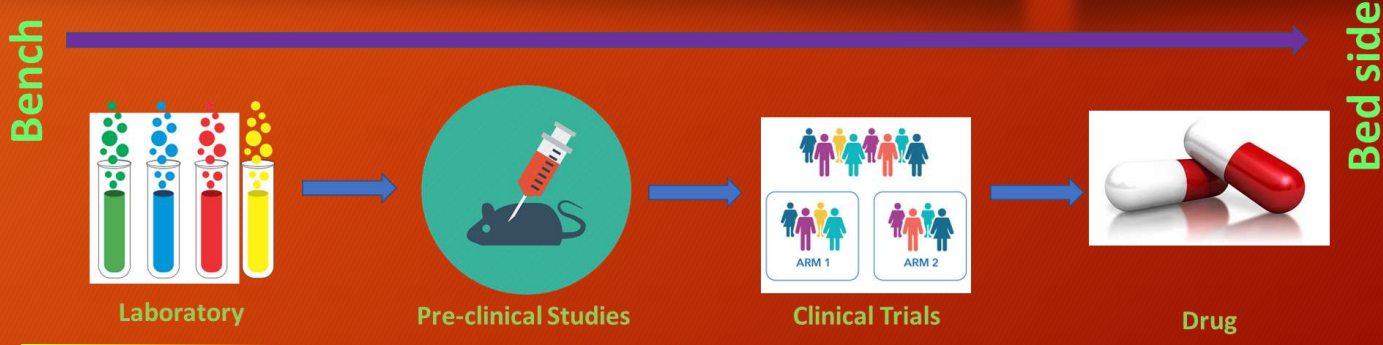
PROSPECTUS

PG Diploma in Clinical Research and Regulation



Sir Ganga Ram Hospital

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India

Scope of Clinical Research in India and abroad:

India has been actively engaged in clinical research for many years and is quickly developing into a significant centre for it. In the health sectors (pharmaceutical, biotechnology/medical device businesses, research institutes, hospitals), which are involved in the creation of novel medications and therapies, there is an increasing need for clinical researchers. There is currently a big need for qualified specialists in this $1 billion market. Clinical research specialists are desperately needed in this quickly expanding industry. Clinical research is a fascinating career option with lots of room for professional advancement. Basic training in this area is required to pursue a career in clinical research.

About Clinical Research

Clinical research is a subfield of medical science that deals with evaluating the efficacy of drugs, diagnostic tools, medical gadgets, and therapeutic methods intended for use on people. These can be applied to diagnose, treat, prevent, or provide respite from an illness. Clinical research is the broad range of biological, pharmaceutical, and technological literature. labour, which allows global firms to establish research facilities here.

Career Opportunities:

A lot of people are in need of competent, experienced clinical research professionals. India's clinical research and pharmaceutical industries are both growing quickly, offering qualified individuals attractive career prospects. It has climbed from Rs. 20 crores to more than Rs. 100 crores during the past five years. With a steady increase in demand, it is anticipated that the clinical research sector will require more than 50,000 employees. In India, where there are only 500–1000 investigators, there is a constant scarcity of trained personnel; in contrast, the US has 50,000 investigators (Source, FICCI, 2018).

According to a Nutrify Today report, India's nutraceutical market is on track to reach the 100-billion-dollar mark by 2030. The overall number of Indians consuming basic nutraceuticals increased dramatically during the pandemic. Customer desire for clean and alternative nutrition is changing, which allows the rise in consumer demand for clean nutrition and transparency in understanding exactly what is in a product they consume. Such goods require extensive study to be developed properly, which inevitably raises the need for qualified clinical researchers to handle the current demand, India will likely need at least 10,000 investigators. Since the start of the product patent regime in 2005, numerous global pharmaceutical corporations and CROs have established.

EMERGING TRENDS IN CLINICAL RESEARCH

Clinical research, a critical component of pharma R&D, ensures a quicker and better return on investment. It also helps organizations deliver better and safer care for patients.

ORDINANCE, SCHEME & SYLLABUS FOR Diploma in Clinical Research and Regulation

Course Title: PG Diploma in Clinical Research and Regulation

Type of Course: 1 Year PG Diploma course

Medium of instruction: English

Course Fees: Rs. 2 Lakhs

Pattern: Semester wise

Award of the Degree: Degree will be awarded to those passing all the semesters as per rules and regulations.

DURATION OF THE COURSE: The duration of the course shall be 1 year consisting of two semesters. Each semester extends for 6 months' duration from the date of commencement of the course.

