

Training the Masses – Electronic Protocol Training

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1. Background

Maintaining a complete Trial Master File can be challenging for any study team. When working at a Comprehensive Cancer Center with dozens of investigators across multiple satellite sites, collecting training documentation in real time can be especially difficult. At the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, monitoring and auditing reports notably include at least minor findings related to protocol training documentation.

2. Goals

- Utilize an electronic training platform to allow more efficient documentation of protocol training attestation
- Reduce instances of missed protocol training documentation
- Minimize the burden on research staff by eliminating the need to obtain physical signatures to capture training

3. Solutions and Methods

The Quality and Education Team partnered with the IT department to develop an application to assist in training documentation. The app is able to house protocol portals, and within each portal a designated study team. Clinical Research Specialists, who are responsible for study maintenance at the Indiana University Melvin and Bren Simon Comprehensive Cancer Center, can designate study team member roles and add or delete team members as a study progresses and team members change. Once defined, IRB approved documents can be uploaded and automatic e-mail notifications will be sent to the members listed within the defined protocol. The app is designed so that: all supporting documents must be opened before a staff member can attest; and any related versions can be linked. For instance, if a staff member logs in to attest to study start up training and a new amendment has since been approved, the staff will also be directed to the most recent documents.

4. Outcomes

Currently we have been piloting this app with a single disease-oriented team, refining the process as problems present themselves. When the app runs smoothly it makes obtaining protocol training significantly less time consuming. We've found that the primary challenge associated with the app is that documents do not show up for the reviewer however, IT has been able to resolve this issue when it occurs. Secondly, the app does not send recurring reminders to attest to training at this time, which in turn requires the CRS to send out training reminders multiple times. Lastly, we do not have enough information to understand every aspect of the protocol training app and how to utilize it most effectively at the present time.

5. Lessons Learned

Category: Training and Quality Assurance – Work In Progress

Moving forward, we will adjust the app to send out automatic reminders weekly for two weeks followed by daily until the trainee has reviewed the relevant protocol documents. Also, we plan to add the function to allow monitors to review training attestation electronically, eliminating the need to house training in regulatory binders for review. Finally, we plan to expand the pilot to multiple disease oriented teams in order to gather more feedback and address issues with the app before expanding to the Clinical Trials Office in its entirety.