



FIRST-IN-HUMAN SOLUTION

for small and large molecules



ALTASCIENCES
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YOUR DRUG DEVELOPMENT PARTNER

Altasciences has decades of experience designing, conducting, and reporting on first-in-human (FIH) clinical trials. Small or large molecules, simple or complex trials, we have the expertise, purpose-built facilities, and seamless processes to deliver quality with speed and ease. Benefit from our customized approach, including clinical pharmacology units and integrated, state-of-the-art bioanalytical laboratories in the U.S. and Canada.



CLINICAL FACILITY

Los Angeles, CA

[▶ Video site tour](#)

**PRECLINICAL AND
BIOANALYTICAL FACILITY**
Seattle, WA

**PRECLINICAL AND
BIOANALYTICAL
FACILITY**
Columbia, MO

UNIQUELY ORGANIZED FOR EARLY PHASE

With [clinical pharmacology units](#) in the U.S. and Canada, we offer you two regulatory pathways (IND or CTA). The clinics' flexible formats can be configured to the specific requirements of your program. This includes specialized areas for intense monitoring and procedures, secure facilities with Schedule I licensing, and in-house pharmacies with compounding and full investigational product (IP) drug preparation capabilities. Comfortable, efficient, and well-equipped for long or short stays, our clinics are staffed by experts working with a fully integrated eDC system to ensure participant safety, and the accurate, timely collection of your data.

▶ [Experience the difference](#)

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CLINICAL FACILITY
Montreal, Canada

▶ [Video site tour](#)

**BIOANALYSIS AND
RESEARCH SERVICES**
Laval, Canada

PRECLINICAL FACILITY
Scranton, PA

CDMO FACILITY
Philadelphia, PA



CLINICAL FACILITY
Kansas City, KS

▶ [Video site tour](#)

Our operations and organization focus on early phase drug development, so your FIH trial will never compete for resources with larger, later phase trials. We will help move your molecule through to proof of concept, providing support for preclinical, clinical, bioanalytical, and manufacturing processes, to give your program maximum momentum. Beyond proof of concept, you can continue to benefit from our specialized assessments, scaled-up manufacturing, bioanalytical laboratories, and the full array of research support services.

Your FIH project is managed by a cross-functional team, including **dedicated project management** and **centralized scheduling** that ensures you hit your critical milestones.



With seamless processes running between the clinic and the bioanalytical lab, co-housing your data enables easy, transparent communication between teams and locations, and strict attention to early phase timelines.

SETTING YOU UP FOR SUCCESS

Entering human clinical trials requires planning and preparation of all the critical moving parts, so that your trial starts off on the right foot.

SCIENTIFIC AND REGULATORY CONSULTING

Our unparalleled team of [scientific, regulatory and medical writing experts](#) is at your disposal. Whether for a single study or a full program, our team is ready to help you with writing your Investigator's Brochure (IB), pre-IND meetings and preparation, briefing books, IND filing, CTA preparation, study design guidance, and protocol writing. This comprehensive support, through Altasciences or in collaboration with your regulatory team, enables FIH readiness and accelerates study start-up.



PARALLEL PROCESSING

We expedite the start of your FIH trial by initiating certain elements of study start-up while your IND/CTA is undergoing regulatory review. Once the review period is complete and your study is cleared for start from the relevant governmental bodies, your clinic activities can begin immediately.

Our complementary and integrated services add value and ease to the start of your human clinical trials.

Manufacturing

Our clinic-ready, small molecule manufacturing experts quickly formulate your drug product and deliver it to the clinical site, ready for dosing. Seamless integration of processes between the CDMO and the clinic, including shared methods and transparent exchange of data, ensures that your small molecule FIH trial kicks off on time, and meets its milestones throughout. If needed, certain types of dosage or formulation changes can be handled on the fly.



Bioanalysis

Our state-of-the-art [bioanalytical labs](#) are equipped for all your small molecule and biologic FIH trial needs. We have a large, dedicated, method development team to handle de novo method development, or transfer of existing methods, to get your clinical study started without delay.

Combining trial conduct and bioanalysis with Altasciences delivers significant benefits:

- Timed interim sample analysis for dose escalation decisions
- Rapid turnaround of PK/PD analysis between cohorts
- Biomarker development and validation for exploratory or primary endpoints
- On-site flow cytometry
- Centralized scheduling between clinic and lab
- Single point of contact with a dedicated program manager for streamlined communication



Study Conduct Specialty

We have conducted more than 400 FIH trials at our clinics since 2010, and are conducting 30 per year across our locations. Adaptive designs that allow for changes based on analysis of human data collected during the trial are easily accommodated by leveraging our integrated clinical conduct, bioanalytical, and manufacturing capabilities.

Our three- to four-week database build time allows for go-live before screening begins, so that data is captured in real time from day one.



