

PARTNERSHIP

It's what turns services into solutions.



CLINICAL

AGILITY. *It's what gets you from the clinic to the cabinet.*

Frontage's clinical teams have set new standards for rapid start-up and efficient study conduct. In addition, experienced staff provide study management services for all phases of clinical research, including monitoring, data management, biostatistics, and medical writing, to take each study from start to finish.

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

FRONTAGE CONDUCTS A WIDE RANGE OF STUDY TYPES EACH YEAR INCLUDING:

- First-in-human
- Single dose escalation, Multiple dose escalation
- Absolute and relative bioavailability
- Drug/Alcohol interaction studies
- Bioequivalence studies
- Phase II-IV efficacy and safety
- Food effect studies

CLINICAL PHARMACOLOGY EXPERTISE

- Protocol development
- Study design

- Pharmacokinetics/Pharmacodynamics (PK/PD)
- Modeling and simulation

CLINICAL OPERATIONS FACILITIES

- More than 200 beds
- Two clinical research facilities
- Experienced clinical staff, with advanced cardiovascular life support (ACLS) certification
- Participant populations which include healthy volunteers and patient

Centrally-located facilities near metropolitan areas, universities and public transportation hubs provide access to a wide range of study participants and specialty populations.

PROJECT MANAGEMENT

As the primary point of contact for clients, Frontage's project managers work closely with investigators and sites to ensure studies are executed according to established timelines and budget. The project manager integrates all deliverables and facilitates communications between sites and sponsors.

SITE MONITORING

Frontage's CRAs work closely with investigator sites to ensure protocol and GCP-ICH compliance. Starting with site identification and selection, we provide initiation, interim and close-out monitoring.

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PHARMACOVIGILANCE

Frontage's pharmacovigilance efforts are led by physicians for medical monitoring, and are supported by a team of safety specialists. We track, manage, report and reconcile serious adverse events. We also prepare regulatory documentation and safety reports.

DATA MANAGEMENT

Data management capabilities range from plan development, CRF design, and database build to database lock. We use a variety of EDC systems that provide fully compliant and precisely targeted solutions for conducting data management and review on your studies. The systems we use ensure data accuracy and integrity with up to the minute reporting and review capabilities.

PROGRAMMING, ANALYSIS AND REPORTING

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

- PK analysis
- Statistical programming and analysis
- Statistical support for data safety monitoring boards
- CDISC

MEDICAL WRITING

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

- Protocols
- Informed consent form
- Clinical study reports
- Narratives
- Annual and periodic safety reports
- CTD modules
- Abstracts

QUALITY ASSURED

Frontage's standards are exacting and stringent. Our teams follow clearly documented quality control procedures to ensure consistent and accurate results. We retain experienced staff who are accessible and ready to help throughout the planning, conduct and close-out of your project.

Frontage is a full service CRO which closely collaborates with pharmaceutical and biotech companies to help them bring promising drug candidates to market.

We offer solutions to help our clients in analytical testing, product development, DMPK, bioanalysis, clinical, and biometrics. What sets us apart is our ability to collaborate closely with our clients to ensure a deep understanding of their drug development goals and our ability provide flexible solutions that are customized to each client's needs.

At Frontage, we are committed to providing rigorous scientific expertise to ensure the highest quality and compliance on each project. Frontage proudly serves innovator, generic and consumer health companies from IND enabling through late stage clinical projects. Frontage successfully assists clients to advance hundreds of molecules through development to commercial launch in global markets. This partnership with our clients is how we turn services into real solutions that get our clients ahead.

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

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