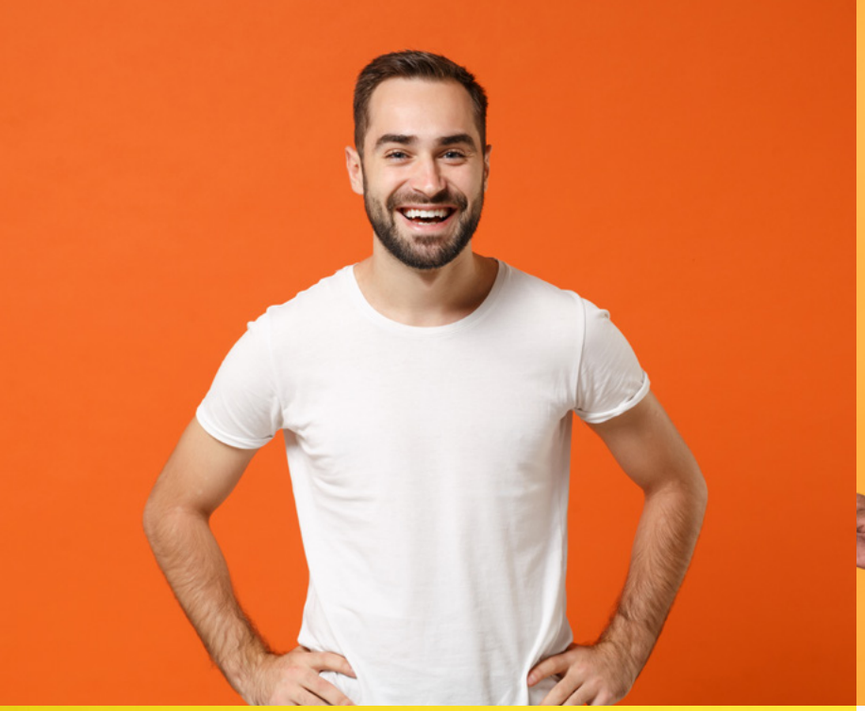

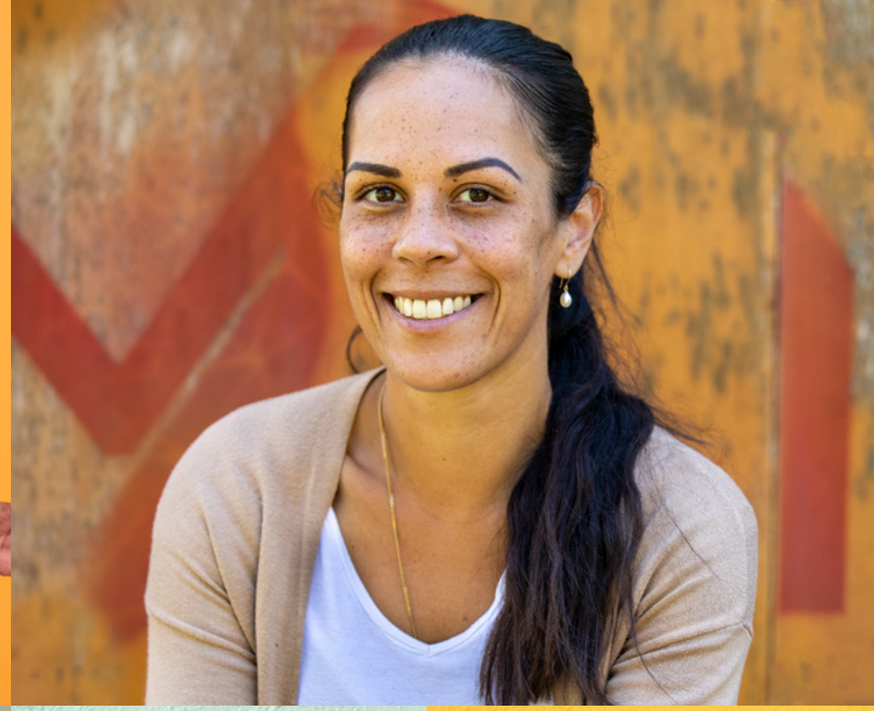


FIRST-IN-HUMAN SOLUTION

for small and large molecules

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Listen to a recording of this eBook

YOUR DRUG DEVELOPMENT PARTNER

Benefit from our customized and integrated approach, which includes a range of services, from nonclinical research to clinical pharmacology, in-house bioanalysis and data management, to biostatistics and regulatory guidance—with a team of medical writers to deliver reports for submissions.

