ICBio Clinical Research Pvt. Ltd

Bangalore

ICBio is a leading Contract Research organization

An ISO 9001: 2015 Company

www.icbiocro.com

Innovative Center for Bio Sciences

ICBio
Excellence in Biosciences

Introduction

ICBio Clinical Research Pvt. Ltd is a leading CRO, based in Bangalore, INDIA, approved by **DCGI, CDSCO, NABL** accredited clinical laboratory, having in-house R & D recognised by **DSIR**, Department of science and technology, Our site / facilities have been inspected / approved by **MOH Kazakhstan**.

We conduct Clinical trials **Phase II to IV and Bio-availability / Bio-equivalence Studies (Bio Studies) for Pharma, Herbal and Cosmetics**. We have good recognition in service industry with services worldwide.

We have conducted **BA/BE studies** for submission various regulatory agencies **worldwide like FDA Philippines, Vietnam, Tanzania, MOH Kazakhstan, all CIS countries**.

Accreditation & Certification

Drug Controller General of India (DCGI)

NABL
Accreditated Laboratory

ISO 15189: 2012 / NABL

DSIR Recognition for In-House R & D

ISO 9001:2015

Ministry of Health, Kazakhstan

Accreditation & Certification in process

Instituto de Salud Publica de Chile

National Pharmaceutical Regulatory Agency

New Clinical Facility with 48 beds

We follow…

Studies conducted with strict adhere to

- ICH-GCP, GLP and 21 CFR (part 11) guidance's.
- We also adhere to timely execution of projects within budget and accurate, reliable and comprehensive data by following applicable regulatory guidelines.
- We are Client focused, flexible and also cost effective CRO in India.
- we focus on quality and add value services to our clients.
- We have served a more than 30 satisfied customers. We have consistently exceeded our customers' expectations in terms of quality, speed and affordability.
- We have a long track record of evaluating the safety and efficacy for a wide range of therapeutic indications, with the support of its pan India network of Investigators and sites.

Facility

- ICBio has a well-designed, State of art infrastructure to conduct various activities with independent operational areas for Clinical Trials, BA/BE studies, Medical Writing, Clinical Data Management.
- Our BA/BE facility has State of art infrastructure to conduct BA/BE studies, with Access controlled area's like Clinical Units / CPU, Bio analytical and Diagnostic / Clinical Laboratory, Volunteer screening, Volunteer Information centers , Archives, intensive care units and pharmacy.
- Tie up with Super Specialty hospital for conduct of BA/BE Study on patient population as well as Clinical trials.
- Located with easy access to basic transportation system.


ICBio
S.P & SONS
ICBio
Clinical Research
ICBio CRO

CLINICAL FACILITY

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CENTRAL LABORATORY SERVICES

- In-house NABL Accredited labs
- Screening of Volunteer
- Safety Sample Analysis after study Demographic Data, Medical and Medication Histories, General Physical Examination and Systemic Examination, ECG, Chest X-ray, Hematology, Biochemistry, Serology and Urine analysis
- Integrated with LIMS

LC-MS/MS (Shimadzu 8040)

DOCUMENTATION AND ARCHIVAL

- Protocol & Report Writing.
- Clinical research coordinator
- Access Controlled Archival

Archival 1

Archival 2

Documentation work stations

Our Services

Drug Development & Commercialization Partners in India

Our Services

- Clinical (Phase II & IV) Development
- Bioequivalence & Bioavailability Studies
- PK / PD Studies
- Regulatory Affairs, Consulting (End-to-End)

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Our Services

- Clinical Trials - Phase II-IV; Proof of Concept & Early Phase studies
- Data Management
- Medical Writing
- Post Marketing Surveillance
- Investigator Initiated, Observational, Non interventional studies
- Safety & Pharmacovigilance

Clinical Trials ; Phase II-IV

- Small pilot studies to large multicenter international clinical trials, Proof of Concept & Early Phase studies
- we have strategic relationships, with hospitals and worked with 150 sites with 18 plus therapeutic areas across 17 cities in India & effectively conducted Clinical trial phases.
- Investigator/Site identification and selection
- Project management and site monitoring, site Close out.
- In House Central laboratory (NABL Accredited) and nationwide network to pickup sample.
- Medical monitoring and safety monitoring
- Bio-statistics and report writing

Bioavailability/ Bioequivalence (BA /BE) studies

- Our expertise Team has ensured the development many validated bio-analytical methods.
- Dedicated team to develop and validate new methods for BA/BE studies.
- Our team is competent to develop and validate a minimum of 5 methods every month.
- our Bio Studies portfolio includes various BA/BE Studies, and PK / PD & Patient Studies.
- ICBio has an active volunteer database of 6000 volunteers, including healthy volunteers and female volunteers.

