

A light gray outline map of India is positioned in the background of the central text.

Capabilities & Quality Delivery System in Clinical trial service

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Institute of Biology + Clinical Research (IBCR)

Ensuring Health & Wellness

Welcome note

Institute of Biology and Clinical Research (IBCR), India is a new initiative from a group of clinical professionals, physicians, officials and scientists, which offers wide range of services in the field of biology and medical research.

IBCR attempts to bring up quality drug development programs in the second class cities of the country with airport connectivity, where one will find true ethical relation between physicians and patients.



**Current Indian Healthcare
Landscape**





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India has the 2nd highest number of qualified doctors in the world. Of every six medical doctors in the US, one is Indian

While clinical trials cost approximately \$300 to 350 million in US, they cost only about \$25 million in India

India's huge population and the prevalence of a wide spectrum of disease conditions offer a wide patient-resource for clinical trials

INDIAN HEALTHCARE CAPABILITY

Investigational New Drug stage costs about \$100 to 150 million in US, but costs only around \$10 to 15 million in India

700,000 science and engineering graduates & 1500 PhDs qualify annually. Over 15,000 scientists

Indian companies are offering custom synthesis services at 30-50% cost savings compared to global costs



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India is emerging as favorable destination for clinical research ahead of countries like Israel, Philippines, Canada, China, Ireland & Russia in terms of Overall Climate (*Gartner Report, January 2003*)

Better patient recruitment, retention and compliance

Large pool of treatment naïve patients from multiethnic and multiracial backgrounds

INDIAN HEALTHCARE CAPABILITY

Maximum number of approved GMP plants outside USA. Appreciable 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. Surplus English speaking technical professionals.

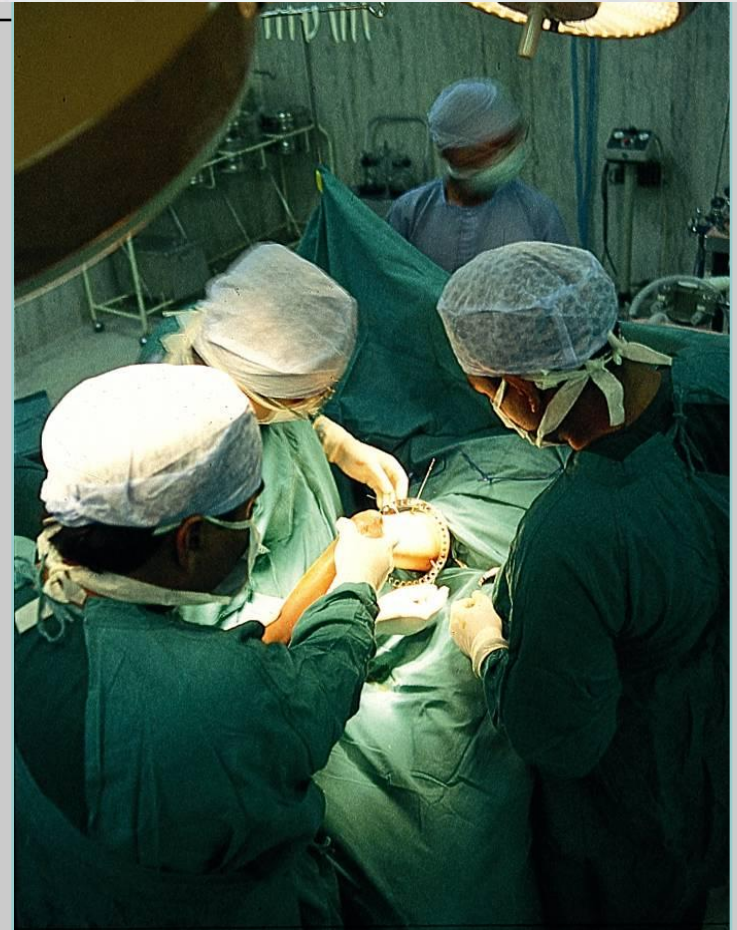


INDIAN HEALTHCARE CAPABILITY

Over 60,000 cardiac surgeries done per year with out comes at par with international standards

