

Clinical Development Services



Trials to Triumph

November 2008

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Lotus Labs Pvt. Ltd.

Lotus Labs is a leading Clinical Research Organization of international repute with comprehensive expertise in Clinical Trials

- With its nerve centre at Bangalore, Lotus Labs is a wholly owned subsidiary of the fifth largest generic pharmaceutical company in the world, Actavis PTC ehf.
- At Lotus, confidentiality, intellectual property protection, efficiency and cost containment form the basis of all clinical research activities



Our services include:

- **Clinical Services**
 - Medical Diagnostics
- **Bio-analytical Services**
 - Bioavailability and Bioequivalence Services (Pk/Pd)
 - Assay Bank
- **Clinical Development**
 - Data Management
 - Biometrics
 - Clinical Information
 - Clinical Trials Lab Services

Clinical Development Services @ Lotus

Comprehensive range of services to global pharmaceutical and biotech companies for managing Phase I to Phase IV clinical trials within the Indian sub-continent



Click on the service to view details

Service Offerings



Clinical Operations

- **Investigator Management**
 - Identification & assessment
 - Budget negotiations & contracts
 - Site payments
- **Ethics Committee Approvals**
 - IRB submission facilitation
 - Obtaining IEC approvals
- **Site Monitoring**
 - Site selection, initiation, monitoring, close-out
- **Project Management**
 - Time, cost & resource management
 - Study tracking
- **Investigator Meetings**
 - Planning, organization & conduct
- **Training**
 - Site staff
 - Monitors on Clinical Trial procedures & regulations
- **Medical/safety monitoring & reporting**
 - Including coding review

Service Offerings



Regulatory Affairs

- Clinical Trial Applications
- Drug import Licenses
- Safety updates
- Submission of trial status updates
- Submission of CSRs
- Regulatory consultancy

Service Offerings



Site and Supplies Management

▪ Process

- Suitable candidate selection (network/HR database)
- CT training (regulations & guidelines)
- Study training (procedures & documents)
- Placement on site

▪ Personnel

- CRCs
- Doctors
- Para-medics

▪ Clinical study supplies management

- Procuring supplies & equipment
 - Storage, assessment, diagnostics, IP dosing, sample collection
- Distribution to sites

▪ Investigational Product Management

- Import
- Storage
- Logistics & Distribution to sites

Service Offerings

Medical Diagnostic Services

- **Central Laboratory Services (NABL & CAP accredited)**
 - Hematology
 - Biochemistry
 - Serology
 - Urinalysis
 - Capabilities for other tests



Service Offerings



Medical Writing

- Literature search & document development
 - Protocol, amendments
 - SIS/ICFs
 - CRF
 - Diary cards, QoLs
 - E3 reports (CSR)
 - Publication manuscripts
 - Investigator Brochure

Service Offerings



Quality Assurance

- **Quality Assurance**
 - Development of SOPs
 - Site audits
 - Systems audits
 - Vendor/service provider audits

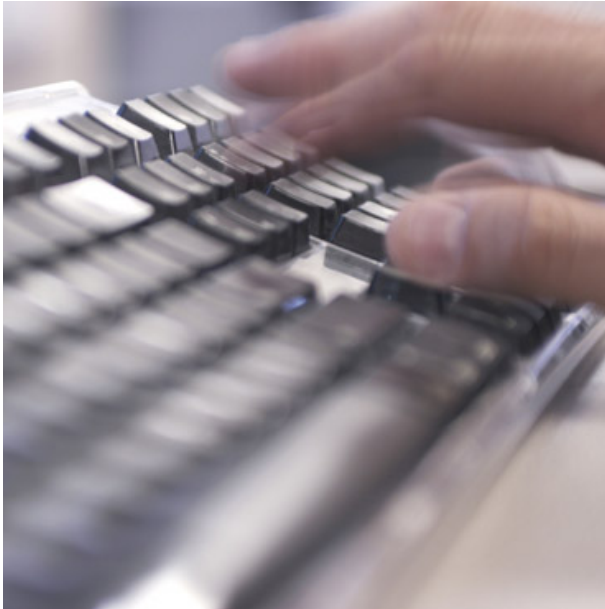
Service Offerings

Bio-analytical Services



- Bioavailability and Bioequivalence Services (Pk/Pd)
- Method development, feasibility & validation
 - Development of ~ 200 validated bio-analytical methods with the wherewithal to analyze over 20,000 samples per month

Service Offerings



Biometrics

- Statistical aspects of study protocol
- Definition of endpoints
- Design of the study, patient's pathway
- Inclusion and exclusion criteria
- Estimation of sample size
- Design of data entry, data management, data validation, data transfer
- Statistical analysis plan
- Randomization
- Documentation, Design of CRF

Infrastructure @ Lotus

Facility at St. John's Academy of Health Sciences



Lotus Labs has signed an MOU with St. John's Academy of Health Sciences, Bangalore - a 1200 bed multi-specialty hospital, among India's leading medical institutions - for conducting Phase I, II and III trials. The Clinical Development Team of Lotus Labs works from this facility.

