrity	Perform temperature log reconciliation and verify the functioning of the temperature monitoring device or backup system

5. Declarations

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Author Contributions

HD: conceptualized, drafted, reviewed, and submitted the manuscript.

Ethics Approval and Consent to Participate

Ethical approval was not required for this publication as the scenarios presented are based on professional practice observations and do not constitute human subject research.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Not applicable

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Artificial Intelligence (AI) Declaration

An artificial intelligence (AI) tool was used to generate the infographic included in this manuscript. The author reviewed and validated the content to ensure accuracy and relevance to clinical trial monitoring practices.

6. Abbreviations

The following abbreviations are used in this manuscript:

AI	Artificial Intelligence
CAPA	Corrective and Preventive Action
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Council for Harmonization
IP	Investigational Product
PI	Principal Investigator
WHO	World Health Organization

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