THE OFFICAL HANDBOOK

ISO 9001 : 2015 Certified

POIZDEDGE INSTITUTE FOR CLINICAL EXCELLENCE

For Students and Faculty

--- "Transforming Aspirations into Clinical Achievements."

2026 - 2027 Edition

28 Pages | A4 Size

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Welcome Message

A Note from the Founder

Hi!

I would like to begin with quotes close to my heart - "Be the change that you wish to see in the world" (Mahatma Gandhi) "Opportunities don't happen, you create them" (Chris Grosser).

When I first imagined this space - **PEICE**, I wasn't thinking about platforms or protocols but about people, curious enough to question **what we know, brave enough to test what we believe, and committed enough to turn evidence into impact**. My goal was to create the learning environment that I once searched for—**rigorous, inclusive, and deeply connected to real clinical impact and** a place where learning feels relevant by combining real-world relevance, expert guidance, and a global learning environment . You are prepared for real world opportunities besides building confidence in research and healthcare making you succeed and beyond.

You are not alone in this journey. You are here because you believe in science with purpose. We are here to help you turn that belief into skill, impact, and opportunity.

By joining us, you become part of that vision.

Welcome to the next chapter of your career.

— Founder

Mrs.Bhanu Melvin

About The Poizdedge Institute

A Legacy of Clinical Excellence

PEICE - The PoizdEdge Institute has taken its birth from the thought of sharing and inculcating Clinical Research knowledge that builds confidence , prepares you to be POISED any time and for all opportunities'. Its a fact that we need to be equipped to be prepared to face and not to depend on someone to create an opportunity.

When we are POISED, Every call showcases an OPPERTUNITY.

@ PEICE actions speak.

Our Vision, Mission

Mission

At The PoizdEdge Institute for Clinical Excellence, our mission is to empower aspiring and re-emerging professionals in the life sciences domain with the knowledge, confidence, and practical skills needed to excel in their careers. We strive to bridge the gap between academic learning and industry expectations through comprehensive, hands-on training in clinical and research tools, professional development programs, and personalized interview preparation.

Our goal is to nurture capable, confident, and career-ready individuals who can make meaningful contributions to the clinical research and healthcare industry.

Vision

To be a leading global hub for clinical excellence and professional empowerment —where every learner, regardless of background or career gap, gains the skills, confidence, and clarity to thrive in the life sciences and healthcare industry.

We envision creating a community of professionals who embody competence, confidence, and compassion, driving innovation and quality in clinical practice worldwide.

Our Core Values

Excellence

We strive for the highest standards in education, training, and professional development.

Empowerment

We help learners rebuild confidence, rediscover purpose, and unlock their full potential.

Integrity

We uphold honesty, transparency, and ethical conduct in every interaction and training process.

Inclusivity

We embrace diversity and believe that everyone, regardless of career gaps or background, deserves an equal opportunity to succeed.

Our Core Values

Innovation

We continuously evolve our teaching methods, tools, and programs to match the dynamic needs of the life sciences industry.

Lifelong Learning

We nurture curiosity and a growth mindset, encouraging our learners to view learning as a continuous journey.

Collaboration

We foster teamwork and knowledge-sharing to build a strong, supportive community of professionals.

Faculty

Mrs. BhanuMelvin
Founder PEICE Subject Expert

Mrs. Preethi
Pharmacology Expert

Mrs. Cassia
CDM Expert

Mrs. Anila Anoop
Clinical Research Expert
Doctorial Scholar

Mrs. Cassia
CDM Expert

Our Courses - Overview

Empowering Careers in Life Sciences

Program	Duration
1.Clinical Reserch	2 Months
2.Pharmacovigilance	2 Moths
3.Clinical Data Management	2 Months
4.Regulatory Affairs	2 Months
5.Clinical SAS Programming	3 Months

Curriculum

The curriculum has been designed after giving a lot of thought keeping in mind every Inspiring aspirants with zeal to accomplish and step into the field of Clinical research. The intention of this curriculum was to guide aspirants to acquire knowledge and clear interviews with confidence and c

Every Course here will have the basics of Pharmacology and Clinical research as an added addition to the main course

Pharmacology (Common to all courses)

Module 1: Introduction to Clinical Research Process

- Clinical Research Industry
- Difference between Clinical Research and Clinical Trials
- Clinical Research Terminologies
- General Medical Terminologies (More commonly used in clinical trials

Module 2: General Pharmacology and Mechanism of Drug Action

- Basics of Pharmacology
- Pharmacodynamics
- Pharmacokinetics
- Routes of Administration
- Dosage forms

Module 3: Drug Development Process and Clinical Drug Development Phases

- Drug discovery
- Target Identification
- Lead Identification & Optimization
- Drug classification
- Preclinical studies

