INFORMATION BROCHURE

India’s Largest Clinical Research & Pharmacovigilance Courses

12,000+ Alumni | 500+ Cities | 30+ Countries

Clinical Research

India became a member of WTO/GATT/TRIPS in 1995 and implemented the product patent regime in 2005. As part of WTO/GATT/TRIPS, Pharmaceutical Industry has the rights to patent products as well as processes throughout the world including India. This has led to significant growth in the pharmaceutical industry and increased the stakes of multinational companies in Indian operations.

In light of these changes, Clinical Research has emerged as a leading knowledge-based industry of the new millennium. Clinical research is carried out on healthy volunteers and patients with diseases to ensure that the drug to be marketed is safe and effective. It takes approximately 12 years and US $1.5 billion to introduce a new drug to the market. The clinical research industry in India is growing rapidly and the country is projected to conduct nearly 5% of all global clinical trials in the next 5 years. Being a sunrise industry, it is offering exciting career avenues as well as an accelerated growth path. India is being looked upon as a favorable destination for conducting global clinical trials due to the following advantages:

- Lower drug development cost
- Abundance of patients with genetic diversity
- Wide spectrum of disease
- Trained medical professionals
- Skilled manpower and IT-enabled infrastructure at a lower cost
- Proficiency in the English language

Pharmacovigilance

Pharmacovigilance is the pharmacological sciences relating to detecting, assessing, understanding, and preventing adverse effects, particularly long-term and short-term side effects of therapeutic drugs, devices, and biologics. Setting up stringent laws by regulatory bodies (e.g. US-FDA, DCGI, EMEA, etc.) has led to the adoption of a systematic Pharmacovigilance framework worldwide. This in turn led to the creation of a large number of jobs pertaining to this field.

The worth of the Pharmacovigilance market worldwide was U.S. $186 million in 2008 and according to a newly released report by Global Market Insights, Inc., is expected to exceed USD 8 billion by 2024. At present, India is the fourth largest producer of pharmaceuticals in the world and therefore is a surfeit of drug brands with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India offers unique advantages for the growth of pharmacovigilance that include:

- Rapid induction of New Chemical Entities and high-technology pharmaceutical products
- Abundance of patients with genetic diversity
- Presence of lacs of formulation in the domestic market
- Presence of a large number of licensed drug manufacturers in India
- Potentially large world-scale Adverse Drug Reaction (ADR) database

Both Clinical Research and Pharmacovigilance offer employment opportunities to **undergraduate and postgraduate students from the fields of medicine, pharmaceutical sciences, life sciences, and biotechnology**. However, being a specialized field of study, these require a specific skill set to carry out various operations, as per the global norms. We at **Catalyst Clinical Services Pvt. Ltd.** are committed to developing India as a hub for global clinical research by catering to the profession's ever-growing training and compliance needs through specialized training courses and workshops.

Basic, Advanced, and Specialty Courses

With an Alumni base of more than **12,000+ participants** across **30+ countries**, Catalyst Clinical Services Pvt. Ltd. (Catalyst) is indisputably the pioneer of clinical research training in India. All the courses offered by Catalyst are skill development programs (through distance learning) with an aim to equip the participants with the knowledge and competency required for the clinical research and/or pharmacovigilance profession. Based on the competency levels, the various courses offered by Catalyst are as follows:

Competency Level	Course	Duration
Entry Level	Professional Diploma in Clinical Research (PDCR)	6 months
Entry Level	Professional Certificate in Pharmacovigilance (PCPV)	6 months
Advanced Level	Advanced Certificate Program in Scientific Writing and Creation of Essential Trial Documents (SW)	6 months
Advanced Level	Advanced Certificate Program in Project Management (PM)	6 months
Advanced Level	Advanced Certificate Program in Clinical Trial Monitoring (CTM)	6 months
Specialty Level	Oncology Clinical Trials Training (OCTT)	6 months

