



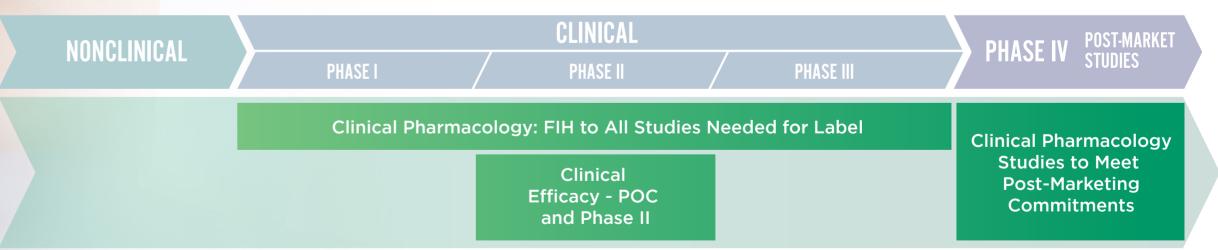
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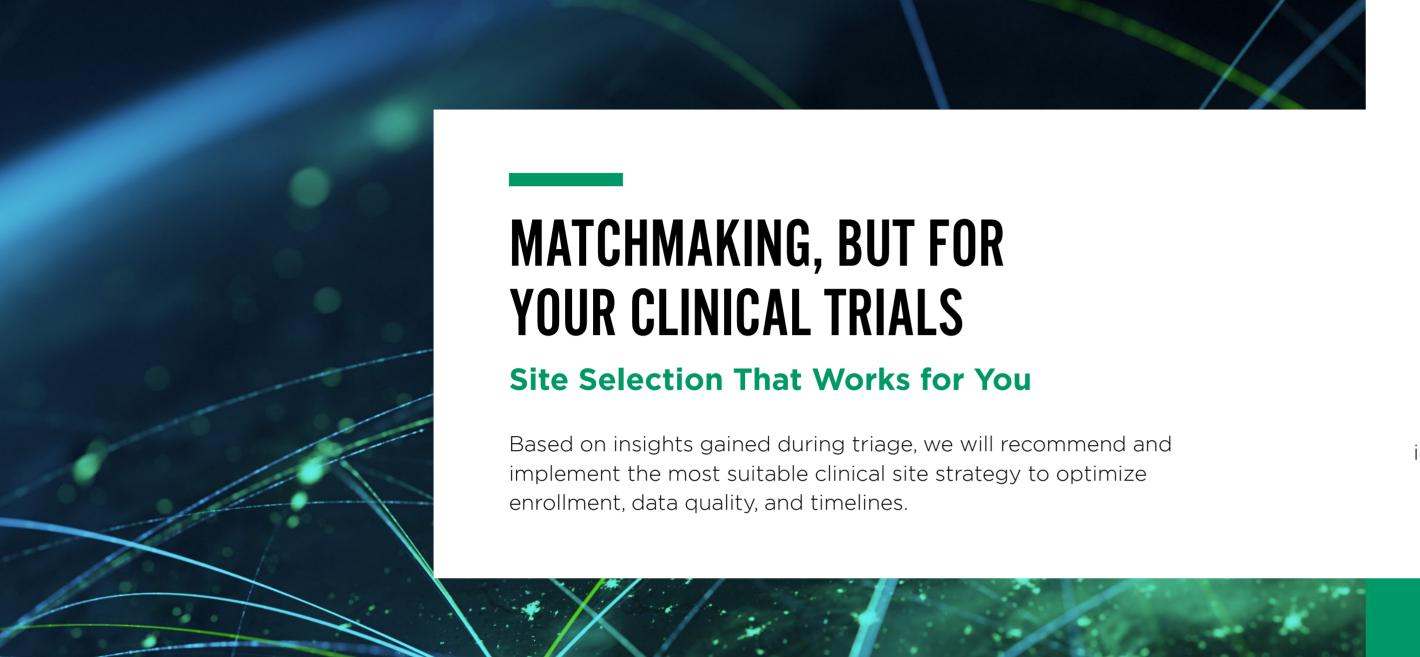
# BROADENING THE SCOPE OF YOUR CLINICAL RESEARCH

As clinical trials have evolved and become more complex, the need for diverse patient populations and flexibility in trial design has become increasingly essential. A one-size-fits-all design, bed capacity limitations, and the need to access specific patient populations should never restrict your program.

