

# MOVING IN UNISON



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## 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, comprehensive clinical pharmacology, medical writing, biostatistics, data management, and bioanalysis services; all tailored to your specific research requirements.





## PRECLINICAL FACILITY

Seattle, U.S.A



## CLINICAL FACILITY

Fargo, U.S.A



## BIOANALYSIS AND RESEARCH SERVICES

Laval, Canada



## CLINICAL FACILITY

Kansas City, U.S.A.



## CLINICAL FACILITY

Montreal, Canada





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## PRECLINICAL DRUG DEVELOPMENT

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.

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.

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.



## 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
- Conducts hundreds of NHP studies per year
- 140 custom-designed animal rooms, including European housing
- Barrier facilities for NHPs, dogs, mini pigs, and rodents
- Client-dedicated NHP colonies
- Archive facility and services on site

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# 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

- Rats
- Mice
- Guinea pigs
- Rabbits
- Mini-pigs
- Swine
- Dogs
- NHPs
  - Cynomolgus
    - Cambodian
    - Chinese
    - Vietnamese
    - Mauritian
  - Rhesus
    - Chinese

## In-House Supporting Capabilities

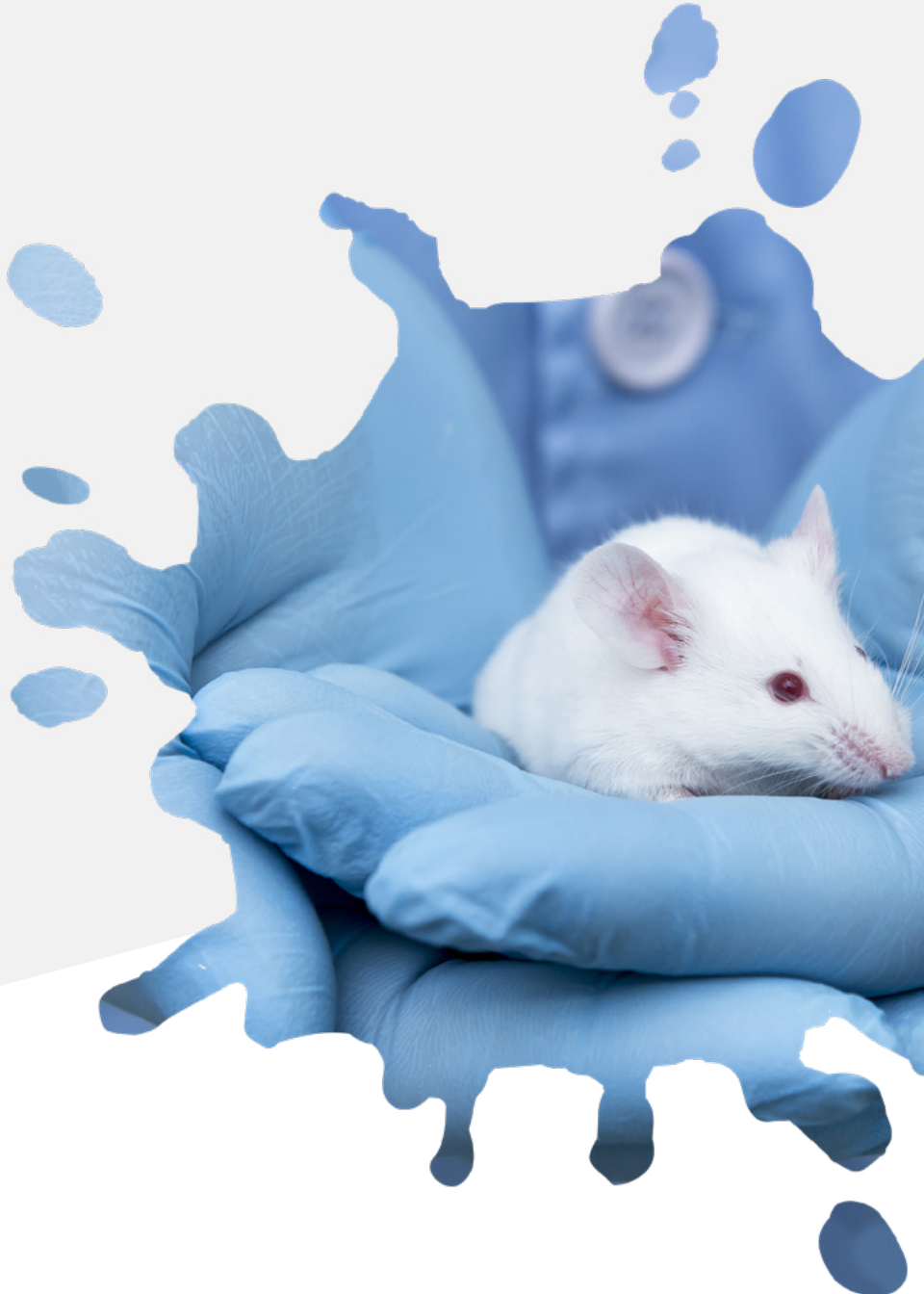
- Anatomic pathology
- Clinical pathology
- Immunohistochemistry
- Specialized necropsies
- Analytical biology
- Analytical chemistry
- Formulation
- Bioanalysis
- PK/TK data analysis
- SEND
- Archiving

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# OUR COMMITMENT TO ANIMAL WELFARE

Our preclinical staff, led by our Chief Animal Welfare Officer, is fully trained and committed to the highest standards in laboratory animal care. 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

### **USE OF HUMANE ENDPOINTS**

to minimize pain and discomfort

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

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

### **VETERINARIAN COMMITTEE**

for decision making in difficult euthanasia situations



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## CLINICAL SERVICES

For your early phase clinical studies, our experts in the design and conduct of clinical pharmacology and early efficacy studies ensure the data generated meets your objectives — working with you to leverage preclinical data in the design of the studies that take your programs through to proof of concept. Our expertise covers all the clinical pharmacology studies required for regulatory submissions across a wide range of therapeutic areas, covering small molecules, biologics, and 505(b)(2) or Hybrid applications.