Key Highlights

- Ease of training
- Self-learning study modules/matchbook course
- Assignment-based evaluation
- Self-paced schedule (1-6 months)
- Hands-on training
- Industry-wide recognition
- Placement assistance

Program Director

Sanjay Gupta (M.B.A., M. Pharm) is a well-known clinical research expert having over 20 years of extensive clinical research experience. He has personally conducted and supervised over 100 clinical trials (Global registration trials, Exploratory Phase-II trials, Phase-I trials, Investigator-initiated trials, etc.) across a wide range of therapeutic areas including Oncology, Endocrinology, Psychiatry, Critical Care, Infectious Diseases, Andrology, Ophthalmology, etc.

He has presented his research work in various International Journals and Conferences including the American Society of Clinical Oncology (ASCO), Seminars in Oncology, the British Journal of Cancer (BJC), Gastric and Breast Cancer (GBC), and the British Journal of Radiology (BJR). He has authored 10 books and written articles on the clinical research field the for periodicals Chronicle Pharmabiz and Express Pharma Pulse. His books “The Big Book of Clinical Research” and “All You Need to Know about Clinical Research” has been widely acclaimed by key stakeholders across the clinical research industry. He is the founder member of the Society for the Promotion of Ethical Clinical Trials (SPECT) in India and also the Network Coordinator for a cancer trials network set up by the University of Oxford, London (India and UK).

Course # 1: Professional Diploma in Clinical Research (PDCR®)

PDCR® is a skills development course with a primary focus on drug discovery, clinical research, and Good Clinical Practice guidelines. The aim of the course is to equip the participant with the knowledge and competency required for the clinical research profession. The course material includes four customized study modules and an Assignment booklet.

Course Curriculum

Module Number	Study Module Title and Content
1	**Introduction to Pharmaceutical Medicine** • Introduction and the Drug Development Process • New Drug Discovery • Clinical Development of Drug • Essential Clinical Trial Documents • Clinical Trials Terminology
2	**Good Clinical Practice (GCP) Foundations** • History of GCP - milestones in the evolution of GCP • Principles of GCP • Applicable Guidelines/Rules for conducting clinical trials in India • World Medical Association Declaration of Helsinki • Clinical Study Process • The Management of Clinical Studies (Sponsor) • Ethics in Clinical Research • Informed Consent • Serious Adverse Event (SAE) • Challenges in the Implementation of GCP Guidelines • Biostatistics
3	**Drug Regulatory Affairs (Clinical Trials)** • Overview of Regulatory Environment in USA, Australia, Europe, and India • Data to be submitted along with the Application to conduct clinical trials or import or manufacture new drugs for sale in the country • Import of New Drugs for clinical trials in India • Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
4	**Roles and Responsibilities of Clinical Trial Personnel** • Roles and Responsibilities of Sponsor • Roles and Responsibilities of Investigator • Roles and Responsibilities of ERB/IRB/IEC • Roles and Responsibilities of Regulatory Authority (US-FDA/DCGI) in relation to clinical trials • Roles and Responsibilities of Clinical Research Associate (CRA)/Monitor • Roles and Responsibilities of Auditor • Roles and Responsibilities of Clinical Research Coordinator/Site Manager • Roles and Responsibilities of contract research organizations (CROs) • Roles and Responsibilities of Clinical Data Manager (CDM) • Roles and Responsibilities of Clinical Biostatistician

Career Path

- Clinical Research Coordinator/ Trainee Clinical Research Associate
- Clinical Research Associate/ Senior Clinical Research Associate
- Project Manager/Team Lead/ QA Associate
- Manager Quality Assurance/ Manager Clinical Operations
- Director- Clinical Operations

Course # 2: Professional Certificate in Pharmacovigilance (PCPV™)

PCPV™ is a skills development course with a primary focus on adverse event reporting. The aim of the course is to equip the participant with the knowledge and skills required for the pharmacovigilance profession. The course material includes one customized study module and an Assignment booklet.

