



**Partners in Implementing  
Optimal  
Scientific Business Solutions  
to  
Drug, Device, Diagnostics  
Development Industry  
Service Providers**

**Overall experience includes over four hundred preclinical, clinical trial (Phase I to IV) approvals, product registrations, marketing authorisations, covering a large number of therapeutic and product categories.**

- **Drug Development**
- **Medical Device & Diagnostics Development**
- **Business Solutions**

**Optimus**  
**Pharma Consulting**

[www.optimuspharmaconsulting.com](http://www.optimuspharmaconsulting.com)

# Knowledge & Expertise @ work for you....

TO DELIVER YOUR PROJECTS ON TIME AND WITHIN BUDGET....



## FOR SERVICE PROVIDERS

### SERVICES

- **Regulatory** Strategy; Implementation
- Preclinical; Clinical Study Approvals (Phase I – IV, BA / BE Studies)
- Import / Export / Market Authorisations
- **Clinical Analytics** : CRF Services : Design, Annotation, CDASH, SDTM, ADaM ;  
**Biostatistics** Services (Phases II – IV, including BA / BE Studies; Speciality analytics)
- **Medical Writing** : Study documents / Reports / IND / NDA / CTD / e-CTD / MAA

### AUDITING (INDEPENDENT)

- Due diligence & gap analysis (Quality Management Systems)
- Standard Operating Procedures
- Clinical Sites & Study Audits (Phase I to IV; BA/BE EMEA; FDA; WHO, ICH GCP and Indian GCP)

### CALL OPTIMUS..... DURING

- Project overloads; Special requirements; Quick turnarounds, Rescue projects, Specific Customer Demands, Focus on Core Competencies etc.,

### BUSINESS SOLUTIONS

- **Stem Cells** (Regulatory, Development, Manufacturing, Market Authorisations)
- **Stats-in-a-box**
- **Quality Management System** (Strategy; Creation; Implementation; Pre-Audit Support)
- **Dossier Management** (Essential Documents, Drug Safety, Regulatory)

### BUSINESS BENEFITS

- Projects tracked in real time, delivered on schedule within service levels agreed upon – reducing development costs
- Providing localized strategic and process expertise to attain business competitiveness – delivering approvable projects faster
- Faster design, planning and implementation processes – leading to increased ROI
- Improved regulatory compliance
- Improved drug development productivity, risk mitigation, increased revenue.

### INDUSTRY FOCUS

Clinical Research Organisations; Providers of Pre Clinical Services; Clinical Service Providers; Bioavailability / Bioequivalence Service Providers; IRB's; IEC's; Clinical Study Sites; Medical Device; Diagnostics

### THERAPEUTIC EXPERTISE

Oncology; Immunology; Endocrine disorders; Cardiovascular; Central nervous system; Anti-infective; Gastrointestinal; Ophthalmology; Genitourinary; Ophthalmology; Respiratory; Blood disorders; Nutraceuticals etc.,

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