GOALS

• To create a stream-lined, online, collaborative process for research team members to maintain FDA CCT participant binders in an audit ready state

• To create a standardized audit tool template to be utilized for trials enrolled in the EIS program, as well as adapted for all current and future FDA CCTs

• To efficiently identify and resolve all missing and/or incomplete source documentation by aggregating trial data in an accessible and secure location

BACKGROUND

To facilitate on-going readiness of cancer clinical trials (CCTs) at risk for inspection by the Food and Drug Administration (FDA), the Abramson Cancer Center (ACC) Lymphoma Group enrolled FDA-inspection high risk CCTs (FDA CCTs) in an external inspection support program (EIS) operated by the ACC Department of Operations, Compliance and Monitoring (DOCM). At initial EIS enrollment of the first high risk CCT, there was no consistent audit preparation process in place for the Lymphoma Group. A digital audit tracking tool (ATT) was developed to create a uniform, stream-lined, collaborative process which could be utilized for current and future CCTs.

SOLUTIONS/ METHODS

The EIS program requirements necessitated creation of the ATT to enable all research team members to review participant binders in a standardized and collaborative fashion via an online Excel spreadsheet shared through Penn+Box. The ATT assures that all audit review progress is available for review by all members of the research team and enables preparation and maintenance of FDA CCT participant binders in a FDA-inspection readiness state.

OUTCOMES

The utility and efficiency of the ATT has resulted in exemplary monitoring reviews by the EIS program. The processes for audit readiness have become more streamlined and collaborative across the Lymphoma Group and have resulted in similar exemplary monitoring reports in other EIS program-enrolled trials.

LESSONS LEARNED / FUTURE DIRECTIONS

The use of the ATT has been essential and its collaborative nature has resulted in the ATT being adapted for use in other FDA CCTs. The ATT will continue to be shared with other CRU research groups for implementation by their research staff for their CCTs enrolled in the EIS program.