Total Intake: 10 Student/year

ELIGIBILITY FOR ADMISSION:

Candidates wishing to apply for the course need to fulfil the following eligibility criteria:

- Minimum eligibility needed for applying to the course is graduation completed from a recognized university with a minimum aggregate score of 50% (Aggregate of three/ four years for graduate degree holders) (45% for SC/ST/OBC candidates) at the level of graduation.
- The successful completion of graduation from a recognized university in any of the:
  - Health sciences [Medicine, Dental, Pharmacy, Nursing, Ayurveda, Homeopathy, Unani etc.]
  - Life science graduates [Biotechnology, Botany/Zoology, Biochemistry, Pharmacology, Microbiology, Toxicology, etc.]
  - Post-graduates in above disciplines can also apply.

Selection Procedure:

Candidates will be selected on the basis of marks obtained in the entrance test and interview.

Attendance and progress:

- A candidate is required to put in **at least 80% attendance** in individual courses.
- The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

Program/Course credit structure

As per the philosophy of the Credit Based Semester System, certain quantum of academic work viz. theory classes, seminars, assignments, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extracurricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week/per activity.

Credit assignment:

Academic work

- A regular record of attendance, in Theory, Research work presentation, and Dissertation shall be maintained by the department/teaching staff of respective courses.
- The total number of credits assigned in the course is 200.

PG Diploma in Clinical Research and Regulation Course Scheme of Instruction

1st Semester				
Sl. No.	**Module Code**	**Module**	**Duration**	**Credits**
1.	**DCRR-101**	**Introduction to Clinical Research**	**150 Hours**	**10**
		Conceptualizing the Clinical Trial Study/Protocol		
		Protocol Review, Implementation & Monitoring		
		Data Quality & Results Reporting		
2.	**DCRR-102**	**Introduction to Clinical Pharmacology**	**150 Hours**	**10**
		Pharmacokinetics & Pharmacodynamics		
		Drug Metabolism and Transport		
		Pharmacokinetics and Drug Therapy in Special Populations		
		Assessment of Drug Effects		
		Drug Discovery and Development		
3.	**DCRR-103**	**Assignment/Editorial/Workshop**	**150 Hours**	**10**
Total Credits = 30				

2nd Semester				
Sl. No.	**Module Code**	**Module**	**Duration**	**Credits**
1.	**DCRR-201**	**Pharmacogenomics and Pharmacotherapy**	**150 Hours**	**10**
		Statistics in Clinical Research		
		Hypothesis Generation and Validation		
		Introduction to Pharmacovigilance		
2.	**DCRR-202**	**Quality Assurance & Quality Control**	**150 Hours**	**10**
3.	**DCRR-203**	**Assignment/Editorial/Workshop**	**150 Hours**	**10**
Total Credits = 30				

Elective Modules				
Sl. No.	Module Code	Module	Duration	Credits
Only One to be Chosen				
1.	DCRR-E-101	Nutraceuticals	150 Hours	10
2.	CRR-E-102	Traditional Medicine		
3.	CRR-E-103	Pharmacogenomics		
Total Credits = 10				

Total Course Credit			
Semester-1	Semester-2	Elective Courses	Total
30	30	10	70

PG Diploma in Clinical Research and Regulation Course Scheme of Examination

Scheme for end-semester examinations

1st Semester				
Sl. No.	Module Code	Module	End Semester Exams	
			Marks	Duration
1.	DCRR-101	Introduction to Clinical Research	50	1 Hr
		Conceptualizing the Clinical Trial Study/Protocol		
		Protocol Review, Implementation & Monitoring		
2.	DCRR-102	Introduction to Clinical Pharmacology	50	1 Hr
		Pharmacokinetics & Pharmacodynamics		
		Drug Metabolism and Transport		
		Pharmacokinetics and Drug Therapy in Special Populations		
		Assessment of Drug Effects		
		Drug Discovery and Development		
3.	DCRR-103	Assignment/Editorial/Workshop	50	1 Hr
Total			150	

2nd Semester				
Sl. No.	Module Code	Module	End Semester Exams	
			Marks	Duration
1.	DCRR-201	Pharmacogenomics and Pharmacotherapy	50	1 Hr
		Statistics in Clinical Research		
		Hypothesis Generation and Validation		
		Introduction to Pharmacovigilance		

2.	**DCRR-202**	**Quality Assurance & Quality Control** **Data Quality & Results Reporting** **Business management, Professional Communication, and Personality development.**	**50**	**1 Hr**
3.	**DCRR-203**	**Assignment/Editorial/Workshop**	**50**	**1 Hr**
Total			**150**	

