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

Optimizing Oncology Trial Data Management Through Vendor Support

B. McGough[1], A. Joshi[1], L. Drake[2], J. Mehnert[1], B. Pothuri[1]

[1]Laura and Isaac Perlmutter Cancer Center at NYU Langone Health; [2]Omega Healthcare Management Services

1. Background

Oncology clinical trials continue to increase in complexity and volume, placing substantial demands on data coordinators. Their roles extend beyond data entry and query resolution to include patient registration, Serious Adverse Event (SAE) submissions, monitoring visit coordination, and other critical trial management activities. At our institution, rapid program growth further increased these demands, with patient accrual rising 14.7 percent from fiscal year 2023 to 2025. As the number of active studies and enrolled patients rose, some trials developed data backlogs that threatened timelines, data quality, sponsor slot allotment, and authorship on abstracts/manuscripts. Also, the months-long hiring and training process limited our ability to scale quickly. To address these challenges, leadership partnered with a vendor to provide targeted data entry and query resolution support for sponsored trials, ensuring timely, accurate data while reducing strain on internal teams and sustaining overall study performance.

2. Goals

The primary goal was to improve Case Report Form (CRF) timeliness and data quality using oncology-experienced vendor support while avoiding staff overload. Secondary goals included enhancing data integrity, supporting study growth and continued recruitment, increasing academic recognition, ensuring long-term operational sustainability, and reducing costs, with the sponsor likely covering the lower vendor expense versus an internal Full-Time Equivalent (FTE).

3. Solutions and Methods

In 2023, leadership engaged Omega Healthcare, a U.S.-headquartered organization with operations in India, to provide dedicated data entry support for selected high-volume, complex oncology clinical trials. Omega delivered protocol-specific onboarding, structured quality oversight, and operational management. Quality Analysts audited at least 10 percent of each team member's work monthly to ensure ≥95 percent accuracy, while Operational Managers handled daily assignments, performance monitoring, and issue resolution. U.S. and offshore leadership supported escalations and maintained alignment with sponsors and internal stakeholders. Omega coordinators integrated with Disease Management Groups, trained in source document review and Electronic Data Capture (EDC) processes, and participated in biweekly meetings to review metrics, address issues, and drive continuous performance improvement.

4. Outcomes

After adding vendor support and increasing Omega coordinators from two to six (2023–2025), monthly data entry task volume increased by 116 percent (mean 164 to 354 cases/month), rising from 63–114 in late 2023 to a peak of 614 in September 2024 and 582 in December 2025, while average handling time (AHT) decreased by 25.6 percent (51.5 to 38.3 minutes). Query resolution volume increased by 156 percent (mean 289 to 740 queries/month), reaching a peak of 1,031 tasks, while AHT remained stable despite workload expansion (17.7 to 18.7 minutes). Overall accuracy was maintained at 99.49 percent.

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Omega also supported two GYN oncology studies with backlogs, starting at 13 data entry tasks (AHT 54.5 mins) in December 2023, peaking at 89 tasks (AHT 30 mins) in May 2024, and averaging approximately 30–40 tasks monthly (AHT ~60 mins) through 2025.

5. Lessons Learned and Future Directions

Omega provided operational support through defined roles, clear expectations, and consistent communication. Rapid onboarding and vendor-led Electronic Medical Record (EMR)/EDC training increased internal capacity, proving more effective than alternative vendors. Initial challenges highlighted the importance of structured training, routine Quality Assurance (QA), and ongoing coordination. Based on these results, we plan to expand Omega's role to cooperative group trials and scale support during periods of growth.