

Implementation of Electronic Protocol Training and Response System Using Florence eBinders



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1. Background

Protocol training documentation can be time consuming, overburdensome, is a common deficiency found during Investigator Site File (ISF) reviews during monitoring visits and audits, and is often an administrative barrier impacting clinical trial activation and protocol amendment implementation.

Moffitt's former protocol training documentation process utilized email document distribution and voting buttons to attest to self-training, requiring manual tracking and cumbersome PDF conversions to file the training documentation within the ISF.

2. Goals

The goals of developing and implementing the eTraining process were to:

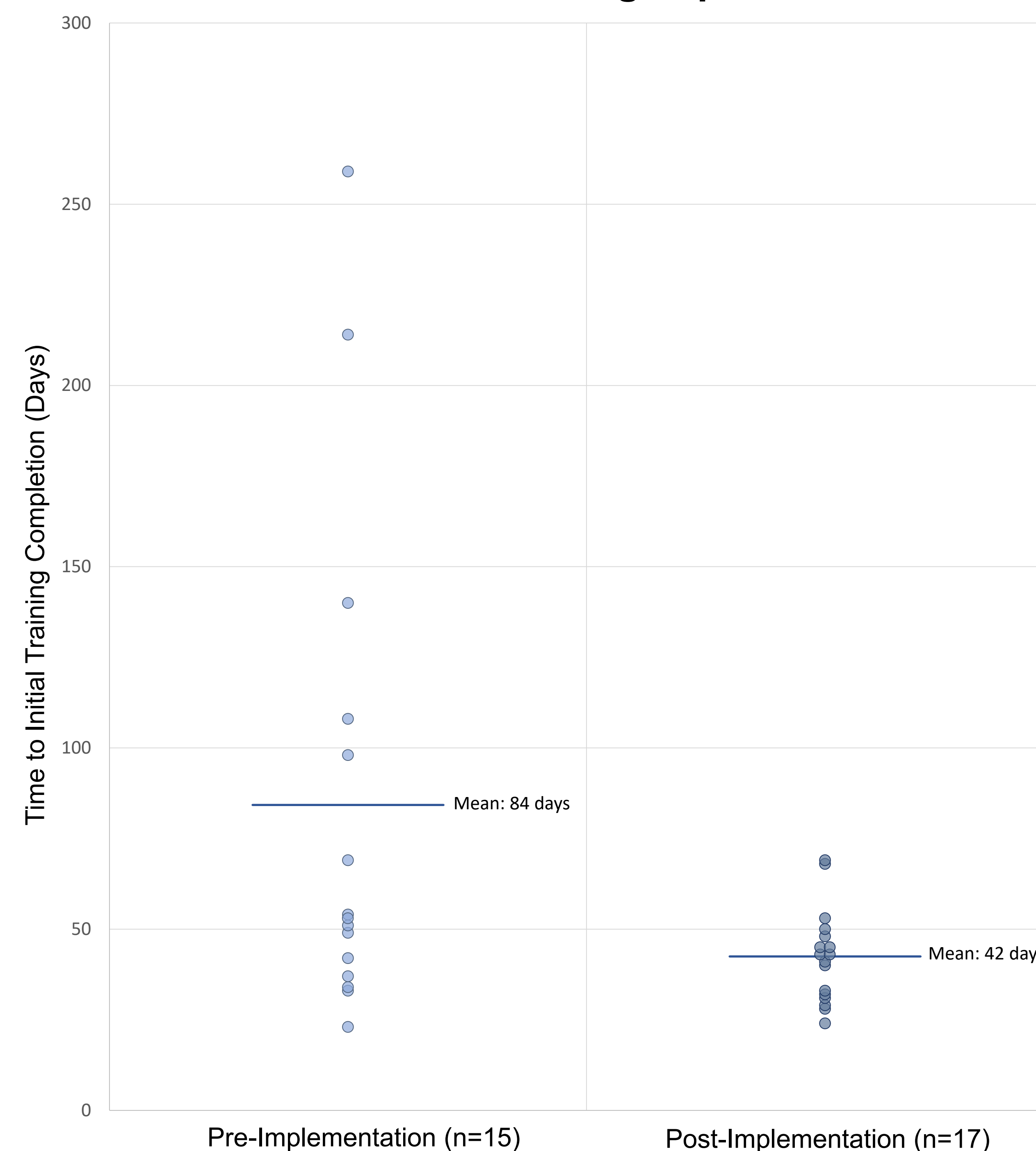
- (1) Reduce the time required to send, collect, file, and reconcile staff protocol-training records;
- (2) Shorten the overall timeline from start of protocol training collection through full completion; and
- (3) Decrease both the number of protocol-training-related monitoring findings and the time 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 initiation from the SIV (for initial)/IRB approval (for amendments) to SRC approval;
- (2) Requiring a single email sent to staff for protocol training;
- (3) Assigning 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.

