Category: Trial Recruitment and Study Conduct (IITs) - Completed Project

Electronic Subject Data Collection Within an eBinder System

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1. Background

Our site began implementing a 21 CFR Part 11-compliant eBinder system in 2020 with an initial scope of regulatory binders. We quickly realized the capabilities of the system beyond an electronic Investigator Site File and have since expanded our use of the system to include electronic Subject Data Collection (eSubject Data) management. Electronic Subject Data Collection allows for a fully digital patient record and supports more efficient workflows for data collection and transcription. Following a pilot by our Phase I and COVID clinics, a toolkit was developed and rolled out to support the adoption of eSubject Data by all disease teams within our cancer center.

2. Goals

1. Increase adoption of eSubject ata to improve workflows for data capture and transcription
2. Convert institutional templates into standardized electronic forms
3. Create resources and tools supporting broad adoption of electronic data capture

3. Solutions and Methods

The eSubject Data toolkit provided four types of resources:

1. Guidance documents
2. Standardized electronic forms: institutional templates modified into electronically fillable forms and eLogs
3. Example forms: forms provided with standard structure, allowing study specific customization (i.e., subject eligibility)
4. Tutorial videos: tutorials for modifying templates into electronically fillable forms

In addition, each team was provided a series of trainings from our support team, including guidance on binder setup, side-by-side instruction for their first trial, and assistance with study specific modifications for eLogs.

4. Outcomes

1. Three disease teams are fully utilizing the eSubject Data process with an additional five teams in the process of implementing
2. Data coordinators have been able to remain as remote staff and have real-time access to source data
3. Study teams have centralized access to consolidated research files
4. Monitor visits can occur remotely with access to subject data, without teams having to scan and upload documents to our eBinder system
5. Investigators report increased satisfaction because of real-time access to subjects' research data

5. Lessons Learned and Future Directions

The adoption of eSubject Data across disease teams has been slower than anticipated, from this a few key lessons were identified:

- First, despite being provided an extensive toolkit for eSubject Data adoption, many teams lack the personnel resources to invest the time to learn and transition to new workflows. We identified this as an opportunity to train centralized resources to support the transition work and remove the burden from the teams. We will monitor whether this investment will lead to an increase in the adoption of eSubject Data.
- Second, more change management support is needed, especially with faculty who may be initially resistant to new technology and processes. We will leverage faculty and teams who have deployed eSubject Data to continue to support the change management, training, and education needs for broader adoption.