As part of this arrangement - unique association of a CRO with a premier medical Institution - Lotus Labs has an exclusive facility at the St. John's Academy offering the full array of Clinical Services in addition to hospital based bioequivalence and special population studies. This facility is fully equipped with a 10 bed Phase I unit.

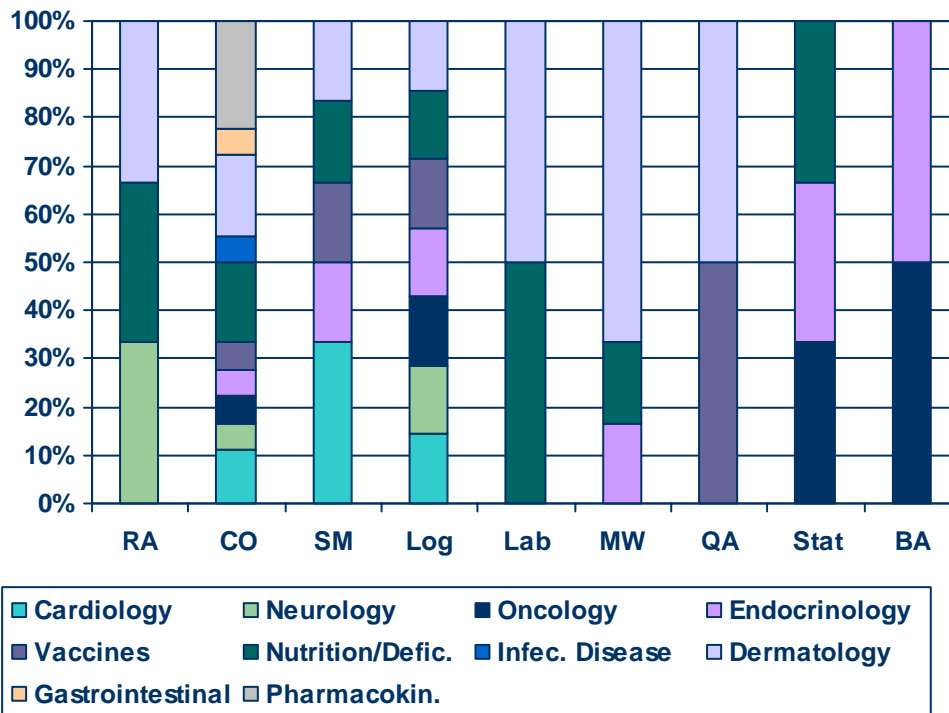
Team @ Lotus

Lotus Clinical Development Team is lead by a Oncology Surgeon with more than 15 years of experience in clinical trials.

The team includes Project Managers, Monitors, Medical Monitor, Pharmacist, Clinical Trials Materials Manager, Project coordinator, Clinical Research Associates & auditor/QA.

The average experience of the team is around 5 years.

Experience



- 21 Clinical Trials
 - Phases: I to IV
 - Phase I : 2
 - Phase II : 1
 - Phase III: 15
 - Phase IV: 3
- 120 sites (India, Bangladesh)
- Over 4800 subjects
- FDA submission studies

Bio generics at Lotus

- Lotus has experience with conduct of studies on bio generics, vaccines and bio similars (Phase I, II,III).
- Lotus has worked on erythropoetin, GCSF, vaccines and immunoglobulins.
- Lotus can undertake “start to finish” activities including regulatory approval, clinical, analytical and reporting for regulatory submission studies.
- Lotus has worked for Indian and Overseas sponsors for the clinical conduct of the studies.

The Lotus Advantage

- Excellent infrastructure to manage Clinical Trials
- Benefit of lower cost for running studies
- Team with vast Professional Experience
- Expertise in various therapeutic segments
- Association with St. Johns Hospital, leading multi-specialty hospital in Bangalore
- Network of @ 120 sites spread over India and Bangladesh with a combined inpatient bed strength of over 2000
- Access to patients in major therapeutic segments
- Active out patient departments in major segments
- Fast turn around time

Quality Systems

- Routine training & qualifying tests
- Area specific SOPs
 - Eg. Clinical Operations covered by over 50 SOPs
- Internal Audits by QA team
- Limiting reliance on personal know-how by process standardization
- Compliance to all applicable local & international clinical trial regulations

Clients

- Global Pharma Companies
- Indian Pharma Companies
- Global Nutrition companies
- NGOs & academic organizations
- Small / Medium sized Pharma companies located outside India