CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

CERTIFIED EU CLINICAL TRIALS PROJECT MANAGER™

CCT ™

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

CCT™
CERTIFIED EU CLINICAL TRIALS PROJECT MANAGER™

PROGRAM OVERVIEW

Recent data reveals **67% of clinical trials face delays, with regulatory compliance issues accounting for 40% of setbacks, costing €3.2 billion annually in the EU**. This striking reality emphasizes the critical importance of expert project management in clinical trials. Advanced knowledge of EU regulatory landscapes, risk management, and stakeholder coordination is vital for project managers to minimize delays, optimize resource allocation, and accelerate the delivery of innovative therapies to European patients.

This certified program will provide you with an intensive, hands-on understanding of EU clinical trials management, tailored specifically for project management professionals navigating Europe's complex regulatory landscape. You will gain in-depth knowledge of the **EU Clinical Trial Regulation, CTIS portal operations, GCP standards, and the regulatory transition from Directive 2001/20/EC** that has transformed clinical research across European healthcare systems.

The program emphasizes leadership in managing multi-national trials, with focused training on cross-border submissions, ethics committee coordination, and National Competent Authority (NCA) interactions. Core frameworks such as **risk-based quality management, pharmacovigilance systems, EudraVigilance reporting, and investigational medicinal product (IMP) supply chain management are used to illustrate how regulatory compliance, safety monitoring, and operational excellence** contribute to successful trial delivery.

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PROGRAM OVERVIEW

You will also explore patient recruitment strategies, informed consent processes, and GDPR compliance to ensure ethical trial conduct across diverse European populations.

Through realistic trial scenarios and structured case studies, you will build skills in regulatory submission management, inspection readiness, and crisis response protocols. Practical modules include **adverse event reporting, Development Safety Update Reports (DSURs), Advanced Therapy Medicinal Products (ATMP) regulatory pathways, MedTech device trials, and AI-driven clinical research applications**. Advanced tools such as centralized monitoring systems, quality assurance frameworks, and corrective action planning will further strengthen your capability to manage complex trials while maintaining the highest standards of patient safety and data integrity.

Upon completing the program and passing the Chartered exam, you will attain the **Certified EU Clinical Trials Project Manager (CCT™) designation**. This credential will demonstrate your advanced expertise in integrating EU regulatory frameworks into clinical trial management, driving excellence in research delivery and significantly accelerating patient access to innovative therapies across European healthcare settings.

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KEY SKILLS YOU WILL GAIN

From This Program

EU CLINICAL TRIAL REGULATION (CTR)
CTIS PORTAL NAVIGATION
CLINICAL TRIAL APPLICATION (CTA)
ETHICS COMMITTEE SUBMISSIONS

EMA & NCA COORDINATION
SAFETY REPORTING AND PHARMACOVIGILANCE
CLINICAL TRIAL MANAGEMENT SYSTEM (CTMS)
GOOD CLINICAL PRACTICE (GCP) STANDARDS

TRIAL PROTOCOL DEVELOPMENT
PATIENT RECRUITMENT & RETENTION
PATIENT PARTICIPATION
INFORMED CONSENT PROCESSES

VULNERABLE POPULATION SAFEGUARDS
GDPR & DATA CONFIDENTIALITY
MEDTECH DEVICE TRIALS AND AI
PHARMACOVIGILANCE SYSTEMS
EUDRAVIGILANCE REPORTING

ADVERSE EVENT (AE) MANAGEMENT
DEVELOPMENT SAFETY UPDATE REPORTS

YOUR FACULTY DIRECTOR

Professor Sandip Mitra

Award-Winning Clinical Research Expert

Professor Sandip Mitra is a distinguished expert with over 20 years of experience in clinical research and EU regulatory affairs. He is a leading authority committed to advancing the fields of clinical trials project management and European pharmaceutical development through innovative research, education, and strategic industry collaboration. Throughout his career, Professor Mitra has held several prominent leadership roles, including **UK National Lead for Research Delivery (NIHR), Principal Investigator, and Expert Consultant, across academia, healthcare, and global pharmaceutical organizations.**

As a renowned clinical trials leader, Professor Mitra has successfully managed **large portfolios of Phase 1-4 trials, supervising postgraduate researchers and securing significant industry partnerships with AstraZeneca, GSK, Novartis, and Baxter**. His expertise has empowered countless project managers and healthcare professionals in EU regulatory compliance, multi-national trial coordination, and advanced therapeutic medicinal product development.

Recognized for his exceptional contributions to clinical research excellence, Professor Mitra has received multiple national awards and maintains consistent 9/10 teaching ratings across prestigious **UK universities including UCL, Oxford, Manchester, and Sheffield**. He is a highly regarded Key Opinion Leader, NIHR Ambassador, and expert reviewer, with specialized certifications and memberships in prestigious research organizations, further cementing his status as a trusted authority in EU clinical trials management.

