

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

Developing a Standardized Data Management Framework to Improve Query Lifecycle Efficiency in a Newly-Established Site Disease Group

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1. Background

The rapid initiation of new clinical trial programs frequently exposes gaps in operational infrastructure, particularly in data management standardization and onboarding. In 2025, the Theranostics site disease group (SDG) at the University of Miami Sylvester Comprehensive Cancer Center launched four early-phase oncology trials. While institutional onboarding provided general cancer center orientation, standardized role-specific training and cross-functional workflow guidance for data specialists were limited, highlighting opportunities to formalize data management infrastructure. Early sponsor monitoring reports identified significant query backlogs and prolonged query aging, highlighting the need for structured systems to ensure regulatory compliance, data integrity, and operational efficiency.

2. Goals

To implement and evaluate a scalable data management framework designed to reduce query backlog, improve query resolution time, and enhance cross-team communication within the newly established Theranostics clinical trials program.

3. Solutions and Methods

A centralized Excel-based query tracking system was developed to standardize documentation of all sponsor queries across four active trials (10 enrolled patients). The tracker captured patient identifiers, visit details, query descriptions, action items, responsible personnel, and timestamps (query open date, intervention date, resolution date), while also enabling protocol deviation tracking.

To address repetitive documentation burdens, laboratory calculations required by study protocols (e.g., protocol-specific eGFR formulas) were consolidated into centralized calculation logs. These logs captured relevant laboratory values, calculation variables, visit dates, and principal investigator sign-off within a single longitudinal record, replacing multiple individual notes-to-file and improving documentation consistency and audit readiness.

The tracker was further integrated into internal communication workflows between data management, clinical research coordinators, nursing staff, and management. Action items were documented and time-stamped within a shared system, promoting transparency, shared accountability, and structured follow-up during high-volume operational periods. Sponsor monitoring reports (November–February) and internal tracker metrics were used to evaluate query aging and resolution timelines pre- and post-implementation.

4. Outcomes:

Within four months of implementation:

- Open queries per monitoring visit decreased from 100 to 19 (81 percent reduction).

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- Average query aging decreased from 122 days to 21 days (83 percent reduction).
- Mean query resolution time decreased from 55 days to 5 days (91 percent reduction).

Sponsor feedback shifted from concern regarding data backlog to positive recognition of improved data timeliness and organization. The tracking framework was adopted by clinical research coordinators and management within the SDG.

5. Lessons Learned and Future Directions:

Early-phase program growth without standardized data infrastructure can result in significant variability in query management and onboarding practices. Centralized tracking with time-stamped accountability mechanisms improves operational transparency and accelerates resolution timelines.

Currently, a Data Management Guide is being developed as a standardized institutional reference for data specialists. This evolving guide outlines common query categories (e.g., investigational product accountability, drug administration documentation, laboratory calculations, clinical significance determinations), defined data retrieval pathways, and key institutional contacts. By reducing reliance on informal, individualized training, the guide aims to support consistent onboarding and establish reproducible best practices across site disease groups. Expansion of this framework across additional site disease groups is planned to further enhance institutional data quality and monitoring readiness.