



**An Integrated Contract Research & Testing Organization**

**Clinical Research & Pharmacovigilance  
Services**

VLL/CR/ 2011/01/12



# Clinical Research & Pharmacovigilance services



## Services:

- Healthy volunteer studies
- Clinical studies in patients
- Central Lab Services
- Medical Writing
- Pharmacovigilance

## Backed by

- Quality Systems
- Technology
- Human Resources



# Healthy Volunteer Studies

- **Bioavailability/Bioequivalence studies** on various dosage forms: Tablets, capsules, film strips, gels, jellies, oral solutions, dermal patches and injectibles; under several study designs
  - Single dose, cross over studies
  - Single dose, replicate design studies
  - Multiple dose, steady state design studies
  - Parallel design studies
- **Safety and efficacy studies on cosmetics**

**Total No. of clinical studies completed so far: 1200+**

# BA/BE Studies: Capacities

- Volunteer database of 20,000 healthy volunteers, including female volunteers
- 200 bed clinic capacity
- Fully equipped ICU (8 beds)
- A pool of 27 Mass Spectrometers (LC MS, GC MS and ICP-MS) across 2 Sites in Hyderabad
- 13 Deep Freezers (four -20's, two -20 walk-in-chamber and seven -70's)
- In-house Clinical Lab: among the most sophisticated in India

# Summary of Regulatory Submissions

<b>Regulatory Agency</b>	<b>Studies conducted since</b>	<b>No. of pivotal studies conducted so far</b>
US-FDA	2002	>250
WHO	2000	>15
EU	2001	>50
DCGI (India)	1994	>400
Others (Health Canada, TGA, MCC, etc.)	2000	>50

# We offer superior value thru..

- **Deep Experience to advise you better on study design:** Our work is part of more than 150 ANDAs and 505.B.2 applications in regulated markets
- **Better Project Management:** Meticulous planning to complete the project well ahead of promised date; Frequent communication with the sponsor reg. the progress of the project
- **Unique capabilities in PK analysis:** Availability of a diverse set of analytical methodologies such as LC MS, GC MS, ICP MS, RIA, ELISA, etc.

# Clinical studies in patients

- Phase II-IV trials
- PK studies
- Clinical end point studies



**Site Management Services:** CRCs, Site collaborations

**Site Monitoring services:** Project Management, Regional CRAs, Medical Monitoring

**Clinical Investigators:** Across multiple TAs, multiple sites, pan-India.

# Site Management Services

- Investigator support
  - CRC Service, Investigator/ Site training
- Site Support Study Conduct-
  - Feasibilities & Site Qualification
  - Site facilities preparation- Ready for Initiation, Monitoring, Close-out
  - Site preparation for Audit
- Study Process Management
  - IEC/IRB Mgmt- Setting up/ improving on IRB/IEC structure/functions
  - Study Conduct; Study Drugs Mgmt
  - Facilitating Regulatory audits

# Site Monitoring

- **Services:**
  - Site feasibility, Investigator and Site Selection
  - Site Initiation
  - Interim Monitoring
  - Site Close-outs
  - Project Management
- **Regional CRAs:** Delhi, Lucknow, Varanasi, Kolkata, Chennai, Bangalore, Mumbai, Pune, Chandigarh, Vizag, Guwahati, Ahmedabad - **optimizes logistics and cost.**
- Coordinating Site Audits by external auditors.

# Site Collaborations



- Vimta is associated with multiple (>100) clinical trial sites with good experience in GCP trials;
- Vimta has exclusive MOUs with 11 hospital Sites (India) for site management; Vimta's CRCs at these sites.
- More than 150 investigators across various TAs.
- Pan-Indian presence, more in South India for better logistics & cost control.

