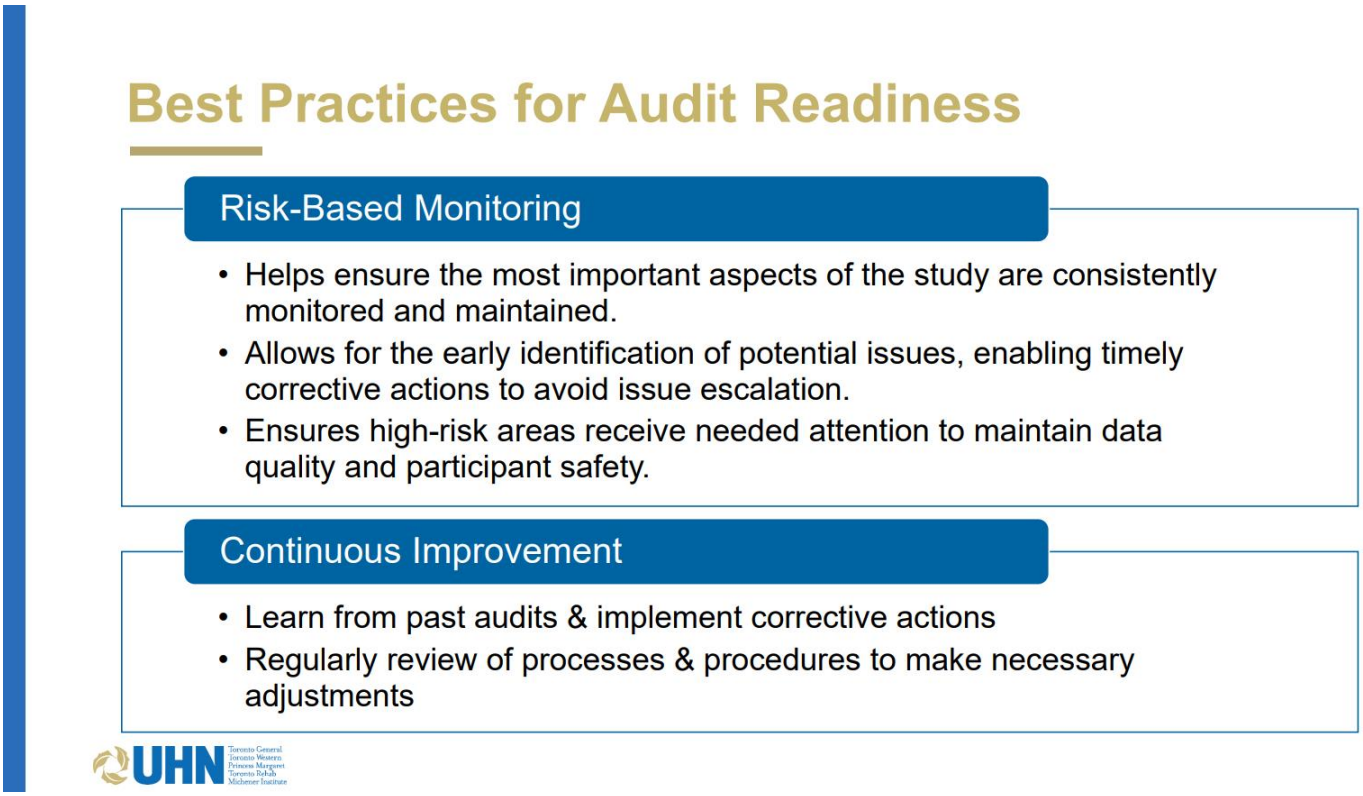
ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 28 March 2025

(i) KEY PRESENTATION

Ensuring audit readiness in clinical research studies by Heidy Morales, Research Quality Associate, Research Quality Integration, UHN (slides attached)

Audit readiness maintains patient safety, data integrity, and regulatory compliance. Key points from the presentation:

- Documentation (make sure accurate and complete) is a cornerstone of audit readiness. Keep Trial Master Files (TMFs) up-to-date and easily accessible, and include essential documents such as signed informed consent forms and completed case report forms (CRFs).
- Be mindful of the regulatory framework including Health Canada requirements, ICH GCP E6 and Division 5.
- Best practices for audit readiness include (see slide below): (i) risk-based monitoring which involves focusing on critical areas of the study to identify and prioritize monitoring efforts, and identifying potential issues early and implementing corrective actions; and (ii) continuous improvement which involves learning from past reviews or audits, and regularly reviewing processes to make proactive adjustments.



