CEBIS
ENERGIZING DISCOVERY

A GLOBAL FULL SERVICE CRO

GET STARTED

CEBIS
ENERGIZING DISCOVERY

Your Strategic Partner in Global Clinical Development

- End-to-end support for the complete product lifecycle
- Globally integrated CRO with operations in over 30 countries
- Patient-centric by design, delivering superior retention and data quality

RECRUITMENT STRATEGY

PROPRIETARY SOFTWARE

CEBIS is committed to revolutionizing our clinical trial processes and optimizing the potential of digital solutions for improved healthcare delivery. As part of our ongoing commitment to operational excellence, we have embarked on a strategic initiative to develop a proprietary application.

- **Full-time, in-house, multilingual recruiting staff**
- **Screening facilities with direct access to public medical records.**
- **Proprietary Software to identify potential participants.**
- **Provenability to meet recruitment milestones**
- **Proactive and study-focused recruitment strategies**

Salient Features

In-house, Multilingual Recruiting Staff
Our dedicated team is available full-time to assist physicians in navigating the app and the referral process.

Direct Access to Screening Dashboard
The application provides physicians with direct access to screening facilities, streamlining the process of referring patients for clinical trials.

Proprietary Software
Leveraging advanced algorithms, the application utilizes a proprietary software to identify potential participants for various clinical trials.

Study-Focused Recruitment
The application embodies our commitment to proactive and study-focused recruitment strategies. By giving doctors real-time updates on ongoing studies.

CEBIS
ENERGIZING DISCOVERY

DELIVERABLES DRIVEN BY INTEGRATED SOLUTIONS

End-to-End Services

MEDICAL WRITING
e.g., Protocols, Investigator Brochures (IBs), CRFs, ICFs, Clinical Study Reports & Manuscripts, Regulatory Submission Documents

CLINICAL OPERATIONS
Study Start-Up
- Site Selection, Contracts & Budgets
- Site Ethics & Regulatory Submission
- Site Activation

Clinical Monitoring
Centralized Data Review
Risk Identification and Change Planning
Amendments, Annual Reports, Follow-up Submission
Trial Closeout and Reporting

SAFETY AND PHARMACOVIGILANCE
Signal detection & case processing
periodic & expedited reporting
QPPV office consulting & support

BIOMETRICS
- Data management (data coding, data cleaning, data validation, database lock)
- Biostatistics (data analysis, data report, data interpretation)

TRIAL MASTER FILE
Electronic & paper TMF management
Independent TMF inspection readiness

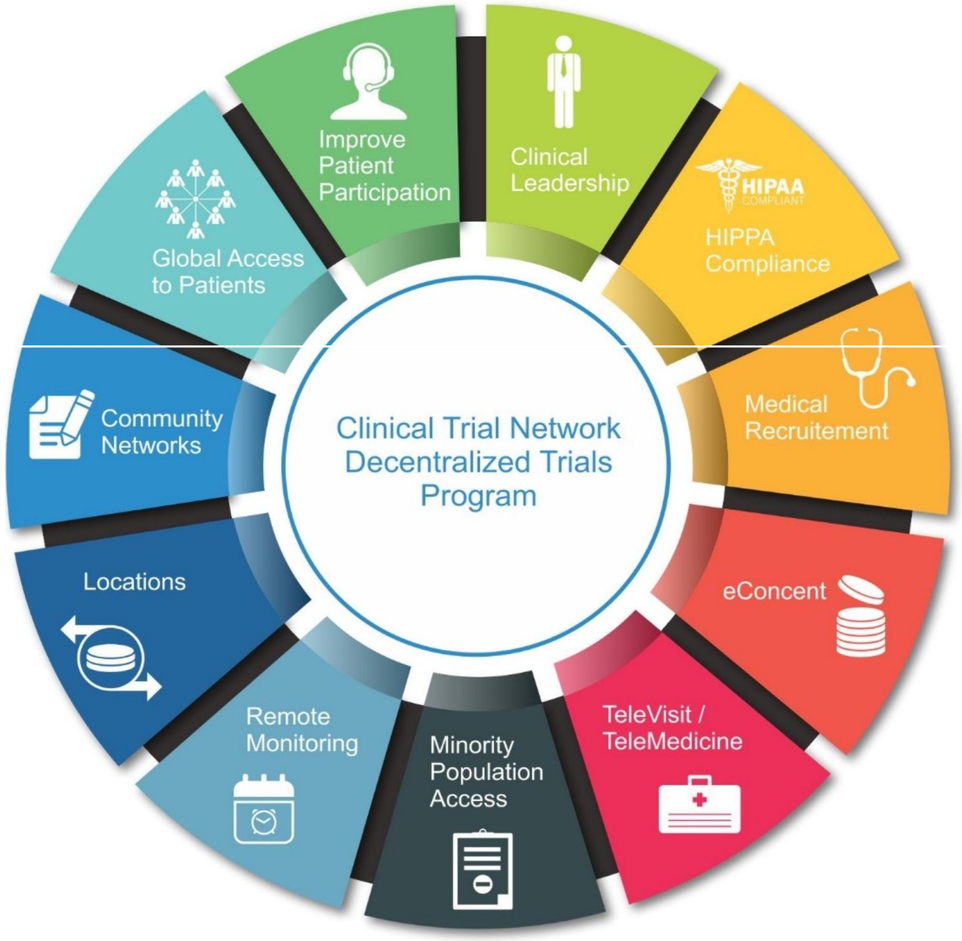
PAYMENTS
- EC & CA/site/vendor payments
- Patient reimbursement services

