CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

CERTIFIED UK CLINICAL TRIALS PROJECT MANAGER ™

CCT ™

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

CCT™
CERTIFIED UK CLINICAL TRIALS PROJECT MANAGER™

PROGRAM OVERVIEW

UK clinical trials project management is highly complex due to multifaceted challenges like recruitment, regulatory approvals, and resource coordination. On average, pharmaceutical-led **projects face 102 days for R&D approvals, 90 days for ethics, and 83 days for regulatory clearance**, significantly slowing trial initiation. Additionally, **45% of multicenter trials fail to recruit 80% of target participants on time, leading to costly delays**. Managing numerous stakeholders across diverse sites and adhering to stringent regulations adds significant operational complexity in UK trials.

This certified program is designed to equip you with robust, end-to-end knowledge of clinical trial project management within the UK's regulatory ecosystem. You will gain a comprehensive understanding of **UK Clinical Trials Regulation, MHRA and HRA requirements, the Clinical Trial Authorisation (CTA) process, and Combined Review submissions through the Integrated Research Application System (IRAS)**. You will explore the **full trial lifecycle from protocol design and site initiation to monitoring, data management, pharmacovigilance, and study closure** ensuring compliance with both national and international standards.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

PROGRAM OVERVIEW

Through practical case studies and interactive sessions, you will develop the ability to apply **Quality-by-Design principles, conduct effective risk-based quality management (RBQM), and oversee vendors, CROs**, and research sites with measurable KPIs. The program also covers critical competencies in **ethical approvals, informed consent (including e-Consent for vulnerable populations), safety reporting under E2 and E19, and maintaining inspection readiness** through strong documentation practices, including the Trial Master File (TMF) and Good Documentation Practices (GDP).

Beyond regulatory compliance, you will develop proven clinical trial project management strategies to **anticipate and mitigate trial delays, accelerate ethics and governance approvals, and optimize patient recruitment** across NHS networks. Through real world case studies and practical applications, you will master **stakeholder alignment across sponsors, CROs, investigators, and regulatory authorities**, while integrating validated digital systems to strengthen audit readiness and real-time data oversight.

Upon successful completion, you will attain the **Certified UK Clinical Trials Project Manager (CCT™)** designation, a globally recognized certification that validates your professional competence to lead, manage, and oversee complex clinical trials in compliance with MHRA, HRA, and ICH-GCP (R3) standards. This industry-recognized certification has lifelong validity and positions you as a trusted leader in the UK clinical research and project management.

ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

KEY SKILLS YOU WILL GAIN

From This Program

- CLINICAL TRIAL PROJECT PLANNING
- ICH-GCP (R2/R3) COMPLIANCE
- MHRA & HRA REGULATORY NAVIGATION
- CLINICAL TRIAL AUTHORISATION (CTA) MANAGEMENT
- NHS RESEARCH GOVERNANCE APPLICATION
- ETHICAL APPROVAL & INFORMED CONSENT MANAGEMENT
- PROTOCOL DESIGN & AMENDMENT CONTROL
- QUALITY-BY-DESIGN (QBD) IMPLEMENTATION
- RISK-BASED QUALITY MANAGEMENT (RBQM)
- VENDOR & CRO OVERSIGHT
- SITE SELECTION & PERFORMANCE MONITORING
- BUDGETING & RESOURCE ALLOCATION
- CONTRACT NEGOTIATION & MANAGEMENT
- DATA INTEGRITY & ALCOA++ PRINCIPLES
- ELECTRONIC DATA CAPTURE (EDC) OVERSIGHT
- PHARMACOVIGILANCE & SAFETY REPORTING (AE/SAE/SUSAR)

YOUR FACULTY DIRECTOR

Fiona Wallace, BSc (Hons)

Renowned Clinical Research Director, Global Trainer, and Certified GCP Compliance Expert

Fiona Wallace is an accomplished clinical research leader and educator with over 25 years of global experience spanning CROs and pharmaceutical organizations across multiple continents. As **Director of FW Clinical Research, she has successfully led Phase I–IV clinical trial studies across multiple disciplines**, bringing deep operational insight into every stage of the clinical trial process.

Renowned for her engaging and practical teaching style, Fiona designs high-impact learning solutions that drive workforce engagement, retention, and regulatory excellence. Her expertise covers **clinical monitoring, project management, global clinical regulatory training, and inspection readiness, with a strong focus on GCP compliance, data integrity, and patient safety**.