OUR PARTICIPANTS

Over 70% of FORTUNE 500 Companies Have Attended Our Accredited Programs Before

PROGRAM AGENDA

MODULE 1 - OVERVIEW OF CLINICAL TRIALS FRAMEWORK

- History of Clinical Trials
- Trials Ecosystem in Europe
- EU Trials - Shift from Directive 2001/20/EC
- Focus: Safety, Transparency and Efficiency
- Key Differences vs. Directive

MODULE 2 - REGULATORY AUTHORITIES AND THEIR ROLES

- Understanding Ethics
- EU Regulatory Authorities and Ethics Committees
- EMA's Coordination Role, NCA Jurisdiction per Member State
- Ethics Review and Trial Approval
- Guidance and Resources to Execute Trials

MODULE 3 - CLINICAL TRIALS AND APPLICATION PROCESS

- Trial Designs & Clinical Trial Protocol
- Submitting a Clinical Trial Application (CTA)
- Using the EU CTIS Portal
- Required Documents and Dossier
- Submission Timelines and Review
- Contracts and Budgeting
- New Initiatives and Trial Designs

MODULE 4 - GOOD CLINICAL PRACTICE (GCP) STANDARDS

- Good Clinical Practice (GCP) Standards
- Core Principles of GCP
- Sponsor/Investigator Responsibilities
- Subject Protection and Data Integrity
- Case Studies - Rare Disease Trials & Gene Therapy Trials

MODULE 5 - SAFETY REPORTING IN CLINICAL TRIALS

- Pharmacovigilance & Safety Monitoring
- Adverse Event (AE) & Serious AE reporting
- Development Safety Update Reports(DSURs)
- Use of EudraVigilance

MODULE 6 - PATIENT PARTICIPATION & INFORMED CONSENT

- Ethical & Legal Safeguards
- Informed Consent Process & Forms
- Special Provisions for Vulnerable Groups
- Patient Recruitment and Retention
- Equality, Diversity and Inclusive Research
- GDPR and Data Confidentiality

MODULE 7 - INVESTIGATIONAL MEDICINAL PRODUCTS (IMPS) MANAGEMENT

PROGRAM AGENDA

- Handling IMPs Across Trial Phases
- Manufacturing and Labeling Requirements
- Supply Chain and Traceability, Storage, Dispensing, and Accountability
- EU Regulatory Pathways for ATMPs

MODULE 8 - DELIVERING MULTI-NATIONAL TRIALS IN THE EU

- Overcoming Hurdles to Deliver Multinational Randomised Trials
- Managing Cross-Border Submissions
- Dealing with Multiple NCAs
- Harmonizing Ethics Approvals
- Navigating National Variances

MODULE 9 - INSPECTIONS AND AUDITS

- Inspection Readiness & Compliance
- Common Findings and Risk Areas
- Roles in Sponsor/Investigator Site Audits
- CAPA Planning and Follow-up

MODULE 10 - TRIAL CLOSE-OUT AND ARCHIVING

- Finalization and Reporting
- Reporting Trial Results and Transparency
- Meeting Archiving Standards
- Data Access and Retention Timelines

MODULE 11 - CLINICAL TRIALS IN MEDTECH (DEVICES & ARTIFICIAL INTELLIGENCE)

- Device vs. Drug Trials
- Device Classification
- How to Conduct Device Trials
- Big Data and Machine Learning
- Device Case Exemplars
- Case Studies: Cart-T Cells in Europe & AI and Clinical Trials

MODULE 12 - RISK-BASED QUALITY MANAGEMENT IN CLINICAL TRIALS

- Implementing a Risk-Based Approach
- Identifying and Evaluating Trial Risks
- Centralized vs. On-site Monitoring
- Quality Assurance and SOP Alignment

MODULE 13 - CLINICAL TRIALS LEADERSHIP & MANAGEMENT

- Leadership and Excellence in Trials
- Building and Sustaining a Successful Trials Team
- Clinical Trials Management Skills

YOUR CHARTER DESIGNATION

Chartered Institute of Professional Certifications' programs are unique as they provide you with professional charter designations and marks that can be used across your lifetime once you have completed our programs.

Upon completion of the program and successfully passing the Chartered exam, you will be awarded the prestigious **Certified EU Clinical Trials Project Manager (CCT™)** designation, which can be showcased in your resume, CV, and other professional credentials. Developed by the esteemed **Chartered Institute of Professional Certifications**, positions you as a leader in managing complex, multinational clinical trials within the European regulatory landscape. It demonstrates your mastery of the EU Clinical Trials Regulation, patient safety, risk mitigation, regulatory compliance, and best practices essential to driving trial quality and ethical standards. This certification will enhance your credentials, showcase your leadership in clinical trial project management, and empower you to advance innovative therapies efficiently and compliantly across Europe.

The program's content has been independently accredited and certified by the **Continuing Professional Development (CPD) organization**, guaranteeing adherence to rigorous standards of professional development.

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Chartered Institute of Professional Certifications

All of Chartered Institute of Professional Certifications programs are fully accredited programs. The professional charters and designations are trademarked credentials that can only be used by professionals who have completed and passed our accredited program. It is also independently accredited by CPD as adhering to the highest standards of continuing professional principles.

OUR FACULTY DIRECTORS

We Collaborate With Instructors From Renowned Institutions

HARVARD UNIVERSITY

Wharton University of Pennsylvania

Stanford University

University of Michigan

LSE The London School of Economics and Political Science

Columbia Business School

London Business School

CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

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