Course 01: Clinical research

Industry-Ready Clinical Research Professional Program – 2025

Module 1 – Foundation of Clinical Research & amp
Module 2 – Clinical Operations and Site Management
Module 3 – Clinical Data Management, EDC & Pharmacovigilance
Module 4 – Regulatory Affairs, Emerging Technologies & Career Building
Module 5 – CV building & Self understanding
Module 6 – Interview Readiness

Objectives & Learning Outcomes:

By the end of the course, learners will understand the entire clinical research process from concept to post- marketing, gain exposure to industry tools and regulatory frameworks, and become ready for entry-level roles like CRA Trainee, CDM Associate, PV Executive, or Regulatory Coordinator.

Course 02: Pharmacovigilance:

"Global Pharmacovigilance & Drug Safety Program – 2025"

Module 1 – Introduction to Clinical Research & Drug Development
Module 2 - Foundation of Pharmacovigilance and Drug Safety
Module 2 – Global PV Regulations, ICSR Processing & Case Management
Module 3 – Aggregate Reporting, Signal Detection & Risk Management
Module 4 – Automation, AI in PV, and Career Development
Module 5 – CV building & Self understanding
Module 6 – Interview Readiness

Objectives & Learning Outcomes:

By the end of this course you will be equipped with ample amount of knowledge on how to report and identify an adverse event, importance of reporting, current methodologies and future trends as well. This knowledge helps you to take up job roles as PV Associate, PV executive, Safety data officer etc.

Course 03: Clinical Data Management

"Global Pharmacovigilance & Drug Safety Program – 2025"

Module 1: Fundamentals of Clinical Data Management
Module 2: Regulatory and Quality Standards
Module 3: Clinical Trial Data Collection, cleaning & validation
Module 4: Tools and Softwares & EDC platforms
Module 5: Data Management Deliverables
Module 6: Soft Skills & Career Preparation

Objectives & Learning Outcomes:

By the end of this course you will be equipped with sample amount of knowledge on how to report and identify an adverse event, importance of reporting, current methodologies and future trends as well. This knowledge helps you to take up job roles as PV Associate, PV executive, Safety data officer etc.

Course 04: Global Regulatory Affairs

“Global Pharmacovigilance & Drug Safety Program – 2025”

Module 1: Introduction to Regulatory Affairs & Global Drug Development
Module 2: Regulatory Documentation and Dossier Preparation
Module 3: Global Regulatory Pathways and Market Authorization
Module 4: Regulatory Compliance, Audits, and Emerging Trends

Objectives & Learning Outcomes:

This 1-month course equips graduates with regulatory and compliance knowledge needed to enter clinical research. It integrates global regulatory systems, eCTD dossier preparation, compliance strategies, and digital regulatory trends.Graduates can pursue careers as Regulatory Affairs Associates, Documentation Specialists, Compliance Officers, and Regulatory Coordinators in global pharmaceutical and clinical research organizations.

2-Month Crash Course Curriculum on SAS Programming (2025 Edition)

Course Title: Clinical & Statistical Data Programming using SAS – From Base to Advanced Level

Module 1: Introduction to SAS Environment & Concepts (Week 1)
Module 2: Data Handling & Manipulation Techniques (Week 2)
Module 3: Working with SAS Procedures & Reporting (Week 3)
Module 4: Data Cleaning, Validation, and Basic Statistical **Procedures (Week 4)**

Month 2: Advanced SAS Programming (Automation, SQL & Clinical Applications)

Course Title: Clinical & Statistical Data Programming using SAS – From Base to Advanced Level

Module 5: Advanced Data Step Programming (Week 5)
Module 6: SAS SQL Programming (Week 6)
Module 7: SAS Macros and Automation (Week 7)
Module 8: Advanced Procedures, Clinical Applications & Project
(Week 8)

Objectives & Learning Outcomes:

By the end of the 2-month course, participants will be able to:

✅ Write, debug, and execute SAS programs using Base and **Advanced concepts:**

✅ Manage, clean, and manipulate large datasets

✅ Perform data summarization and statistical analysis

✅ Use PROC SQL and Macros for automation

✅ Generate clinical reports compliant with CDISC standards

✅ Transition into SAS Programmer or Clinical Data Analyst roles

Admission Process
&
Criteria

Your Journey to Clinical Excellence Starts Here Easily

Step-in-Step Guide

1. Online Application
2. Document Sub Req

Required Documents

1. Online Application
2. Document Sub Req

Virtual Engagement & Attendance Policy

Ensuring Active Participation in the Learning Environment

Defining Virtual Attendance

- Active engagement is critical for success. This includes participation in scheduled live online classes and timely viewing of assigned online video classes (recordings), alongside any associated activities.

