



**Trusted CRO Partner for  
Global BA/BE Studies & Phase-I**  
**Ethics | Efficient | Compliance**

[About Us](#)





## Audit-Ready Indian CRO with Proven SRA Submissions

Ethics | Efficient | Compliance

[About Us](#)





## About Us

Glocare Labs Pvt. Ltd. is a leading Contract Research Organization (CRO), established in 2017 and headquartered in Chennai, India. We specialize in delivering high-quality, end-to-end clinical research services to the pharmaceutical, biotechnology, and healthcare industries.

Committed to scientific excellence, regulatory compliance, and client satisfaction, we partner with our clients throughout every stage of the clinical development

At Glocare Labs, we blend deep domain expertise with innovative solutions to accelerate the development of safe and effective therapies -ultimately contributing to improved global health outcomes.

## Why Choose Us



Expertise in regulatory affairs and ethics submissions



NABL approved Bio-analytical lab with sophisticated LC-MS/MS machines



Fast study start-up and Volunteer recruitment



CDSCO-approved facility with 60-bed clinical unit and 2 ICU beds



Well experienced team to handle special studies like Trans Dermal Patch, Inhalation, Nasal spray and Injection studies



Approved by the Public Health Institute of Chile (ISP) since 2021



A dedicated, independent, and experienced Quality Assurance (QA) unit is responsible for verifying that all data generated is accurate, complete, and compliant with current regulatory guidelines



In-house NABL-accredited Clinical diagnostic lab



Compliant with ICH-GCP and global GCP/GLP guidelines



Contract Research Organisation

[in](#) Glocare Labs Pvt Ltd (CRO)

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# Services



## Bioavailability and Bioequivalence Studies

We offer comprehensive clinical research solutions tailored to meet the diverse needs of our clients. Our integrated services span the full clinical studies, ensuring high-quality outcomes and timely project execution aligned with global regulatory standards.

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## Clinical Unit

Our state-of-the-art Clinical Pharmacology Unit is equipped with 60 beds, designed for maximum flexibility in conducting a wide range of clinical studies ensuring compliance with ethical standards.

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## Bioanalytical Laboratory

Our Bioanalytical Laboratory is a core component of Glocare Labs clinical research infrastructure, designed to deliver precise, reliable, and regulatory-compliant analysis of drug concentrations in biological matrices.

[See More](#)

## Clinical Diagnostic Laboratory (CDL)

Our Diagnostic Laboratory at Glocare Labs is NABL-accredited (National Accreditation Board for Testing and Calibration Laboratories) and operates in full compliance with ISO 15189:2012 standards, ensuring the highest levels of quality and ...

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## Medical Writing

Our Medical Writing Team plays a critical role in supporting Bioavailability/Bioequivalence (BA/BE) studies with clear, accurate, and regulatory-compliant documentation. Our writers combine scientific expertise with...

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## Biowaiver Studies & In Vitro Dissolution Services New

At Glocare Labs, we offer specialized biowaiver study services for generic drug development under BCS-based regulatory pathways. Our services support dossiers that aim to waive in vivo bioequivalence studies through scientifically justified in...

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## Pharmacovigilance

We provide comprehensive Pharmacovigilance (PV) services to ensure the safety and efficacy of pharmaceutical products throughout their lifecycle. Our solutions are designed to help pharmaceutical companies comply with global...

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## Regulatory Support Services

We deliver end-to-end Regulatory Support services designed to accelerate approvals, ensure compliance, and streamline operations across Bioavailability/Bioequivalence (BA/BE) studies.

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# Bioavailability and Bioequivalence Studies

We offer comprehensive clinical research solutions tailored to meet the diverse needs of our clients. Our integrated services span the full clinical studies, ensuring high-quality outcomes and timely project execution aligned with global regulatory standards.

Our service offerings include:

## • Study Design and Planning

- Clinical study design tailored to regulatory and therapeutic requirements
- Studies include Single and multiple dose studies with fasting and fed state
- PK/PD studies
- Special population studies (Eg. Post-Menopausal and geriatric studies)
- Informed Consent Form (ICF) and protocol development

## • Regulatory and Ethics Approvals

- Regulatory submissions and approvals for project initiation
- Pre-study approvals from Independent Ethics Committee (IEC)/Institutional Review Board (IRB)

## • Clinical Phase Execution

- Subject recruitment and management
- Full conduct of the clinical phase in compliance with GCP

## • Bioanalytical Services

- Precise and validated methods for bioanalysis across multiple matrices

## • Project Oversight

- Dedicated project management throughout the study
- Pre- and post-project regulatory support

## • Data and Reporting

- Clinical data management using industry-standard platforms
- Biostatistical analysis and interpretation
- Medical writing and integrated clinical study report preparation

## • Regulatory Submission Support

- CTD/eCTD submissions for global regulatory bodies

## • Archival

- Secure storage and archival of data and study materials for future reference and audit readiness

Our multidisciplinary team ensures that every aspect of your clinical study is managed with precision, integrity, and regulatory compliance.

