CERTIFICATE IN CLINICAL RESEARCH FOUNDATIONS

Program Overview

This comprehensive Clinical Research Training Program is designed to provide participants with a thorough understanding of the principles, practices, and regulations governing clinical research. The program covers essential topics from the foundations of clinical research to the regulatory aspects, equipping participants with the knowledge and skills needed to excel in this dynamic field. Each module includes assessments to ensure comprehension and facilitate progression through the program.

Course Name: Certificate in Clinical Research Foundations

Course Code: OSS001

Type: Online/ Self-paced

Certification: Certificate of Completion from OSSINC Institute of Clinical Research

Program Highlights

- Duration: 1 Month
- 100% Online
- Flexible Schedule
- E-Books Library
- Self-tests: 200 MCQs
- Weekly evaluations
- Final Case Study
- Certificate on completion

What You'll Gain

- Understanding of clinical research principles
- Knowledge of trial ethics and patient safety
- Familiarity with safety monitoring and regulations
- Confidence to pursue higher studies in clinical research
- An industry-level- Level recognized certificate to enhance your career prospects

Who Should Enrol

- B.Sc / M.Sc in Life Sciences, Biology, Microbiology, Biotechnology
- B.Pharm / M.Pharm / Pharm.D
- BPT / MPT (Physiotherapy)
- BDS / MDS, MBBS, BHMS, BAMS, Nursing graduates
- Medical laboratory technologists & allied health professionals
- Anyone from a science background exploring Research Career

Detailed Module-Wise Syllabus

Module 1 – Foundations: Introduction to Clinical Research

- Introduction to Clinical Research with History

- Drug Development Process & Its Phases
- Basics of ICH-GCP
- Ethics Committees
- Role & Responsibilities of Investigator
- Roles & Responsibilities of Sponsor/CRO
- Medical Writing
- Terminologies & Glossary

Module 2 – Clinical Trial Essentials

- Study Design (RCT, Blinded, Placebo)
- Study Startup
- Protocol & Case Report Forms (CRF and eCRF)
- Informed Consent Process
- Essential Documents (TMF & eTMF)
- Laboratory Management
- Vendor Management
- Monitoring of Clinical Trials
- Audit & Inspections

Module 3 – Safety & Data

- Pharmacovigilance Basics (SAE, ADR & AE Reporting)
- SAE reporting & Compensation
- 21 CFR Part 11
- CRF Design

- Clinical Data Management (EDC, Queries, Validation)
- Introduction to Biostatistics in Research
- Unblinding of Drugs

Module 4 – Regulatory & Final

- Overview of Regulatory Authorities (FDA, EMA, CDSCO)
- ICMR Guidelines
- NDCTR 2019 (India Focus)
- CDSCO & Application process

Learning Format

- Introductory Video for each topic
- PDF Study Material
- 2 Faculty Lectures via Zoom call/ Google Meet
- e-books Library

Assessment & Evaluation

- Module 1–3: 50 MCQs each (multiple-answer possible)
- Module 4: 48 MCQs + 2 MCQ-based case vignettes

Certification Details

- Certificate issued by OSSINC Institute of Clinical Research
- Certificate after successful completion
- Industry-oriented certification (non-degree)

Career Support / Outcomes

- Career guidance & counselling for Clinical Research roles
- Assistance in identifying suitable organizations & application platforms
- Resume building & professional profile
- Interview preparation with common FAQs & performance tips
- Industry insights on current hiring trends & employer expectations

OSSINC
Institute of Clinical Research

CONTACT US

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Important Disclaimer

The syllabus may be updated from time to time to remain aligned with evolving regulatory guidelines, industry standards, and best clinical research practices.