ICBio Clinical Research Pvt Limited

Your trusted Clinical Research Partner

Corporate Presentation 2024

About Us

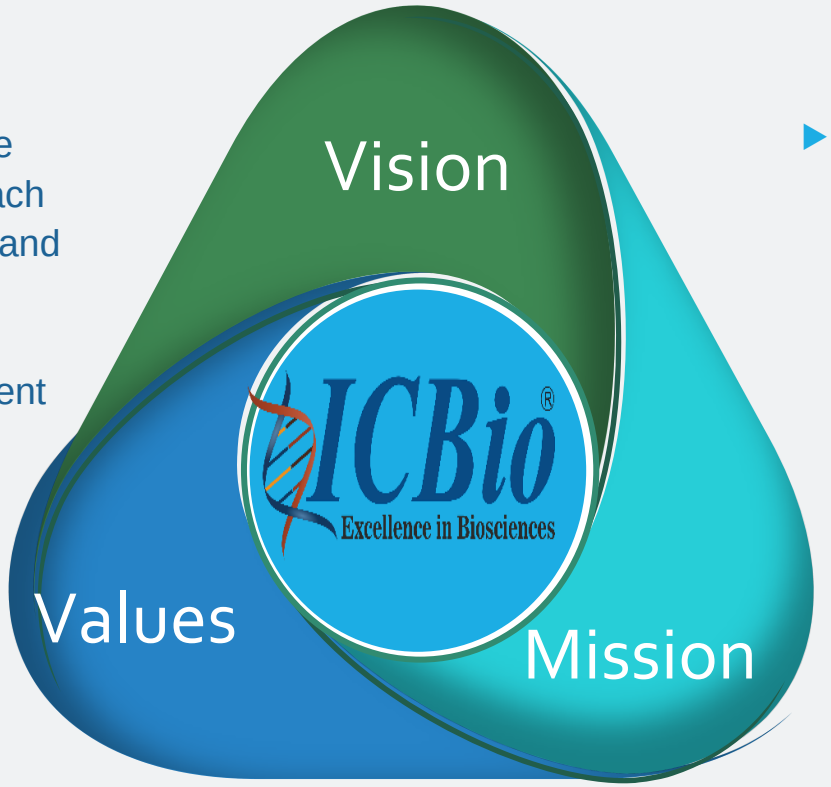
ICBio is an independent full-service Contract Research Organization (CRO), based in Bengaluru ,INDIA established in 2008 providing comprehensive, quality & integrated and end to end clinical research solutions; specialized in providing Bioavailability / Bioequivalence Studies, Clinical Trials Phase I – IV, pharmacovigilance and clinical safety services.

ICBio® Excellence in Biosciences

About Us

- 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 Regulations
- Innovations 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®
Excellence in Biosciences

