Category: Network Operations, Decentralized Trials, and Multi-site Research – Completed project

Adverse Event Collection and Reporting Improvement Project

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1. Background

Adverse event (AE) collection was completed on a paper-based system to capture all required elements on events experienced by patients enrolled in a clinical trial. This resulted in extended time from AE identification to EDC reporting. Several deficiencies were identified with this system, including:

1. Variation in AE collection templates across teams (i.e., headers, attributions, signature sections)
2. Lack of consensus on AE collection method (i.e., paper logs, Investigator emails, Excel)
3. Maintenance of multiple source documents requiring duplicate entry between systems leading to increased number of queries and slowing reporting efforts impacting Sponsor's ability to conduct ongoing analysis
4. Lack of a centralized process that would support staff coverage and continuity in the event of extended absences or transitions

2. Goals

Our goals were to establish a single, centralized system and implement a process that supports real-time AE collection and reporting while reducing duplication of entry and supporting Direct Data Connections (DDC) in the future.

3. Solutions and Methods

A pilot was conducted consisting of several collection methods (i.e., paper, customized smart phrase, Epic based module). Feedback from all stakeholders was analyzed to support the selection of a single system moving forward: Epic AE Activity Log module. Over the next four months, a working group was established with representation from all teams, including Investigator leadership. The group was responsible for developing policy, working instructions and mapping department workflows to support implementation. Research IT systems leadership was engaged to provide support in automating and using existing technology to optimize efficiency. The team communicated their progress with formal presentations at department meetings. Additional focused feedback was solicited from protocol Sponsor partners.

4. Outcomes

Upon finalization of supporting documents and tools, the implementation of the Epic AE Activity Log module, across the therapeutic trial portfolio, at two campuses and eight network locations, was launched. Resources, such as identified team super-users, were available to assist the research staff and to meet with Investigators to reinforce the use of this new tool, ensure adherence and provide valuable feedback. A focus group convened at three months post launch to assess utilization, compliance, and address user responses from these first 12 weeks. Feedback from data coordinators supported that the utilization resulted in increased speed of AE entry into the EDC as result of a single, centralized platform. In addition, the group communicated system reports that reflect adoption and utilization metrics. These reports, for example, provide the ability to analyze aging AE attributions and investigator sign-off, which in turn helps to identify where targeted follow-up or more one-on-one training is needed.

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5. Lessons Learned and Future Directions

Key Lessons Learned:

1. Consistent and thorough communication between all individuals involved in AE collection cycle
2. Flexible approach, when appropriate, regarding AE entry and responsibility workflow
3. Sensitivity to clinic operations, research staff space allocation, and equipment functionality
4. Balance time and effort between retired processes and the transition to newly implemented system

Future Directions:

1. Incorporate additional reporting tools of key quality metrics
2. Reinforce user engagement and solicit continued feedback
3. Pilot DDC opportunities
4. Expand use of AE module to all COH enterprise locations

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