

Course Prospectus



**Micro Therapeutic Research Labs Pvt Ltd
(Training Division)
Sri Sai Clinical Research Institute Pvt Ltd (SCRI)
“Rajam Bhavanam”, No.6, Kamarajar Salai,
Selaiyur, East Tambaram, Chennai - 600 059.
Tamil Nadu, India.**

Course Prospectus

Introduction

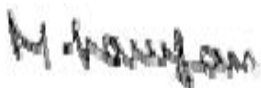
Micro Therapeutic Research Labs Pvt Ltd is a Clinical Research Organization a private limited Chennai based company registered in India. MTR provides clinical research services from preclinical to Clinical Studies (Phase I to Phase IV) and Data Management Services. MTR training division (offers Post Graduate Certificate in Clinical Research (PGCR), Post Graduate Certificate in Clinical Data Management and Statistics (PGCDM) and Post Graduate Certificate in Bio-Analytical Instrumentation (PGBI) in the name of **SRI SAI CLINICAL RESEARCH INSTITUTE PVT LTD (SCRI)** since 2007.

MTR is focused in specializing in specific specialist areas of Therapeutic and Diagnostic discipline. It provides an Independent Global frame work for International education, training, & exchange of information for Clinical Research Professional and to foster Professional Excellence in design and Execution of clinical research, thereby contributing to enhancing the clinical research culture in India.

SCRI Post Graduate Certificate course is offered as per the standard of international program. We hope you enjoy the Prospectus of this course useful for your career advancement.

Please read through this prospectus. We are sure that you will find a course that will benefit your work, your company and your career. If you have a training need that is not met by one of the courses please let us know. We are always keen to hear of new ideas and to listen to what you need. If you want to know more about the content of any of our courses then please contact us at our premises, Sri Sai Clinical Research Institute Pvt Ltd (SCRI), "Rajam Bhavanam", No.6, Kamarajar Salai, Selaiyur, East Tambaram, Chennai - 600 059, Tamil Nadu, India. Land mark: - Near Selaiyur Police Station.

We look forward to meeting you on one of our courses in the future.



Managing Director



Post Graduate Certificate in

- ❖ *Clinical Research*
- ❖ *Clinical Data management & Statistics*
- ❖ *Bio-Analytical Instrumentation.*

About the Institute

Sri Sai Clinical Research Institute Pvt Ltd (SCRI) is devoted to developing expertise for clinical research professionals. The SCRI is a training division of Micro Therapeutic Research Labs Pvt. Ltd (MTR) which intend to provide students hands-on training in various aspects of clinical research and development. MTR is an independent clinical research organization that serves the Pharmaceutical and Biotechnology industries world wide to provide full services in all aspects of clinical research and development including bio-informatics, biotechnology and other health care related activities.

Course Objectives

Clinical Research is a sunshine industry that spells an opportunity of 50,000 jobs by 2010 in India alone and more than 2,50,000 jobs globally. Before each medicine makes it to the market, it has to pass a lengthy approval process in which many Clinical Research Professionals are required.

The course would endow an introduction to the area of clinical trials, with more detailed coverage of some of the key issues to be considered in their design, analysis, documentation and interpretation.

A Multi-dimensional future career

One new development that is contributing to India's economy in a big way is the emerging field of Clinical Research-the study of drug and its effects on human subjects with the aim to determine its safety and efficacy. India's medical expertise, legal & regulatory framework, and availability of a large and homogenous patient population have lead to a growing number of Clinical Trials being carried out within the country.

The fast evolving world offers new business processes and novel job opportunities. But not all careers can be expected to provide a promising future. Some may become obsolete in a short time. However, challenges and careers in Clinical Research will continue to be in the limelight. Search for new drugs is constantly on to find safer, better and cheaper alternatives. The market for research & development of these drugs is certain to grow forever, making Clinical Research a wise career decision for a rewarding future.

