Category: Clinical Trial Operations – Work in Progress

Adapting Adverse Event Log Creation During COVID-19: Development of the Winship eAE Log Application

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1. Background

Oncology clinical trial protocols are highly regimented and complex, outcomes are centered on timing, and patient safety is paramount. One of the challenging aspects is the tracking and assessment of an adverse event (AE) that occurs during a clinical trial. While AE tracking is typically performed in near real time with paper logs, site workflows have historically been inefficient, time consuming, and labor intensive, requiring multiple in-person interactions. With the onset of the COVID-19 pandemic, every aspect of cancer care and clinical operations was strained, and inefficiencies in analog AE recording processes were extrinsically magnified, as the transfer of paper documents involving in-person interactions was deemed unsafe. To address these challenges, a new electronic AE tracking tool, the eAE Log application, was created.

2. Goals

The highest priorities in design of the eAE Log were ICH GCP requirements, maintaining regulatory compliance regarding access and storage of patient data aligning with FDA Title 21 CFR part 11 guidelines, and usability with automated workflows and escalation rules. Comprehensive audit trails were thus a requirement in providing an ongoing log of activity and changes to AE assessments.

3. Solutions and Methods

We relied upon our clinical trial management system (CTMS) as the single source of truth regarding clinical trial management and subject enrollment to circumvent entry of duplicate data. The eAE Log supplements data pulled in real time from the CTMS with the typical assessments required for adverse events (e.g., attribution to drug/device/procedure, seriousness of AE), and allows staff to remotely monitor AEs across all studies to which they are assigned in a single easy to use interface.

4. Outcomes

Data from this initiative shows steadily increasing staff adoption since implementation with promising timelines demonstrating faster turnaround from AE creation to assessment and signature. We will report the challenges that were encountered in the implementation of this technology, as well as lessons learned from the process.

5. Lessons Learned

The eAE log has provided an easy to use and dependable electronic method of AE reporting at a time when study staff and investigators were restricted from in-person interactions during the COVID-19 pandemic. The tool also supports remote monitoring and auditing. To further promote utility to users,

future refinements for the software include incorporation of serious adverse event and deviation reporting, as well as possible implementation of new logs, including medical history and concomitant medications and procedures.