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
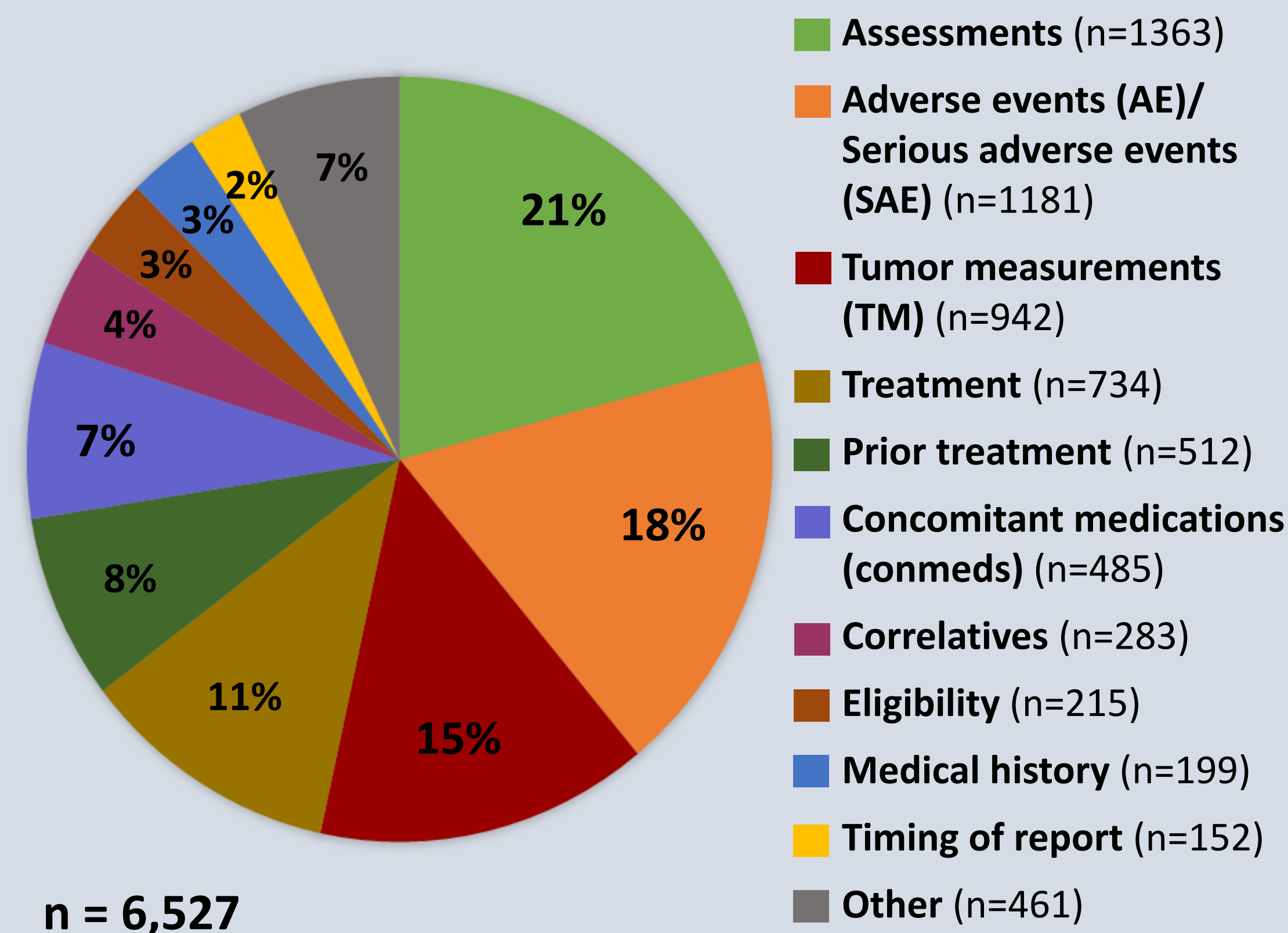
Query reports pulled from thirteen studies.
n = 25,989

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Total queries minus automated & cancelled queries.
n = 6,527

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Queries sorted into **11 major** categories.

Outcome

- **Assessments** (n=1363) — 21%
- **Adverse events (AE)/ Serious adverse events (SAE)** (n=1181) — 18%
- **Tumor measurements (TM)** (n=942) — 15%
- **Treatment** (n=734) — 11%
- **Prior treatment** (n=512) — 8%
- **Concomitant medications (conmeds)** (n=485) — 7%
- **Correlatives** (n=283) — 4%
- **Eligibility** (n=215) — 3%
- **Medical history** (n=199) — 3%
- **Timing of report** (n=152) — 2%
- **Other** (n=461) — 7%

n = 6,527

Category	Query example
Assessments	"Amylase, lipase, TSH are all required to be done at Day 1. Explain why they were missed."
AE/SAE	"To avoid the use of other, please consider using 'somnolence' for this AE term."
TM	"Please confirm whether any lymph nodes are > 15 mm in short axis."
Conmeds	"Please select as 'hydrocortisone valerate' as generic name."

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