



ICBio Clinical Research Pvt. Ltd.

Clinical Research & Consultancy services

Objectives of this Presentation

- Introduction about ICBio
- Insight into India becoming one of the most favored destination for global clinical research, medical and healthcare companies.
- To explore opportunities to become a strategic partner and deliver, quick, economical and efficient entry into the Indian market, while allowing you to focus on core business.

About ICBio

- Established in 2005 as an Academic institute, ICBio, in 2008, expanded its venture into the field of providing Clinical Research related services and ever since delivering effectively to CROs & Pharmaceutical Companies.
- One of the leading CROs based in Bangalore working towards delivering excellence in the field of Life Sciences and Healthcare.
- Invincible attitude and passion to produce a positive impact in what we do, we constantly endeavor success.
- ICBio believes in its responsibilities, equips talent with the right skill set and induce a dynamic attitude to deliver industry expectations and beyond.

Vision and Mission

- **Vision**

To become 'one-point' contact for all Clinical Research requirements of our clients through delivery of Quality, Cost effective, Time bound and Value added services with focus on achieving a benchmark solution.

- **Mission**

Our mission is to become one of the best contract research partners for the life sciences industries to assist in the development of quality products by providing superior performance and services with high class project out come on time and in right budget.

Core Values

ICBio Emphasizes on a Strong and Long term business association through commitment on:

- Customer Satisfaction.
- Quality.
- Integrity.
- Strategic partnership.
- Customized 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 .
- Favored destination a head 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 1 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 .
- Top medical/technical universities in Asia.
- High qualified graduates with fluent communication in English to meet global arena

INDIA – Hub of Global Clinical Research

- 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 .
- 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 and also in house CROs set up by leading Pharma companies.
- Strong IT industry availability of IT skilled manpower

Services @ ICBio

ICBio is a fully integrated research facility capable of providing 360 degree support for the full circle of clinical trials, right from clinical trial support services to the pharmaceutical companies, biotechnology and medical device industry and assist in their product development.

Key services offered are :

1. Pre Clinical Research Services
2. Clinical Research services
3. Clinical Research Educational & Training Programs
4. Medical Writing
5. Business & Consulting Services
6. Human Resources solution in Clinical Research domain

ICBio service Capabilities

Pre Clinical Services

- Target Discovery
 - Target identification
 - Target Validation
- Lead Discovery
 - Lead identification
 - ✓ Lead optimization
- ✓ Pre Clinical
 - ✓ Chemistry
 - ✓ Invitro ADME
 - ✓ Invivo ADME
 - ✓ Pharmacokinetics
 - ✓ Efficacy
 - ✓ Safety
 - ✓ Toxicology

Investigational New Drug Application

Note: ICBio does not provide services to the Areas that are Grayed out

Clinical Trial Services

✓ Phase I

✓ Phase II

✓ Phase III

✓ SMO

- ✓ Site Initiation
- ✓ Site Training
- ✓ Site Monitoring

✓ CDM

- ✓ CRF Designing
- ✓ Database Designing
- ✓ Data Management
 - ✓ Data Entry
 - ✓ Data Cleaning

✓ Medical Coding

✓ Quality Control

✓ Database Locking

✓ SAE Reconciliation

New Drug Application (NDA)

✓ Phase IV (Pharmacovigilance /
Post Market Surveillance)

&

✓ Adverse Reaction reporting

Services @ ICBio

- A National Network of ICH – GCP trained sites
- Conduct of OPD-based and in-patient trials across all therapeutic areas, including specialty segments like oncology
- Larger patient numbers as compared to traditional sites
- Shorter time frames for study start up & recruitment
- Lower costs
- GCP-trained clinical research staff consisting of Principal Investigators, Research Physicians, Nurses, Clinical Research Associates, Clinical Research Coordinators, Clinical Data Coordinators, Medical Coders, Patient Recruitment Specialists & Administrators
- Unique Patient Recruiting System – “Clinical relations” system both at the Hub and Sites
- Centralized Feasibility, Contract Development & Budgeting, Project Management for sites, Clinical Relations & Quality Control

Network @ ICBio

- Large network of highly qualified investigators and investigative sites, These investigators and sites undergo a rigorous review process that includes examination of over 150 different data points and each is expected to meet and exceed in three critical areas that are:
 - Equality
 - Ethics
 - Performance

Network @ ICBio

- On an ongoing basis, the ICBIO study coordinators and project management team visit, review and evaluate new clinicians and sites to be added to the network. This due diligence process does not end once a site has been accepted into the network, but instead is ongoing with reevaluation taking place annually and based on dynamic performance records. Below are some facts about the ICBIO network for your review..
- Over 40 research centers and hospitals nationwide
- Nearly 700 investigators
- Over 150 data points are collected and evaluated for each site
- 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

