Category: Emerging Technology – Completed Project

Improving Adverse Event Reporting With EHR-To-EDC: A Pilot Study

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1. Background

Adverse event (AE) reporting is critical to ensuring patient safety in clinical trials yet is predominantly manually entered into electronic data capture systems (EDCs) through a time-consuming, error-prone process. Scalable electronic health record (EHR) EHR-To-EDC technologies, such as IgniteData's Archer solution, reduce the need for manual entry, minimize errors, and increase the data throughput of research teams. Leveraging EHR-To-EDC is therefore critical for sites to keep up with study conduct in an ever-growing resource-constrained environment. Capturing research data, such as AEs, in a structured, consistent manner in the EHR, broadens the scope of data eligible for EHR-To-EDC, and is essential for promoting accurate and timely entry into EDCs.

2. Goals

Memorial Sloan Kettering Cancer Center, an early adopter of EHR-To-EDC, has been scaling its IgniteData portfolio for more efficient entry of laboratory results and vital signs since Q4 2024. AEs were identified as the most valuable dataset to target next. This pilot was conducted to:

- Determine technical feasibility of transferring AEs in a real-world setting
- Evaluate efficiency gains compared to manual entry, and
- Capture lessons learned to inform a broader implementation

3. Solutions and Methods

We reviewed the portfolio of trials utilizing EHR-To-EDC (total, 28; investigator-initiated trials [(IITs]), 21; externally sponsored studies, seven) and selected a phase two IIT for the pilot. The selection process considered electronic case report form (eCRF) compatibility with EHR-To-EDC, data availability, and prior data manager (DM) experience with the electronic workflow. A mapping exercise and end-to-end testing using synthetic data was performed prior to the pilot to validate technical configuration among EPIC's AE Module, HL7-FHIR, and the eCRF. We defined time-based and volume-based exit criteria for the pilot: three months of use or a minimum of 40 AEs entered electronically, whichever came first.

4. Outcomes

The volume threshold of 40 AEs was reached prior to the three-month period. Of the fields captured in the EDC, 82 percent (9/11) were eligible for entry with EHR-To-EDC and with Archer's built-in change detection, updates to those fields could easily be identified and pushed downstream. In a survey using the five-point Likert Scale, the DM reported that entering AEs with EHR-To-EDC was easy to use (5/5) and preferred it over manual data entry (4/5). Statements assessing perceived time and efficiency savings received neutral ratings (3/5) with the free-text response clarifying that an additional step is

required to exclude baseline AEs. A preliminary review revealed a decrease in time to entry by 20 percent from 16.6 days to 13.3 days.

5. Lessons Learned and Future Directions

This pilot proved it is possible to transfer AEs captured in EPIC's AE Module to the EDC via a FHIR-compliant EHR-To-EDC solution. However, it also surfaced several limitations with EPIC's Module including a lack of discrete fields for indicating baseline, insufficient capture of details for "Other, specify" AEs and actions taken, and lack of required field constraints on seriousness and outcome. Requests were submitted to EPIC to address these limitations. As part of next steps, we will add AEs by default to all new IITs using Archer, work with external sponsors interested in piloting AEs, and begin discovery into the next dataset for EHR-To-EDC.