CELEBRATING 18 Years of EXCELLENCE

Connecting services across the product lifecycle

ICBio® Excellence in Biosciences

ICBio Clinical Research

ICBio is an independent full-service Contract Research Organization(CRO), based in Bengaluru, INDIA, specialized in delivering high-quality, end-to-end clinical research solutions to Bio-pharmaceuticals, Pharmaceuticals, Bio-similar, cosmetics, medical devices, and nutraceutical companies.

OUR SERVICES

- Bio-availability / Bio-equivalence Studies
- Clinical Trials Phase I – IV
- Pharmacovigilance
- Biometric Services
  - Data Management
  - Statistical Program & Bio-Statistics
  - Regulatory & Medical Writing

CDSCO — Drug Controller General of India (DCGI)

ANVISA

مجلس الصحة لدول مجلس التعاون — Gulf Health Council

وزارة الصحة العراقية

MHRA

NABL — Accreditated Laboratory
GCLP Accreditation

NPRA MALAYSIA

وزارة الصحة و وقاية المجتمع — MINISTRY OF HEALTH & PREVENTION

ZAMBIA MEDICINES REGULATORY AUTHORITY

U.S. FOOD & DRUG ADMINISTRATION
FEI # 3011421852

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Why ICBio As Partner

Scalability
(In- House training Programs)

Single partner
Convenience

Tailored personalized solutions

SPOC
Single Point of Contact

Cost Effective

Quality and Compliance with excellence
KPI & SLA Driven

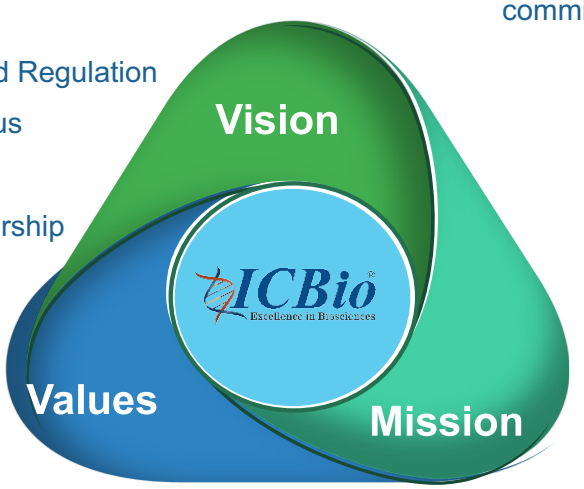
Subject matter Experts for each Process
(Industry Experts)

Technology Automation Support

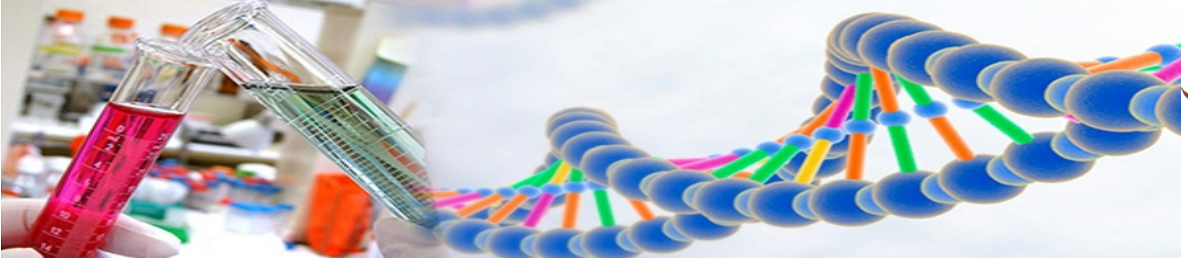
Our Vision, Mission & Core Values

To be a trusted **one-stop destination** for our clients delivering end-to-end services throughout the product lifecycle, with a commitment of patient safety.

- Quality with Excellence
- Patient-Centric Approach
- Commitment to Client and Regulation
- Innovation with Continuous Improvement
- Empowerment and Ownership
- Honesty and Integrity



By embracing a growth mindset and through unwavering commitment and dedication to excellence, we aim to create impactful changes for our clients and patients, ultimately transforming lives worldwide in the healthcare industry.



