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ICBio Profile

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. Simply put, we do more than point you in the right direction. We give flight to medical research. Our approach to transforming the clinical trial landscape will continue to make a difference to healthcare patients around the world.

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. Our quality management system fully complies with ISO 9001:2008 standards.

ICBio Therapeutic Expertise and Experience



Broad therapeutic area experience produces quality clinical trial management

Over the years, our focus on quality science has allowed us to attract and retain some of the most experienced clinical and medical research experts in our industry. 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.

ICBIO's Therapeutic Expertise group provides scientific and medical expertise for clinical development worldwide. 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 recruited well over 24,000 patients from targeted populations for studies in our core therapeutic areas, which are:

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 and site management services that help ensure that you get the most from your Phase II/III trials.

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: Clinical development program and protocol design, Integration of scientific/clinical, regulatory, and Training for core team members (e.g. CRAs)



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 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 150 research sites and hospitals nationwide

Nearly 500 investigators

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

ICBio Services

ICBIO 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. ICBIO distinguishes itself by having facilities inside hospitals to allow rapid recruitment of patients and volunteers. In Phase II-III, ICBIO 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 is a lucrative 'One Point Contact' for all clinical research requirements.

Our comprehensive services include:

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

Clinical Trial Feasibility and Patient Access Planning

Helping our client take a wise decision

ICBio begins a trial with careful approach and first freeze the client requirements towards 'Clinical trial Feasibility analysis'. ICBio has in-house database with 150+ research sites across India of which, 50+ are our associate sites. The profile of these sites have been audited and approved against 150 key data points before declaring the feasibility.

Here ICBio makes sure that investigational sites & infrastructure, investigators & qualification, geographic location & ease of accessing them, patient demographics & daily patient turn over for a particular condition, etc, are scrutinized before moving ahead to conduct the trial.

This knowledge and experience can be exploited to provide our clients with best sites in terms of Quality, Time and Budget. ICBio Ensures Robust Site selection with consistent and realistic recruitment rates.

Sample Clinical trial feasibility data points under ICBio include:

- ✓ **National incidence data:**
 - Current status and projected growth rates
 - Updates and upgrades as and when available
- ✓ Regional incidence data, growth rates and comparison with other global regions
- ✓ Number of physicians nationally and locally treating a specific condition
- ✓ National and regional health association, support and advocacy groups for a condition
- ✓ Standard of care information for a condition including number of clinical trials taking place nationally (aggregate, condition-specific and regional)

Sample site feasibility analysis data points under ICBio include:

- ✓ Patient load per month
- ✓ Standard of care treatment
- ✓ Types of medical equipment at each site and their experience conducting clinical trials
- ✓ Profile of competing clinical trials at site
- ✓ EDC capabilities
- ✓ IRB Details including meeting times, frequency, makeup

PI and Site Selection

Reap the benefit of our experience and expertise to get the best sites and patients

Identification of potential study sites is one of the vital steps in effective trial management and overall success of any clinical trial. ICBio has experts to identify investigators & evaluating site staff, facilities, clinical research expertise and patient demographics. We have a network of 900+ investigators and 100+ sites & a stringent selection criterion to short list sites for our clients.

ICBio initiates the process of identifying physicians working within areas of highest prevalence of epidemiology with a high patient turn over on a daily basis and also those investigators having high clinical trial experience, or capable of becoming potent investigators. This leads to high and effective patient recruitment and randomization rates.



Services offered by ICBio under PI and Site selection include:

- ✓ Therapeutic specialty with trial experience
- ✓ Geographic location in relation to disease prevalence
- ✓ Patient demographics & patient load
- ✓ Standard of care
- ✓ Annual office visits by condition
- ✓ Personnel qualifications & thought leadership (KOLs)
- ✓ Facility, equipment and infrastructure specifications
- ✓ IRB meeting frequency, turnaround times and composition
- ✓ Competitive study landscape (Accessibility to airports for transport of time-critical lab samples)
- ✓ Experience working with ELS and performance record

Regulatory Services

In the dynamic Indian regulatory environment, with more than 25 recent changes in local and national regulations related to the conduct of clinical trials, it is the continuous vigilance and learning to adapt, that leads one to understanding the guidelines and laws and be compliant. ICBio has the capability to track, anticipate and / or react to changes and the credibility to track necessary records to resolve issues quickly. ICBio ensures providing effective regulatory services helping our clients to proceed effectively and successfully by assisting in the following activities:

National Regulatory Services:

- ✓ Pre-submission discussions with Drugs Controller General's Office (DCGI)
- ✓ Application for permission to conduct clinical trials for New Drug / Investigational New Drug and determine correct Category Status (Category A or Category B)
- ✓ Interactions with the DCGI office and head to resolve questions and submit amendments
- ✓ Obtain import/export licenses for CTM & Samples
- ✓ Handling of all Customs related issues
- ✓ Government fee submissions
- ✓ Protocol amendment submissions
- ✓ Post regulatory approval compliance

