Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

Implementation of Electronic Protocol Training and Response System Using Florence eBinders

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1. Background

Protocol training documentation can be overburdensome to study staff, time consuming, is a common finding during Investigator Site File (ISF) reviews and is often an administrative barrier impacting clinical trial activation and protocol amendment implementation.

Moffitt's former process for documenting protocol training was to email protocol documents to study staff and utilize voting buttons to solicit a response that the materials had been reviewed. This system required manual tracking and repeated follow up with non-responders. Additionally, this left the regulatory team with a large collection of emails that needed to be converted to PDF and filed within the ISF.

2. Goals

The goals of developing and implementing the eTraining process were to reduce the time required to send, collect, file, and reconcile staff protocol-training records; shorten the overall timeline from start of protocol training collection through full completion; and decrease both the number of protocol-training–related monitoring findings and the time needed to resolve those findings.

3. Solutions and Methods

The proposed protocol eTraining process introduced key efficiencies to address the administrative burdens, time spent, and quality issues presented by in-person or self-training attestation documentation by: (1) moving training collection to an earlier timepoint; (2) requiring a single email sent to staff requiring protocol training documentation; (3) providing the ability to assign automatic signature reminders through the Florence eLog; (4) providing a complete list of individuals requiring protocol training at the onset; and (5) providing access to all study staff.

4. Outcomes

Since the adoption of the protocol eTraining process, a total of 17 studies have been activated in the Immune Cell Therapy (ICE-T) program with an average completion time of 42 days from the date of the initial training email request to the last e-signature obtained. The preceding 17 studies opened prior to the process were reviewed for comparison: eight of the trials were activated with incomplete staff training documentation, two remained incomplete at study closeout, and the remaining 15 had an average completion time of 84 days. A total of 49 protocol amendments have been implemented using the eTraining process, with an average completion time of 34 days.

Monitoring reports for eight ICE-T Investigator Initiated Trials (IIT) that had at least one amendment and one monitoring visit post-implementation were reviewed for the number of missing staff training attestation documentation that were cited as findings from both before and after implementation. The average missing staff attestations before implementation was 14, the average missing staff attestations after implementation was two. One IIT opened after the implementation of the protocol eTraining process had three monitoring visits conducted with zero findings related to protocol training documentation.

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5. Lessons Learned and Future Directions

In an ever-changing landscape of new technologies and new capabilities constantly emerging, current processes should continue to be evaluated to identify possible implementations, integrations and improvements. Monitoring and audit findings should continuously be tracked, and root causes analyzed to help identify where improvements can be made, possible automation can be implemented, and/or possible roadblocks can be removed.