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.

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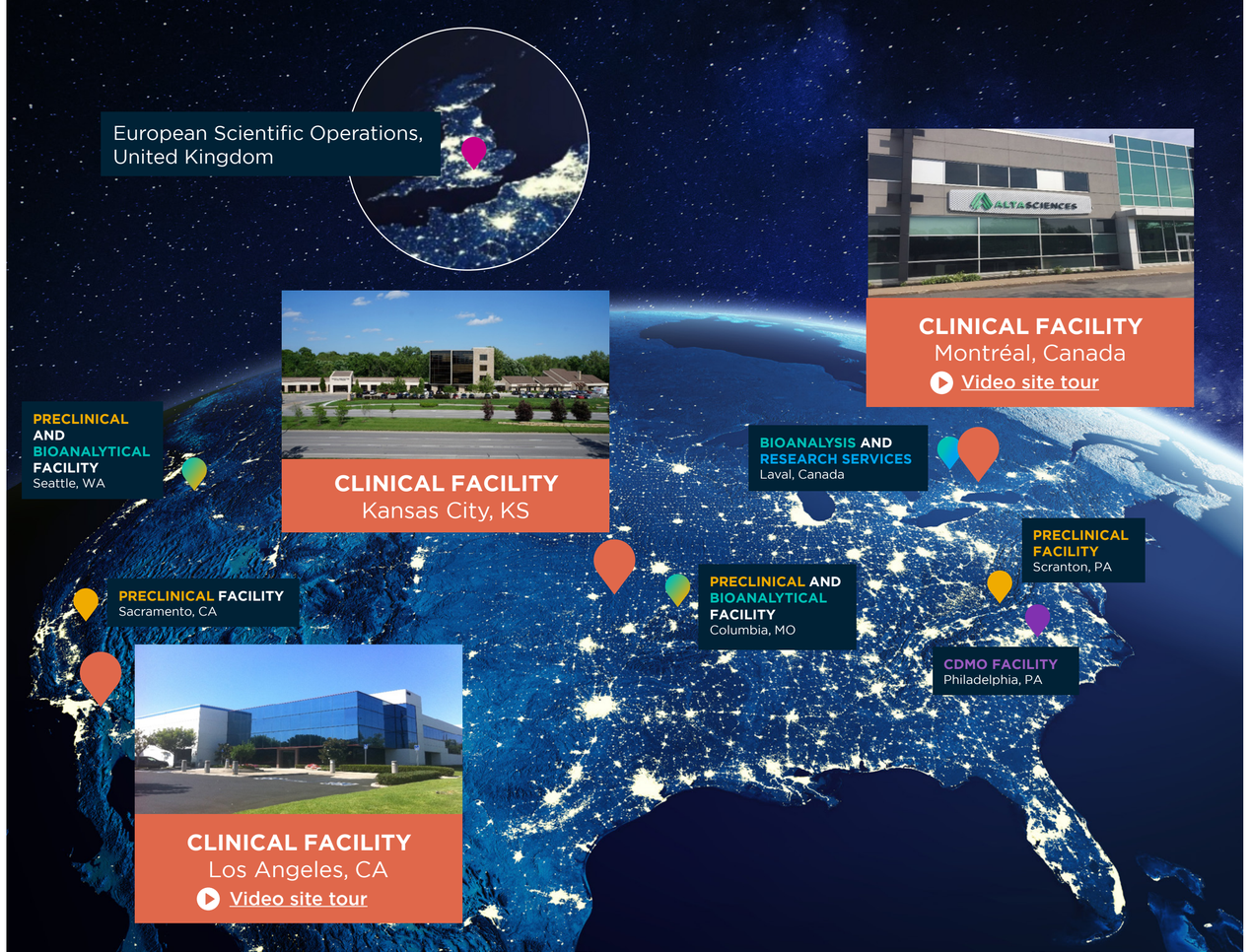

UNIQUELY ORGANIZED FOR EARLY PHASE

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 Electronic Data Capture (EDC) system to ensure participant safety, and the accurate, timely collection of your data.

Experience the difference

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 CRO 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 automated processes, data analysis and reporting are seamless, allowing for transparent and proactive communication between teams and sites, and strict attention to early-phase timelines for rapid dose escalation.

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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 preparation and meeting support, 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.

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PARALLEL PROCESSES

We expedite the start of your FIH trial by initiating planning elements of study startup, even while your preclinical IND/CTA is undergoing regulatory review. Once the review period is complete and your study is cleared for start from the relevant regulatory agencies, your clinic activities can begin immediately.

