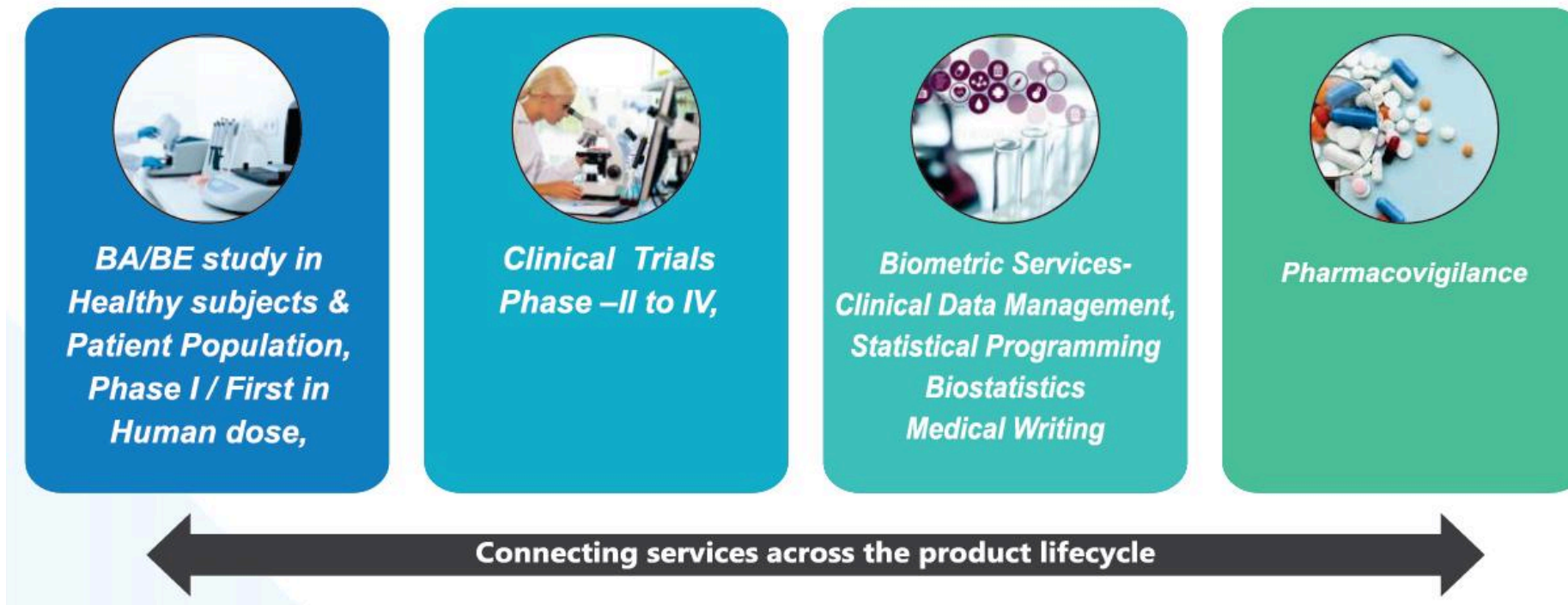




ICBio Clinical Research Pvt Limited

Your trusted Clinical Research Partner





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
- ▶ 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.



18 plus Years of excellence

< 5%

Staff attrition rate



500 + Trials Supported

1000+ BA/BE Studies

01

Point of contact



150+ Research sites across 17 cities

20 Therapeutic Areas

10,000+

Pre-screened candidates



56 Countries around the globe

80+ Satisfied Clients

ICH GCP
GLP, 21 CFR
Part 11 Compliant



Rapid Deployment-

14 days

Achievements We Celebrate

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



NABL
Accredited Laboratory

Drug Controller General of India (DCGI)



وزارة الصحة ووقاية المجتمع
MINISTRY OF HEALTH & PREVENTION



The Ministry of Health
Republic of Kazakhstan



**ZAMBIA MEDICINES
REGULATORY
AUTHORITY**



**NPRA
MALAYSIA**



ISO 14001

Clinical investigation of medical devices for human subjects- Good clinical practice

Accreditations and Certifications

The Management



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.



Mrs. Pushpalatha
Director
19 Years of Experience

She has been awarded bachelor's degree in engineering from VTU, she has been in IT industry and has rich experience in software developments, analysis, design, implementation and training. with over 19 years of experience in HRMS / administration, started her career @ IBM and worked as software developer, later promoted system administrator.

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.

Strategic Location

New facility

- ▶ 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.

Old facility



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

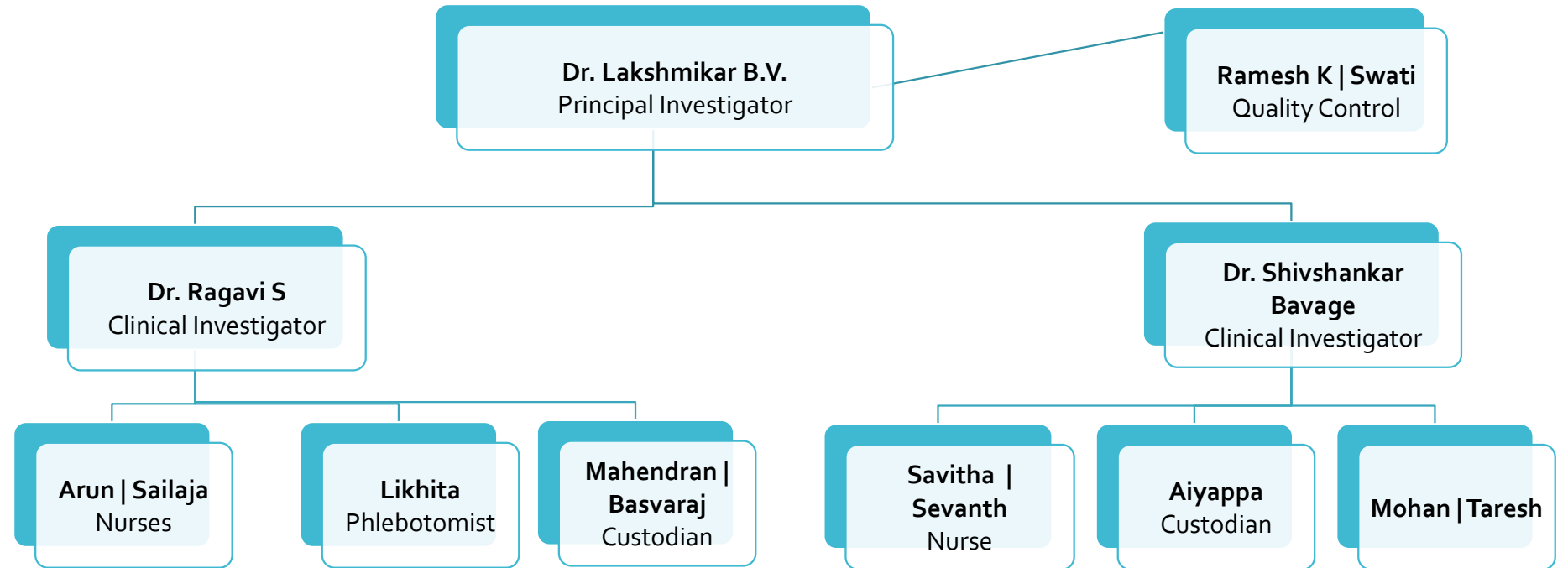
Shown for the purpose of historical representation