Institutional Review Board / Ethics Committee Services (Sample Only – Not a complete list of services or requirements):

- ✓ Protocol with application performance
- ✓ Approval of the Head of the Institution
- ✓ Informed Consent Process (ICF in regional languages)
- ✓ Case Report Forms and Follow-up Cards
- ✓ Preclinical animal data, Clinical Trial data & IB
- ✓ Regulatory clearances from DCGI/ other Regulatory Bodies
- ✓ Agreement to report SAE to IEC
- ✓ Assist the PI in completing 1572
- ✓ Inspection readiness preparing the site or sponsor for regulatory inspections
- ✓ Regulatory submissions for Clinical Trial Approval
- ✓ Financial issues related to PI and institutional payments, patient related expenses, etc.

Project Management

Recruit investigators through our direct contact and in-house investigator database

Effective project management is always a key to successful project completion. ICBio, provided effective project management services through its skilled project management team in following areas:



- ✓ 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

Site Management services

Customized strategies... successful trials

ICBio uses Oracle Clinical for Clinical Trial Management. We have an experienced work force with an effective project management team implementing our plan with utmost care. Prime emphasis is on maximizing Quality, Optimizing project budget, Meeting all time lines while always focusing to ensure all TATs from us and sites are met. We also support in IEC/IRB and RA submissions and Pre-study qualification visits. We provide customized team and focus on each project which works on study documents designed per client preference and approval with further inputs as required.

ICBio organizes and ensures efficient site training with regular investigator meetings right from the study start and then through the conduct stage to ensure high quality of data so that queries are minimized and that they are effectively addressed. We also provide site related financial support in trial (Investigator fees, etc)

Our clients are always having latest updates with respect to their trials being conducted through ICBio.

Services under Site Management Include:

- Providing 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
- 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
- Customized teams
- Effective Patient recruitment
- Continuous interaction with clients through Regular planned / Adhoc meetings
- Support designing, review and approval of study documents
- Investigator management (Contracts, Fees, administration, etc)
- Vendor Management (Lab, Scanning, Translation, etc)

Data Management

Delivering through World Class Tools and Expertise

Clean, high-quality data is one of the most critical elements of any clinical trial.

ICBio has skilled team and capabilities to deliver data management services in various therapeutic areas across different phases, from phase I to IV, for data used for global regulatory submissions.

ICBio has planned to secure all of its client's data through 21CFR Part 11. We have FSP and FTE models for effective delivery of data management services.

We use Oracle Clinical Data base for effective clinical data management and TMS Review system with MedRA dictionary for medical coding.

Services offered under Clinical Data Management are:

- ✓ Case Report Form (CRF) Design and Production
- ✓ Programming and Validation of Edits for Consistency Checks
- ✓ Database Design and Validation
- ✓ Data Entry Screens
- ✓ Remote Data Entry (RDE)
- ✓ CRF Log and Tracking
- ✓ CRF Review with Double Data Entry and Verification
- ✓ Clinical Data Review, Query Generation and Resolution
- ✓ Correction Processing
- ✓ Audit Trail Generation (Per 21CFR Part 11)
- ✓ Adverse Event reporting and Concomitant
- ✓ Medical Coding
- ✓ Data Quality Reviews and control
- ✓ Database Lock and Archiving
- ✓ Database Status Updates
- ✓ SAS Data base designing
- ✓ Report Generation (Business Objects and Crystal Reports)

Drug Safety and Pharmacovigilance:

ICBio is dedicated to provide a strategic team to clients meeting their expectations and beyond. The team can effectively provide active management of drug safety, risk management and patient health during the entire lifecycle of a product from preclinical through the conclusion of the marketing period of a product.

The services include right from helping setting up a data base, managing the adverse events, Global safety reporting, regulatory reporting, Coding through Global dictionaries like MeDRa, strategic planning for trend analysis and risk management.

Services of ICBio under Drug safety and Pharmacovigilance include:

- ✓ World class services in terms of delivering Quality data
- ✓ Short lead-in times, clear and concise processes tailor made to meet client expectations ultimately leading to effective client management and their satisfaction
- ✓ Provide our support across all global time zones (24/7 services)
- ✓ Deliver services within time and budget, further assist in lowering the overall cost base for drug safety activities that is ensured through focus on
 - Re-allocation of resources
 - Lower recruitment and headcount expenses
- ✓ Focus on Strong QA and QC sticking to compliance and leading to
 - Reduction in business risk to due favorable inspection outcomes
 - Faster time to market

Medical Writing and Submission

ICBio can deliver the following services with our efficient work force that are ICMJE (International Committee Medical Journal Editors) and GPP (Good Publication Practices) trained and experienced in effective training plan for every function with high emphasis on quality.

