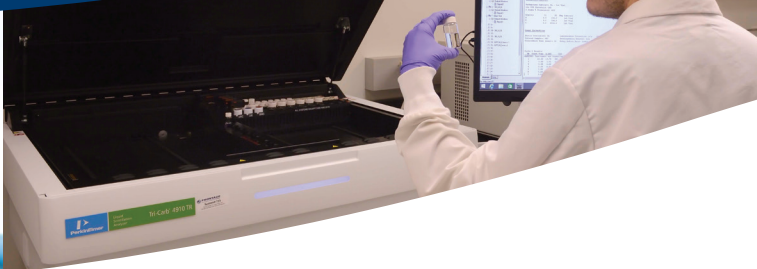


PARTNERSHIP >

It's what turns services into solutions.



FRONTAGE

PARTNERSHIP: *It's what turns services into solutions.*

Founded in 2001, Frontage is a full service CRO with over 500 employees globally. Headquartered in Exton, PA, Frontage has additional laboratories and clinical centers in Somerset and Secaucus, NJ, and Shanghai and Suzhou, China.

Our integrated core services include:

- DMPK
- Bioanalysis
- CMC (Chemistry, Manufacturing & Control)
- Early Phase Clinical (Phase I-II)
- Biostatistics & Data Management

What sets us apart is our ability to collaborate closely with our clients to ensure a thorough understanding of their drug development goals and our ability to provide flexible solutions that are customized to each client's needs. At Frontage, we are committed to providing rigorous scientific expertise assuring the highest quality and compliance for 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.

DMPK

INSIGHT: *It's how your candidates become real contenders.*

At Frontage, our scientific staff applies proven techniques and best-in-class approaches to generate data for critical milestones and decision-making during drug discovery and development. The highly trained and experienced scientific team provides broad and in-depth expertise/advice to clients on appropriate study designs, execution of studies, and interpretation of the data.

PROVIDE
SCIENTIFIC INPUT
TO INFLUENCE
SELECTION OF LEAD
DRUG CANDIDATES

We offer extensive drug metabolism and pharmacokinetic capabilities for new chemical entities and compounds in development. For agrochemicals, DMPK services include GLP residual analyses,

radiolabel mass balance, and in vitro/in vivo metabolism studies.

- Structural Optimization in Early Discovery
- Pharmacokinetic Studies in Rodents, Dogs & NHP
- In Vitro ADME (Discovery & Development)
- Non-GLP Bioanalytical Studies
- Radiolabel Studies (including Mass Balance)
- Metabolite Identification/Profiling

BIOANALYTICAL

EXPERTISE. *It's how you get from the molecule to the market.*

Frontage's experienced staff and state-of-the-art instrumentation delivers data you can trust. We have extensive experience in analysis of small molecules, therapeutic proteins, antibodies, vaccines, and oligonucleotides. Frontage provides

you with a full range of bioanalytical solutions to support the entire drug development program - preclinical, clinical, TK/PK and BE studies. We have expertise in antibody drug, antibody drug conjugates (ADC), and biomarker analysis using various platforms.

We have validated more than 1,500 proprietary and non-proprietary methods and the annual throughput of more than 500,000 samples analyzed in regulated GLP settings. Our senior scientists average 10-15 years in complex method development and validation. The majority of our scientific teams hold advanced degrees.

- Global Bioanalytical Services (60+ LC-MS/MS systems)
- Preclinical & Clinical Support (TK, PK, & BE studies)
- Biologics Assay (proteins, antibodies, vaccines, ADC, etc.)
- Biomarker Services
- Bioanalysis of Oligonucleotides

OVER 70%
OF OUR SCIENTISTS
HOLD ADVANCED
DEGREES

FRONTAGE FACT: *Frontage has an unparalleled compliance and quality track record with 29 FDA inspections across GXP*

PARTNERSHIP >

It's what turns services into solutions.



CMC (CHEMISTRY, MANUFACTURING, AND CONTROL)

QUALITY. *It's how you get from formulation to the pharmacy.*

With an outstanding compliance history, the CMC team at Frontage operates under strict adherence to ICH and US FDA GMP guidelines. Our facilities and processes undergo routine audits and inspections from sponsors and regulatory authorities.

Frontage's CMC portfolio of services spans the entire drug product development of oral solids, topical, and sterile, from proof-of-concept, preclinical through clinical trials, and commercialization support. We have extensive experience in formulation development, analytical method development and validation, technical transfer, and clinical trial materials (CTM) manufacturing, as well as commercial product release and stability testing for US, EU and Asian markets.

- Analytical Method Development/Validation & Sample Testing
- Formulation Development for IND, NDA & ANDA
- GMP Manufacturing of CTM (Oral Solids, Topical, Sterile)
- Commercial Product Release & Stability Testing

WE HAVE AN UNPARALLELED COMPLIANCE AND QUALITY TRACK RECORD

CLINICAL

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

With over 20 years of experience, Frontage's early phase clinical research team has set new standards for rapid study start-up and execution. We have a wide range of subject populations which allows us to recruit your study faster.

Our broad expertise with diverse study types, including first-in-human, SAD/MAD, BA/BE, DDI and first to file ensure optimized design and expedited study conduct. Our project management team has experience in the execution of complex trials with novel compounds and delivery systems as well as management of multicenter studies for hard-to-fill panels.

Our complete suite of clinical services is enhanced by EDC which ensures efficient capture of data for quick delivery of clinical reports.

- Multiple Clinical Centers in US & China with over 600 beds globally
- Complete suite of services from start-up to delivery of study reports
- Easy access to Frontage laboratory services, such as CMC & Bioanalysis
- Diverse expertise in study types, administration routes & disease areas

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

BIOMETRICS

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

Frontage's biometrics team, processes, infrastructure and training are built on industry-leading standards. Our team specializes in providing high quality, comprehensive data management (EDC and SDTM), biostatistics, and SAS programming services.

We work closely with clients to design, assemble and manage customized project teams in any phase and therapeutic area on a regular or 'as-needed' basis. Combining the critical expertise and the can-do attitudes of our employees, we can meet any challenge in biostatistics and SAS programming.

CREATIVELY DELIVER MULTIPLE SOLUTIONS IN BIOSTATISTICS AND SAS PROGRAMMING

- Expert & Project Level Statistics Support
- SAS Programming Support
- EDC & Data Management
- Preclinical to Phase IV Development Support
- CDISC-Compliant Datasets & e-Submission Packages



FOR MORE INFORMATION,

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OR VISIT US AT:

frontagelab.com