MOVING IN
UNISON
OUR EXPERTISE AT A GLANCE

Altasciences is a forward-thinking, mid-size, early phase contract research organization with a unique company focus on supporting drug development from lead candidate selection to proof of concept. With over 25 years of industry experience, we provide preclinical and clinical solutions to an international customer base of biopharmaceutical companies.

All our services encompass both large and small molecules, and are fully compliant with global regulatory requirements.

Altasciences’ full-service offering includes program management, preclinical safety testing, clinical pharmacology services, medical writing, biostatistics, data management, and bioanalysis services; all tailored to your specific research requirements.
PRECLINICAL DRUG DEVELOPMENT

With Altasciences as your partner, you can plan for phase I/II studies at the outset, ensuring a smooth transition from preclinical to First-in-Human (FiH) studies.

We have an AAALAC-accredited, USA-registered purpose-built facility, with OLAW Assurance and BSL-2 certification, which is fully compliant with FDA, OECD, and GLP requirements.

Altasciences’ solution offering includes IND/NDA-enabling toxicology, safety pharmacology, and laboratory services. Our team of scientists and technicians has been conducting toxicology studies for decades, and is committed to working as an extension of our clients, moving in unison, going above and beyond to meet your critical milestones.
OVERVIEW OF OUR PRECLINICAL FACILITY

Altasciences offers a full range of *in vivo* GLP and non-GLP preclinical evaluation studies in both rodent and non-rodent species. Our purpose-built facilities are designed to support efficiencies and standardized workflows to thoroughly assess the safety of your molecule.

**210,000-sq.-ft. purpose-built facility**

- Over 250 highly skilled team members
- Barrier facilities for NHPs, dogs, mini pigs, and rodents
- Conducts hundreds of NHP studies per year
- Client-dedicated NHP colonies
- 140 custom-designed animal rooms, including European housing
- Archive facility and services on site
PRECLINICAL SERVICES

Toxicology Services

- Lead Optimization
- General Toxicology (acute, sub-chronic, chronic)
- Safety Pharmacology (CNS, cardiovascular, respiratory)
- Immunotoxicology/Immune Function
- Pharmacokinetics (PK)
- Pharmacodynamics (PD)

Radiation Biology

- Total Body
- Partial Body
- Lung
- Cutaneous
- Gastrointestinal

Routes of Administration

- Oral (gavage, capsule, diet)
- Parenteral (intravenous bolus, subcutaneous, intramuscular, intraperitoneal, intrathecal, intra-articular)
- Infusion
- Ocular
- Intranasal
- Intradermal, topical
- Rectal
- Intravaginal
Species
- Rodents (rats, mice)
- Guinea pigs
- Rabbits
- Dogs
- Non-human primates (cynomolgus, rhesus, others upon request)
- Mini-pigs
- Swine

In-House Supporting Capabilities
- Anatomic pathology
- Clinical pathology
- Immunohistochemistry
- Specialized necropsies
- Analytical biology
- Analytical chemistry
- Formulation
- Bioanalysis
- PK/TK data analysis
- SEND
- Archiving
Our preclinical staff is fully trained in laboratory animal care. Led by our Chief Animal Welfare Officer, our team is committed to the highest standards in animal welfare. We are focused on environmental enrichment, and understand the importance of compassion, sensitivity, and adherence to regulatory guidelines.

Our methodologies, procedures, and equipment are refined to decrease stress on the animals, improve workflows for technicians, and ensure the success of your study. As part of our C.A.R.E. program, we are committed to the 3Rs (replacement, reduction and refinement).
Unique Handling, Animal Care, and Housing:

- AAALAC accreditation
- Passive restraint NHP procedure cages
- EU-compliant group housing for NHPs
- Mini-pig habitat caging configured to allow for snout-to-snout interactions
- Comprehensive environmental and animal enrichment program
- Consistent healthcare, welfare, and enrichment from point of origin to final destination
- Dedicated animal enrichment staff and NHP behaviorist

**ANIMAL WELFARE COUNCIL**

is made up of veterinarians, scientists, and members from the community

**C.A.R.E.**

a contract signed by every employee to iterate their commitment to prioritizing the humane care of animals used in research

**USE OF HUMANE ENDPOINTS**

to minimize pain and discomfort

**VETERINARIAN COMMITTEE**

for decision making in difficult euthanasia situations
Altasciences’ clinical experts are at the ready when needed. Using your preclinical data and with a comprehensive understanding of your needs, we develop a clinical study design, take care of the trial conduct, and produce the relevant reports — efficiently, effectively, and on time. Each year, we successfully complete hundreds of clinical trials to proof of concept, in a wide range of therapeutic areas.