Achievements We Celebrate

500 + trials supported

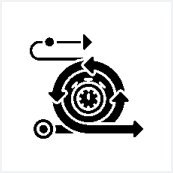
80+ satisfied clients

MOU with 150+ research sites across 17 cities

1000+ BA/BE Studies

Less than- **5%** staff attrition rate

Rapid Deployment- **14 days**



20 Therapeutic Areas

56 countries around the globe

16 + years of excellence

Single point of contact

21 CFR, ICH GCP and GLP Compliant

10,000+ pre-screened candidates

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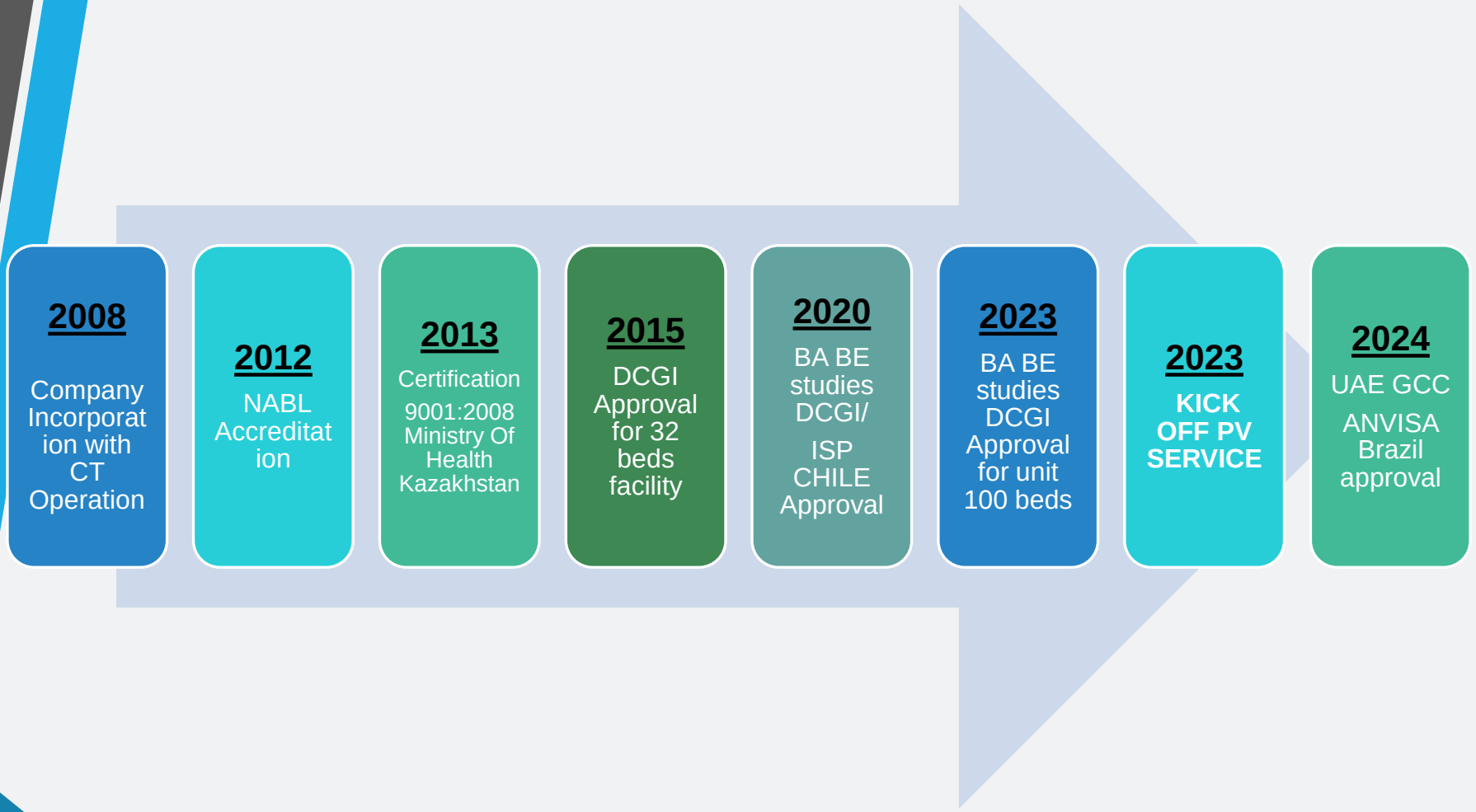
Our Journey



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Accreditations and Certifications

Drug Controller General of India (DCGI)

NABL
Accredited Laboratory
GCLP Accreditation

MHRA

ANVISA

U.S. FOOD & DRUG ADMINISTRATION
FEI # 3011421852

The Ministry of Health Republic of Kazakhstan

MOH Iraq

EMA

ZAMBIA MEDICINES REGULATORY AUTHORITY

وزارة الصحة و وقاية المجتمع
MINISTRY OF HEALTH & PREVENTION

NPRA MALAYSIA

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

CERTIFIED ISO 45001:2018 COMPANY

International Organization for Standardization ISO 14001:2015

International Organization for Standardization ISO 9001:2015

ISO 14155:2020
Clinical investigation of medical devices for human subjects- Good clinical practice

ICBio Excellence in Biosciences

ICBio Team-Meet Our Expertise

Dr. Meera singh
Head-PV
16 Years of Experience

Dr. Lakshmikar B V
Head
Clinical/ Investigator
24 Years of Experience

Dr. Harish S.
CEO / Director,
23 year of experience

Mr. Murugan P
Chief Operating officer.,
20 Years of Experience

Mrs.Pushpalatha
Director
14 Years of Experience

Balaji Radhakrishnan
Head-QA, M. Pharm,
15 Years of Experience

Praveen Kumar
Head-Bio Analytical
M.Sc. Analytical Chemistry, 15 Years of Experience

Dr. Ankita Das
Investigator/ Pathologist,
MBBS, MD Pathology,
7 Years Experience

Mr. Anand N. Chougule
Manager- Operation
M.Pharm,
07 Years of Experience

Dr. Vidhya Sreekumar
Principal Investigator
MD/Pharmacology
05 Years Experience

ICBio Team

Each of our scientists has a university degree in pharmacy, life sciences, or dentistry

Team of 70 + staff members

Senior	5 to 8 years
Mid level	4 to 5 years
Junior	0 to 2 years
Project management	8 to 25 years

