



ALTASCIENCES

# FIRST IN HUMAN (FIH) A CRITICAL MILESTONE

Our experts in the design and conduct of first-in-human studies work closely with you to meet your objectives and milestones. We ensure participant safety with stringent risk mitigation plans, customized based on molecule target and available data.

## EXPERIENCE

- **30 FIH studies** per year
- Over **360 FIH studies** performed since 2010

## EXPERTISE

- Small molecules
- Biologics
- Most dosage forms
- Higher risk novel targets

## AGILITY

- **Adaptive design** – experience with design and conduct
- **Fast turnaround** of data for dose escalation decisions, while ensuring safety is a priority

## PARTICIPANTS

- Combined database of **400,000 participants**
  - Healthy normal
  - Patients
  - Special populations
- **Rapid recruitment** of full panels – even with weekly escalations
- **Excellent retention rates** for studies with short or long stays

## RESEARCH SERVICES

- We expertly translate your **preclinical data** into clinical trial design and conduct
- **Full support service model** to complement clinical offerings from protocol design to CSR delivery (see details on reverse)

### A Full-Service CRO

We have 25+ years of experience conducting clinical pharmacology trials in state-of-the-art facilities across North America. Our expertise meets the needs of essentially any early phase study for regulatory submission, across a wide range of therapeutic areas, on behalf of clients of any size. Every client is important to us.

**580+**  
beds

**285+**  
clinical studies  
annually

# COMPREHENSIVE FULL-SERVICE OFFERING

- Manufacturing Services
- Analytical Services
- Regulatory Support
- Clinical Monitoring
- Bioanalysis for Small and Large Molecules
- Program Management
- Project Management
- Protocol Development and Medical Writing
- Scientific Publication Writing
- PK/PD Data Analysis and Interpretation
- Data Management
- Biostatistics
- Support Services for Nonclinical Studies



Altasciences offers a simplified pathway for full drug development programs so you can work with a single, integrated partner from lead candidate selection, to preclinical testing to proof of concept, and beyond. We can support your entire program end to end, or you can partner with us for just one element — we offer you complete flexibility.