Category: Trial Start-up, Activation, Regulatory, and Protocol Development – Completed project

A Review of Florence Regulatory eBinder Implementation and Lessons Learned

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1. Background

The Clinical Trials Office (CTO) Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) managed regulatory documents through paper files, a shared network drive, and NYULH cloud-based storage website until March 2022. These methods posed challenges: paper files consumed significant physical space, sponsors could not access the shared network drive, and were limited in how the cloud-based storage system could be utilized. These challenges were further exacerbated during quarantine in 2020. With reduced on-site presence and virtual meetings, collecting hand-written signatures became problematic. CTO leadership decided to introduce an e-regulatory binder solution, Florence.

2. Goals

PCC established three primary objectives for this transition:

1) Enhancing compliance, particularly with signature collection
2) Consolidating storage solutions into one platform
3) Enable regulatory staff to work remotely

3. Solutions and Methods

After vendor selection, NYULH Medical Center IT collaborated with Florence on technical needs and security clearance. Over the 12-week implementation period, CTO regulatory leadership met with Florence specialists to establish templates and develop an SOP. Post-implementation, an 8-minute training video on signing documents was provided by Florence, supplemented by office hours and in-depth trainings from regulatory leadership and Florence for everyday users.

After finalizing the Florence SOP, any studies activated thereafter had a regulatory binder created in Florence. Most legacy studies were converted to Florence, except for those nearing closure.

4. Outcomes

Since implementation began in March 2022, over 300 legacy studies have been transitioned into Florence, a significant achievement by the regulatory team. Each binder conversion took approximately 4-8 hours, which was a substantial burden on the team.

Automated sign-off reminders from Florence, pending signature reports, ability to sign from mobile device and parallel signing by investigators have contributed to increased compliance. Feedback has been positive from study team, monitors and investigators.

With e-binder migration, regulatory staff was able to engage in full-time remote work and PCC CTO was able to recruit to regulatory vacancies nationwide, leading to the turnover in regulatory from 26 percent in 2021 to 15 percent in 2023.

The transition to Florence has enabled PCC to consolidate the current paper files and archive older protocols. As e-binders for studies activated after March 2022 have been created within Florence, paper files are not being utilized therefore saving physical space.

5. Lessons Learned and Future Directions

The transition to Florence came with a heavy administrative burden. Using an external resource could have reduced the extensive administrative and technical support needed for setup. A vendor-provided resource dedicated to transitioning paper files into Florence would have been helpful.

Study team members have given feedback regarding binder structure and user-friendliness, leading to its refinement. Detailed guidance regarding document filing and naming conventions have been implemented as a solution.

Even with significant progress, there is room for improvement in compliance and timeliness. Over the next year, PCC will be exploring how we can leverage reports in Florence to aid this effort. Further integration in document sharing with monitors and sponsors would be beneficial, alongside efforts to garner increased buy-in from monitors to using Florence.

Overall, the utilization of Florence is anticipated to enhance efficiency and further bolster compliance efforts.