The Facility

Clinical Facility

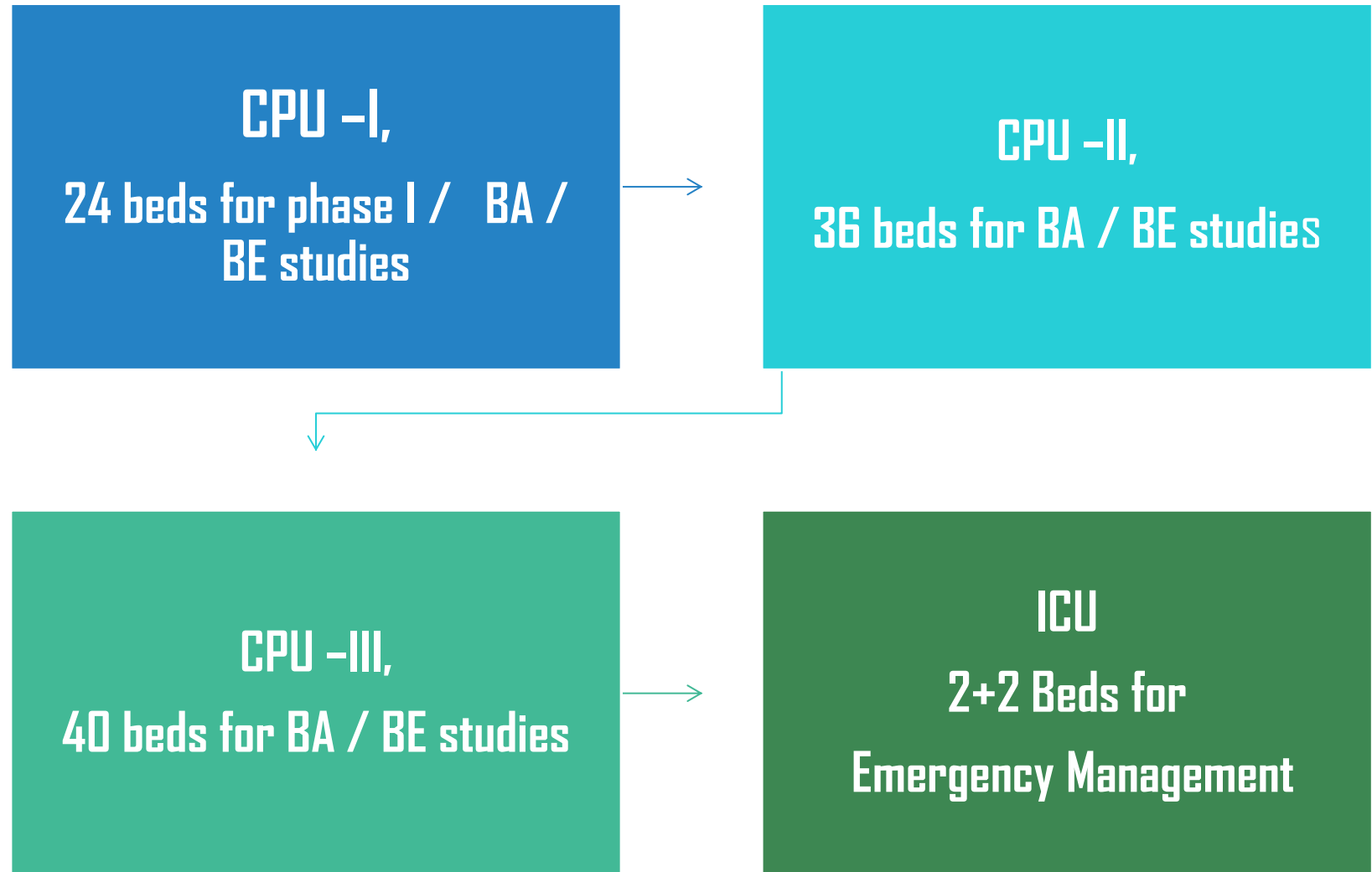


Clinical Organogram



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.