- Be mindful that a sponsor / auditor may come back to the site to: (i) audit a different study but potentially with the same team/PI; and (ii) complete a follow-up audit to review how corrective/preventive actions have been implemented, based on findings from an initial audit. When they come back is up to the sponsor/auditing group.

- Common audit issues are:
    - Training gaps: training or delegation occuring after work has been performed; missing or incomplete delegation logs;
    - Missing records: missing consent forms, case report forms, or questionnaires;
    - Inconsistencies: discrepancies between procedures performed and standard operating procedures (SOPs).
    - Safety reporting: inadequate or delayed assessments of adverse events, failure to report events as required by site and IRB/REB.

(ii) PROBLEM PRESENTATION

Presented by: Trina Hynes

Role in Clinical Research: Research Coordinator

Brief Description of the Situation/Scenario:

According to ICH GCP and the Food and Drug Regulations, Part C, Division 5, all “Essential Documents” must be retained for 15 years. There is a list of Essential Docs. in ICH GCP E6 and plenty of other comments/definitions in the regulations that paint a picture of what MUST be retained. However, the line between retain and don’t retain feels fuzzy when it comes to coexistent health information that was not used to create/inform trial data.

Trina's top questions:

For studies conducted at a health center (ie. hospital or outpatient clinic), is the QI required to retain ALL health care documents? For example, if the study only collected CT scans, is the QI also responsible for retaining unrelated x-rays (no AEs to be reported), or routine colonoscopies (no AEs) if these procedures were never reported to the study? Should the QI retain the entire hospital chart if the study staff made certified copies of the records related to an SAE already?

The regulations typically say essential documents “include, but are not limited to … “. Is it an expectation that health centers would be retaining much more than what is deemed essential as a best practice or are there other regulations that specify the limit of “not limited to …”? Sometimes it feels like we retain extra data to prove that we didn’t miss critical information (ie. keeping an unrelated CT scan to prove that there was no AE detected to report), which I feel isn’t the purpose of keeping essential docs.

DISCUSSION OF THE PROBLEM

The community discussed the retention of source data and essential documents in clinical trials.

There were views on whether to archive all related clinical trial documents, including those not directly linked to the trial, to ensure no adverse events were missed.

The community also discussed the challenges of distinguishing between clinical trial and unrelated health data.

Discussion points included the following points, with no definitive answer to the grey zone in which the question of archiving non-essential documents lies:

- In terms of archiving clinical data, keeping hospital charts and outpatient clinical records, determining what records are essential to retain, proving no adverse events were missed.

- Health information systems are variable which can mean disjointed medical record systems, potential for missing adverse events, and difficulty tracking patient records across different healthcare settings.

- The importance of institutional policies and consent forms in determining what to retain including determining what records are required by the protocol, understanding the limits of the consent form, and balancing institutional requirements with research needs.

- The cost and logistical implications of retaining extensive records – a balance between best practice and pragmatism e.g. using electronic systems like Epic to archive patient records, implementing data lakes for long-term record storage, and flagging clinical trial patient charts for extended retention. Additionally, there are heavier resource requirements if record keeping is extensive, the cost of archiving comprehensive records, and different logistical limitations at different healthcare sites.

- Documentation strategies included noting non-protocol medical procedures, getting the PI to sign off on record reviews, and creating documentation to prove no adverse events occurred.

It was suggested that the problem submitter check with the quality team and institutional policies, review current practices and REB advice on archiving clinical trial data to clarify exact requirements for keeping non-protocol medical records.

Ultimately the goal is to have clear, efficient and compliant recordkeeping practices.

RESOURCES

Clinical Trials Transformation Initiative – principles to govern: Protocol design, feasibility, patient safety, study conduct, study reporting, and third-party engagement.
https://ctti-clinicaltrials.org/our-work/quality/qbd-quality-by-design-toolkit/teach-others-about-qbd/exploring-the-critical-to-quality-ctq-factors/