This is where our **Multi-site solution** comes in. With Altasciences, you have the option to utilize one or more of our three clinical sites, one or more of our external partner sites, or a combination of both, for a hybrid approach. We remove the barriers to common limitations, giving your clinical program almost endless possibilities.









#### **Altasciences' Clinical Sites**

Leveraging our state-of-the-art facilities and experienced staff, our clinical pharmacology units in Montréal, Los Angeles, and Kansas City offer controlled environments ideal for early-phase trials, intensive monitoring, and complex protocol deployment.



#### **External Partner Sites**

Our established network of trusted external clinical research sites broadens geographic reach and patient diversity, particularly beneficial for specialty populations and late-phase studies.



#### **Hybrid Models**

Combining the strengths of internal and external sites, hybrid trials enable flexible study designs, centralizing essential procedures within Altasciences' clinics while extending recruitment through external partners. This approach maximizes patient access without compromising oversight or data integrity.

# \_ DID YOU KNOW? \_\_\_\_

Altasciences has a global network of 350 + specialized investigational sites.



# HOW DOES A MULTI-SITE SOLUTION BENEFIT YOUR PROGRAM?

### **Accelerated Proof of Concept (POC) Trials**

By utilizing geographically diverse sites to targeted patient populations, reduce recruitment timelines with quicker and more efficient go/no-go decisions.

# Stronger Efficacy Data in Phase Ib/IIa

By accessing real-world patients through external or hybrid models, we can generate richer data representative of real and diverse communities. laying a solid foundation for late-phase trials and regulatory submissions.

### With Multi-site trials, you're no longer bound by:

- single-site patient pools
- site capacity bottlenecks
- geographic recruitment barriers

### With Altasciences, you gain:

- greater speed to start and speed to data
- a **fit-for-purpose** site strategy that aligns with your protocol
- the ability to **scale trials** efficiently as your pipeline grows
- expanded clinical capabilities without facility or equipment constraints to meet your Phase Ia, Ib, and Phase Il study requirements

Multi-site trials at Altasciences aren't just an operational choice; they're a strategic advantage that give you the flexibility, reach, and expertise to start your complex studies with precision and confidence.





# CONNECTING THE RIGHT PARTICIPANTS TO YOUR CLINICAL TRIALS

### **Expanded Patient Access**

Multi-site solutions can expand your trial beyond our in-house clinics to a strategic network of external sites across North America. This flexibility enables us to meet you where you are and, more importantly, where your patients are, for a more agile and tailored clinical trial experience.

With a multi-site solution, you will benefit from:

- increased flexibility in patient recruitment and geographic reach
- greater access to specialty populations that may not be available within Altasciences' internal clinical facilities

We can deliver comprehensive, scalable, and patient-focused solutions, which are especially critical for studies involving hepatic and renal impairment, CNS disorders, and dermatologic and ophthalmologic conditions.