Time to Initial Protocol Training Completion Before and After eLog Implementation



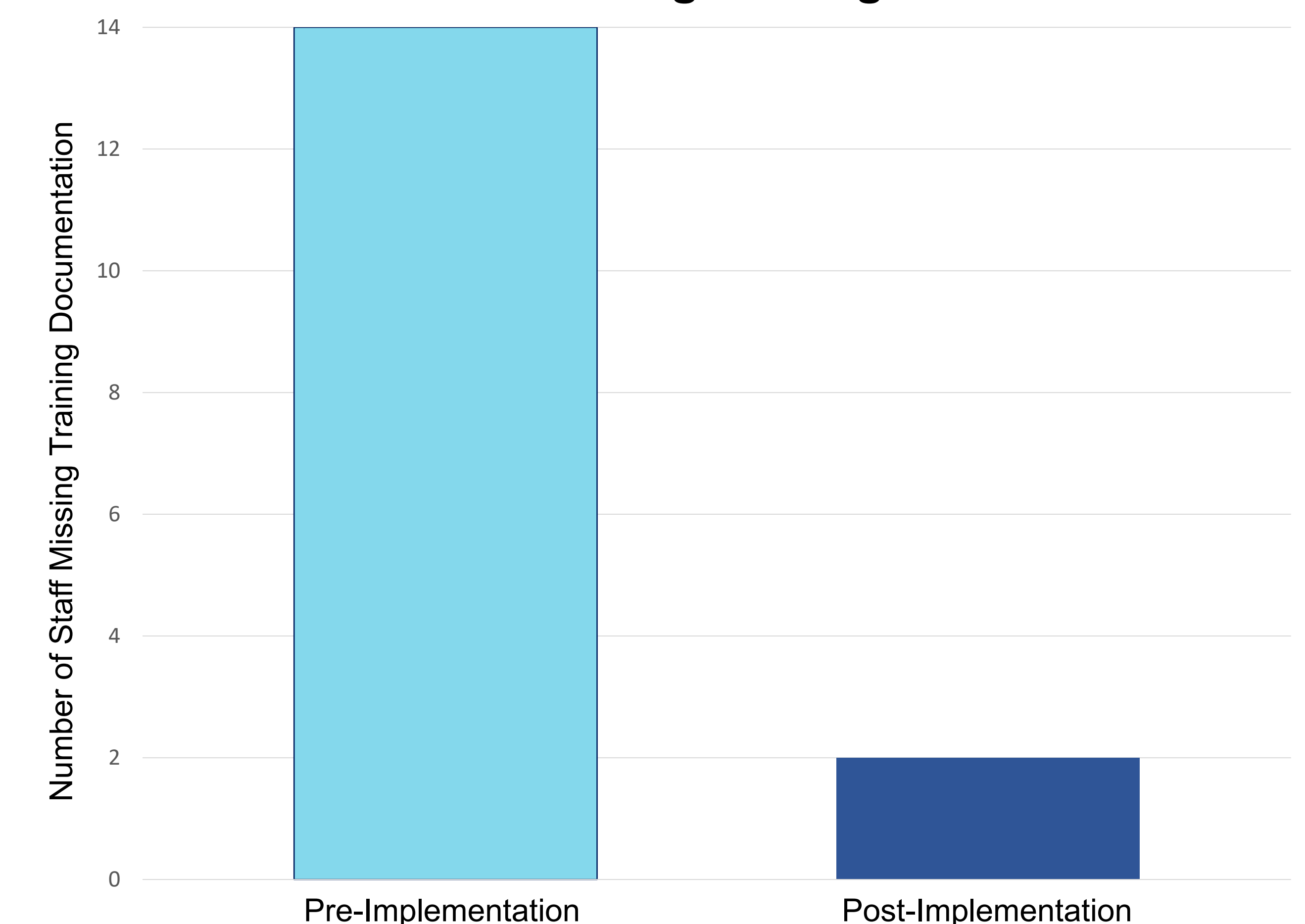
4. Outcomes

Training Timeline Improvement

The 17 studies activated immediately preceding and the 17 studies activated immediately after the implementation of the eTraining process were reviewed:

- (1) The 17 studies activated pre-implementation:
 - a. 8 activated with incomplete training documentation
 - b. 2 remained incomplete at the time of close out
 - c. Average time to completion for the other 15 studies: 84 days
- (2) The 17 studies activated post implementation:
 - a. Average time to completion: 42 days

Missing Protocol Amendment Training Monitoring Findings



Reduction in Monitoring Findings

8 investigator initiated trials (IITs) that had at least one amendment and one monitoring visit post-implementation were reviewed for the number of missing staff training attestation documentation.

- (1) Average missing staff attestations before the implementation per monitoring visit: 14
- (2) Average missing staff attestations after implementation per monitoring visit: 2
- (3) 1 IIT activated post implementation had 3 monitoring visits with 0 findings related to protocol training documentation.

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.