ICBio Clinical Research Pvt Limited

Your trusted Clinical Research Partner

ICBio®
Excellence in Biosciences

Corporate Presentation 2025

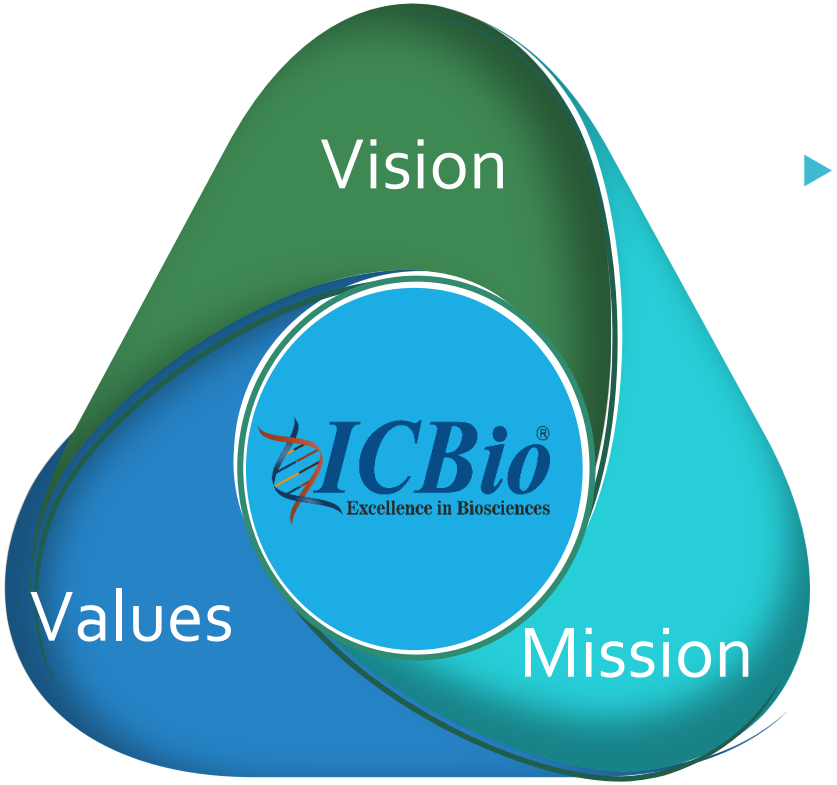
www.icbiocro.com

About Us

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

- 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
- Iinnovations 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

18 plus Years of excellence

500 + Trials Supported

1000+ BA/BE Studies

150+ Research sites across 17 cities

20 Therapeutic Areas

56 Countries around the globe

80+ Satisfied Clients

Rapid Deployment-

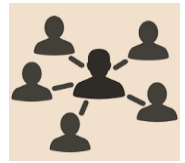
14 days

< 5%

Staff attrition rate

01

Point of contact



10,000+

Pre-screened candidates

ICH GCP

GLP, 21 CFR

Part 11 Compliant

Our Journey


2008
Company Incorporation with CT Operation
2012
NABL Accreditation
2013
Certification 9001:2008 Ministry Of Health Kazakhstan
2015
DCGI Approval for 24 beds facility
2020
DCGI Approval 32 beds facility
2023
Started New Facility with 100 beds & received DCGI Approval
2024
Facility received UAE Approval.
2025
Facility received ANVISA Brazil Approval

Accreditations and Certifications

ANVISA

MHRA

وزارة الصحة العراقية
IRAQI MINISTRY OF HEALTH
FOUNDED 1920 تأسست

NABL
Accreditated Laboratory

Drug Controller General of India (DCGI)

وزارة الصحة و وقاية المجتمع
MINISTRY OF HEALTH & PREVENTION

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

The Ministry of Health
Republic of Kazakhstan

ZAMBIA MEDICINES REGULATORY AUTHORITY
ZAMRA

NPRA
MALAYSIA

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

CEO

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

Dr. Harish, a pioneer of the Clinical Research industry and the head of the leading CRO in India, received his post-graduate degree in Biochemistry from Kuvempu University and his doctorate degree from Miami University, FL.
A Biochemist by profession, Dr. Harish, began career as a corporate trainer and currently Founder Director & CEO of ICBio CRO. Dr. Harish has over two decades of experience in the coordination of all phases of global and domestic clinical trial activity in India, where he has coordinated all aspects of global and domestic clinical trial, BA /BE Studies. His background includes developing and revising clinical trial-related SOPs, Protocol, as well as developing SOPs for CROs and Ethics Committees, as well as budgeting for clinical trials.

Operations Team

Dr. Vimal Teja
Sr. Vice President

Highly committed medical professional with over 26 years of cumulative experience in the domains of Healthcare, Clinical Research and Pharmaceutical sectors.

Started his career in Clinical Research in 2007, as a principal investigator and spearheaded over 3500 BA/BE & late phase trials. Overtime diversified into clinical research operations.

Dr Lakshmikar BV
Principal Investigator

Medical professional with over 32 years of unparalleled experience in the domains of Clinical Research and Healthcare.

Started his career in Clinical Research in Late phase trials, and further diversified into BA/ BE in the capacity of Principal Investigator. Working with ICBio since inception of this site.

Mr Praveen Kumar
Bioanalytical Investigator

An accomplished bioanalytical research professional with over 17 years of experience. Holds a Master's degree in Analytical Chemistry, specializing in the development, validation of complex bioanalytical methods for small and large molecules. proficient in using elemental analyzers and immunoassay platforms.