Elective Modules				
Sl. No.	**Module Code**	**Module**	**End Semester Exams**	
			Marks	**Duration**
Only One to be Chosen				
1.	**DCRR-E-101**	**Nutraceuticals**	**50**	**1 Hour**
2.	**CRR-E-102**	**Traditional Medicine**		
3.	**CRR-E-103**	**Pharmacogenomics**		
Total			**50**	

Grand Total Marks: 150+150+50 = 350

Promotion and award of grades

A student shall be declared PASS and eligible for getting grade in Diploma of Clinical Research if he/she secures at least 50% marks in that particular course.
A student shall be eligible to get his/her CGPA upon successful completion of the course of 1st and 2nd semesters within the stipulated time period as per the norms.

Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course. The letter grades and their corresponding grade points are given in table below

Table: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Very Good
60.00 – 69.99	C	7	Good
50.00 – 59.99	D	6	Fair
Less than 50	F	0	Fail
Absent	AB	0	Fail

The student who remains absent for any end-semester examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

Declaration of class: The class shall be awarded on the basis of CGPA as follows:

FIRST CLASS = CGPA OF 6.00 AND ABOVE

SECOND CLASS = CGPA OF 5.00 TO 5.99

THIRD DIVISION = CGPA OF 4.00 TO 4.99

Placement Assistance and Corporate Relations

The Institute has partnered with many organizations for providing placement assistance to its participants. Besides, it has a robust placement cell comprising senior level Human Resources professionals and Talent Acquisition experts which maintain close links with the business industry. This cell is continuously engaged in promoting the employability of our participants. Institute has great corporate relations with various global pharmaceutical, healthcare, and food giants.

Syllabus

1st Semester

1. Introduction to Clinical Research (30 Hours)
• History of Clinical Research
• Overview of Clinical Research
• Overview of Clinical Research
• FDA product regulation
• Ethical Principles in Clinical Research
• Research Ethics
• Legal Issues in Clinical Research

2. Conceptualizing the Clinical Trial Study/Protocol (30 Hours)
• Introduction to Clinical Study Design
• Information Resources for Clinical Research
• Choosing a Research Question
• Designing Trials Efficiently
• Overview of Hypothesis Testing
• Sample Size and Power
• Issues in Randomization
• Measures
• Quality of Life
• Study Participant Selection
• Considering Inclusion in Research
• Health Disparities Research
• Research with Vulnerable Participants
• Health Research Linked to Disasters and Other Humanitarian Crises
• Virtual Clinical Trial {Role of Artificial Intelligence (AI) and Machine Learning (ML)}

3. Protocol Review, Implementation & Monitoring (30 Hours)
• Developing Protocols and Manuals of Operating Procedures
• Technology Transfer
• Institutional Review Boards -Overview
• Mock IRB
• Data and Safety Monitoring Committees

4. Introduction to Clinical Pharmacology (30 Hours)
• Introduction to Clinical Pharmacology and Therapeutics
• Introduction to Pharmacokinetics/Pharmacodynamics
• Drug Absorption and Bio-availability
• Case Study: The Impact of Food on Bioavailability
• Case Study: Steady-State Calculation
• Introduction to Pharmacology and Drug Development
• Understanding the Basics of Pharmacology
• Practical Pharmacology

- Case Study: Practice with Prescriptions
- Biochemical Mechanisms for Drug Toxicity
- Case Study: Statins & Hepatotoxicity

5. Pharmacokinetics & Pharmacodynamics (30 Hours)

- Compartmental Analysis of Drug Distribution
- Case Study: Effect of Protein Binding on V_d
- Noncompartmental vs. Compartmental Approaches to Pharmacokinetic Analysis
- Case Study: Nonlinear PK Calculation
- Population Pharmacokinetics
- Population PK Terminology
- Chemical Analysis of Drugs and Metabolites
- Case Study: Introduction to Mass Spectrometry
- Pharmacokinetics/Pharmacodynamics of Protein Drugs
- Case Study: PK/PD of TNF Blockers

6. Drug Metabolism and Transport (30 Hours)

- Introduction to Drug Metabolism and Transport
- Pathways of Drug Metabolism
- Case Study: "Victims & Perpetrators" in Therapeutics
- Drug Transporters in ADME and Drug Action
- Case Study: Transporter Mediated Drug-Drug Interactions
- P-Glycoprotein and Drug Transport
- Case Study: The Mystery of Loperamide
- Membrane Transport
- Membrane Transporters in Drug Development
- Drug Transport Across the Blood Brain Barrier
- Permeability of the Blood Brain Barrier