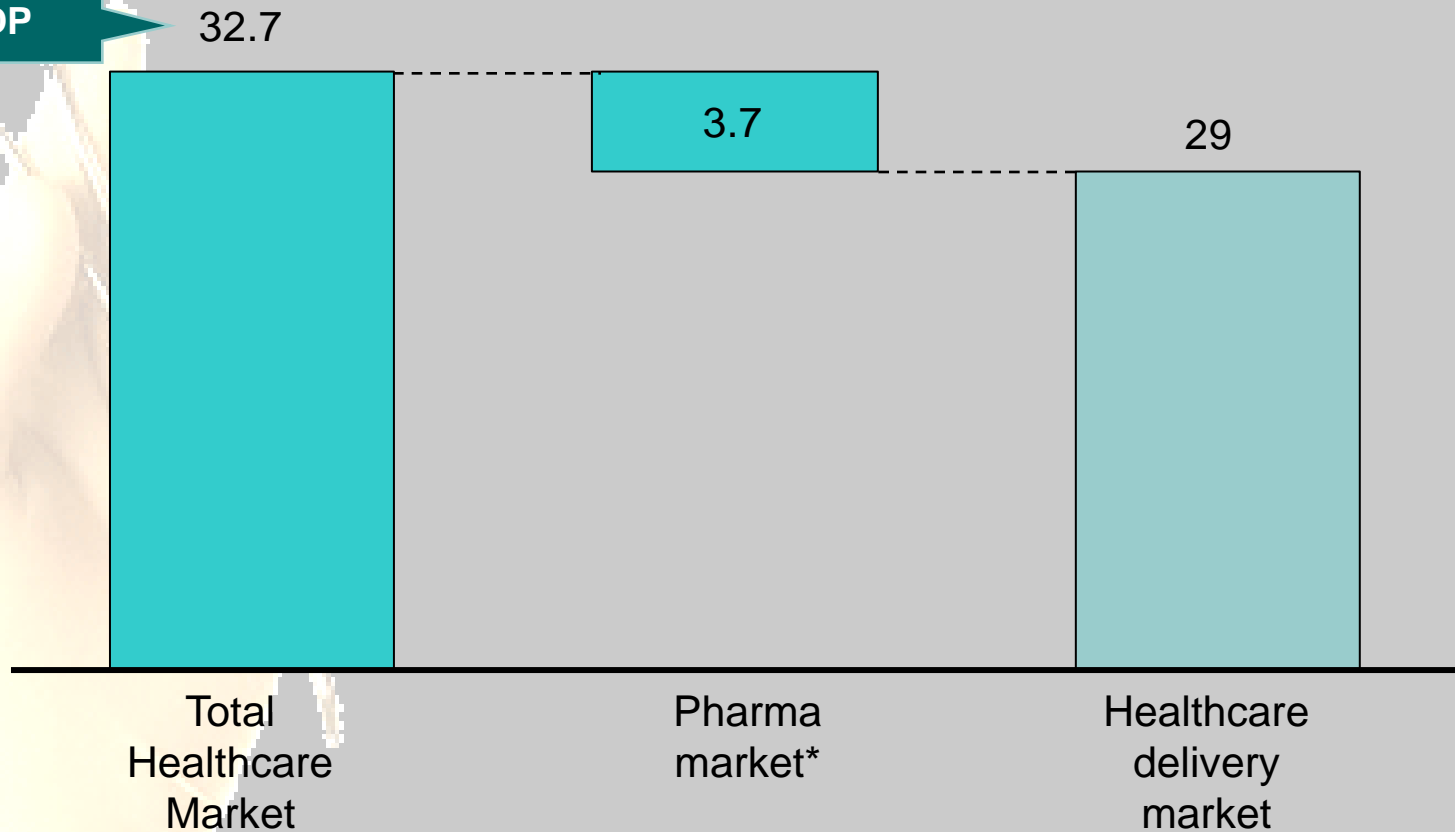
❖ Multi organ transplants like Renal, Liver, Heart, Bone Marrow Transplants, are successfully performed at one tenth the cost.

