

# PARTNERSHIP

It's what turns services into solutions.



## BIOMETRICS

**INTELLIGENCE.** *It's how you turn data into decisions.*

Accurate, statistically-sound data delivery is essential for any clinical trial or bioequivalence study. Rely on a team who 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.

CREATIVELY  
DELIVER MULTIPLE  
SOLUTIONS IN  
BIostatISTICS AND  
SAS PROGRAMMING

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.

- **Biostatistical Analysis and Programming:** Frontage's versatile statistical programming and analysis capabilities support clinical studies or standalone projects. We create statistical analysis plans, deliver interim and final analyses, or convert legacy data into current FDA-accepted formats.
- **Data Management:** Led by staff who specialize in the collection and processing of clinical data, our modules are well-designed and tested to streamline data collection and reduce queries. We design data capture solutions using

industry-accepted tools. For generic studies, we offer technology solutions based on your data analysis needs.

- **Medical Writing:** Choose from a full range of regulatory-ready deliverables for clinical documentation support – including study protocols, investigator brochures, informed consents and clinical study reports – that require concise communication of scientific and technical data.
- **Pharmacokinetic (PK) Analysis:** Our highly experienced clinical pharmacologists provide PK analyses and data interpretations. We use the latest version of Phoenix WinNonlin for robust and consistent results, every time.

## CDISC SUPPORT

Frontage's biometrics team offers specialized expertise in data standards established by the Clinical Data Interchange Standards Consortium (CDISC). We bring in-depth experience and electronic tools that allow us to set up standards before or after a clinical study has completed. We offer a pre-and post conversion process using state-of-the-art tools, developed with our software development partner that design and map CDASH, SDTM and ADaM, and deliver data sets, define.pdf, and hyperlinks as well as the SAS code that is used to generate the deliverables. All data deliverables are fully validated. Frontage focuses our efforts on

# PARTNERSHIP

It's what turns services into solutions.

producing state of the art tools and processes that allow us to remain nimble, flexible and efficient, even as data standards continue to change.

## QUALITY ASSURED

Frontage believes that quality is the key to any successful project. We have built robust quality controls throughout every stage of the project. By our strict adherence to established operating procedures, you are assured of the integrity of your data.

## DATA MANAGEMENT SERVICES

- CRF design
- Data management plan
- Database development and validation
- Medical coding
- Data review and query management
- Database closure and archive

## BIOSTATISTICS

- Protocol development and sample size calculation
- Statistical analysis plans and mock TLFs
- Interim analyses and DSMB support

## MEDICAL WRITING

- Protocols
- Informed consent
- Investigators' brochure
- Clinical study reports in ICH format
- CTD documents

---

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](mailto:sales@frontagelab.com) **OR VISIT US AT:** [frontagelab.com](http://frontagelab.com)

### Headquarters, Bioanalytical and DMPK Services

700 Pennsylvania Drive  
Exton, PA 19341

**P: +1 610.232.0100**

**F: +1 610.232.0101**

### GMP Manufacturing and CMC Services

75 East Uwchlan Ave.  
Suite 100  
Exton, PA 19341

### Clinical Services

200 Meadowlands Parkway  
Secaucus, NJ 07094

### Biometrics

100 Franklin Square Dr.  
Suite 305  
Somerset, NJ 08873

