CEBIS

ENERGIZING DISCOVERY

CLINICAL RESEARCH

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About US

Founded in 2007, CEBIS has embarked on a remarkable journey of dedication and innovation in the field of clinical research. Over the past two decades, we have grown from a promising start-up into one of the world's leading clinical research organizations.

- **Inception:** CEBIS was established with a clear mission to assist the pharmaceutical industry in achieving its healthcare objectives. From the very beginning, our commitment to excellence set us on a path of steady growth and success.

- **Growth and Expansion:** Over the years, we have expanded our footprint across three continents– Europe, North America, and Asia. With over 30 locations worldwide, we've become a global force in clinical research.

BOARD OF DIRECTORS

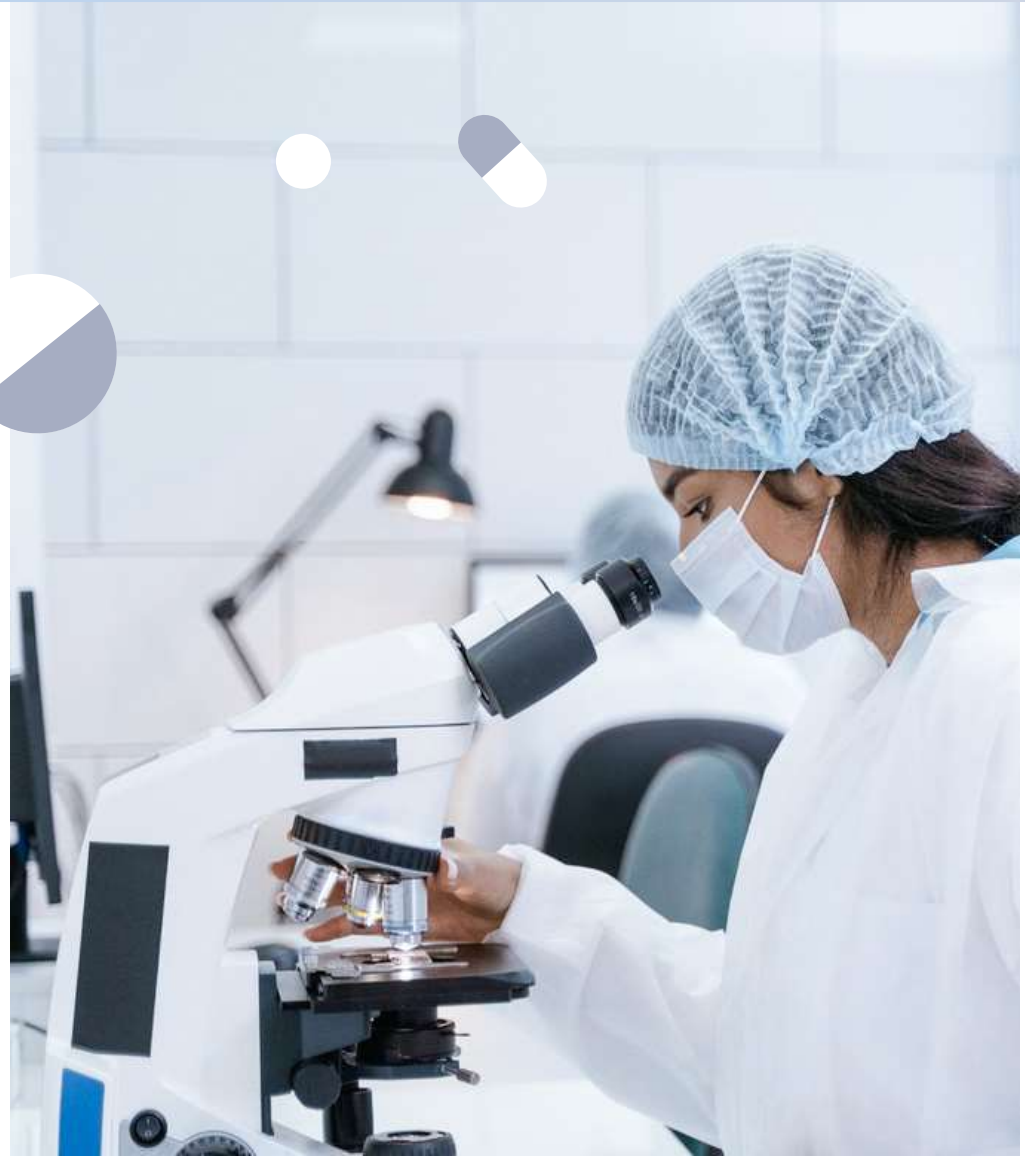
						
Dr. Mihai Manolache, PhD Chairman of the Board of Directors	Dr. Tausif Monif Ph.D. Chief Executive Officer	Dr. Nawab F. Baloch Chief Operating Officer	Andreea Manolache President Corporate Governance	Mr. Salman Pathan President Global Supply Chain	Ms. Uma Janapareddy President – Technologies & Innovation	Mr. Dopesh Raja Mulakala President India Operations