# **Altasciences' Volunteer and Special Populations**

- Alzheimer's
- Asian/Ethnobridging
- Asthma (regular or allergy-induced)
- Atopic dermatitis/acne
- Cardiovascular (hypertension, high cholesterol, metabolic disorders)
- CNS disorders
- COPD
- COVID

- Depression and major depressive disorder (MDD)
- Dermatologic conditions
- Elderly
- Genotyped and biomarker-specific individuals
- Gout
- Healthy normal
- Hepatic impairment
- Metabolic-associated fatty liver disease (MAFLD)

- Metabolic dysfunction-associated steatohepatitis (MASH)
- Obesity
- Ophthalmologic conditions
- Pain (lower back, neuropathic, etc.)
- Post-menopausal individuals
- Recreational drug users
- Renal impairment



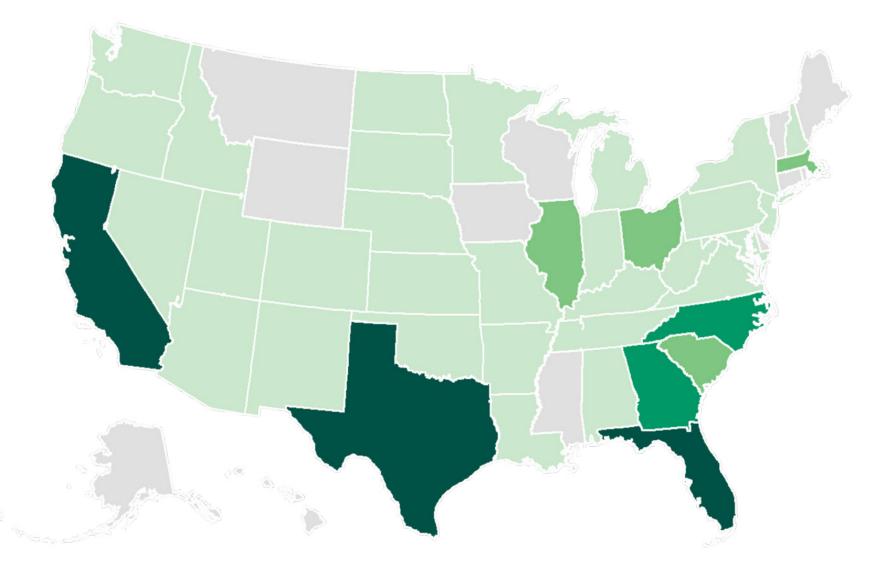
# **United States**

# **Extended Geographic and Demographic Reach**

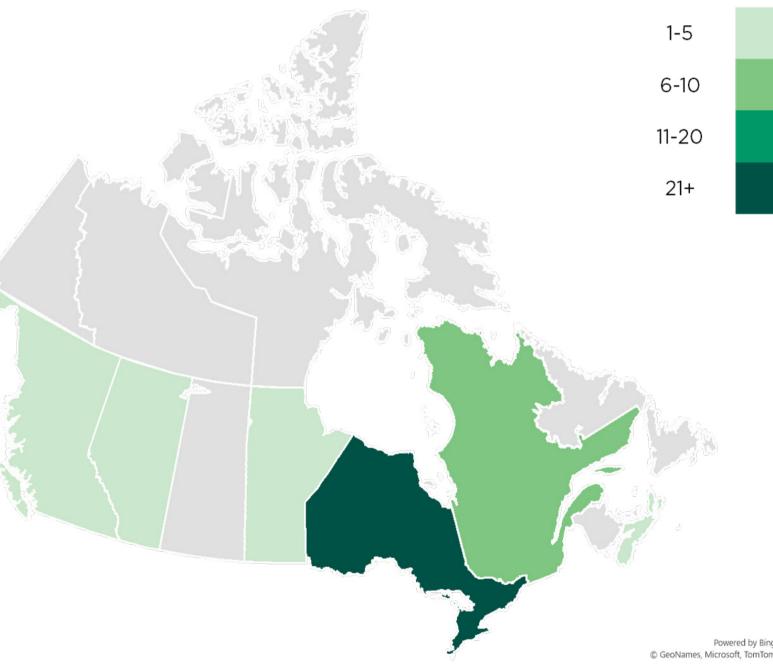
Your clinical trials often hinge on having access to the right patient population at the right time. With our ever-expanding network of **over 350 affiliate sites** across the United States and Canada, your program will benefit from a diverse and high-density population of participant groups for all-encompassing clinical trials.