ICBio®
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Facility

World class state of the art BA/BE facilities conforming to highest compliance with an emphasis on quality and safety at all standards. Capabilities: 132 bed facility spanning 4CPUs with Bio-analytical testing services, ICH GCP, GCP, 21 CRF part-11 compliant. Database of over 10,000 registered volunteers and easy access to a diverse population, Multiple governance systems ensure 100% adherence to regulatory guidelines Independent QA department with SOPs, training and audits, Pre-conduct study approval by ACE Ethics Committee

Unit - I

Unit - II

Strategic Location

* Well connected to Bengaluru International Airport

* UPS back Up – 32.5 KVA generator * Access Controlled * State of the Art Clinical Facility
Clinical Pharmacology Units, Bioanalytical, Documentation and Archival.

CPU –I, 24 beds for phase I / BA / BE studies	CPU –II, 36 beds for BA / BE studies
CPU –III, 40 beds for BA / BE studies	CPU-IV 32 Beds

- Total facility- 40,000 square feet.
- Demarcated areas for dedicated area of operation
- CPU, our CPU can handle 3 simultaneous studies in a day.
  Update 100 subject's studies
- The CPU efficiently handles data
  * Seamless sample collection up to 100 subjects in a day.
  *

ICU

Pharmacology Unit

- 132-bedded Clinical
- 6 bedded Intensive Care Unit
- Recreational Area
- Putting volunteer comfort first, No second-level beds

Centralized NABL AccreditedLIMS Integrated Path Lab-GCLP certified

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

Accreditation by NABL, recognizing technical competence

Demonstrating proficiency in delivering pathology services

Commitment to reliability, professionalism, and efficiency in medical services

Documentation Area

Access Controlled separate Archive Room

Efficient Protocol & Report Writing Team

Clinical research professionals to ensure GCP & GDP

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ICBio- Experience Expertise Global Reach

World-class BE facilities adhering to highest compliance with attention to quality & safety at every stage standards. 100 bed facility across 3 CPUs facility with Bio-analytical testing services, ICH GCP, GLP, 21 CRF Part-11 complaint, Clinical Capability: Database of 10,000+ registered volunteers and ready access to diverse populations Multiple governance systems ensure 100% adherence to regulatory guidelines Independent QA department with SOPs, training and audits, Pre-conduct study approval by ACE Ethics Committee - DCGI registered IECs at Bengaluru, Periodic certification to ISO 9001, ISO 27001, ISO 15189, Self-identification with USFDA.

18+ years of experience

Single Point of Contact

500+ Trials supported

1000+ BA/BE Studies

<5%
Staff attrition rate

150+ Research sites across 17 cities

20+ Therapeutic areas

21 CFR
ICH GCP
GLP Complaint

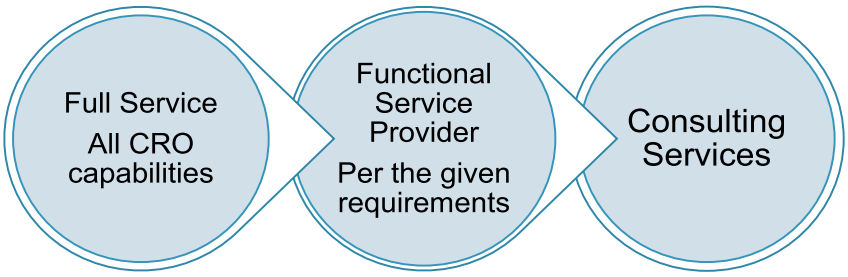
56 Countries around the globe

10,000+
Pre-screened candidates

80+ Satisfied clients

Rapid Deployment- 14days

Tailored Solutions



Bioavailability and Bioequivalence Services

Phase I & BA/BE Experience & Capabilities

Our Bio-availability & Bio-equivalence team is experienced in delivering outcomes which are efficient, timely, cost effective, high-quality, adhering to regulatory needs in **fast track to achieve your first-to- market strategy.**

we're your end-to-end partner for Bio-availability & Bio-equivalence services:
From concept to Regulatory submission - Study Design, study Conduct, Bioanalysis, Data Standardization in CDISC, eCTD & Dossier Preparation, data archival, and Pharmacovigilance.
At ICBio, we don't just conduct studies—we master them across dosage form evaluations, Our expertise spans:

- Single dose, multi-dose, dose escalation,
- Ascending dosed (SAD /MAD)
- PK /PD studies,
- Clinical end point studies,
- Glucose clamp studies,
- Single and double-blind methodologies
- Precision dose escalation studies
- Cutting-edge PK/PD endpoint analyses
- State-of-the-art glucose clamp investigations
- Proof of concept and exploratory research
- Pioneering "first in man" repeat studies.
- Specialized nutritional assessments
- Tailored trials for unique populations
- Comprehensive drug interaction evaluations
- Drug interaction
- Injection and inhalation studies

Our track record of delivering high-quality outputs for complex studies is unparalleled. When you choose ICBio, you're not just getting a service provider—you're partnering with industry leaders who turn clinical challenges into scientific breakthroughs. Excellence isn't just a goal—it's our standard.

Global Compliance, Uncompromised Quality

- State-of-the-art facilities approved by DCGI, ANVISA, MOH KAZAK, UAE, GCC, NPRA Malaysia, MOH Kazakhstan.
- Self-identified with USFDA FEI # 3011421852
- Studies accepted globally: Health Canada, MHRA, EU, TGA Australia, ISP Chile.
- ISO 9001-2015 and ISO 27001-2013 certified
- NABL-accredited clinical laboratories (ISO15189-2012)
- we ensure at most quality and compliance for generic companies worldwide

Availability of several LC-MS/MS platforms for elemental analysis and LBA capability, as well as scientifically built and compatible systems and processes. High-tech labs enabling Sciex-4000 Sciex-4500 Sciex-5500 LC-MS/MS analysis along with perkin Emler ICP MS.

Conducted 1000 + BA/BE studies successfully, ICBio has an active volunteer database of 10000 +++ volunteers, Including healthy male, female and post menopausal volunteers. MOUs with leading corporate hospitals & successful seamless execution of patient based studies

Experience with Route of administration

Injection

Oral

- Tablet (IR, ER, DR, OD, EC)
- Capsule (Soft Gel, MR)
- Chewable Tablets
- Suspension
- Granules
- Sublingual

Rectal

Transdermal

Topical

Vaginal

Pulmonary

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Pharmacokinetics(PK), Biostatistics & Report Compilation

Experienced Team:

- Biostatisticians
- SAS Programmers
- PK Scientists
- Report Writers
- Report Compilators

Diverse Study Experience:

- Crossover
- Parallel
- Partial replicate
- Fully replicate
- Steady state
- Two -stage bioequivalence
- In-vitro bioequivalence

Advanced Analysis Capabilities:

- PK/PD analysis using Phoenix® WinNonlin ®
- Statistical analysis with SAS® software

Regulatory Compliance:

- Report writing adhering to ICH E3 format
- Study data submission in CDISC standards
- Centralized report compilation as per eCTD standards

Bioanalytical Services

Comprehensive LC/MS/MS bioanalytical services provided by experienced scientists including method development, validation, and sample analysis as per current regulations.

Accurate quantitative analysis at picogram levels.

Over 250+ bioanalytical methods in biological matrix.

