Clinical Research
Excellence Foundation

Clinical Research Courses

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+91 8422800400

Visit Website

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About Clinical Research Excellence Foundation

- Our Organization is a trusted leader in delivering comprehensive educational and consultancy services to the clinical trial industry, backed by over two decades of expertise.
- We specialize in education, medical and regulatory writing, SOP development, manuscript writing, regulatory approvals & on-site training.
- We offer training modules in ICH GCP, NDCT, ICMR guidelines, and clinical research courses.
- Led by seasoned faculties with extensive experience as investigators, regulatory and industry experts, our team has been recognized nationally, including invitations to present at the Ministry of Science and Technology, Government of India. With a commitment to excellence, we empower professionals and institutions to achieve success in clinical research.

Why study at Clinical Research Excellence Foundation

Our clinical research courses place you at the forefront of a globally recognized medical and research ecosystem

With access to the right resources, expertise & hands-on experience through internship at leading hospitals, you will develop the expertise to launch or fast-track your career

Our curriculum is designed based on real-world clinical trials scenarios to equip you with practical skills that meet industry demands

Clinical Research Excellence Foundation

Choose the course that best suits your career goals:

1. Advanced Postgraduate Diploma in Clinical Research **including internship**
2. Postgraduate Diploma in Clinical Research
3. Diploma in Clinical Research
4. Diploma in Pharma-covigilance

→ What is unique about these courses?

- **Comprehensive Site Training:** The only organization offering training on all critical aspects of clinical trial conduct at trial sites. Students learn site qualification, initiation, monitoring, and closeout visits, along with patient screening, recruitment, and follow-up processes for various trial phases and indications.
- **Ethics Committee Preparation:** Specialized training on preparing ethics committee dossiers, presenting trials to committee members, and ensuring audit readiness for regulatory inspections.
- **Advanced System Training:** Participants gain expertise in using IVRS/IWRS and electronic data capture platforms.
- **Hospital and Industry-Ready Skills:** Hands-on experience through internship at leading hospitals & research institutes.
- **Placement assistance:** We conduct mock interviews, help in resume building and provide placement guidance to prepare you for the job market.

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Brief about the courses

Name of Course	1. Advanced Postgraduate Diploma in Clinical Research (CR-01)	2. Postgraduate Diploma in Clinical Research (CR-02)	3. Diploma in Clinical Research (CR-03)	4. Diploma in Pharmacovigilance (CR-04)
Duration	6 months* (lecture) + 3-6 months internship	6 Months*	3 Months	3 Months
Weekly Workshop Schedule	3 Hours every Saturday and Sunday	3 Hours every Saturday and Sunday	3 Hours every Saturday and Sunday	3 Hours every Sunday
Modules	13	12	8	8
Exam Pattern	MCQ and case-study based questions (100 marks/module)	MCQ and case-study based questions (100 marks/module)	MCQ and case-study based questions (100 marks/module)	MCQ and case-study based questions (100 marks/module)
Certificates	1. Advanced Postgraduate Diploma in clinical research 2. Marksheet 3. Internship Certificate	1. Postgraduate Diploma in Clinical Research 2. Marksheet	1. Diploma in Clinical Research 2. Marksheet	1. Diploma in Pharmacovigilance 2. Marksheet
Fees in Rs	~~90,000~~ 75,000/- (17% off)	~~60000/-~~ 40,000/- (33% off)	24000/-	30000/-
Batches starting	Every Jan & July	Every Jan & July	Every Jan, Apr, July, Oct	Every Jan

*Crash course with 3 months duration (lectures) also available: same modules will be covered by taking additional lectures for course CR-01 & CR-02.
** 50% passing marks are required for every module.