7. Pharmacokinetics and Drug Therapy in Special Populations (30 Hours)

- Introduction
- Pharmacokinetic Considerations in Patients with Renal Impairment
- Case Study: Drug Dosing in Patients with Chronic Kidney Disease
- Product Management
- Pharmacokinetics in Patients Requiring Renal Replacement Therapy
- Continuous Renal Replacement Therapy: Who, When, Why, & How
- The Liver and Drugs
- Case Study: Dose Adjustments Based on Child-Pugh Score
- Drug Therapy in Pregnant and Nursing Women
- Case Study: Risks of Phenobarbital During Lactation
- Developmental and Paediatric Pharmacology
- Developmental Changes That Influence Drug Disposition
- Drug Therapy in the Geriatric Population
- Case Study: DOACs in the Elderly
- Pharmacokinetics and Obesity
- Case Study: Drug Dosing in Obesity

8. Assessment of Drug Effects (30 Hours)
• Introduction to Assessment of Drug Effects
• Biomarkers of Drug Effects
• Pharmacodynamic/Response Biomarkers
• Pharmacodynamic and Pharmacokinetic Modelling of Data
• PK/PD Modelling Exercise
• Disease Progression Models
• Key Concepts of Disease Progression Modelling
• Role of Pharmacodynamics in Drug Development
• Pharmacodynamic & Proof of Mechanism Biomarkers

9. Drug Discovery and Development (30 Hours)
• Introduction to Drug Discovery and Development
• Quantitative Systems Pharmacology
• Pre-Clinical Drug Development
• Clinical Trial Monitoring
• Integrating Diverse Data Sources into Computation Models
• Computational Methods of Drug Discovery and Design
• Computational Methods Key Definitions
• Combinatorial Drug Screening
• Case Study: BRAF & MEK Inhibitors in Melanoma
• Natural Products
• Decisions on Screening Natural Products
• Drug Formulation & Delivery
• Biopharmaceutics Classification System
• Considerations in the Development of Biologics
• Biosimilar
• Drug Development in the Paediatric Population
• Clinical Research Involving Children
• Animal Scale Up and First-in-Human Studies
• Estimating the Starting Dose in FiH Studies
• Dose Selection and Optimization in the Adult Population
• Case Study: Secukinumab Dosing Optimization
• Design of Clinical Drug Development Programs
• Clinical Drug Development Path
• FDA Approval Considerations
• Discussion on Clinical Trial Endpoints
• Good Laboratory Practices
• Good Clinical Practices
• Good Documentation Practices
• Good Manufacturing

2nd Semester

10. Pharmacogenomics and Pharmacotherapy (30 Hours)
• Introduction to Pharmacogenomics and Pharmacotherapy
• Pharmaco-metabolomics: Implications for Clinical Pharmacology
• Case Study: SSRIs & Pharmaco-metabolomics
• Dose Modifications Based on Pharmacogenomics Research
• Case Study: Dosing Guidelines for Azathioprine & TPMT
• Clinical Pharmacogenomics Testing
• Drugs & Genes
• Clinical Drug Interactions
• Case Study: Clinical Implications of Grapefruit Juice
• Clinical Assessment of Adverse Drug Reactions
• Case Study: Describing Adverse Events Using CTCAE
• Post-Marketing Drug Safety Surveillance
• Case Study: Med Watch Voluntary Reporting
• Quality Assurance for Drug Therapy
• Medication Use Evaluation

11. Statistics in Clinical Research (30 Hours)
• Introduction
• Purpose of Statistics in Clinical Research
• Fundamentals of Statistics in Clinical Research
• Preparation of the protocol.
• Development of the research.
• Analysis, documentation, and presentation of results.

12. Hypothesis Generation and Validation (30 Hours)
• Introduction
• Hypothesis Creation
• Data Collection and Network Connection
• Information Extraction
• Large Scale Validation of Hypothesis

13. Introduction to Pharmacovigilance (30 Hours)
• Introduction
• Passive surveillance.
• Active surveillance.
• Cohort event monitoring.
• Targeted Clinical Investigations.
• Adverse Event Case Management
• Signal Intelligence and Risk Management

14. Quality Assurance & Quality Control (30 Hours)
• Introduction
• Failure Testing
• Statistical Process Control
• Total Quality Management
• QC Methods: Inspection, Testing, Statistical Methods