Course Curriculum

Sr. No.	Topic and Content
1	Introduction to Pharmacovigilance (PV) and Risk Management
2	Standard Terms and Definition of Pharmacovigilance
3	**Global Perspectives PV and ADR Reporting** • Functions of a National Pharmacovigilance System • Minimum Requirements for a Functional National Pharmacovigilance System • Basic Steps in Setting up a Pharmacovigilance Centre • How to Join the WHO Program for International Drug Monitoring? • Procedure for Joining the WHO Drug Monitoring Program • Pharmacovigilance Methods • Relationship/Casualty Assessment • Signal Generation in Pharmacovigilance
4	**Guidelines and Standard Governing PV** • ICH Guidelines • US-FDA Guidelines • CFR Guidelines • European Union Guidelines • CIOMS Guidelines • Joint CIOMS-WHO Working Group on Drug Development Research and Pharmacovigilance in Resource-Poor Countries (2006) • CIOMS-WHO Working Group on Vaccine Pharmacovigilance • Pharmacovigilance Program of India (PvPI) • List of ADR Monitoring Centres under PvPI
5	**Global AE reporting System and Reporting Forms** • Definitions and Terminology Associated with Clinical Safety Experience, ICH (E2A) • Expectedness of an Adverse Drug Reaction • Reporting of Adverse Drug Reactions • ADR/AE Reporting Procedure • AE Reporting Form - United States: MedWatch Form 3500 and 3500A - Medicines and Healthcare Products and Regulatory Agency's Vigilance Reporting Form - Yellow Card - Universally Accepted ADR Reporting Form CIOMS I Form - Suspected Adverse Drug Reaction Reporting (SADRR) Form - Medeffect Canada and Canada Vigilance Program - Therapeutic Good Administration Australian Vigilance System – Blue Card - VAERS: Vaccine Adverse Event Reporting System
6	Individual Case Safety Reports (ICSRs)

Sr. No.	Topic and Content
7	Medical Directory for Drug Regulatory Activities (MedDRA)
8	Periodic Safety Updates Reports (PSURs)
9	Expedited Reporting and Requirements
10	Pharmacovigilance Inspections

Career Path

- Drug Safety Associate/Pharmacovigilance Associate
- Drug Safety Scientist
- Aggregate Report Scientist
- Team Leader or Team Manager
- Director/Vice President

Course # 3: Advanced Certificate Program in Scientific Writing and Creation of Essential Trial Documents (SW)

This is a skill development course with an aim to equip the participant with the skills and competencies required for the specialized job function of Medical Writing. By participating in and successfully completing this training course, one can specialize in the field of scientific/medical writing through a unique hands-on training experience. The course material includes one customized study module, an Assignment booklet, and hands-on training material.

Course Curriculum

Sr. No.	Topic and Content
1	Introduction to Clinical Research, Guidelines, and Standards Governing Clinical Research
2	Clinical Study Process
3	Development of Standard Operating Procedures (SOPs)
4	Protocol
5	Informed Consent Document (ICD)
6	Clinical Report Form (CRF)
7	Data Validation Plan (DVP)
8	Clinical Study Report (CSR)
9	Publication
10	Glossary

Course # 4: Advanced Certificate Program in Project Management (PM)

This is a skill development course with an aim to equip the participant with the skills and competencies required for the specialized job function of clinical trial project management. By participating in and successfully completing this training course, one can specialize in the project management field of clinical trials through a unique hands-on training experience. The course material includes one customized study module, an Assignment booklet, and hands-on training material.

