CASE STUDY

Clinical Data Management Monitoring Intelligence

Client	Industry	Solution
Contract Research Organization in San Diego, California	Clinical Research Services Trial Management	AI-Powered Clinical Data Quality Real-Time Monitoring Platform

Challenge

San Diego CRO managing 45 concurrent clinical trials experienced 25% data query rates requiring manual resolution, $6.2M annual costs from data cleaning and monitoring activities, inconsistent data quality across multiple study sites and therapeutic areas, delayed database lock timelines affecting regulatory submission schedules, and difficulty detecting protocol deviations and safety signals in real-time during trial execution.

AI Consulting Approach

• Clinical Data Analysis: AI consultants analyzed historical trial data, query patterns, and monitoring reports to identify data quality optimization opportunities using natural language processing and anomaly detection technologies.

• Comprehensive Data Intelligence: Machine learning models processing clinical data entries, monitoring reports, and protocol requirements to automate data quality checks and real-time trial monitoring.

AI Solution

• Automated Data Quality Assessment: AI system analyzing clinical data entries in real-time to identify inconsistencies, missing values, and potential protocol deviations before they require formal queries

• Intelligent Query Management: Machine learning platform prioritizing data queries by impact and urgency while suggesting automated resolutions for routine data discrepancies

• Real-Time Safety Monitoring: Advanced algorithms continuously monitoring adverse events and safety signals across all trial sites with automated alerting for serious events

• Protocol Compliance Analytics: Intelligent system tracking protocol adherence and identifying sites or investigators requiring additional training or oversight

Implementation (28 weeks total)

• Data Architecture (6 weeks)

• AI Model Development (10 weeks)

• Integration Testing (9 weeks)

• Validation Training (3 weeks)

Key Results

Data Quality:
• 8% data query rates (vs. 25%), $3.8M reduction in data management costs, 60% faster database lock timelines, improved regulatory submission readiness

Trial Monitoring:
• 85% improvement in protocol deviation detection speed, enhanced safety signal identification, better site performance management

Business Impact:
• $4.9M annual value creation, strengthened regulatory compliance capabilities, 215% consulting ROI, improved client satisfaction and trial quality

Technologies:
• Clinical data analytics platform
• natural language processing
• anomaly detection algorithms
• real-time monitoring systems
• regulatory compliance automation