❖ Patients from over 55 countries treated at Indian Hospitals.



INDIA SPENDS US \$ 32.7 BILLION ON HEALTHCARE

7.2% of
GDP



* Retail

Source: National Accounts Statistics 2008; McKinsey analysis

IN TERMS OF DELIVERY, PRIVATE PROVIDERS CAPTURE 63% OF THE US \$ 23 BILLION SPEND

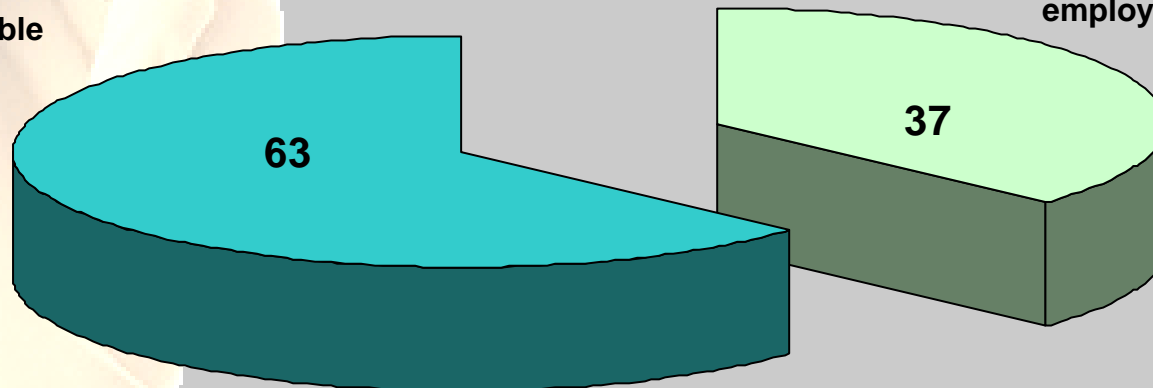
Healthcare provision, 2008

Per cent of total spending

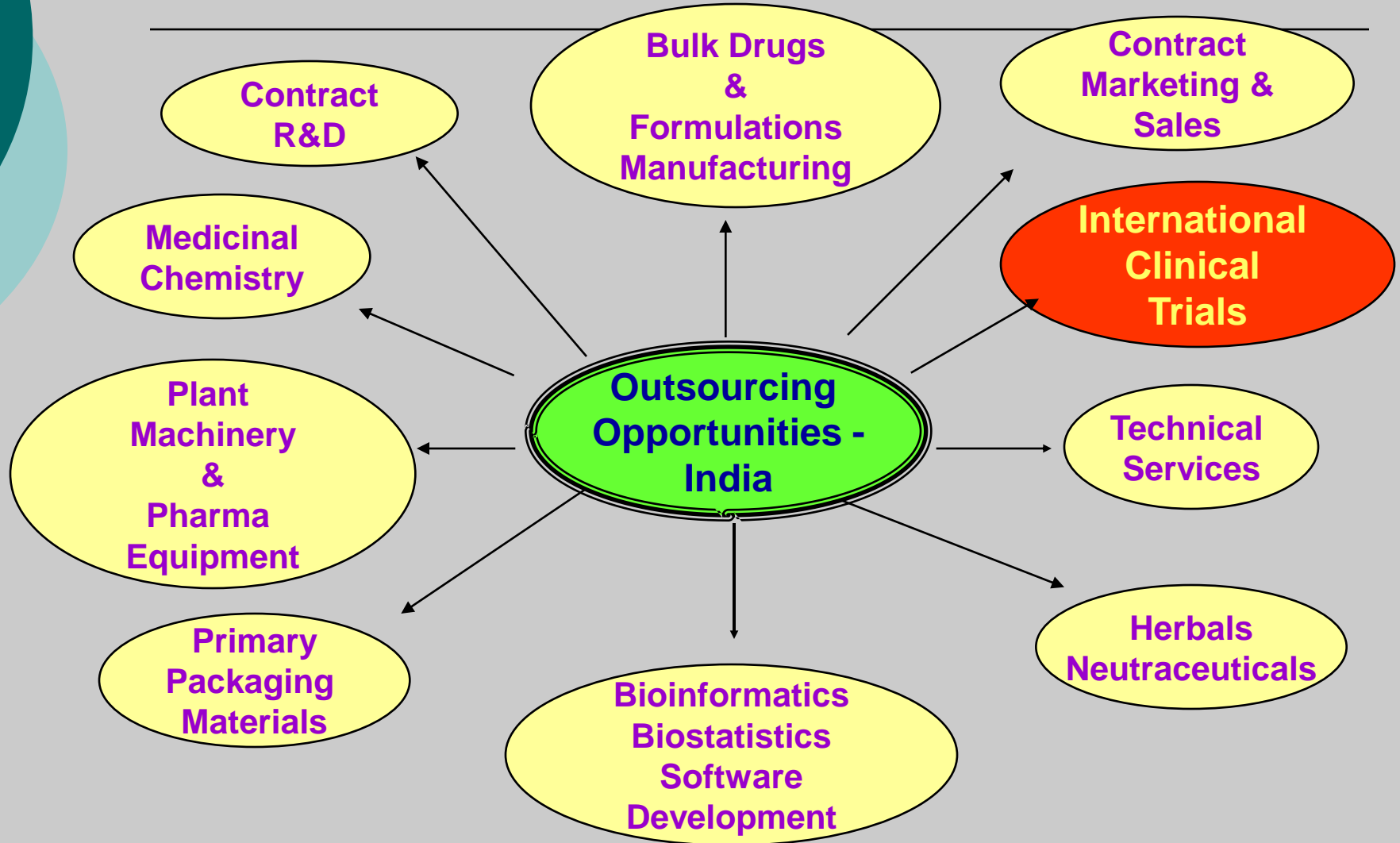
100% = US \$ 23 billion

Private providers
(individual, charitable
and for-profit)

