Impact on Compliance Following Florence eBinder Implementation

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Background

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

The Perlmutter Cancer Center (PCC) at NYU Langone Health (NYULH) previously managed regulatory documents through paper, a shared network drive, and NYULH's cloud-based file storage system, until March 2022. The cloud-based file storage system was adopted as a temporary solution to facilitate remote work during the Covid-19 pandemic. However, the PCC has since transitioned all documents to Florence, an FDA 21 CFR Part 11 electronic regulatory binder and signature collection system.

In recent years, regulatory compliance, particularly delegation and training logs, were cited as most of our monitor and auditor findings. Since fully integrating with Florence, there has been a noticeable increase in overall compliance.

As the Quality Assurance Unit (QAU) conducts internal audits on PCC's trials semiannually, we are interested in evaluating the impact Florence has had on compliance, from our regulatory team and study team members. This review will solely focus on data from the QAU internal audits to ensure data consistency and standardized methodology.

Goals

When searching for an e-regulatory binder system, our top priorities were compliance and user-friendliness for both study team members and investigators. Specifically, we aimed to:

1) Increase compliance regarding missing signatures and timeliness of signatures

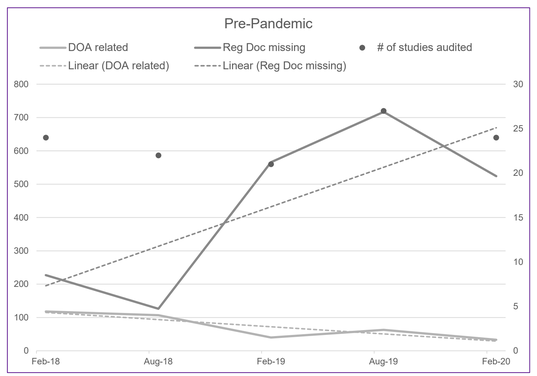
2) Improve compliance in the creation of logs and the timely maintenance of protocol-related documents

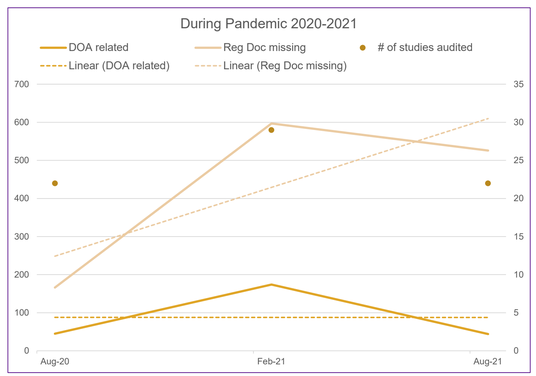
Solutions and Methods

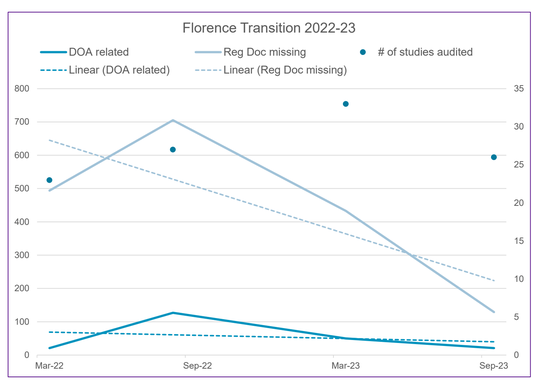
Regulatory specialists are tasked with maintaining regulatory binders to ensure they are audit-ready at any given time. This involves 1) creating delegation logs at study start-up and updating them throughout the study lifecycle in real-time 2) Generating training logs at study start-up and for any relevant amendments 3) Ensuring that study documents approved by the Institutional Review Board (IRB) are promptly filed in the regulatory binder system.

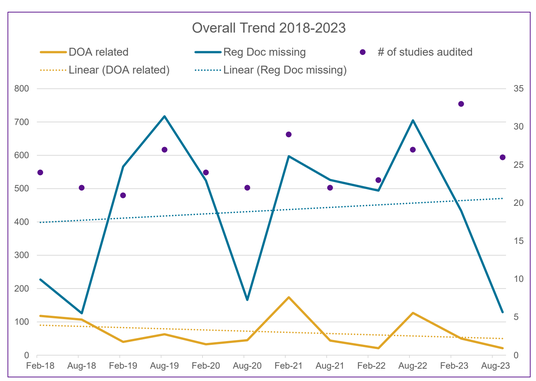
These areas are subject to scrutiny during the semiannual internal audits conducted by the QAU since February 2018, which are routine audits of interventional, therapeutic, cancer-related studies at PCC. Studies are selected at random by NYU Biostatistics Resource from a pool of actively enrolling studies, and audits are conducted following the NCI CTMB guidelines, focusing on 7 different areas including regulatory documentation. Audit results are categorized per NCI guidelines and sent to the Principal Investigators, as well as entered into QAU's internal database.

For the purpose of this presentation, we examined audit findings in 2 specific categories, from 2018 to 2023: 1) Delegation log missing or 2) incomplete essential documents missing (including investigator training and qualification)









Outcomes

Florence implementation began on March 17, 2022 and we aimed to transition all binders by April 2023. Over 300 studies were uploaded to Florence by the end of 2023.

The QAU audit findings reveal that between February 2018 and September 2023, there was an overall decrease of 82.2% in the number of audit findings relating to the delegation log, and a decrease of 43.2% for missing essential documents. In particular, since 2022, the number of audit findings have decreased drastically.

Lessons Learned and Future Directions

While we have observed a notable decrease in findings concerning the delegation log and essential documents, there is still room for further improvement. Through analyzing reports in Florence on timeliness and identifying missing signatures, we have devised a new workflow to enhance the promptness of collecting training log signatures. Additionally, we have noticed that a substantial amount of time and effort is dedicated to managing the delegation log by both investigators and the regulatory team. As a result, we are considering transitioning to a central delegation log system in the near future. The goal of this project would be to reduce the number of signatures required for collection, including those of Principal Investigators.

Like any new system, there are adjustments needed to align with our current workflows and users' preferences. Some users were initially hesitant to embrace Florence as the new platform for document signing, as it introduces additional steps such as sign-in and PIN numbers compared to the traditional paper route. Nonetheless, it offers significant advantages, making it easier for staff to maintain and generate reports on any missing signatures.

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