Clinical Facility

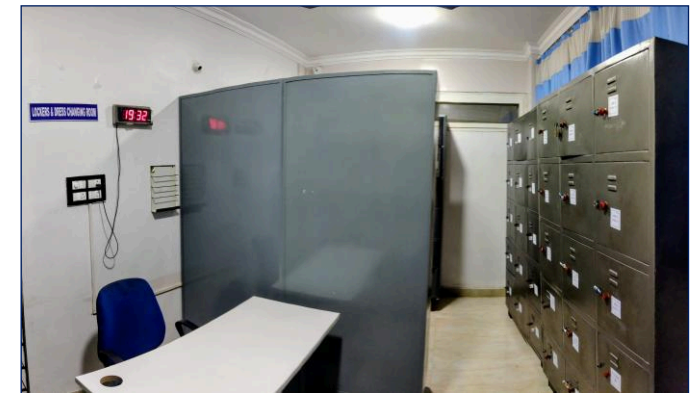
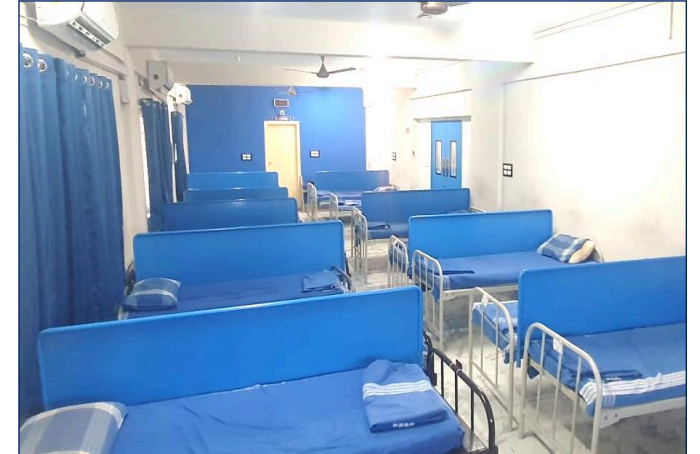
- ▶ Fully Equipped Sample processing
- ▶ Nurse Calling System
- ▶ Fully equipped ICU
- ▶ Tie up with referral hospital.
- ▶ GPS synchronized clocks
- ▶ Yellow lights for light sensitive drugs

100-beds staggered over 3 CPUs.

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

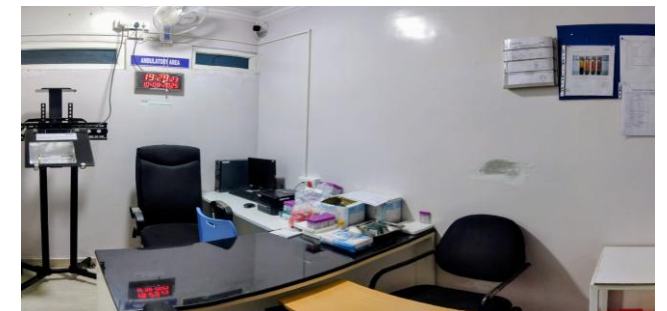
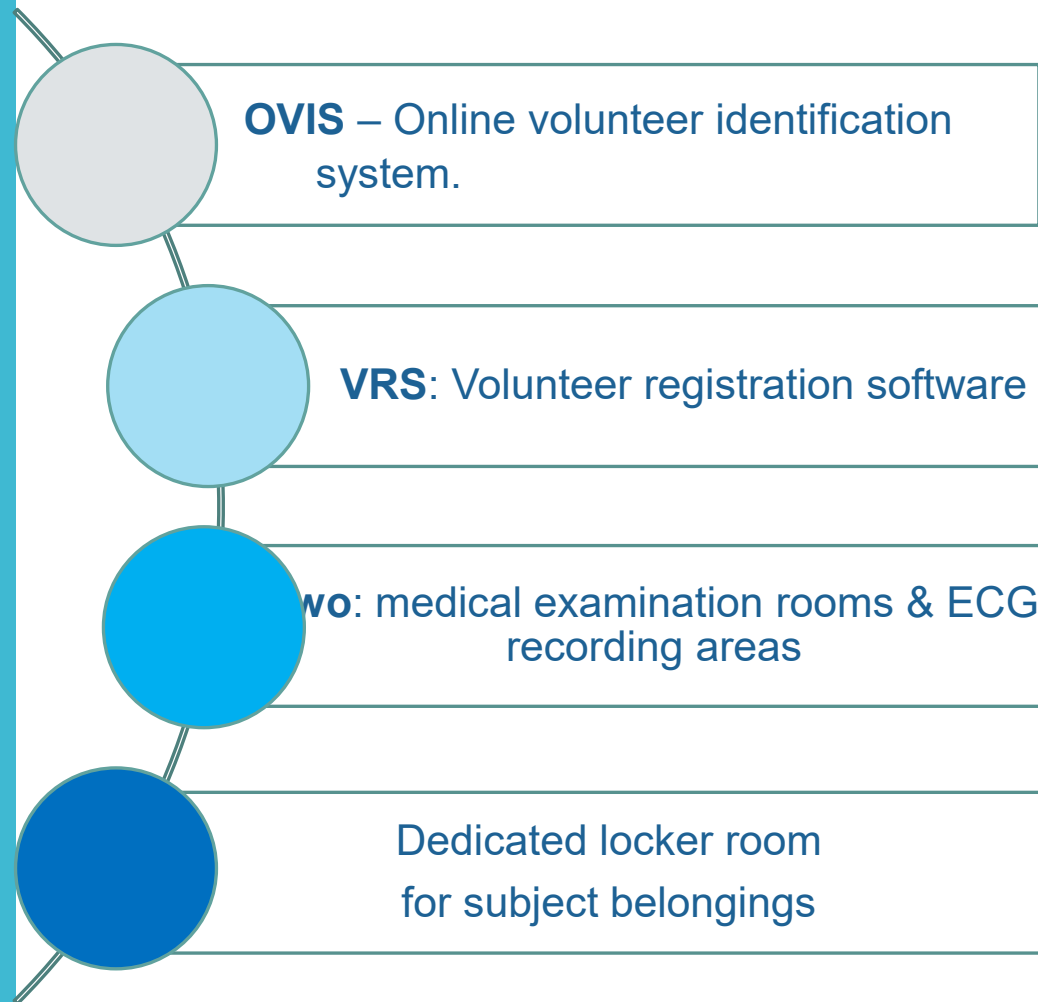
Dedicated areas for volunteer registration, screening, check-in, ambulatory sample collection etc.