Over 1.5 million samples analyzed

ICP-MS for elemental

Upright freezers (-70° C) and (-20° C)

21 CFR compliant digital temperature monitoring system.

6 LC/MS/MS, API 4000, 4500, Sciex 5500, Shimadzu 8040,8050, Front end Variants : HPLC & UFLC

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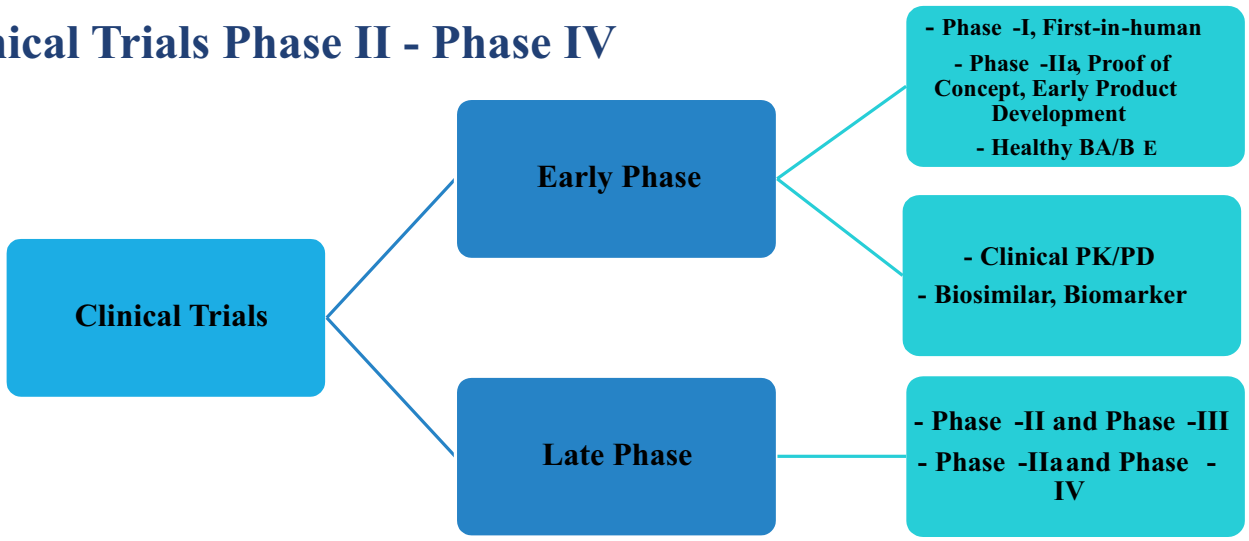
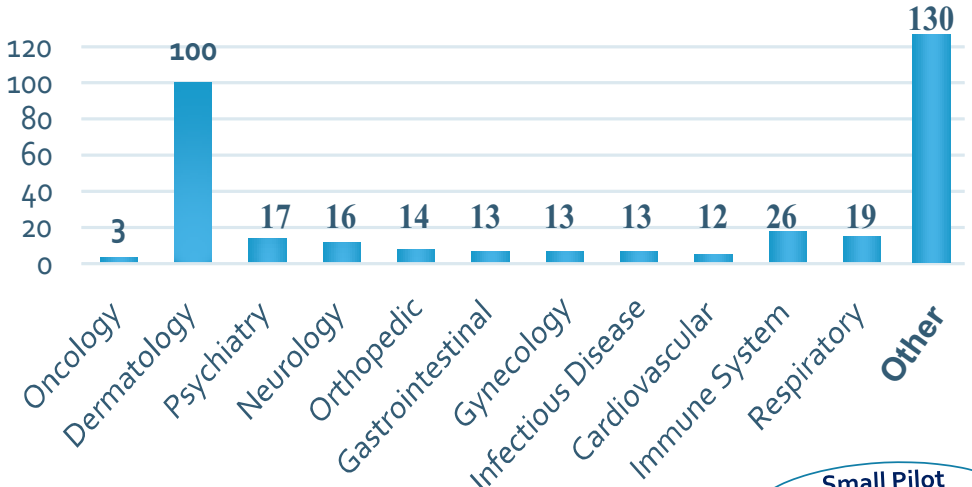
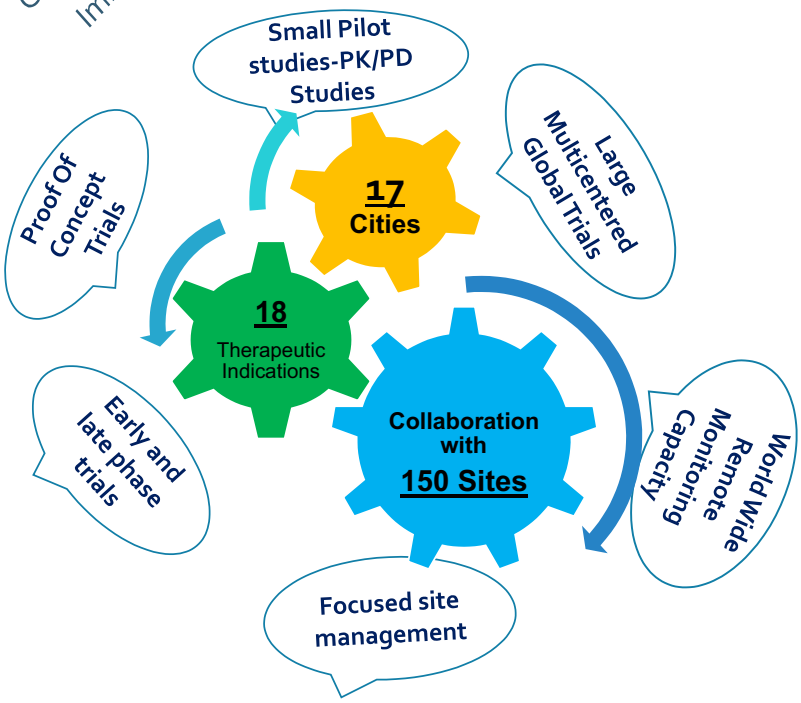
Clinical Trials Phase II - Phase IV



