Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Creation and Implementation of Automated Report Sections for Streamlined IND Annual Reports

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1. Background

The Investigator Initiated Trials Regulatory Team is responsible for writing and submitting the Food and Drug Administration (FDA) Investigational New Drug (IND) Annual reports for each IND-held study. All Adverse Events (AE) data for clinical trial participants at the University of Kansas Cancer Center are housed in our Clinical Trials Management System (CTMS). The simplification of these raw data for the IND report was tedious and time-consuming, attributable to the need to manually go through all AEs experienced since study activation.

2. Goals

To alleviate manually preparing the data for the annual reports, the goal was to automate the creation of AE reports for the allotted sections.

3. Solutions and Methods

To automate report generation, we used Microsoft Azure Data Studio to create SQL queries that transformed, filtered, and aggregated raw data from our CTMS into a report. We partitioned the data by patient study ID and AE, then ordered it by Grade (descending) and AE Start Date (descending). This ensured the latest and highest-grade AE for each participant was selected. The query filtered out baseline events not included in the report. We used SQL JOIN statements to retrieve AE categories from a reference table and aggregated the data to count events for each combination of AE, AE Category, Event Grade, Expectedness, and Relatedness. For reports with multiple drugs, we created a separate query to count events for each drug individually. Finally, we grouped the data into columns and provided event counts per participant in a spreadsheet. These queries are now stored in the SQL database for future reference and can be integrated into the FDA Annual report template.

4. Outcomes

By implementing automated AE reports for each study for pulling when needed, the time needed to complete annual reports have significantly decreased. During the exploration of creating these automated reports, the team noticed inconsistencies in drug attribution, spelling, input order, and incomplete data, which lead to the clean-up of these data by the input teams. Therefore, this observation and project also contributed to more accurate reports. With the completion of these automated reports and clean-up, the IIT regulatory department has a higher equitable bandwidth.

5. Learned and Future Directions

During the report development, challenges in data cleansing and organization required the creation of specialized queries to clean and format the data, ensuring accurate results when integrated into AE queries. This project underscored the importance of maintaining data consistency and accurate attribution in AE reporting. Inconsistent attributions will continue to be corrected so records match.

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