

cliantha<sup>®</sup>  
research



**Driving  
Success in  
Dermatology  
Clinical Drug  
Development**

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USA | CANADA | EUROPE | INDIA

## Overview

The rising prevalence of topical drugs globally has made it imperative to understand the types of studies needed to support generic drug applications to the regulatory bodies.

The success of a topical drug often hinges on the results of bioequivalence studies making it essential to partner with an experienced and reliable CRO to design and conduct bioequivalence studies.

Clantha Research is full service global CRO with a unique approach to clinical development & is well suited to manage some of the industry's most complex and challenging topical product clinical studies.

## Topical Products: Dosage Form Experience



Transdermal Delivery System  
(TDS Patch)



Cream



Gel



Lotion



Ointment

## TYPES OF STUDY

- Skin Irritation and Sensitization (I/S) study or (“HRIPT: Human Repeat Insult Patch Test) patch study
- Pharmacokinetic, Adhesion and Irritation patch study
- Pharmacokinetic study with cream/ gel/ lotion/ ointment

## EXPERIENCE

### Transdermal Delivery System (TDS Patch):

Buprenorphine

Clonidine

Diclofenac

Estradiol

Fentanyl

Granisetron

Lidocaine Wear Study

Nitroglycerin

Norelgestromin/Ethinyl Estradiol

Rivastigmine

Rotigotine

Scopolamine

Selegiline

### Cream

Doxepin Hydrochloride

Ivermectin

Lidocaine/Prilocaine

Spironolactone

### Gel

Clindamycin + Anhydrous Benzoyl Peroxide

Dapsone

Diclofenac

Estradiol

Progesterone

### Ointment

Crisaborole

## CHALLENGES



Recruitment due to large sample size, long housing and multiple ambulatory visits.



Studies to be conducted in different geographical conditions (I/S studies)



Complex dosing procedure



Single adhesion/ irritation scorers for entire study



Possibility of PK sample contamination

## CLIANTHA ADVANTAGE

### Experience

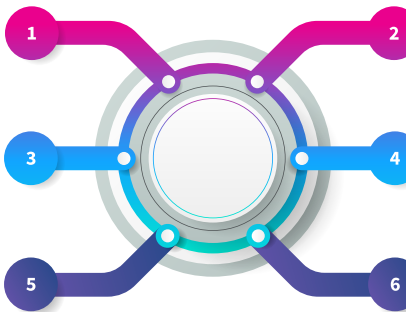
Conducted >175 studies & enrolled >5000 subjects (< 5% dropout)

### Well Trained & Experienced Team

50+ trained applicators, adhesion & irritation scorer

### Multiple Geographical Sites

India (Ahmedabad, Noida, Vadodara) & North America (USA & Canada)



### Proven Expertise

Established 'Interscorer reproducibility' between two different geographical sites.

### Subject Database

92000+ (Male, female & PM female)

### Infrastructure and Instrumentation Capabilities

Latest instruments, CPU & walk-in facility for topical studies.

Contact Cliantha today for more information about how we can enable you to make product launch decisions faster

**For more information contact:**  
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