OUR VISION

The primary objective of our organization is to facilitate patients in obtaining a precise diagnosis, providing them with opportunities to avail the most up-to-date therapies accessible, and supporting them in sticking to drug admin istration standards, thereby ensuring a high level of treatment adherence.

OUR MISSION

We are committed to accelerate the development of safe and effective treatments through our experience, professionalism and ethical standards, contributing to better quality of life and better treatment alternatives.



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‘Idea to Market’ Services

At CEBIS, we specialize in turning visionary ideas into thriving market realities. Our 'Idea to Market' services are designed to be your trusted partner on the journey from concept inception to a successful product or service launch.

1. Clinical Trial Management:

- Medical Writing (Protocol, Investigator Brochures (IBs), CRF, ICF)
- Regulatory support (Regulatory & EC/ IRB Approvals), (Initial Submission, Amendments, Annual Reports and Follow-up)
- Conducting clinical trials (Phase I –IV)
- Expert project management to ensure efficient trial execution.
- Article Writing, Poster design, Abstract Preparation, Article Adaption to Journal Requirements, Follow-up Until Publication

2. Site Management and Monitoring:

- Network of investigator sites across the United States for multi-center trials.
- Experienced site monitoring teams ensuring protocol adherence and data quality. GCP Training and Monitoring (Site Initiation Visit, Site Monitoring Visits, For-cause Visits, Close-out Visit, Audit Visits, Co-monitoring Visits, Risk-based Monitoring, Inspection Readiness Visits)
- Efficient site start-up and closeout processes.

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3. PMOS (Post Marketing Observational Studies)

- Post Marketing Observational Studies (PMOSs)
- The staffs are qualified by education and experience to perform PMOSs.

4. Disease Registries

CEBIS has experience in building disease registries to serve as a basis for calculation of incidence and prevalence of diseases.

5. Regulatory Affairs

- In-depth knowledge of the USFDA regulatory landscape.
- Clinical Trial Application (CTA), Amendments and Modifications.
- Regulatory strategy development, Submission support, FDA interactions, Product registration.
- Post authorisation product launch, Line extension, Variation support and Product Life cycle management.

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6. Data Management and Biostatistics

- Cutting-edge data management systems for accurate and reliable results (Data Coding, Data Cleaning, Data Validation, Database Lock)
- Electronic data capture (EDC) and eClinical solutions.
- Statistical analysis (Data Analysis, Data Report, Data Interpretation) and interpretation to support decision-making.

