FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

CLINICAL OPERATIONS

Driving high-quality outcomes with accountability and transparency

CASE STUDIES

As a Pharmaceutical/Biotech company, nothing is more frustrating than working with a CRO team who only identifies problems, and then asks you to solve them. At Firma, our experienced team members provide value by embracing their partnership role and supporting you with issue identification, proposing and deploying mitigation strategies, and following through to resolution. We constantly examine the best way to conduct your clinical trial to facilitate rapid study start, ensure proper trial oversight, maintain quality outcomes, and achieve your trial timelines.

Learn how three clients relied on Firma Clinical Operations to provide quality trial oversight, produce accurate file reconciliation, and facilitate timely database lock.

IMMEDIATE ISSUE IDENTIFICATION AND RESOLUTION FOR TIMELY FDA SUBMISSION

Client: Mid-sized pharmaceutical company

Project Focus: Trial master file (TMF) rescue in advance of FDA submission

Request: Client TMF, previously handled internally, was not adequately prepared for upcoming FDA submission for drug approval. Firma performed a complete quality check (QC), document classification, and file reconciliation of a hard-copy paper Trial Master File (TMF) across a series of completed and ongoing studies for support of the client's upcoming FDA submission.

Approach: Firma received, inventoried, and transitioned the documents from multiple hard copy paper sources to a Part 11-compliant electronic file management system.

Results: The solution enabled immediate identification of issues for timely escalation and resolution, and allowed the client a resulting streamlined, consistent file structure for support of their upcoming FDA submission. Firma's efforts ensured the client met their communicated FDA deliverable timeline, and with high-quality submission materials.

ENSURE CLEAN DATA FOR RAPID DATABASE LOCK

Client: Small biotech company

Project Focus: Supplemental monitoring support

Request: Firma was requested to provide supplemental clinical monitoring support for a client who was previously assuming these responsibilities directly. The client asked for Firma's assistance to specifically address:

- ▷ Data backlog due to rapidly increasing enrollment
- ▷ Adherence to budget restrictions
- ▷ Maintaining and accelerating the project timeline

Approach: Firma CRAs were deployed to complete source data verification (SDV), reduce and eliminate the data backlog, and ensure clean data to meet the rapidly approaching database lock.

Results: Working in conjunction with the client and trial staff, the Firma team was able to resolve all outstanding queries, complete 100% SDV on over 1,000 outstanding data points, and drove the project to successful database lock within expected timeline, facilitating data review by the client.

MINIMIZE ISSUES IN eTMF CONVERSION AND MANAGEMENT

Client: Small device company

Project Focus: TMF conversion

Request: Firma converted the paper TMF of an ongoing study to our electronic master file and managed the resulting system.

Approach: A TMF team was assigned to:

- ▷ Assess the needs of the sponsor
- ▷ Audit the current paper file
- ▷ Ensure that the resulting eTMF would be the complete and auditable study file
- ▷ Maintain the file for the study duration

Results: The Firma team successfully transferred the paper TMF into electronic form and continued to manage the eTMF in the electronic system. Management included file receipt, document QC, document classification, and appropriate filing. The sponsor is now better positioned to maintain their research progression and ultimate submission to FDA.

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For more information on how we can help you drive high-quality outcomes with accountability and transparency, email **sales@firmaclinical.com** or visit **firmaclinical.com.**