Over 25 Years of Clinical Research Excellence
With facilities in both the US and Canada, Altasciences Clinical Research offers comprehensive Phase I/II drug development, including all required support services.

We offer quality solutions to pharmaceutical, biotechnology and generic drug companies across the world, with a focus on customer service.

We continuously look for ways to improve our relationships and range of services, to create an environment that provides value for our customers, respect for our volunteers and growth for our employees.

Phase I/II

Bioequivalence

505(b)(2)

Bioanalysis

Clinical Support Services
Clinical Facilities

- Over 600 beds in North America
- Healthy normal volunteer and patient population trials
- Rapid recruitment and study start-up with a combined database of over 225,000 volunteers
- Exceptional retention rates in studies with both long and short-term confinement
Clinical Trials Customized to Individual Project Needs

- Protocol Development/Medical Writing
- Regulatory Services
- Clinical Conduct
- Bioanalysis
- Data Management
- Biostatistics
- PK and PD Analysis
- Project Management
**Bioanalysis**
- Preclinical to Phase IV support
- High throughput bioassays for drug quantitation (operating 24/7), capacity of 60,000 samples/month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

**PK and PD Analysis**
- Robust non-compartmental analysis using WinNonlin® v6 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

**Biostatistics**
- Appendices (TFLs) for CSR
- Reconciliation of external data (e.g. safety lab)
- Creation of CDISC compliant FDA submission-ready package
- Data cleaning
- CDISC mapping for legacy data

**Data Management**
- Medrio eClinical EDC
- CDISC standards fully integrated
- Database lock available within 2 to 4 weeks of last subject’s final visit
Volunteer Relationship Management

For effective matching of study requirements to volunteer medical profiles

- Screening facilities with direct access to public transportation
- Proactive and study-focused recruitment strategy through multiple media channels
- Extensive screening histories maintained for effective recruitment
- Facilities designed for optimum recruitment and retention
- Proven ability to meet recruitment milestones

Combined database of over 225,000 volunteers
Self-Serve Volunteer Portal

Volunteers can:

- Update their profiles
- View studies suggested for them
- Book appointments and view study calendars
- Communicate with the recruitment team
- Give live screening feedback
Early Development Trials in Healthy Normal Volunteers and Special Populations

- Human Abuse Liability and Substance Abuse
- Renal/Hepatic Impairment
- Biosimilars
- Adaptive Study Design
- First-in-Human
- 505(b)(2)
- Proof-of-Concept
- Driving Simulation
- Cognitive Testing

- Single Ascending Dose
- Multiple Ascending Dose
- Food Effect
- Early Cardiac Safety Assessment
- Thorough QT
- Dose-Ranging and Tolerability
- Drug-Drug Interaction
- Pharmacokinetics/Pharmacodynamics
- Bioavailability/Bioequivalence
We Meet Your Timelines

Our clinical pharmacology units are known for the rapid recruitment of healthy normal volunteers and patient populations as well as fast study start-up timelines which are unmatched in the industry.

We have extensive expertise in early clinical pharmacology trials and the experienced team for successful execution. At Altasciences we believe that sound planning is the cornerstone of a successful clinical trial. To that end, we map the study activities carefully to eliminate potential challenges.
Areas of Expertise

- Adaptive designs involving healthy and patient cohorts
- Multiple routes of administration including oral, sublingual, subcutaneous, intramuscular, infusion, inhalation, intranasal, transdermal, intra-articular, vaginal and rectal
Specialized Areas of Expertise

Human Abuse Liability

• An industry leader in the conduct of substance abuse clinical trials including opioids (oral and nasal snorting), sedative hypnotics and stimulants
• Awarded a 5-year, $10-million contract with the National Institute on Drug Abuse to conduct clinical pharmacology studies to support the development of new medications for the treatment of substance abuse disorders
• Access to a large database of substance abusers and recreational drug users for rapid study enrollment and start-up

Early Cardiac Safety Assessment

• Experienced using High Precision QT Analysis to allow TQT-like statistical power in early phase clinical trials
• De-risking drug candidates by providing a more precise indicator of arrhythmia liability prior to late state development thus saving sponsors considerable time and money
• Member of the Cardiac Safety Research Consortium (CSRC) participating with industry leaders on key issues impacting cardiac safety
Cognitive Testing

