THE UNIVERSITY OF KANSAS CANCER CENTER

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

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Background

- The Investigator Initiated Trials (IIT) Regulatory Team is responsible for writing and submitting the FDA IND Annual reports for each IND-held study at The University of Kansas Cancer Center.
- 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.

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.

Solutions and Methods

To automate report generation, we used Microsoft Azure Data Studio to create SQL queries that transformed, filtered, and aggregated raw data (*Image 1*) 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.

PAT_STUD	TX_NAME	GRADE	ADVERSE_	START_DT	END_DT	RELATION	AE_ID	ACTION	AE_DISCO	AE_LOGGE	AE_RECOV	OUTCOME	DRUG1	ATTRIBUTI	ACTION_D	DRUG2	ATTRIBUTI	EXPECTEDNESS
147815-10	Alpelisib:	2	Cataract	########	9/25/2024	Attributior	61425	Medical/Surgical Int		########	Recoverec	Left catara	Alpelisib	Not Relate	None	Sacituzum	Not Relate	Expected
147815-10	Alpelisib:	1	Weight los	6/2/2022		Attributior	62372	None		########	Ongoing at	end of stu	Alpelisib	Possibly R	None	Sacituzum	Possibly R	Expected
147815-10	Alpelisib:	2	Back pain	1/2/2025		Attributior	63945	Counteractive Medic		########	Ongoing a	new bone	Alpelisib	Not Relate	None	Sacituzum	Not Relate	Expected
147815-10	Alpelisib:	2	Mucositis	4/25/2022	5/4/2022	Attributior	46255	Counteractive Medic		########	Recovered/	resolved	Alpelisib	Possibly R	None	sacituzum	Possibly R	Expected
147815-10	Alpelisib:	2	Diarrhea	4/23/2022	4/27/2022	Attributior	46256	Treatment Delay / Hc		########	Other	Grade Cha	Alpelisib	Possibly R	Treatment	sacituzum	Possibly R	Expected
147815-10	Alpelisib:	1	Diarrhea	4/28/2022	5/4/2022	Attributior	46257	Counteractive Medic		########	Recovered/	resolved	Alpelisib	Possibly R	None	sacituzum	Possibly R	Expected
147815-10	Alpelisib:	1	Neutrophi	4/28/2022	5/4/2022	Attributior	46258	Counteractive Medic		########	Recovered/	resolved	Alpelisib	Unlikely	None	sacituzum	Probably I	Expected
147815-10	Alpelisib:	2	Fatigue	4/11/2022	4/14/2022	Attributior	46059	Counteractive Medic		########	Other	Grade Cha	Alpelisib	Unlikely	None	sacituzum	Possibly R	Expected
147815-10	Alpelisib:	1	Headache	4/11/2022	5/4/2022	Attributior	46060	Counteractive Medic		########	Recovered/	resolved	Alpelisib	Unlikely	None	sacituzum	Unlikely	Expected
147815-10	Alpelisib:	1	Nausea	4/11/2022	5/4/2022	Attributior	46061	None		########	Recovered/	resolved	Alpelisib	Possibly R	None	sacituzum	Possibly R	Expected
147815-10	Alpelisib:	1	Constipati	4/11/2022	5/4/2022	Attributior	46062	None		########	Recovered/	resolved	Alpelisib	Unlikely	None	sacituzum	Unlikely	Expected
147815-10	Alpelisib:	1	Confusior	7/14/2022	7/21/2022	Attributior	47298	None		########	Recovered/	resolved	Alpelisib	Not Relate	None	sacituzum	Not Relate	Unexpected
147815-10	Alpelisib:	1	Cough	7/4/2022	7/21/2022	Attributior	47299	None		########	Recovered/	resolved	Alpelisib	Not Relate	None	sacituzum	Not Relate	Unexpected

Image 1. Example of raw AE report pulled from CTMS before project implementation

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 (*Diagram 1*).

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 (*Image 2*). These queries are now stored in the SQL database for future reference and can be integrated into the FDA Annual report template.

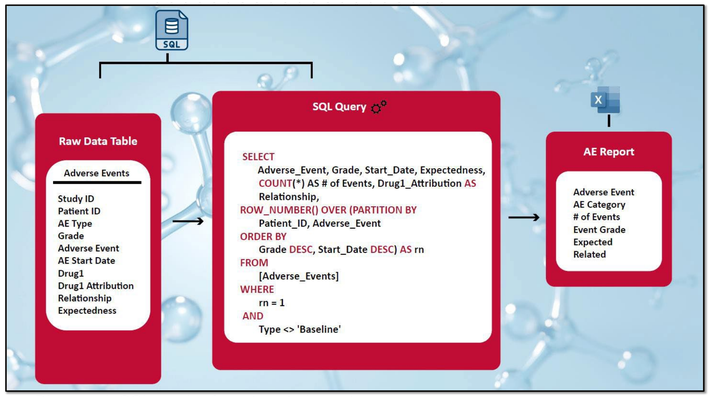

Diagram 1. SQL queries for automated reports

Category	Adverse Event	Number of Patier	Event Grade	Alpelisib Relatedness	Sacituzumab Govitecan Relatedn	Expectedness
Blood and lymphatic system disorders	Anemia	2	1	Possibly Related	Possibly Related	Expected
	Anemia	1	1	Probably Related	Probably Related	Expected
	Anemia	1	2	Not Related	Possibly Related	Expected
	Anemia	1	2	Possibly Related	Possibly Related	Expected
	Anemia	1	2	Probably Related	Probably Related	Expected
	Anemia	1	2	Unlikely	Definitely Related	Expected
	Anemia	1	2	Not Related	Not Related	Unexpected
	Eosinophilia	1	1	Possibly Related	Possibly Related	Expected
Eye disorders	Blurred vision	1	1	Possibly Related	Possibly Related	Expected
	Cataract	1	2	Not Related	Not Related	Expected
Gastrointestinal disorders	Abdominal pain	1	1	Not Related	Not Related	Unexpected
	Abdominal pain	1	2	Not Related	Not Related	Expected
	Ascites	1	3	Not Related	Not Related	Unexpected

Image 2. Example AE report pulled from CTMS after project implementation

Outcomes

- Time needed to complete annual reports have significantly decreased.
- Prior to this project, each study's AE section took 2-10 hours to complete, varying by number of patients, AEs, and years open. Following implementation of automated AE sections, each IND report took <2 hours in their entirety.
- During creation of these first 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.
- Project will contribute to more accurate reports in the future.
- IIT regulatory department has a higher equitable bandwidth.

Future Directions

- Data cleansing and organization efforts for more accurate and efficient reports