The Facility

Strategic Location

- Well connected to Bengaluru International Airport

Facility

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

Facility

* This facility is now not operational and has been disposed.

Shown for the purpose of historical representation

Clinical Facility

Clinical 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.

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

ICU
2+2+2 Beds for Emergency Management

Clinical Facility

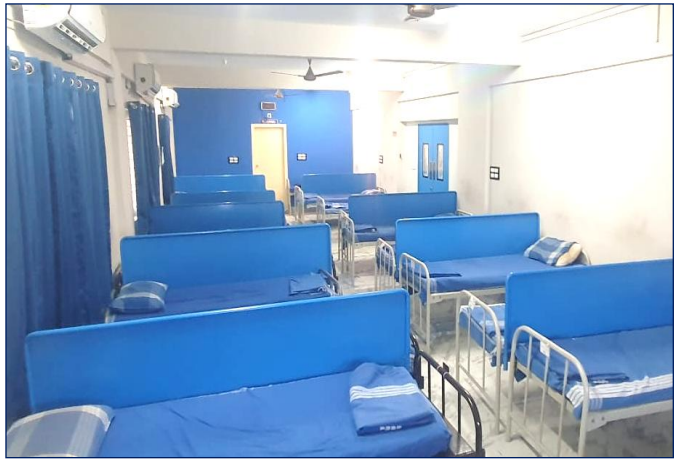
- Fully Equipped Sample processing
- Nurse Calling System
- Fully equipped ICU
- Tie up with referral hospital.
- GPS synchronized clocks
- Yellow lights for light sensitive drugs

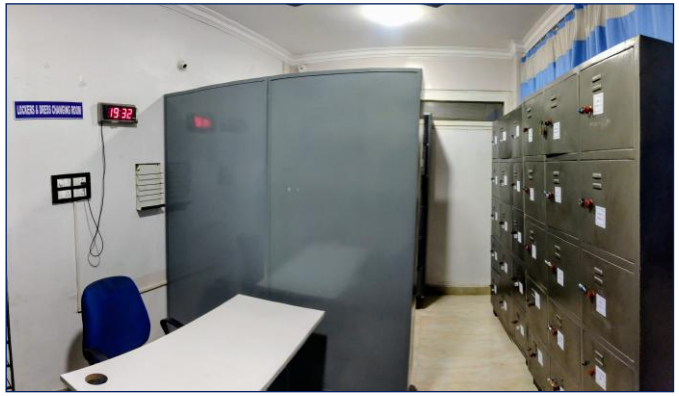
100-beds staggered over 3 CPUs.

All beds and toilets are equipped with wireless nurse calling system.

Dedicated areas for volunteer registration, screening, check-in, ambulatory sample collection etc.

Dedicated Recreation, sample collection, & dining





Screening, Registration & Check-in Facility

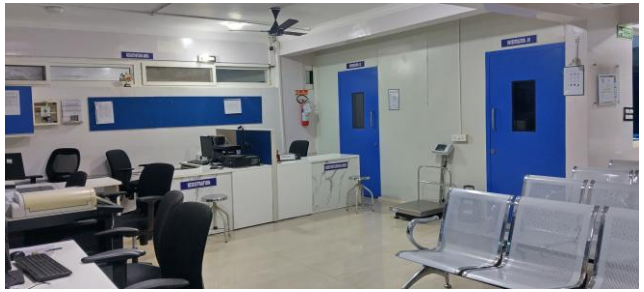
- Dedicated Volunteer Screening area
- Volunteer check-in and ICF area
- Volunteer's Locker & dress change & frisking area

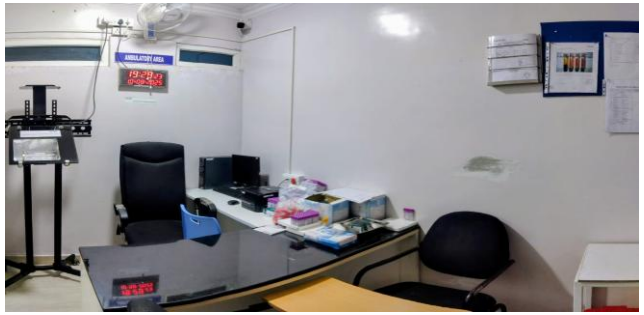
OVIS – Online volunteer identification system.

VRS: Volunteer registration software

wo: medical examination rooms & ECG recording areas

Dedicated locker room for subject belongings





Pharmacy

- Dedicated Pharmacy
- Walkin stability chamber with ~600 ft^3 capacity.
- Temperature and Humidity controlled.
- 21 CFR Complaint software for RH and Temperature management

Clinical Facility – CPU - I

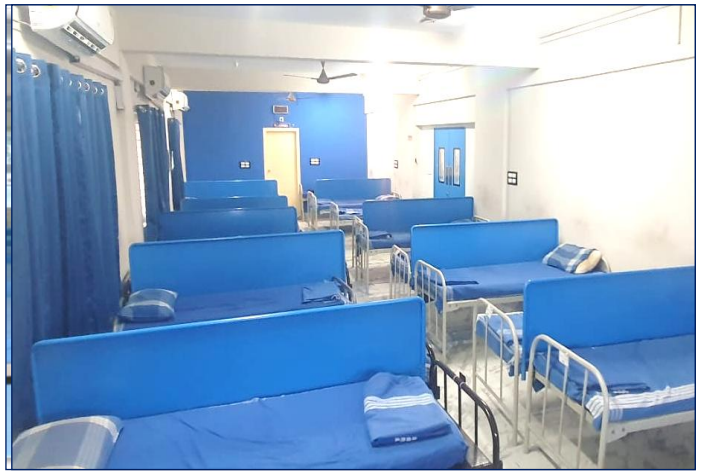
- Total facility- **40,000 square** feet.
- **CPU – I**
- CPU – II
- CPU – III
- 24 hours Ambulance Service during studies.

