



ICBio Clinical Research Pvt. Ltd.

Clinical Research & Consultancy services

Objectives of this Presentation

- Introduction about ICBio
- Insight into India , 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

- ICBio is a CRO; fully integrated Clinical Research service provider; whose dedication to providing outstanding medical research is fueled by an unrivaled commitment to quality. ICBio is transforming clinical trials through our people, innovation and transparency.
- Offering services in different countries and serving sponsors for 3+ years, we have different a level of expertise that has enabled us to work on a variety of compounds, ranging from niche treatments and therapies to blockbuster drugs. Our distinct combination of expertise and insight delivers results in every phase of clinical research.
- We serve clients across all phases of pharmaceutical and biotech drug development by combining therapeutic and operational expertise with local knowledge.
- We share the same level of involvement, commitment, and passion as our clients—a dedication to collaboration that delivers life-saving products with more efficiency and greater speed.

About ICBio

- ICBio officers and staff members provide quality services to all its clients / customers and to ensure optimum utilization of its resources. In order to achieve this, every individual of ICBio will adhere to ICH GCP its compliance in all spheres of activities.
- ICBio is continuously working towards the excellence to endeavor the continuous success. We are striving on the strong foundation of scientific expertise, ethical culture and technological development.
- We are committed for high quality standards of services and maintain the timelines and strict confidentiality adhered to international level of guidelines and regulations to deliver the true value of client's need.

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 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.
- ICBio follows its core values of **‘Customer Satisfaction, Quality, Integrity, Strategic partnership and customized Services and maintain consistency in its deliverables compliance to the global standards.**

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

ICBio Services



- ICBio is a fully integrated research facility capable of assisting clients in their product development, right from Lead optimization to clinical trial services to the pharmaceutical companies, biotechnology and medical device industry and assist in their product development.
- IC BIO offers a full range of clinical drug development services worldwide.
- We have a successful track record of managing programs in all phases of clinical development. IC BIO distinguishes itself by having facilities inside hospitals to allow rapid recruitment of patients and volunteers. In Phase II-III, IC BIO has executed many pivotal trials that led to FDA and/or international regulatory approval. In late phase, we assist clients with the post-approval process by planning and conducting large, simple studies, registries, outcome studies, and risk management programs.
- Choosing an appropriate partner for the drug development process is the most critical step in Clinical Research. ICBio provides professional, innovative, effective and most comprehensive clinical trial solutions for the needs of pharmaceutical, biotechnology and other Healthcare industries globally in their clinical development by evolving various strategies to ensure timely execution of clinical projects and cost-competitive services.

ICBio Services

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

ICBio Services

- Clinical Trial Feasibility and Patient enrollment Planning
- PI & Site Selection
- Site Management Operations
- Project Management
- Clinical Data Management
- Drug Safety & Pharmacovigilance
- Medical Writing & Submission
- Biostatistics and Programming
- GCP Training
- Pre Clinical Services
- Regulatory Services

Therapeutic Expertise



- ICBIO Therapeutic Expertise is comprised of board certified physicians and industry experts. The group covers a broad range of therapeutic areas and provides ICBIO staff with training and support during operational delivery of clinical services.
- We provide services through all phases of drug development and, specifically, in the areas of clinical medicine, biostatistics and regulatory submission strategies.
- ICBio has asset of experience conducting pivotal clinical trials in all the major therapeutic areas. Our global experience and resources are essential for conducting cost-efficient and timely trials for your novel therapies.
- Six key areas in which we have the most extensive trial experience are Cardiovascular/Endocrine/Metabolism, Obstetrics/Gynecology , **Neurosciences (neurology and psychiatry)** and Dermatology. In these areas, we offer broad study experience and direct knowledge of study requirements, risk management, and best implementation. With experienced and dedicated clinical and medical teams, and in-house therapeutics area expertise, we offer effective study design, start-up, and site management services that help ensure that you get the most from your Phase II/III trials.

Therapeutic Expertise



Other clinical therapeutics areas where we have trial experience include:

- **Endocrine/Metabolism**
 - Diabetes, Obesity, Hyperlipidemia
- **Neurosciences** (neurology and psychiatry)
 - Anxiety, Depression,
- **Rheumatology**
 - Osteoarthritis,
- **Trichology**, - Alopecia, Hair loss treatment
- **Dermatology**
 - Sun Screens, Epilation, Psoriasis, Acne,
- Obstetrics/Gynecology
- Allergy/Immunology
- Orthopedics
- Gastroenterology
- Ophthalmology
- Pulmonology

- Anesthesia
- Pediatrics
- Genitourinary
- Women's Health
- Preventive Medicine
- Infectious Diseases
- Herbals & Nutraceuticals
- Cosmetics

In addition to supporting every trial conducted by ICBIO, our therapeutic experts perform stand-alone consulting services including:

Training for core team members (e.g. CRAs)

Site Management Services

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

ICBio Network

- 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
- On an ongoing basis, the IC BIO 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 IC BIO network for your review.
- Over 150 research sites and hospitals nationwide
- Nearly 500 investigators
- IC BIO 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 IC BIO study coordinator (when involved in an IC BIO study)
- IC BIO clinical operations team has managed investigative sites that have Undergone successful US FDA inspections

Advantages with ICBio

- 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

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

Pre Clinical Services

- *Preclinical Services*
- *Clinical Laboratory Services*
- *Laboratory Animal Services*
- *Miscellaneous In vivo 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.

Pre Clinical Services



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

Pre Clinical Services

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

- ServicesSerum 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.





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.

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