35 Years
Listening
Leading
Learning

Vimta
Driven by Quality. Inspired by Science.

Asia's Most Comprehensive Clinical Research Organization

- Pharmacokinetic Studies
- Phase II to IV Trials
- Clinical End Point Studies
- Central & Biomarker Lab

2500+	1500+	350+
Studies in 20 Years	Regulatory Submissions	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

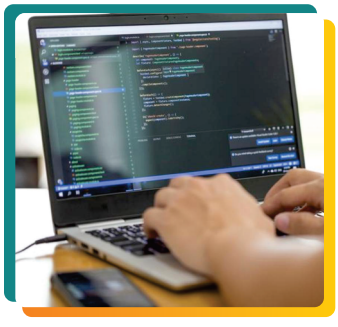
Capable of holding and conducting BE on controlled drugs or narcotic medicine

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 pharmacogemonics 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
- Injectables- IV,IM,SC
- Dermal patches
- Inhalations
- Suppositories
- Ointment & creams
- Rectal foam

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

FDA INSPECTED · BfArM APPROVED · WHO RECOGNIZED · SAHPRA CERTIFIED · MHRA APPROVED · ISO 17025 ACCREDITED · NPRA CERTIFIED · CDSCO CERTIFIED

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