24-beds

2 bedded **intensive care unit**

Refrigerated **Centrifuges**.
Wireless Nurse Calling System

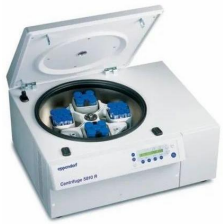
CPU-I has Dedicated Recreation, sample collection, & dining



Clinical Facility – CPU - II

- Total facility- **40,000 square** feet.
- CPU – I
- **CPU – II**
- CPU – III
- 24 hours Ambulance Service during studies.

36-beds



Yellow Monochromatic Lights

Refrigerated **Centrifuges**.
Wireless Nurse Calling System

CPU-II has Dedicated Recreation, sample collection, & dining

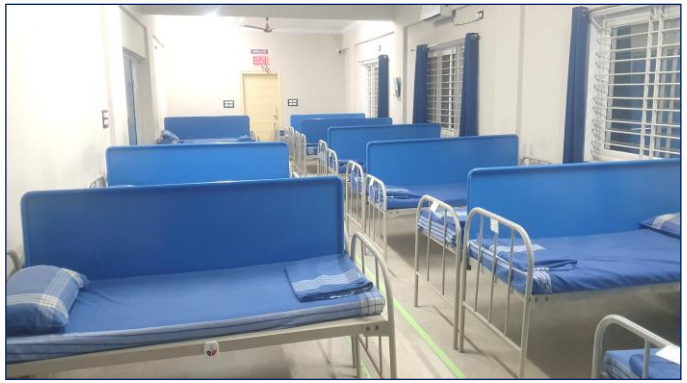
Clinical Facility – CPU - III

- Total facility- **40,000 square** feet.
- CPU – I
- CPU – II
- **CPU – III**
- 24 hours Ambulance Service during studies.

40-beds

2 bedded **intensive care unit**

GPS Synchronized
Clocks in all CPUs



CPU-III has Dedicated Recreation, sample collection, & dining

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Diagnostic Laboratory

Centralized NABL Accredited
LIMS Integrated Path Lab-GCLP certified

ICBio®
Excellence in Biosciences

Diagnostic Laboratory

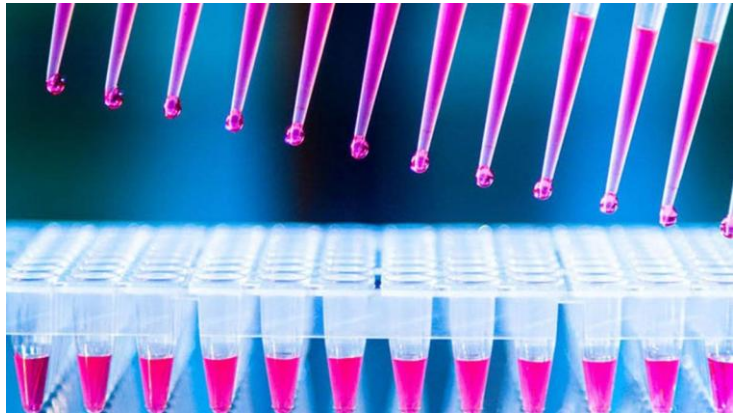
- Centralized Laboratory
- NABL accredited
- LIMS integration
- GCLP certified

- 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



Bioanalytical Facility

Bioanalytical Lab

ICBio®
Excellence in Biosciences

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

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

Multiple LCMS/MS 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.

www.icbiocro.com

Bioanalytical Facility

There are **TWO** API 4000 LC/MS/MS system (Liquid Chromatography/ Mass Spectrometry).

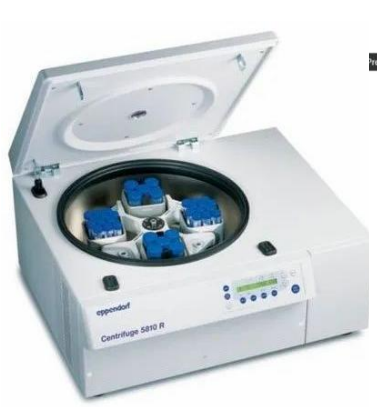
There are **TWO** SCIEX API 4500, often referred to as the Triple Quad 4500 or QTRAP 4500, which is a high-sensitivity, benchtop LC-MS/MS system.

There is **ONE** SCIEX API 5500, (Triple Quad 5500 or QTRAP 5500), which is a high-sensitivity, benchtop LC-MS/MS system.

Bioanalytical Facility

There is **ONE** Perkinelmer Nexion 1000 (ICP-MS), which is highly-sensitive, for detecting and quantifying trace elements and isotopes in various samples.

There are other support equipment like **SPE, Nitrogen Evaporator, Vibramax, Refrigerated Centrifuges, fume hoods, cyclo-mixers, milli-Q water system, Hot air oven, micro balances,** etc.