ADMINISTRATIVE & LOGISTICAL SERVICES
- End to end administrative support
- Comprehensive logistics services and supply chain

CEBIS
ENERGIZING DISCOVERY

EVOLUTION MODEL
Decentralized (DCT)/Hybrid Clinical Trials

- DCT boosts trial patient recruitment, retention, and population representation while capturing rich, real world data (RWD) and reducing costs.
- Eliminating the need for in-person contact between the study team and the trial participant and data is enabled through virtual and real-time tools
- Bridge the gap between the research team and the patient allowing research teams to remotely conduct follow-up monitor vitals.
- Usage of digital device (Wearables, Phones, Tablets) from patient enrollment to drug administration, vital signs, and follow-ups.
- Compliance and Cost are also very favorably impacted by employing the DCT /Hybrid model.



CEBIS Integrated Service Portfolio

Service Division	Core Offerings
Clinical & Regulatory Services	Phase I-IV Clinical Trials, Medical Devices, Dietary Supplements, Regulatory Affairs, Medical Writing, Post-Marketing Studies (PMOS)
Patient Experience Programs	Patient Adherence & Retention, Direct-to-Patient Services, Behavioral Science Integration, Technology-Based Interventions
Supplies & Logistics	Global Logistics Management, Clinical Supply Management, Cold Chain Storage & Delivery, Comparator Sourcing, Labelling & Packaging
Data Sciences & Technology	Data Management & Biostatistics, Electronic Data Capture (EDC/eCRF), Interactive Response Technology (IRT/IWRS), AI-driven Trial Modeling
Drug & Device Safety	Global Pharmacovigilance (PV) Hub, Qualified Person for Pharmacovigilance (QPPV) Services, Adverse Event Reporting, Risk Management
Pre-Clinical & Early Phase	GLP-Accredited Pre-Clinical Testing, Bioavailability/Bioequivalence (BA/BE) Studies, First-in-Human (FIH) Trials, PK/PD Analysis

CEBIS
ENERGIZING DISCOVERY

Global Footprint Local Expertise

CEBIS International's global reach is the result of over a decade of stra tegic, organic growth and targeted mergers, enabling us to manage co mplex international trials with precision and local insight.

Key Operational Hubs

USA (Houston, Boston, Chicago)
Switzerland (Lugano)
Romania (Bucharest)
India (Ahmedabad, Hyderabad)

Extensive Site Network

Access to over 300 clinical research sites and 2,000+ Principal Investigators in the US and Europe.

Deep Regulatory Exper

Proven experience across di verse regulatory environments, including EMA and FDA requirements.

CEBIS
ENERGIZING DISCOVERY

Full-Spectrum Clinical Trial Management From First-in-Human To Market

Comprehensive Phase I-IV trial execution for drugs and biologics

Specialized expertise in Medical Devices Pre-CE Mark to PMCF, and Dietary Supplements.