# Clinical Unit



Our state-of-the-art Clinical Pharmacology Unit is equipped with 60 beds, designed for maximum flexibility in conducting a wide range of clinical studies ensuring compliance with ethical standards.

## **Key Features:**

- CCTV Surveillance: 24/7 monitoring for safety and protocol adherence
- Dedicated Zones: Separate areas for subject screening, dosing, sample collection, and monitoring
- Regulatory Compliance: Fully aligned with GCP, CDSCO, and international regulatory standards

## **Emergency Backup Systems:**

- Uninterrupted Power Supply (UPS) and diesel generators ensure continuous operation of critical equipment and environmental controls
- Fire safety systems, emergency lighting, and clearly marked evacuation routes
- On-site availability of emergency crash carts, oxygen supply, ambulance and resuscitation equipment

## **Medical Staffing:**

- A fully qualified team of in-house physicians, Investigators and nurses trained in GCP and emergency response
- 24/7 medical coverage during study periods
- Established SOPs for adverse event (AE) and serious adverse event (SAE) management, with escalation protocol

This robust infrastructure ensures a safe, compliant, and efficient environment for the conduct of high-quality clinical research.

# Bioanalytical Laboratory



Our Bioanalytical Laboratory is a core component of Glocare Labs clinical research infrastructure, designed to deliver precise, reliable, and regulatory-compliant analysis of drug concentrations in biological matrices.

## Capabilities & Features:

- State-of-the-art LC-MS/MS systems for high-sensitivity quantitative analysis
- HPLC system for method development and sample processing
- Validated methods for a wide range of analytes across plasma, serum, urine, and other biological samples
- Strict adherence to Good Laboratory Practice (GLP) and regulatory guidelines (CDSCO, USFDA, EMA)

## Facilities Include:

- Dedicated sample processing and extraction areas
- Controlled temperature sample storage rooms (refrigerators and deep freezers with temperature monitoring)
- Stability chambers for sample integrity testing under various conditions
- Secure data acquisition and storage systems ensuring traceability and audit readiness

## Expert Team:

- Experienced bioanalytical scientists, method developers, and QA personnel
- In-house capability for method development, validation, and transfer

Proficient in handling complex matrices and challenging analytes

# Clinical Diagnostic Laboratory (CDL)



Our Diagnostic Laboratory at Glocare Labs is NABL-accredited (National Accreditation Board for Testing and Calibration Laboratories) and operates in full compliance with ISO 15189:2012 standards, ensuring the highest levels of quality and competence in medical testing.

## Key Highlights:

- **Accreditation:**  
NABL-accredited under ISO 15189:2012, ensuring internationally recognized quality and technical standards for medical laboratories
- **Quality Assurance:**  
Stringent internal quality control protocols and regular proficiency testing maintain the accuracy, reliability, and consistency of results
- **Sample Quality:**  
Diagnostic samples are sourced from reputed medical institutions such as Vellore Medical College and AIIMS, ensuring a high standard of biological material for accurate analysis and validation
- **Testing Capabilities:**  
A broad spectrum of diagnostic tests including hematology, clinical biochemistry, Urine analysis, and microbiology  
Fully equipped with automated analyzers and managed by qualified laboratory personnel

Our diagnostic services support both routine clinical evaluations and complex study-specific testing requirements, contributing to the overall integrity of our clinical research operations

# Medical Writing



Our Medical Writing Team plays a critical role in supporting Bioavailability/Bioequivalence (BA/BE) studies with clear, accurate, and regulatory-compliant documentation. Our writers combine scientific expertise with regulatory insight to produce high-quality documents that meet global submission standards.

## Our Expertise Includes:

- Protocol and Investigator's Brochure (IB) Development  
Scientifically sound, ICH-compliant documents tailored to study objectives
- Informed Consent Forms (ICF)  
Ethically and legally compliant forms written in clear, vernacular language
- Clinical Study Reports (CSRs)  
Comprehensive and structured reports in line with ICH E3 guidelines, including PK/PD summaries and safety evaluations
- Regulatory Submission Documents  
Preparation of Common Technical Document (CTD) modules for eCTD submissions, including overviews, summaries, and Module 4 and 5 content
- Safety and Adverse Event Narratives  
Concise documentation of adverse events for regulatory review

# Biowaiver Studies & In Vitro Dissolution Services New



At Glocare Labs, we offer specialized biowaiver study services for generic drug development under BCS-based regulatory pathways. Our services support dossiers that aim to waive in vivo bioequivalence studies through scientifically justified in vitro dissolution profiles and robust comparative analysis.

