CTMS Optimization: A Tale of One Platform, Three Clinical Sites, and One Combined Dataset to Improve Trial Activation, Portfolio Management, and Clinical Trials Reporting

M. Mavredes, K. Bouker, M. Marafelias, T. Impallaria, E. Richards

Georgetown Lombardi Comprehensive Cancer Center

1. Background
The Lombardi Comprehensive Cancer Center (LCCC) consists of three clinical sites. Managing harmonized consortium-wide metrics, to measure progress and guide operational decision making for LCCC, requires entering and accessing clinical trials data in two separate accounts from a single CTMS vendor, OnCore. Previously, each site manually generated single-site reports, which were collated to present consortium-wide metrics. To standardize consortium operations, LCCC set consortium-wide data entry and quality assurance practices and data locks to ease the issuance of metrics.

2. Goals
The CTMS Optimization Project goals included:
- Provide at-a-glance metrics via dashboards to LCCC Leadership, Clinical Research Leadership, and Disease Group (DG) Leaders
- Increase efficiency and accuracy of LCCC consortium reporting, measured by a decrease in the person-hours required to provide reports and reproducibility of clinical trials metrics across the consortium
- Harmonize operations across the institutions (e.g., eCRF validation, standardized reporting intervals, monitoring plan)
- Ensure portfolio management via disease group and PRMC activities (e.g., dashboards, reports) and prioritization of institutional, multi-institutional, and national protocols to shift protocol portfolio in alignment with NCI expectations

3. Solutions and Methods
LCCC deployed a multifaceted approach to include: (1) determining and implementing a predictable reporting cadence with standardized dashboards and reports, (2) deploying TIBCO Jaspersoft Studio to create custom coded reports in Java/XML/SQL with dynamic visualizations benchmarked against NCI standards, (3) distributing pilot reports including pipeline activity, time to activation, accruals trends, and portfolio composition to various stakeholders across LCCC, (4) establishing a continuous improvement process to ensure relevance of reports and dashboards, and (5) soliciting stakeholder feedback for additional improvements. These efforts required collaboration across the IT departments within the LCCC consortium for synchronization.

4. Outcomes
There are immediate outcomes and anticipated outcomes (future directions). Immediate outcomes include providing LCCC and Clinical Research Leadership and each DG at-a-glance quick reference dashboards and reports, saving over 200 hands-on person hours via coding and automation, condensing >80 reporting files monthly, and providing customized reports to accurately and efficiently capture data across all modules in OnCore. The quick reference dashboards and reports contain data visualizations, which benchmark LCCC clinical trials data against NCI expectations, for time to activation and accruals progress. Additional custom reports led to aggregating and analyzing consortium accruals data and auto-population of the PRMC Scientific Progress Review Committee agenda, to increase efficiency of review and reduce error.
5. Lessons Learned and Future Directions
There is a gap in services provided by Advarra for managing clinical trials data for NCI-Designated Comprehensive Cancer Centers. Bridging the gap with internal solutions allowed LCCC to provide consolidated consortium reports and dashboards to LCCC and Clinical Research Leadership, along with DG leaders – an essential component to assessing progress and tracking activity. Future directions include deploying consortium-wide task lists to capture additional data points for reporting, customized monthly reports to be uploaded to a cloud environment to feed an interactive dashboard run via automated coding, and conducting a feasibility review to determine automated data transfer to provide fully automated real-time dashboards for consortium-wide access.