Bioanalytical Methods

Sr. No.	MV No./Compound	Bioanalytical Assay	Sample Volume (mL)	Validated Range	Light Sensitive	Biological Matrix	Instrument Model
1	MV_001_00 (Prazosin)	LC-MS/MS	0.250	0.500 – 120.816 ng/mL	Yes	Human Plasma	SCIEX - 4500
2	MV_002_00 (Bisoprolol)	LC-MS/MS	0.250	0.301 – 118.962 ng/mL	No	Human Plasma	SCIEX - 4500
3	MV_003_00 (Empagliflozin & Metformin)	LC-MS/MS	0.250	5.087 – 807.490 ng/mL & 31.210 – 5004.012 ng/mL	Yes	Human Plasma	SCIEX - 4500
4	MV_004_00 (Valsartan & Sacubitril)	LC-MS/MS	0.250	15.055 – 8018.841 ng/mL & 15.001 – 4075.445 ng/mL	Yes	Human Plasma	SCIEX - 4500
5	MV_005_00 (Tacrolimus)	LC-MS/MS	0.250	0.254 – 125.025 ng/mL	Yes	Human Blood	SCIEX - 4500
6	MV_006_00 (Gliclazide)	LC-MS/MS	0.100	0.049 – 6.662 µg/mL	No	Human Serum	SCIEX - 4500
7	MV_007_00 (Rosuvastatin)	LC-MS/MS	0.400	0.202 – 80.790 ng/mL	No	Human Plasma	SCIEX - 4500
8	MV_008_00 (Losartan, Losartan Carboxylic acid & Hydrochlorothiazide)	LC-MS/MS	0.400	3.003 – 1501.509 ng/mL, 3.005 – 1502.727 ng/mL & 1.002 – 500.978 ng/mL	Yes	Human Plasma	SCIEX - 4500
9	MV_009_00 (Amoxicillin & Clavulanic acid)	LC-MS/MS	0.250	0.106 – 18.008 µg/ml & 0.052 – 9.003 µg/ml	Yes	Human Plasma	SCIEX - 4500
10	(MV_010_00) Esomeprazole	LC-MS/MS	0.100	2.011 – 3011.477ng/mL	Yes	Human Plasma	SCIEX - 4500
11	(MV_011_00) (Nitroglycerin, 1,2-Dinitroglycerin & 1,3-Dinitroglycerin)	LC-MS/MS	0.500	0.056 – 7.539 ng/mL , 0.056 – 7.500 ng/mL & 0.056 – 7.500 ng/mL	Yes	Human Plasma	SCIEX - 4500
12	(MV_012_00) Levetiracetam	LC-MS/MS	0.100	0.525 – 65.546 µg/mL	Yes	Human Plasma	SCIEX - 4500

Bioanalytical Methods

Sr. No.	MV No./Compound	Bioanalytical Assay	Sample Volume (mL)	Validated Range	Light Sensitive	Biological Matrix	Instrument Model
13	(MV_013_00 Palbociclib	LC-MS/MS	0.100	3.059 – 304.373 ng/mL	No	Human Plasma	API - 4000
14	(MV_014_00) Sitagliptin	LC-MS/MS	0.200	15.008 – 5002.593 ng/mL	No	Human Plasma	API - 4000
15	(MV_015_00) Sertraline	LC-MS/MS	0.250	0.301 – 303.164 ng/mL	No	Human Plasma	API - 4000
16	(MV_016_00) Ibrutinib	LC-MS/MS	0.200	1.016 to 503.925 ng/mL	No	Human Plasma	SCIEX - 4500
17	(MV_017_00) Sunitinib	LC-MS/MS	0.250	0.109 to 199.377 ng/mL & 0.515 to 200.785 ng/mL	No	Human Plasma	SCIEX - 4500
18	(MV_018_00) Sorafenib	LC-MS/MS	0.100	10.106 – 7018.353 ng/mL	No	Human Plasma	API - 4000
19	(MV_019_00) Abiraterone	LC-MS/MS	0.200	0.408 – 405.509 ng/mL	No	Human Plasma	API - 4000
20	(MV_020_00) (Empagliflozin & Linagliptin)	LC-MS/MS	0.200	0.412 to 405.128 ng/mL	No	Human Plasma	API - 4000
21	(MV_021_00) (Rifaximin)	LC-MS/MS	0.250	0.106 – 15.080 ng/mL	No	Human Plasma	API - 4500
22	(MV_022_00) (Baclofen)	LC-MS/MS	0.200	1.010 to 1018.517 ng/mL	No	Human Plasma	API - 4000
23	(MV_023_00) (Diosmin & Hesperetin)	LC-MS/MS	0.200	10.169 – 988.369 ng/mL , 5.027 – 506.580 ng/mL	No	Human Plasma	SCIEX - 4500
24	(MV_025_00) (Tadalafil)	LC-MS/MS	0.200	1.041 – 1008.009 ng/mL	No	Human Plasma	SCIEX – 4500