Experience in 500 + Clinical Trials across 18+ Therapeutic area





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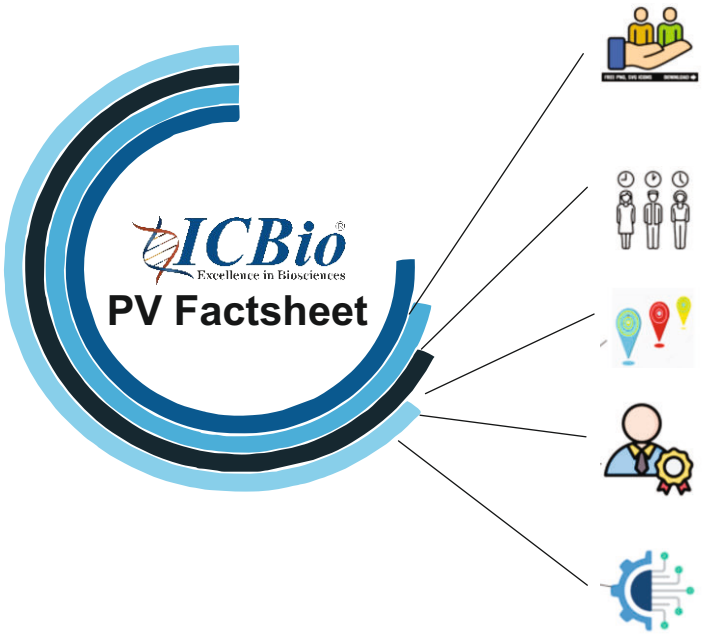
Pharmacovigilance Service

- Individual Case Safety Report (ICSR) Services
- Aggregate Reports Services
- Signal And Risk Management Services
- Literature Screening and Review
- Risk Management Plan (RMP) development.
- QPPV Services
- Pharmacovigilance System Master File (PSMF)
- PV Consulting and Additional Support

ICBio PV Fact Sheet



15+ clients
24000 + ICSR cases - annually
100+ Aggregate reports (PSUR/PBRER/DSUR etc.)
Signal Detection for 50+ products
70000+ Literature Review

