A Review of Florence Regulatory eBinder Implementation and Lessons Learned

NYU Langone Health

Perlmutter Cancer Center
An NCI-designated Comprehensive Cancer Center

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Background

The Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) is an NCI Designated Comprehensive Cancer Center.

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 secured 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.

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

We aimed to complete the transition by April 2023, allowing for a little over a year to add all our binders.

Future Goals for this project include:
1. Reorganizing Central Documents (e.g., personnel and laboratory documents)
2. Leveraging Florence report functions to improve compliance and timeliness of collecting signatures.
3. Exploring how we can use Florence to aid during monitor visits

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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.

In March 2022, after finalizing the Florence SOP, all studies activated thereafter were to have regulatory eBinders created in Florence. Existing paper study binders were also converted to Florence unless close out was imminent. This process included uploading study documents from NYULH cloud-based storage drive as well as scanning physical paper documents into the system. Central documents, including medical licenses, curriculum vitae, CITI training certificates, as well as all laboratory certificates and reference ranges were also filed into the Florence system.

Outcome

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% in 2021 to 15% 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.

Lessons Learned and Future Directions

The transition to Florence came with a heavy administrative burden. Because it is not possible to pause study activities and devote uninterrupted time to transition study binders to Florence, we had to transfer studies in phases. This disjointed process led to confusion amongst non-regulatory team members accessing the study binders. 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 alleviated some of this confusion and burden on our regulatory team.

Transitioning paper binders posed notable challenges, particularly with delegation logs. During the pandemic, the inability of study team members to access the office led to the creation of electronic versions of these logs. Consequently, upon transitioning to Florence, reconciling both the original paper and electronic versions proved to be unexpectedly difficult. Consequently, we granted extensions beyond the targeted April 2023 deadline for certain studies.

Following a period of Florence use, study team members were invited to provide feedback. Their input on binder structure and user-friendliness has facilitated refinements in our workflows. In response, detailed guidance regarding document filing and naming conventions have been implemented as a solution. We maintain regular meetings with the Florence team to provide ongoing feedback on what would benefit our users.

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.