Category: Clinical Trials Operations - Completed Project

Adverse Event Reporting System

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1. Background

Historically at our institution, adverse events were extracted from free text physician notes. As expected, all of the required elements were not documented and Common Terminology Criteria for

Adverse Events (CTCAE) terminology was rarely used. The result of this method led to many queries which imposed a mountain of work upon our research staff who were tasked with determining the grade, attribution, start date, action(s) taken, and seriousness of the event.

With the implementation of electronic medical records we embarked upon the goal of establishing a more efficient and accurate way of capturing adverse events (AE). Our first attempts were successful in capturing some but not all of the required adverse event information. We still were not using CTCAE terminology consistently and properly.

Collectively our research staff partnered with our IT department and clinical staff representatives to develop an electronic application within our clinical trials management system (CTMS) to capture the required elements.

2. Goals

- Provide a user-friendly electronic system to capture all required data elements
- Decrease the workload associated with monitor/sponsor inquiries/queries
- Increase compliance of adverse event reporting

3. Solutions and Methods

Arkansas Adverse Event Reporting System (AR-AERS) is an application developed to allow clinical research staff to systematically collect AE information in order to increase compliance and inform research findings. AR-AERS allows the entry and review of new and ongoing AEs, as well as their resolution. AR-AERS uses the CTCAE version as determined by the study protocol.

There are many benefits of using AR-AERS:

· Improves the timeliness and accuracy of reporting

· Minimizes duplicate documentation and under-reporting of AEs

· Promotes subject safety

· Reduces the number of queries

· Provides a systematic, comprehensive way of capturing AE documentation and tracking ongoing AEs

Integration with our CTMS and the UAMS electronic medical records system allows AR-AERS to automatically enter and grade abnormal labs per the CTCAE criteria for active research subjects.

The research nurse in collaboration with the patient and the physician documents all adverse events.

In regards to CTCAE, AR-AERS:

· Allows for accommodation of multiple CTCAE versions

· Systematically separates CTCAE into symptoms and diagnoses

· Groups items for ease of finding the correct distinction to use when documenting AEs, and

· Alphabetizes lists for easy location

4. Outcomes

- Decreased number of AE-related queries
- Decreased time/effort in answering queries
- Increased understanding of adverse event reporting requirements
- Systematically captured all required data elements that can be easily reported to sponsors

5. Lessons Learned

- We underwent several rounds of modifications to get the workflow correct.
- Clinical staff representation was vital to ensure accurate and efficient workflows.
- Immediate physician workflow was complex and time consuming, but after much effort the process has been simplified extensively resulting in improved physician engagement.