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



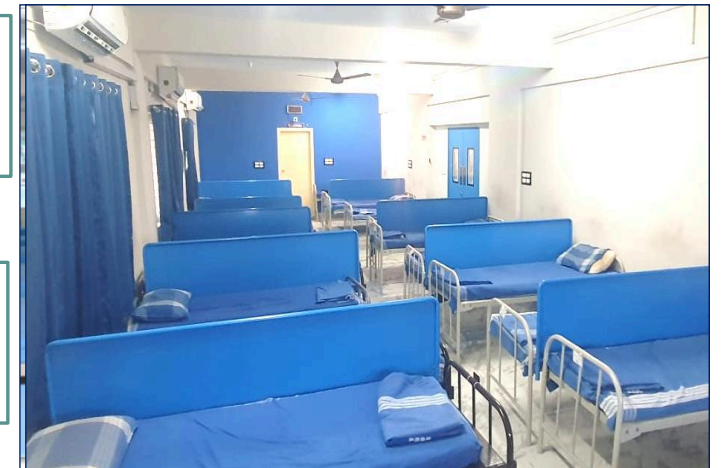
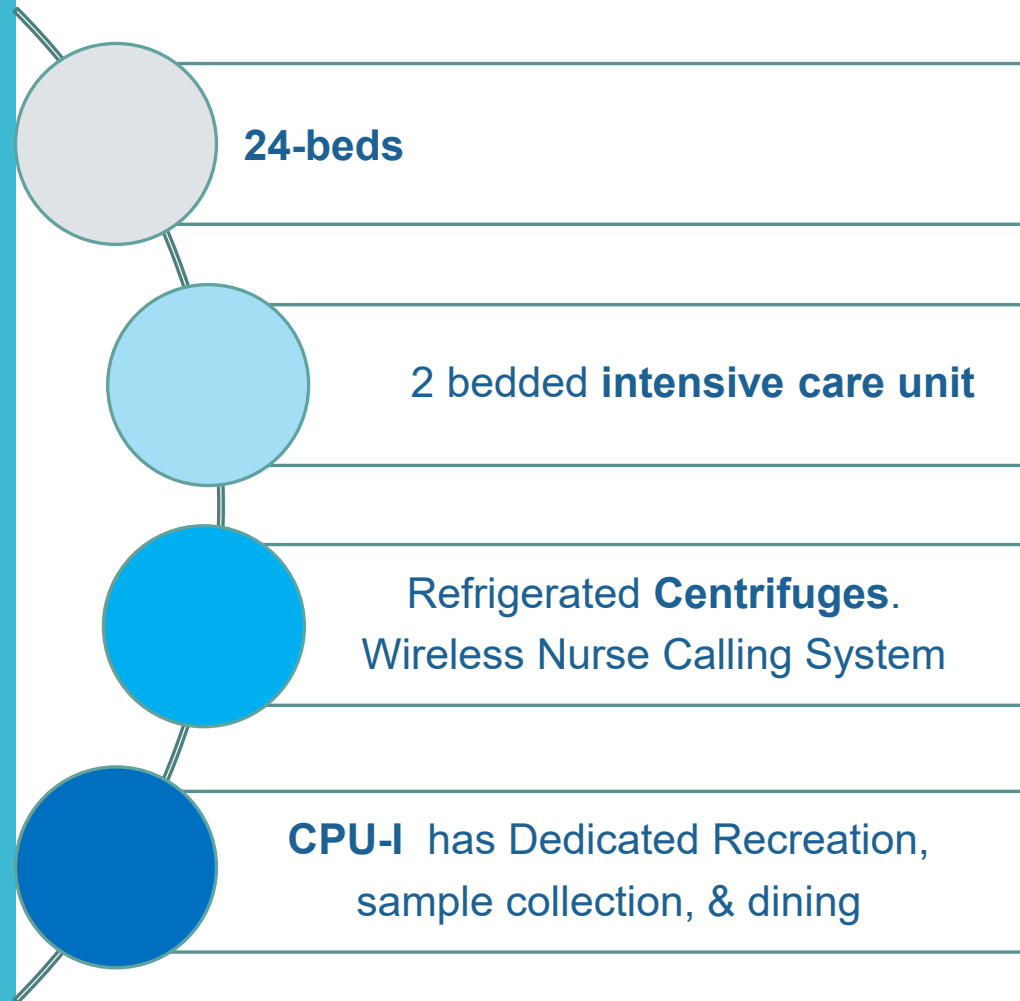
Pharmacy

- ▶ Dedicated Pharmacy
- ▶ Walkin stability chamber with ~600 ft³ capacity.
- ▶ Temperature and Humidity controlled.
- ▶ 21 CFR Complaint software for RH and Temperature management



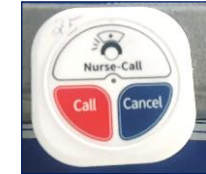
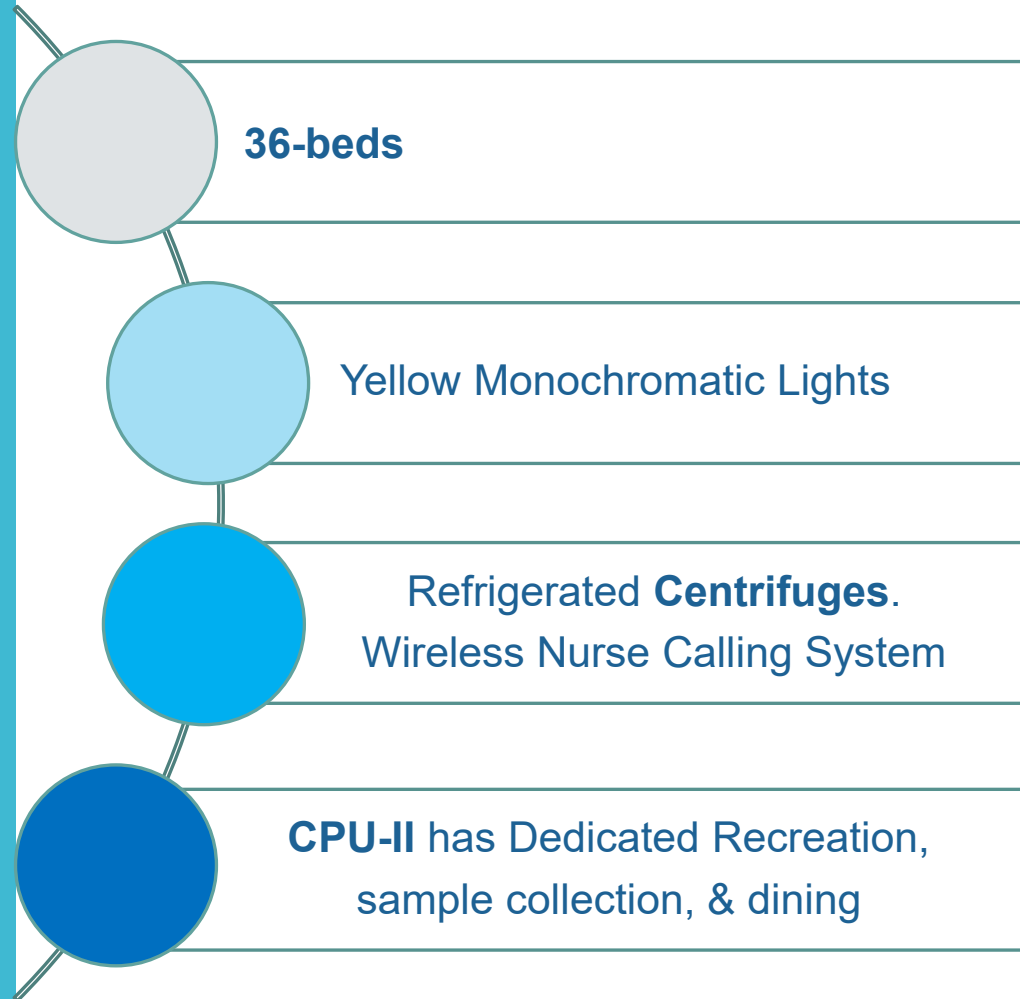
Clinical Facility – CPU - I

