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

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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.

Goals

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

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.

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.

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.

Solutions & Methods

The dashboard was developed in Tableau by connecting to the backend of the CTMS system (Oncore) and the EDC system (Advarra EDC). It's uses:

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

Fig 1: Summary and Detailed View of Protocol Deviations by Category
Displays the summary count (bar chart),Includes the category legend, Mentions the detailed view (with variables like Deviation Date, Action Taken, etc.).

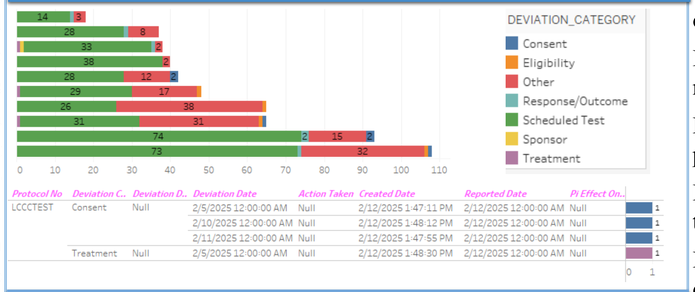


Fig 2: Summary and Detailed View queries and query statuses by protocols & site names. Displays the summary count (bar chart),Includes the Query status legend, Mentions the detailed view (with variables like site name, visit info and query text , creation, respond and closed dates.

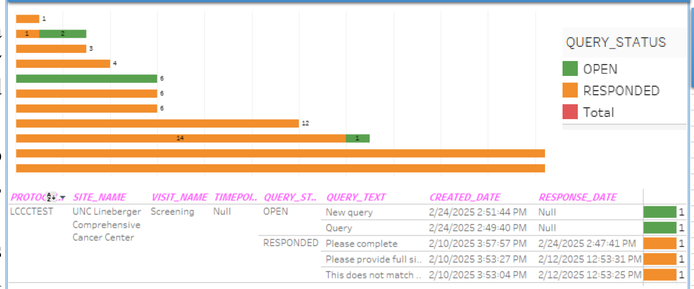
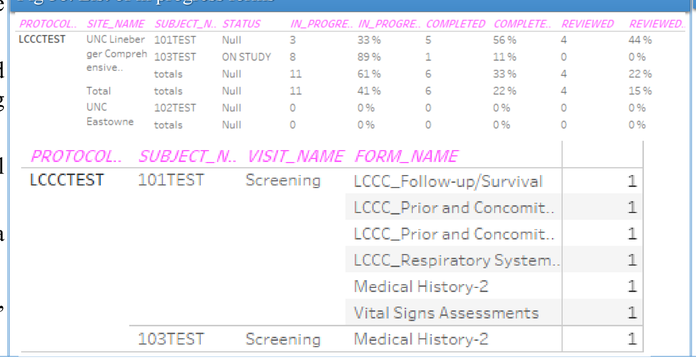


Fig 3a. List of study protocols, subject statuses and forms statuses namely counts and percentages of approved, missed, in progress, locked forms.
Fig 3b. List of in progress forms



Outcomes

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

Increased Efficiency: streamlining data management processes to reduce manual tracking and quickly identify bottlenecks.

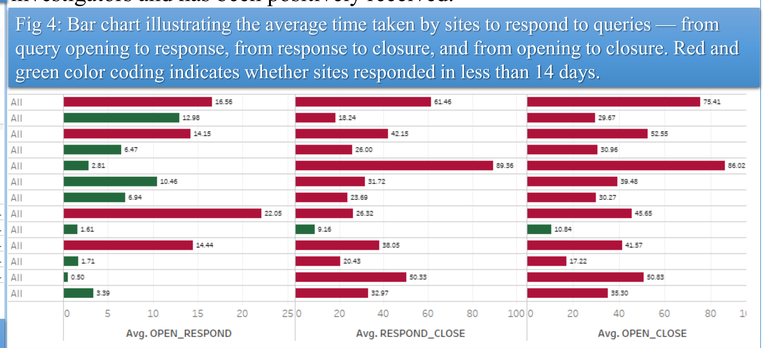
Real-time Insights: giving researchers immediate visibility into trial progress for timely and informed decision-making.

Improved Data Quality: ensuring high-quality data collection through real-time monitoring is crucial for robust trial results.

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 disease group leaders and investigators and has been positively received.

Fig 4: Bar chart illustrating the average time taken by sites to respond to queries — from query opening to response, from response to closure, and from opening to closure. Red and green color coding indicates whether sites responded in less than 14 days.



Lessons Learned & Future Outcomes

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

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.

Continuous Improvement: regular updates and enhancements based on user feedback are essential to maintaining the dashboard's effectiveness.

Training and Support: adequate user training and support is vital.

Future directions for the dashboard:

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