Clinical Services at Frontage

Clinical

FULL SUITE OF SERVICES ENSURES RAPID EXECUTION OF YOUR PHASE I-II PROGRAM.

Frontage's clinical teams have set new standards for rapid start-up and efficient study conduct. Our experienced staff provides study management services for all phases of clinical research, including study design, protocol and ICF development, IRB submission, study execution, data management, pharmacokinetic/pharmacodynamic analysis, programming, biostatistics, and medical writing, to take each study from start to finish.

Frontage Conducts a Wide Range of Study Types Each Year Including:

- First-in-human
- Single and multiple ascending dose escalation
- Absolute and relative bioavailability/bioequivalence/ food effect
- Drug/Drug and Drug/Alcohol interaction
- Cardiac safety (TQT)
- Proof of concept in healthy volunteers
- Phase II

Clinical Pharmacology Expertise

- Study design
- Protocol development
- Pharmacokinetic/Pharmacodynamic analyses using latest version of Phoenix WinNonlin
- Modeling and simulation

Clinical Operations Facilities

- 160-bed facility in northern NJ with 3 separate units that are configurable to accommodate various study designs
- Secure, limited-access pharmacy
- Experienced clinical staff with advanced cardiovascular life support (ACLS) certification
- Close proximity to metropolitan areas, universities and public transportation hubs provide access to a wide range of study participants, specialty populations, and medical professionals and facilities.

Project Management

As the primary point of contact for clients, Frontage's project managers work on-site to interact closely with investigators and site personnel. This helps to ensure studies are executed according to the protocol and that we adhere to established timelines and budget. The project manager integrates all deliverables and timelines and facilitates communication between site personnel and clients.

Site Monitoring

Frontage will contract independent monitors using a third-party vendor that has undergone Frontage QA qualification.

Biometrics

Accurate, statistically-sound data delivery is essential for any clinical trial. Rely on a team that can ensure concise and ready-to-file clinical data. Our processes, infrastructure, and training are built on industry-leading standards. Frontage's biometrics team will put their expertise and years of experience to work for you.

Whether you require full-service or just one or two components, Frontage is ready to provide what is needed to support your drug development program.

Data Management Services

- eCRF design
- Database development, validation, and user acceptance testing
- Data validation plans, edit check programming and testing
- EDC account management, training, and support
- Data management plans
- External data upload and reconciliation
- Medical coding
- Database lock and archive

Programming, Biostatistics and Reporting

Frontage's experience ensures data analysis is accurate and verified. Using the most up-to-date tools and software standards, our biostatistics and programming teams are knowledgeable in all phases of clinical research.

Services include:

- Statistical input into study designs and protocols
- Power calculations
- Statistical analysis plans and reports
- Statistical programming, including CDISC-compliant datasets and generation of e-submission documents (SDTM/ADaM define.xml and Reviewer's Guides, annotated CRFs)
- Statistical interpretation of data
- Statistical support for data safety monitoring boards
- CDISC conversion of legacy datasets

Medical Writing

Our medical writers prepare documents according to the appropriate regulations and are fully compliant with ICH and industry standards.

- Protocols
- Informed consent forms
- Clinical study reports
- Narratives
- Investigator brochures
- Integrated summaries of safety/efficacy
- Annual and periodic safety reports
- CTD modules
- Abstracts/manuscripts
- Documents to support interactions with health authorities

Quality Assured

Our QA group promotes excellence by ensuring adherence to our processes and a rigorous training curriculum. The Frontage team considers quality and compliance as nonnegotiable requirements.

Frontage Laboratories, Inc. is a contract research organization (CRO) that provides integrated, science-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of molecules through development and file regulatory submissions in the United States, China, and other countries.

FOR MORE INFORMATION, CONTACT US AT: *sales@frontagelab.com* **OR VISIT US AT:** *frontagelab.com*