Advantages with ICBio

- Our Independent Patient Database
- Our Patient Recruitment System
- Centralized Quality Control
- HUB - Single Point For All Negotiations And Queries
- Active Advertising For The Sites

Advantages with ICBio

- 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

Benefits to our Clients

- 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

Therapeutic Area expertise with ICBio

- **Gastro Intestinal**
 - Eg: Dyspepsia, GERD, Ulcers, Reflux Oesophagitis, Diarrhea, IBS, etc.,
- **Dentistry**
 - Eg: Paedodontics and preventive dentistry, etc,
- **Cardio Vascular**
 - Eg: Hypertension, Preventive Cardiology, Stable Angina, DVT prevention, etc,
- **Endocrinology**
 - Eg: Diabetes, Obesity, Pre-Diabetes, Dyslipidemia , Metabolic Syndrome, etc,
- **Rheumatology**
 - Eg: Osteoarthritis, RA, Osteoporosis, Chronic back pain, etc,
- **Immunology**
 - Eg: Allergies, Common Cold, Vaccines, etc,
- **Neurology**
 - Eg: Headache, Migraine, Chronic Pain, Appetite Disorders, Addictions (example: Smoking, etc,.) , etc,

Therapeutic Area expertise with ICBio

- **Dermatology**
 - Eg: Psoriasis, Acne, Eczema, Atopic Dermatitis, etc,
- **Urinogenital**
 - Eg: Overactive Bladder, BPH, Sexual Dysfunction, etc,
- **Psychiatry**
 - Eg: Anxiety, Depression, etc,
- **Women's healthcare**
 - Eg: HRT, Menstrual Disorders, Contraception, etc,
- **Preventive**
 - Eg: Prostate Cancer Prevention, Vaccines, etc,
- **Oncology**
 - Eg: Breast Cancer, Lung cancer, Pain Management, Leukemia, etc,

Regulatory Framework

- 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 Organization) to regulate Clinical Research.
- Further strengthening of environment by setting up National Drug Authority.
- Intellectual Property protection – India recognizes both process and product patents.
- Duty Free Import of Clinical Trial Supplies.
- Easier Drug Importation Procedure.
- ICMR Guidelines on the Safety Human Subjects.

Clinical Research Services



I. Project Management.

- Recruit investigators through our direct contact and in-house investigator database
- Train investigators and site personnel
- Patient recruitment and retention
- Prepare clinical development plan
- Randomization, repackaging, coding and labeling of investigational drugs
- Schedule monitoring activities
- Arrange and conduct steering committee meetings
- Provide clean and locked data
- Archiving
- Study site support Site feasibility studies
- Site/Investigator identification and selection
- Site initiation
- Study close-out
- Query Management

Clinical Research Services

II. Site Management

- Help the investigator in screening patients
- Assisting investigators in the Informed Consent Process
- Coordination and management of laboratory samples, courier and follow-ups of lab reports
- Drug accountability and dispensing at the site
- Investigational product management, dispensing, temperature monitoring and accountability
- Preparation, attendance and follow-up of monitoring
- Completing CRF entry
- Preparation, attendance and follow-up of Audit
- Preparation & forwarding the necessary information of closeout
- Prepare the required documents for submission to the Ethics Committee
- Initiating and submitting for Ethics Committee approval

Clinical Research Services



III. Clinical Data Management

- Data Management Plan
- Database Design & Setup
- Edit Checks Programming & Validation
- CRF Management using a
- Validated Indexing & Tracking system Validated Manual Double Data Entry
- Central Lab Data Import
- Medical / AE Coding
- Query Management
- Manual Data Quality Control
- Statistical Analysis
- Clinical Study Report

IV. Regulatory Services

- Inspection readiness preparing the site or sponsor for regulatory inspections
- Regulatory submissions for Clinical Trial Approval.

Clinical Research Services



V. Medical Writing

ICBio ensures you a synchronized balance between demands and challenges that comes across together with writing associated to research and Medical Industry work profile.

Our Service in Medical Writing

We have highly experienced professionals to give your study an enriching feel through effective Medical Writing. In broad terms our services in medical writing includes.

Protocol Writing

SOP Writing

Clinical Research Report Writing

Abstract and Excerpt Writing

Designing 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

Clinical Research Services

VI. Central Lab Services

- ICBio Provides central Lab Facilities
- Laboratory Data Handling & Processing
- Source Data Management

VII. Ethics Committee

- ICBio facilitates Independent Ethics Committee services to CRO

Business Management Services

- Market Entry Strategy Services.
- Setting up Indian Subsidiary and Joint Ventures.
- Office infrastructure & Human Resource.
- Representative Office.
- Market Research.
- Identify Office /Clinic/Business Premises and lease negotiations.
- Business Strategy.
- Finding Distributors.
- Licensing Technology.
- Product Registration & Regulatory Services.
- Contract Manufacturing.

