

Accelerate your IND with Frontage's ALL-in-ONE suite of services



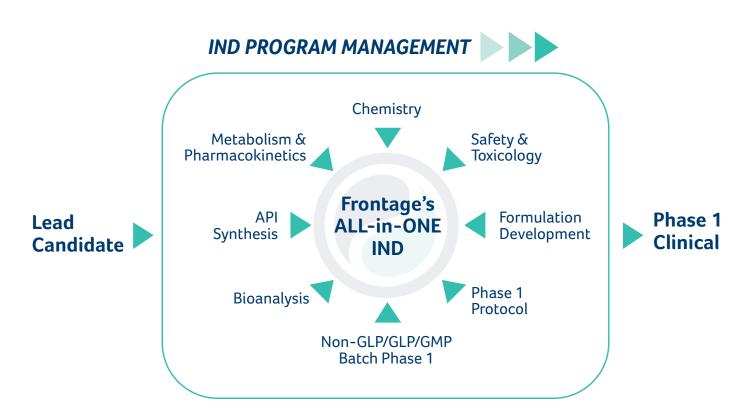
Frontage Laboratories' IND Enabling Services

The right services, the right size, the right solution for every phase of your program.

Managing an Investigational New Drug (IND) program and submission is a daunting task, requiring extensive planning and ongoing coordination of multiple scientific disciplines, each interrelated and reliant upon the other to achieve each successive milestone.

Relying on multiple vendors, each undertaking a portion of the program, can contribute further complexity to an already complex initiative and introduce increased risk of errors and delays.

At Frontage, we simplify the effort and reduce the risk by offering all of the critical IND-enabling services required to bring your lead candidate to Phase 1 in an organization sized to minimize complexity and maximize communication – **ALL-in-ONE**.

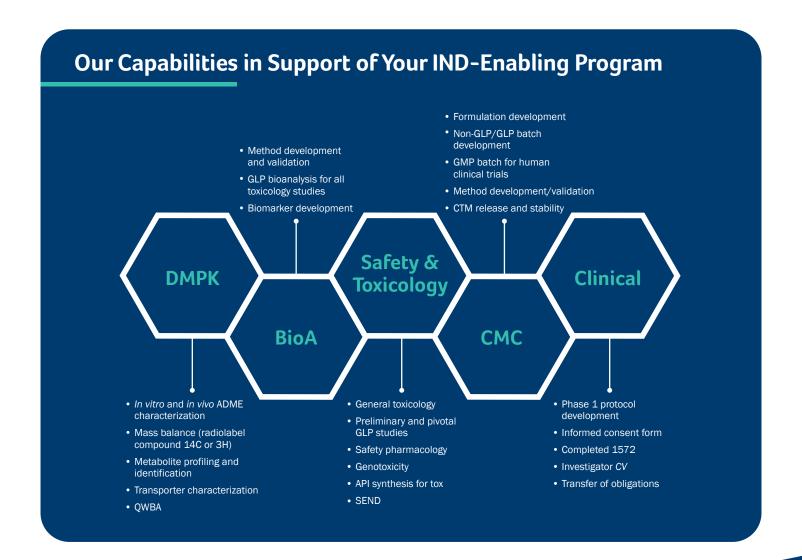




The Right Services

At Frontage, we offer a complete range of services to move from lead candidate selection to first-in-human. By providing the right comprehensive end-to-end services, we can accelerate your IND program. Consolidating your studies with Frontage provides the benefit of consistent quality, enhanced efficiency, and optimal cross functional communications, **ALL-in-ONE**.

Our range of IND-enabling capabilities includes API synthesis, Formulation development, Drug Metabolism and Pharmacokinetics, Safety and Toxicology, Bioanalysis, Chemistry, Manufacturing and Controls (CMC), non-GLP/GLP/GMP batch production, Phase 1 protocol development, and more.





The Right Size

At Frontage, we believe that effective communication underlies the success of everything we do, and as a mid-size CRO, we are the right size to ensure we are always focused on our customers and their needs. Timely, consistent and clear communication, both internally and with our customers, is essential to ensuring successful outcomes.

Our optimal size gives our project managers the advantage of being able to work more closely with our experts, and yours, to effectively coordinate all aspects of your program and guide your projects along the drug development timeline – **ALL-in-ONE**.

Regardless of your program size, our dedicated project leaders will work closely with your team to ensure your project gets the attention to detail and support it deserves.





The Right Solutions

We recognize that every client has unique and specific needs. The Frontage team of qualified project managers, study directors and scientists work on a coordinated basis to listen to you and to make sure that your expectations are clearly understood. Whether you have CNS, oncology, metabolic or other therapeutic programs, the Frontage team has the experience and resources to assist you in developing a solution that will meet your needs.

Our **ALL-in-ONE** suite of IND-supporting services, coupled with our right-size organization, ensures nimbleness of response that can take months off a typical IND timeline. That is what having the right services and being the right size is all about.

Whether you are a small start-up or a larger pharmaceutical client, we have the expertise and capability to customize a program to move your IND program from start to finish.

Typical ALL-in-ONE IND-Enabling Program

| DMPK | In Vitro Stability Studies | In Vitro Metabolism Studies | Reaction Ph | nenotyping | | |
|-------------------|---|---|-------------|------------------------------------|-------------------------------|---|
| | | Blood-to-Plasma Ratio | CYP Inhibit | ion/Induction | Protein Binding | |
| | Pharmacokinetics and In Vivo Metabolism in Preclinical Species | | | | | Rat Mass Balance & Route of Excretion |
| BioA | Method Development and Validation | | | | | |
| | Bioanalytical Testing for TK | | | | | |
| Safety and Tox | Dose Range-Finding / MTD Pivotal Tox: Rodent and Non-Rodent - GLP | | | | | |
| | | AMES Assay | | | Toxicokinetics Determinations | |
| | Formulation Analysis | Safety Pharm – in vivo & in vitro - GLP | | | | |
| | Formulation Homogeneity and Stability End-of-Tox Ch | | | | End-of-Tox Chara | acterization |
| | | Micronucleus Assays | | | SEND Dataset Preparation | |
| СМС | Non-GLP/GLP Batches for Animal | Preformulation & Formulation Develo | pment | GMP CTM B Human Pha | | PDR: DP Composition, Process, Labeling and Packaging |
| | Dosing Sample Analysis | Test Method Developme Validation | | Prototype, Demo Batch Stability | | CTM Batch Release & Stability |



Highlights of Frontage's IND Expertise

- Comprehensive end-to-end services ALL-in-ONE
 - Scientific expertise
 - Enhanced efficiency
 - Effective cross-functional communications
- Optimal size allows for effective coordination of qualified project managers, study directors and scientists
 - Team of multiple scientific disciplines with over 100 PhDs
- Over 500 IND-supporting studies in past 2 years
- Accelerated IND timeline via integrated program management
- Flexibility to customize programs

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

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