FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

DATA SERVICES

Speed regulatory submissions with efficient, high-quality data and analyses

As a pharmaceutical/biotech company, outside of patient safety, the integrity and cleanliness of your data is the most important aspect of your clinical trial. Key decisions undertaken at trial start could impact your ultimate analysis and submission success; and everything from your statistical design, the flexibility and usability of your database platform, the speed of database build, data cleaning efforts, database lock, and statistical analysis has an impact on your outcomes and company success. Something this important to patients and your company needs to be supported by an experienced and focused team.

Your study deserves quality-driven, clinical expertise that ensures collaboration and cross-functionality among personnel within medical, data management, and biostatistics. Our approach to data management and biostatistics begins with a broad knowledge base in all aspects of the clinical trial process and a dedication to cross-training all team members prior to study initiation. With robust, scalable, and software-independent processes, we efficiently capture, maintain, clean, and deliver data for your project regardless of phase, therapeutic area, size, or method of data capture.

Proven Data Services experience

Ensure accurate study results and increase the speed of study start and quality submissions by leveraging our vast data management and biostatistics experience. Our team of PhD- and MS-level professionals adheres to a single set of global standard operating procedures, offering their detailed and extensive knowledge of pharmaceutical development to benefit your entire data management and biostatistics planning, execution, and analysis. This expertise is demonstrated by our involvement in 48 successfully submitted NDAs to date.

2x
Faster database build and release than industry standard

180+
Studies across a variety of therapeutic areas

16+
Oncological indications

70+
Medical device studies/imaging studies

5+
Orphan drug approvals

48
NDAs supported

Experience to deliver high-quality, statistically sound data from study start or study rescue

Benefit from our clinical expertise, cross-functionality, and proven flexible workflows as we:

- Expedite trial start with our 30-day database build and release timeline - more than 2x faster than the industry standard of 68 days
- Increase efficiency with robust cross-functional training of all team members
- Provide data management and biostatistics experts who have also undertaken extensive physician-led protocol training for each project (at no sponsor charge)
- Deliver high-quality results with QC and double programming implemented into all QA processes
- Ensure accurate medical coding from a fully-trained medical coding team

OUR EXPERTISE IS YOUR ADVANTAGE

With speedy database integration and summary analyses, we can help you meet regulatory requirements, every time.

Expedited workflows and rescue leads to agency approval

In need of speedy rescue for one or multiple studies for an agency submission? Let us organize and deploy teams to implement your database build, write your SAPs and mock tables, and create CSR shells to meet your original timeline.

Flexible and timely integration of additional analyses

Our vast experience in NDA support ensures that our team provides the resources necessary for a timely and high-quality submission. From data integration of multiple studies to ISS and ISE analyses, we deliver CDISC-compliant data sets on time, every time.

Meeting corporate FDA timelines with confident and comprehensive leadership

Do you need confidence that your CRO can meet your corporate timelines? Our experts can undertake additional analyses requested for your NDA by deploying a team of clinicians, statisticians, and SAS programmers to review your protocol, CRFs, and database structure, and perform your analyses on time.

"Firma delivers when they commit to a study. The quality of their work is always high and they have never missed a timeline regardless of protocol amendments throughout the study lifecycle." — *Vice President, Clinical Development, mid-sized biotech*

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For more information on how you can speed regulatory submissions with efficient, high-quality data and analyses, email **sales@firmaclinical.com** or visit **firmaclinical.com.**