



ICBio Clinical Research Pvt. Ltd.

Clinical Research & Consultancy services

Agenda



ICBio – Introduction and Service Offerings

India – Emerging Destination for Clinical Research Services

ICBio – Operations

ICBio – Experience & Capabilities

ICBio – A Strategic Partner



ICBio – Update

- No of Clients – 15
- Employees – 52 Total
- Revenue – \$ 500000 (last yr.)
- Revenue - \$ 650000 (Current yr.)

**Industry
partnerships**

ABLE
SCDM
ACRO

INDIA –Hub of Global Clinical Research

- ❑ **100 million plus English speaking/trained professionals (Largest outside US) & Over 2 million science graduates**
- ❑ **Large pool of treatment naïve patients from multiethnic and multiracial backgrounds.**
- ❑ **Better patient recruitment , retention and compliance**
- ❑ **Maximum number of approved GMP plants outside USA**
- ❑ **Economical Operations and scale to delivery**
- ❑ **Higher GMP/GLP/GCP compliance**
- ❑ **Excellent quality management, Technology and infrastructure**
- ❑ **Strong IT industry availability of IT skilled manpower**

ICBio – Service Offerings

Study Feasibility

- Strong network of 900+ investigators and an already established association of 50+ sites
- Robust Database for prospective Investigators and investigational Sites

Site Management

- Strong network of ICH –GCP trained sites and GCP Trained clinical research staff
- Investigator and Vendor Management

Project Management

- Site Initiation and Training
- Implementation of Clinical Monitoring Plan
- Query Management

Medical Writing

- Study Protocol Development
- Narrative writing and Documentation of other reports for regulatory submissions
- Abstract preparation and Literature support

Data Management

- Database Design and Validation
- Remote Data entry & double Data entry
- Adverse event coding
- SAS Database designing
- Database lock and archiving

Bioequivalence / Bioavailability Studies

- Clinical Pharmacology Unit Services
- Bioanalytical Services
- Biostatistical Services
- QA/QC

ICBio – Service Offerings

Bioanalytical

- Systems and SOPs in accordance to globally acceptable regulations
- Method development
- Method Validation
- Sample analysis
- Method Transfer
- LC/MS/MS, ICP-MS, GC/MS, HPLCs, ELISA

Biostatistics and Programming

- Design and Development of Statistical Analysis Plan and Quality control of all Trail documents
- Analysis and Reporting of PK, PD, DNA and pharmacoeconomics

Drug Safety and Pharmacovigilance

- Setting up a safety Database
- Management of Adverse events
- Medical Coding
- Trend Analysis

Pre Clinical Safety

- Pharmacokinetic studies
- Toxicology Studies
- Lab Services
- Clinical trail Services – Phase I,II, and III

GCP Training

- GCP Training (ICH-GCP; India-GCP)
- Regulatory and Ethics India
- CRA & Clinical Trial Monitoring
- Becoming a Clinical Trial Investigator
- CRC & Study Conduct

Regulatory Services

- Regulatory submissions for Clinical Trails and follow ups
- Communication management with Authorities
- Post regulatory compliance

Therapeutic Area Experience

Therapeutic Areas	Capability/Experience
Cardiovascular	+++
Oncology	+++
Endocrine	++
Metabolism	++
Obstetrics/Gynecology	++
Neurosciences (neurology and psychiatry)	++
Dermatology	++
Immunology	+
Urogenital	+
Diabetes	++
Infectious Diseases	+

Availability of Therapeutic experts to support Clinical Trails and perform stand-alone consulting services

ICBio Operations



Continued Commitment
to the Clinical
Operations Market

- ICBio has been servicing the Clinical Operations market for last 3 years
- 150 research sites and hospitals nationwide
- ICBIO investigative sites are located in more than 17 cities across India
- Sites specializing in more than 14 therapeutic areas
- Each site is supported by a full-time ICBIO study coordinator (when involved in an ICBIO study)
- ICBIO clinical operations team has managed investigative sites that have Undergone successful US FDA inspections



➤ **Indian clients**

Natural Remedies, OLS, Micro Labs, Kumar Organic Products Limited, Airier Pharma, SBL Pvt Ltd, GenPharma International, Globela Pharma etc..

Global Clients

Jimjam Pharmaceuticals, Dolphin Pharmaceuticals, Delim Cosmetics and Pharma, Zhejiang Xianju Pharmaceutical Co Ltd etc...

ICBio - A Strategic Partner

ICBio Advantages

Customer Benefits

- Our Independent Patient Database & Patient Recruitment System
 - Centralized Quality Control
 - HUB -Single Point For All Negotiations and Queries
 - Rapid Budget and Contract Turnaround
 - Successful Patient Enrollment Results
 - Diverse Range Of Clinical Trial Experience
 - State-of-the-art Facilities and Equipment
 - Full-time, Trained and Experienced Staff
 - Qualified and Specialized Investigators
 - Effective Standard Operating Procedures
 - Proven Quality Assurance Programs
- Increased number of quality patients per site
 - Cost effective patient recruitment
 - Faster patient recruitment
 - Better patient retention through professional care and supporting environment to patients
 - Clean and Consistent high quality data on time
 - Consistent trial Conduction & Documentation
 - Decreased frequency of site monitoring visits–Saves time and cost
 - Single Point Of Contact (SPOC) to meet your requirements on all contractual matters across all sites
 - Ultimately to lead our clients to meet all their project timelines within time and within budget

Contacts

ICBio Clinical Research Pvt. Ltd.

16 , ICBio Tower, Yelahanka Main Road,
Chikkabetahalli, Vidyaranyapura

Bangalore - 560 097, INDIA

Tel: +91 80 2364 1042 / 43

Mobile: +91 99001 11996/ 97

Fax: +91 80 2364 1033

e-mail: info@icbiocro.com

Website: www.icbiocro.com

Dr. Harish.S

Director – Business Development

E-mail: harish@icbiocro.com

Mobile: +91 99001 21064