Bioanalytical Methods

Sr. No.	MV No./Compound	Bioanalytical Assay	Sample Volume (mL)	Validated Range	Light Sensitive	Biological Matrix	Instrument Model
25	(MV_027_00) (Promethazine)	LC-MS/MS	0.200	0.218 – 61.630 ng/mL	No	Human Plasma	API – 4000
26	(MV_028_00) (Imatinib)	LC-MS/MS	0.100	8.068 – 4202.163 ng/mL	No	Human Plasma	API – 4000
27	(MV_029_00) Osimertinib	LC-MS/MS	0.200	5.077 – 2226.744 ng/mL	Yes	Human Plasma	API - 4000
28	(MV_031_00) Gefitinib	LC-MS/MS	0.200	2.026 – 502.536 ng/mL	Yes	Human Plasma	API - 4000
29	(MV_032_00) Crizotinib	LC-MS/MS	0.200	3.041 to 450.492 ng/mL	Yes	Human Plasma	API - 4000
30	(MV_033_00) Teriflunomide	LC-MS/MS	0.200	15.33 – 5554.315 ng/mL	Yes	Human Plasma	SCIEX - 4500
31	(MV_034_00) Venetoclax	LC-MS/MS	0.200	10.051 – 2955.753 ng/mL	Yes	Human Plasma	SCIEX - 4500
32	(MV_036_00) Nintedanib	LC-MS/MS	0.100	0.315 – 101.924 ng/mL	Yes	Human Plasma	SCIEX - 5500
33	(MV_038_00) Nilotinib	LC-MS/MS	0.100	15.010 to 3002.017 ng/mL	Yes	Human Plasma	API - 4000
34	(MV_039_00) Bosentan	LC-MS/MS	0.100	6.029 to 2407.688 ng/mL	No	Human Plasma	SCIEX - 5500
35	(MV_040_00) Metformin	LC-MS/MS	0.200	30.231 to 5014.829 ng/mL	No	Human Plasma	SCIEX - 4500
36	(MV_027_00) (Promethazine)	LC-MS/MS	0.200	0.218 – 61.630 ng/mL	No	Human Plasma	API – 4000

Document Archival facility

Document Archival

- 6 Shelves compactor
- Fireproof locker for electronic data
- Stainless steel Dossier storage racks.

ICBio®
Excellence in Biosciences

Information Technology

ICBio® Excellence in Biosciences

IT Backup Plan

ELECTRONIC DATA GENERATED BY INSTRUMENTS

(HPLC MS, DATA LOGGERS, etc.)

Cloud Server

(Daily Basis)

& also

NAS Mirror backup

Monthly Verification by IT personnel

IT-001-00

ICBio®
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Phase I & BA/BE Studies

Phase I & BA/BE Experience & Capabilities

ICBio® Excellence in Biosciences

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

Experience with Route of administration

Injection

Oral

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

Rectal

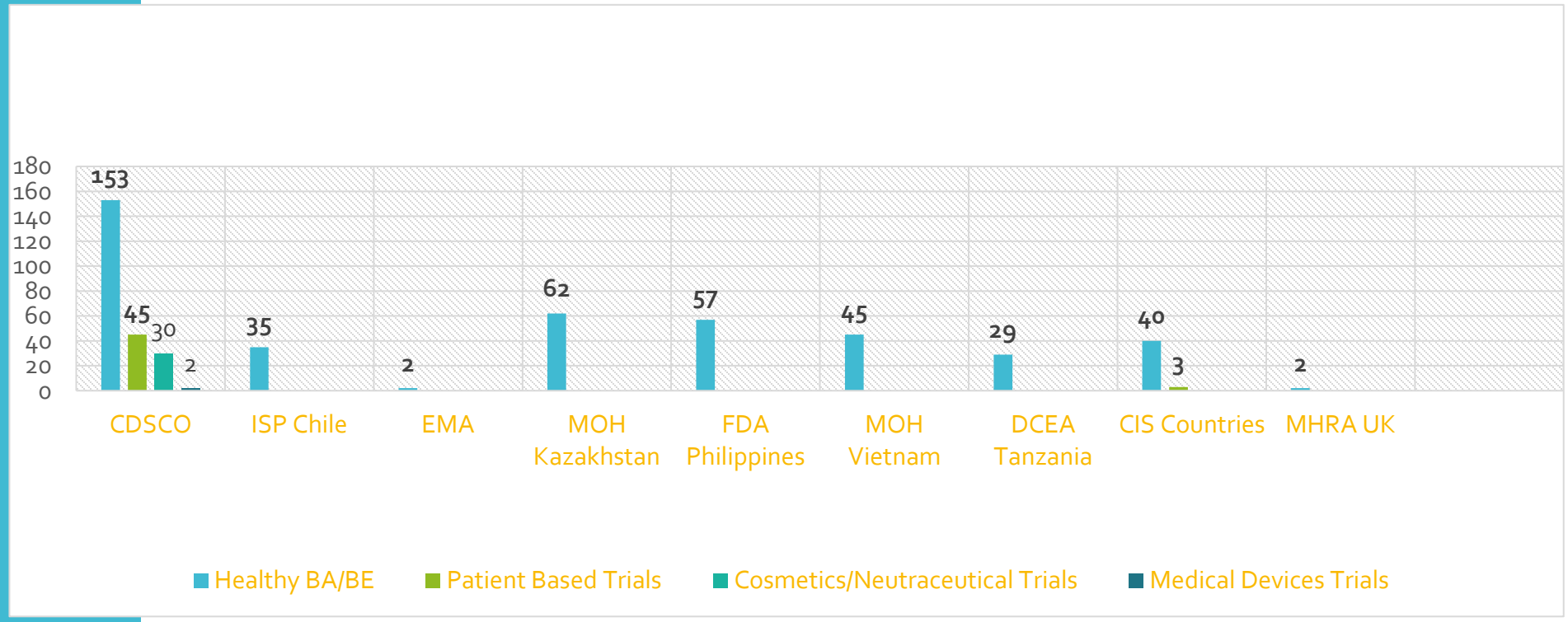
Transdermal

Topical

Vaginal

Pulmonary

Phase I BA/BE Studies Experience



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

❖ICBio has an active volunteer database of **10000 plus volunteers**, including healthy male / female volunteers **and post menopausal** volunteers