Bioavailability/ Bioequivalence (BA /BE) studies

Types of studies:

- Fasting and Fed condition
- Single and multiple dose in healthy subjects
- Drug-drug interaction, drug-food interaction
- Special | Patient Population (PK | PD) studies
- Crossover Studies / Parallel / Two-stage design / Steady state studies / Partial / Full replicate studies
- Cosmetic and safety evaluation studies

Our strength:

- Regulatory Submission and Approval; BE NOC and Import license
- Bioanalysis (MD, MV, Sample analysis)
- Long term storage for plasma samples/ investigational products
- ICH E3 Report (Paper / eCTD)
- In-house Archives

PK | PD and Patient Studies

- we offer best-in-class services to conduct Patient population PK studies and clinical endpoint studies on healthy volunteers and patient population to assist our clients with their drug development programs.
- We have an extensive volunteer database and also have tie up with major hospitals and investigators' to conduct patient PK studies and Clinical end point studies.
- ICBio Team have enormous experience of conducting studies in all the major therapeutic areas.
- Enriched by extensive experience and ably supported by cutting edge technology, teams at ICBio have conducted several Pharmacokinetic and Pharmacodynamic studies. As part of the pk studies on Patient and Special Population portfolio

Bio-Analytical Services

Offering wide range of Bio-Analytical services, advanced facilities, equipment and highly-trained personnel for custom method development, assay validation, and sample analysis using modern LC/MS/MS equipment to support Pharmaceutical NCE and Generic Drug Development.

The Bio-Analytical Team has developed a deep understanding of the specific regulatory requirements of international regulatory agencies such as FDA, EMEA, ANVISA, WHO, MCC, TGA and DCGI.

Our method data bank have few new drug assays, with the standards set by international regulatory authorities.

Bio-Analytical Services

All analytical methods developed and validated at ICBio CRO are compliant with latest international regulatory requirements with assurance of precision recovery and stability checks.

We offer the flexibility and specialized expertise to either transfer your clinical assay or develop a method from scratch and validate the assay for the bio-analysis in a cost effective and timely manner. Our staff has developed Bio-Analytical methods including routinely quantifying levels in pg/ml.

ICBio has developed various validated assays for multiple analytes, metabolites, prodrugs and light and temperature-sensitive compounds in various biological matrices.

Our Bio-Analytical facility

- LC-MS/MS
- 4,000 square-foot bio-analytical area
- Spacious Sample Separation Area
- Solid Phase Extraction Systems (48 well plated)
- Nitrogen Evaporators
- Refrigerated Centrifuges
- Freezer (-20°C) and Deep Freezers (-80°C)
- Automatic temperature recording device
- Dedicated Servers for LCMS/MS data
- All our systems use validated software that is CFR 21 Part 11 compliant.
- The Bio-Analytical data is electronically transferred and documented.
- All study samples at ICBio are stored in secure freezers with temperatures ranging from - 20° C and -80° C. These freezers are monitored round the clock with power backup.

Clinical Data Management

CDM team has vast experience in the process of collection, cleaning and management of subject data in compliance with regulatory standards.

The team works towards providing high-quality data by keeping the number of errors and missing data as low as possible and gathers extensive data for analysis.

The team provides Data management services, Report writing and Regulatory submission services in best in class timelines in the industry.

Clinical Data Management

The team has rich experience in handling various industry benchmark EDC tools such as Inform, other tools. CDM team provides end to end data management services from Study start-up to Study closeout.

Our strength

- **Case Report form (CRF) design and Review**
- **Data Management Plan**
- **Database Setup and Validation**
- **Remote Data entry & double Data entry**
- **CRF log & Tracking**
- **Adverse event coding**
- **Database lock and archiving**
- **Coding in MedDRA & AC check**

Regulatory Affairs

ICBio Regulatory Team has successfully completed various audits from Indian & International regulatory agencies.