Human Resources solution in Clinical Research

ICBio Manpower services:

ICBio Manpower provides Strategic resourcing to our clients to meet their employee supplies

- Services delivery to clients to meet dynamic work requirements through a well established Recruitment and Training division.
- Providing Clinical Research Service verticals, solutions and services covering different geographies.
- Focus is to raise productivity through improved quality, efficiency and cost-reduction across workforce, enabling clients to concentrate on their core business activities.

Our specialist teams work for clients across a range of industries, sourcing quality candidates for permanent, contract and temporary positions within commercial, professional, public service and industrial sectors.

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Pre Clinical Services

Innovative Center for Bio Sciences



Pre Clinical Services



- ***Preclinical Services***
- ***Clinical Laboratory Services***
- ***Laboratory Animal Services***
- ***Miscellaneous Invivo Services***

Regulatory & Non regulatory compliance per Good Laboratory Practice (GLP):

- Type of studies
 - Pharmacokinetics, Efficacy and Toxicological studies
- Type of compounds
 - Pharmaceuticals, Biologicals, Agrochemicals and Cosmetics
- Guidelines to be used
 - ICH,OECD, EPA, IP, BP, USP, Schedule Y & others.

Pharmacokinetic studies

- Studies in rats and mice
- Single Dose PK
- Dose proportionality studies
- Absolute Bioavailability
- Multiple Dose Pharmacokinetics
- Multiple routes of administration: Intravenous, oral, Subcutaneous, intramuscular, intraperitoneal and dermal.
- Tissue distribution
- Acute efficacy screening models
- Chronic efficacy screening models
- Based on the project suitable animal models will be used for screening
- Development of new animal models
- Genetically modified animal models

Toxicology Studies

- Acute toxicity Study
- Acute dermal irritation/corrosion
- Acute eye irritation/corrosion
- Skin sensitization
- Repeated dose 14/28 day toxicity
- Repeated dose 90 day toxicity
- Chronic studies
- Reproductive toxicity
- Mutagenicity

Lab Services

- **Surgical Services**
 - Cannulation - Jugular vein
 - Customized surgeries
- **Histopathological services**
 - Gross pathology
 - Organ collection and preservation
 - Tissue processing
 - Embedding
 - Sectioning
 - Slide preparation
 - Slide evaluation
- **Clinical Pathology Services**
 - Serum chemistry
 - Plasma chemistry
 - Hematology
 - Urinalysis

About Lab Animals

- Rats
 - Wistar
 - Sprague Dawley
- Mouse
 - Swiss albino
 - Balb/C
 - C57bl6
- Hamster
 - Golden (Syrian)
- Guinea pig
 - Dunkin Hartley
- Rabbit
 - New Zealand White

Import of transgenic, efficacy and other specific strain from reputed international organizations.

Miscellaneous Invivo Services

- Drug Controller approved Drug Testing Laboratory for all drugs & cosmetics involving laboratory animals.
- Drug Testing Laboratory Services as per IP, BP & USP
- Report in Form 39 of Drugs & Cosmetics Act
- Abnormal toxicity studies in mice
- Pyrogen testing in rabbits
- LAL test
- Quality plasma & serum
- Bioassays – FSH, LH, HCG, Insulin, EPO etc.
- Vaccine toxicity testing
- Antibody production in rabbits and guinea pigs.

Certifications

- CPCSEA Registration Certificate – (No. 25/10/2003 – AWD)
(Committee for the purpose of control and supervision of experiments on animals)
- Karnataka state - Drugs controller and Licensing Authority approval
- Licensed under Import/Export license for foreign trade regulation
(License # 0750000272/7/00/01)
- Institutional Animal Ethical Committee (IAEC)
CPCSEA approved
- Institutional Bio Safety Committee (IBSC)
RCGM (Review Committee on Genetic Manipulation) approved
- Animal facilities per CPCSEA guidelines

Pre Clinical Facility Tour



Pre Clinical Facility Tour



Pre Clinical Service Models

Plan I: Renting of Animal rooms

- Rooms for exclusive use of the company will be provided on monthly rental basis with and without skilled human resource on demand.
- Company can establish own laboratories or can use ICBio* laboratories on pay and use basis.
- Rental period ranging from 6 months to 2 years which can be extended with fresh Agreement

Plan II: Process outsource to ICBio*

Complete range of preclinical studies for regulatory submission or Customized studies

- Company can outsource complete animal experiments
 - PK, Efficacy, Safety and Toxicology studies
- Customized studies as per sponsor protocol.

ICBio* - Services provided through ICBio subsidiary

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THANK YOU