



CLINICAL RESEARCH CONSULTING SERVICES

OBJECTIVE OF THIS PRESENTATION

- Cliniminds is a leading clinical research and healthcare firm specializing in providing consulting, entry strategy, regulatory and business development services to the clinical research, medical and healthcare companies.
- India today is one of the most favoured destination for the global clinical research, medical and healthcare companies.
- Cliniminds would like to be your entry strategy partner in order to provide you hassle free, cost effective and efficient entry in the Indian market, and allow you to focus on core business.
- This presentation would provide you with the initial information on the clinical research market and services offered by Cliniminds.

ABOUT US & KEY BUSINESS AREAS

Cliniminds was established in the year 2004 by a group of Senior Professionals from Pharmaceutical, Clinical Research & Healthcare industry to provide business consulting and training services to clinical research, healthcare and medical companies. Key services offered are :

- ✦ Business & Consulting Services
- ✦ Human Resources Solutions in Clinical Research domain
- ✦ Clinical Research Educational & Training Programs

CLINICAL RESEARCH – KEY STATISTICS

- ❖ ***2012 Projected Industry Spending on CRO Services and Investigator Grants billion*** **\$2**
- ❖ ***Current Size of Indian clinical research industry*** **\$300m**
- ❖ **Number of CROs - current** **80**
- ❖ **Number of MNC & Indian Pharmacos in Clinical Research** **70**
- ❖ **Clinical Research Market Growth (Annual)** **40%**

- ⊕ Full time & Site Staff Required in 2012 50,000
- ⊕ New Protocols received by Indian Regulator
everyday 20
- ⊕ Patients / Subjects Required in 2012 350,000
- ⊕ Over 3,000 new Certified Investigators will
be required in 2008 and over 12,000 by
2012
- ⊕ Healthcare Industry would need over 200,000 new
professionals by 2012
- ⊕ Presence of major clinical research players

INDIA'S VITAL CLINICAL STATISTICS

- ✦ Cancer: 3 million
- ✦ Diabetes: 34 million
- ✦ HIV: 8-10 million
- ✦ Epilepsy: 8 million
- ✦ Hypertension: 150 million
- ✦ Schizophrenia: 1 million
- ✦ Asthma: 40 million
- ✦ Alzheimer's: 1.5 million
- ✦ Cardiac-Related Deaths: 2 million
- ✦ Recruits for genetic studies
- ✦ 600,000 practicing physicians
- ✦ 14,000 hospitals
- ✦ 700,000 beds
- ✦ 17,000 medical graduates per year

REGULATORY FRAMEWORK FOR CLINICAL RESEARCH

- ⊕ Positive Regulatory Environment – Protocols Approved by DCGI / Schedule Y in reasonable time frame and is getting better
- ⊕ Government is making registration of CROs mandatory along with registration of clinical trials
- ⊕ CDSCO (Central Drugs Standard Control Organisation) to regulate Clinical Research
- ⊕ Further strengthening of environment by setting up National Drug Authority
- ⊕ Intellectual property protection – India recognises both process and product patents
- ⊕ Duty Free Import of Clinical Trial Supplies
- ⊕ Easier Drug Importation Procedure
- ⊕ ICMR Guidelines on the Safety of Human Subjects

KEY OPPORTUNITIES FOR CROs & PHARMA COMPANIES

- ✦ BA/BE Facilities (Greenfield & acquisitions options)
- ✦ Phase II-IV Services
- ✦ Clinical Trial Monitoring
- ✦ SMO
- ✦ Data Management
- ✦ Central Research Laboratories
- ✦ Pharmacovigilance
- ✦ Training & Education
- ✦ Medical Writing
- ✦ Subject Recruitment & Retention
- ✦ Specialized Support Services
- ✦ Staffing Services

INDIA HUB OF GLOBAL CLINICAL RESEARCH

- ✦ India is one of the top 3 countries where companies plan to spend the most R&D dollars over the next 3 years.
- ✦ 10-year Tax Holiday on R&D investments
- ✦ Favoured destination ahead of countries like Israel, Philippines, Canada, China, Ireland & Russia in terms of Overall Climate (*Gartner Report, January 2003*)
- ✦ Powerhouse in R&D (*e.g. GVK Wyeth R&D Deal*)
- ✦ Over 60 CROs offer Phase I to IV trials complying with ICH-GCP guidelines.
- ✦ Over US\$300 million FDI expected in the next 18 months
- ✦ With 150 hospitals and rapidly increasing stand alone investigators serving as sites for clinical trials, India is emerging as one of the fastest recruiter of subjects across the world.
- ✦ Some of the top medical/technical universities in Asia