- Formulation of regulatory strategies
- Compilation of the Study application
- Regulatory Liaising for all Clinical trial activities
- Response to regulatory agency queries
- Procurement of drug import licenses
- Procurement of NOC for export of biological samples
- Tracking of applications and approvals
- Safety Reporting
- Submission of Clinical Safety Report (CSR)
- Renewal of Import License

Medical Writing Services

Our Medical writing team

- Is qualified and well experienced to comply with the requirements of various regulatory report guidelines.
- Ensure that all regulatory submission documents are clear, concise, accurate & fully compliant with all applicable ICH and regulatory guidelines with submission reports provided in eCTD and CTD formats.
- Rapid turn around-time is ensured for all final reports.
- Is well trained in the compilations of abstracts, manuscripts and publications.
- Our Medical Writing services comprise Protocol, Investigation Brochures, Informed Consent Documents, Case Report Forms, Study Reports,
- Study modules, eCTD, Scientific Papers for publication..

Medical Writing Services

- Dossier Compilation as per
- ASEAN Common Technical Dossier (ACTD)
- Common Technical Dossier (CTD)
- Drug Master File
- Drafts Data - Process Validation, Stability Study Reports
- Compilation of Periodic Safety Update Reports (PSUR)
- Submission-ready Documentation (Hyperlinked eCTD formatting)
- Clinical Study Reports
- Integrated Safety & Efficacy Reports
- Pharmacovigilance & Safety Reports
- Presentations, Posters & Manuscripts

Clinical Laboratory

The Clinical Laboratory is **Certified by NABL**.

The laboratory is equipped with **state-of-the-art infrastructure**, an array of advanced equipment, well trained and highly experienced personnel, with latest **Laboratory Information Management System (LIMS)** for online data transfer, ensure shorter turn-around time with exemplary levels of consistency and quality. equipped to carry out a vast array of investigations that include

- **Hematology**
- **Urine Analysis**
- **Biochemistry**
- **Clinical Pathology**
- **Endocrinology**
- **Serology**

Quality Assurance Programs

Quality assurance team will monitor the clinical activities, focuses on the quality and implementation of various Quality Control (QC) and Quality Assurance (QA) procedures.

our Quality Assurance activities cover Internal Audits by QA team for area specific SOP compliance.

The QA Head reports directly to the Management. Quality Assurance systems at ICBio are compliant with relevant local & international regulations.

our archival facility is designed with utmost security and is temperature & humidity controlled to ensure long term archival of study and related documents. All studies are digitally archived for back-up retrievals.

We have competencies to address regulatory and sponsor queries, and recommend best practices based on feedback received.

we have in-house capabilities to perform:

- Site Audits
- Systems / Process Audits
- Vendor Audits
- Document Audits (Protocol, Clinical Study Reports & essential Clinical Trial documents)

Industries served

- Pharmaceuticals
- Biotechnology
- Nutraceuticals & Herbals
- Cosmetics, Personal care & OTC Products

Type of Studies (Clinical Trials)

- Double Blind, Placebo controlled Safety and Efficacy studies
- Open Label studies
- Active comparator studies
- Phase IV studies

Capability to conduct different type of dosage forms

- Immediate Release
- Sustained / Controlled Release
- Biphasic release
- Dispersible tablets
- Mouth Dissolving Films
- Suspensions
- Effervescent tablets
- Creams / Ointments

Type of Studies (Cosmetics studies)

SKIN CARE : Lightening, Ageing, Acne / oil control, Redness/Sensitive skin, wrinkle assessment, Moisturizers, Elasticity / Firmness, Deodorant/Perfumes

