ALTASCIENCES
CLINICAL SERVICES

TOPICAL CLINICAL TRIALS

Altasciences' Experience

- 25+ years of innovator and generic drug development
- Hundreds of studies completed
- Combined database of over 400,000 participants
- Experience with all marketed TDS products, including narcotics, CNS, hormonal, nicotine, and analgesics
- Fully versed on FIH, NDA, and ANDA study requirements for North America and Europe
- Recent experience of approximately 35 studies involving irritation, sensitization, adhesion, PK/PD (e.g. skin biopsies, various dermal response scales, and assessments), and safety, involving over 2,500 participants
- Local affiliations with dermatologists
- Phase I to proof of concept in atopic dermatitis

Clinical Experience

- PK/PD dermal devices/implants
- Adhesion
- Irritation and sensitization (HRIPT)
- Intranasal vasoconstriction
- Franz diffusion cell *in vitro* skin permeation
- Allergy testing
- Topical pain models, including cold pressor test (CPT) and electronic von Frey
- Iontophoresis (with lidocaine for pain)
- Microarray

Expertise

- Vast majority of products and system types:
  - Ointments, creams, gels, solutions/sprays
  - Transdermal systems, micro needle patches
  - Self-administration (pump) patches
  - NCEs, narcotics, analgesics, nicotine, CNS, corticosteroids, etc.
- Continual interface and input from industry experts
- Highly experienced visual readers with routine cross-validation of consistency
- High-precision adhesion assessment process
- Proprietary tools and ImageJ software to enhance the adhesion analysis process through computerized adhesion determination
- Multiple sites to meet FDA requirements of irritation and sensitization trials

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Altasciences' Clinical Solution

500+ 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

- 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 (HAP)
- Metabolic disorders
- Ophthalmology
- Pain
- Physical dependency
- PK/PD (including large panels)
- POC in patients and special populations
- Renal and hepatic impairment
- Topical/transdermals

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**, with space for 20 more
- Inhalation/insufflation 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

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 participant recruitment to participant 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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