BA-BE & PHASE - I CAPABILITIES

EXPERIENCE:

- Conducted over 6000+, studies (In India & US both in CPU & Hospital setup)
- Extensive experience in Phase 1 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	NO. OF STUDIES
Bioavailability & Bioequivalence (BA/BE)	6000 +
First-in-human (FIH)	31
Single Ascending Dose/Multiple Ascending Dose (SAD/MAD)	27
Drug-Drug Interaction (DDI)	24
PK/PD	23
Food Effect	15

CAPABILITIES:

CLIANTHA RESEARCH, INDIA

12 Clinical Units • 513 Beds • 14 ICU Beds & 20 Doctors

Central Lab accredited by CAP & NABL

55,000+ healthy subjects database

CLIANTHA RESEARCH, US

Locations: St. Petersburg, FL &Neptune, NJ

3 Clinical Units, 148 Beds, 13 ICU beds

Utilize Local Central Laboratory

Access to special population with Renal/ Hepatic impairment and Atopic Dermatitis

CLIANTHA RESEARCH, CANADA

Locations: Mississauga

3 Clinical Units, 100 Beds, 6 ICU Beds

Utilize local central laboratory

11,000+ HNV database

Access to special populations in respiratory diseases

20,000+ patient database.

cliantha
Science • Integrity

EXPERIENCE WITH ROUTE OF ADMINISTRATION:

INJECTION

ORAL
• Tablet (IR, ER, DR, OD, EC) • Capsule (Soft Gel, MR)
Chewable Tablets • Suspension • Granules • Sublingual

RECTAL

TRANSDERMAL

VAGINAL

PULMONARY

EXTENSIVE EXPERTISE

- FIH
- First to File BE
- Fentanyl inhaled and lollipops
- CII and Estrogen Patch with skin assessments
- Naltrexone Challenges
- CII CNS Depressant (narcolepsy indication) DDI's
- Serotonin Receptor Agonist Sub Q and Intranasal
- FIH IV NSAID with site assessment
- μ-opioid antagonist MAD, BA
- Topical Antiseptic BE with bacteria colony count
- Factor X inhibitor with punch biopsy
- Factor X and Warfarin reversal (IV)
- Over 130 Participants dosed with NG tube
- Extensive Experience with using a Benzodiazepine as an antidote
- PK-PD studies for biosimilars
- Anti Epileptic FIH, SAD/MAD, and DDI
- Anti Psychotic SAD/MAD with Spinal Tap

REGULATORY EXPERIENCE

- Successful track record of Scientific, Clinical & Medical interactions with regulatory authorities and ethics committees
- Experience in studying FIH in patients & special populations
- Team has experience in presenting to Health Canada & USFDA for approval of studies