Pharmacokinetics(PK), Biostatistics & Report Compilation

ICBio® Excellence in Biosciences

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

ICBio® Excellence in Biosciences

ICBio®
Excellence in Biosciences

Clinical Trials Support

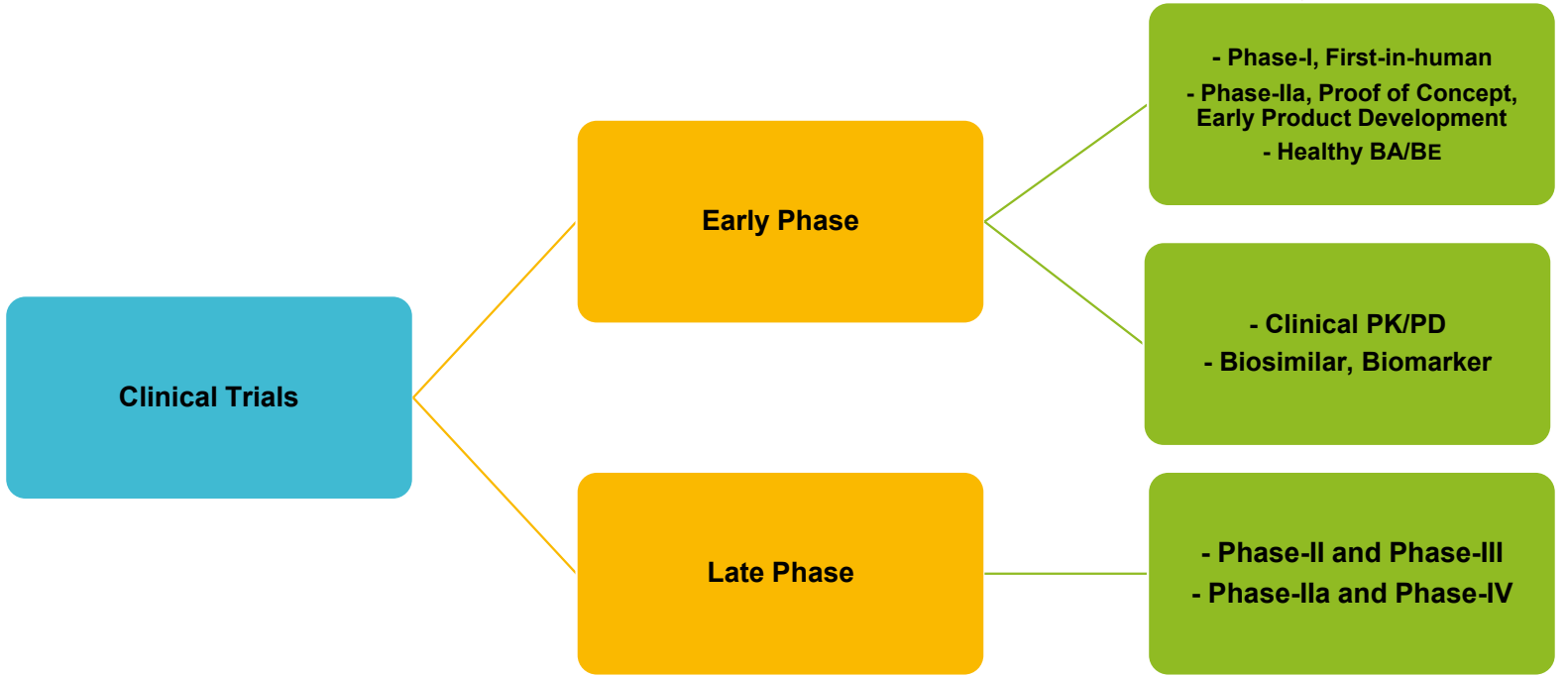
Clinical Trials Phase II – Phase IV

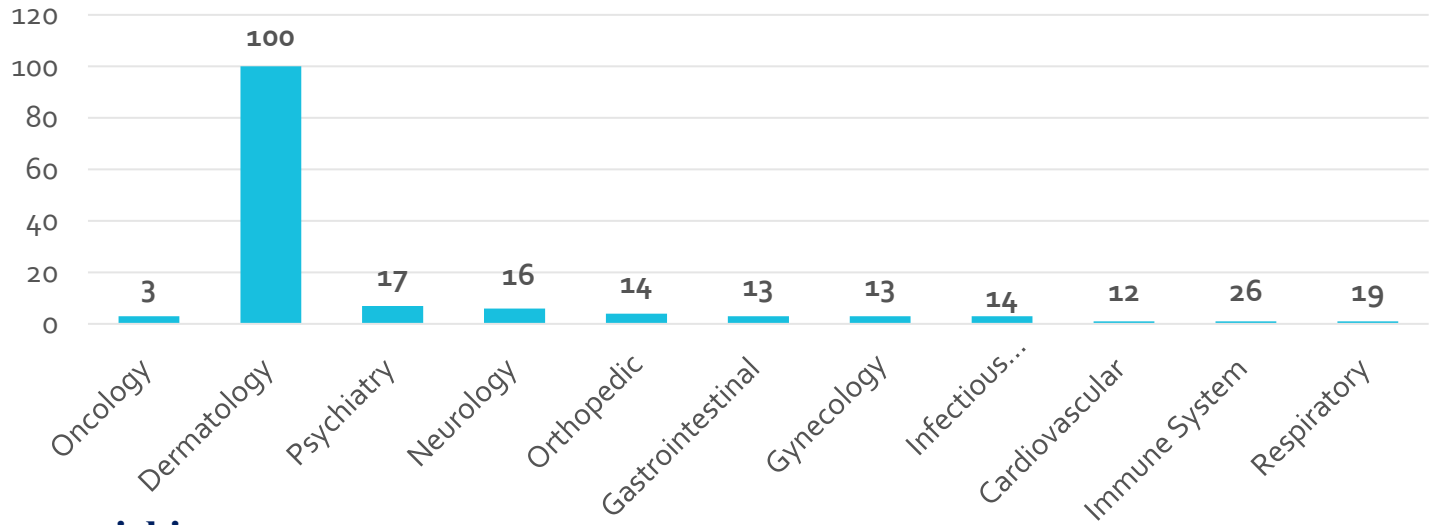
ICBio
Excellence in Biosciences

Experience in

500 + Clinical Trials across

18 Therapeutic area





Clinical Trials Support

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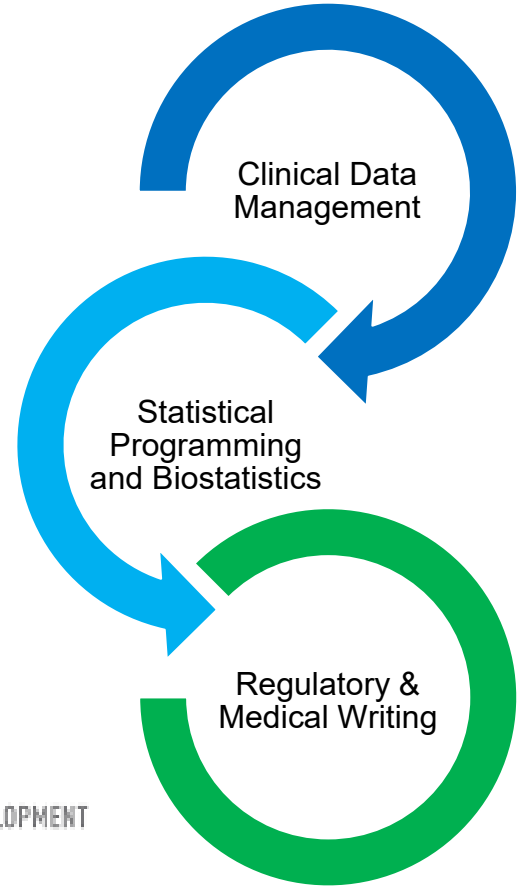
Biometrics Services

