

Clinical Project Management Training



Our Clinical Project Management course provides a comprehensive introduction to the key principles, strategies, and responsibilities involved in managing clinical trials effectively. Designed for professionals working in or aspiring to enter clinical research project management, this course explores the full lifecycle of a clinical trial, from study initiation and planning through execution, monitoring, and closeout.

Developed by industry experts with extensive experience in clinical operations and project leadership, the course blends practical insight with essential theoretical knowledge. Learners will gain a solid understanding of project management methodologies, Good Clinical Practice (GCP), and Good Documentation Practice (GDocP), all critical to maintaining data integrity, participant safety, and regulatory compliance.

Through engaging, self-paced online learning, participants will learn how to plan, track, and deliver clinical projects efficiently, manage timelines and budgets, mitigate risks, and lead cross-functional teams effectively. The course also provides guidance on stakeholder communication, quality oversight, and managing the complex regulatory landscape that governs clinical research.

Whether you are new to clinical project management or looking to strengthen your existing skills, this course offers practical tools and knowledge that can be applied immediately in your professional role.

Course Learning Outcomes:

- **Clinical Trial Lifecycle Management:** Gain proficiency in managing clinical trials from study start-up to closeout, including protocol development, site selection, and monitoring.
- **Regulatory Compliance:** Understand and apply GCP and GDP standards to ensure adherence to regulatory requirements and maintain data integrity.
- **Project Planning and Execution:** Learn to develop detailed project plans, manage timelines, budgets, and resources, and implement risk management strategies.
- **Team Leadership and Communication:** Enhance skills in leading cross-functional teams, stakeholder communication, and conflict resolution.
- **Documentation and Reporting:** Master the creation and maintenance of essential clinical trial documentation, ensuring compliance with regulatory standards.

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COURSE CONTENTS:

MODULE ONE

- What is project management?
- The role of a clinical project manager
- Becoming a clinical project manager
- Other roles
- Clinical trial phases
- Clinical study design
- Ethics committees
- Regulatory and advisory bodies
- Good clinical practice
- Good documentation practice
- Qualities of a good project manager
- Effective communication
- Report writing
- Project milestones
- Clinical research milestones
- Virtual team meetings

MODULE TWO

- Before a trial
- Project planning
- Regulatory and ethics submissions
- Site selection
- Informed consent
- Essential records
- Electronic records
- Record control
- Overseeing monitors
- Effective teams
- Budget management
- Management of service providers
- Progress tracking

MODULE THREE

- During a trial
- Site initiation visits
- Supporting monitors
- Risk management
- Electronic systems
- Participant safety and safety reporting
- Quality management
- Preparation
- Underperformance
- Issue management
- Audits and inspections
- End of study
- Exam
- Accessing your certificate

SUITABLE FOR:

This course is ideal for professionals in the **pharmaceutical, biotechnology, and clinical research** sectors, including:

- Clinical Project Managers and Associate Project Managers
- Clinical Research Associates (CRAs)
- Clinical Trial Assistants (CTAs)
- Regulatory Affairs Specialists
- Quality Assurance and Compliance Officers
- Study Coordinators and Site Managers seeking to move into project leadership roles.

Duration: Approx. 8 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.



Training
Online 4U