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



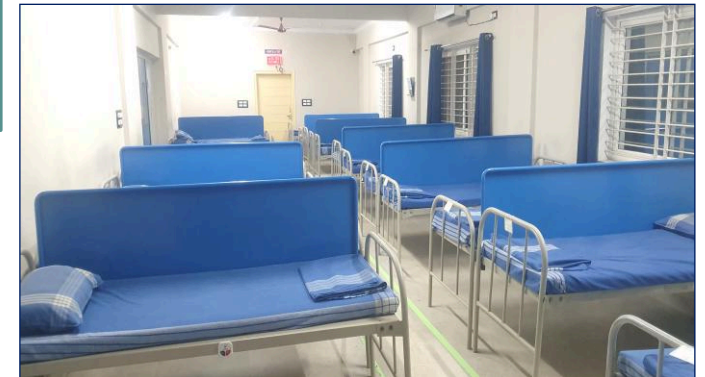
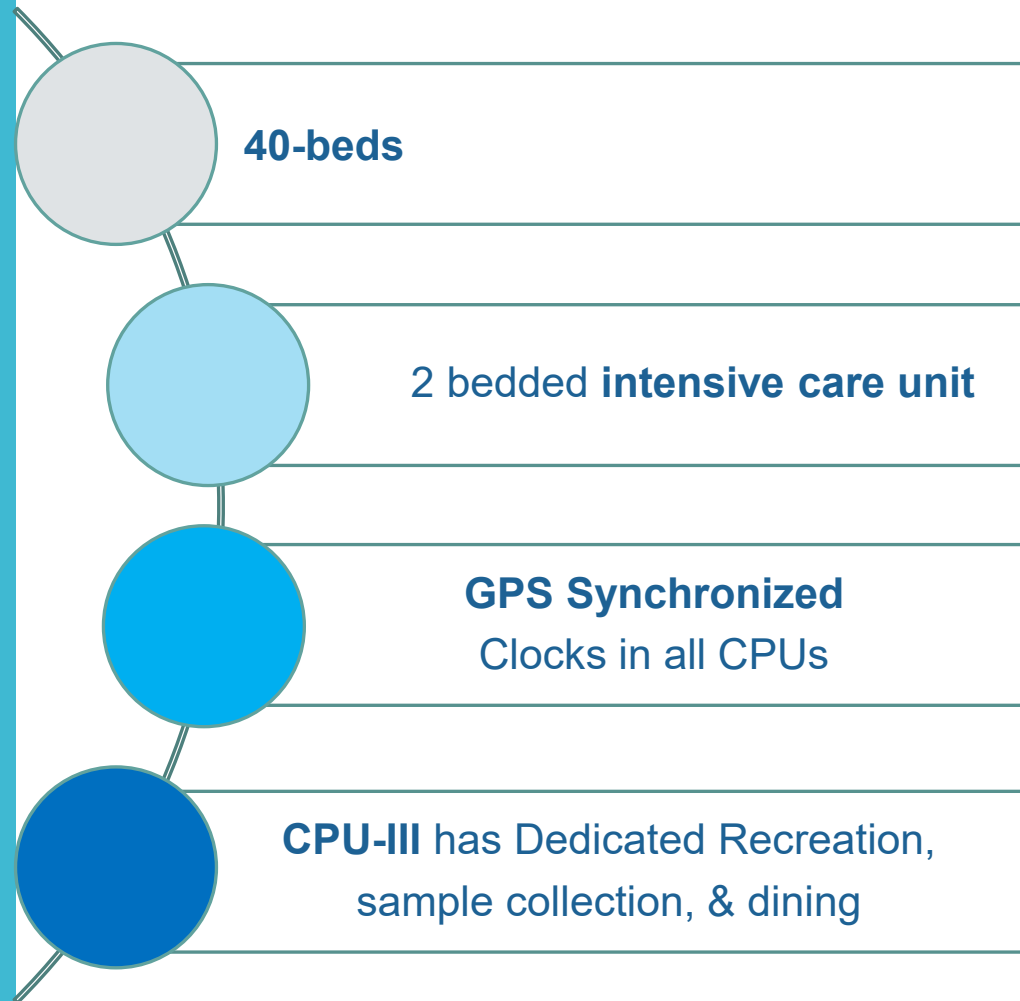
Clinical Facility – CPU - II