Course Curriculum

Sr. No.	Topic and Content
1	Introduction to Clinical Research, Guidelines, and Standards Governing Clinical Research
2	Project Milestones Planning and Forecasting
3	Cost Estimate and Financial Planning
4	Logistics Planning, Vendor Selection, and Management
5	Creation of Trial Master File
6	Management of Regulatory Document Submission
7	Co-ordination of Individual Site Set-up Activities
8	Import/Export Requirements for Clinical Trials
9	Organization of Investigator Training Meeting
10	Study Initiation, Conduct, and Milestones Tracking
11	Audit(s) and Quality Assurance
12	Regulatory Inspection
13	Study Closeout (trial completion, suspension, termination, etc.)
14	Glossary

Course # 5: Advanced Certificate Program in Clinical Trial Monitoring (CTM)

This is a skill development course with an aim to equip the participant with the skills and This is a skill development course with an aim to equip the participant with the skills and competencies required for the specialized job function of clinical trial monitor/clinical research associate. By participating in and successfully completing this training course, one can specialize in the field of clinical trial monitoring through a unique hands-on training experience. The course material includes one customized study module, an Assignment booklet, and hands-on training material (Dummy Clinical Trial Monitoring Kit™).

Course Curriculum

Sr. No.	Topic and Content
1	Introduction to Clinical Research, Guidelines, and Standards Governing Clinical Research
2	Investigator Site Selection/Assessment
3	Development of Monitoring Plan
4	Site Initiation, Review of Essential Trial Documents, Delegation of Duties and Responsibilities at Individual Site
5	Clinical Trial Monitoring
6	Inventory Planning and Tracking
7	Source Document Verification (SDV)
8	CRF Review, Collection, and Coordination of Data Management Activities
9	Serious Adverse Event (SAE) Review and Regulatory Compliance
10	Investigational Product (IP) Accountability and Management
11	Escalation, Management, and Prevention of Violations/Deviations
12	Tracking of Enrolments, Payments, and Ongoing Correspondence
13	Site Closure
14	List of Essential Documents Before the Clinical Phase of Trial Commences
15	List of Essential Documents During the Clinical Conduct of Trial
16	List of Essential Documents After Completion or Termination of Trial
17	Glossary

Course # 6: Oncology Clinical Trials Training (OCTT™)

OCTT™ is a skills development course with a primary focus on the management of oncology clinical trials. The objectives of the training course are:

- To arm clinical research professionals with the knowledge and skills required for carrying out oncology clinical trials.
- To provide in-depth training on monitoring and management of oncology clinical trials.
- To identify and answer the major challenges that are seemingly inherent to the oncology clinical trial process.

The course material includes two customized study modules, an Assignment booklet, and hands-on training material (Dummy Clinical Trial Monitoring Kit™).

Course Curriculum

Module Number	Study Module Title and Content
1	**Fundamentals of Oncology Clinical Trials** • Introduction to Drug Discovery Process • Guidelines and Standards Governing Clinical Research • Essential Clinical Trial Documents • Ethics Committee/Ethics Review Board • Informed Consent Process • Overview of Cancer and Oncology Clinical Trials • Diagnosing Cancer: Staging and Disease Assessment • Safety Evaluation in Oncology Clinical Trials (WHO, CTC) • Efficacy Evaluation in Oncology Clinical Trials (WHO, SWOG, RECIST) • Glossary
2	**Oncology Clinical Trials Monitoring** • Development of a Monitoring Plan • Site Initiation, Review of Essential Trial Documents, Delegation of Duties and Responsibilities at Individual Site • Clinical Trial Monitoring • Inventory Planning and Tracking • Source Document Verification (SDV) • CRF Review, and Coordination of Data Management Activities • Serious Adverse Event (SAE) review and Regulatory Compliance • Investigational Product (IP) Accountability and Management • Management and Prevention of Deviations • Site Closure Monitoring Visit

Duration

The duration of each of the training courses is 6 months. Since the courses are offered on a self-paced schedule, these can be completed earlier if desired by a participant. Similarly, if a participant is unable to submit the Assignment within the prescribed timeframe or is unable to qualify on the first attempt, the course duration can be stretched up to a maximum of 10 months. Failure to qualify within 10 months would lead to the cancellation of the candidature thereby requiring a fresh enrolment.

