Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Florida Clinical Research Audit Preparation and Quality Process

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1. Background

The Mayo Clinic Florida clinical research audit process—spanning notification, preparation, execution, and post-audit follow-up—has historically lacked cohesion, resulting in inefficiencies and unclear responsibilities. A significant gap was identified in the availability of resources and educational materials offering practical, application-focused guidance. This prompted the development of an initiative to provide actionable resources and education for both cancer and non-cancer clinical research personnel.

2. Goals

A process will be developed that engages leadership and staff from the time of audit notification through post-audit activities. This includes adequately notifying all applicable stakeholders, ensuring audit readiness of a clinical trial, providing support and resources during audit execution, and providing complete and timely audit follow up. Additionally, metrics will be developed to monitor the number of clinical trial audits performed at Mayo Clinic Florida, why each audit was conducted, and areas in which audit findings were received.

3. Solutions and Methods

The initiative is structured into three phases: Phase I – education and notification, Phase II – pre-audit study review and preparation, and Phase III – post-audit follow-up and corrective action plans. A survey was conducted to assess the existing resources available on the Mayo Clinic intranet. Stakeholders from the Protocol Development Unit, Data, and Study Coordination units across both cancer and non-cancer research were consulted to identify gaps and address needs within the current process.

4. Outcomes

Phase I has been successfully completed, including an awareness campaign that highlighted different types of audits and strategies for managing them. Resources have been created and made available to all staff. Additionally, a dedicated distribution list for audit notifications was established, ensuring leadership is promptly informed of audits or suspected audits. A designated leader responds within 1-2 days, providing stakeholders with email and calendar templates to confirm awareness. This has prevented extended delays between site notification of an audit and subsequent notification of all stakeholders. Phase II is underway, with the piloting of the Audit Kickoff Assessment Form and Audit Kickoff Meeting Process. Feedback from these initial implementations has been highly positive, and additional resources for study preparation are in development.

5. Lessons Learned and Future Directions

A standardized, comprehensive audit process empowers research teams and ensures audit-readiness. Phase I establishes clear stakeholder notification; Phase II provides a structured approach to study review and preparation via the Audit Kickoff Assessment form and meeting process and Phase III focuses on post-audit follow-up. Implementation thus far (Phase I and II) has shown positive impacts on team preparedness, increased confidence, and stronger leadership support. Phase III will culminate in complete and timely post-audit follow-up processes, including collection of standardized information from which meaningful metrics can be established.