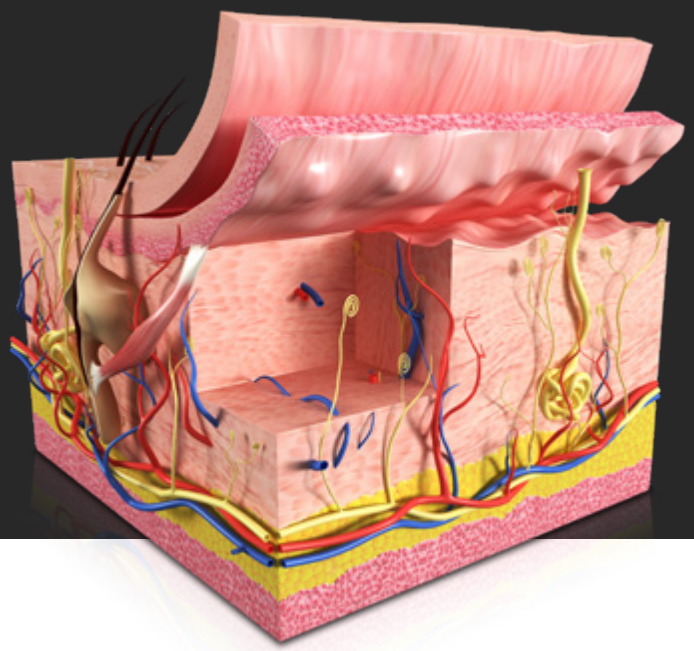
Altasciences
CLINICAL RESEARCH

Topical Products



Altasciences' Experience

- Team with >25 years' experience
- Completed hundreds of studies
- Database of **225,000** volunteers
- Worked 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**

Altasciences CLINICAL RESEARCH ALGORITHME PHARMA

Altasciences CLINICAL RESEARCH VINCE & ASSOCIATES

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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

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

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)

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

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

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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