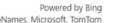
Multi-site trials allow us to go beyond the physical limits of our 585-bed clinical units, reaching patient populations that may otherwise be outside the reach of our own facilities—whether by geography, demographic, or indication.

Whether you're working on a targeted population or on an expedited timeline, our hybrid and external site capabilities help you move forward with confidence.



# Canada











# PLACING YOUR STUDY WHERE IT MAKES THE MOST SENSE

# **Strategic Site Identification**

Altasciences has over a decade of experience managing Multi-site trials across internal clinics and external partners. We continually expand our rigorously verified network of sites to ensure access to high qualifying facilities for a variety of therapeutic areas and trial phases.

All external sites undergo formal vendor qualification by our quality assurance team, and qualification by our clinical research associates (CRAs), maintaining the quality and compliance standards sponsors expect when they choose Altasciences.

case study insights ensure that Pre-vetted networks and of incoming studies already have a strong framework for site feasibility.

#### **Early Engagement and Collaboration**

Site identification and outreach begins at the proposal phase, ensuring ample lead time for site engagement, smooth start-up, and coordinated recruitment planning.

#### **Data-Driven Feasibility and Recruitment Planning**

To match your studies with the most suitable clinical pharmacology units, we look at therapeutic experience data, historical enrollment metrics, and site feedback. We conduct feasibility outreach assessments using customized forms and direct calls with partner sites to gather their insights on each study, and explore any potential issues or limitations they foresee. We can even typically draft and return a site plan within a few days. The insights gathered during this period help to shape study design and anticipate operational challenges—for more accurate proposals and project planning.

#### **Integrated Oversight for Complex Projects**

By combining in-house clinical know-how with external site capabilities, our hybrid model ensures there are no timeline gaps between phases. We handle it all: contracts, budgets, feasibility, and start-up. It's this kind of centralized oversight that ensures a seamless experience and minimizes risk to maximize efficiency as you move from first-in-human into Phase Ia and IIb clinical trials.

#### **Budget and Contract Negotiation**

We will prepare a site budget comparison for you and ensure smooth clinical trial agreement negotiations. Pre-established master clinical trial agreements with our top-tier strategic site partners guarantee expedited contracting.

# SITE QUALIFICATION TRIAGE AND FEASIBILITY

# **Smooth Study Start-Up**

Every new clinical program begins with a rigorous and structured evaluation process designed to identify the most efficient and effective path forward for your studies. We will ensure that your unique scientific and operational requirements are fully understood and met long before the first patient is enrolled.

As we evaluate the trial design, we simultaneously assess the investigational product's (IP) administration requirements, storage conditions, and safety profile. Guided by these factors, we ensure that the selected sites possess the necessary infrastructure to manage the program safely and in full compliance with country regulations.

For studies targeting specialized populations, we engage our external partners early on to develop effective, tailored recruitment strategies and assess feasibility at the outset, ensuring successful outcomes.

### **Our Triage Process**

## **IDENTIFICATION**

### **FEASIBILITY**

# PRE-SELECTION

# **SELECTION**

# CONTRACT AND STARTUP

We create a targeted list of potential sites by filtering our network based on study requirements. geographic location, therapeutic area and indication, and inpatient requirements. For trials involving rare or specialized populations, this step is critical to proactively identify

potential recruitment challenges.

Sites on the list receive a feasibility questionnaire and, if required, a budget request. Sites then provide information on clinic availability, enrollment projections, study design feedback, and supporting documentation.

responses are reviewed and audited to identify the most suitable candidates. This data is used to develop a recommended list of sites.

Recommendations be presented to you for approval. You may choose to be actively involved in the final site selection process or, if preferred, rely on our team's recommendation to provide well-informed decisions.

Selected sites are introduced to the contracts team and project/program manager to begin the start-up process and finalize agreements.