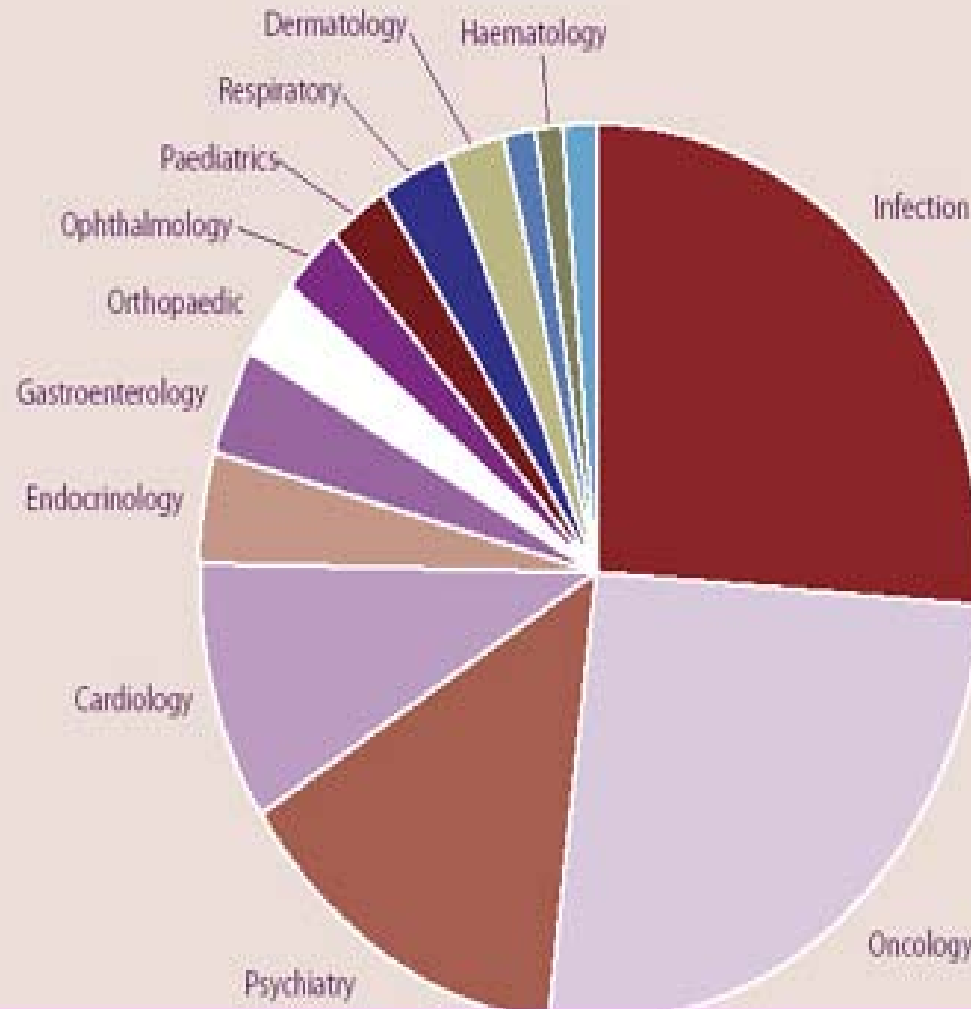
INDIA HUB OF CLINICAL OF CLINICAL RESEARCH

- ✦ The clinical community is populated with high level English communicating, western-trained graduates
- ✦ Sophisticated technological infrastructure
- ✦ 100 million plus English speaking / trained professionals (Largest outside US)
- ✦ Over 2 million science post graduates
- ✦ Large pool of treatment naïve patients from multiethnic and multiracial backgrounds
- ✦ Better patient recruitment, retention and compliance
- ✦ Participants generally benefit, as the trials conducted in India, mostly in phase II - IV, provide improved care and cost savings as procedures and drugs are provided at no charge

INDIA – HUB OF CLINICAL RESEARCH

- ✦ Cost effective operations – India offers significant cost savings
- ✦ Higher GMP/GLP/GCP Compliance
- ✦ Maximum number of approved GMP plants outside USA
- ✦ Excellent quality management, Technology and infrastructure
- ✦ Increasing presence of all Pharma majors, CROs & also in-house CROs set up by leading pharma companies
- ✦ Strong IT industry availability of IT skilled manpower