## Our Biowaiver Expertise Covers:

- In vitro dissolution testing across multiple pH conditions (1.2, 4.5, and 6.8)
- Development and validation of discriminatory dissolution methods
- f2 similarity factor analysis and model-independent comparisons
- Biopharmaceutics Classification System (BCS) justification reports
- Scientific rationale for biowaiver eligibility (BCS Class I/III)
- Risk assessment and regulatory strategy planning
- CTD Module 2.3 and 2.7.1 documentation for submission

Our team ensures full compliance with EMA, WHO, and USFDA biowaiver guidelines, supporting dossiers across regulated and semi-regulated markets.

Contact us to learn how our in-vitro and regulatory biowaiver support can accelerate your generic product registration while reducing development costs.

# Pharmacovigilance



We provide comprehensive Pharmacovigilance (PV) services to ensure the safety and efficacy of pharmaceutical products throughout their lifecycle. Our solutions are designed to help pharmaceutical companies comply with global regulatory requirements, mitigate risks, and protect patient health.

## Our Pharmacovigilance Services Include:

- Adverse Event (AE) Reporting & Management  
Timely collection, assessment, and submission of Individual Case Safety Reports (ICSRs) in accordance with international regulations.
- Signal Detection & Risk Management  
Continuous monitoring for safety signals and implementation of risk minimization strategies to support product safety profiles.
- Literature Surveillance  
Regular screening of scientific and medical literature for adverse events and safety updates related to client products.
- Aggregate Reporting  
Preparation of Periodic Safety Update Reports (PSURs), Periodic Benefit-Risk Evaluation Reports (PBRERs), and Development Safety Update Reports (DSURs).
- Medical Review & Quality Assurance  
In-depth medical evaluation of safety data and implementation of robust QA processes to ensure accuracy and compliance.
- Regulatory Submissions  
End-to-end support for submission of safety data to global health authorities, including FDA, EMA, MHRA, and others.

# Regulatory Support Services



## For BA/BE Studies | Clinical Research (CRO)

We deliver end-to-end Regulatory Support services designed to accelerate approvals, ensure compliance, and streamline operations across Bioavailability/Bioequivalence (BA/BE) studies.

### Regulatory Support Services:

Our team provides comprehensive regulatory support, including:

- Preparation and submission of Bioavailability/Bioequivalence (BA/BE) study protocols for regulatory approval
- Guidance through New Drug Approval (NDA) processes, including dossier compilation and submission
- Preparation and management of regulatory dossiers (e.g., CTD/eCTD formats) for various regulatory agencies
- Assistance with licensing applications, renewals, and post-approval variations
- Coordination with regulatory authorities and support during review and approval cycles
- Ensuring compliance with local and international regulatory requirements

## Facilities

[Virtual tour](#)[Gallery](#)[Events](#)

# Accreditations & Approvals

## International Standards & Approvals

- ISP Chile (Instituto de Salud Pública de Chile):**  
Our clinical studies have been successfully audited and approved by ISP Chile, affirming our capability to conduct trials in accordance with stringent Latin American and global regulatory standards.
- DCGI Approval (India):**  
Approved by the Drugs Controller General of India (DCGI) for conducting BA/BE studies, ensuring full compliance with Indian regulatory and GCP guidelines.
- European Union (EMA):**  
EMA submission completed – Approval from the European Medicines Agency is currently pending, demonstrating our preparedness and commitment to entering regulated EU markets.



ISO 9001:2015



ISO 14001:2015



ISO 27001:2022



GLP / GCP



TC- 11523



- ISO 9001:2015, ISO 14001:2015, ISO 27000:2022: These accreditations affirm our dedication to quality management systems (QMS), environmental management systems (EMS), and information security management systems (ISMS), reflecting our holistic approach to operational excellence.

## Career

### The Easiest Way to Get Your New Job

We offer jobs right now

 Name\* Phone No\* Role\* Email ID\* Highest Qualification\* Upload Your CV Choose File Message SUBMIT

## Contact Us

Let's collaborate to advance your clinical research goals. We welcome inquiries about our services and potential partnerships.

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