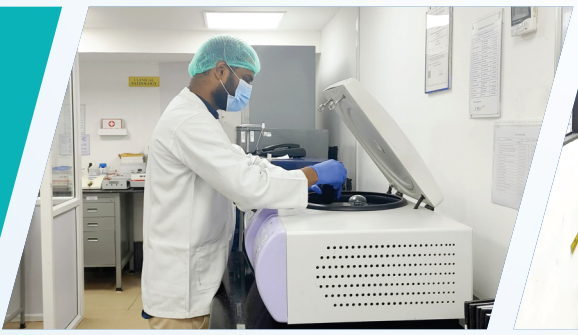
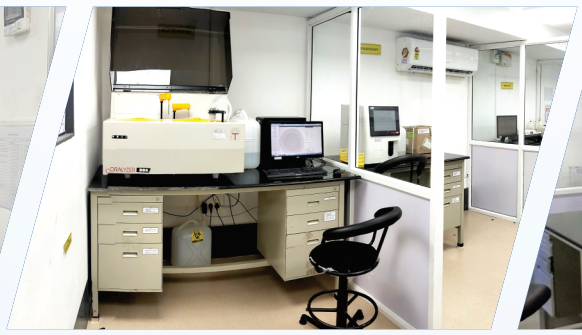
Ethical, Efficient & Compliant





GLOCARE LABS

Contract Research Organisation

ABOUT US

Glocare labs is providing a comprehensive service related to clinical trials and BA/BE for Pharma industries.

We are an ISP Chile approved CRO

We have a high experienced, qualified, trained, clinical and technical team to provide professional service with strict adherence to regulatory requirements while also remaining cost effective.

Our SOPs activities are consistent with local & global regulatory guidelines.

Glocare labs a CDSCO approved CRO is also accredited with and follow **ISO 9001:2015, ISO 14001:2015, ISO 27001:2022** for our activities. Glocare Diagnostic labs is approved by NABL.

Our technical team undertakes projects ranging from protocol development to completion of the study reports for regulatory submissions.

We have a competent team and the staff are well trained to international standards for conducting the clinical studies. We bring Quality, Compassion, Innovation and efficiency to the ethical research needs of the life sciences organizations world-wide.

Our Vision:

We aim to be a trusted partner in supporting your research and clinical trials. Through the provision of efficient, value-based solutions and a collaborative approach, Glocare Labs offers intelligent solutions against challenging timelines.

Our Mission:

At Glocare Labs, we are committed to delivering the most effective, innovative, ethical and comprehensive global systems for clinical research with efficiency, quality and passion.

Our Strategy:

Quality is our priority, continuous improvement, meeting customer expectations / requirements and adhering to regulatory compliance are the key to our strategy.

Our Values:

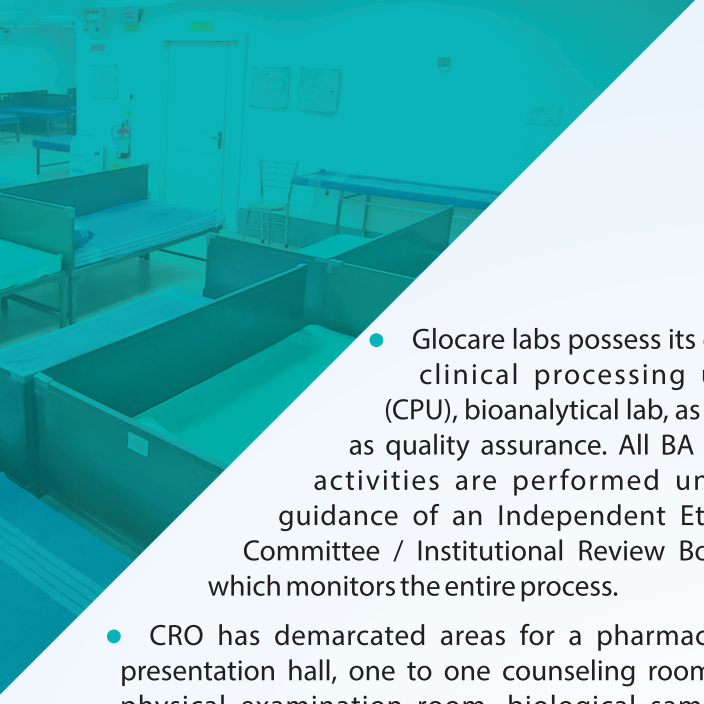
We are committed to exceeding the quality standards demanded by our clients, patients, and regulatory authorities.

Facilities:

- Our clinical and bioanalytical facilities and processes are inspected by the Drugs Controller General of India (DCGI) and ISO auditors assuring our clients full satisfaction for the study execution.
- All operations are driven by GCP and GLP systems as well as applicable national and international regulations.
- The team is powered by highly specialized medical professionals. We endeavor to constantly build on optimal processes complimenting your needs.
- 24/7 operative clinical and analytical equipment ensuring clients timelines are always met.

