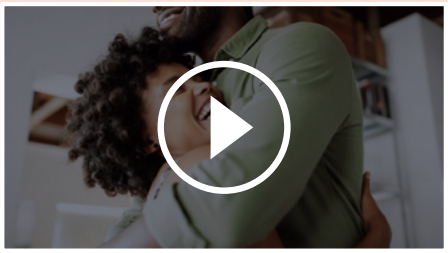
ALTASCIENCES
CLINICAL SERVICES

CLINICAL SOLUTIONS

FOR EARLY PHASE DRUG DEVELOPMENT

Expertise in all clinical pharmacology studies required for regulatory submission across a wide range of therapeutic areas



INDUSTRY EXCELLENCE AND EXPERIENCE

- **30+ years** of innovator and generic drug development
- Successful history of working with regulatory agencies internationally
- Multimillion-dollar, multi-year government contracts with the FDA and NIDA
- Multiple CRO Leadership **Awards** in numerous categories
- CEO recipient of PharmaVOICE Red Jacket lifetime award

580+ BEDS IN THE U.S.A. AND CANADA

- Upscale facilities to ensure optimal recruitment and retention rates, for short and long-term confinement
- On-time delivery of full participant panels and quick study start up

COMBINED DATABASE OF OVER 400,000 PARTICIPANTS

- With extensive screening histories
- Direct access to healthy normal, special, and patient populations
- Dedicated recruitment and outreach for Asian/non-Asian ethnobridging studies
- Additional patient access through partnerships with hospitals and management of independent investigational sites

CLINICAL SERVICES THAT MEET GLOBAL REGULATORY REQUIREMENTS

Full range of clinical pharmacology solutions:

- Adaptive, Integrated FIH (SAD/MAD)
- Asian/non-Asian Ethnobridging
- Biologics
- Biosimilars
- Cardiac Safety (EPQT/TQT)
- CNS Center of Excellence
- Cognition
- Comparative Bioavailability (BA) and bioequivalence (BE)
- Driving Simulation
- Drug-drug Interaction (DDI)
- Factor 8 Analysis
- Food, Age, Gender Effect
- Human Abuse Potential
- Metabolic Disorders
- Ophthalmology
- Pain
- Physical Dependency
- PK/PD (including large panels)
- POC in Patients and Special Populations
- Renal and Hepatic Impairment
- Topical/Transdermals

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Purpose-Built Facilities

- Secure pharmacies with video monitoring and retinal scanning, pharmacists experienced with narcotics and complex compounding
- Suite of **12 on-site driving simulators**, with space for 20 more
- Inhalation facilities, including negative pressure rooms with video monitoring
- Qualified staff and spaces for thorough and early QT studies
- Long-term stay facilities
- Outpatient and return units
- Dedicated participant screening facilities

Therapeutic Areas

- Abuse-Deterrent Formulations
- Cardiology
- Dermatology
- Gastroenterology
- Hematology
- Immunology
- Infectious Diseases
- Metabolism and Endocrinology
- Neurology
- Oncology
- Ophthalmology
- Orthopedics
- Psychiatry
- Respirology
- Rheumatology
- Substance Use Disorders
- Urology
- Women's Health

Multiple Routes of Administration

- Oral
- Parenteral (intravenous bolus, subcutaneous, intramuscular, intraperitoneal, intrathecal, intraarticular)
- Ocular
- Intranasal
- Intravaginal
- Sublingual
- Infusion
- Inhalation
- Topical
- Rectal

Exceptional Quality and Safety Standards

- Dedicated research physicians oversee all aspects of clinical trials to ensure that medical and technical procedures are completed to the highest standard of quality, from subject recruitment to subject discharge
- Full-time research pharmacists, highly skilled in extemporaneous and intravenous preparation, including biologics, work in a negative pressure, HEPA-filtered compounding room

Comprehensive Full-Service Offering

Available as stand-alone services, or as part of a development package:

- Manufacturing and Analytical Services for Small Molecules
- Scientific, Regulatory, and Strategic Guidance
- Protocol Development
- Project Management
- Bioanalysis (Small and Large Molecules)
- Data Management
- Biostatistics
- Reporting
- CDISC
- Archiving

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