Category: Trial Recruitment and Study Conduct - Work in progress

Utilizing Lessons Learned and Setting Up for Future Success: The CTO Pilot with eConsenting

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1. Background

Indiana University Simon Comprehensive Cancer Center (IUSCCC) Clinical Trials Office's (CTO) goal to become paperless began with eConsent. With this goal in mind, several key stakeholders collaborated to bring an eConsenting platform to the disease-oriented teams in the office.

2. Goals

1. Utilize a platform to transition from paper consents to an electronic consent library.
2. Save physical space and transition to a paperless office.
3. Provide easy, efficient process for subjects to consent electronically and provide single-point access to all electronically stored consent forms for study staff, subjects, and sponsors.
4. Provide greater flexibility for clinic staff to recruit subjects.
5. Provide greater flexibility for subjects to consent when distance, illness, or other factors may prohibit them from returning to clinic.

3. Solutions and Methods

- The CTO contracted with a third-party provider to develop a 21 CFR Part 11 compliant eConsent system.
- The CTO purchased 8 iPads for distribution and use throughout the various clinics.
- The Regulatory and Quality Teams provided multiple group and one-on-one training sessions to ensure staff were fully trained on the use of the system.
- Key CTO stakeholders engaged in weekly meetings with the development team to troubleshoot and re-design elements of the system as pain points were identified.

4. Outcomes

Through eConsenting, patients could either review documents on their personal device and sign remotely on their device, via tablet in clinic, or via paper with the option of digitally storing the document which allowed subjects easy access to their consent documents once signed.

Remote consenting allowed subjects and staff ample time to review the consent information, ask questions, and provide answers to questions, as well as providing greater flexibility to staff in utilizing breaks between clinic patients to consent subjects remotely.

Auto-populated fields, such as date of signature and consent version, ensured the correct consent version, provided protection from inaccurate or illegible entries, and prevented transcription errors.

The system required both patients and staff to be technologically proficient. Struggles on both sides included difficulty navigate the system and documents, completing the two-factor authentication identity verification process via text or email, and submitting signatures.

Transitioning to eConsent required training to adhere to system protocols, which was time consuming and cumbersome. Technology gaps with subjects and staff occasionally caused excess delays for patients

in clinic during the process compared with the quicker paper consent method. Adopting eConsent required the team to carry laptops, connect to printers, download, and print documents.

5. Lessons Learned and Future Directions

Regulatory compliance during the consent process is essential, however, the end-user experience should also be easy and efficient. Improving navigation for patients who lack technological proficiency emerged as a key improvement area. The lessons learned with this eConsenting pilot resulted in the business decision to seek an alternative solution.

The CTO was able to utilize REDCAP eConsenting for non-FDA regulated, non-therapeutic studies in the interim while other products were explored.

The CTO plans to implement a new eConsenting product in 2024 and incorporate all the lessons learned into the success of the new system.