Government and public
employers*



OUTSOURCING OPPORTUNITIES - INDIA





Indian Clinical Research Facts

Nascent but Fast Growing

- *India's Clinical Development Sector* -

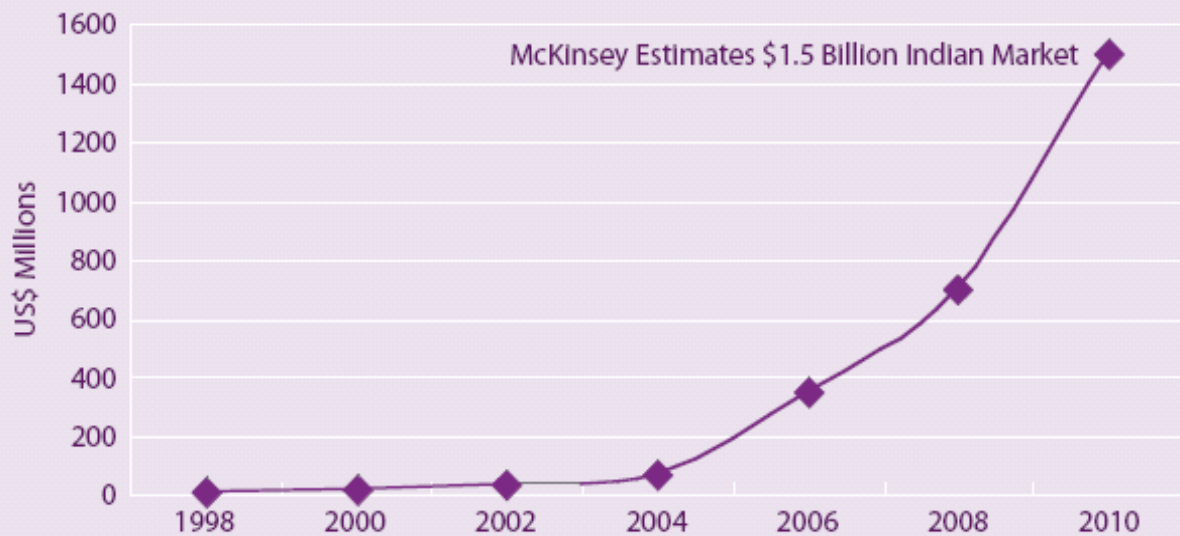
- Annual Revenues USD 200+ M with 40% growth in past year
- 240 international studies recruiting subjects = 1.2% of the total studies worldwide
- 66% of international clinical trials are Phase III
- 207 sites FDA registered
- 40,000 subjects participated in clinical trials to date (<0.02% of population)



