



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

- **65 FIH studies** designed and conducted in the last three years
- Over **360 FIH studies** performed since 2003

## 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 **350,000 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.

**500+**  
beds

**285+**  
clinical studies  
annually

# Comprehensive Full-Service Offering

## Manufacturing Services

### Product Development and Manufacturing Capabilities

- Formulation and development
- Process optimization
- GMP clinical supply manufacturing (Phases I-IV)
- Scale-up and engineering batch manufacturing
- Validation batch manufacturing
- Commercial batch manufacturing

### Dosage Type and Process Capabilities

- Liquid-filled hard shell capsules
- Capsule banding
- Powder blending
- Powder-filled capsules
- Over-encapsulation
- Injectable vial filling
- Solutions and suspensions
- Gels and creams
- Clinical packaging (bottles and blisters)
- Potent product handling
- Particle size reduction (wet/nano milling)

### Controlled Substance Manufacturing Capabilities

- DEA manufacturing license (Schedules I-V)

### Facility expansion capabilities, including dedicated space and equipment, as required to meet project demands

- Man-In-Plant
- Perform supplier audits

## Analytical Services

- Development and validation of critical methodologies
- Drug product release testing
- Stability testing
- Controlled substance testing

## Bioanalysis

- Team of more than 200 dedicated Scientists
- Can process over 60,000 study samples/month
- LC-MS/MS and ligand binding capabilities
- Extensive in-house database of over 620 assays covering 600 molecules
- Experience with method feasibility, transfer, development and validation in a wide spectrum of biological matrices in both animal species and humans
- Industry experts supporting Microsampling (Mitra® VAMS™ and dried blood spots) for preclinical and clinical programs
- Designated containment Level 2 (CL2) areas for work with Risk Group 2 (RG2) pathogens
- SCC GLP accredited
- Biomarker expertise that will provide fit-for-purpose results

## Program Management

- Program Manager oversees the complete program
- Extensive expertise in single or multiple site clinical trials

## Medical Writing

- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

## Pharmacokinetics (PK) and Pharmacodynamics (PD)

- Robust non-compartmental analysis using WinNonlin® v8 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

## Data Management

- Protocol review and planning
- Database build - average 4-6 weeks from final protocol to "go-live"
- Efficient eCRF setup and simple technical requirements

## Biostatistics

- Sample size estimations and randomizations schemes
- Statistical analysis plan with mock tables, figures and listings (TFLs)
- SAS® programming and validation of the results
- CDISC-compliant datasets and FDA submission-ready package

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