CASE STUDY

Boosting Efficiency in Oncology Trial

How Smarter Data Management Drives Better Results

Situation

A mid-sized global biotechnology company partnered with Caidya to support its oncology clinical portfolio, including multiple Phase 1A and 1B studies across various countries. The collaboration covered data management, clinical programming, global clinical analytics, and project management.

The company aimed to improve operational efficiency, enhance data quality, and strengthen communication to accelerate timelines and ensure regulatory compliance.

Caidya's role was to provide a unified, strategic approach to managing complex clinical activities while remaining adaptable to changing study needs.

Challenge

Caidya identified several operational and data management challenges jeopardizing study timelines and stakeholder confidence:

•**Fragmented External Vendor Data Management:** Delays and quality issues in Data Transfer Specifications (DTS) and reconciliation programming led to excessive, inaccurate queries, backlogs, and inconsistent processes. Communication gaps and insufficient training exacerbated these issues, resulting in reactive oversight rather than proactive quality control.

•**Inefficient Safety Reporting Forms (SRFs):** The sponsor's reliance on PDF-based SRFs generated large volumes of data daily, requiring manual review and reconciliation efforts, causing delays and overloading automation tools.

•**Variability in Project Management and Data Management Processes:** Non-standardized forms, meeting structures, and tracking systems led to inconsistencies, inefficiencies, and challenges in portfolio-level oversight and delivery quality.

These obstacles threatened not only timelines and data integrity but also impacted site engagement and overall sponsor confidence.

Solution

To address these challenges, Caidya implemented a comprehensive, portfolio-wide strategy:

Centralized External Vendor Data Management (EVDM): Created a dedicated EVDM team to centralize accountability, standardize reconciliation workflows, implement quality KPIs, and provide proactive oversight. This included extensive training and clear communication channels between sponsors, vendors, and sites, transforming external data management into a strategic, quality-focused function.

Streamlined Safety Reporting: Shifted SRF generation from PDF to Excel, capturing only new or updated data, synchronizing email alerts with SAE reports, and adding naming conventions for easy identification of query-related records—reducing manual workload and boosting efficiency.

Standardized Project and Data Management Tools: Developed sponsor-specific templates, forms, trackers, and governance frameworks to unify portfolio processes. This included controls for database migration, data management plans, timeline templates, and meeting trackers to improve transparency, resource management, and deliverable quality.

50% Reduction in reconciliation time across studies

Outcome

Within six months of these implementations, Caidya delivered significant measurable improvements:

•**Enhanced Data Quality and Efficiency:** Reconciliation duration was cut by 50%, query volume decreased by 40%, and backlogs were eliminated, resulting in improved site engagement and sponsor confidence.

•**Improved Safety Reporting:** SRF process automation reduced manual effort and system load, allowing the team to focus on case review and accelerating case processing timelines.

•**Operational Consistency and Portfolio Optimization:** Standardized forms and governance boosted team collaboration, ensured timely and high-quality deliverables, and fostered financial efficiencies for both sponsor and CRO.

This partnership evolved from a small pilot project to managing 24 studies across 13 compounds with over 160 global resources, consistently delivering strong, on-time, high-quality results with positive sponsor feedback. The strategic innovations introduced by Caidya set a new standard for portfolio-level clinical trial management and data integrity.

40% fewer queries, boosting site engagement

Streamlined SRFs cut manual work

Standardized tools improved quality

Caidya transformed a complex oncology portfolio by centralizing external data management, streamlining safety reporting, and standardizing project tools—cutting reconciliation time by 50%, reducing data queries by 40%, and easing manual workloads. This approach boosted data quality, sped timelines, and strengthened collaboration across global studies, setting a new standard for portfolio efficiency and partnership.