Fully integrated services including medical writing, project management, monitoring, and biostatistics

CEBIS
ENERGIZING DISCOVERY

CEBIS
ENERGIZING DISCOVERY

Dedicated Early-Phase & Bioequivalence Facilities

CEBIS possesses specialized infrastructure and deep scientific expertise in conducting early-phase clinical research Integrated within our early-phase services are comprehensive-Biomalytical and Bioavailability/Bioequivalence (BA/BE) capabilities

- **Dedicated Early-Phase & Bioequivalence Facilities**
- **GLP-accredited pre-clinical and clinical facilities in North America, Europe, and India.**
- **Expertise in complex study designs: First-in-Human (FIH), Single/Multiple Ascending Dose (SAD/MAD), and 505(b)2 products.**
- **Full Bioanalytical and Bioavailability/Bioequivalence (BA/BE) study services.**

CEBIS
ENERGIZING DISCOVERY

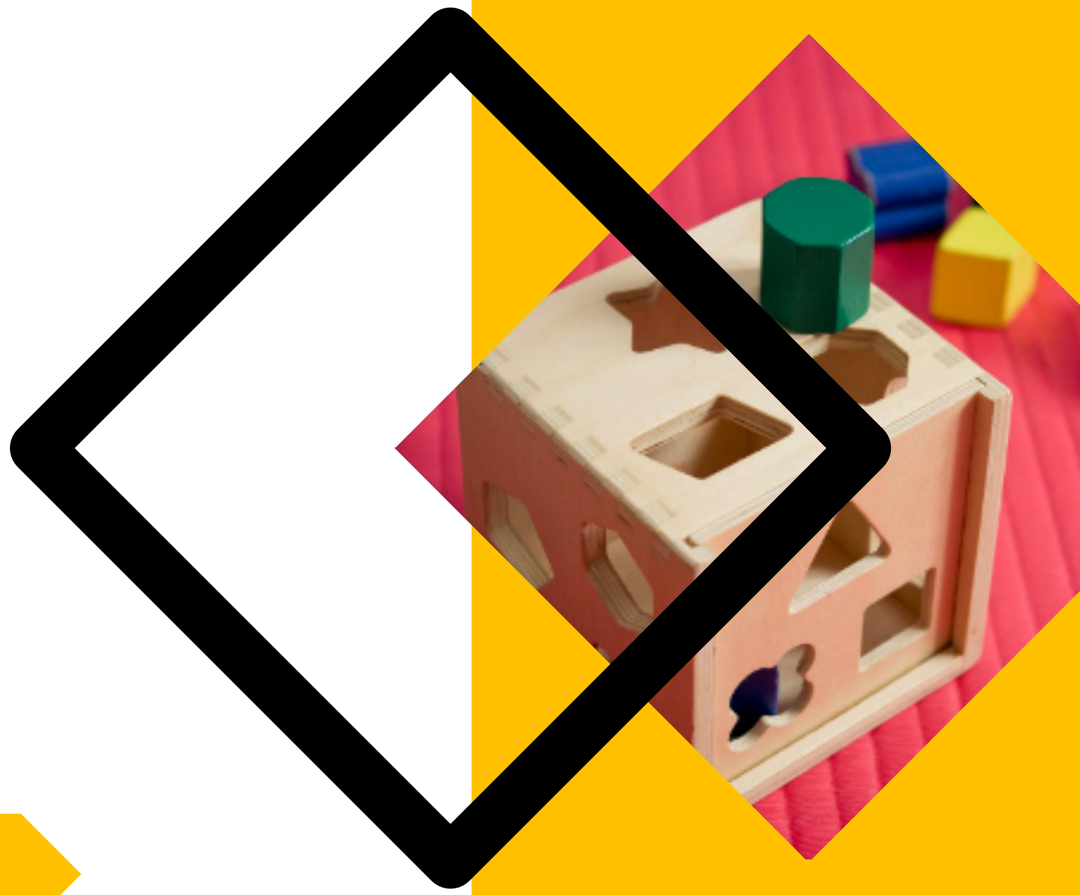
Modernizing Clinical Trials with Decentralized & Hybrid Solutions

- Designing and executing fully decentralized and hybrid trials to reduce patient burden and increase access.
- Leveraging an integrated ecosystem: Direct-to-Patient services, in- home nursing, and digital health technologies (EDC, ePRO).
- Enhancing recruitment, improving retention, and capturing high- quality, real-world data.

CEBIS
ENERGIZING DISCOVERY

Driving Trial Success Through Patient Experience & Adherence

The Patient Experience Programmes are a cornerstone of CEBIS's strategy and a significant competitive differentiator. This unit far goes beyond standard patient recruitment and engagement, offering a sophisticated suite of services designed to actively support patients and ensure their successful participation in clinical trials or to support a product already on the market.



