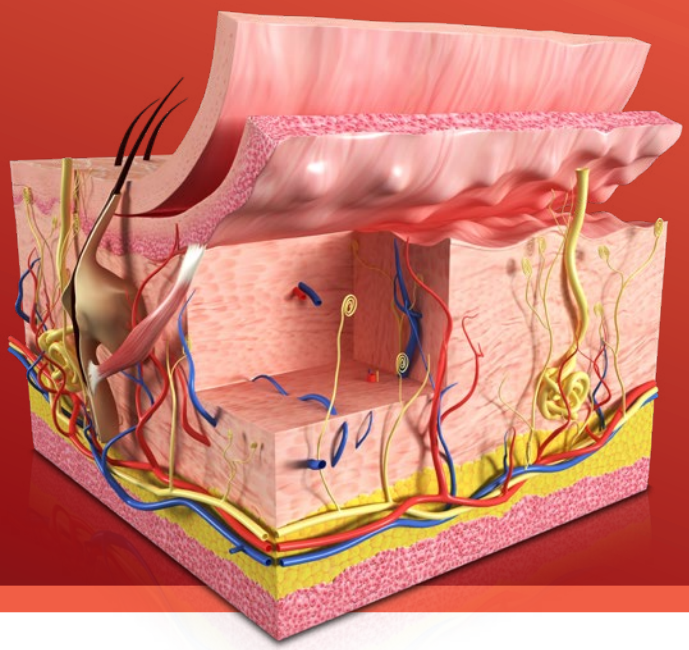
ALTASCIENCES
CLINICAL SERVICES



Topical Products

Altasciences' Experience

- Team with over 25 years experience
- Hundreds of studies completed
- Combined database of 345,000 participants
- Experience with all marketed TDS products, including narcotics, CNS, hormonal, nicotine, analgesics, etc.
- Fully versed on FIH, NDA and ANDA study requirements for North America and Europe
- Recent experience of approximately 32 studies involving irritation, sensitization, adhesion, PK, PD (eg: skin biopsies, various dermal response scales and assessments) and safety, involving over 2500 subjects
- 27 topical vasoconstrictor studies involving over ~1200 subjects
- Local affiliations with dermatologists
- Phase I to proof of concept in atopic dermatitis

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.
- 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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Support Services

Bioanalysis

- Bioanalytical capabilities are supported by over 100 highly-trained specialists, working with the latest equipment in state-of-the-art, purpose-built laboratories
- 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 current regulations
- Clinical trial protocol development, review and evaluation
- Integrated ICH E3-compliant clinical study report (CSR)

Project Management

- Project Manager (Project Leader) oversees the complete program conduct and deliverables
- Extensive expertise in managing single or multiple site clinical trials, across a wide range of therapeutic areas
- Close collaboration with key internal and external stakeholders ensures seamless and timely communication for successful project completion

Toxicokinetics and Pharmacokinetic Analysis

- Comprehensive preclinical TK and clinical PK and PD data analysis and interpretation
- 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

- Team with over 20 years of experience
- Electronic Data Capture
- 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

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