MAYO CLINIC

Improving Quality: Audit Readiness Team (ART)

Authors: Lisa Winkowski, Katrina Croghan M.S, CCRP, Keith Severson, Heidi Kogut, Angela Jurrens M.A., Angela Fritsche, MPA, Grzegorz Nowakowski, M.D., Aaron Mansfield, M.D.
Comprehensive Cancer Center, Mayo Clinic

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.

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.

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 (CAPA), implementation, and effectiveness assessment

REFERENCES

REDCap 12.4.25 - © 2023 Vanderbilt University

SOLUTIONS AND METHODS

AUDIT READINESS TEAM SET UP

- Enterprise-wide staff members from the Compliance and Quality Unit (CQU), Regulatory Unit, and Quality Management and Education
- Site specific staff members: include 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 set-up ensures that the CCTO research staff have access to resources and SMEs; along with ensuring ART member availability during an audit.

AUDIT NOTIFICATION EFORM

- When study teams are notified of an audit, the CCTO research team submits a REDCap Audit notification eForm communicating key information to the CQU. The eForm includes information such as:
  - Team members (i.e., Principal Investigator (PI), CCTO staff, etc),
  - Location of audit,
  - Type of audit,
  - Protocol information
  - Requested date for audit

ART PROCEDURE

- The Notification eForm is then automatically submitted to the CQU
- CQU reviews the notification and assigns ART members to assist the research team.
- CQU provides the research team with materials to aide in preparation for the upcoming audit, including:
  - Audit Manual
  - Audit checklist (specific to each type of audit)
  - Tips and Tricks videos on communication best practices
- Prior to the audit, the assigned ART members will meet:
  - Provide introductions
  - Provide expectations of the audit and ART
  - Learn about the audit (i.e.- the rationale for the audit) in terms of the study team notation and workflow
- During the audit study teams will send questions to the ART members to help problem solve while the study team is addressing auditor questions.
- Post audit, ART will attend the Exit interviews/meetings to help focus on any outstanding items. After the finding have been submitted to the site, ART will help address questions, comments and concerns alongside the study team. Any CAPA items will also be addressed through the Compliance CAPA Plan process.

ART TRACKING

- ART procedure is tracked through REDCap starting with the audit notification eForm and walking through meeting updates, and audit findings. Tracking is intended to:
  - Identified trends and/or significant concerns
  - Provided all items to Data Safety Monitoring (DSM) chair for review and determination of next steps.
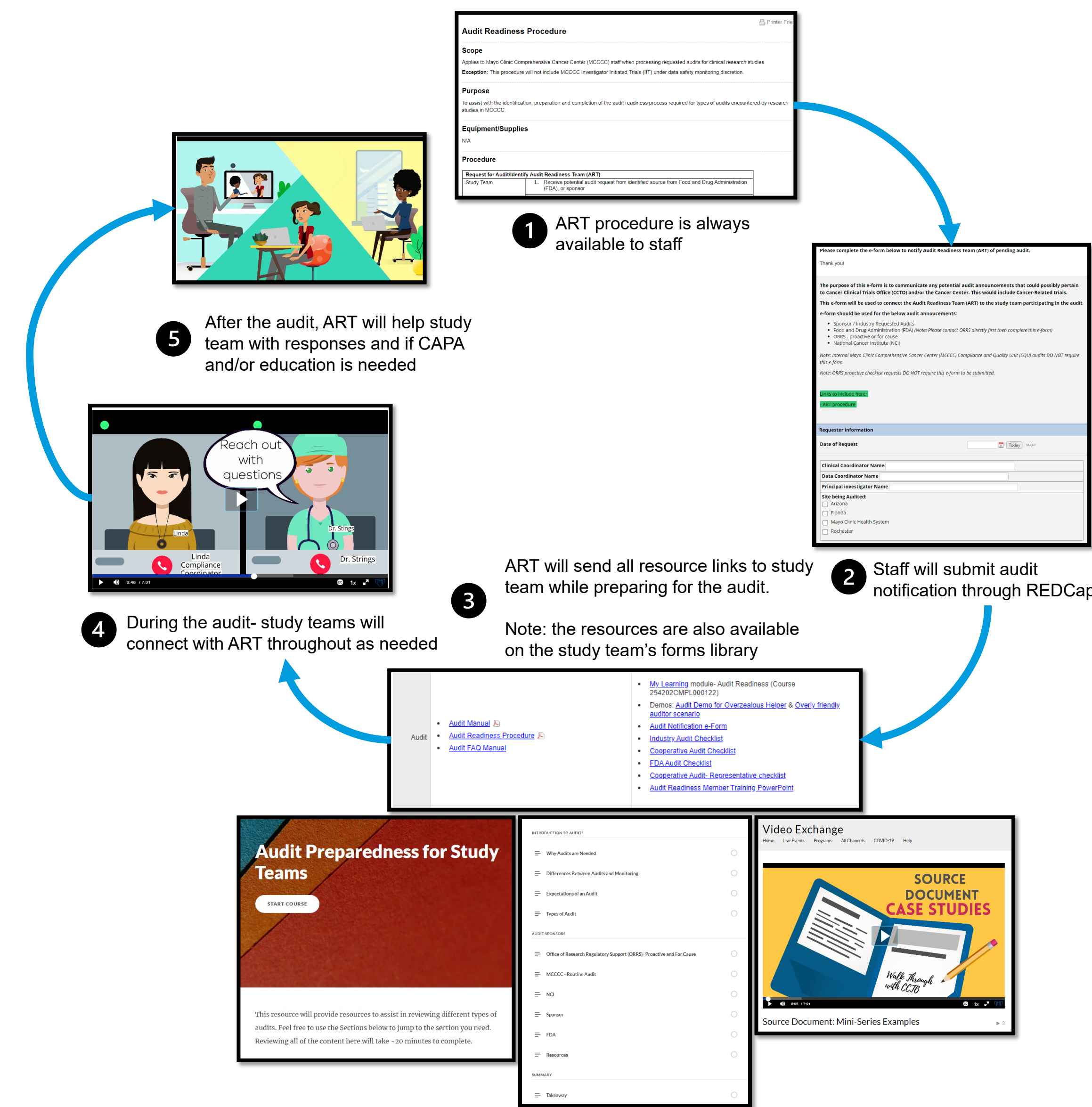
FIGURE 1

Figure 1 represents the ART process while presenting all identified audit resources for study teams

OUTCOMES

The implementation of the ART has:

- Improved the consistency of materials across all MCCCC locations.
- 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.
- 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.

LESSONS LEARNED

Tracking of audit results is critical in aiding us with process improvements and educational opportunities.

FUTURE DIRECTION

Moving forward MCCCC DSM Committee will be reviewing the outcomes to assist with assessing and determining the operational and educational needs for our CCTO.

ACKNOWLEDGMENT

Huge thank you to the Audit Readiness Team members who have volunteered their time to help study teams through audits. To you we say, 'ART Assemble'.