BA-BE & PHASE - I CAPABILITIES

EXPERIENCE:

- Conducted over 5866, 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	# OF STUDIES
Bioavailability & Bioequivalence (BA/BE)	5866
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
Locations: Ahmedabad, Noida, Vadodara

12 Clinical Units • 513 Beds • 14 ICU Beds & 25 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, 90 Beds, 6 ICU Beds

Utilize Local Central Laboratory

11,000+ HNV database

Access to special populations in respiratory diseases

20,000+ patient database.

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

EXPERTISE

- Single and multiple dose
- Parallel, Cross over, Partial Replicate and Full Replicate
- Fasting, Fed & Sprinkle Applesauce
- Long housing (confinement up to continuous 17 days)
- Studies
  -Demanding frequent blood sampling
  -With long washout up to 45 days
  -Requiring continuous cardiac monitoring
- Special Population
- Multiple dose studies with 5 - 7 consecutive daily dosing
- Hospital set-up BE studies
- Proof of Concept studies

REGULATORY EXPERIENCE

- 46 clinical audits
  (USA: 8, Canada: 10, India: 28)
- 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