

## **Impact on Compliance Following Florence eBinder Implementation**

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### **1. Background**

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.

### **2. Goals**

- 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

### **3. Solutions and Methods**

Regulatory specialists are tasked with maintaining regulatory binders to ensure they are audit-ready at any given time. This involves:

- Creating delegation logs at study start-up and updating them throughout the study lifecycle in real-time.
- Generating training logs at study start-up and for any relevant amendments.
- Ensuring that study documents approved by the Institutional Review Board 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 this presentation, we examined audit findings in two specific categories, from 2018 to 2023:

- Delegation log missing or incomplete
- Essential documents missing (including investigator training and qualification)

#### **4. Outcomes**

Florence implementation began on March 17, 2022, and we aimed to transition all binders by April 2023. Between February 2018 and September 2023, there was an overall decrease of 82.2 percent in the number of audit findings relating to the delegation log, and a decrease of 43.2 percent for missing essential documents.

#### **5. 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 master delegation log system soon.