Case Studies

Cancer Center Eliminates Clinical Trial Event Reporting Backlogs and Recoups Millions

Who we helped: *A top Cancer Center, treating over 60,000 patients annually and experiencing steady growth year over year, sought to resolve a significant and growing backlog in their clinical trial data management system (CTMS).*

Challenges

- Chronic understaffing driven by increasing patient volume, growing trial complexity, and limited local resources
- Ongoing financial pressure to reduce costs while increasing revenue
- Clinical research resources unable to prioritize data entry into CTMS
- Backlog in event reporting leading to billing delays and revenue loss

Solution

- Deployed remote GCP- and HSP-credentialed data managers with clinical backgrounds and oncology training
- Leveraged a cost-effective, offshore agency model
- Provided appropriate staffing levels to eliminate backlog and support ongoing data entry
- Implemented event reconciliation checklists to ensure complete and timely event reporting and billing

Outcome

- Scaled and stabilized capacity and productivity with qualified staff
- Achieved significant annual savings on clinical research staffing
- Enabled internal on-site clinical resources to operate at the top of their license
- Cleared backlog of event reporting, restoring proper billing cycles to enable the recovery of millions in revenue for industry-sponsored trials

Case Study: CTMS Data Entry

Academic Health System Enhances Cancer Registry

Who we helped: *A large health system, including an NCI-designated cancer center and multiple CoC-accredited facilities, sought help with accreditation compliance and streamlining processes*

Challenges

- Extensive and variable abstracting backlog across facilities
- Inefficient and manual case finding process created bottlenecks
- Several hospitals out of compliance with follow-up rate
- Pending Commission on Cancer (CoC) special study to be completed
- Several facilities were in the process of converting to a new cancer data management software system

Solution

- Automated processes to reduce data duplication, missed cases, and typographical errors
- Built a case-finding interface between health system's EHR and registry software
- Created more frequent path report review process
- Added auditing process and tools
- Supported transition to new data management software

Outcome

- All 1,500 backlog cases cleared within 90 days
- Improved efficiency increased team abstraction productivity
- Reduced registry labor costs overall
- Improved data quality and feedback via auditing tools
- On-time completion of required CoC special study data submission
- Enabled data-informed strategic decision-making

Clinical Trials: Regulatory Compliance Excellence

Who we helped: *NCI-Designated facility sought to optimize for the clinical enablement of their on-site clinical research staff*

Challenges

- Hiring qualified research personnel for on-site work became increasingly difficult post-pandemic
- Regulatory compliance demands pulled staff into administrative tasks, reducing time for collaboration with research and clinical care teams
- Non-compliance with regulations could have put the study on hold, delaying patient treatment

Solution

- CurateIQ provided 2 FTEs to maintain regulatory documentation
- GCP- and HSP-certified FTEs who met site and IRB requirements granted remote access to eBinders and CTSU
- Formally aligned with the facility on documentation requirements through a standardized checklist
- Full review of each protocol binder at least quarterly and as requested by the facility

Outcome

- On-site research staff were relieved of the burden of regulatory maintenance for NCI clinical trials
- Enabled on-site staff to dedicate more time to high-impact care team collaboration and patient care
- External audits with minimal to no regulatory findings
- Over 10 years of successful partnership

Case Study: Clinical Trials Regulatory

Seamless EHR Data Migration Ensures Research Continuity and Compliance

Who we helped: *A top academic cancer center undergoing a system-wide EHR conversion relied on Omega to migrate critical adverse event data swiftly and precisely–preserving research continuity and ensuring data accuracy before go-live.*

Challenges

- Complex data environment due to differences in the EHR systems, complicating data migration
- Significant pressure to ensure timely, complete, and accurate encounter-level data to enable timely reporting to sponsors
- High-volume, specialized workload requiring clinical expertise to accurately identify and record adverse events

Solution

- Rapid onboarding of qualified resources from Omega's internal pool and new hires to meet immediate project demands
- Developed SOPs, targeted training, and a quality audit framework to ensure accuracy and consistency in data migration practices
- Collaborated closely with the Clinical Trial Nursing teams to align on priorities and ensure workflow consistency

Outcome

- Project completed on time and within budget, meeting all client milestones
- Successful manual migration of all adverse event data to the new EHR ahead of the go-live deadline
- Seamless transition ensured no disruptions to ongoing research activities, with accurate data flow from the new EHR to sponsor's EDC

Case Study: EHR Data Migration

Enhancing Artificial Intelligence Performance Through Expert Human Oversight

Who we helped: *A leading healthcare provider partnered with Omega to validate and refine proprietary artificial intelligence (AI) tool to de-identify documents at scale*

Challenges

- AI tool using NLP to detect PHI for de-identification was producing incomplete and inaccurate tagging, requiring a significant level of human validation and correction
- Nuanced clinical data and variable documentation patterns made model training difficult to scale reliably
- High compliance risk, project success was critical to prevent inadvertent PHI release

Solution

- Rapidly onboarded qualified resources from Omega's internal pool and new hires to meet immediate project demands
- Developed detailed annotation guidelines and best practices to ensure consistency across annotators and model-training iterations
- Established a continuous feedback loop between to validate, correct, and enhance PHI tagging accuracy

Outcome

- Reduced PHI identification errors, strengthening data quality and supporting compliance with HIPAA standards
- Enhanced model accuracy and reliability via expert human validation and targeted feedback loops
- Improved client readiness for future NLP initiatives through knowledge transfer and best-practice documentation

Case Study: NLP Annotation

Academic Medical Center Uses RWD in Outcomes Research

Who we helped: *A leading NCI-designated Cancer Center partnered with Omega to curate lung cancer patient records for research into the efficacy of immunotherapy treatment*

Challenges

- 3,100 lung cancer patient records to be curated, including complex treatment and outcomes data
- Data sourced from EHR included longitudinal office, radiology, and pathology physician notes
- Short timeline for data curation required to meet research objectives

Solution

- An experienced team of data curators with specific training in immunotherapy treatments for lung cancer were deployed
- Client's Research Electronic Data Capture (REDCap) database was assessed and customized with integrated quality review fields
- Auditor reviews with automated quality reporting provided transparent data quality assurance

Outcome

- 3,100 Patient records were successfully curated within the required 6-month timeline
- Client's analysis of the delivered research-ready data used in peer-reviewed publication submission
- 96.5% data accuracy delivered, ensuring reliability of curated datasets for research use