- **Specialized team of clinical psychologists, behavioral scientists, and in-field nurses.**
- **Core Services: Patient adherence management, retention services, and direct-to-patient engagement and logistics.**
- **Technology-enabled interventions to support patients throughout their trial journey.**

Specialized Logistics

Validated cold chain storage and delivery

for temperature-sensitive biologics and therapies.

Temperatur controlled p

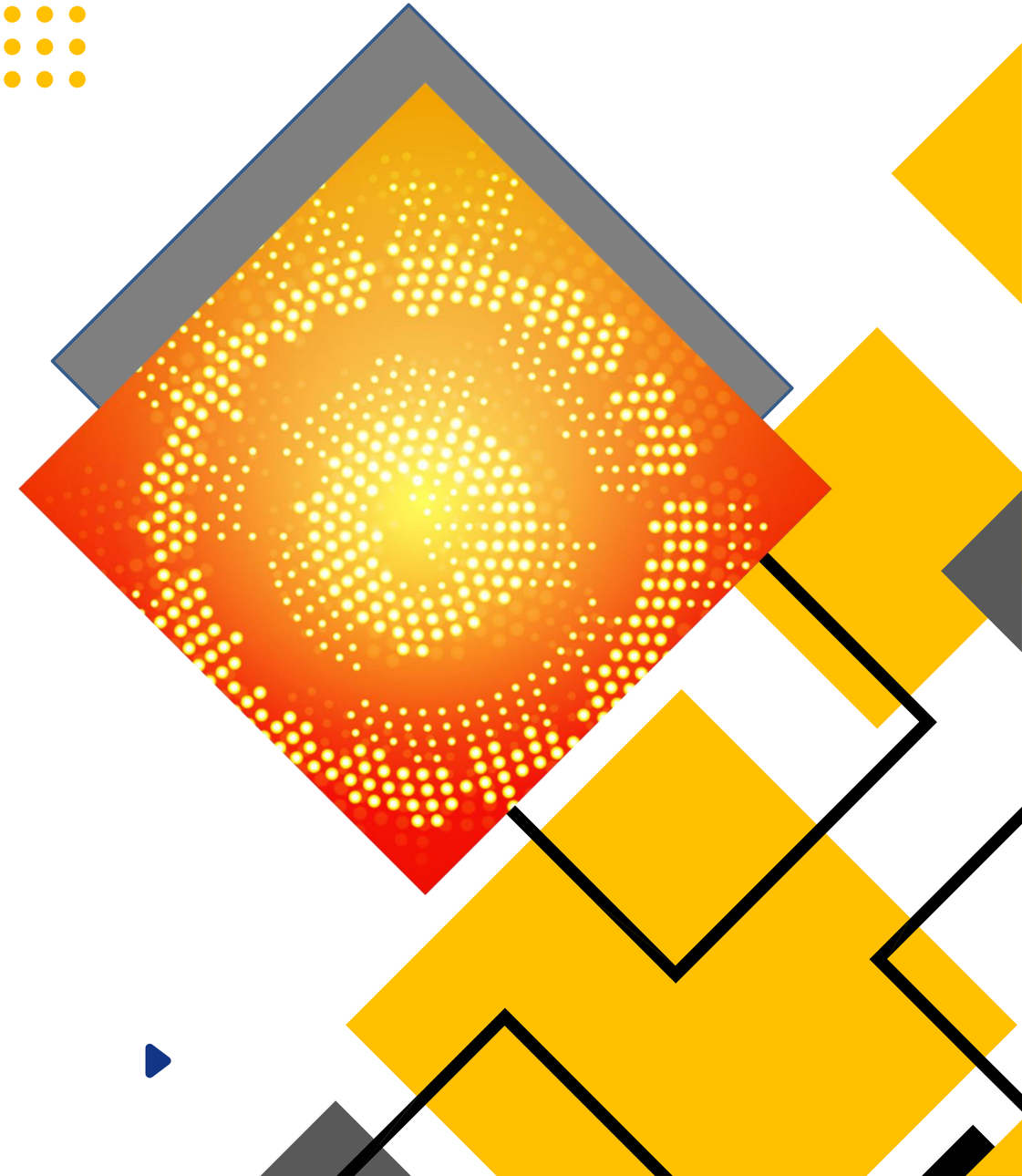
to ensure product inte

Strategic comparator sourcing

including controlled substances.

Clinical trial materials lab packaging

In-house



CEBIS
ENERGIZING DISCOVERY

Navigating Global Regulatory Complexity

CEBIS provides comprehensive regulatory affairs services, acting as a strategic partner to guide clients through the intricate and dyn amic global regulatory landscape.

