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## CLINICAL RESEARCH

VIMTA is the No.1 choice in India for excellent quality clinical research services. VIMTA has rich experience, vast knowledge, advanced technologies and IT powered processes to conduct studies. With strong local know-how and international regulatory experience VIMTA is the right partner for conducting clinical research studies in India.

VIMTA's expertise and leadership in Bioequivalence and bioanalysis services over the years has been extended to offer wider range of clinical research services. VIMTA's success is driven by its commitment to support customers win through thorough understanding of the critical importance of time, effective project management and GCP & GLP compliance.

### Services

- Bioequivalence/Bioavailability Studies
- Clinical Trials (Phases II to IV)
- Clinical End Point Studies
- Claim Studies
- Clinical Testing and *In-vitro* testing of Cosmetic Products
- Central Laboratory Services

### Bioequivalence/Bioavailability Studies

With 20 years experience, and expertise enriched through conduct of over 2800 studies and development of ~375 bioanalytical methods, including a strong global regulatory track record, VIMTA can help design and conduct a study successfully. VIMTA's strength is its team of highly ethical, experienced, knowledgeable, multi-disciplinary, customer focused professionals.

### Specializations

- Complex design studies
- Studies on complex molecules (highly variable drugs)
- Studies in special populations, patient based PK studies
- Studies on different dosage forms – e.g., injectables, ODS, patches, oral suspensions, etc.
- Apple sauce fed studies
- Steady state studies
- Large subject studies (pool of over 29000 volunteer database)

BA/BE Services include study designing, ICF & protocol development, pre-study approvals for project initiation, subject recruitment & clinic, bioanalytical services, project management, pre & post project regulatory support, clinical data management, statistical services, medical writing services, integrated report preparation, CTD/eCTD submission and data archival.

### Facilities & Technologies

#### Clinic

- In house volunteer screening
- In house CAP accredited clinical lab for safety assessments
- Multiple Clinical Pharmacology Units with overall capacity of 180 beds
- Fully equipped inhouse ICU as well as tie ups with multi speciality hospitals for handling medical emergencies
- Pharmacy for controlled storage of Investigational Products
- In-house catering facility to provide standardized food

#### Bioanalytical

- Wide range of Mass Spectrometers enabling development and validation of highly selective and sensitive methods.
- Large number of equipment for rapid turnaround
- Different variants of LC-MS/MS, GC-MS, GC-MS/MS and ICP-MS for elemental analysis
- ELISA analyzer for Large Molecule preparations
- Dedicated equipment & scientists for each project

### Successful Regulatory audits

USFDA

MHRA

BfArM

WHO

DCGI

DRAs of Denmark, Portugal & Sweden