McKinsey Report

Indian CR market will grow to US \$1.5 billion in value by 2010.

Figure 3. Indian CR Market



Source: McKinsey's Report



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Our Legacy

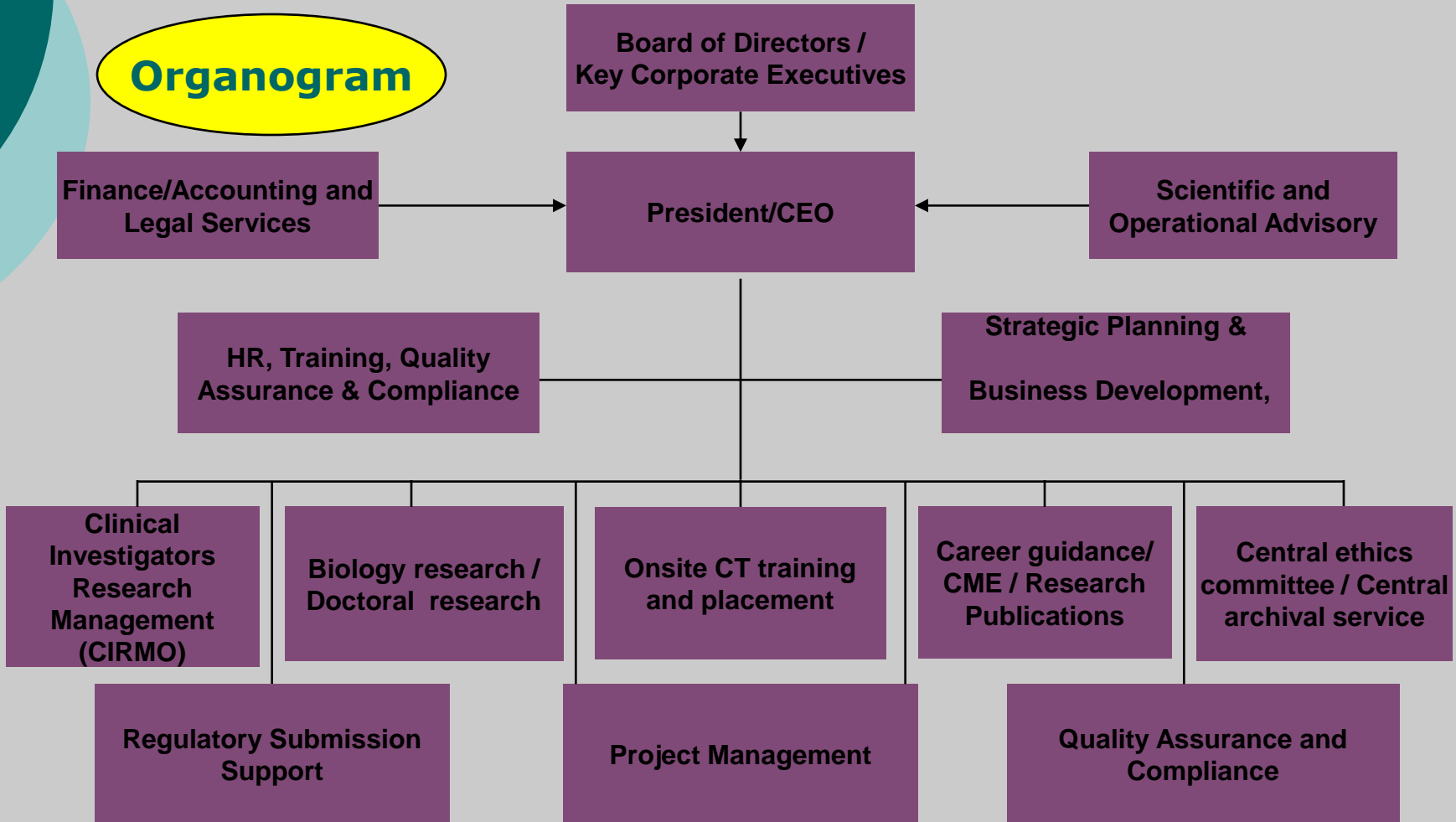
- ✓ **Customer Focused**
- ✓ **Can-Do-Spirit**
- ✓ **Continuous Improvement**
- ✓ **Ethical and Professional**