We have clinical locations in the U.S. and Canada, with 600 beds and a database of 365,000 participants (healthy normal and patient populations). We can also access a wide range of additional patient populations through relationships with local hospitals. Regardless of participant type or length of stay, our recruitment and retention rates are excellent, with 95% on-time panels, year after year.
Our clinical services include expertise in:

• First in Human
  - Single Ascending Dose (SAD)
  - Multiple Ascending Dose (MAD)
• Proof of Concept
• Bioavailability (BA)/Bioequivalence (BE)
  - Food Effect  – Gender Effect
  - Age Effect  – PK/PD
• PK in Special Populations
• Drug-Drug Interaction (DDI)
• Bridging Studies
• Comparative Bioavailability/PK Studies
• 505(b)(2)

Specialties include, but are not limited to:

• Biologics/Biosimilars
• Infectious Diseases
• Human Abuse Potential (HAP) with New Chemical Entities and Abuse-Deterrent Formulations (ADF)
• Substance Use Disorders
• Metabolism and Endocrinology
  - NAFLD/NASH
  - Type I and II Diabetes
  - Obesity
• Renal and Hepatic Impaired
• Pain Models and Inflammation
• Topical Vasoconstrictor/Irritation-Sensitization
• Cognitive Testing
• Driving Simulation
• Imaging
• QT Assessment
• Smoking/Vaping
• Cannabis
PARTICIPANT RELATIONSHIP MANAGEMENT

We have a combined database of over 365,000 participants and systems in place that effectively match study requirements to participant medical profiles. We offer rapid recruitment and study start-up while ensuring participant retention throughout the trial.

- Full-time, in-house recruiting staff
- Screening facilities with direct access to public transportation
- Proactive and study-focused recruitment strategies using multiple media channels
- Extensive screening histories for effective recruitment
- Facilities designed for optimum recruitment and retention
- Proven ability to meet recruitment milestones
CLINICAL TRIAL POPULATIONS

Participant and Special Populations
• Healthy Normal Volunteers (HNVs)
• Elderly
• Overweight and Obese
• Pediatric/Adolescent
• Post-Menopausal Women
• Substance Abusers and Recreational Drug Users
• Smokers

Patient Populations
• Allergy
• Asthma
• ADHD
• Atopic Dermatitis
• Anxiety Disorders
• Binge Eating Disorder
• COPD
• Constipation
• Diabetes
• Dyslipidemia
• Epilepsy
• Fibromyalgia
• GERD
• Gout
• Glaucoma
• Hepatitis
• Hypercholesterolemia
• Hypertension
• Lupus
• Major Depressive Disorder
• Migraine
• Osteoarthritis
• Osteopenia
• Overactive Bladder
• Pain and Inflammation
• Panic Disorder
• Premenstrual Dysphoric Disorder
• Psoriasis
• Restless Legs Syndrome
• Sleep Disorders

Others upon request
We have state-of-the-art, purpose-built laboratories at our locations in the U.S. and Canada, with designated containment Level 2 areas for work with Risk Group 2 pathogens. Staffed by highly-skilled analysts, and shifts running 24/7 (as needed), we can process over 60,000 study samples per month.

Responsive and flexible, our team of over 100 bioanalytical subject matter experts is there for you, throughout all stages of your drug development pathway. Following clear processes, in accordance with GLP and current FDA/EMA guidelines, and supported by our unique array of platforms and large list of validated assays, our team ensures the most effective methods for your individual programs.
**BIOANALYSIS**

*From Discovery to Preclinical to Phase IV — Method Development, Validation, and Sample Analysis*

Experience with a wide spectrum of biological matrices in both animal species and humans, including serum, plasma, blood, urine, feces, tissues, cerebrospinal fluid, and vitreous humor.

**Small and Large Molecule Capabilities**

**Small Molecules**
- Extensive in-house database of over 620 assays covering 600 molecules
- Customized, unique solutions in derivatization, chiral separation, drug stabilization, and multiple metabolite quantitation
- State-of-the-art instrumentation to achieve low quantitation with limited sample volume
- Certain small molecules are suitable for our state-of-the-art ligand binding platforms

**Large Molecules**
- We evaluate each request and provide customized workflows to allow accurate platform selection by hybrid LC-MS or ligand binding.
- Our experienced and dedicated research and development scientists develop validation-ready assays, customized to your needs, using advanced instrumentation.
LC-MS/MS

Capabilities supported by:
- Over 34 LC-MS/MS instruments, including Sciex 5000, 5500, 6500+, and Selexion with Nexera UHPLCs
- HRMS including the Sciex 6600, and ThermoFisher Q-Exactive
- Micro-flow and nano-flow capabilities for the front end of our HRMS systems

Ligand Binding

Our ligand binding group is equipped with:
- Mesoscale S600 Electrochemiluminescence sector imager
- BioTek Synergy H4 Multimode Plate Reader using absorbance, fluorescence, or luminescence
- Luminex 200 system
- Simoa HD-1 analyzer
- BioTek EL406 microplate washer/dispenser
- BD Biosciences FACSCanto™ II cytometer
- SpeedVac for tissue extraction
- Percellys® Evolution homogenizer
- Droplet Digital PCR and qPCR analysis