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Our Facilities

Our Facility

Unit -I

Strategic Location

- Well connected to Bengaluru International Airport

Facility

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

Unit -II

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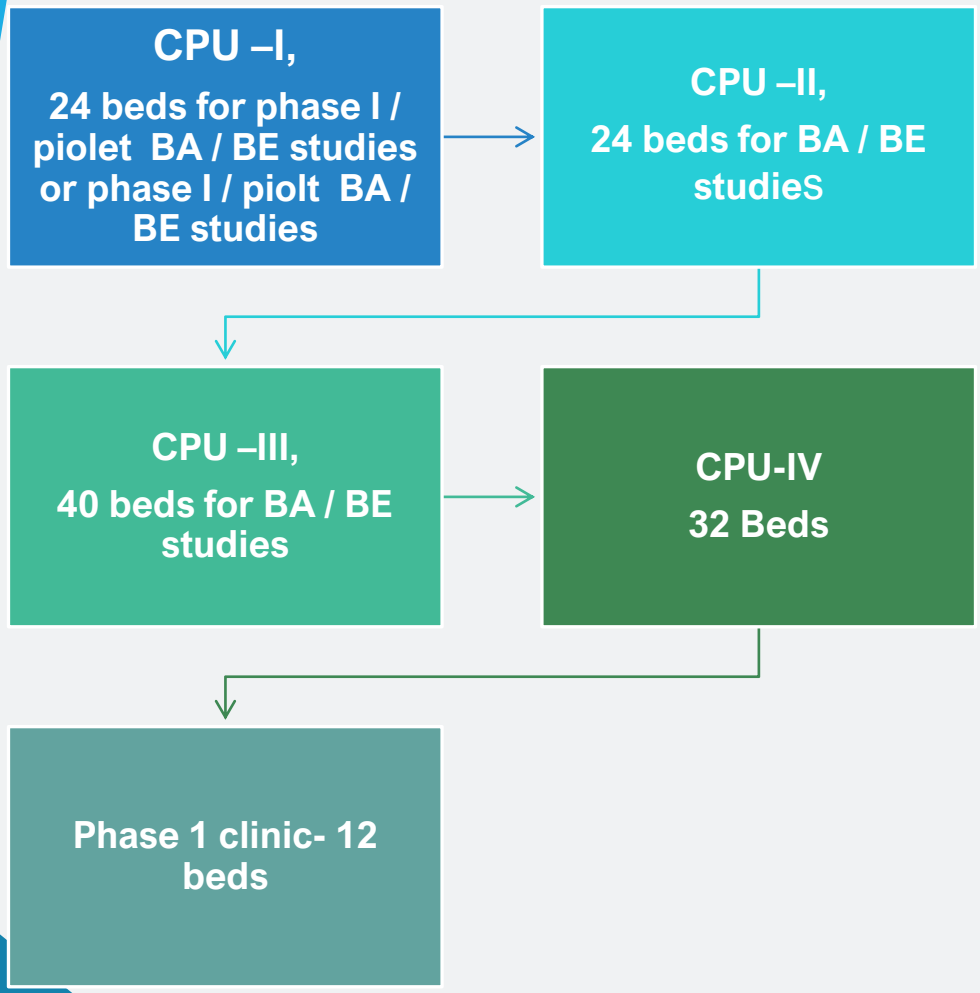
Our Facility



- Total facility- **40,000 square** feet.
- Demarcated areas for dedicated area
- CPU- The CPU can handle three concurrent studies in a single day.
- Update **100 subject's studies**
  - The CPU efficiently handles data collection for up to 100 subjects in a day.

ICBio® Excellence in Biosciences

Pharmacology Unit

- 132-bedded Clinical
- 6 bedded intensive care unit
- Putting volunteer comfort first
  No second-level beds
- Re Creational Area

Bioanalytical Lab

Comprehensive LC/MS/MS bioanalytical services provided by experienced scientists

Services include method development, validation, and sample analysis as per regulations

Multiple LCMSMS machines utilized to expedite analysis, saving time in time-bound studies

Accurate quantitative analysis at picogram/mL concentrations

Complex bioanalysis of bound and total drug compounds

Hormone and vitamin analysis expertise

150 molecules analyzed with 5-point method validation

6 LC/MS/MS

API 4000, 4500, Shimadzu 8040,8050,

Front end Variants : HPLC & UFLC

Over 250+ bioanalytical methods in biological fluids

Over 1.5 million samples analyzed

ICP-MS for elemental

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

Digital temperature monitoring system.

