Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

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

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1. Background

The Huntsman Cancer Institute Research Compliance Office (RCO) had an outdated process for issuing queries during monitor/audit visits via a Word document.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

1. Lack of Standardization: The RCO Monitoring/Audit team had different report formats, often varying between individuals. Each person categorized their queries subjectively.
2. Lack of Data Trends: Outside of any major findings, it was difficult to track trends or identify areas where additional training might be needed.
3. Lack of Change Controls/Audit Trails: When using Word to issue queries the RCO didn't have a way to document change control. There were examples of queries accidentally being deleted or improper storage of data on shared electronic locations, resulting in lost time trying to recover deleted or mishandled data.

2. Goals

To address these challenges, we needed a standardized electronic query process.

The standalone electronic case report (eCRF) is attached to any subject enrolled in a study during routine monitor/audit visits. 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 have 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.

3. Solutions and Methods

We created a standardized eCRF in OnCore, allowing us to easily compile the data, search for trends, and identify training needs.

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4. Outcomes

We have used query data to inform and improve processes in the following ways:

1. Source Documentation: As work returned to hybrid/in-person, we saw an increase in the source documentation queries in 2022 and 2023. We hosted Compliance Corner training for research teams geared toward source documentation best practices. Additionally, we used our reviews to remind study teams about our institution's source documentation policy. With this informed training focus, we have seen an overall improvement in research chart organization, with a decrease in the number of source documentation queries.
2. Inadequate Query Resolution: The study team's responses were inadequate to consider a query resolved, resulting in prolonged query resolution. We conducted another Compliance Corner

presentation for research staff with examples of how to resolve a query. Additionally, we identified areas where the Monitor/Audit team needed training to write a query clearer, making the problem and recommended solution more understandable.

5. Lessons Learned and Future Directions

Overall, this standardized query form has improved communication and review outcomes between RCO and research teams. It is a helpful tool to proactively identify potential issues before they become a bigger issue for subject safety and/or data quality.

We are updating the query form to clarify descriptions and reduce the number of free text "Other" fields. We are adding a drop-down option to reference applicable standard operation procedures (SOPs) and regulations to support our findings. These changes aim to further improve communication with the study teams and provide targeted training within our monitoring team.

Future directions include finding better tools for faster data handling and building standardized automated reports generated from OnCore.

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