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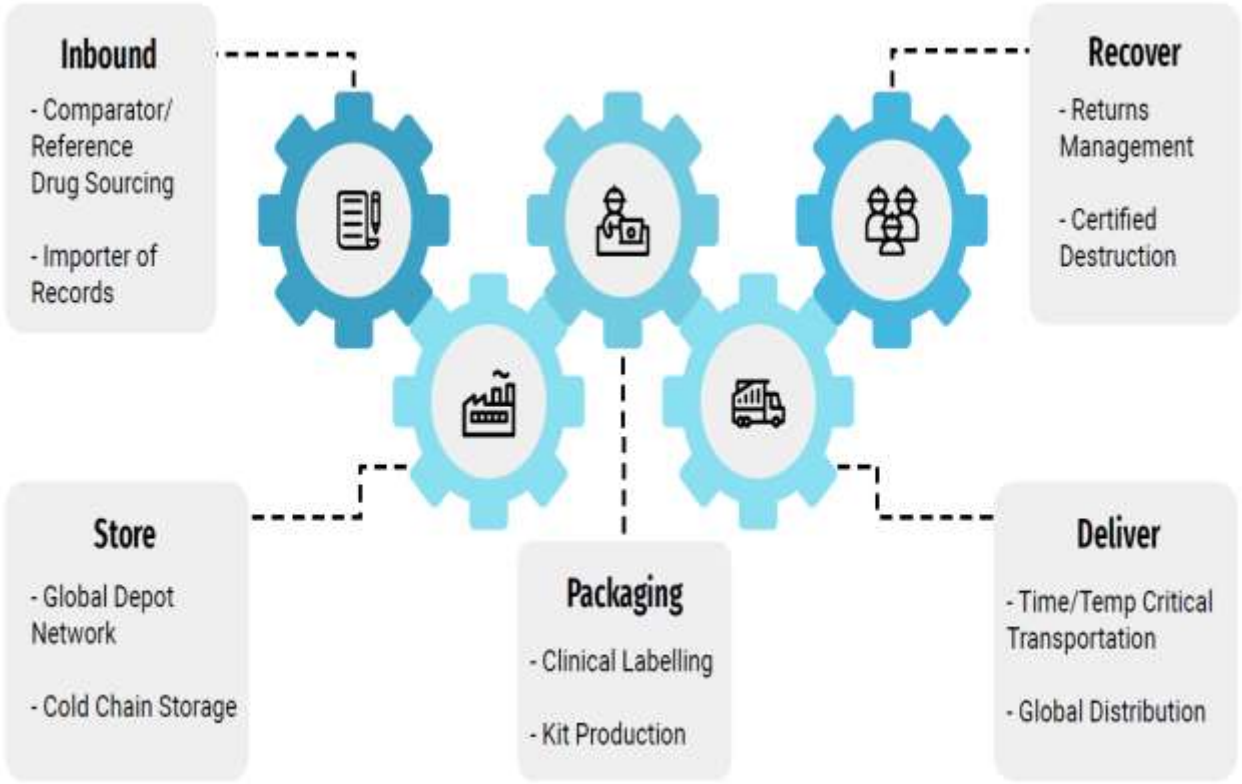
7. Clinical Trial Supplies and Logistic Management:

- End-to-End Clinical trial support.
- Sourcing of comparators/RLD and ancillaries.
- Clinical Packaging, Labelling and Kitting
- IMP Management at trial site (IWRS), Randomisation and Placebo Manufacturing
- Global depot and distribution network
- IMP Importation, Border-crossing, Importation of record, return management and destruction
- GMP warehousing and Cold chain Management.

All CEBIS Clinical packaging and labelling services in the USA strictly adhere to cGMP and EU GMP guidelines, as well as comply with EU Clinical Trial Regulation (CTR) and 21 CFR standards.



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CEBIS Clinical Trial Services (Phase I-IV)

- The Clinical Research and Regulatory Services Division oversees Phase I to phase IV projects worldwide.
- CEBIS has the expertise of performing Adaptive Designs for Clinical Trials of Drugs and Biologics.
- Projects are conceptualised in Consultation with Expert (e.g., Regulatory Agencies, KOL).
- Ability to conduct Phase I studies on a patient population.
- CEBIS offers to conducts PK studies on new molecules, repurposed or modified formulations.
- Conducting complex studies including FIH (SAD/MAD) and on 505(b)2 products.
- We use the latest technology and one such use is AI in clinical trial Modeling and simulation.
- Use clinical trial technologies to improve milestones, generate high quality data.
- Use of risk-based monitoring tools to increase the study performance

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CEBIS Clinical Trial Services (Phase I-IV)

CEBIS has Expertise in Target Therapeutic Areas with a Focus on Specialization to Speed Up Clinical Development.

1. Onco- Haematology
2. Gastroenterology
3. Immunology
4. Rheumatology
5. Gynaecology
6. Chronic Kidney Disease
7. Infectious disease
8. Rare and Orphan disease
9. Cell and gene therapy
10. Neurology
11. Autoimmune and allergy
12. COVID-19
13. Paediatric

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CEBIS Bioequivalence/Bioavailability Services

- CEBIS has a DCGI Inspected and **USFDA Audited (with No 483)** state-of-the-art clinical site located in **Gandhinagar India**, with all necessary infrastructure and expertise for conduct of pharmacokinetic studies supporting IND/NDA/ANDA filings.
- We offer our sponsors a comprehensive package, including protocol design, regulatory support, analytical quantification, pharmacokinetic, biostatistical and CSR compilation.
- The CEBIS multidisciplinary team effectively coordinates between its internal and external stakeholders to ensure seamless and effective study execution.
- CEBIS volunteer database is robust including both male and female healthy volunteers that enables fast and efficient recruitment.
- In-house bioanalytical capabilities enable fast and accurate analysis of clinical samples.
- A strong team of pharmacokinetic scientists, biostatistician subsequently derive data through validated software for compiling the final CSR to be used for regulatory filings.