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Centralized NABL Accredited
LIMS 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

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ICBio® Excellence in Biosciences

Documentation Area

- Access Controlled separate Archive Room
- Efficient Protocol & Report Writing Team
- Clinical research professionals to ensure GCP & GDP

Phase I & BA/BE

Phase I & BA/BE Experience & Capabilities

Type of Study	No. of Studies
Bioavailability & Bioequivalence (BA/BE)	1,000+
First-in-human (FIH)	3
Single Ascending Dose/Multiple Ascending Dose (SAD/MAD)	2
Drug-Drug Interaction (DDI)	4
PK/PD	8
Food Effect	5

MOUs with leading corporate hospitals & successful seamless execution of patient-based studies

Injection

Oral

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

Rectal

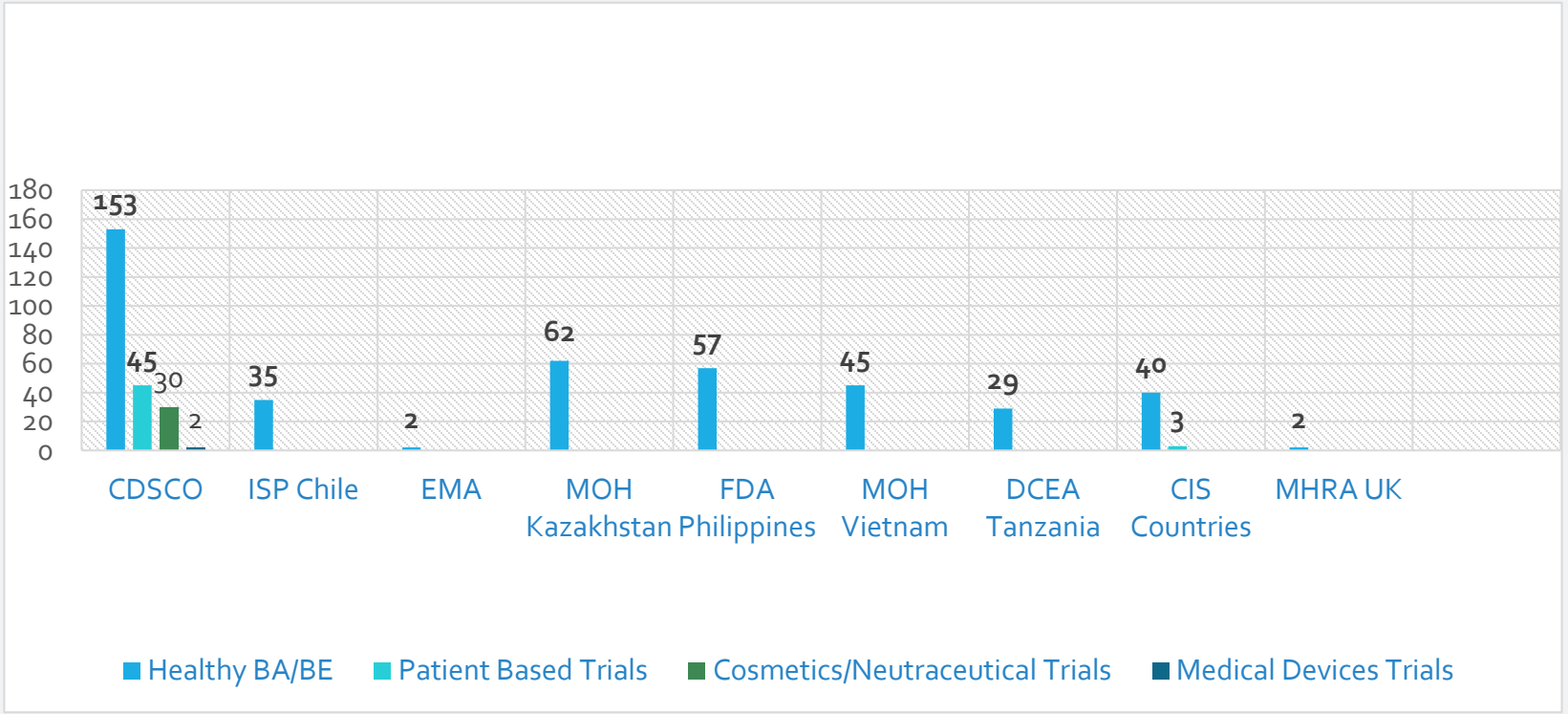
Transdermal

Vaginal

Pulmonary

Experience with Route of administration

Phase I BA/BE Studies Experience



❖Conducted **1000 + BA/BE studies** successfully

❖ICBio has an active volunteer database of **10000 +++ volunteers**, including healthy volunteers and female volunteers.

