

Improving Quality: Audit Readiness Team

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1. Background

Mayo Clinic Comprehensive Cancer Center (MCCCC) participates in an abundance of clinical trials, therefore increasing the chances of receiving an audit request. Audit requests range from industry sponsors, Food and Drug Administration (FDA), cooperative, and institutional. To assure our clinical research staff are “audit ready,” the MCCCC designed and implemented an Audit Readiness Team (ART) to provide clinical research staff with the highest level of support and materials for every type of audit.

2. Goals

To ensure “audit ready” status and produce “clean”/finding-free audits, the goals for ART are to:

- Provide audit prep assistance to clinical research staff
- Provide “on-call” resources during an audit
- Assist study teams with post-audit clean-up efforts, i.e., audit response, corrective and preventative action, implementation, and effectiveness assessment

3. Solutions and Methods

Since MCCCC spans across multiple locations, the ART is set up with enterprise-wide staff members from the Compliance and Quality Unit (CQU), Regulatory Unit, and Quality Management and Education, along with location specific “boots on the ground” subject matter experts (SME) from our Cancer Clinical Trial Office (CCTO) Coordination Units and Protocol Development Units (PDU). This setup ensures that the CCTO research staff have access to resources and SMEs; along with ensuring ART member availability during an audit.

When notified of an audit, the CCTO research team submits a REDCap audit notification eForm communicating key information to the CQU. This information includes team members (i.e., principal investigator, CCTO staff, etc.); location of audit; type of audit; protocol information; and the requested date for the audit to occur. The CQU then reviews the notification and assigns ART members to assist the research team. The CQU also provides the research team with materials to aid in their preparation for the upcoming audit.

Prior to the audit, the assigned ART members will then meet with the research team to provide introduction and clarity to ART’s role and to also understand the rationale for the audit. ART is available for all cancer-related trials and tracked through REDCap. Identified trends and/or significant concerns are provided to the Data Safety Monitoring (DSM) chair for review and determination of next steps.

4. Outcomes

The implementation of the ART has improved the consistency of materials across all MCCCC locations. It has also provided the research teams with quick and direct access to SMEs and an abundance of resources to help in the preparation, conduct, and post-audit activities. It has shown that the research staff feel more confident, as they are better prepared and understand how to continue to improve their files to ensure “audit readiness.” Development of this team highlighted gaps in the location of resources and materials, which has now been incorporated into key guidance documents, checklists, and trainings.

Category: Quality Assurance & Remote Monitoring and Auditing - Completed Project

5. Lessons Learned and Future Directions

Tracking of audit results is critical in aiding us with process improvements and educational opportunities. Moving forward, the MCCCC DSM Committee will be reviewing the outcomes to assist with assessing and determining the operational and educational needs for our CCTO.