



GCTRO

CLINICAL RESEARCH

Your gateway to Global Clinical Research

Our Services

GCTRO is a full service CRO. We provide the entire gamut of Clinical Services, IT support and Consulting Services which can be utilized on a selection basis for any phase Clinical Trial.

Technology Services:

- ▶ Electronic Data Capture
- ▶ Data Management
- ▶ Document Management
- ▶ eCTD
- ▶ Structured Product Labeling
- ▶ Bio Statistics

Clinical Services:

- ▶ Clinical Pharmacology
- ▶ Pharmacokinetic
- ▶ Proof Of Concept
- ▶ Protocol Design
- ▶ Clinical Monitoring
- ▶ Clinical Trial Management
- ▶ Data management
- ▶ Patient Recruitment
- ▶ Medical Writing & Submission
- ▶ CTM and Ancillary services
- ▶ Project Management
- ▶ Regulatory Affairs
- ▶ Quality Systems and Audit

Why Choose GCTRO as your CRO

Management and Consulting Team:

GCTRO has a highly experienced team of professionals who have decades of experience in different aspects of Clinical Research in US and altogether covering the end to end spectrum of any Phase 1- IV Clinical Research project.

Focus:

Our focus is on providing complete Early Phase (Phase I and Phase II) Clinical Trials outsourcing solution to the medium and small pharmaceutical, biopharmaceutical and device manufacturing companies in US and Europe. Our dedicated Early Phase facilities in Delhi, India and Hawaii, US gives our client a reduced time for the delivery of the results at a greatly reduced cost to the Sponsor.



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Early Phase Facilities:

We have two facilities where we carry out the Clinical Studies. Our presence in US and India provides you reduced time-to-market for promising new compounds at a very competitive price.

Hawaii, USA:

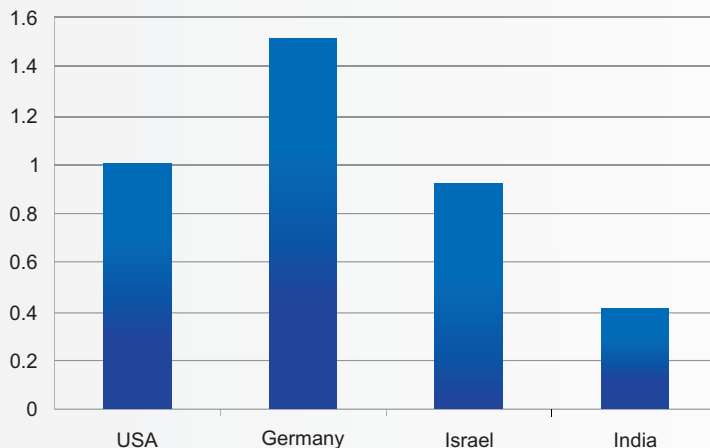
We have a modern 50-bed residential unit for various inpatient and Phase I Trials which is fully equipped to handle a wide range of Phase I - IV Clinical Trials. The new building has a total area of 15,000 square feet. The Phase I facilities include 50 beds (25 each on 2 separate floors) and 2 laboratories (1 for each floor). Our new headquarters also has exam, eye and telemetry suites; sub-zero freezer room; pharmacy; commercial kitchen; and a laundry room. Our new facility also includes its own power generator to ensure that there will be no disruption to our operations even in cases of power failure. We are affiliated with laboratories, radiological services, ophthalmologic and cardiology consultants, and a broad range of physician specialists. Our in-house staff comprises Psychiatrists, Specialty Physicians, Psychologists, Therapists, Registered Nurses, as well as Clinical Research Coordinators.

Delhi, India:

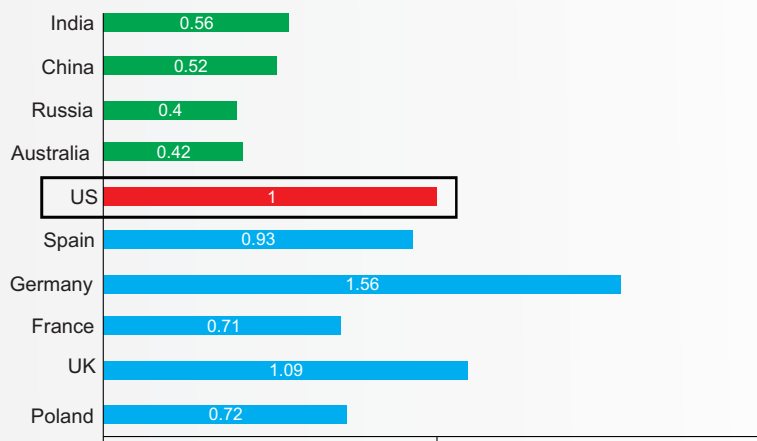
A modern fully airconditioned 40 bed unit fully equipped along with a sophisticated analytical laboratory. The Unit's personnel are well qualified and experienced in Global Clinical Trials. The unit has two Intensive Care Units to handle emergencies and a well equipped pharmacy. In addition, it covers formulation development, pre clinical studies, clinical trials including BA / BE Studies and provides all sort of analytical and R & D support to pharmaceuticals and biotechnology industry. It has well organized team of professionally qualified and experienced scientists, technicians, medical doctors and experts in their respective fields. It provides complete solution for product development, formulation development, testing and analysis of products to pharmaceuticals, biotechnology and other industries. It has an established quality systems for the execution of projects along with the SOPs for sample handling, labelling, preparation, instrument calibration/ verification, analysis and reporting of results. Some of the main facilities of the bio-analytical laboratory include chromatography laboratory with HPLCs and GCs, LC-MS / MS laboratory, ICP- MS laboratory, GC- MS laboratory, Cold room and deep freezer for sample storage.

A Case study for cost comparison to conduct the study in India

The graph is representing an average cost/patient to compare with other countries for conducting a mid-stage clinical study for a SNRI for pain management



Cost Comparisons by Country



Source: FastTrack Systems Global Cost Databases

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