18 YEARS OF EXCELLENCE IN RESEARCH

cliantha research

BA-BE & PHASE-I CAPABILITIES

EXPERIENCE

- Extensive experience in Phase I Trials
- FIH, SAD/MAD, BA/BE, DDI, Food Effect, PK/PD
- Population: Male, Female, Elderly Male, Post Menopausal, Children (US) & Special population

Type of Study	Location	# of Studies
Bioavailability & Bioequivalence (BA/BE)	India/NA	6000+
First-in-human(FIH)	India/NA	31
Single Ascending Dose/Multiple Ascending Dose (SAD/MAD)	India/NA	27
Drug-Drug interaction(DDI)	India/NA	24
PK/PD	India/NA	23
Food Effect	India/NA	15
Skin Blanching	NA	100+
Transdermal Delivery Systems Studies	India/NA	200+

CAPABILITIES

CLIANTHA RESEARCH, INDIA
Locations: Ahmedabad, Noida, Vadodara

- 4 Clinical Units, 718 Beds, 24 ICU Beds
- 20 Bed Phase I unit
- Central Lab accredited by CAP & NABL
- 73,000+ healthy subjects database

CLIANTHA RESEARCH, US
Locations: St. Petersburg, FL

- 48 Beds
- Local Central Laboratory
- Secured pharmacy with DEA license for schedule 2, 2N, 3, 4 and 5

CLIANTHA RESEARCH, CANADA
Locations: Mississauga, ON

- 2 combinable units with 60 Beds
- 1 ICU Phase I unit with 8 Beds
- Access to special population in respiratory diseases
- Environmental Exposure Chambers for Allergy and Dry Eye

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EXPERIENCE WITH ROUTE OF ADMINISTRATION

Oral [5500+]

- Tablet (IR, ER, SR, MR, CR, DR, ODT, Chewable)
- Capsules
- Chewable Tablets
- Suspension
- Granules
- Sublingual

Dermal [170+]

- Ointment
- Cream
- Patch
- Gel

Pulmonary [15+]

- Nasal Spray
- MDI
- DPI

Injection [40+]

Rectal [5+]

Vaginal [10+]

DIFFERENT STUDY TYPE AND DESIGNS

- Parallel, Cross over, Partial, Replicate and Full Replicate
- Long housing (confinement up to continuous 17 days & long washout up to 120 days)
- Long duration (demanding blood sampling up to 80 days)
- Proof-of-concept
- Phase I studies
- Special population: Geriatric, post-menopausal women, Allergic, Dry Eye, Pain
- Multiple dose studies

REGULATORY EXPERIENCE

- 56 Clinical Audits (USA: 10, Canada: 10, India: 36)
- Experience in studying FIH in patients & special population
- Successful track record of Scientific, Clinical & Medical interactions with regulatory authorities and ethics committees
- Team has experience in presenting to Health Canada & USFDA for approval of studies
- In-house preparation of Clinical Trial Application and IRB package