Quantitative analysis using LC-MS/MS

- Experience with monoclonal antibodies, antibody-drug conjugates, and proteins (intact and peptide quantification)
- Automated immunoaffinity sample preparation producing high-throughput assays with impressive sensitivity
- Biomarkers and endogenous analytes
- Labile metabolite quantitation
- Industry experts supporting Microsampling (Mitra® VAMS and dried blood spots) for preclinical and clinical programs

Our ligand binding assay types:
- Immunogenicity
  - ADA (screening, confirmatory, and titration)
  - nAb by non-cell based and cell-based assays
- Quantification methods using various platforms
- Hybridization ELISA/ECLIA of various types (ligation, dual hybridization)
- Functional cell-based assays
- Antibody response (TDAR)
- Biomarkers
- Cell lineage and functional immunophenotyping by flow cytometry
- PCR analysis
COMPREHENSIVE FULL-SERVICE OFFERING

Altasciences offers a full support service model to complement our preclinical, clinical and bioanalytical offerings:

- Bioanalysis
- Protocol Development
- Project Management
- Data Management
- Biostatistics
- Analytical Chemistry
- Pharmacokinetics/Pharmacodynamics
- Toxicokinetics
- Anatomic Pathology
- Clinical Pathology
- Reporting
- SEND
- CDISC
- Archiving
- Scientific, Regulatory and Strategic Guidance
FOCUSED ON QUALITY EVERY STEP OF THE WAY

All studies are conducted with 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.

We provide:

• QA leadership, with over 20 years of experience

• RQAP-GLP Registered Auditors Team actively involved in the U.S. and Canadian regulatory QA community (SQA, PRCSQA, CCSQA)

• Harmonized QA approach

• In-house QA teams to ensure trials are conducted per protocol and within ICH/GCP/CFR guidelines

• Comprehensive SOPs and employee training records

Our QA team oversees:

• SOP management

• Regulatory audits

• Sponsor audits

• GCP/GLP data audits

• On-site inspections

• Supplier audits

• GLP accreditation

• On-site GLP-compliant archiving
OUR COMMITMENT TO SAFETY

- Full-time, dedicated research physicians oversee all aspects of clinical trials
- Daily participant assessment by an Investigator
- Staff certified in Advanced Cardiac Life Support (ACLS) on-site 24/7
- All clinical staff are certified in Basic Cardiac Life Support
- 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
INTEGRATED SOLUTION

Altasciences offers a simplified pathway for full drug development programs. Our outsourcing platform enables you to work with a single, integrated partner from lead candidate selection to proof of concept. Our Program Managers are the single point of contact for a comprehensive, full-service package designed to minimize hand-offs, resulting in shorter timelines and reduced costs. Our mantra is: Tell us once™.
Our unique structure leverages the extensive preclinical and clinical background of our executive management team and scientists, supporting a truly integrated end-to-end solution, from lead candidate selection to proof of concept. Our scientific team will work closely with you to design the most efficient preclinical or clinical studies that meet all regulatory requirements. Our goal is to make the process seamless for you as you move from one milestone to the next.
WHY ALTASCIENTES?

TRUST
You can trust the quality of our data, the expertise of our staff, and the strength of our commitments.

TELL US ONCE™
Is our proactive sharing of your preferences, product information and study results across all Altasciences’ teams. You should never have to waste time repeating yourself.

SIZE AND SPEND DON’T MATTER
Every client matters. Whether you place one study or multiple programs, we ensure that each client feels equally important, and knows that we are committed to making their project a success.

WE HAVE YOUR BACK
We believe in transparency, responsiveness, and the importance of being dependable and honest. We treat our clients like colleagues and their projects as our own.

SCIENTIFIC AND OPERATIONAL EXPERTISE
We apply our scientific and operational expertise to ensuring that we deliver the highest quality, customized services in the most efficient manner, for each individual program. We have what it takes to move your molecule from preclinical to proof of concept in one integrated process.
OUR WORK SPEAKS FOR ITSELF

“It was easy to work with them and they were always willing to take the time to discuss any concerns and respond to questions.”

Marie-Francoise Temam, Associate Director, Clinical Operations

Idenix, a wholly-owned subsidiary of Merck & Company

We have been very pleased with their record of timely recruitment, including ensuring an inventory of back-up study participants.”

Hélène Dulude, B.Pharm., Ph.D., Director, Clinical Development

Locemia Solutions ULC

“I recommend this site because of the expertise and quality of trials performed.”

Okba Haj-Ali Saflo, Clinical Research Scientist

Chemo Group

“...the communication between our teams was optimal, from the first protocol draft to the delivery of the final report.”

Maxime Ranger, President and CEO

glcare pharma inc

[Altasciences] is an important partner in our development efforts and we recommend them for any ligand-binding requirements.”

Bryan Tayefeh, Assistant Director, Alliance Management

Ionis Pharmaceuticals, Inc.
Altasciences — a mid-size, full-service CRO that delivers big impact with a personal touch, from lead candidate selection to proof of concept.