With 25+ years of experience delivering clinical services, we conduct trials in state-of-the-art facilities in the U.S. and Canada, with 600 beds and a database of 365,000 (healthy normal and patient populations). 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**



## BIOANALYTICAL LABORATORY SERVICES

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, 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:**

- 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

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. We can support your entire program end to end, or you can partner with us for just one element — we offer you complete flexibility. 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™.



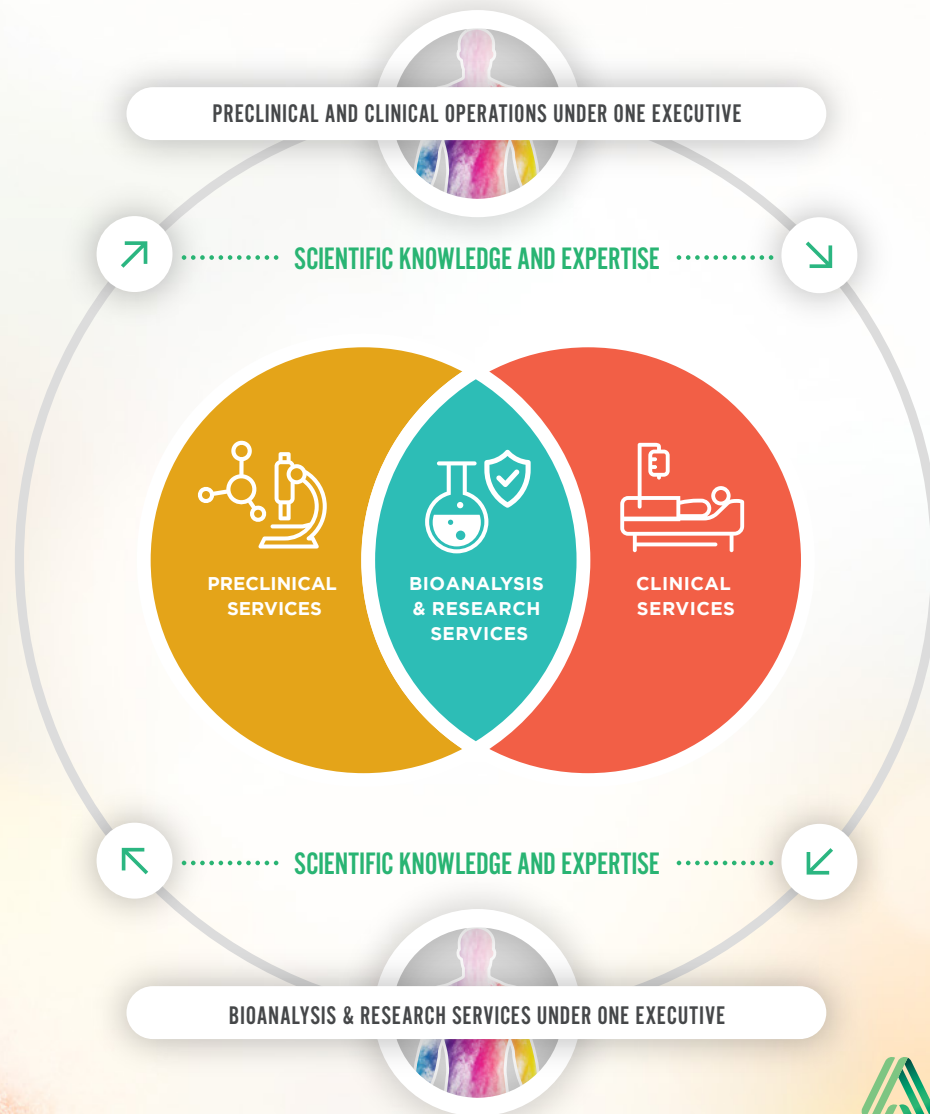


# OUR APPROACH

## Unique management structure under two executives:

- Operations — preclinical to clinical research
- Research Services — program management, bioanalysis, biostatistics, data management, regulatory, medical writing, etc.

We streamline processes and integrate into our clients' teams and their projects; we help them make educated, fast and more comprehensive early drug research decisions. Whether a single study or complete program, our goal is to simplify your drug development process with speed and ease. We work closely with you to design the most efficient preclinical or clinical studies that meet all regulatory requirements. We offer a flexible and customized approach for study start-up, design, and conduct, and an industry-leading Quality Management System that is consistently applied across all services.



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# WHY ALTASCIENCES?

## 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

“ *[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.**

“ *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**

“ *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**

“ *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**



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



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