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Organogram





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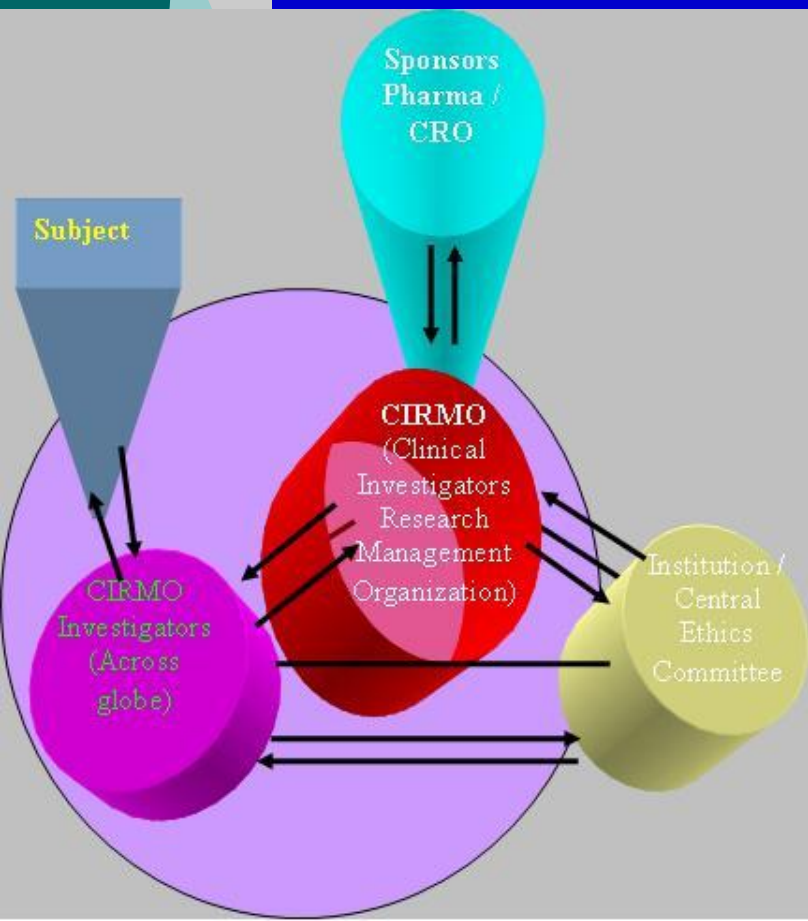
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IBCR Initiative & Vision

Clinical Investigator's Research Management
Organization (CIRMO)



CIRMO Model



Advantages

Applicable to multiple sites, multiple CRO & Sponsors, multiple Investigators and to multiple projects.

