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

Optimizing Data Quality and Trend Tracking in Oncology Clinical Trials: IIT Data Dashboard

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1. Background

Clinical Trials are the cornerstone of medical advancement, demanding meticulous data collection and management to ensure reliable and valid results. The integrity of these trials hinges upon the timely and accurate completion of case report forms (CRFs). Managing data entry activities across trials and sites presents significant challenges. With quality in mind, a centralized, real-time data management dashboard was developed that provides a consolidated view of data entry activities that are crucial for ensuring the timely and accurate collection of high-quality clinical trial data. Research pod leadership can monitor risk to data quality and enact mitigation strategies earlier in the process to avoid problems that would typically be detected too late.

2. Goals

The primary goals of the oncology clinical trial dashboard are to:

1. Operational Insights: Assess site performance using patient retention, data completeness, and query resolution time metrics. Evaluate data quality through query rates, missing data, and discrepancies. Analyze workload distribution for efficient resource allocation.
2. Real-time Risk Monitoring: Continuously track data quality metrics to quickly identify and resolve missing data, discrepancies, and high query rates, ensuring data accuracy and reliability.
3. Graphical Representations: Within research pods, share visual summaries of deviations, SAEs, and query details by site and subject to oversee protocol compliance and track study trends.

3. Solutions and Methods

The dashboard was developed in Tableau by connecting to the backend of the clinical trials management system (CTMS) system (OnCore) and the electronic data capture (EDC) system (Advarra EDC).

The dashboard is shared in several ways:

1. Trends, graphical representations, and significant findings are shared during research pod meetings with the study team, including Investigators.
2. The Tableau dashboard will be shared with clinical data managers, clinical managers, and clinical leads, and it can be disseminated to data entry staff.
3. The data will be refreshed weekly and sent to the above parties via automated email.
4. Specialized dashboards will be sent to other functional group leaders, i.e., deviation dashboards to regulatory staff.

4. Outcomes

The oncology clinical trial dashboard is expected to achieve several positive outcomes:

1. Increased Efficiency: streamlining data management processes to reduce manual tracking and quickly identify bottlenecks.
2. Real-time Insights: giving researchers immediate visibility into trial progress for timely and informed decision-making.

3. Improved Data Quality: ensuring high-quality data collection through real-time monitoring is crucial for robust trial results.
4. Better Resource Allocation: analyzing site performance and workload distribution to allocate resources more effectively and support sites needing additional assistance.

Qualitative feedback was obtained from research pod leaders and investigators and has been positively received.

5. Learned and Future Directions

The development and implementation of the oncology clinical trial dashboard have provided several valuable lessons:

1. Customization is Key: tailoring the dashboard to meet the specific needs of different user groups (e.g., clinical leads, data management associates, regulatory managers) has been crucial for its success.
2. Continuous Improvement: regular updates and enhancements based on user feedback are essential to maintaining the dashboard's effectiveness.
3. Training and Support: adequate user training and support is vital.

Future directions for the dashboard include:

1. Advanced Analytics: incorporating advanced analytics to predict trends and identify potential issues before they arise.