Category: Training, Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Electronic Source Documentation in Epic Reduces Key Audit Findings and Aids in Remote Coordinating and Auditing

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1. Background

In 2018 space for paper charts became increasingly limited. Auditing revealed source wasn't being created or reviewed in a timely manner. Additionally, the clinical trials office (CTO) and cancer clinics are in separate buildings making obtaining principal investigator (PI) signatures difficult. Moreover, research logs weren't standardized and current protocols were hard to access through a virtual private network (VPN) in clinic. A solution for these documentation shortcomings beyond increased staffing and space was needed.

2. Goals

The use of standardized electronic logs and SmartPhrases in our electronic medical record system, Epic, was intended to increase timely creation of source documentation, reduce delays in maintaining source and PI reviews, and reduce the number of internal audit findings attributable to paper source usage. This was also intended to allow for remote auditing and monitoring.

3. Solutions and Methods

In 2019 the CTO implemented the use of electronic source documentation in Epic. The CTO developed Epic SmartPhrases to standardize source documentation and visit notes. Electronic logs were developed within Epic for lab/EKG clinical significance (CS), adverse events (AE), medical history, con-meds and RECIST to enable PI review and sign-off. In 2019 protocols were transitioned to an online eRegulatory system (Complion).

4. Outcomes

Comparing normalized internal audit data from subjects consented in 2017-2020, our standardized metrics have quantified the benefits of documenting primarily within electronic systems. The accompanying graph details the most significant percentage changes in key audit findings during this time period. Below the change in frequency of each is summarized, and a brief description of which electronic documentation tool or abandoned paper source-based practice impacted each.

- One hundred percent decrease in:
    - Not documenting the consent process (SmartPhrase for consent discussion)
    - 6+ month delinquencies in data entry (no printing and wet-ink signature delays)
    - Eligibility documentation occurring after treatment (education, visit SmartPhrases, and allowing confirmations via email)
    - Eligibility criteria from incorrect protocol version (use of eRegulatory)
- Thirty-two percent decrease in AEs not being assessed by PIs/Sub-Is in a timely manner (electronic AE logs)

- Twenty-six percent decrease in three to six months data entry delinquencies (no printing and wet-ink signature delays)
- Twenty-five percent decrease in documentation of eligibility procedures after eligibility was confirmed (electronic CS, medical history, and RECIST logs; and visit SmartPhrases)
- Eighteen percent decrease in PIs not documenting CS in a timely manner (electronic CS logs and visit SmartPhrases)
- Seven percent decrease in RECIST not being assessed in a timely manner (electronic RECIST logs)

5. Lessons Learned

While a change from paper to electronic source improved key audit findings, other contributing factors were: increased staffing, detailed workflows, and an educator position. Each electronic tool was developed gradually allowing early adopters to test and champion use with peers. Having electronic documentation by 2020, the CTO easily continued auditing, monitoring, and data entry activities remotely during the COVID-19 restrictions. In the future we hope to implement electronic consenting within a Part 11-compliant system, and to find solutions to allow our EPIC records to interface directly with data capture systems to reduce transcription errors and free up additional staff time to focus on clinical duties.

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Figure: