Clinical Solutions for Early Phase Drug Development

ALTASCIENCES
CLINICAL SERVICES

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

INDUSTRY EXCELLENCE AND EXPERIENCE

- **25+ 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

400+ 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 345,000 PARTICIPANTS

- With extensive screening histories
- Direct access to healthy normal, special, and patient populations
- 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:

- First in Human
- Proof of Concept
- Relative Bioavailability
- PK/PD
- Cognitive Testing
- Drug-Drug Interaction
- Bioequivalence (NDA and ANDA)
- 505(b)(2)
- Biologics/Biosimilars
- Cannabis
- Driving Simulation
- Thorough QT
- Renal and Hepatic Impaired
- Drug-Alcohol Interaction
- Human Abuse Potential
- Physical Dependency

PURPOSE-BUILT FACILITIES

- Secure pharmacies with video monitoring and retinal scanning, pharmacists experienced with narcotics and complex compounding
- Suite of 10 on-site driving simulators
- 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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