ICBio® Excellence in Biosciences

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:

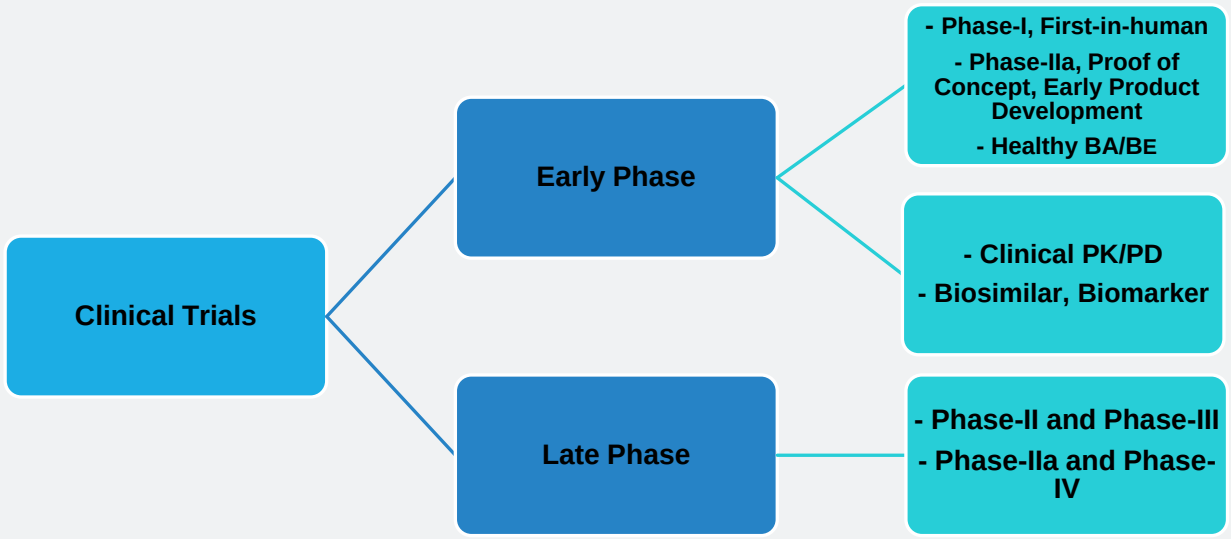
- PK/PD analysis using Phoenix® WinNonlin®
- Statistical analysis with SAS® software

Regulatory Compliance:

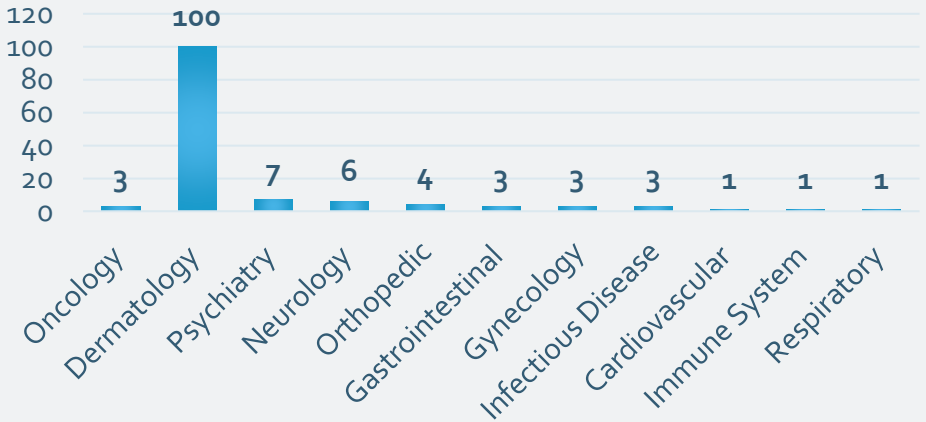
- Report writing adhering to ICH E3 format
- Study data submission in CDISC standards
- Centralized report compilation as per eCTD standards