15. Data Quality & Results Reporting (30 Hours)
• **Preliminary Biostatistics**
• Research Misconduct: Fabrication, Falsification, & Plagiarism
• Quality Management and Clinical Research
• Data Management & Case Report Form Development
• Clinical Data Interchange Standards (CDISC)
• Clinical Trials Registration & Results Reporting
• Ethics in Paediatric Clinical Pharmacology
• Case Study: Paediatric Extrapolation
• Ethics in Adult Clinical Pharmacology

16. Business Management, Professional Communication, and Personality development.
• **Business Management**
• **Professional Communication**
• **Personality Development**

17. Assignment/Editorial/Workshop
• Assignments related to Clinical research or clinical trial.
• Scientific article writing or Presentation of scientific article.
• Attending a workshop/Conference

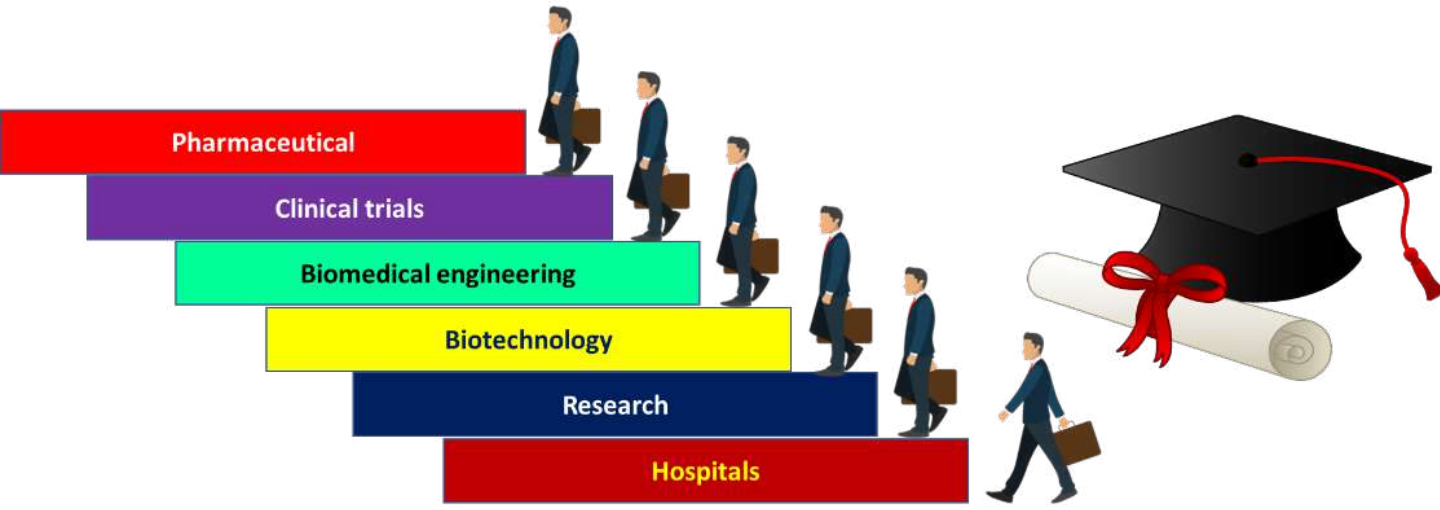
Elective Modules

1. Nutraceuticals (30 Hours)
• Food Chemistry and Biochemistry
• Human Nutrition and Physiology, Clinical dietetics
• Nutraceuticals and Functional Foods
• Biostatistics, Instrumentation, and Biological Evaluation
• Microbiology, Quality, and process control
• Development and marketing of nutraceutical products: Product Development, Packaging, and Safety Evaluation
• Molecular Biology and Biotechnology for Nutraceuticals and Functional Foods
• Quality Assurance, Regulatory Affairs, and Intellectual Property Rights

2. Traditional Medicine (30 Hours)
• Taxonomy and Cultivation of Medicinal Plants
• Ethno Medicine
• Pharmacognosy
• Herbs and Drug Action
• Quality Evaluation of Herbal Medicines: Challenges and opportunities
• Extraction and Other Downstream Procedures for Evaluation of Herbal Drugs
• Analysis of Herbal Drugs

3. Pharmacogenomics (30 Hours)
• Fundamentals of Pharmacogenomics
• Molecular Biology
• Bioethics
• Bioinformatics and Biostatistics
• Applied Pharmacogenomics
• Modern Techniques in Genetics
• Analytical Techniques
• Laboratory Techniques
• Personalized Medicine in Clinical Practice
• Commercial and Regulatory aspects of Pharmacogenomics

PG DIPLOMA IN CLINICAL RESEARCH AND REGULATION



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