www.icbiocro.com

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

- ✓CRF Design & 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

Biostatistics services

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.

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Pharmacovigilance Service

Pharmacovigilance Service

ICBio
Excellence in Biosciences

Individual Case Safety Report (ICSR) Services

Aggregate Reports Services

Signal And Risk Management Services

Literature Screening and Review

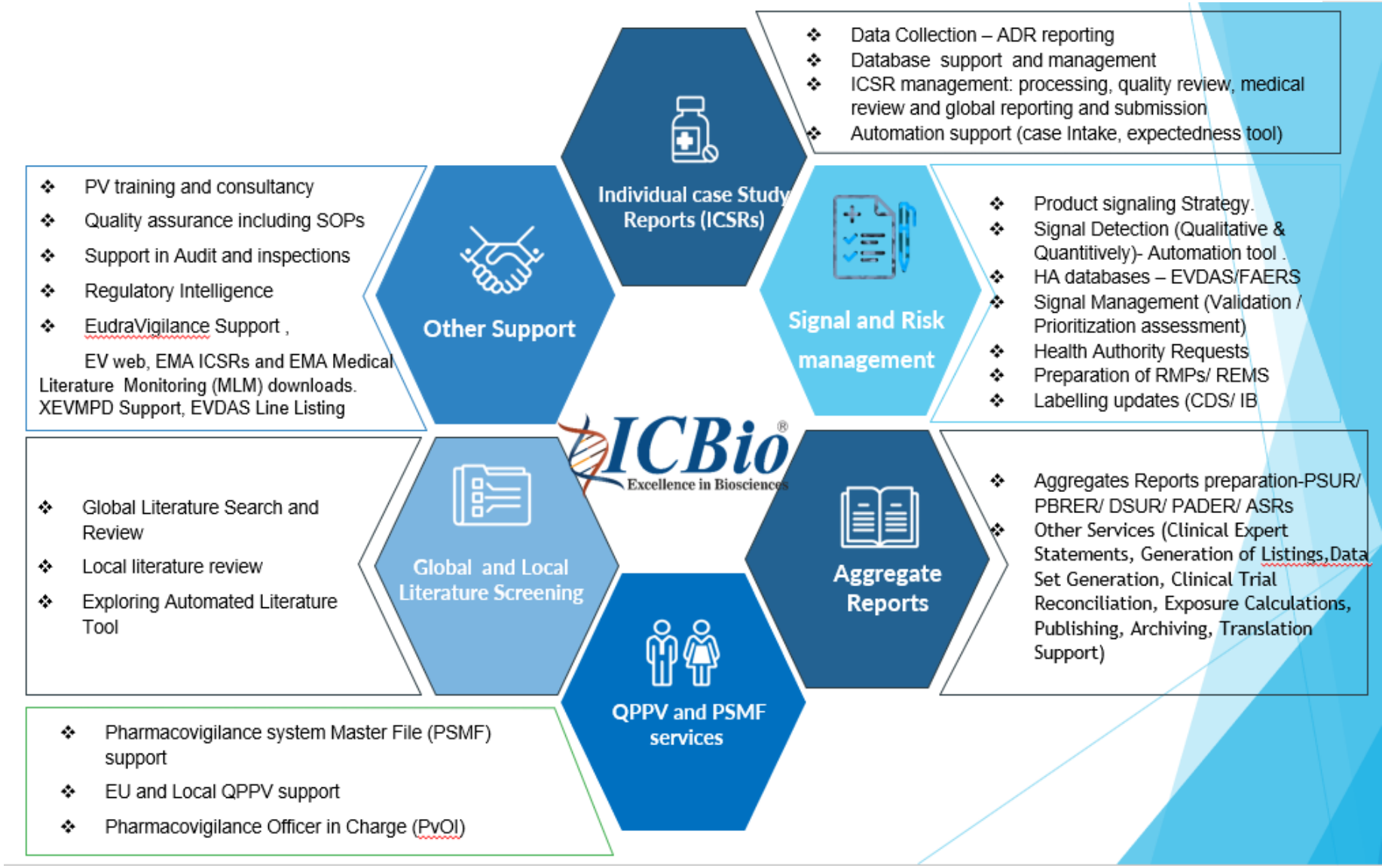
Risk Management Plan (RMP) development.

