Using Centralized Review of Queries to Improve Data Integrity, a Canadian Clinical Trials Perspective

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1. Background

The success of a clinical trial is dependent on the integrity of the data entered into an electronic data capture (EDC) system to draw meaningful and accurate conclusions on the intervention. Data integrity is achieved through the generation and resolution of queries. Queries refer to discrepancies in data entered, issued by the sponsor to the site. Over 150 clinical trials are conducted through the Clinical Trials Support Unit (CTSU) at Princess Margaret Cancer Centre (PM) annually. It was recognized that the volume of queries in these trials posed a significant time and cost burden to the CTSU. This led the CTSU to identify potential solutions to prevent common data queries.

2. Goals

The objective is to assess if centralized review of queries by a data coordination unit can result in improved data accuracy and reduce the number of queries by 25% over the next year. Our goal is to achieve this through implementation of standardized tools that will ultimately save time, cost, and resources.

3. Solutions and Methods

A retrospective analysis of thirteen studies from a large cooperative group was performed from October 2017 to October 2018, resulting in analysis of 25,989 total queries. Filters were applied to eliminate system generated (automatic) and cancelled queries, focusing on 6,527 manually generated queries from sponsor data managers. Common categories were coded with sub-categories to determine the prevalence of query types, further prioritizing subsets of data where meaningful changes could be implemented.

4. Outcomes and Future Directions

FIGURE 1. QUERY TYPE CATEGORIES (N=6527)
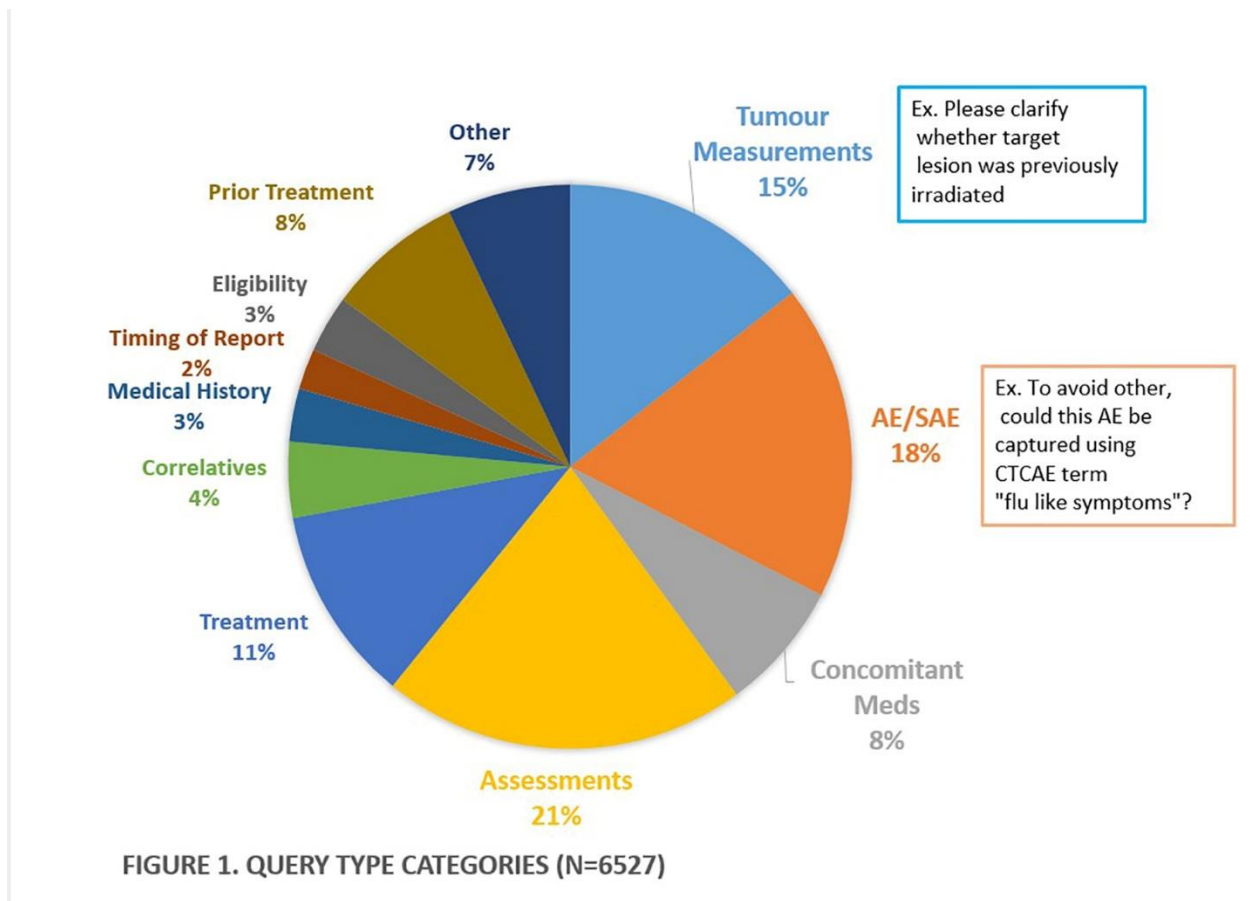
Four categories were identified as areas for immediate implementation of solutions: Assessments, AE/SAE, TMs, and Concomitant medications.

These measures are being implemented within the CTSU:

1. TM: Standardization of TM Worksheet with instructions to customize to protocol specific requirements (i.e. measurement criteria, radiation field, clarification notes)
2. AE/SAE: Creating a reference document of common "other" terms to avoid (i.e. Other: Drowsiness vs. CTCAE: Somnolence)
3. Concomitant Medications: Revising standard operating procedures (SOP) to allow coordinators to input generic vs. trade names for concomitant medications to minimize use of "Other: Specify."
4. Assessments: Implementing a study visit checklist with protocol specific requirements (i.e. labs) to avoid missed assessments and tests conducted out of window
5. General: Implementing a "Study Summary" tool, with process and data entry specifics for each trial, to ease study transfer process between coordinators.

By performing a centralized review of these common queries, the CTSU learned that queries that were once thought to be unique to specific trials were actually found across multiple studies. This project was staff directed and has generated enthusiasm and positive morale within the team. The self-directed education in this project has been a powerful tool leading to improved awareness of data integrity.

The next step is to further implement and evaluate the effectiveness of our tools based on an interim analysis at 6 months. Ongoing feedback within the trials team and sponsor will enable us to apply new solutions to other categories not addressed. Through collaboration with various stakeholders, we hope to expand these findings to research departments across PM and to different sponsors as well.