DATA SHEET

Data Management & Biostatistics

Expertise That Reduces Risk

61+/58
NDA SUBMISSIONS/ APPROVALS

1,180+
STUDIES SPANNING BROAD THERAPEUTIC AREAS

16+
ONCOLOGICAL INDICATIONS

70+
MEDICAL DEVICE/ IMAGING STUDIES

5+
ORPHAN DRUG APPROVALS

2x
FASTER DATABASE BUILDS (VERSUS INDUSTRY STANDARD)

Give us your tightest timeline and we will speed regulatory submissions with efficient, high-quality clinical trial data and insightful analyses.

Ensure your data tells the clearest and most compelling story—every time—regardless of phase, therapeutic area, size of study, or method of data capture. Firma's clinical experience means we deliver high-quality and statistically sound data, fast and efficient database integrations, and summary analyses that you can count on.

SPEED, ACCURACY, AND TRUST

Experience means we can deliver the speed, accuracy, and consistency you need. Our PhD- and MS-level professionals offer their detailed and extensive knowledge of pharmaceutical development to benefit your entire data management and biostatistics planning, execution, and analysis.

Database Builds in 4 Weeks or Less

Closely Integrated Teams

Customer-driven Performance

Experts with Physician-led Protocol Training

Dedicated Partners

Strategic Consulting

FIRMA CLINICAL RESEARCH

DATA SHEET

"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 Company

DRIVEN BY PRECISION AND COMMUNICATION

Medical, data management, and biostatistics work together at Firma, starting with physician-led protocol training for each project, so you always get cross-functional intelligence. Our vast experience in NDA support ensures that our team provides the resources necessary for a timely and high-quality submission.

The Firma Data Services team...

- has never missed a commitment
- guarantees high-quality deliverables
- is experienced in study rescues
- brings recommendations to the table when issues arise
- closely integrates medical and statistical aspects of studies
- utilizes medical coding in SAS instead of an expensive add-on EDC coding module
- is adept with Rave, Inform, Medrio EDC and other EDC database builders
- carries out many activities in parallel to shorten time to database lock
- provides medical writers with importable in-text tables—no need to QC
- has extensive early phase expertise
- has completed 61+ NDA submissions with 58 approved and 3 under review

DATA SERVICES

Firma has completed more than 1,180 studies spanning a broad range of therapeutic areas and specializes in delivering:

Quality Data

Submission success depends on the integrity and cleanliness of your data. We deliver high-quality results with double programming for all programs.

Fast, Flexible Workflows

Expedite a trial start with our four-week (or less) database build. We consistently achieve a database build-and-release timeline that is 2x faster than the industry standard. We also provide top-line results three days after a database lock and in one week provide a full set of draft tables.

Strategic Consulting

Firma is more than a consultant. We are a collaborative problem-solving partner, invested in finding ways to improve every project in which we are involved. PhD- and MS-level professionals, with expertise in pharmaceutical development, guide the planning, execution, and analysis we do and can consult on protocol design or DSMB collaboration.

Study Rescue

At risk of missing a regulatory submission? Firma has a culture of urgency and will do what it takes to accelerate your struggling study.

EDC Expertise

Expert EDC programming decreases the need for add-on EDC modules such as randomization, blinded review, and adjudication modules.

FIRMA CLINICAL RESEARCH