

Implementation of a Standardized Query Form Using OnCore for Monitoring and Auditing Investigator Initiated Trials (IITs)

Heather Özkal, Erin Bethscott, Kelli Thorne
Huntsman Cancer Institute, University of Utah

BACKGROUND

The Huntsman Cancer Institute Research Compliance Office (RCO) had an outdated process for issuing queries during monitoring/audits via a Word document. This process had several challenges that were exacerbated when we moved to fully remote work, including:

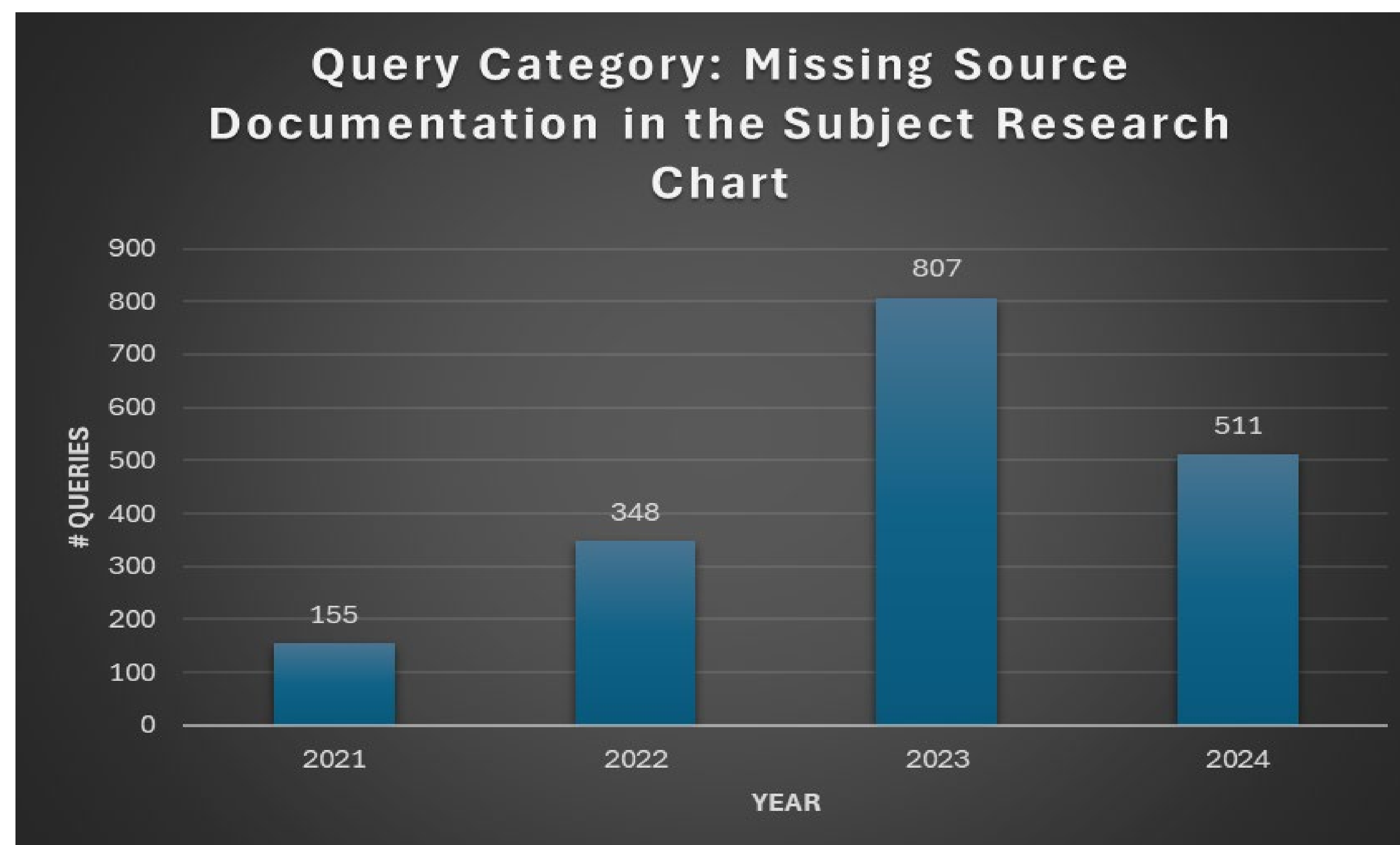
- Lack of Standardization
 - Report formats varied between individuals.
 - Queries were categorized subjectively.
- Lack of Data Trends
 - Trends and additional training needs were difficult to identify and track.
- Lack of Change Controls/Audit Trails
 - Queries were accidentally deleted.
 - Improper data storage led to lost time trying to recover deleted or mishandled data.

GOALS

To address these challenges, we needed to establish a standardized electronic query process using an electronic case report form (eCRF) in OnCore that would allow us to easily compile data, search for trends, and identify training needs.

SOLUTIONS AND METHODS

The RCO Data Management team created a query form (eCRF) which could be attached to any subject's OnCore record. During routine monitoring and auditing, the standalone eCRF is activated and queries are entered for each monitor visit. Since the form's creation in 2021, RCO leadership has been reviewing query trends on a quarterly basis. With nearly 10,000 unique queries, we've established a robust database of all queries issued in OnCore, allowing us to actively identify trends and training needs for both RCO staff and research teams.



CONTACT

- Heather Özkal, MBA, CCRP: Heather.Ozkal@hci.utah.edu
- Erin Bethscott, MPH, CCRC: Erin.Bethscott@hci.utah.edu
- Kelli Thorne, MPH, CCRP: kelli.thorne@hci.utah.edu

OUTCOMES

Overall, this standardized query form has improved communication and review outcomes between RCO and research teams. We have used query data to inform and improve the following processes:

- Source Documentation
 - 2022 and 2023 saw an increase in the number of source documentation queries issued (see table).
 - We trained research teams on source documentation best practices, which led to an improvement in research chart organization and reduced the number of source documentation queries.
- Query Resolution
 - Query responses were often inadequate to be considered resolved, resulting in prolonged query resolution.
 - We trained research staff with examples of how to resolve a query.
 - We also trained the monitor/audit team on how to write a query more clearly.
 - Both response accuracy and turnaround time were improved.

LESSONS LEARNED AND FUTURE DIRECTIONS

- Clarify some descriptions and reduce the number of free text "Other" fields that are available on the query form
- Use AI or other tools for faster data handling
- Build standardized reports to facilitate quarterly query data reviews