Clinical Trials Support

Clinical Trials Support



500 + Clinical Trials across 18 Therapeutic area



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Clinical Trials Support

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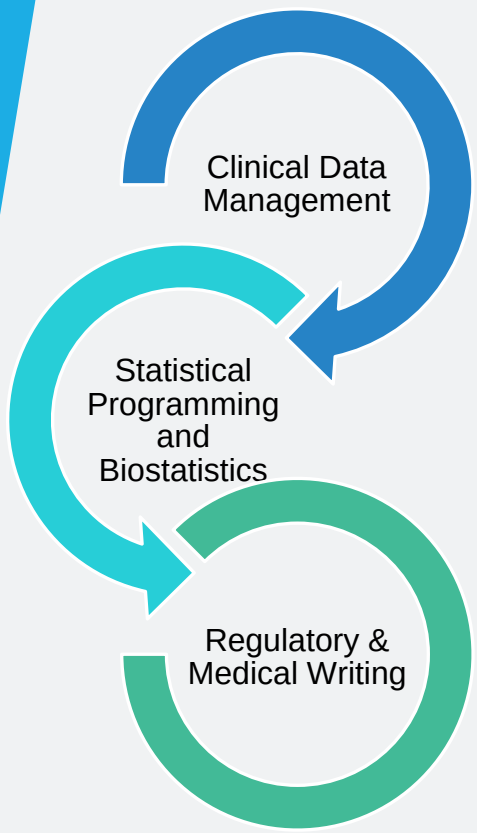
Biometrics Services

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

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Biometrics Services

BIOMETRICS TEAM DEDICATED TO ENHANCING EFFICIENCY AND REDUCING DEVELOPMENT COSTS.

PROACTIVE APPROACH TO IDENTIFY AND MITIGATE RISKS IN CLINICAL TRIALS.

COMMITTED TO HELPING YOU ACHIEVE GREATER OPERATIONAL EFFICIENCY.

DRIVE IMPROVEMENTS AND COST SAVINGS IN CLINICAL TRIAL PROCESSES.

ANTICIPATE AND ADDRESS POTENTIAL CHALLENGES IN ADVANCE FOR SMOOTHER TRIAL

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Clinical Data Management

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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 Med DRA & AC check
- ✓Data processing; Remote Data entry & double Data entry
- ✓Database lock and archiving

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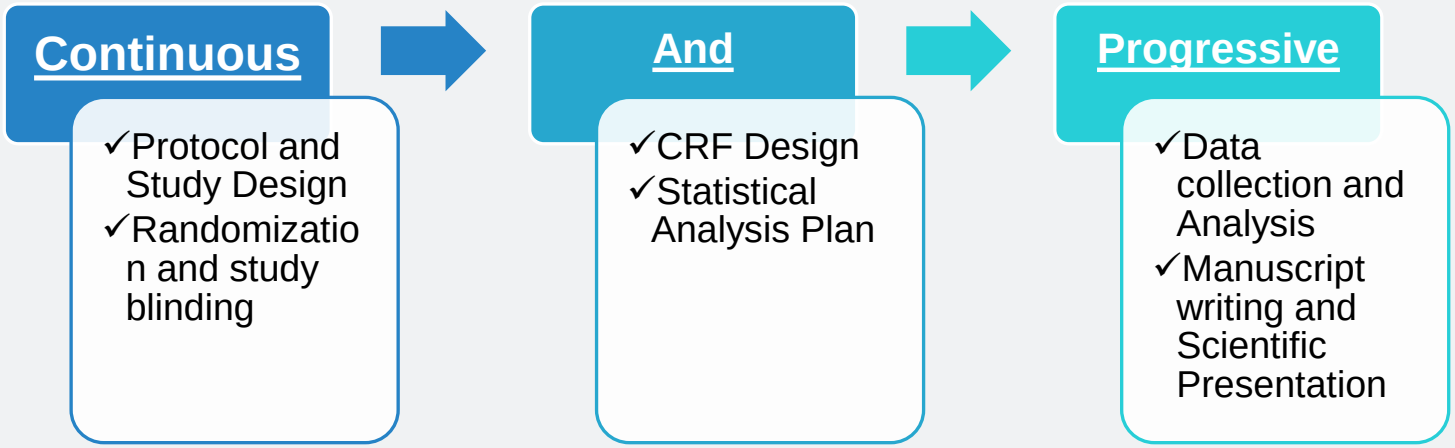
Biostatistics

Biostatistics services



- 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.