Figure 4. Clinical Trials Done in India



KEY PHARMA COMPANIES IN CLINICAL RESEARCH

- ◆ *Abbott, Mumbai*
- ◆ *Chiron, Mumbai*
- ◆ *Astra Zeneca Pharma India Ltd, Bangalore*
- ◆ *Astra Zeneca Foundation, Bangalore*
- ◆ *AventisPasteur, Delhi*
- ◆ *Pfizer Ltd, Mumbai*
- ◆ *Pfizer Biometrics, Mumbai*
- ◆ *Altana(Zydus), Mumbai*
- ◆ *Eli Lilly, Delhi*
- ◆ *Boston Scientific, Delhi*
- ◆ *Hospira, Delhi*
- ◆ *Merck ,Delhi*
- ◆ *Sanofi Aventis Syntho Lab, Mumbai*
- ◆ *GSK, Glaxo SmithKline Pharmaceuticals Ltd,Mumbai*
- ◆ *Novartis International Clinical Development Center, Mumbai*
- ◆ *Novartis Pharma, Mumbai*
- ◆ *Roche,Mumbai*
- ◆ *Sandoz, Mumbai*
- ◆ *Wyeth, Mumbai*
- ◆ *BMS, Mumbai*
- ◆ *Novo Nordisk, Bangalore*
- ◆ *Lundbeck, Bangalore*
- ◆ *Eisai Pharmaceuticals, Mumbai*

- ◆ *LG Life Sciences, Delhi*
- ◆ *Bayer, Mumbai*
- ◆ *GE, Delhi*
- ◆ *Johnson & Johnson, Jansenn Cilag, Mumbai,*
- ◆ *Cordi Baxter, Delhi*
- ◆ *BD Biosciences, Delhi*
- ◆ *Bharat Biotech, Hyderabad*
- ◆ *Bharat Serum, Mumbai*
- ◆ *Cadila Pharmaceuticals*
- ◆ *Cipla, Mumbai*
- ◆ *Emcure, Pune*
- ◆ *Fulford India Mumbai*
- ◆ *Indus Biotherapeutics, Ahmedabad*
- ◆ *IPCA, Mumbai*
- ◆ *Shreya Biotech, Pune*
- ◆ *Shantha Biotechnics Pvt. Ltd. Hyderabad*
- ◆ *Sun Pharma, Mumbai*
- ◆ *Torrent Pharmaceutical Ltd, Gandhi nagar,*
- ◆ *USV Ltd. Mumbai*
- ◆ *Wockhardt, Mumbai*
- ◆ *Zydus Cadilla, Ahmedabad*
- ◆ *Biocon, Bangalore*
- ◆ *Cadila Pharmaceuticals, Ahmedabad*
- ◆ *Intas Pharmaceuticals Ltd., Ahmedabad*

- ◆ *Glenmark Pharmaceuticals Ltd., Mumbai*
- ◆ *Himalaya Drugs ,Bangalore*
- ◆ *Lupin Ltd., Pune*
- ◆ *Nicholas Piramal,Mumbai*
- ◆ *Panacea Biotech, Delhi*
- ◆ *Ranbaxy Research Laboratories, Delhi*
- ◆ *Ranbaxy Research Laboratories, Gurgaon*
- ◆ *Serum Institute of India, Pune*
- ◆ *Torrent, Ahmedabad*

KEY CROs IN INDIA

Quintiles	Ahmadabad / Bangalore
Synchron	Ahmedabad /Bangalore
Lambda	Ahmedabad
Genpact	Delhi/Bangalore
Siro Clinpharm	Mumbai
I-Gate	Mumbai
Reliance Clinical Services	Mumbai
PPD	Mumbai
Onmnicare	Bangalore
ICON	Bangalore
Clin Trac	Bangalore
PharmaNet	Bangalore
Pharm-Olam	Bangalore
Aizant	
Lotus Labs	Bangalore
Vimta	Hyderabad
GVK	Hyderabad
BioServe Clinical Research	Hyderabad
Apothecaries	Delhi
Clinsys	Delhi/Noida
Fortis	Delhi/Noida
Kendle	Delhi/Gurgaon
Bioassay	Baroda
Clinworld	Bangalore
Perinclinical	Mumbai
Quest Life Sciences	

