Category: Quality Assurance & Remote Monitoring and Auditing - Completed project

Use of the DSMC Console in OnCore to Facilitate Review of Investigator-Initiated Trials by the Institutional Data and Safety Monitoring Committee

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1. Background

The Wilmot Cancer Institute's (Wilmot) Data and Safety Monitoring Committee (DSMC) at the University of Rochester (UR) monitors all Wilmot-sponsored interventional Investigator-Initiated Trials (IITs). Studies are reviewed annually or semi-annually based on the risk level assigned by the Protocol Review and Monitoring Committee (PRMC).

Before 2022, preparation was cumbersome and time-consuming. The DSMC Report Form was based on a retired internal Institutional Review Board (IRB) reporting system that summarized study, subject, and safety information for Continuing Review. The categories on this form differed from the ones in the institution's Clinical Trials Management System (CTMS), which caused confusion and frequently resulted in errors. Supporting documents including adverse event (AE)/serious adverse event (SAE) data, detailed SAE reports, and deviation reports were submitted as attachments in Microsoft Word or Excel format.

For each study on the agenda, the DSMC Chair and Safety Coordinator (SC) reviewed the documents before the meeting and requested corrections to ensure complete and correct data were provided to the committee for review. This pre-meeting reconciliation took approximately five hours of the Chair's time and 15 hours of the SC's time each month; however, questions often remained, causing delays in approval.

2. Goals

1. Decrease time spent by study teams preparing and making corrections to DSMC reports
2. Decrease time spent by Chair and SC requesting corrections and tracking versions
3. Increase the quality of reports to minimize Conditional Approvals

3. Solutions and Methods

UR implemented OnCore as an enterprise-wide CTMS in September 2020 to track study and subject information and financials. Wilmot began requiring SAEs for all IITs to be reported through OnCore in April 2021; reports are easily amended and follow-up reports are linked to the initial report. In January 2022, Wilmot began requiring deviations for all cancer studies to be recorded in OnCore. The DSMC Console pulls all of this information into one easy-to-read report for each study, which the DSMC began using in place of the DSMC Report Form with supporting documents in January 2022. In January 2023, committee members were given direct access to view the information in OnCore.

4. Outcomes

1. Study and subject information are updated in real-time in OnCore and reviewed monthly for completeness and accuracy
    - No additional time is needed to prepare this data for the DSMC
2. Study and subject information no longer require expert pre-review, allowing administrative staff to prepare for meetings

    - SAE reports and deviations are updated/corrected in OnCore, ensuring the current version is always in the report.
3. Having complete and current information available for committee review minimizes the need for clarifications, allowing the committee to finalize its determination during the scheduled meeting

5. Lessons Learned and Future Directions:

Technology implemented for one purpose, such as tracking study and patient data, can be leveraged for other purposes, such as DSMC monitoring, to improve efficiency and quality of study oversight.

While some committee members prefer to review a document exported from the DSMC Console, others are comfortable navigating OnCore themselves. With practice, we anticipate increasing the use of the live DSMC Console in OnCore over an exported report.