400+

FIH trials

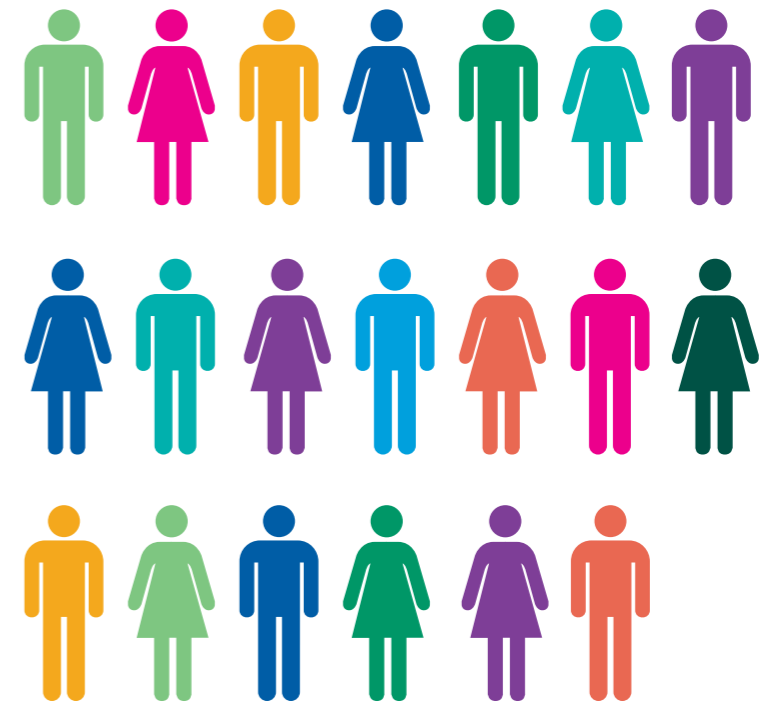
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30

trials per year

Recruitment and Retention

Our participant database contains comprehensive profiles of over 400,000 volunteers from healthy normal and patient populations, and we benefit from relationships with nearby hospitals and medical facilities for additional access to patients and special populations.



Dedicated Study Team

We treat your FIH program as our own. Your dedicated cross-functional study team will handle every aspect of your trial, including managing any third-party vendors involved. The team is focused on your success, scheduling activities so that your safety and bioanalytical data is ready for dose escalation meetings, and all study decisions are data-driven. Leveraging our proprietary scheduling system, and custom-designed information sharing platforms, our teams are always aligned around your goals and critical milestones.

Specialized Evaluations

Depending on the therapeutic area of your molecule, and the related regulatory requirements, we offer in-house expertise to conduct targeted evaluations:

- CNS Center of Excellence
 - Driving simulation (10 in-house simulators, 13,000 drives conducted)
 - Human abuse potential and abuse-deterrent formulation expertise
 - Physical dependency
 - Factor 8 analysis
 - Cognitive impairment analysis
 - Pain scales
- Cardiac safety - early and thorough QT analysis
- Ophthalmics
- Pulmonary function tests
- Imaging
- CSF collection
- PBMC collection and separation
- Asian/non-Asian ethnobridging
- Renal and hepatic Impairment



PUTTING PARTICIPANT SAFETY FIRST

Our safety procedures are rigorous, and our operations and facilities are designed to ensure that participant safety is a primary objective in every trial.

- Feasibility/risk assessment – from receipt of first requirements until study completion
- Investigator assesses subjects daily
- 24/7 Advanced Cardiac Life Support (ACLS) provider coverage on-site
- Basic Cardiac Life Support certification for all clinical staff
- Crash carts on-site
- Scenario-based response training
- Telemetry with pulse oximetry
- Strategically placed panic buttons
- Proximity to major hospitals




WE DELIVER ON OUR PROMISE

In addition to integrated, comprehensive core FIH trial services, we support your trials with on-staff, complementary [research support](#) expertise (available as full-time equivalent [FTE] or per project) in:

- Protocol development
- Clinical trial monitoring
- Data management
- Biostatistics
- Medical writing and reporting
- Archiving

The processes and systems we have built to maximize communication and efficiency ensure that your project stays on track, without roadblocks or bottlenecks. Relevant data from each process, each stage, is stored in a central database so that learnings carry through from service to service; preclinical research to manufacturing, clinical trials and bioanalysis. Everyone involved in your study has access to the all the necessary information, in realtime.

A vibrant, celebratory scene featuring four individuals. In the center, a woman with long blonde hair and round sunglasses blows a stream of colorful confetti towards the camera. To her right, another woman with dark hair and sunglasses also blows confetti. In the background, a man with a wide smile and a black hat looks on. On the far left, a woman with dark hair is partially visible. The background is a bright, sunlit outdoor setting, possibly a beach or festival, with a blurred crowd and buildings. The overall atmosphere is one of joy and achievement.

IMAGINE the benefits of a dedicated early phase drug development company at your side, handling all the facets of your project from end to end.

At Altasciences, we do more than imagine... **WE DELIVER.**

ABOUT ALTASCIENCES

[Altasciences](#) is a forward-thinking, mid-size contract research organization offering pharmaceutical and biotechnology companies a proven, flexible approach to [preclinical](#) and [clinical pharmacology](#) studies, including [formulation, manufacturing, and analytical services](#). For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include [preclinical safety testing](#), [clinical pharmacology and proof of concept](#), [bioanalysis](#), [program management](#), medical writing, biostatistics, [clinical monitoring](#), and data management, all customizable to specific sponsor requirements.

Altasciences helps sponsors get better drugs to the people who need them, faster.



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