

Adverse Events Logs: Transformation From Paper Forms to an Electronic Health Record Integrated Platform

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1. Background

Adverse events (AE) reporting is an integral part of clinical trials. Conventional paper forms are commonly used for AE documentation, but the process is labor-intensive, time-consuming, and prone to error, as the medical information needs to be manually extracted from the electronic health records (EHR) and again transferred into the study-specific databases. Here we report our transition to an EHR-based AE reporting platform.

2. Goals

With the emergence of COVID-19 pandemic, we decided to transition to an electronic EHR-based AE log to reduce touchpoints, allow remote access for research teams and study monitors, and improve documentation accuracy and workflow efficiency.

3. Solutions and Methods

Initially, developing EHR-based templated notes, which resembled the conventional tables in paper logs, provided a quick but temporary solution. Preparation of these templated notes was time-consuming, and identifying new or changed AEs in the tables was difficult. In the second phase, we implemented the Epic foundation AE activity within the research module of our EHR. However, as we were one of the early adopters of this platform, we had to devise creative ways to modify the customizable parts of the original build to achieve our desired functions. In the first released version, discrete attributions (using multiple-choice buttons) were only available for investigational drugs. Therefore, the initial workflow heavily depended on using pick lists (SmartLists™) within the comments section to document required datapoints including attributions to anything other than the investigational drugs. This laborious workflow required reactivation of every pick list by the investigator to select the appropriate attribution.

The next Epic upgrade of the AE activity allowed discrete attributions for procedures. Using this opportunity, we created a customized list of categories (e.g., “disease under study,” “hormonal therapy,” “radiotherapy,” etc.) which significantly enhanced the usability of this platform. In addition, we created EHR-based reports to monitor the latest status of the AE logs (reviewed by the investigator, pending review, etc.). We designed a survey to assess user satisfaction and identify areas for improvement. We asked our team members about their preferred AE reporting method regarding 16 activities, including finding the appropriate AE term and grade, time spent creating and reviewing AE logs, identifying AE changes over time, accessing patient’s chart for clinical review, and risk of error.

4. Outcomes

This presentation will share our experience and details of the optimization and implementation process. We received input from 106 research team members (Investigator=26, Research staff=53, Study monitor=27). Survey participants preferred the EHR-integrated AE activity in all 16 surveyed categories and reported higher satisfaction rates using this method when compared to paper forms and templated notes in EHR.

5. Lessons Learned and Future Direction

EHR-integrated AE logs can improve accuracy and efficiency, eliminate paper access and storage issues, provide remote access to study teams and monitors, and facilitate reporting and monitoring of AEs during trials. Although some customization and functionality enhancements were necessary, our investigators and research staff preferred the EHR-integrated AE logs over paper forms and other AE reporting methods.

Figure