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Capabilities

- BA / BE Studies (Healthy Subjects)
- Single and Multiple dose
- Studies needing continuous Infusion Pump
- PK-PD Studies (Healthy & Patients)
- Proof of Concept Studies (PoC)
- Special Patient Population (Geriatrics, Post Menopausal Females)
- Drug- Drug Interaction Studies
- Food- Drug Interaction Studies
- Irritation, Sensitization & Adhesion Studies

Below is a list of drug formulations that can be studied with our experience.

- Solid oral administration
  - ✓ IR
  - ✓ ER
  - ✓ MR
- Orally disintegrating tablets
- Products for inhalation
- Transdermal patches
- Depot injections
- Derma products on patients and Healthy Volunteers.

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Departments and Infrastructure

1. Clinical
2. Bioanalytical
3. Biostatistics and Data Management
4. IT
5. QMS and Independent Quality assurance
6. Project Management

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CRO Facility

Clinical Pharmacology Unit (CPU)

- Clinical Area Spread about in 15000 Sq Ft Area.
- Trained and experienced staff with more than 20 years of collective experience (>400+Combined Project experience including Bioequivalence, Early & Late Phase Clinical Trials, Large-Molecules (Biosimilar) & Clinical end point BE studies)
- Capacity for 140 beds (70 beds, two clinics)
- CEBIS volunteer database is robust including both male and female healthy volunteers that enables fast and efficient recruitment.
- Subject Housing Area with Separate Wards for Male & Females.
- Dedicated Dosing Area and workstations with provision for light sensitive drugs
- Dedicated state of the art ICU with Cardiac Monitoring & Full Time Ambulance readiness.
- Dedicated Pharmacy with Access Control.
- Refrigerated centrifuge and Deep freezer (-20 ^{o}C) for sample separation and storage.

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Clinical Pharmacology Unit (CPU)-Infrastructure

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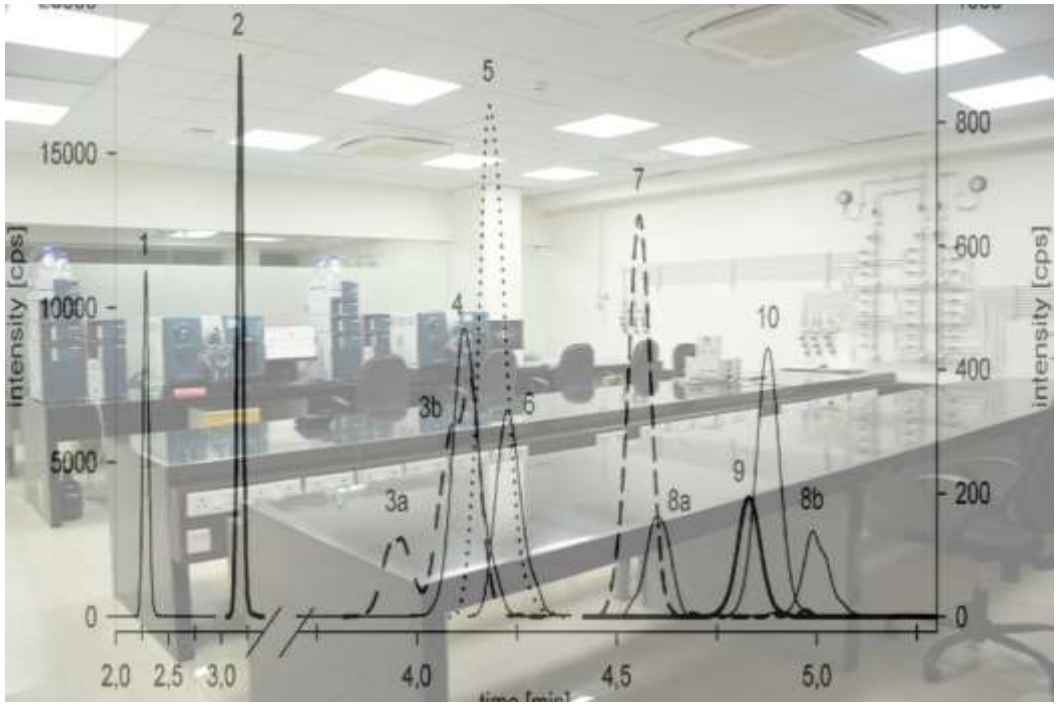
Bioanalytical (BA)