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Pharmacovigilance Service

Pharmacovigilance Service Offerings

Individual Case Safety Report (ICSR) Services

Aggregate Reports Services

Signal And Risk Management Services

Literature Screening and Review

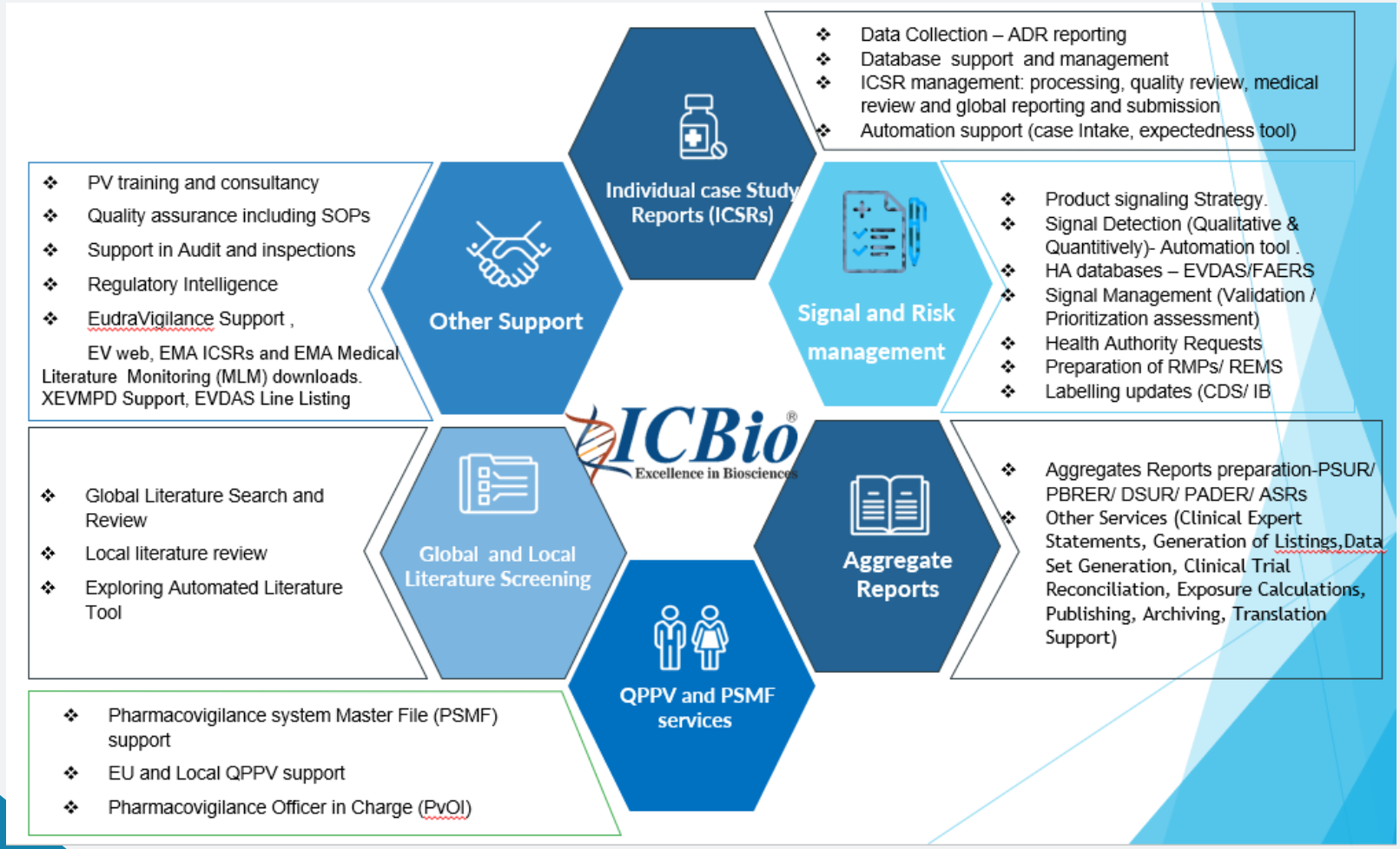
Risk Management Plan (RMP) development.

QPPV Services

Pharmacovigilance System Master File (PSMF)

PV Consulting and Additional Support

Comprehensive Pharmacovigilance (PV) Solutions



Quality Management System

Quality Management System

Monitoring: Team closely monitors QC and QA procedures.

Quality control (QC): Ensuring high standards and reliability.

Quality assurance (QA): Ensuring quality, accuracy, and compliance.

Implementation: Properly implementing QC and QA procedures.

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Quality Check and Assurance

- QA activities cover Internal Audits
- Compliant with relevant local & international regulations

Site Audits

Systems / Process Audits

Vendor Audits

Document Audits (Protocol, Clinical Study Reports & essential CT documents)

- Security measures
- Temperature and Humidity Control
- Digital Archiving
- Backup Retrievals