KEY CITIES ATTRACTING CLINICAL RESEARCH INVESTMENTS

- ✦ Delhi & NCR Region
- ✦ Mumbai
- ✦ Pune
- ✦ Ahmedabad & Vadodara
- ✦ Hyderabad
- ✦ Bangalore
- ✦ Chennai

SERVICES OFFERED BY CLINIMINDS

- ✦ Business Support Services / Consulting Services
- ✦ Investigators' Site Identification & Qualification Services
- ✦ Regulatory Services
- ✦ Medical Writing Services
- ✦ Clinical Research Training / ICH GCP Education
- ✦ Trained Clinical Research Coordinator and other site personnel for trial sites

BUSINESS SUPPORT SERVICES

- ✦ Market Entry Strategy Services
- ✦ Extensive assistance in setting up the Indian operations; or research facility (e.g. BA/BE, Phase I, Analytical Lab)
- ✦ Setting up Indian Subsidiary and Joint Ventures
- ✦ Selecting Outsource Service Providers, viz. Indian CROs; Central Labs
- ✦ Legal assistance
- ✦ Office Infrastructure & Human Resource
- ✦ Representative Office
- ✦ Market Research
- ✦ Real Estate & Facility Support Services - Office / Clinic / Business Premises and Lease Negotiations
- ✦ Business Strategy
- ✦ Product Registration & Regulatory Services

INVESTIGATORS' SITE IDENTIFICATION & QUALIFICATION SERVICES

- ✦ The regulations state clinical investigators must be qualified, as evidenced through training and experience. Hence the selection of the right clinical investigator(s) is not only an important task in the Clinical Development Plan, but it is part of the regulations.
- ✦ Through its network, Cliniminds can help you develop the plan for identifying potential investigators and eventually qualifying those investigators that will be best suited to conduct your clinical trial.
- ✦ Cliniminds has extensive national database of experienced and potential investigators.
- ✦ Pre-qualifying research sites to determine interest and availability
- ✦ Obtaining quick turnaround of CDAs and site surveys
- ✦ Setting the stage for direct and ongoing communication between sites and sponsors/CROs

REGULATORY SERVICES

- ⊕ Preparation and submission of complete range of regulatory documents to IECs and Drug Controller General of India
- ⊕ Drug Import
- ⊕ Obtain permissions to conduct clinical trials in India
- ⊕ Preparation & Training for Regulatory Audits

MEDICAL WRITING SERVICES

- ✦ Protocol Writing
- ✦ SOP Writing
- ✦ Clinical Research Report Writing
- ✦ Abstract and Excerpt Writing
- ✦ Writing Case Reports forms
- ✦ Documentation for Regulatory Submission
- ✦ Literary Medical Writing
- ✦ Marketing & PR Medical Writing
- ✦ Medical writing for Web
- ✦ e-learning web portals for online education

TRAINED CLINICAL RESEARCH COORDINATORS

- ✦ Cliniminds provides the site the ICH GCP trained research coordinators so as the study runs smoothly.

GCP TRAINING

- ✦ Training Programs for Investigators & other members of clinical research team.
- ✦ Key training programs are :
 - ✦ ICH GCP Training on Clinical Research
 - ✦ Conduct & Management of Clinical Trials
 - ✦ Monitoring
 - ✦ Regulatory Affairs
 - ✦ Pharmacovigilance
 - ✦ Investigator Training
 - ✦ Quality Assurance
 - ✦ Subject Recruitment & Retention
 - ✦ Medical Writing
 - ✦ Biostatistics
 - ✦ Data Management

CLINIMINDS TEAM

- ✦ Cliniminds team consists of full time professionals from the industry and visiting specialised consultants.
- ✦ Some of the key members are :
 - ✦ Mr. Kamal Shahani, Director & CEO
 - ✦ Dr. Suneet Sood, Medical Advisor & Head – Medical Writing
 - ✦ Dr. Eti Dinesh, Manager – Operations & Regulatory Affairs
 - ✦ Mr. Jitto Thomas, Project Management

Contact Us

Cliniminds
C-55 Preet Vihar, 1st Floor
Main Vikas Marg
Delhi 110092

Tel : 011 42427800 Fax : 011 42427802

Email : info@cliniminds.com

Mobile : 9873888671; 9810068241

www.cliniminds.com; www.mediminds.com

THANK YOU FOR YOUR TIME

www.cliniminds.com
www.mediminds.com