Clinical Facility:

- Clinical Division has a 60 bedded housing facility along with alarms for every bed, and an ICU to manage any kind of medical emergency. We liaise with a nearby (within 2 km) multi-specialty hospital to manage any serious adverse reactions requiring hospitalization.



- Glocare labs possess its own clinical processing unit (CPU), bioanalytical lab, as well as quality assurance. All BA / BE activities are performed under guidance of an Independent Ethics Committee / Institutional Review Board, which monitors the entire process.
- CRO has demarcated areas for a pharmacy, a presentation hall, one to one counseling rooms, a physical examination room, biological samples collection room, and separate dining & recreation. We also have OVIS (Online Volunteer Information System) to prevent cross participation of volunteers.
- All activities are monitored and recorded through CCTV.
- Our clinical team includes Principal Investigator, Clinical Investigator, Medical Officer, Clinical Research Associate, Pharmacist, Medical Writer, Phlebotomist, Staff Nurse, Volunteer Requirement Officer, Consultant Biostatistician, Independent Quality Assurance Team and Quality Control.

Bio Analytical:

- Our bioanalytical lab is accredited with ISO 17025 -2017
- The bioanalytical laboratory is equipped with state-of- the-art instruments and automation equipments for performing a diverse range of analysis on biological samples. Our SOPs comply with Good Laboratory Practices and continuously progresses to keep pace with the requirements of international regulatory agencies and the pharmaceutical industry.
- Our highly qualified team of scientists with in-depth knowledge in instrumentation and application of LC-MS/MS technology enables timely method development. We validate our analytical methods as per global regulatory requirements / customer need.
- We offer validated methods for drugs in all major therapeutic areas, ready to be used with a short lead time to analyze drugs and metabolites in biological fluids.

Medical Writing:

- Our medical writers have long track records in scientific and/or clinical research areas, ensuring that all medical writing requirements are met in an efficient and timely manner.
- We capture a wide range of medical and scientific documentation for customers.

- Development of Protocol, Informed Consent Form (ICF) and Case Report Form (CRF).
- Preparation of Clinical Report, Analytical Report and Statistical Report.
- Adverse event and concomitant medication reporting to Independent Ethics Committee.
- Preparation of annual safety reports, individual case safety reports, and periodic safety update reports.
- Preparation of abstracts and research and/or review articles, and short communications.
- Report writing in compliance with ICH E3 guidelines / applicable regulatory submission.
- Site-specific and country-specific reports.
- Experience in dossier preparation, submission, tracking of BENOC and import licenses from DCGI and CDSCO.

Regulatory Supports:

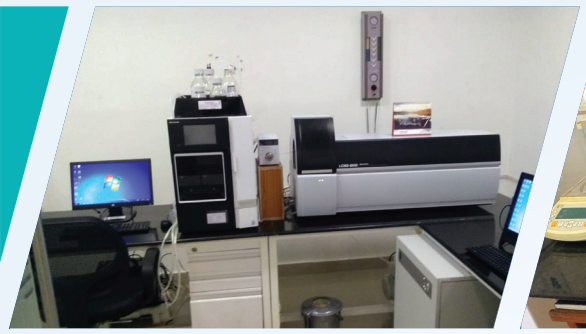
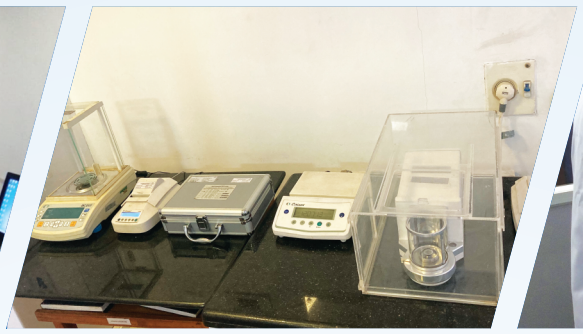
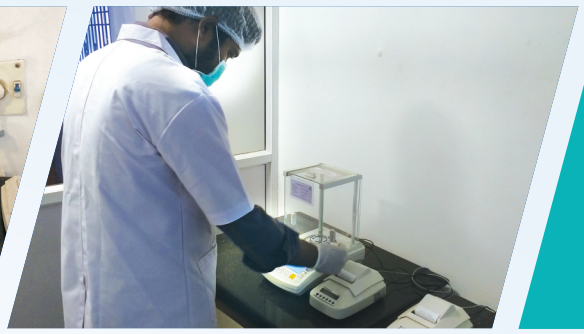
- New drugs approvals
- BA / BE Study protocol approval
- Import licenses / Test licenses
- Export BE NOC's
- Global clinical trials NOC's
- Regulatory dossier

Diagnostic Lab:

Our diagnostic lab is accredited with **ISO 15189:2012**. Medical laboratories requirements for quality and competence is NABL approved.