With Altasciences guiding your study feasibility, you can move from opportunity to study start-up, backed by strong data, a decade of expertise, and a dedicated team committed to your success.

### Our meticulous triage and feasibility process reduces risk and accelerates timelines by ensuring:

- early identification and mitigation of recruitment challenges
- selection of the most appropriate sites tailored to your protocol needs
- alignment of operational resources with trial complexity
- transparent communication and strategic collaboration from the very start



# THE POWER OF INTEGRATION: A MULTI-SITE SOLUTION THAT GOES BEYOND THE CLINIC

By partnering with Altasciences for a Multi-site study, your clinical trial will benefit from greater access to patient population pools with the added bonus of an integrated, cross-functional drug development team.

#### **Comprehensive Bioanalytical Support**

Expanded capacity for method development, validation, and sample analysis enables us to support a greater volume and range of studies. Each external site is provided with our customized sample collection kits to avoid sourcing and procurement delays, thereby ensuring accurate, efficient, and safe preparation, collection, and shipment of your clinical samples from the trial site to the lab.



**Discover our sample collection kits** 

#### **Seamless Preclinical Transitions**

Enjoy smooth handoffs and continuity across development phases. We ensure your program moves from preclinical to clinical without losing momentum or oversight.

#### **Centralized Project and/or Program Management**

Multi-site doesn't mean more complexity. An Altasciences program manager will serve as the main point of contact, coordinating internal teams and external sites to keep your study on time and on budget, managing timelines, vendors, and patient enrollment from Phase Ib to Ila.

#### **Medical Writing and Regulatory Affairs**

We can tailor all your documentation to meet any regional or country-specific site requirements, ensuring regulatory compliance and avoiding delays.

#### **Adaptive Data Services**

Larger, more diverse trials generate more data, and we're built for it. We use multiple industry-leading electronic data capture (EDC) technologies suited to your requirements-providing customized solutions and real-time access to data, for faster decisions while emphasizing patient safety.

#### **Precise Clinical and Medical Monitoring**

Our experienced CRAs provide exceptional monitoring across all study sites, regardless of location or number of sites. Our CRAs ensure compliance with GCP and your study protocol, safeguard patient safety, and maintain data integrity from site qualification to closeout, to meet the demands of complex, data-rich studies.

Additionally, our medical monitoring team provides continuous physician oversight throughout your trial, reviewing safety data, assessing adverse events, and offering medical guidance to ensure participant well-being, adherence to protocols, and the preservation of the scientific integrity of your study.

Multi-site trials are designed to reduce complexity and expand possibilities, giving you peace of mind that every phase of your trial is fully aligned, regardless of how many sites are in use for your program.



# LET'S GET STARTED

At Altasciences, we will help you find the right solution for your clinical development needs. We will leverage our internal capabilities with those of our trusted external network to empower you to take on complex or specialized studies with the flexibility, speed, and efficiency needed to move forward without compromise.

From reviewing patient population access to feasibility recommendations, you will benefit from a responsive team, a proven model, and a clinical partner committed to helping you reduce risk, accelerate timelines, and bring innovative therapies to those in need, faster.

**Contact us today** to get started on your Multi-site clinical program.

# ADDITIONAL RESOURCES

### **Fact Sheets**

- Clinical Trial Site Selection and Management
- Clinical Solutions for Early-Phase Drug Development
- Special and Patient Populations

#### Video

• Site Identification, Selection, and Management

#### **Webinars and Podcasts**

- Strategic Site Identification: A Proven Approach
- A Fork in the Road: Assessing Diversity in Early-Phase Clinical Trials
- Ethnobridging in Phase I Clinical Trials

### **Case Study**

• Streamlining Clinical Trial Start-up for Accelerated Drug Development



# **ABOUT ALTASCIENCES**

Altasciences is a forward-thinking, mid-size contract research organisation 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.

We help sponsors get better drugs to the people who need them, faster.

**CONTACT US** 

**LEARN MORE** 