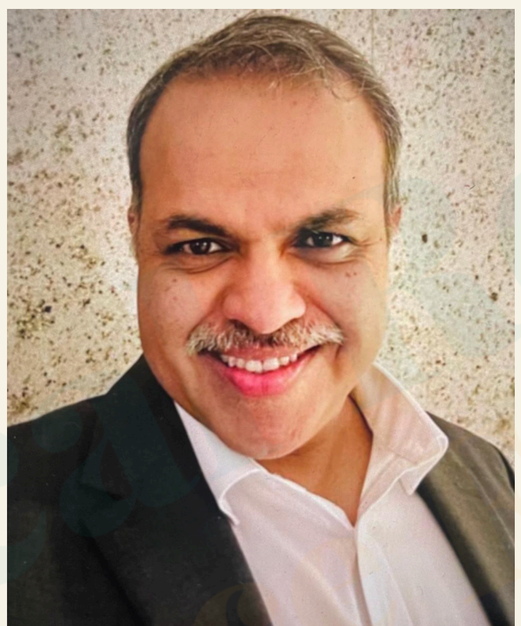
Faculties

Dr. Heena Gandhi
Senior Regulatory Officer- Rutgers University, New Jersey, USA

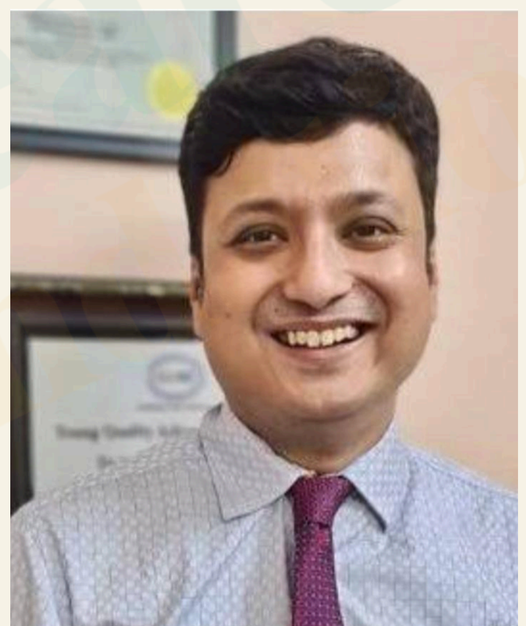
Dr. Vijaykumar Gawali
Head of Dept. – Clinical Research & Academics International Clinical Research Mentor

Dr. Medhinee Kulkarni
Drug Safety Physician at Parexel

Dr. Niraj Pandit
Director Research and Innovation, Sumandeep Vidyapeeth deemed to University, Vadodara



Dr. Mukul Manchanda
Principal Vice President Technology, Healthcare & Big data analytics



Dr. Subhrojyoti Bhowmick
Vice President Project Development and Academic Initiatives KPC Medical College & Hospital, Calcutta.

Ms. Vaishali Deshpande
Clinical Research Consultant specializing in GXP compliance, Chairperson of Ethics Committees at Sancheti Hospital, Ruby Hall Clinic

Dr. Chandrashankar Gupta
Chief Controller of Data Processing Services at Raptim Research Pvt Ltd, Mumbai

Mr. Ronak Shah
Research Associate - Sumandeep Vidyapeeth Deemed to be University

1. Advanced Postgraduate Diploma in Clinical Research

Module 1: Clinical Research Introduction & Stakeholders in Clinical Research

- Overview
- Evolution of ethical and regulatory frameworks
- Roles and responsibilities of Investigators, Sponsors, and Contract Research Organizations

Module 2: Pharmacology in Clinical Research & Drug Development Process

- Basics of pharmacology
- Pharmacodynamics & pharmacokinetics
- Drug discovery process

Module 3: National & International Guidelines Governing Clinical Trials

- ICH-GCP guidelines
- NDCT rules
- ICMR guidelines
- CFR guidelines

Module 4: Clinical Trials Conduct at Clinical Trial Sites

- Site feasibility studies & ethics committee dossier
- Site qualification, initiation, monitoring, closeout visits
- Patient management: screening, recruitment & follow-up and audit preparation

Module 5: Clinical Trial Data Management

- Overview
- E-tools and systems: working with eCRFs and Interactive Web Response Systems (IWRS)

Module 6: Quality Assurance and Quality Control in Clinical Trials

- Quality management system: fundamentals of QA and QC
- Corrective action and preventive action

