Ensuring Audit Readiness in Clinical Research Studies

Clinical Research Professionals ECHO
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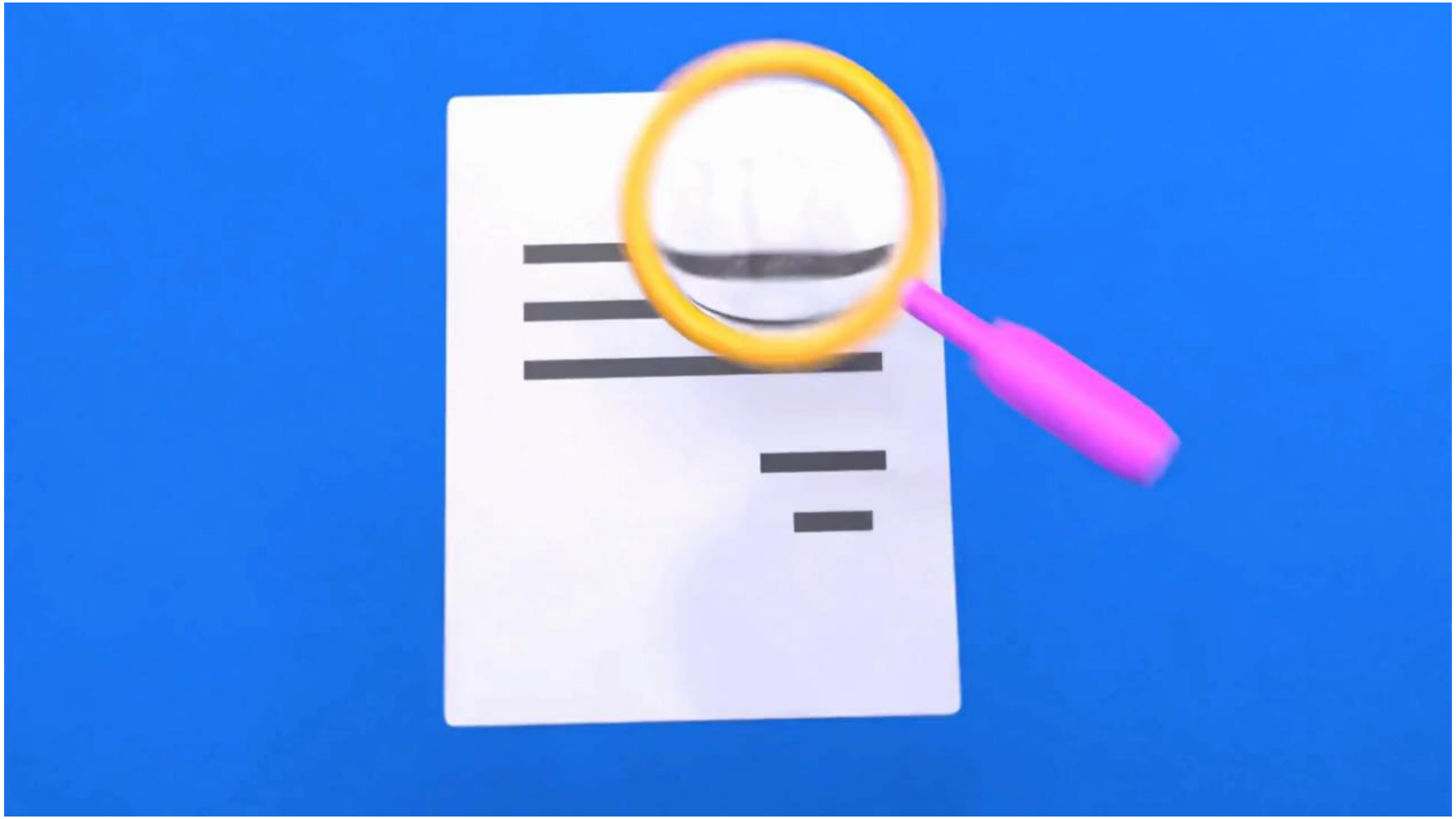
Agenda

- Introduction
- Audit Objectives
- Regulatory Framework
- Key Components of Audit Readiness
- Best Practices
- Site Selection & Preparation
- Summary / Q&A

Audit Readiness



Audit Objectives

- Audits allow research teams to:
  - **Protect** the rights, safety & welfare of human research participants
  - **Assess and monitor** ongoing compliance with regulatory requirements*
  - **Verify and validate** the accuracy, reliability and integrity of the **data** generated

Regulatory Framework

- Health Canada (HC) Requirements
  - HC sets guidelines to ensure the safety and efficacy of clinical research studies
  - Standards used:
    - Good Clinical Practices Guideline - ICH GCP E6
    - HC: Part C - Division 5 of the Regulations
      - the Food and Drug Regulations (FDR), Division 5

Key Components of Audit Readiness

- Documentation:
  - Accurate and complete documentation is key to audit readiness.
    - Trial Master Files (TMFs), informed consent forms, case report forms (CRFs), and other essential documents.
  - Ensure all documents are up-to-date, well-organized, and easily accessible.
  - Regularly review & update documentation to reflect any changes in the study protocol or procedures.

Key Components of Audit Readiness

- Training & Compliance:
  - Regular training sessions ensure all staff involved in the study understand their roles and responsibilities.
  - Training should cover:
    - Study protocol, GCP guidelines, study-specific procedures, specific regulatory requirements, etc.

Compliance with regulatory standards is key for audit readiness.

Best Practices for Audit Readiness

Risk-Based Monitoring

- Helps ensure the most important aspects of the study are consistently monitored and maintained.
- Allows for the early identification of potential issues, enabling timely corrective actions to avoid issue escalation.
- Ensures high-risk areas receive needed attention to maintain data quality and participant safety.

Continuous Improvement

- Learn from past audits & implement corrective actions
- Regularly review of processes & procedures to make necessary adjustments

Selection Site(s) for Audit

Selection is **based on risk-based criteria**, including but not limited to:

- The phase in the drug development process
- Clinical trial design - objectives, complexity, blinding, size, endpoints
- Participant population / high accrual
- New therapies / type of drug
- Indication for drug(s) used in the trial
- Marketed drug for a new indication
- Significant or frequent reports of serious adverse drug reactions
- Notices from Sponsors of protocol deviations

Site Preparation

- Electronic access logistics
- Organizing Templates & Tools
- Complete any outstanding corrective actions
- Know your procedures (SOPs)

Site Preparation – Tips for Staff

- View the experience as a learning opportunity
- Accept help in preparation
- Try not to make everything look perfect
- Avoid writing excessive Note-to-Files
- Be confident; you are an expert in your role
- Prepare for some long days

Site Preparation

Use a study file checklist

Common audit issues :

- Training after delegation
- Delegation after work
- Missing records
- Inconsistencies
- Safety reporting

Site Support

Reach out to your local Quality Team for support*

- Pre-inspection audit
- Quality Review (mini-audit)
- Training Session & Overview on Inspection Readiness

Questions / Comments

Contact: rqi@uhn.ca

Study Records Retention

- Regulated Studies
  - 15 years as per Health Canada requirements
- Non-regulated studies
  - 10 years (at least) or as per institutional policy