Eligibility

Candidates who are currently pursuing or have completed the following curriculum are eligible for enrolment:

- B. Pharm, M. Pharm, PharmD, Ph.D.
- MBBS, MD, DNB, DM
- BDS, MDS
- BAMS, BHMS, BUMS
- BPT, MPT
- Life Sciences: B.Sc., M.Sc., Biotechnology
- Working Professionals

Application and Fee

The course fee for different categories of participants is as follows:

Sr. No.	Course	Participant Category and Fee		
		Indian Participants	**Indian Participants Residing Overseas**	**Foreign Nationals**
1	Professional Diploma in Clinical Research (PDCR®)	Rs. 14,000	Rs. 19,000	US $ 350
2	Professional Certificate in Pharmacovigilance (PCPV™)	Rs. 14,000	Rs. 19,000	US $ 350
3	Advanced Certificate Program in Scientific Writing and Creation of Essential Trial Documents (SW)	Rs. 16,000	Rs. 21,000	US $ 375
4	Advanced Certificate Program in Project Management (PM)	Rs. 16,000	Rs. 21,000	US $ 375
5	Advanced Certificate Program in Clinical Trial Monitoring (CTM)	Rs. 16,000	Rs. 21,000	US $ 375
6	Oncology Clinical Trials Training (OCTT™)	Rs. 18,000	Rs. 23,000	US $ 400

Evaluation

The duration of each of the above courses is 6 months. Since the courses are offered on a The evaluation is based on the grading of assignments. The assignments are required to be submitted to the Course Coordinator on or before the scheduled date. Assignments reaching after the scheduled dates will not be considered for evaluation.

A letter grade system is used for grading the assignments. These letter grades are:

A	Excellent	80% and above
B	Very Good	≥ 60% and < 80%
C	Good	≥ 50% and < 60%
D	Satisfactory	≥ 40% and < 50%
E	Unsatisfactory	< 40%

Candidates securing a D grade (qualifying grade) and above will be eligible to receive the Certificate of Completion for the Professional Diploma in Clinical Research (PDCR®)**,** Professional Certificate in Pharmacovigilance (PCPV™), and Oncology Clinical Trials Training (OCTT™) courses respectively. Whereas, **candidates securing a B grade (qualifying grade) and above will be eligible to receive the Certificate of Completion** for the Advanced Certificate Program in Scientific Writing (SW), Advanced Certificate Program in Project Management (PM), and Advanced Certificate Program in Clinical Trial Monitoring (CTM) courses respectively. If a candidate fails to secure a minimum qualifying grade for a respective course, he/she will be given one more chance to re-appear upon payment of the applicable fee. A fresh set of assignments will be issued to the candidates on request. If a candidate fails to pass his/her second attempt, he/she will be ineligible for the award of the certificate. In that case, the candidate has to apply for a fresh registration. There is no provision for the re-evaluation of assignments. The evaluated Assignments will be discarded after 6 months from the result declaration date for the respective batch.

The decision of Catalyst Clinical Services Pvt. Ltd. will be final and binding to all the students. All legal disputes will be subject to New Delhi's jurisdiction only. Catalyst Clinical Services Pvt. Ltd. reserves the right to change the rules and regulations from time to time in its sole and absolute discretion. The latest amended rule/regulation will be applicable if any such change is made.

Issue of Fresh Set of Assignments (Re-appear)

Candidates who are unable to qualify for the course on the first attempt can make a written request for the issue of a fresh set of assignments. For all such requests, a processing fee of Rs. 5000/- will be applicable. The same fee is applicable to those candidates also who are unable to submit the assignments within the stipulated time frame*.

Issue of Duplicate Copy of Grade Card and Certificate

A request for the issue of a duplicate copy of the grade card and certificate can be made to the Course Coordinator stating the reason thereof. For the issue of a duplicate copy of the grade card or certificate, a processing fee of Rs. 500/- will be applicable.

* The total course duration cannot exceed 10 months from the start date of a batch.

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