We have expertise in drafting client customized SOPs, PDs (procedural documents) and WIs (Work Instructions) as well as working on client systems and SOPs We also have expertise in designing effective web based document management system

Services under Medical Writing include:

- ✓ Developing Protocol
- ✓ Developing Informed Consent Form (ICF)
- ✓ ICH E3 compliant CSRs (Clinical Study Reports) for regulatory submission (local and global)
- ✓ Preparing PSUR s (Periodic Safety Update Reports)
- ✓ Narrative Writing
- ✓ Preparing ASRs (Annual Safety Reports)
- ✓ Writing Abbreviated Reports
- ✓ Designing letters to editors for medical journals
- ✓ Manuscript Writing
- ✓ Abstracts and Poster Preparation
- ✓ Preparing CTRD (Clinical Trial Registry Database) summaries
- ✓ Compilation of Investigator's Brochure (IB)
- ✓ SOP writing
- ✓ Designing Case report Forms
- ✓ Documentation for Regulatory Submission
- ✓ Medical and scientific literature reviews
- ✓ Marketing & PR Medical Writing
- ✓ Medical writing for Web
- ✓ e-learning web portals for online education

GCP Training

It is very important that training for both new and experienced clinical research professionals is considered with utmost importance as it is a critical component of any drug development program. It is especially important in India because of the relatively young age of the industry and its dynamicity.

ICBio ensures regular (Continuous and ADHOC) training and education on GCP for all those who require or seem to require and many a times recommend or make it a mandate to attend the training as a fresh training or as a refresher both for internal work force as well as external, but associated to the trials.

The training is imparted with a team having hands-on clinical trials experience as well as training experience in training physicians, executives, CRCs, CRAs, etc, in the clinical research process.

This way, ICBio ensures a strong foundation to all those involving in the clinical research leading to their success in future. We can also strategically provide tailor made training programs per client preference and requirements.



Topics covered by ICBio under GCP training include, but are not limited to:

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

Biostatistics and Programming

- ✓ This service is available under either FSP (Functional full service provider model) or Piece meal service specific to biostatistics consultation is available for our clients
- ✓ SAS certified / experienced programmers with system expertise in SAS 9.1.3 and SAS 9.2
- ✓ Services are spread across planning and designing the analysis to developing reports of the analysis of trials across all phases and across studies like Observational, exploratory, genomics, Proteomics or pharmacological molecules and registries that are compliant per ICH-E3 and CTD
- ✓ Generating Randomization lists for our trials under FSP or piecemeal service for the trials as well as emergency envelopes
- ✓ Design and development of effective client and protocol specific statistical analysis plan
- ✓ Statistical data monitoring to ensure adherence to protocol and related ethics
- ✓ Quality control of all the trial related documents and statistical output (double programming)
- ✓ Meta-analysis and clinical summary preparation
- ✓ Independent data review and support services through IDMC/DSMB to our clients
- ✓ Analysis and reporting of PK, PD, PGX (pharmacogenomics), DNA and pharmacoeconomics
- ✓ Regular planned, Adhoc and Post-hoc analysis, Translational research data analysis and data mining

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	Type of compounds	Guidelines to be used
<ul style="list-style-type: none"> • Pharmacokinetics • Efficacy • Toxicology 	<ul style="list-style-type: none"> • Pharmaceuticals • Biologicals • Agrochemicals • Cosmetics 	<ul style="list-style-type: none"> ✓ ICH ✓ OECD ✓ EPA ✓ IP ✓ BP ✓ USP ✓ Schedule Y & others

Pharmacokinetic Studies	<ul style="list-style-type: none"> ✓ 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
Efficacy Studies	<ul style="list-style-type: none"> ✓ Acute efficacy screening models ✓ Chronic efficacy screening models
Toxicology Studies	<ul style="list-style-type: none"> ✓ Based on the project suitable animal models will be used for screening ✓ Development of new animal models ✓ Genetically modified animal models

Lab Services	Surgical Services	<ul style="list-style-type: none"> ✓ Cannulation - Jugular vein ✓ Customized surgeries
	Histopathological services	<ul style="list-style-type: none"> ✓ Gross pathology ✓ Organ collection and preservation ✓ Tissue processing ✓ Embedding ✓ Sectioning ✓ Slide preparation ✓ Slide evaluation
	Clinical Pathology Services	<ul style="list-style-type: none"> ✓ Based on the project suitable animal models will be used for screening ✓ Development of new animal models ✓ Genetically modified animal models
About Lab Animals	Rats	<ul style="list-style-type: none"> ✓ Wistar ✓ Sprague Dawley
	Mice	<ul style="list-style-type: none"> ✓ Swiss albino ✓ Balb/C ✓ C57bl6
	Hamsters	<ul style="list-style-type: none"> ✓ Golden (Syrian)
	Guinea Pigs	<ul style="list-style-type: none"> ✓ Dunkin Hartley
	Rabbits	<ul style="list-style-type: none"> ✓ New Zealand White
	Dogs	<ul style="list-style-type: none"> ✓ Beagle Dogs

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

Miscellaneous In vivo 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

Contact us

for your needs in product development, we here to serve your esteem organization

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