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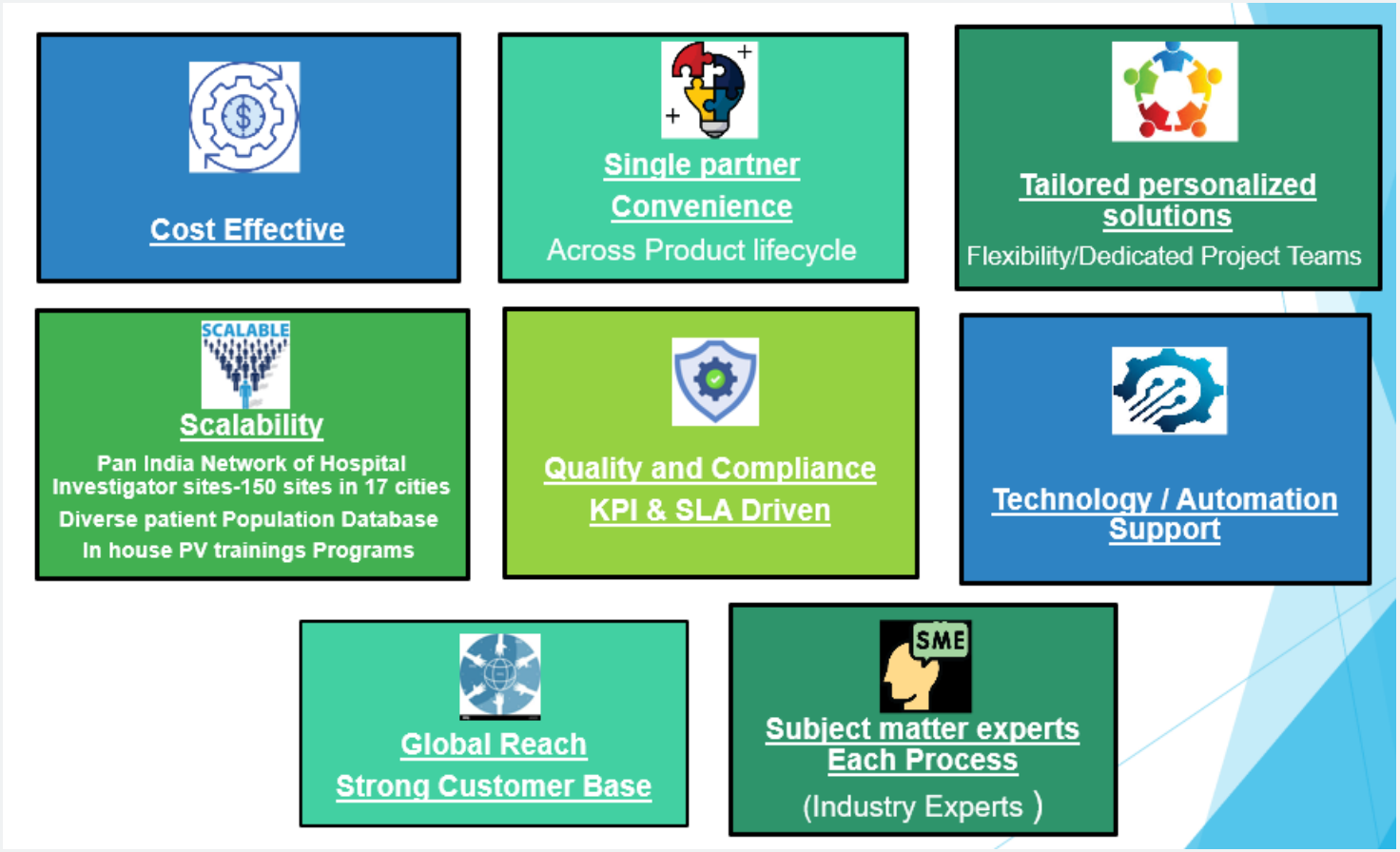
Why ICBio



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Testimonials

"I was pleased by their ability on time completion of BE studies and help us for global submission of the BE study reports, very much pleased no hidden cost on any studies in our 8 years of association."

Md. Ali Akbar, Manager, International Business, Bangladesh.

"The ICBio CRO is a major resource that makes it much easier for my team to consider performing and participating in clinical trials and we appreciate their expertise and services."

Evelyn Peña De, MD, Gerente Técnico de Investigación Clínica, Chile. LATAM.

"The Clinical Trials Unit is well-equipped and qualified to provide clinical research services."

Richard Malter, New Zealand

"The services of ICBio Research personnel have led to successful planning and execution of my studies."

Muhammad Rashid Farooq, Manager Regulatory Affairs, Iran

"I have been exceedingly pleased with ICBio clinical research personnel who have been readily available, prompt, fully prepared and attentive during research subject enrolment."

Andrew Adams, Director, OX25 5HD UK

We look forward to assisting you, please feel free to reach out to us !

RFP Link

ICBio Clinical Research Pvt.Ltd.

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