Category: Clinical Trial Operations – Completed Project

eRegulatory Process and Software Implementation in Times of Crisis

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1. Background

The week of March 16, 2020, the staff of our clinical trials office began a sudden and immediate shift to full time remote work. All our original study documentation was maintained on paper. We were two months away from launching a new eRegulatory software, Florence eBinders. There were many reasons to delay the implementation, but one solid reason for us not to: eSignatures (compliant with FDA 21 CFR Part 11 guidelines). This functionality has allowed us to not only continue research administration remotely, but to improve our turnaround times for processing regulatory documents during a pandemic. This is how we worked through those initial months of the pandemic into the present.

2. Goals

- Implement an organization-wide eSignature tool and document workflows
- Facilitate a remote/paperless environment
- Shift to remote monitoring and close-out to keep studies moving forward

3. Solutions and Methods

We paused our initial implementation to develop an interim process for eSignatures. Using Adobe eSignature and forms creation features, we developed processes/education for frequently used forms. We trained staff via video, written instruction sheets, online presentations, and one-to-one support sessions facilitated by our quality assurance and education department (QA&E). This took about two weeks.

It was frequently communicated that we would continue the implementation of our eRegulatory system. Florence staff worked with us to adapt their system training to this remote environment. It was important to not lose the momentum built in the planning phase, so we only paused long enough to assess if and how to move forward.

We provided abundant communication and follow-up when we finally did train for the system and updated processes. We did two weeks of supplemental departmental training developed in collaboration with our regulatory managers and QA&E to help staff clearly understand how these changes would affect them. Training was provided in multiple group sessions and follow-up videos. We also conducted virtual office hours and open group sessions for two weeks following the training to answer questions and provide hands-on demos.

Using this initial comprehensive training and communication model with our data and clinical implementations, we began processing SAEs, uploading eSource, and remote monitoring in Florence with all major implementation completed by April 2021.

4. Outcomes

- 60,000+ signatures (since July 2020)
- Signature receipt times from 3 to 4 weeks to an average of 6 days
- 9500+ eSource documents uploaded (since April 2021)

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- 780+ SAEs signed-off (since January 2021)
- 800+ studies remotely managed and monitored (since July 2020)

5. Lessons Learned and Future Directions

- Additional administrative support would have been beneficial; the QA&E team had to de-prioritize quality-related and other educational activities to do low-skilled administrative tasks (i.e., converting documents to fillable forms)
- Clarify goals more than you think is needed; it is easy to lose sight of what needs to be accomplished in a high-stress and chaotic environment
- Follow up with staff to quicken integration into daily workflows

As we move forward with continuous improvement, we hope to focus on adding additional document workflows to Florence for clinical staff and to determine our risk threshold of eliminating paper documentation once it has been converted to eSource.

Figure: