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

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**Background**

Queries refer to discrepancies in data entered for clinical trials, issued by sponsor to the site.

The volume of queries in these trials posed a significant time and cost burden, leading to the identification of potential solutions to prevent common data queries.

**Goals**

To determine if centralized review of queries can:
- Improve data accuracy
- Reduce the number of queries by 25% over the next year
- Save time, cost, and resources

**Methods**

- Query reports pulled from thirteen studies. \( n = 25,989 \)
- Total queries minus automated & cancelled queries. \( n = 6,527 \)
- Queries sorted into 11 major categories.

**Outcome**

- Assessments (n=1363)
- Adverse events (AE)/Serious adverse events (SAE) (n=1181)
- Tumor measurements (TM) (n=942)
- Treatment (n=734)
- Prior treatment (n=512)
- Concomitant medications (conmeds) (n=485)
- Correlatives (n=283)
- Eligibility (n=215)
- Medical history (n=199)
- Timing of report (n=152)
- Other (n=461)

**Discussion**

- **Measures being implemented within CTSU:**
  - TM worksheet – customize to protocol specific requirements (i.e. clarification notes)
  - AE/SAE reference document – list of common “other” terms to avoid
  - Standard operating procedures (SOP) revision for conmeds – to allow coordinators to input generic vs trade names to minimize use of “Other: Specify”
  - Study visit checklist – to avoid missed assessments and tests conducted out of window
  - “Study Summary” tool – data entry specifics for each trial to ease transfer process between coordinators

- **Lessons learned:**
  - Noted improvement in data accuracy through increased awareness
  - Queries preventable with detailed guidelines and clear communication

**Conclusion**

Our next steps will entail:
- Performing interim analysis to review if goals achieved
- Collaborating with all study sponsors and implementing tools across all studies
- Sharing our findings with other teams