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Module 7: Pharmacovigilance & Safety Monitoring

- Adverse event and reporting serious adverse events
- Pharmacovigilance Methods: signal detection, data mining, and risk management planning

Module 8: Medical Device Clinical Trials

- Medical device rules, 2017
- Medical device classification
- Materiovigilance
- Trial phases

Module 9: Research Methodology and Biostatistics

- Literature review
- Study design
- Basic statistics

Module 10: Medical Writing

- Preparation of protocols, informed consent forms, investigator's brochures, and case report forms
- Clinical study reports

Module 11: Virtual Clinical Trials & Emerging Technologies

- AI in clinical trials
- E-Consent and E-PRO: leveraging digital tools for patient consent and outcomes
- Remote monitoring

Module 12: Soft Skills for Clinical Research Professionals

- Professional development
- Communication skills
- Mock interviews

Module 13: Internship

We provide internship programs at premier hospitals and research institutes in India, ensuring that you can access invaluable hands-on training close to home.

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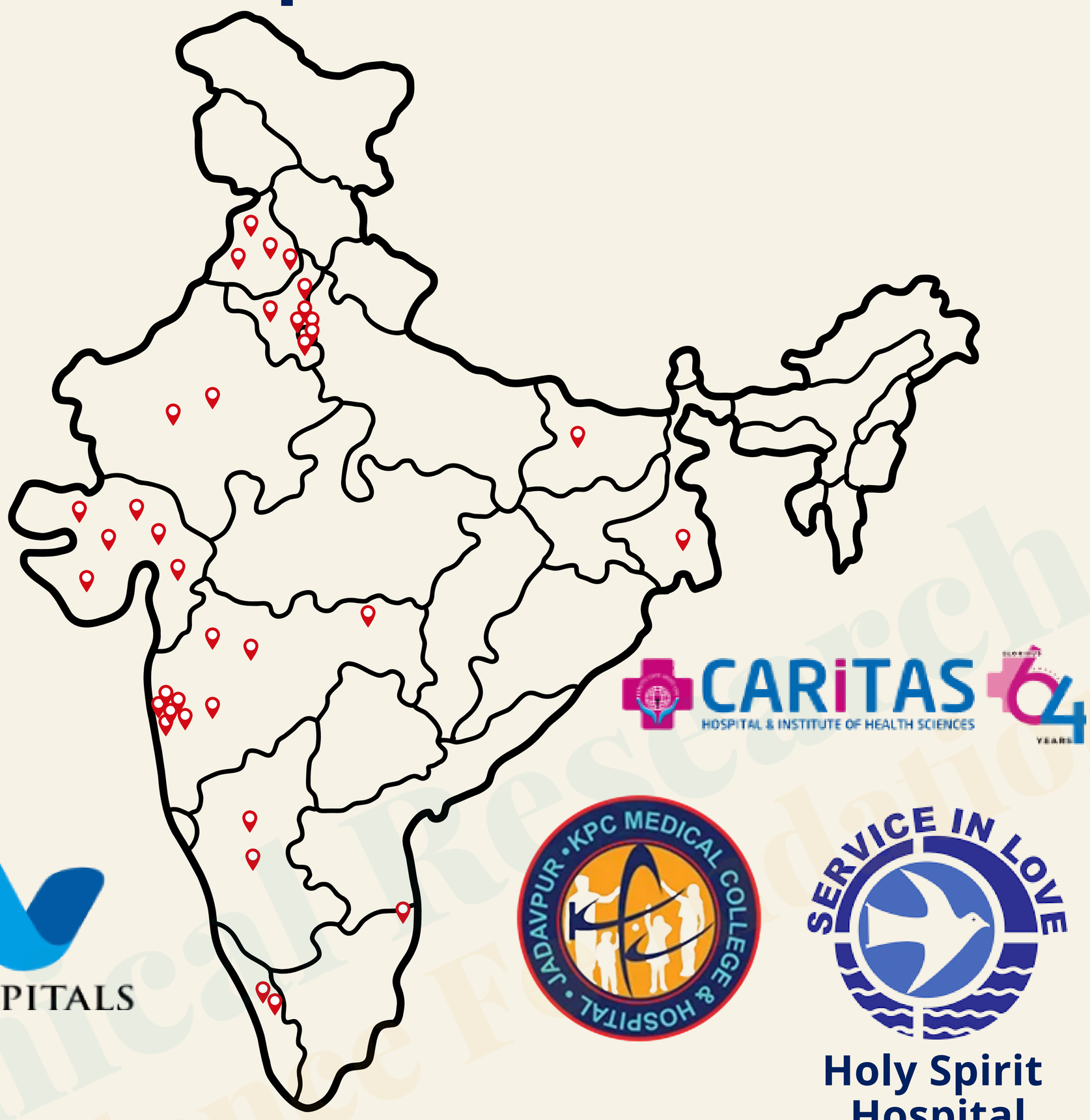
Internship centres



