Florida Clinical Research Audit Preparation and Quality Process

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ABSTRACT

BACKGROUND

The clinical research audit process at the Mayo Clinic in Florida, encompassing notification, preparation, execution, and post-audit follow-up, has historically lacked structure, leading to inefficiencies and unclear responsibilities. Additionally, a significant deficiency in resources and educational materials providing practical, application-focused guidance was identified. These shortcomings prompted an initiative to deliver actionable resources and education to both cancer and non-cancer clinical research personnel at the Mayo Clinic in Florida.

METHODS

The initiative is structured into three phases: Phase I emphasizes education and notification, Phase II concentrates on study review and preparation, and Phase III focuses on post-audit activities and metrics. An assessment was conducted to evaluate the existing resources. Stakeholders from the Regulatory, Data, and Study Coordination units, encompassing both cancer and non-cancer research, were consulted to pinpoint weaknesses and implement necessary changes.

OBJECTIVES

PRIMARY OBJECTIVE

To provide resources to staff and leadership for **step-by-step guidance** on audit activities before, during, and after an audit

SECONDARY OBJECTIVES

To create **preliminary and continuing education** to staff and leadership on audits and best practices

To deliver **meaningful metrics** from which to improve study conduct quality

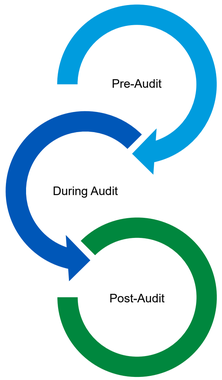
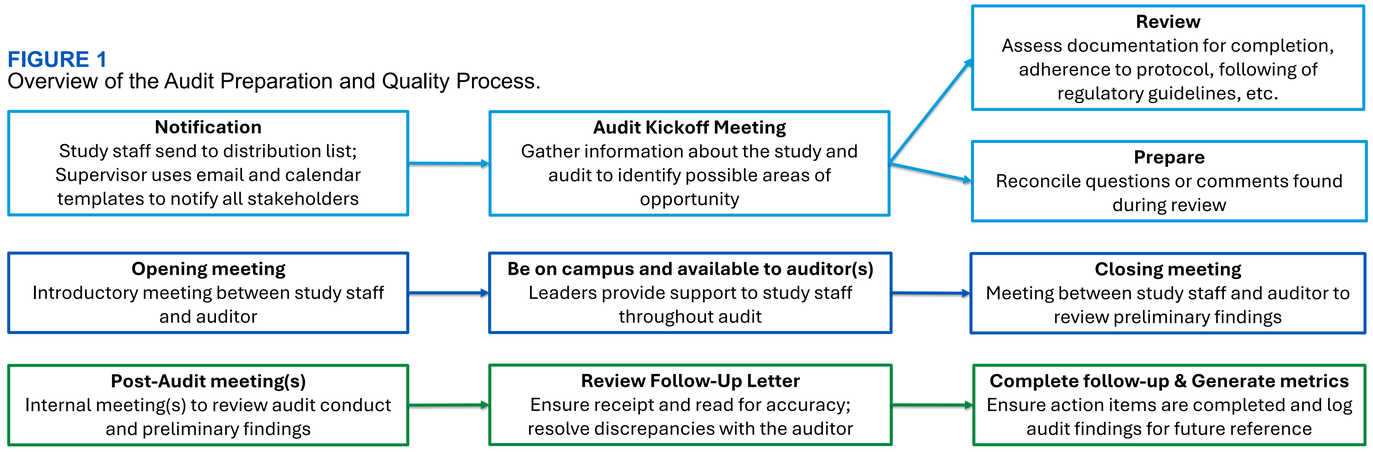


FIGURE 1
Overview of the Audit Preparation and Quality Process.



PHASE I: COMPLETE

Objectives to meet: Step-by step guidance (in progress), Preliminary education (complete)

- Preliminary education
  - Awareness campaign to all clinical studies units
  - Highlighted types of audits and strategies for managing each
- Standardized audit notification process
  - Dedicated distribution list established
    - All audit notifications sent to the same email address
    - Ensures prompt notification of leadership
  - Designated leader responds within 1-2 business days
    - Includes all applicable stakeholders
    - Email and calendar templates utilized to standardize information and resources distributed

PHASE II: IN PROGRESS

Objectives to meet: Step-by-step guidance (in progress), Continuing education (in progress)

- Pre-audit study review
  - Audit Kickoff Assessment Form
    - Collects essential information about the clinical trial and audit
    - Identifies potential areas of focus for the study review
  - Audit Kickoff Meeting Process
    - Assembles all stakeholders
    - Initiates team communication concerning audit-related activities
    - Facilitates the delegation of pre-audit tasks
  - Feedback from initial implementations has been highly positive
- Pre-audit study preparation
  - Additional resources for study preparation are currently in development

PHASE III: TO BE INITIATED

Objectives to meet: Step-by-step guidance (to be completed), Continuing education (to be completed), Meaningful metrics (to be completed)

- Post-audit follow-up
  - Receive follow-up letter and review for accuracy
  - Ensure timely completion of action items
- Corrective and Preventive Actions (CAPAs)
  - Establish a process for completion
  - Utilize a central electronic storage location
- Metrics
  - Determine necessary measures
  - Develop method for logging and tracking information in a user-friendly and efficient manner
  - Utilize a central electronic storage location

CONCLUSIONS

A standardized, comprehensive audit process empowers research teams and ensures audit-readiness. Phase I of the initiative establishes clear stakeholder notification and education; Phase II provides a structured approach to study review and preparation through the Audit Kickoff Assessment form and meeting process; and Phase III focuses on completion of post-audit follow-up tasks and provision of key performance metrics. Implementation thus far (Phases I and II) has demonstrated positive impacts on team preparedness, confidence, and leadership support.

Upon completion of all three phases, staff and leadership will be equipped with **step-by-step guidance** on audit activities, **preliminary and continuing education** on audits and best practices, and **meaningful metrics** for leadership.