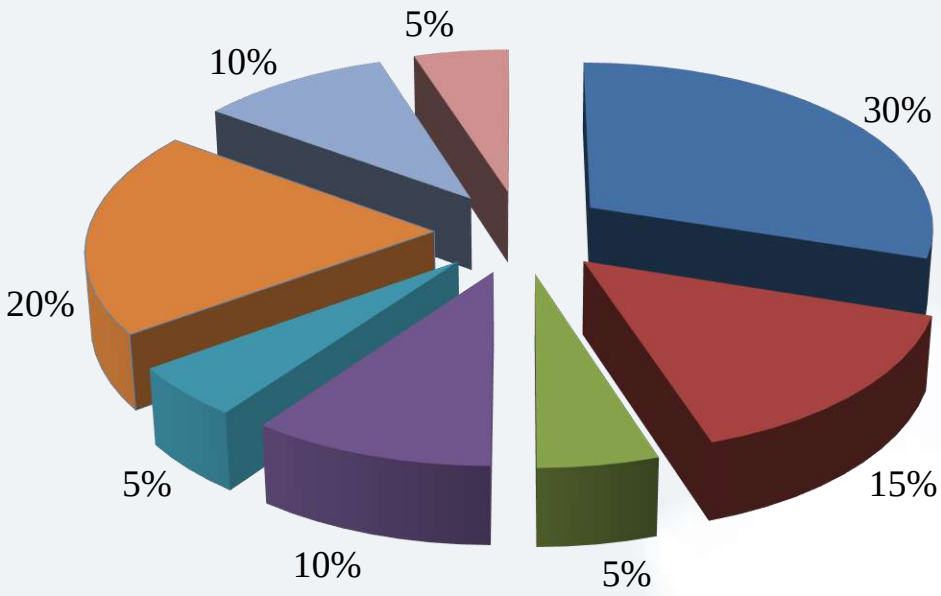
HAIR CARE : Cleaning / Conditioning, Growth stimulation, Growth retardation, Dandruff Control.

OTHERS : Mouthwash, Toothpastes, Weight Loss and Management

Tests : Invivo (human volunteers)

Invitro : Helpful in product development stage.
Eg: SPF: Estimation of protection from UVB (short wave UV light) and UVA (long wavelength UV light).

Experience with different Therapeutic areas



- Metabolic /Cardiovascular disorders
- Dermatology
- Oncology
- Gastrointestinal
- Oral health
- Herbals & nutraceuticals
- Respiratory & Immunology
- Others

Our Strength

- All our Technical staff members are working with ICBio for an average of 6 years
- our Team focus on time line and delivery of the project with over team and our process.
- Allowing us realized our commitment our clients / sponsors
- One point contact for your needs, client relationship manager.
- On Time Project Delivery,
- Repeat Business Rate
- Staff Turnover 5 %
- 55 Staff Members

ICBio Advantages

- ICBio has an established network of about 150 research sites and hospitals nationwide. Few sites have been inspected by USFDA.
- ICBio investigator sites are located in more than 17 cities across India & sites specializing in more than 18 therapeutic areas
- Dedicated Project Management Team with single point of contact, Skilled and Focused Site Management.
- ICBio team has vast experience and expertise in monitoring and managing clinical studies for different regulatory agencies.
- Efficient monitoring of clinical study sites ensures stringent compliance to protocol, GCP and regulatory requirements.
- Monitors ensure to establish effective communication with the study staff to achieve high quality standards.

ICBio Advantages

ICBio team brings in exposure to various regulatory authorities like

- **USFDA**
- **ANVISA- Brazil**
- **EMEA**
- **MoH-Turkey**
- **NPRA-Malaysia**
- **MoH-Kazakhstan**
- **MCC-South Africa**

Pharma Clientele

International Clientele

instavit

Ultra Medica Pharmaceutical Industries

CCL PHARMACEUTICALS

Delta Pharma DELTA

SANDHUS® Step towards wellness ™

RUS BIOPHARM

incepta Incepta Pharmaceuticals Ltd

BIOPHARMA LIMITED

ACME

Wound Market Consulting

Innovative Center for Bio Sciences

ICBio Excellence in Biosciences

Cosmetics , Personal Care & OTC products Clientele

emami

REDHA care
Professional Partnership · For Quality

ITC Limited

Welmedix®
HomeCare PRO
Empowering Caregivers

Sante Mernaud

SANDHUS®
Step towards wellness ™

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Herbals & Nutraceuticals Clientele

ITC Limited

Plant Lipids

Natsyn Catalysts
HERBS, HERBAL EXTRACTS & CATALYSTS

SBL
WORLD CLASS HOMOEOPATHY

VIDYA HERBS U.S.A
COMMITTED TO NATURE

green chem®
Green Chem®
HERBAL EXTRACTS & FORMULATIONS

ABS

British Biologicals
The Protein People

admark herbals limited

Bio-gen Extracts

Natural solutions
For Those Who Care for Health

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Thanking you

Dr. Harish.S
Director
ICBio Clinical Research Pvt. Ltd.
An ISO 9001, ISO 15189, ISO 14001, ISO 27001 & OHSAS 18001 Certified Company

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