

## Asia's Most Comprehensive Clinical Research Organization



Pharmacokinetic Studies



Phase II to IV Trials



Clinical End Point Studies



Central & Biomarker Lab

**2500<sup>+</sup>**

Studies in  
20 Years

**1500<sup>+</sup>**

Regulatory Submissions

**350<sup>+</sup>**

NDA & ANDAs  
Approvals

## SERVICE PORTFOLIO

### Clinical Operations



- Healthy subjects BA / BE studies - PK studies
- Mixed gender population studies
- Drug–Drug interaction studies
- Clinical trials/Clinical end-point studies – PK & PD studies
- Claim studies
- Qualified doctors round the clock
- Skin irritation & skin sensitization
- TDS patch studies
- Glycaemic index determination
- Human performance studies
- Inhalation studies
- Stringent subject compliance
- Dedicated state of the art ICUs

### Bio-Analysis



- Method development & validation
- Subject sample analysis
- Method transfer
- Complex molecule
- Scientists with 10 + years of experience
- Capacity to analyze over 50000 samples per month
- Experience with NCE molecules
- Analysis by LC-MS/MS, ICP-MS
- Database of methods
- 12-15 new method developments every year
- Robust system for failure investigation

### Medical Writing



- Regulatory writing for Protocol/CRF/ICF
- Medico marketing material development

Capable of holding and conducting BE on controlled drugs or narcotic medicine

## SERVICE PORTFOLIO

### Central & Biomarker Lab



- CAP and ISO 15189 accredited
- Full spectrum lab services ( Biochemistry, Hematology, Immunohistochemistry, Serology, Histopathology, Flow cytometry, Genetics, Microbiology, Immunology, Molecular Diagnostics )
- Verified reference ranges for Indian population
- 75 validated biomarker methods
- Validated pharmacogenomics methods viz. HLA B5701; B1502; CYP2D6 etc
- Nation wide network with investigator sites
- Pan India logistics capabilities
- Coagulation studies & immunophenotyping

### Biostatistics & Data Management



- Sample size calculation & randomization management
- Pharmacokinetics & statistical analysis
- Clinical data management
- SAS 9.4 office analytics
- Electronic data capture
- *In vitro* data analysis
- Biosimilar immunogenicity data
- Statistical inputs for study protocol
- CDISC compliant SDTM, ADaM, SEND dataset

### Track Record



#### Matrices

Plasma, Serum, Urine, Whole Blood



#### Validated MABs

Validated large molecules method (MABs) on LCMSMS



#### 505(b)2 Programs

Expedited studies to support first to files & 505(b)(2) programs



#### Validated Methods

400+ validated methods

### Capabilities :

- Oral dosage forms
- Inhalations
- Ointment & creams
- Injectables- IV,IM,SC
- Suppositories
- Rectal foam
- Dermal patches

## ABOUT US

With strong local know-how and international regulatory experience. Vimta is the right partner for conducting clinical research studies in India. We have rich experience, vast knowledge, advanced technologies and IT powered processes to conduct studies.

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.

## Capacities & Facilities



### Clinical

- 180 beds clinic
- 33,000 healthy volunteer database including females
- CAP & ISO 15189 accredited lab
- GLP & GCP Compliant
- PGx volunteer group
- Fully equipped ICU with 24/7 emergency support
- MedRA coding
- In-house canteen facility
- eCRF
- Narcotics drug handling - CBN



### Biostatistics

- WinNonlin
- TRS tool box 6.3 pharma
- SAS office Analytics
- Dedicated servers for statistical data and data management
- Secure storage & transfer of data
- CDISC datasets
- SDTM/ADaM/SEND compliant reports



### Bioanalytical

- 2,50,000 samples per year
- Large pool of LC-MS/MS (28) & GC-MS/MS (17), of different variants
- ICPMS (12) for elemental analysis
- ELISAs for immunogenicity & ligand binding assay
- 30,000 L capacity for sample storage at -20°C & -70°C

## Accreditations & Certifications



 [www.vimta.com](http://www.vimta.com)  
 [bd@vimta.com](mailto:bd@vimta.com)  
 +91 40 27264141

**Registered Office**  
Plot Number 142, IDA Phase 2,  
Cherlapally, Hyderabad - 500051  
Telangana

**Life Sciences Facility**  
#5, M N Science & Technology Park,  
Genome Valley, Shameerpet,  
Hyderabad - 500101, Telangana