End-to-end regulatory strategy and lifecycle management

including full support for Clinical Trial Applications (CTAs) and Investigational New Drug (IND) submissions.

Registration procedures, Common Technical Document (CTD) preparation, and Marketing Authorization

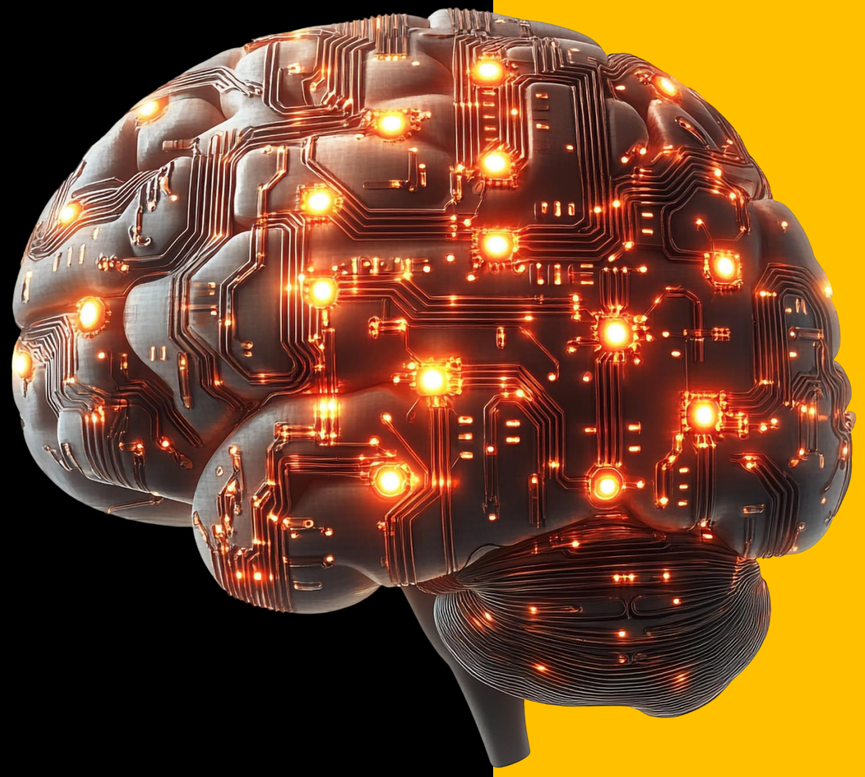
CEBIS
ENERGIZING DISCOVERY

Robust Pharmacovigilance & Drug Safety

- A dedicated Global PV Hub providing end-to-end drug and device safety solutions.
- Scalable, outsourced PV services, including QPPV.
- Adverse event management, from data collection and coding to causality assessment.
- Ensuring timely and compliant safety reporting to regulatory authorities.

CEBIS
ENERGIZING DISCOVERY

Excellence in Data Sciences & Biostatistics



- Integrated Data Management and Biostatistics services leveraging advanced technology platforms like EDC/eCRF and IRT/IWRS to ensure data of the highest quality and integrity.

- A relentless commitment to data quality, enforced through robust validation programming, diligent SAE reconciliation, and stringent quality control processes at every stage.

Unwavering Commitment To Quality & Compliance

A rubust Quality Management System (QMS)
Governs all clinical and operational processes, ensuring full compliance with global standards like EMA and FDA requirements

Our GLP-accredited pre-clinical and clinical facilities provide ultimate assurance of data integrity and regulory acceptance world

CEBIS
ENERGIZING DISCOVERY

CEBIS
ENERGIZING DISCOVERY

SOME OF OUR PARTNERS

GLOBAL PRESENCE

CEBIS is committed to providing you with the comprehensive support and expertise required to achieve your objectives. With an international presence and local knowledge in key regions, we offer the ideal combination of global reach and local expertise.

USA Offices:
- Houston, Texas
- Berwyn
- Dartmouth, MA
- Boothwyn, PA

Canada Offices:
- Mississauga, Ontario

Europe Offices:
- Switzerland
- Romania
- Dublin

India Offices:
- Rasoolpura, Hyderabad
- Gandhinagar, Gujarat
- Mumbai, Maharashtra
- Bangalore, Karnataka

CEBIS
ENERGIZING DISCOVERY

Thank You

For your attention! If you have any questions or would like to discuses further, please feel free to reach out

cebisusa.com

info@cebisusa.com