FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

CLINICAL OPERATIONS

Driving high-quality outcomes with accountability and transparency

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.

Proven Clinical Operations experience you can count on

Our Clinical Operations team is comprised of industry experts with diverse scientific and medical backgrounds. Our core team members have extensive experience managing and monitoring Phase 1-4 trials including: interventional, non-interventional, registry, and device studies across multiple therapeutic areas, study designs, and patient populations.

We have an extensive network of monitors and study managers supporting a vast array of therapeutic areas. Our clinical monitoring staff assists and promotes strategic site management during their onsite visits, enhancing site/PI involvement in clinical trials.

25+
Years of experience with drug, biologic, and device study management and monitoring

10+
Years of Phase 1-4 interventional, non-interventional, registry, and device study experience

50+
Therapeutic areas and study designs

Experienced and customized clinical solutions to meet your timelines

We are a partner who continuously plans and examines ways to achieve your trial goals. You can count on our clinical expertise, creative thinking, and quality-based approach to support:

- ▷ Meeting timelines with targeting patient recruitment and retention
- ▷ Reducing site and investigator burden by implementing robust identification, feasibility, and selection standards
- ▷ Identifying challenges and opportunities for each site with operationalized protocol development and review
- ▷ Leading with data-driven project management through consistent review of performance and trends
- ▷ Ensuring study start-up, maintenance, and close-out are performed per ICH/GCP, local regulations, and SOPs generated from our ISO 9001:2015 certification
- ▷ Developing a customized monitoring approach with a full spectrum of capabilities ranging from 100% SDV to complete Risk-Based Monitoring (RBM)

OUR EXPERTISE IS YOUR ADVANTAGE

Aligning our expertise by applying data-driven approaches allows us to plan strategically, while our flexibility ensures we quickly adapt to changes while maintaining high-quality outcomes. How will you benefit from our team?

Immediate issue identification and resolution for timely FDA submission

Need an experienced team to prepare and deliver a high-quality submission to meet an FDA timeline? Our solutions enable immediate identification of issues for timely escalation and resolution, and ensure streamlined, consistent file structure for support of FDA submissions.

Ensure clean data for rapid database lock

Looking to accelerate your project timeline? We provide supplemental clinical monitoring support and can specifically address your needs. From data backlog to budget restriction adherence, we ensure successful database lock while maintaining your timeline.

Minimize issues in eTMF conversion and management

Convert the paper TMF of your ongoing study to an electronic master file and let us manage the resulting system to minimize issues. We'll help you maintain your research progression for your submission to the FDA.

"I chose Firma because their team demonstrated a high level of industry knowledge, asked great questions to ensure we had thought of potential operational strategies, and took ownership in supporting our trial."
—Chief Executive Officer, emerging biotech company

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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.**