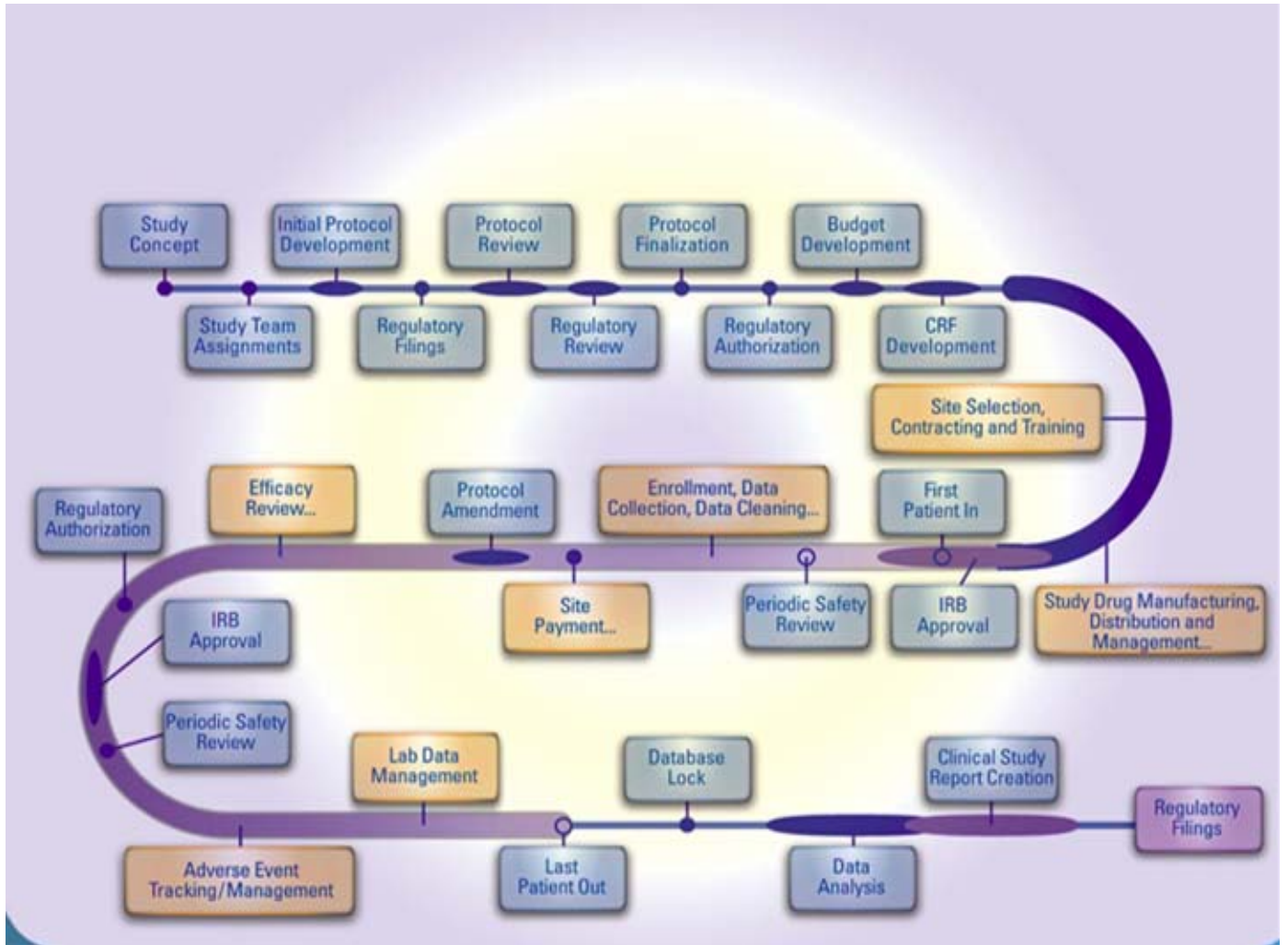
A career in Clinical Research prepares you for a spectrum of roles in the emerging industry. The different types of Clinical Research business like Bioavailability and Bioequivalence studies, site management, data management, pharmacovigilance, quality assurance, medical writing and Bio-IT solutions has created multiple opportunities in different pharmaceutical companies that are fast setting up operations in India. This development has presented Life Sciences, Pharma, Medical & IT graduates and professionals with a plethora of opportunities. Since Clinical Research professionals across different disciplines share many common interests, strength and competencies; there is complete flexibility to switch careers within the field.

Clinical Research Revolution in India

India has an easy access to a large, diverse and therapy-naive population with vast genetic diversity ready to undergo Clinical Trials. Also, India is home to a vast reserve of knowledge and resource base and is strategically located in the arena of global clinical research and trials. India's potential as a favorite outsourcing destination has led many global pharma companies to set up Clinical Research businesses here.