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

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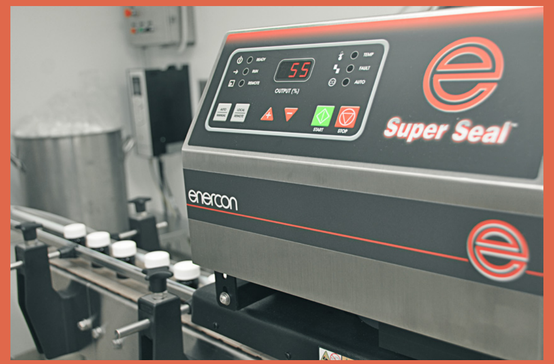
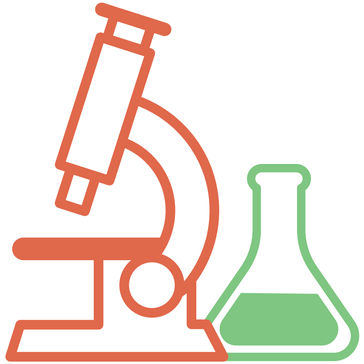
Manufacturing

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, 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 upon request.



Bioanalysis

We have state-of-the-art bioanalytical labs, staffed with the mass spectrometry and ligand binding experts for all your small molecule and large molecule FIH trial needs. We provide *de novo* method development, or transfer of existing methods, to get your clinical study started without delay.



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;
- flow cytometry assessments are available at the co-located lab;
- centralized scheduling between clinic and lab;
- single point of contact with a dedicated project manager for streamlined communication;
- validation and sample analysis; and
- sample shipment logistics expertise, ensuring sample stability.

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Study Conduct

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 our integrated team's analysis of data collected during the trial are easily accommodated by leveraging our integrated clinical conduct, bioanalytical, and manufacturing capabilities.

Using our ClinSpark® platform as both an EDC and a Case Report Form (CRF), we offer real-time error-proofing, data cleaning, rapid query management, instantaneous data review by monitors and sponsors, and improved safety monitoring capabilities.

400+ FIH trials | **30** trials per year

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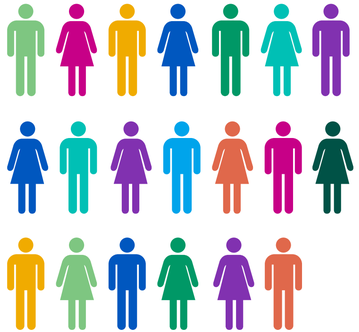
Recruitment and Retention

Our database contains comprehensive profiles of over 400,000 study participants, including healthy normal volunteers, special populations, and patients populations. To supplement our patient access, we partner with specialty sites, local hospitals, and medical facilities. Our in-house participant recruitment finds the best qualified participants for your clinical trial.



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.

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Specialized Evaluations

We offer in-house expertise to conduct targeted evaluations and analysis.

- CNS Center of Excellence
  - Driving simulation (12 in-house simulators, 13,000 drives conducted)
  - Human abuse potential (HAP) and abuse-deterrent formulation expertise
  - Physical dependency
  - 8-Factor analysis
  - Cognitive impairment analysis
  - Pain models
- Cardiac safety—early and thorough QT analysis
- Ophthalmics
- Pulmonary function tests
- Imaging
- CSF collection
- PBMC collection and separation
- Psychedelic research
- Endoscopies
- Biopsies
- Specialty biomarkers

Immunomodulation

- Flow cytometry
- Biomarkers
- ELISpot
- Immunogenicity
- Cell culture
- PBMC isolation
- PK and PD analyses

Study Participant Populations

- Healthy normal volunteers (HNVs)
- Senior citizens
- Asian/Non-Asian for ethnobridging
- Overweight and obese
- Renal and hepatic impairment
- Other special and patient populations

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PUTTING PARTICIPANT SAFETY FIRST

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

- Feasibility/risk assessment—from receipt of first requirements until study completion
- Daily investigator assessment
- 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

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WE DELIVER
ON OUR PROMISE

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

- protocol development
- clinical trial monitoring
- data management
- biostatistics
- medical writing and reporting
- statistical programming
- PK/PD data analysis

The processes and systems we have built to maximize communication and efficiency ensure that your project stays on track, without roadblocks or bottlenecks. Relevant information 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 real time.

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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 30 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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contact@altasciences.com