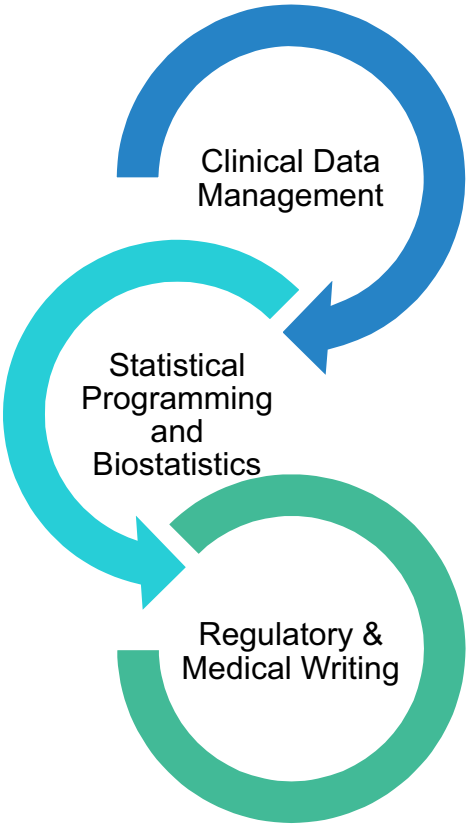
20 FTE supporting PV activities
80% of employee HCPs and 20% Physicians

Company Footprint
India-Benglaru (Head Office)
Global - Australia / LATAM / Kazakhstan

Expertise
15 years of collective experience in PV
in house specialized PV Training programs

Technology Infrastructure
Safety Database / supporting end to end ICSRs
Literature search and review
Automation

Biometrics Services



End to end data management services provided by our experienced CDM team

Efficient analysis of data collection requirements and implementation of effective strategies

Tailor made solutions for quick, reliable, and cost-effective data management

Proficiency in handling industry benchmark EDC tools such as Inform and others

Clinical Data Management

Our Clinical trial Data management services include

- **Design Case Report Form (CRF) & Review**
- **CRF and data query tracking systems**
- **Database setup / Design and Validation**
- **Data Management Plan**
- **Data Cleaning and Reconciliation**
- **Medical Coding Services; Coding in MedDRA & AC check**
- **Data processing; Remote Data entry & double Data entry**
- **Database lock and archiving**

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Biostatistics and programming Services :

ICBio Biostatistics and programming team has a wide range of therapeutic experience, software knowledge, and degrees. We add value to client projects by providing data-driven information, analysis, interpretation, and study design. Our CDISC expertise and can set up a CDISC strategy that aligns with business, financial, and regulatory objectives. We have produced CDISC, SDTM, and ADaM-compliant datasets for over 1000 plus research and have made several CDISC- compliant regulatory filings.

We can customize our extensive clinical biostatistics services to your project's requirements:

- Planning for clinical development, study design, analysis, and endpoint strategies, in addition to supplementary techniques and plans for statistical analysis.
- Create and integrate a randomization schedule with investigational product management, and other project planning requirements.
- Scientifically sound interpretation and reporting of results, combined with efficient, quality production of full-output deliverables Real-time analysis presentations and regular, automated, and secure web postings.

Continuous

- Protocol and Study Design
- Randomization and study blinding

And

- CRF Design
- Statistical Analysis Plan

Progressive

- Data collection and Analysis
- Manuscript writing and Scientific Presentation

Biostatisticians and statistical programmers ensure accurate, high-quality, and timely deliverables

Expertise in statistical analysis for BA/BE study designs, patient-based PK/PD and CE trials, in-vitro studies, and more

Proficient in generating mock shells, TFLs, TFGs, CDISC, SDTM, ADaM, derived data, and other statistical analysis components.

Regulatory Affairs Solutions

End-to-end regulatory services with strategic expertise for efficient lifecycle and data management operations and faster go-to-market. Accelerate results with our global regulatory affairs solutions.

Currently regulatory scenario is rapidly changing, making faster approvals more difficult than ever. It is critical to collaborate with a partner who possesses global experience and expertise, intelligence-gathering strategies, and the ability to shift in real time. With over 16 years of experience, ICBio clinical research business offers end-to-end regulatory solutions and a team of highly engaged, cross-functional regulatory experts to help navigate the evolving global regulatory requirements, accelerate outcomes, and increase the likelihood of approval success.