CIMET'S INAMDAR MULTISPECIALITY HOSPITAL

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- Mohali
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- Bangalore
- Kolkata
- Jaipur
- Amritsar

M|O|C Cancer Care & Research Centre

- Mumbai
- Pune
- Ahemdabad
- Nashik

Sahyadri Hospitals

Peerless Hospital

jothydev's DIABETES HOSPITAL & RESEARCH CENTRE

श्रीKrishna हृदयालय व क्रिटिकल केअर सेंटर

Shri Krishna Hrudayalaya & Critical Care Centre

कर्मचारी राज्य बीमा निगम ESIC सामाजिक सुरक्षा SOCIAL SECURITY

ESIC Medical College & Hospital

SUMANDEEP VIDYAPEETH Deemed to be University Estd. 2007 Vadodara विद्या विनयेन शोभते

Sumandeep Vidyapeeth hospital

2. Postgraduate Diploma in Clinical Research

Modules from Module 1 to Module 12 (except Module 13) will be covered as mentioned in 'Advanced Post Graduation Diploma in Clinical Research + Internship program'
(Refer page 7)

3. Diploma in Clinical Research

Module 1: Clinical Research Introduction & Stakeholders in Clinical Research

- Overview
- Evolution of ethical and regulatory frameworks
- Roles and responsibilities of Investigators, Sponsors, and Contract Research Organizations

Module 2: General Pharmacology in Clinical Research & Drug Development Process

- Basics of pharmacology
- Pharmacodynamics & pharmacokinetics
- Drug discovery process

Module 3: National & International Guidelines Governing Clinical Trials

- ICH-GCP Guidelines
- NDCT Rules
- ICMR guidelines
- CFR guidelines

Module 4: Clinical Trials Conduct at Clinical Trial Sites

- Site feasibility studies
- Ethics committee dossier
- Site qualification, initiation, monitoring, closeout visits
- Patient management: screening, recruitment, follow-up and audit preparation

Module 5: Clinical Trial Data Management

- Overview
- E-tools and systems: Working with eCRFs and Interactive Web Response Systems (IWRS).

Module 6: Quality Assurance & Quality Control in Clinical Trials

- Quality management system: fundamentals of QA and QC
- Corrective action and preventive action

Module 7: Pharmacovigilance & Safety Monitoring

- Adverse event and serious adverse events
- Pharmacovigilance methods: signal detection, data mining, and risk management planning

Module 8: Medical Device Clinical Trials

- Medical device rules, 2017
- Medical device classification
- Materiovigilance
- Trial phases

4. Diploma in Pharmacovigilance

Module 1: Overview of Drug Discovery and Development

- Introduction to drug development: steps from discovery to post-marketing surveillance
- Regulatory milestones
- Introduction to pharmacovigilance (PVG)

Module 2: Introduction to Pharmacovigilance

- Definition and scope
- History of PVG
- Ensuring patient safety, risk minimization, and monitoring adverse drug reactions (ADRs)
- MedDRA