# Summary: Clinical Trials Experience

## Phase-3 Studies

- **Ongoing Studies**
  - Gingivitis, periodontitis: 90 patients, 3 centres
  - Post- Surgical pain: 200 patients, 5 centres
  - Pneumonia/ LRTI: 150 patients, 3 centres
  - Derma- Acne Vulgaris: 100 patients, 5 centres
  - GI studies: GERD & Upper GI study, 200 patients, 5 centres
- **Upcoming Studies:** Osteoarthritis(300 patients), Type-1&2 Diabetes Mellitus (500 patients), Glaucoma (100 patients).

## Phase-4 Studies

- **Ongoing Studies**
  - Acne vulgaris: 2000 patients, 100 centres – report preparation underway
  - Upper GI disease: 2 studies-1500 patients & 100 centres each
  - Phase-4 CT: Neuropsychiatry: 200 pts, 7 centres
- **Upcoming Studies:** Dry eyes & Keratitis (500 patients), Loss of appetite & Liver disorders (3000 patients).

# Central Laboratory Services

- **Range Offerings**
  - Immunogenicity Testing
  - Biomarker Assay Development and Validation
  - PK and PD Assays
- **Safety Monitoring**
  - Specialized Tests/ Novel Technology Platforms
  - DNA Sequencer, Sequenom, Micro arrays, Mass arrays
  - LC-MS/MS, GC-MS/MS and HPLC
  - Automated ELISA and Multiplex Assays
- **Sample Storage & Management**
  - Dedicated storage for long term sample archive
  - 24X7 environment monitoring by BMS
- **SAP-enabled Project Management**

# Medical Writing

- **Scientific Writing:**

- Clinical Research Communications: CT protocols, CRFs, ICF, PIS documents; Investigator's Brochure; IEC/IRB documents preparation; Clinical trial reports- ICH E3 & DCGI formats ;CT forms& reports- Screening, Enrolment, Monitoring;
- Medico- Regulatory documents/ dossiers: CTDs, NDA, 510k& PMA, Schedule Y documents inclu. Therapeutic Rationale, CT applications/reports, Aggregate Safety Reports such as PSURs, DSURs, SBRs, PADERs etc.

- **Publication & Medicomarketing Writing**

- Clinical Trial Reports, Review Articles, Case Reports etc.
- Product Monographs, Manuals, Leave- behind Literature (LBL) etc.
- Organizing CMEs, Doctor meetings, Conferences and its Abstracts.

# Pharmacovigilance Services

- **Vimta's PVG Services** include
  - Individual Case Safety Report (ICSR) Processing
  - Aggregate Safety Report (PSURs/PADERS) Writing
  - Literature Support & Information Systems
- **Case processing:** Home-grown database & expertise in major databases (e.g. Aris-g, Argus Safety, Clintrace)
- **Aggregate Safety Report (PSURs, PADERS, SBRs, ASRs)** writing capability for major geographies.
- Experienced health & Life-sciences' professionals.

# Audits & Accreditations

## ➤ Accreditations

- National Accreditation Board for Testing & Calibration Laboratories (NABL) – [Clinical Lab \(BE study centre\) & Central Lab](#)
- College of American Pathologists (CAP) - [Central Lab](#)

## ➤ Regulatory Audit History (BE study center)

- US FDA – 5 inspections
- UK- MHRA
- Joint inspection by DRAs of Denmark, Sweden, Portugal
- BfArM (Germany)
- Afssaps (France)
- WHO – 4 inspections

# IT Infrastructure

- Hardware:
  - Servers and other hardware components installed and managed by HP
  - First 10 G Passive Network in the Asia Pacific Region
  - Cisco 6513 Integrated Services Router
- Software:
  - Labware LIMS
  - Waters SDMS (Scientific Data Management System)
  - SAS 9.2 Enterprise Guide 4.2
  - WinNonLin Ver 4.1
  - Lotus DomDoc (for Document Management)
  - SAP (for project management)

# Staff: Clinical Research & Central Lab

- Strong scientific team of 310
  - MBBS/MDs: 24
  - Ph.Ds: 7
- Support staff / Field force: 76
- Total: 386

