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

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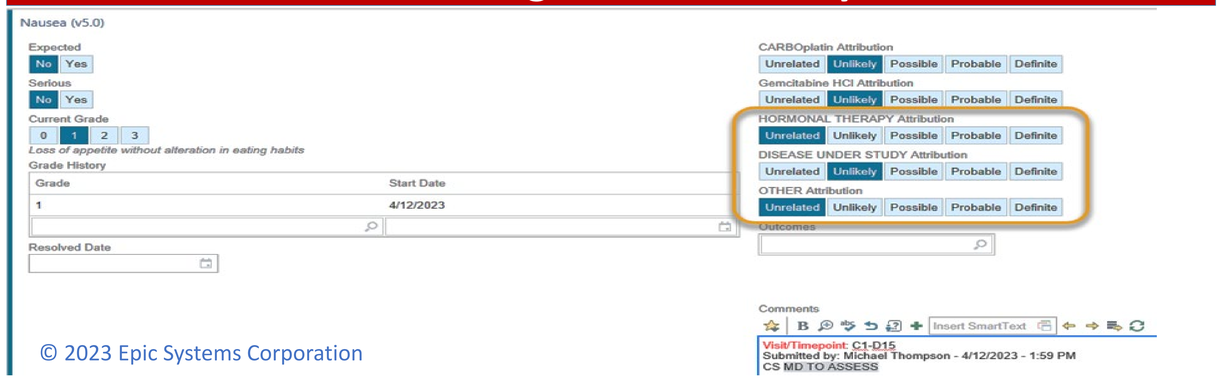
Background

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.

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.

EHR-Integrated AE Activity



Solutions

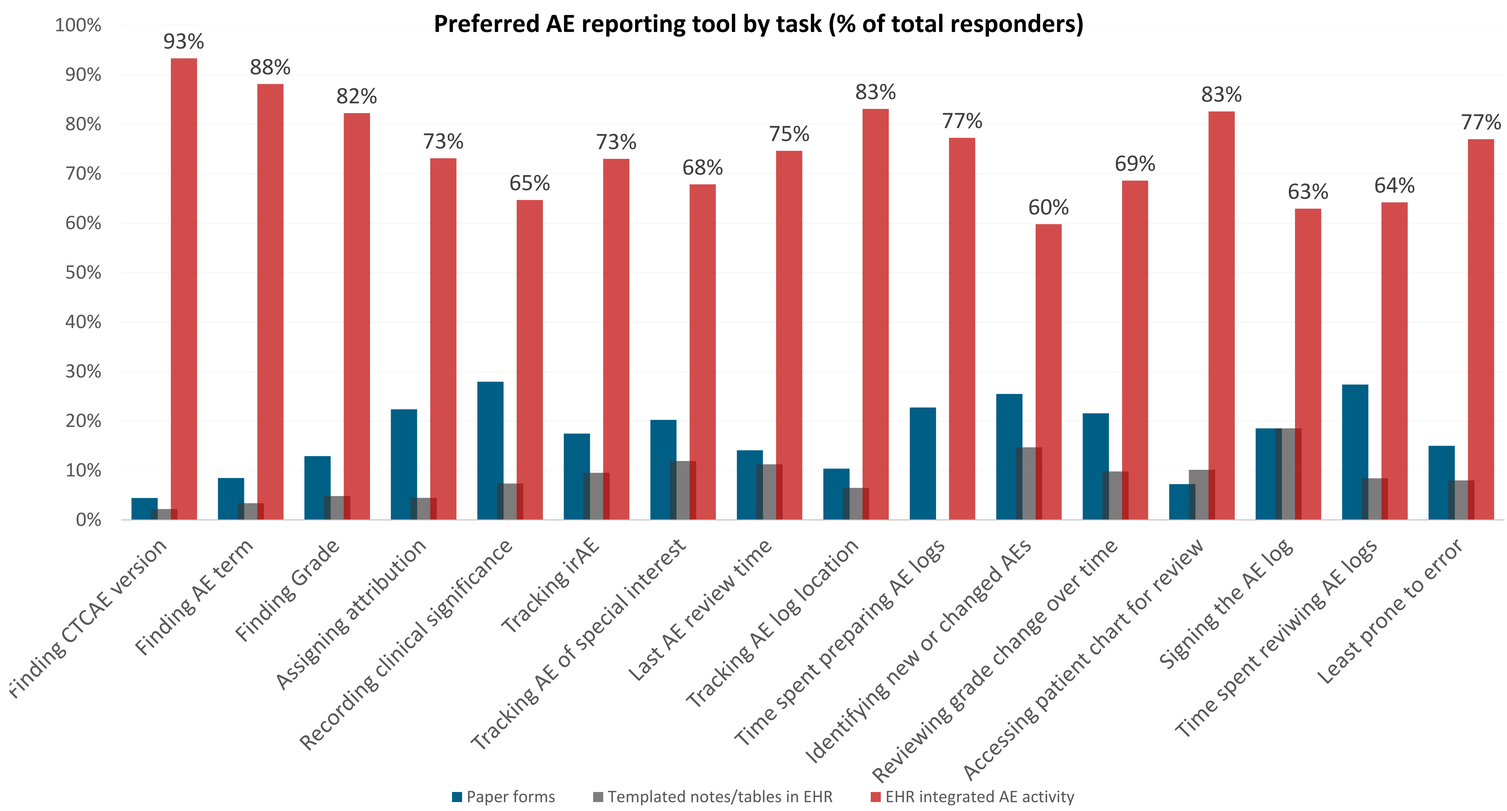
V.1 Research Notes in EHR	V.2 Foundational EHR-integrated AE Activity	V.3 Optimized EHR-integrated AE activity
➢ Templated notes mirrored format of paper logs ➢ Allowed for rapid implementation and required minimal training ➢ AE report preparation was still manual and time consuming ➢ Tracking changes was very difficult	➢ Study-level set up of term set version and study medications for attributions minimized errors ➢ Multiple required data fields had to documented in the comments section (heavily text dependent and laborious) ➢ Required extensive training via multiple modalities ➢ Users struggled with identifying areas that required editing prior to finalizing the AE report review	➢ Repurposed discrete data fields to capture the data items of interest (i.e. IRAE, AESI) ➢ Created placeholder procedure records to enable easier attribution to more general categories (i.e. hormonal therapy, surgery, radiotherapy) ➢ Created customized reports to track the latest status of the report and those pending review by the investigator

Survey Methods

- Cross-sectional survey design
- Survey items queried users' preferred AE log tool when preforming 16 AE report related tasks.

Outcomes

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 optimization and implementation process.



Lessons Learned & Future Directions

EHR-integrated AE logs can improve accuracy and efficiency, eliminate paper record 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.

EHR-integrated platforms provide the potential for automated and system identified AE instances and ultimately direct transfer of the discrete data into the sponsors' databases.

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