We are offering laboratory services exclusively for clinical studies, BA / BE studies, and research projects.

- Sample receipt and coding
- Sample processing
- Sample analysis
- Test results
- Results review
- Reports authorization
- Sample storage & preservation

Quality Management System:

Glocare Labs has a detailed set of Standard Operating Procedure for the clinical and analytical facilities. Our Quality Assurance Team operates separately and reports directly to the management.

- Comprehensive standard operating procedures (SOPs).
- A detailed comprehensive audit plan.
- Quality manual and Quality policy.
- Implementation of systems and procedures as per ICH - GCP and GLP guidelines.
- Preparation and implementation of SOPs.
- Calibration schedule planner for equipments.
- Monitoring online quality control of systems and procedures
- Internal / External audits.

Pharmacovigilance:

We offer services related to pharmacovigilance across all phases of clinical developmentand post approval through a team of dedicated and experienced pharmacovigilance associates and medical monitors.

- Provide end-to-end PV solution
- Flexible safety monitoring services
- Involving all therapeutic areas
- Compliance to applicable regulations

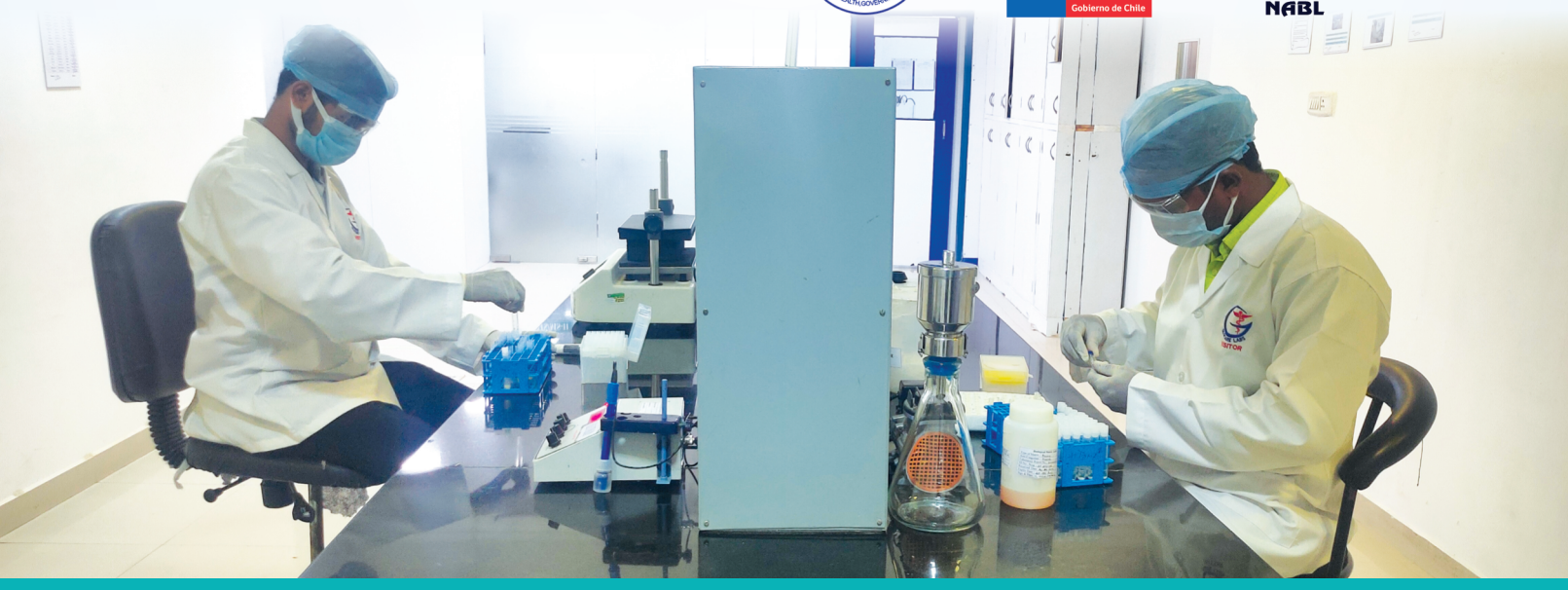
We are accredited with the following certifications

ISO 9001:2015

ISO 14001:2015

ISO 27001:2022

GLP / GCP



GLOCARE LABS

#2A, Ganga Nagar 4th Street, Kodambakkam, Chennai – 600 024, India.
Ph: + 91 44 24726001 | Mob & Whatsapp: + 91 94447 03791
Email: md@glocarelabscro.com, marketing@glocarelabscro.com
Website: www.glocarelabscro.com