Minimum Engagement requirement

- **Live Online Classes:** Students are required to attend a minimum of [X]% of all scheduled live online sessions. Active participation (e.g., asking questions, contributing to discussions) is highly encouraged.

Reporting Absences

- Missed Live Session: If you anticipate missing a live class, please inform your instructor/coordinator via email [X hours] prior. For unexpected absences, notify them within [X hours].

Virtual Engagement & Attendance Policy

Ensuring Active Participation in the Learning Environment

Technical Difficulties

- Students are responsible for ensuring a stable internet connection and functional equipment. In case of platform access issues, contact IT Support immediately and provide evidence (screenshots).

Recording Consent

- All live sessions are recorded for review, quality assurance, and for students to re-watch. By participating, you consent to being recorded.

Code Of Conduct

Upholding Standards for All Students

Expectations

Students are expected to demonstrate respect and integrity in all interactions. This includes adhering to academic honesty, attending classes regularly, and contributing positively to the campus community. Embracing diversity and fostering an inclusive environment are essential, as every student plays a vital role in cultivating a supportive educational atmosphere.

Consequences

Failure to adhere to the code of conduct may result in disciplinary actions, depending on the severity of the infraction. This can range from warnings to suspension or expulsion. It is crucial for students to understand that maintaining high standards not only benefits individuals but also enhances the overall learning environment for everyone.

Examination And Grading System

A Continuous Assessment Model for Online Learning

1. Assessment Methods and Weightage

Assessment at The PoizdEdge Institute is continuous and designed to measure both knowledge retention and practical skill application, consistent with industry standards. All formal evaluations are conducted securely via our online learning platform (LMS).

- Daily Quizes/ Tests
- Module Assessments/Projects

2. Grading Scale and Pass Criteria

Grade	Percentage Range
A	90% - 100%
B	80% - 89%
C	70% - 79%
F	Below 60%
	Fail/Not Certified

Digital Safety & Student Well-being

"Securing Your Learning Experience"

Protecting Your Data

- **Data Security:** The PoizdEdge Institute is committed to providing robust data security. We protect your personal and academic information, handling it with strict confidentiality and in compliance with all relevant privacy regulations.
- **Platform Security:** Our online learning systems utilize comprehensive security measures to protect your access and activity within our platforms.

Online Conduct & Respect

- **Required Conduct:** All communication (live classes, emails, forums) must be professional and respectful, adhering to the Student Code of Conduct.
- **Cyberbullying:** Harassment, bullying, or disrespectful behavior towards anyone in the community will not be tolerated and will result in disciplinary action.

Digital Safety & Student Well-being

"Securing Your Learning Experience"

Support and Wellness

- **Need Support?** If you are facing academic challenges or personal difficulties, please contact our Student Support Services immediately

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- **Digital Wellness:** Remember to schedule breaks and maintain a healthy balance between your studies and personal life.

For Urgent Safety Concerns:
Contact:
email: poizdedgeinstitute@gmail.com

Student Testimonials

Hear From Our Successful Learners

"It was a pleasure learning from Bhanu Ma'am during my Diploma in Clinical Research. She made complex topics in Medical Coding easy to understand, ensured every student followed along, and clarified doubts with practical examples."

Riki Talukdar

"I sincerely appreciate Bhanu Madam for her informative and well-structured Regulatory Affairs classes. She explained complex concepts clearly, used practical examples, and bridged theory with real-world applications."

Krishna D

"I had an opportunity to attend Ms. Bhanu Melvin's class on Clinical Data Management. I appreciated her friendly and approachable demeanor, which made the learning experience very comfortable."

Divya

Contact Us / Quick Reference

Your Central Channel for All Inquires

1.Central Communication Point

For all inquiries—including questions about admissions, academic policies, technical support, or general administration—please direct your correspondence to our central support email address:

Primary Support Email: poizdedgeinstitute.com

For all inquiries—including questions about admissions, academic policies, technical support, or general administration—please direct your correspondence to our central support email address:

2. Quick Reference Information

- **Institute Website:** [Your Institute's Website Link]
- **Phone Support:** [Your General Phone
- **Response Time:** We aim to respond to all emails within [Specify Time, e.g., 24-48 business hours].

Final Thoughts & Looking Ahead

Your Future in Clinical Excellence Starts Now

Your journey with us is more than just acquiring knowledge;
it's about transforming into a **confident, competent, and ethical professional** ready to make a significant impact in the life sciences industry.

Thank For Choosing

The PoizdEdge Institute For Clinical Excellence

“Transforming Aspirations into Clinical Achievements.”