Module 3: Regulatory Guidelines and Laws

- ICH E2A to E2F guidelines, WHO guidelines on safety monitoring
- Regional Regulations: USFDA regulations, EMA guidelines, CDSCO regulations

Module 4: PVG Methodology

- Signal Detection: identifying and analyzing signals for ADRs
- Frameworks for identifying, assessing, and mitigating risks
- Safety surveillance
- Benefit-risk evaluation

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Module 5: Safety Reporting Process

- Individual Case Safety Reports (ICSRs): elements of an ICSR, collecting, validating, and submitting ICSRs
- SAEs, PSURs
- Expedited reporting
- Handling data inconsistencies, root cause analysis for safety issues

Module 6: Introduction to PVG Software

- Key PVG tools
- E-reporting systems
- Software integration: linking PVG tools with other healthcare systems

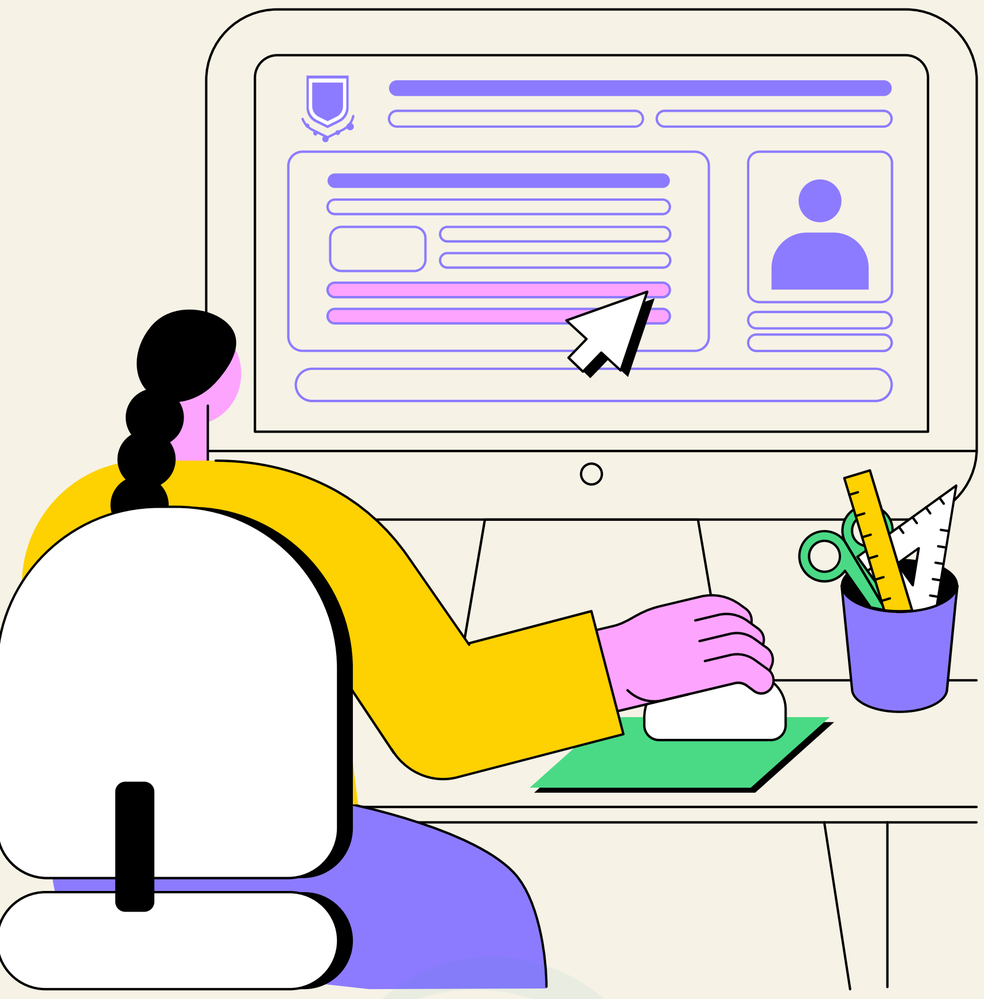
Module 7: PVG Workflow and Database

- PVG Workflow
- Capturing and triaging safety data
- Data entry and quality checks
- Overview of safety databases (e.g., Argus, ARISg), data storage, retrieval, and security

