Adverse Event Reporting System

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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). 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.

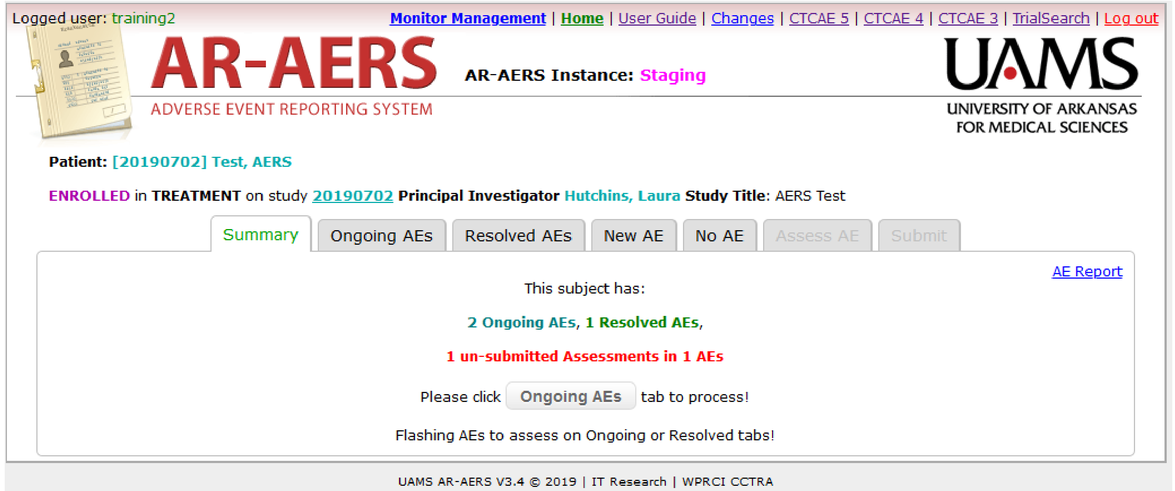
Metrics & Goals to be Achieved

Goal 1: Provide a user-friendly electronic system to capture all required data elements.
Goal 2: Decrease the workload associated with monitor/sponsor inquiries/queries
Goal 3: increase compliance of adverse event reporting

Methods

Arkansas Adverse Event Reporting System (AR-AERS) is an application developed to allow clinical research staff to systematically collect AE information. 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.

The benefits of using AR-AERs has included improving timeliness and accuracy, minimizing duplicate documentation and under-reporting, promotes subject safety, reduces queries, and provides a systematic way of capturing AE documentation and tracking ongoing AEs.

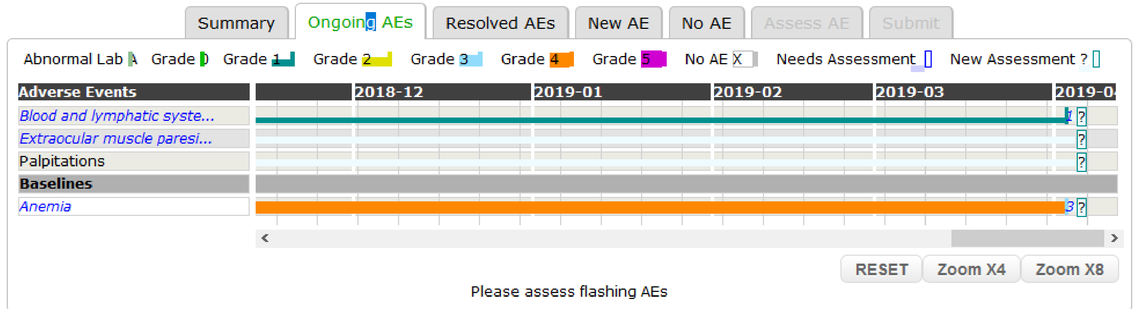


Outcomes

Implementation of this program has allowed us to decrease the number of AE-related queries, decrease time and effort in query resolution, increase understanding of AE reporting requirements, and systematically capture all required data elements that can be easily reported to sponsors. Integration with our clinical trial management suite and with EPIC has occurred. Lastly, we have recently implemented an automated lab grading feature that allows clinical lab results to be pulled in automatically for assessment when needed.

Lessons Learned & Future Directions

Several rounds of modifications happened before we were able to get the workflow correct. Clinical staff representation was vital to ensure accurate and efficient workflows existed. Immediate physician workflow was complex and time consuming but after much effort the process has been simplified extensively resulting in improved physician engagement.



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