Electronic common technical document (eCTD):

Our publishing solution expedites the delivery and validation of submissions by creating regulatory-compliant PDF files and validation tools to ensure quality published outputs satisfy technical requirements for health authority gateways and portals.

- Regulatory submission forecast and planning
- Submission document management and tracking
- Regulatory content management
- Change control management
- Tracking label changes
- Integrating Regulatory information
- Regulatory Intelligence

ICBio collaborates with companies to bring their practical requirements to any region or health authority in an efficient and cost-effective manner, using both a qualitative and quantitative approach.

ICBio's strategy is to work collaboratively with our clients to help them grow. ICBio's expertise in regulatory services allows it to work on both long-term partnerships and fixed project delivery. This includes assisting pharmaceutical companies at every stage of the approval process, from dossier creation and submission to renewals, variations, responding to HA queries, labelling, and pharmacovigilance.

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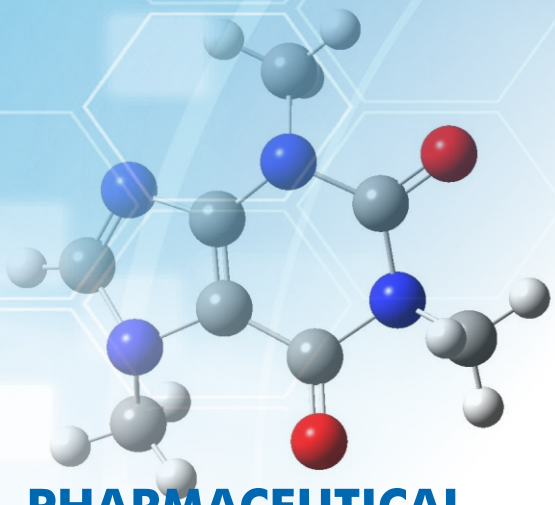


Clinical Dermatology Trials

We offer our services for a wide range of products, from clinical dermatology to oral, hair and skin care products. we do provide clinical trial services for personal care industry, Technical measurements are performed using the highest standard of equipment in the industry.

We have separate imaging facilities with image analysis for accurate quantitative measures. Other services that can be availed include outsourcing volunteers (optional service) and a diagnosis coded data base assists in reaching enrolment targets in a timely fashion. Trials have been conducted in areas of acne, psoriasis and atopic dermatitis as well as fairness, brightening and whitening and anti-wrinkle agents.

PHARMACEUTICAL

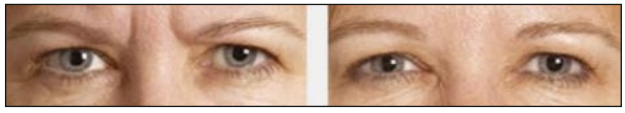
Treatment drug or drug formulation for various Dermatology indications or supplement for the improvement of Skin, Hair and Nail.

- **Patch Testing**
- **HRPT, PIPT**
- **Moisturization Studies**
- **Sunscreen Testing**

COSMECEUTICAL

- Cosmetics
- Personal Care
- Beauty
- Over The Counter
- Skin Care
- Hair Care
- Eye Care
- Oral Care
- Baby Care

  & other products



AESTHETICS

Safety and Efficacy test for :

- Dermal Fillers
- Botulinum Toxin
- Chemical Peels
- Anti-ageing Products

Why to choose ICBio

- ICH GCP, GLP, 21 CFR Part 11 Compliant
- Global Regulatory compliance
- Flexible working hours for global clients,
- SPOC
- 10000 Plus patient populations database
- Single partner convenice
- Rapid Turn Around Time
- On time project delivery.

"To be a trusted **one-stop destination** for our clients seeking end-to-end services throughout the product lifecycle, with a commitment of patient safety."

Vaccines

Please feel free to reach out to us
We look forward to assisting you

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