Category: Training and Quality Assurance – Work In Progress

Use of RedCAP Database to Identify Trends in Non-compliance

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1. Background

Given the growing number of investigator initiated trials, expansion of participating sites and increasing trial complexity (cellular therapy, transplant, CART, vaccine, stem cell, gene therapy) there is no reliable method to capture and compile the aggregate findings from internal auditing and monitoring visits. Monitoring findings from each report are presented to the individual study teams; however, they are not used to categorize trends across the entire investigator initiated trial portfolio. To improve audit readiness and data quality, it is crucial for the Clinical Trials Office Leadership to have a mechanism in place in order to track trends in non-compliance and to develop targeted reeducation sessions.

2. Goals

1. Create a user-friendly tool to identify the trends in non-compliance (GCP gaps, trial conduct, protocol and policy deviations *etc*.) across all investigator initiated trials.
2. Capture all findings from monitoring reports and classify according NCI categories (regulatory, informed consent, eligibility, general data quality, treatment, disease outcome, adverse events and patient case review).
3. Perform severity assessment for these findings per NCI guidelines (critical, major, and lesser).

3. Solutions and Methods

This project utilized REDCap which is a secure, web-based application for building and managing online surveys and databases. The authors composed a series of questions to create the data collection instrument in the form of REDCap survey. The survey function in REDCap was used to easily enter key information from monitoring reports, export these data instantly into excel, pdf, SAS, and SPSS (trend analysis), create reports, and present captured data.

Questions were designed to capture prominent findings in each of the NCI categories as defined above. Additional information including study PI, disease group, monitor name, site, and severity assessments was also collected. This survey link was distributed through REDCap to monitors via email. After every monitoring visit, each monitor entered their findings around the key categories by answering survey questions.

4. Outcomes

Monitors were directed to enter 6 months of data from previous monitoring reports (48 studies, 20 disease teams) and classify findings per NCI guidelines to gather baseline information. These data were used to identify areas improvement to develop targeted education materials. The baseline data also allowed the institution to highlight the successes and knowledge gaps amongst the individual disease teams creating opportunities for knowledge transfer and improvement in work instructions, SOPs and policies.

5. Lessons Learned

While this project is currently in the pilot phase, we have collected baseline information on compliance and current regulatory practices. The project identified the gap between the institutions deviation policy and the NCI deviation categories, resulting in a policy change to better align with the NCI guidelines. We anticipate that this project will create transparency among the disease teams to identify systemic issues across study teams. These observations will enable the institution to implement focused re-audits and appropriately develop educational programs to support the needs of the research community, for example, new staff onboarding, continuing professional development/knowledge transfer, create resources, and better communication of new regulations pertaining to research operations.