A team of well-trained, experience professionals apply their therapeutic, regulatory and operational expertise to consistently solve the challenges that arise during all clinical projects. Clinical operation team conducts phase II - phase IV clinical trials, with ethics, high quality and confidentiality.

Our competency in project management is comprehensive and consistent processes, which conform to global regulatory requirements, from start-up to completion, performance is monitored regularly and measured against contractual timelines. In addition, project costs are tracked to ensure adherence to agreed budgets.

Project Management

All projects are efficiently handled by qualified project managers who are experienced in various therapeutic areas. Project Managers work closely with the sponsor project team from project kick-off and start-up throuh completion of the final study report or contract closure to meet their objective. Our project managers act as a single point of contact for Sponsors throughout the duration of the study, ensuring quality deliverables within the timelines and budget. Protocol-related queries and safety / clinical concerns are addressed through close collaboration of the project managers and medical monitors, ensuring the integrity of clinical trial data and also the principles to be followed to carry out he clinical trial **services in India.** Project teams typically consist of a project director, a project manager, a team leader, site monitors and clinical trial assistant.

Site Management

Delays in study startup and patient enrollment are the major contributors to cost overruns in clinical trials. A properly designed and executed feasibility study can provide a comprehensive assessment of a clinical trial's specific challenges. ICBio works directly with clients to design a feasibility study, design of the study. The Clinical Operations team selects each study site based on the site infrastructure, Personnel, Equipment and access to appropriate patient population. Site management also covers up gradation of site infrastructure to meet clinical trial requirements. We continuously identify new investigators and train them to enrich the investigator database across different therapeutic areas. Site finance management is also handled by our team. We do offer Study Feasibility; Site Monitoring, Site Selection, Audit and Reports which are commonly found in clinical trials services in India. Ethics committee and regulatory submissions also done by ICBio team.

Clinical Monitoring

Regular and continuous Monitoring of Clinical Trials is essential in assuring safety of subjects, data quality and a well-executed study. After completion of every phase of clinical monitoring, ICBio will provide a timely, detailed report. Thus ICBio ensures successful monitoring of all activities of Clinical Trial Process. Our CRA's are trained and experienced to monitor studies from Phase I - IV according to ICH GCP guidelines and relevant national and international regulations or as per the sponsors' monitoring SOP to ensure quality data, protocol adherence and compliance to regulatory guidelines. The team has working knowledge in handling e-systems like Enterprise Project Management, Electronic Data Capture, Clinical Trial Management Systems, Interactive Voice Response Systems and Interactive Web Response Systems. ICBio is able to provide monitoring services where and when your company has a need, often without the burden of expensive travel costs.

Clinical Trial Supply Management

ICBio capabilities include warehousing and distribution of investigational drugs and clinical supplies. These services are often provided as a part of a full clinical services contract but can also be availed of on a stand-alone basis. ICBio has worked with clients in providing CTS management for their clinical trials, the majority being multi-centric Phase III trials. Our facility has been audited by all our sponsors. This has in turn helped us continuously improve our services to meet changing sponsor and regulatory requirements. We have tied up with a logistics services provider to look after your specific requirements.

Our CTS Management services include

- Procurement of import license
- Customs clearance of import shipment
- Receipt of inward bulk shipments
- Management of local shipments to sites
- IP labeling and Randomization generation
- Experience with IVRS
- Storage of investigational product and other trial supplies
- Inventory management