- Bioanalytical Area Spread about in 7500 Sq. Ft Area.
- State of the arts LCMS/MS machines.
- Method library consist list of 250 sensitive Bioanalytical Methods with Different Matrices.
- Trained and experienced staff with more than 20 years of collective experience.
- Experience in handling Complex Bioanalysis (e.g., Sub picograms, Simultaneous estimation, Methods with Derivatization, Endogenous molecules, Multiple analyte etc.
- Provision for handling light sensitive and experience with Control substance products.
- Online (24x7) Temperature and humidity monitoring by Eurotherm device complying 21 CFR Part 11 compliance.
- Access control room with Deep freezers (-20 and -80 C) connected with Eurotherm with alarm system.



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Bioanalytical (BA)-Infrastructure


Deep freezer Area


Sample processing Area


LCMS lab Area

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Biostatistics and Data Management

- ❑ Protocol preparation and Review
- ❑ Sample size calculation.
- ❑ Randomization schedule
- ❑ Statistical Analysis Plan (SAP)
- ❑ CDISC (SDTM) datasets deliverables for submissions to regulatory markets such as USFDA
- ❑ PK and Statistical Analysis
- ❑ CSR Statistical Analysis Report
- ❑ eCRF Design.
- ❑ Data Validation Specifications
- ❑ Data Reconciliation and DB Lock
- ❑ CSR-Clinical Study report (E3)

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QMS and QA System

A Quality Management System (QMS) is a crucial component of any Clinical Research Organization (CRO) to ensure the highest standards of excellence in conducting clinical trials and research studies. Key pillars of CEBIS QMS.

- ❑ Regulatory Compliance
- ❑ Data Integrity
- ❑ Process Standardization
- ❑ Risk Management
- ❑ Continuous Improvement
- ❑ Resource Optimization
- ❑ Risk based Internal Audits and Inspections
- ❑ Training and Competency
- ❑ Patient Safety

IT and Project Management

Dedicated IT and PM team

- Data security and access control
- Defined User Privileges
- Automated data capture from LC-MS/MS system
- Primary and secondary Data backup and archival
- Software Validation
- Computer system life cycle management
- On time project update to all stakeholders
- Mitigation strategy as per the best PMP practices.

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WHY work with us ?

- **Strong Leadership and Impeccable record: M**ore than three decades of collective Global experience across spectrum of services.
- **Accelerated Drug Development:** Our services significantly hasten drug development, reducing time-to-market.
- **Data Integrity:** Precise and dependable data, empowering well-informed decision-making.
- **Robust Data:** Data accuracy and reliability.
- **Regulatory Assurance:** Confidence in regulatory submissions and secure approvals with ease.
- **Tailored Solutions:** Personalized support, perfectly aligning with the unique demands of your projects.
- **Scientific Excellence:** Profound expertise of our scientists, fostering excellence at every step.

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Global Presence

USA

Operations

Research Network America
6917 West Cermak Road,
Berwyn Il 60402
Boston Neuro Research
Center 237 State Rd,
Dartmouth, MA 02748

Headquarters

CEBIS-USA Inc., 7080,
Southwest Fwy, Houston,
Texas – 77074

Logistics

7 Chelsea Parkway, Unit 707,
Boothwyn, PA - 19061

CANADA

Operations & Logistics

2201 Drew Road, Mississauga,
ON L5S1E5, Toronto -
CANADA

Europe

Operations

Lugano Business Centre Via
Maggio 1C, Lugano 6900,
Switzerland
Helios Business Center 47
Theodor Pallady Avenue,
Entrance B, 3rd Floor,
Bucharest 032258, Romania

Logistics

11-15 Tara St., Dublin 2, D02
RY83 Ireland.

INDIA

Corporate HQ

Umajay Complex, 02/G/308/G
and 3/FF/SF/1-20-248,
Rasoolpura, Secunderabad,
Hyderabad - 500003,
Telangana, India

CRO Facility

Nr. Zodiac Farm, Opp. Auda
Garden B/H Vaishno Devi
Temple, Off, Sardar Patel Ring
Rd, Khoraj, Gujarat 382421,
India

For enquiries send us email @
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