Category: Clinical Trial Operations – Completed Project

Automating Protocol Training Documentation: Regulatory Compliance in a Click

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1. Background

A protocol's regulatory binder comprises essential documents and demonstrates the compliance of the investigator, sponsor, and monitor with the standards of good clinical practice and with all applicable regulatory requirements. At MSK these are housed in the Protocol Information Management System (PIMS). Although regulatory binders are electronic, maintenance can be a manual process. Non-compliance with regulatory requirements can have serious consequences for the investigators, the institution, and can impact an application for drug approval. We describe ongoing efforts to optimize the automation of one aspect of the PIMS binder, protocol training documentation. Documentation of protocol training is required before the start of any research related activity and throughout the life of the study. Notable timepoints include at the site initiation visit, when significant amendments are approved by the institutional review board, and ad-hoc to ensure continuous compliance. Historically, this has been a manual process which involves the study team preparing paper logs and collecting signatures or requesting emails from investigators to confirm the training material has been reviewed. Once completed, training documentation was scanned and uploaded into PIMS and the documents were certified.

2. Goals

Success will be analyzed using metrics including time and effort savings as well as a notable improvement in audit findings from the established baseline.

3. Solutions and Methods

A PIMS enhancement was released on September 28, 2020 to automate this process. Training emails, inclusive of training material, can now be electronically initiated by the study team in PIMS. Investigators review and acknowledge their understanding of the training through clicking a URL within the email, automatically generating training documentation that is immediately visible in the regulatory binder.

4. Outcomes

Positive: Protocol training documentation is automatically filed in an organized manner, making it easier to review, track, and maintain. This allows for a consistent standard across the institution. This new process eliminates a potential source of error in regulatory documentation. Preliminary data shows marked improvement in study team time and effort. Thus far, the new process has been well received.

5. Lessons Learned

Future goals include a mechanism to monitor investigator completion and generate notifications.