- Extensive experience in the design and execution of driving simulation studies to evaluate the effects of psychoactive and non-psychoactive drugs on the ability to operate a motor vehicle as detailed in the FDA’s guidance titled Evaluating Drug Effects on the Ability to Operate a Motor Vehicle
- Highly trained staff use electronic Visual Analog Scales (eVAS) to provide automated outcome measures on CNS trials
- eVAS iPad format has rapid set-up and utilizes 21 Part 11 compliant software

Biosimilars

- Develop effective plans and execution strategies for biosimilar trials which require a customized approach based on the therapeutic indication and study-specific goals
- Well-versed in the conduct of diverse complex clinical pharmacology trials in healthy normal volunteers and patient populations with biologics and biosimilars
- Flexible in adapting to the continuously evolving international guidelines such as the immunogenicity requirements for Phase I biosimilar trials
A Process That Works

Study Design
- Protocols, communication plans and contributing ICH reports all meet sponsor specifications
- Projects are tailored to each molecule based on non-clinical and clinical data, as well as sponsor priorities

Study Team
- Principal Investigator leads a team of experienced healthcare professionals
- Study Manager coordinates activities at the clinical sites
- Scientific Project Manager oversees complete program conduct and deliverables

Sponsor Milestones
- Accelerated reporting timelines are available with customized software for scheduling and study milestone monitoring
- Key Performance Indicators ensure timelines are consistently met i.e. Recruitment, Study Conduct and Reporting
Our partnerships with local hospitals increase access to patient populations in key therapeutic areas, providing an extended network of clinical research experience.

We partner with preclinical facilities to provide our clients with a single coordinated team throughout the drug development process, from lead candidate selection to early stage clinical trials.

We minimize delays and time lost during the transition from non-clinical to clinical development.

We partner with Imagix, a radiology practice next to our Montreal clinic, that offers MRI, DEXA, X-ray and ultrasound. We routinely incorporate imaging into Clinical Pharmacology studies.

Industry leader in the conduct of substance abuse clinical trials through relationships that include Cambridge Cognition (e-VAS) as well as consulting partners for protocol development such as Altreos.

As a certified member of the Cardiac Safety Research Consortium (CSRC) we participate with industry leaders on key issues that impact cardiovascular safety, including alternative approaches to ICH E14 for the assessment of arrhythmia liability in early drug development.

We have partnered with Cognitive Research Corporation to provide sponsors with a state-of-the-art driving simulators to test drug-impaired driving. We have also partnered with Cambridge Cognition on a variety of cognitive tests that can be applied to any Clinical Pharmacology study, starting at First-in-Human.
Our Commitment to Safety

- 24/7 Advanced Cardiac Life Support (ACLS) provider coverage on-site
- All clinical staff are Basic Cardiac Life Support certified
- Subjects are assessed daily by an Investigator
- Crash carts available on-site
- Scenario-based response training
- Telemetry with pulse oximetry
- Strategically placed panic buttons
- 24/7 video surveillance/controlled access throughout the facility
- Close proximity to major hospitals
Full-time, Dedicated Research Physicians

Full-time, dedicated research physicians oversee all aspects of clinical trials to ensure that medical and technical procedures are completed to the highest standard of quality, from subject recruitment to subject discharge.
Quality Service
Every Step of the Way

Our expertise, access to both healthy normal volunteers and an extensive spectrum of special populations combined with high quality data have been fundamental in the award of 5-year contracts with both the U.S. Food and Drug Administration and the National Institute on Drug Abuse.

Experienced quality assurance team oversees:

- SOP management
- Regulatory audits
- Sponsor audits
- GCP/GLP data audits
- On-site inspections
- Supplier audits
- GLP accreditation
Quality Assurance

- In-house QA/QC teams ensure trials are conducted per protocol and within ICH/GCP guidelines
- Comprehensive SOPs and employee training records
- Strong foundation in ICH/GCP/CFR
- Real-time Quality Control for all study processes
- Significant company resources invested in QA/QC

Exemplary Regulatory History

All studies are conducted to the highest level of safety and compliance. In addition to sponsor audits we regularly host successful regulatory inspections from agencies such as the FDA, Health Canada, ANVISA, ANSM, MHRA, AGES, AEMPS and SCC.
2017 CRO Leadership Awards Recipient
“We are honored to have been recognized as a leader in the CRO industry. Our mission has always been to provide the highest quality early stage clinical development solutions, while exceeding our customers’ expectations with personalized and timely service. These awards recognize and validate the efforts our employees put in on a daily basis to achieve our goals. I am extremely proud of our team.”

Chris Perkin  
Chief Executive Officer  
Altasciences Clinical Research