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



Clinical Facility – CPU - III

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



Diagnostic Laboratory

Centralized NABL Accredited LIMS Integrated Path Lab-GCLP certified

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

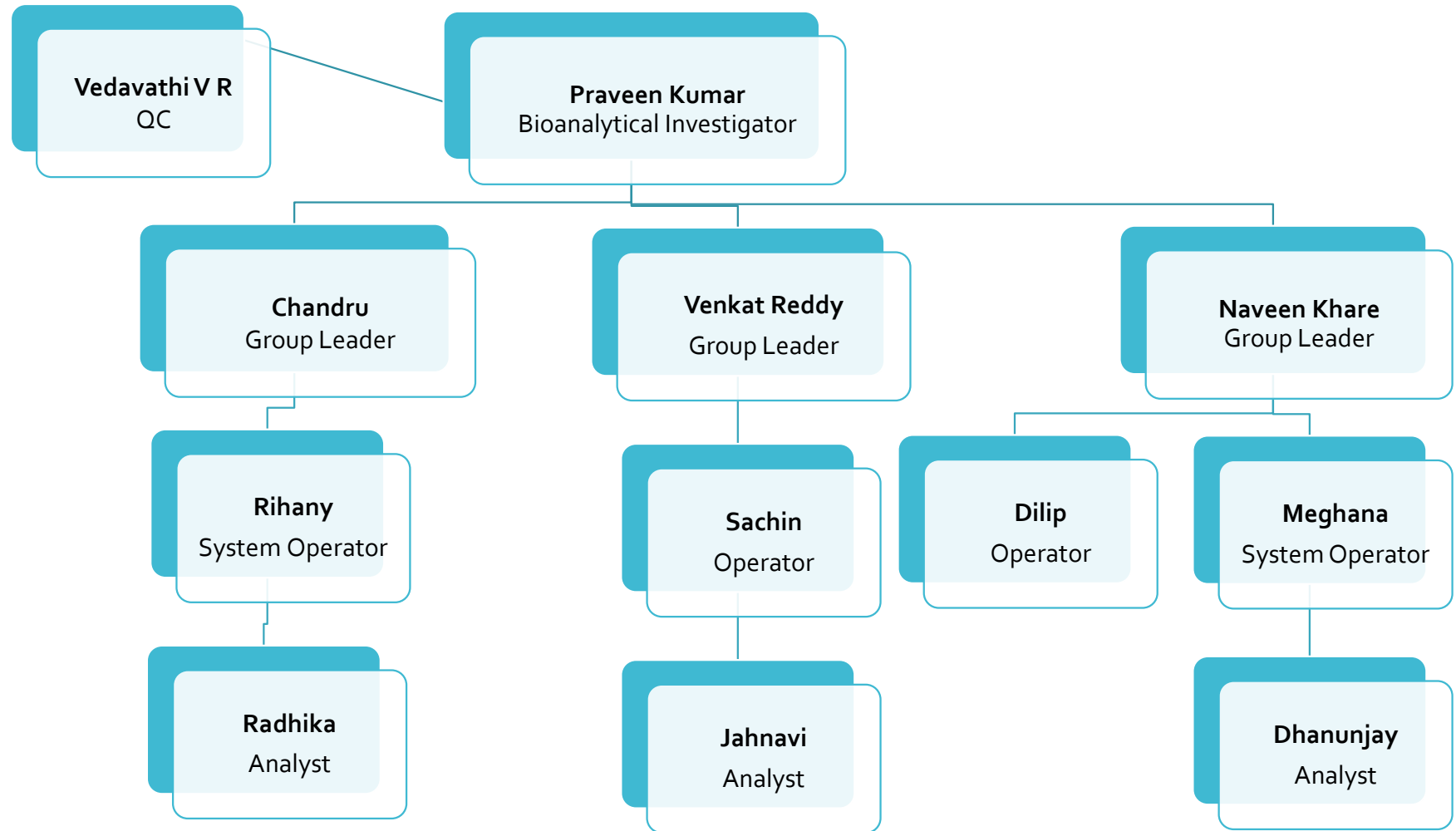


Commitment to
reliability,
professionalism
and efficiency
in medical
services



Bioanalytical Facility

Bioanalytical Organogram



Bioanalytical Lab



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.





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.



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

Phase I & BA/BE Studies

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

Experience with Route of administration

Injection

Oral

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

Rectal

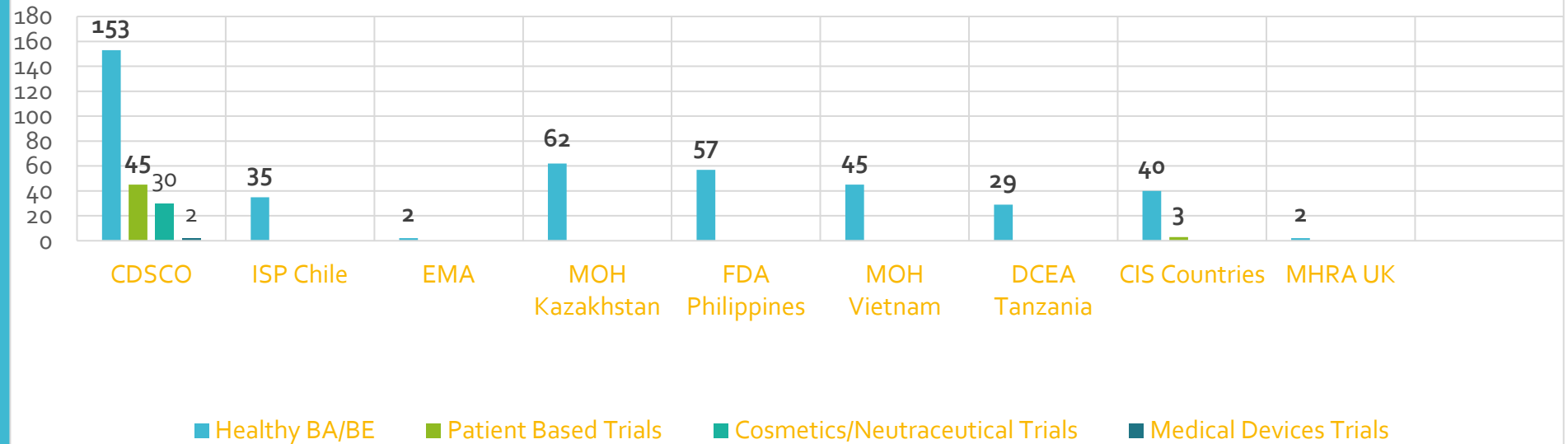
Transdermal

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



Experienced Team:

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

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

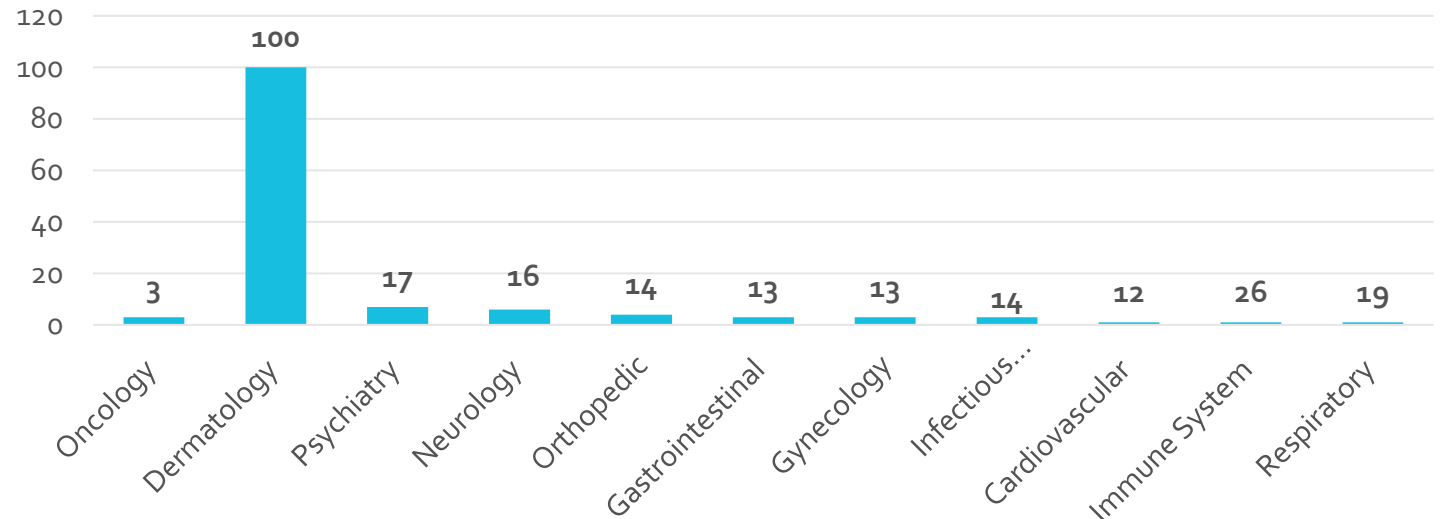
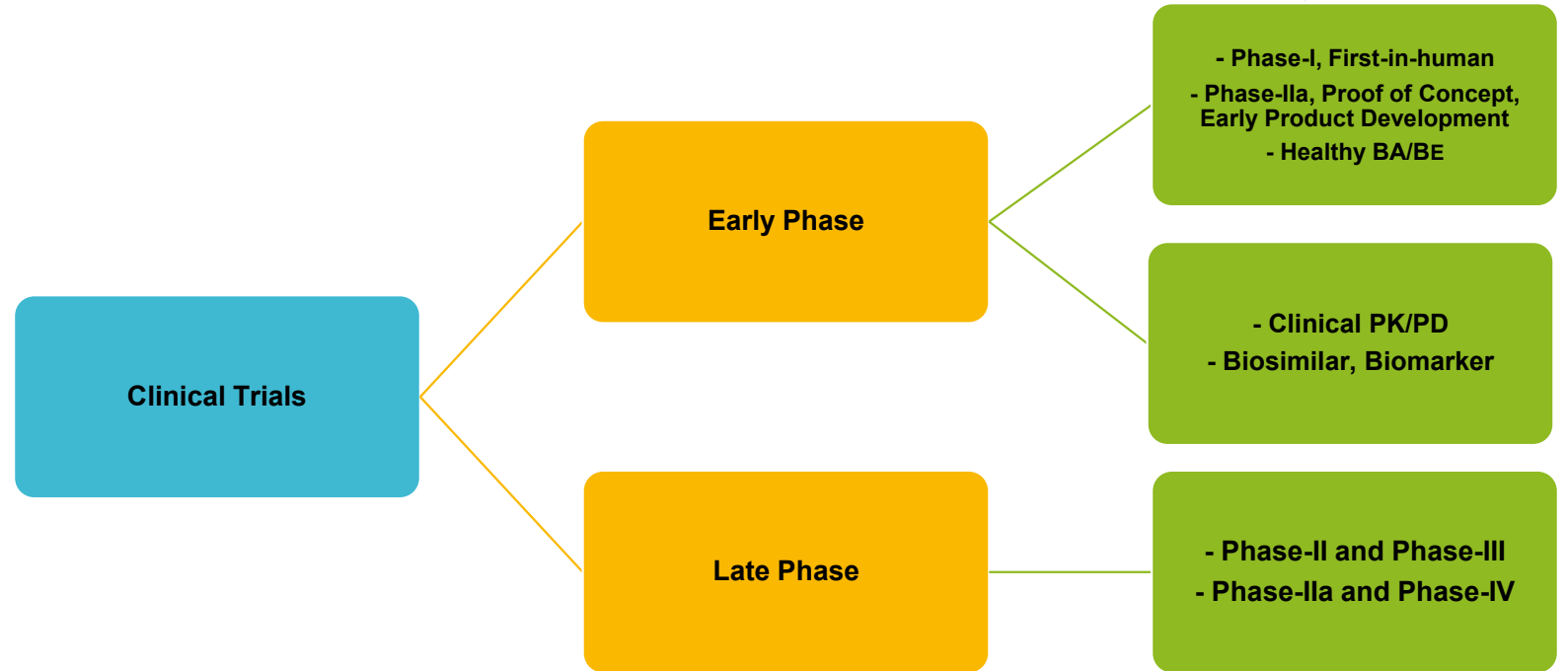
Regulatory Compliance:

- 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 Phase II – Phase IV

Experience in
500 + Clinical Trials across
18 Therapeutic area



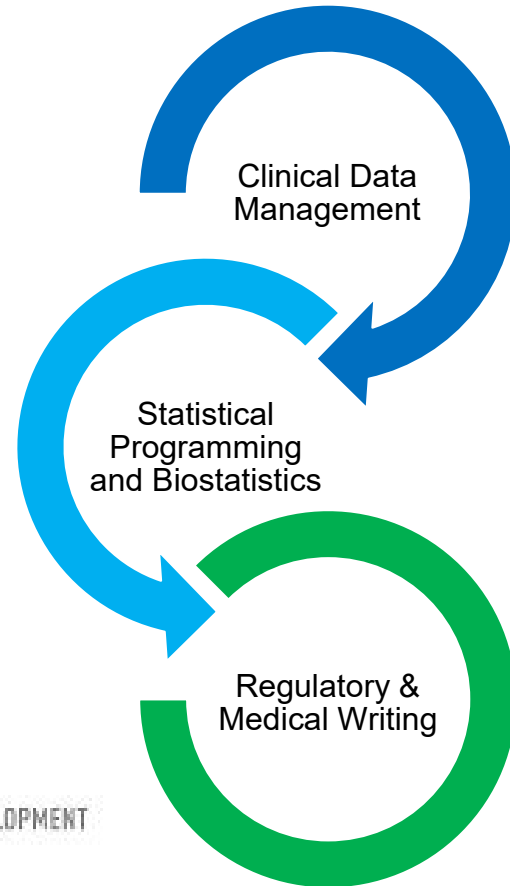
Clinical Trials Support



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



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.

Pharmacovigilance Service

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

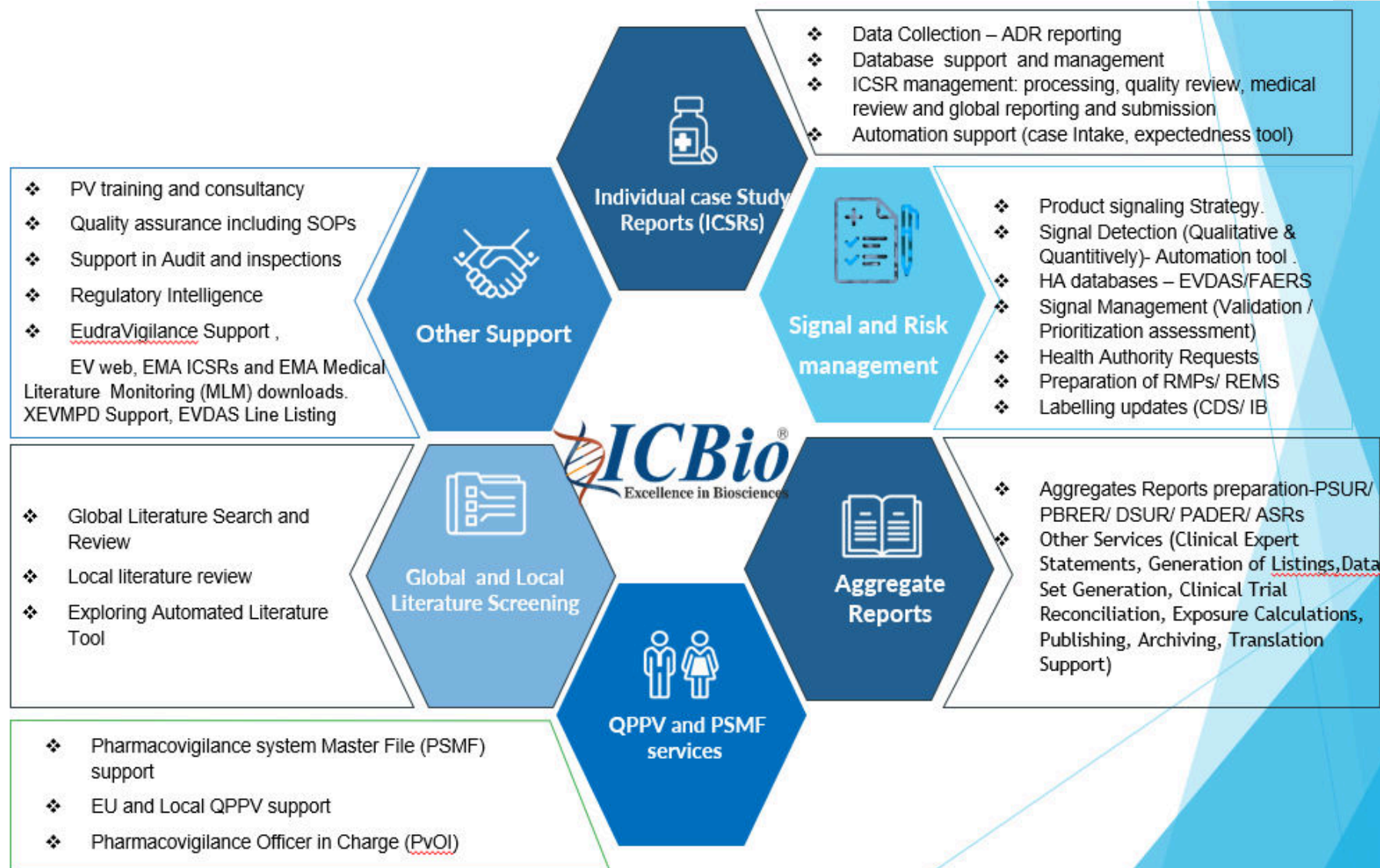


**Pharmacovigilance
System Master
File (PSMF)**



**PV Consulting
and Additional
Support**

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.

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



Cost Effective



Single partner
Convenience

Across Product lifecycle



Tailored personalized
solutions

Flexibility/Dedicated Project Teams



Scalability

Pan India Network of Hospital
Investigator sites-150 sites in 17 cities
Diverse patient Population Database
In house PV trainings Programs



Quality and Compliance
KPI & SLA Driven



Technology / Automation
Support



Global Reach
Strong Customer Base



Subject matter experts
Each Process
(Industry Experts)

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

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Yelahanka Main Road, Vidyaranyapura Bangalore - 560 097, INDIA***

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Mobile: +91 99001 11997

WhatsApp: +9199001 11996

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website: www.icbiocro.com