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Automating Data and Safety Monitoring Committee Communication: Streamlining Operations and Enhancing Data-Driven Decision-Making

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1. Background

The previous manual process for managing the Data and Safety Monitoring Committee (DSMC) communications was time-consuming, requiring hours to sift through emails and manually enter data. This approach was inefficient, slowing communication and placing a heavy administrative burden on the team. The new automated system centralizes the process, allowing DSMC communications to be sent directly to study teams, with responses collected in one place. This streamlined approach enhances follow-up efficiency, reduces delays, and makes tracking pending and completed responses easier.

Previously, identifying trends across a Principal Investigator's (PI) research portfolio or Clinical Research Group (CRG) involved manually reviewing meeting minutes and study records, a process that could take days. With the new integrated dashboards, this data is generated in real-time, enabling quicker decision-making. This improvement reduces time spent on data extraction, increases efficiency, and provides insights for training and study conduct improvements.

2. Goals

- Streamline Committee operations by reducing administrative workload.
- Centralize all DSMC communications in a single system for easier management.
    - Enhance tracking of responses to ensure timely follow-ups.
    - Automate follow-up actions for greater efficiency and consistency.
- Integrate data across systems (DSMC REDCap and OnCore monitoring findings) to build a comprehensive dashboard for tracking common deficiencies across various study levels (PI portfolio, CRG, department-wide).

3. Solutions and Methods

The DSMC and Stanford Cancer Institute`s Clinical Translational Office (SCI-CTO) REDCap teams collaborated to develop a streamlined system for distributing DSMC letters and simplifying response submissions. The team built a dedicated DSMC REDCap system, carefully designing the user interface and identifying the necessary data to be sent and collected, along with the data required for the dashboards. To optimize workflow, the REDCap system was customized to automatically send emails to study teams, leveraging pre-built templates to minimize manual data entry.

After months of planning, including weekly meetings and comprehensive beta testing, the system went live in early 2024. Integration with Tableau dashboards is currently underway and is expected to be completed later this year, further enhancing the system's data analysis and reporting capabilities.

4. Outcomes

- Resource optimization: Automation freed up time for higher-priority tasks, improving overall productivity.
- Enhanced tracking: Real-time response tracking ensures timely follow-ups and prevents oversight.

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- Improved communication: Automated notifications and direct submission links streamline communication and reduce miscommunication.
- Scalability: The system efficiently handles increasing reviews and studies, supporting continuous DSMC optimization.
- Improved user experience: The system offers a simpler response submission process, reducing confusion and ensuring clearer communication regarding action items.

5. Learned and Future Directions

- Initial testing highlighted the importance of continuous feedback to refine the user experience and ensure seamless communication.
- Moving forward, we plan to develop a comprehensive dashboard that will allow study teams to easily track the status of responses across all their studies, providing enhanced clarity and accountability.
- Additionally, we aim to expand the system's functionality by adapting it for use by the Scientific Review Committee, which currently relies on manual processes. This expansion will streamline their workflow, reduce administrative burdens, and further improve operational efficiency.

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