Module 8: Advanced PVG Concepts

- Compiling and analyzing aggregated safety data, preparing DSURs
- AI in PVG, role of big data and analytics

Admission process



→ Step 1: Eligibility screening through interview and document verification

→ Step 2: Fill the application form and complete payment of the course (refer to website: admission process)

→ Step 3: Confirmation of enrolment by email within 2-3 working days

For admission: 

Admissions open 3 months prior to every batch

Comprehensive Coverage of Fees for the Clinical Research Courses

The fee structure for our clinical research courses covers tuition fees for expert-led teaching, course materials, and access to advanced virtual classroom facilities. It includes regular assessments, personalized feedback, and industry interview preparation through resume-building and mock sessions. Students receive supporting literature, hands-on project assignments, and internship as applicable.

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MBBS
BDS
BAMS
BHMS
BUMS

B.Pharm
M.Pharm
PharmD

Graduates/ Post Graduates in Sciences/Life sciences/ Biotechnology

Eligibility

Physiotherapy
Occupational therapy

Public Health
Health Management
Social Sciences

Nursing

Candidates who have passed BSc with Biochemistry/ Microbiology/ Zoology/ Bioinstrumentation or any other allied health sciences or equivalent examination from a statutory Institution/University are also eligible.

MORE INFO »

8422800400 (Mon to Sun 9 am–6 pm, IST)

clinicalresearchexcellencefdn@gmail.com

Visit Website

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Job opportunities post course completion

Clinical Trial Operations- Industry

- Clinical Research Associate
- Clinical Trial Manager (CTM)
- Clinical Operations Specialist
- Clinical Trial Assistant
- Project Manager – Clinical Research
- Monitoring Assistant
- Quality Assurance Specialist for Clinical Trials

Medical Writing

- Medical Writer
- Regulatory Writer
- Scientific Writer
- Medical Reviewer

Clinical Research Operations- Research Site

- Clinical Research Coordinator (CRC)
- Lead-Clinical Research
- Quality Head
- Investigator
- Sub-Investigator

Pharmacovigilance and Drug Safety

- Drug Safety Associate
- Pharmacovigilance Specialist
- Risk Management Specialist
- Signal Detection Analyst
- Post-Marketing Safety Surveillance Officer

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Job opportunites post course completion

Regulatory Affairs and Compliance

- Regulatory Affairs Manager
- Regulatory Submissions Specialist
- Ethics Committee Coordinator
- DCGI Liaison Officer

Academic and Research Institutions

- Research Scientist
- Academic Clinical Research Educator
- Research Fellow
- Principal Investigator in Academia

Data Management and Analysis

- Clinical Data Manager
- Biostatistician
- Data Analyst for Clinical Trials
- Data Validation Specialist
- EDC (Electronic Data Capture) Specialist
- Statistical Programmer

Government & Public Health Roles

- Clinical Research Scientist in Government Agencies
- Research Officer in Public Health Departments
- Program Coordinator for Government-Sponsored Trials

Training and Development

- GCP Trainer
- Clinical Research Trainer
- Investigator Training Specialist

Quality Control and Audits

- Clinical Quality Control Officer
- Site Readiness Auditor

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Clinical Research Excellence Foundation experience

10+ Countries (workshops)

50+ CRO/Sponsor Audits

100+ Trained Professionals

100+ Original Articles

100+ Trained EC Members

300+ International Trials Conduct

1000+ Clinical Trial site monitoring

Experts speak

Dr. Chetan Madre

“Excellent teaching and inspiring mentorship paved way to successful career”

Ms. Priyanka Margaj

“Invaluable expertise and perspectives into clinical research field that truly made a difference”

Mr. Vishal Varma

“Gained all the required knowledge about clinical trial conduct through real-world case studies, gained insights into solving trial challenges”