Category: Quality Assurance, Remote Monitoring, and Auditing – Completed Project

Automating Data Safety Monitoring Committee (DSMC) Progress Reports

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1. Background

For investigator-initiated trials (IITs) not otherwise monitored by a data and safety monitoring board/ committee, the University of Colorado Cancer Center (UCCC) DSMC requires study principal investigators to submit a DSM progress report on a regular basis. The DSMC provided a report template which outlined the required elements to be included in the report. Progress reports were manually updated for each review cycle utilizing data from the study database and clinical trials management system (CTMS). Completing the adverse event (AE) component of the progress report required transcription of data from the database into an Excel spreadsheet. This process was extremely time intensive and susceptible to transcription errors. A more efficient process for compiling the DSMC progress reports was needed.

2. Goals

- Decrease the time required to complete the DSM progress reports
- Decrease transcription errors by extracting the required data directly from the CTMS and study database
- Standardize AE listings to improve DSMC review

3. Solutions and Methods

Using the DSMC progress report template, a custom report was created to pull any available data (e.g., enrollments, screen failures, withdrawals, and protocol amendments) from the CTMS. This populated 63 percent of the required elements of the progress report. Remaining information needed for the progress report is manually entered. AE information was exported from the study database and attached to the report for submission to the DSMC. An Excel template was created that included pivot tables and frequently used data "slicers." This provided a standard format for AE listings and allowed DSMC reviewers to easily identify trends and isolate serious adverse events for review.

Following successful pilot by the IIT team, this new process was rolled out to all research teams required to submit DSM progress reports. Completion instructions were embedded in the custom report to aid teams in report completion.

4. Outcomes

The time required to prepare the progress reports significantly decreased (from approximately eight hours to two hours for an average study), allowing for research personnel to focus that time on other work.

DSMC reviewers noted the following impacts to their reviews:

- Standard report format (information located in same place on all reports) has been helpful when reviewing multiple trials
- Standardization to the answers in the reports has improved (e.g., standard language used for reasons behind the screen fails)

- The reviewers can easily review AE data as the information is arranged in a standardized way and they can manipulate the data as needed
    - Prior to the automated report, some AEs would be sent to the committee in PDF format making review difficult
- Increased confidence in the data
    - Since the report pulls bulk of data directly from OnCore, the reviewers can log into OnCore and see where the data is coming from if they have questions

5. Lessons Learned and Future Directions

Pulling the DSMC progress report data directly from the CTMS and study database does require that the clinical teams are consistent in how the data is entered. Therefore, continued guidance documents outlining these components will help ensure we export clear data. Future plans involve export of deviations from CTMS to be included in the DSM progress reports.