Preparing and Sharing Subject Cases for Remote NCTN Audit

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1. Background
The COVID-19 pandemic restricted travel and in-person gatherings, prohibiting external audits on campus. The implementation of Epic at the University of Illinois Chicago in 2020 made remote chart review feasible. The University of Illinois Cancer Clinical Trials Office established innovative procedures to support preparation and conduct of remote NCTN audits with Alliance, NRG Oncology, and the Children's Oncology Group in 2021.

2. Goals
Success was measured by the ability of the auditors to easily locate source documents remotely, and the ability to resolve auditor queries in real time during the audit.

3. Solutions and Methods
Each audit group had different requirements for subject case file review. Depending on the group requirements, case files were uploaded to the source document portal in the cancer trials support unit (CTSU), accessed via Epic Care Link, and/or uploaded to a secure PHI box. Document preparation for the CTSU portal required the most work, as all source needed to be downloaded from Epic, de-identified in Adobe PDF, and organized into packets prior to upload.

Epic Care Link access drastically reduced the amount of de-identification and uploading of documents necessary, as only documents not in the electronic medical record were required to be uploaded (consents, questionnaires, sample tracking, and adverse event logs). Organizing these documents by study, subject ID, and content simplified navigation.

Communication with the auditors during the process was based on their preference. The most intense audit was with Alliance, where we had a Zoom call that lasted through the day with breakout rooms for each auditor. Our site would send a representative to each room to assist in locating documents and answering questions. In the other audits, a point person was designated to receive emails with questions and findings. That person would work with the team to formulate answers and reply in one succinct email chain.

4. Outcomes
Due to the organization and labeling of source documentation and open lines of communication throughout the audit, our site was able to significantly reduce the number of queries or findings on our final reports. In addition, every audit ended with complimentary notes from the reviewers regarding our level of preparation.

5. Lessons Learned and Future Directions
Obtaining information on how the auditor wishes to view documents and conduct the visit is important to define early in the planning stages. This prevented the team from having to re-organize documents or upload multiple times. For future audits we will share a source data identification log with the auditors that will give instructions on where to find data in either Epic Care Link or the secure PHI box.

Category: Quality Assurance, Remote Monitoring, and Auditing – Work in Progress

As we began to rely on the search and redact feature in Adobe PDF, we realized clinicians frequently used nicknames or misspellings of names when referencing patients in documentation. This made de-identification difficult and we re-trained our clinicians to be careful when referencing patients in clinical documentation.