According to McKinsey Report, the Indian Clinical Research market will grow to USD 2 billion by 2010.

Clinical Research Process



4 phases of Clinical Trial

Phase I

It is the first stage of testing a new drug in healthy human volunteers. A small (20-80) group of healthy volunteers is selected for Phase I research. This phase includes trials designed to assess the safety tolerance, pharmacokinetics, and pharmacodynamics of a drug.

Phase II

Phase II trials consist of a larger group (100-300) and is carried out amongst patients/volunteers, after the initial safety of the study drug has been established in Phase I. This phase determines how well the drug works and helps to assess the dosing requirements and the drug efficacy.

Phase III

Phase III studies are performed on large patient / volunteer groups (1,000-5,000) depending upon the kind of medical condition that is being studied. This phase is aimed at assessment of how effective the drug is and to obtain additional safety data to support marketing claims for the drug.

Phase IV

Phase IV known as Post-marketing Surveillance phase involves the safety surveillance and ongoing technical support of a drug after it receives permission to be sold. This phase is conducted over a much larger patient population and for a longer duration than all the earlier three phases. It is designed to detect any rare or long-term adverse effects.

Faculty of repute

Renowned and experienced names from the Clinical Research industry have come together to form the faculty team at **SCRI**. These expert minds implement a dynamic mix of lectures, case studies and hands-on learning through tried & tested tools and methods. They not only assist students in developing active interest in the curriculum but also in planning a successful career in Clinical Research.

Infrastructure

The state-of-the-art infrastructure at **SCRI** is a perfect complement to the impressive quality of teaching. It assures an academic environment conducive to superior learning and greater exchange of knowledge.

- Well-designed air-conditioned, hi-tech classrooms equipped with projectors and computers to integrate cutting-edge technology with learning experience.
- A well-stocked library with latest books, periodicals, newspapers, journals, prints and records to keep the students updated with the latest happenings in the industry.

Course Details

Currently, SCRI offers the following courses for professionals as well as students aspiring to make a career in Clinical Research:

Post Graduate Certificate in Clinical Research (4 Months)

This first-of-its-kind 4 months PGCR course in India is comprehensively-structured and internationally-styled to match academic standards with industry requirements. Being a 4 months course, it eliminates extra expenses and also ensures a head start to move up the corporate ladder faster.

- Introduction to Clinical Research and its various Phases
- Understanding Drug development and approval process
- Good Clinical Practice (ICH -GCP)
- ICMR Guidelines, Schedule Y
- Study personnel Roles& Responsibilities
- Brief description of clinical trial processes
- Clinical Safety & Pharmacovigilance
- Pharmacodynamics, Pharmacokinetics, BA and BE Studies
- Clinical Trial types and Design
- Basic statistical concepts in clinical trials
- Randomization and Blinding
- Fundamentals of Monitoring and Site Management
- Preparation of essential documents for a study
- Drug Regulatory Affairs
- IRB / IEC, AE & SAE Reporting Procedures
- Creating Standard Operating Procedures for a facility
- Quality Auditing Practices
- Project and Final Exam

Certification

Certification will be provided from "**SRI SAI CLINICAL RESEARCH INSTITUTE PVT LTD**" in association with **Micro Therapeutic Research Labs Pvt Ltd., Chennai.**

Please Note:

- The course does not include any direct trials / experimentation on human or animal subjects.

Duration and Timings

- **4-5 Months Duration for PGCR & PGCDM**

Theory Classes: - 3 classes on an alternative days (Mon to Sat) each session 3 Hrs

Practical Classes: - 3 days a week (Mon to Wed / Thu to Sat) each day 7 Hrs

- **5 Months Duration for PGBI**

Theory Classes: - 10 – 15 classes for each batch.

Practical Classes:- 6 days a week (Mon to Sat).

Note: The class timings will be fixed according to the availability of batch students. These timings will be different for Part time students who want to do courses on weekends.

- **Fees**

Rs.45,000 /- (PGCR),

Rs.45,000 /- (PGCDM) and

Rs.60,000 /- (PGBI)

- Registration Fee Rs.5000/- inclusive of fees
- Installment facility available (For Details contact course coordinator)
- Assist in getting Bank Loans





Sri Sai Clinical Research Institute Pvt Ltd,

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"Rajam Bhavanam", No.6, Kamarajar Salai,
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