

Topical Products

Altasciences' Experience

- Team with 25 years' experience
- Completed hundreds of studies
- Database of **225,000** volunteers
- Worked with the majority of topical products, including narcotics, CNS, hormonal, nicotine, etc.
- Fully versed on BE and NDA study requirements for North America and Europe
- Recent experience of approximately 25 studies involving adhesion, PK, safety, PD, irritation and sensitization, involving over **2000** subjects
- 15 topical vasoconstrictor studies involving over **550** subjects



Clinical Experience

- PK/PD Dermal Devices/Implants
- Adhesion
- Vasoconstrictor (Skin Blanching)
- Irritation and Sensitization (HRIPT)
- Intranasal Vasoconstriction
- Franz Cell in vivo drug transfer
- Allergy Testing
- Topical Pain Models
- Iontophoresis (with Lidocaine for Pain)
- Microarray
- Cosmetic Claims

Expertise

- Vast majority of products and system types:
 - ointments, creams, gels, solution/sprays
 - transdermal systems, micro needle patches, self-administration (pump) patches
 - NCEs, BE, narcotics, analgesics, nicotine, CNS, corticosteroids, etc.
- Continually guided by industry leaders
- 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 the requirements of irritation and sensitization trials

Support Services



Bioanalysis

- Our 20,000-sq.-ft. GLP-Compliant Bioanalytical Facility for Preclinical to Clinical Support
- High throughput bioassays for drug quantitation (operating 24/7) capacity of 60,000 samples per month
- Method feasibility, transfer, development and validations in multiple matrices
- LC-MS/MS and ligand binding assay capabilities

Medical Writing

- Team with over 20 years of experience
- Study design in line with updated regulations
- Clinical trial protocol development
- Protocol review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Scientific Project Manager (Project Leader) oversees the complete program conduct and deliverables from study protocol to reporting
- Extensive expertise in managing clinical trials across a wide range of therapeutic areas
- Close collaboration with key departments and external contractors to ensure seamless and timely communications for successful project completions

Pharmacokinetic (PK) Analysis

- Comprehensive Clinical PK and PD Data Analysis and Interpretation
- Robust non-compartmental analysis using WinNonlin® v6 (Phoenix)
- Rapid turnaround for interim PK evaluation between dose escalation cohorts
- Stand-alone report and/or CSR integration

Data Management

- Team with over 20 years of experience
- Medrio's eClinical EDC
- CDISC standards fully integrated in workflow
- Medical coding using latest versions of medical dictionaries (MedDRA, WHO-DDE)
- Database lock available typically within 2 to 4 weeks of last subject's final visit

Biostatistics

- All Programming done using SAS®
- Randomization list
- Statistical Analysis Plan, including mock TFLs
- Statistical results and appendices (TFLs) for CSR
- Reconciliation of external data e.g. safety lab
- Creation of CDISC-compliant FDA submission-ready package