QPPV Services

Pharmacovigilance System Master File (PSMF)

PV Consulting and Additional Support

Pharmacovigilance (PV) Solutions



ICBio
Excellence in Biosciences

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.

Quality Check & Assurance

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

Site Audits

Systems/ Process Audits

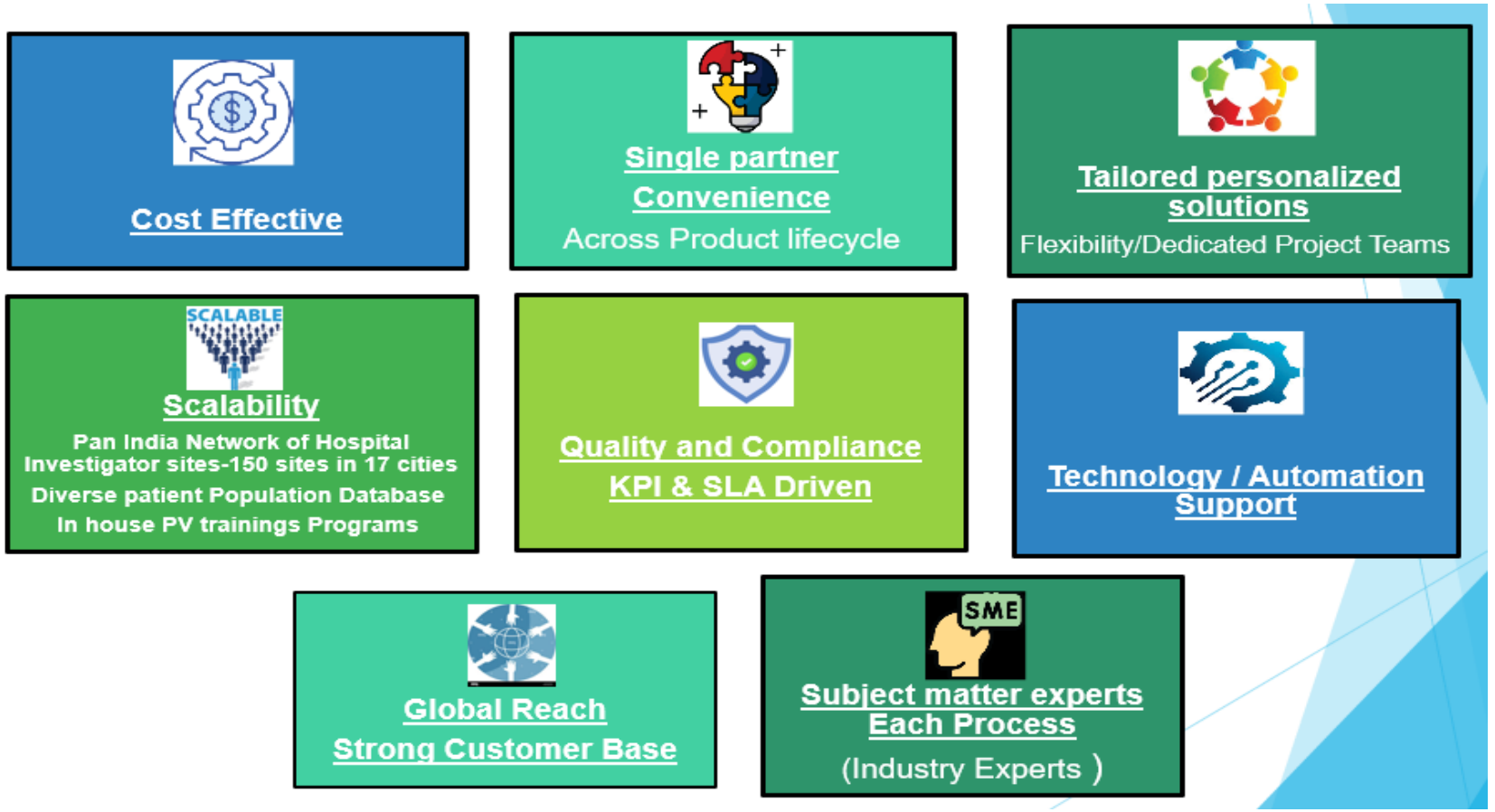
Vendor Audits

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

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

Why ICBio

ICBio® Excellence in Biosciences



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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 !

ICBio Clinical Research Pvt. Ltd.
Reg. Head office
 # 2, ICBio Tower, Devi Circle, Chikkabetahalli,
Yelahanka Main Road, Vidyaranyapura Bangalore - 560 097, INDIA
***Tel**: +91 80 2364 1042 / 43,*
***Mobile**: +91 99001 11997*
***WhatsApp**:+91 99001 11996*
e-mail:info@icbiocro.com / harish@icbiocro.com
***website**: www.icbiocro.com*