Investigators are bound to IBCR and can do research only on IBCR projects.

Data modeling (credibility / consistency & Integrity of data can be achieved)

IBCR is independent to sponsor / CRO.

IBCR trained investigators can be utilized for years and thus no site training costs to sponsors.

Clinical trial execution can be done with one SOP across globe.

The QA audit & subsequent corrective action and preventive action (CAPA) can be implemented immediately to all participating sites across globe.

Flexible to work with multiple sponsor SOP's.

Can achieve reduced timeline for site initiation and FPI.

Competitive project handling by IBCR investigators can be avoided.



Our Services and Core Competences

IBCR understand our client's world and will continuously focus to provide innovative solutions to alleviate the risk involved in the planning and execution of clinical trial projects.

We provide clinical services in the following area;

- Investigator Relations
- Clinical project feasibility
- Clinical Trial Services (Site selection, Clinical trial execution, Site management)
- Clinical Writing / Research publication
- Central Ethics Committee
- Training
- Freelance Monitoring
- Central archival of clinical data
- Pharma Staffing



Therapeutic Expertise

Cardiology
Endocrinology
Neurology
Critical care
General medicine
Pulmonology
Rheumatology
Paediatrics

Oncology
Nephrology
Orthopedics
Gynecology
Dermatology
Ophthalmology
Psychiatry
Infectious diseases



Clinical trial management - Facts

Preferable Service Providers to

PPD, Pra International, Quintiles, Omnicare, Lupin pharma, Reliance Life Sciences, Inventiv International, Siroclinpharm, Veeda CR, Fortis CRL, Clinisys, BMS

- Completed feasibility for more than 85 projects
- Finalized service agreement with more than 140 Investigators
- Developed 13 research sites
- 6 projects awarded; 8 sites activated; 12 sites to be initiated; 32 sites listed for evaluation.



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What Our Clients Say About Us

“They are highly motivated and always go above and beyond to provide us with quality and timely services.”

“You are really a ‘Can-Do’ team! You always try your hardest and find solutions for problems.... your ‘Can-Do’ attitude results in continuous improvements in all of the things you do....”

“We are very impressed by everything your team has done, they have contributed a lot for the quickly completion of the proposed project Feasibility.”



IBCR – Other Support Services

- Drug discovery and Early development research unit.
- Drug IPR filing / In-licensing
- Freelance Clinical Trial Monitoring / Medical writing
- Business Development activities in CR outsourcing from US
- Skill development course in Clinical Research- Fellow of Clinical Profession (FCP)



In-licensing

In the research and development of many products, especially pharmaceuticals, the costs can be get extremely high, causing companies to have second thoughts about the possibility of developing a drug.

Inlicensing takes risk away in any one of a number of different ways to mitigate some of the hazards associated with the product, such as a new drug.

Inlicensing is something many of the phamaceutical companies, such as Pfizer, GlaxoSmithKline, Novartis and others look at on a regular basis.



R&D

- IBCR started its first hybrid training and research institute (Inbiotics) in Kanyakumari (Southern tip of the country)
- IBCR plan to setup an exclusive R&D laboratory for drug research / in-licensing in Trivandrum and will be planned for commissioning by December 2021.
- The proposed investment for the R&D setup is approximately 5 Million US\$.
- IBCR is also offering clinical Ph.D program for corporate professionals and academicians in pharmaceutical chemistry / clinical & biological science / Drug development.



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Business note

- IBCR welcomes you to shake your trustful hands with us in the execution of clinical research program.
- We believe that you will prefer our professional relation and will give us business.

Thank You....

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