A respected **Board Member of The Institute of Clinical Research (ICR), Fiona actively collaborates with UK universities to inspire the next generation of life science professionals**. Her mission is to cultivate excellence, resilience, and ethical integrity across the global clinical research community.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1 - UK CLINICAL RESEARCH LANDSCAPE AND ECOSYSTEM

- Key UK Stakeholders: MHRA, HRA, REC, NIHR, NHS Trusts
- UK Clinical Trials Regulation and Post-Brexit Implications
- Commercial and Academic Trial Dynamics
- Industry Trends and Strategic Opportunities
- Interplay of the EU CTR with GCP R3
- Comparative Analysis of ICH Regions and Their National Regulatory Requirements

MODULE 2 - ICH-GCP PRINCIPLES AND COMPLIANCE (E6 R2/R3)

- Core Principles and Key Updates in ICH E6(R2) & R3
- Responsibilities of Project Managers under GCP
- Data Integrity and Quality Standards
- Integrating GCP into Daily Workflows
- New Approaches by R3 – Risk Proportionate Approach

MODULE 3 - RESEARCH GOVERNANCE AND ETHICS FRAMEWORK

- NHS Research Governance Principles
- Differentiating Research Governance vs. Ethics vs. Regulatory Approvals
- Combined Review and Integrated Research Application System (IRAS)
- Governance Processes in NHS Trusts

MODULE 4 - ETHICAL APPROVAL AND INFORMED CONSENT

- Process of REC and HRA Submission and Review
- Role and Perspective of Ethics Committee Members
- Informed Consent Design (Paper, eConsent, Vulnerable Groups)
- Ethical Considerations in Trial Design

MODULE 5 - CLINICAL TRIAL AUTHORISATION (CTA) PROCESS

- MHRA Submission Requirements and Notification Schemes
- Key Documents: Protocol, Investigator's Brochure, IMPD
- Combined Review Mechanics and Timelines
- Maintaining and Updating CTA Authorizations

MODULE 6 - PROTOCOL DEVELOPMENT AND AMENDMENTS

- Quality by Design and Critical to Quality Factors

PROGRAM AGENDA

- Scientific and Operational Alignment in Protocol Drafting
- Substantial vs. Non-Substantial Amendments
- Managing Protocol Changes and Timelines

MODULE 7 - SITE SELECTION, INITIATION, AND OVERSIGHT

- Feasibility Assessments and Site Qualification Criteria
- Conducting Efficient Site Initiation Visits (SIVs)
- Ongoing Site Engagement and Performance Management
- Handling Non-Compliance and Protocol Deviations

MODULE 8 - PROJECT MANAGEMENT TOOLS AND TECHNIQUES

- Project Lifecycle Planning and Milestone Tracking
- Risk Assessment and Risk-Based Quality Management (RBQM)
- Budget Control, Forecasting, and Resource Allocation
- Issue Escalation, Continuous Improvement, and Documentation

MODULE 9 - CLINICAL TRIAL CONTRACTS AND VENDOR MANAGEMENT

- Vendor Identification, Selection, and Qualification
- Contractual Terms, Negotiation, and Templates (CROs, Sites, Vendors)
- Oversight Responsibilities and KPIs for Third Parties
- Managing Amendments, Service Delays, and Deliverables
- Practical Measures for How to Conduct Oversight and What an Inspector Would Want to See in Place

MODULE 10 - DATA MANAGEMENT AND EDC OVERSIGHT

- Data Lifecycle in Clinical Trials and Regulatory Expectations
- CRF Design, Query Management, and Database Lock
- Computerised Systems Validation (CSV) and Audit Trails
- Ensuring ALCOA++ Principles and GDPR Compliance

MODULE 11 - SAFETY REPORTING AND PHARMACOVIGILANCE

- Definitions and Classifications of AEs/SAEs/SUSARs

PROGRAM AGENDA

- Safety Documentation: DSUR, SUSAR Timelines
- Role of DMCs and Safety Monitoring Boards
- Reporting to MHRA and Ethics Committees
- Revised Safety Reporting Requirements Under R3 in Alignment with E2 and E19

MODULE 12 - MONITORING, QA, AND INSPECTION READINESS

- Centralized, Remote, and On-site Monitoring Models
- Quality Assurance (QA) vs. Quality Control (QC)
- MHRA Inspection Process, Planning, and CAPA Management
- Common Audit Findings and Mitigation Strategies

MODULE 13 -TRIAL MASTER FILE (TMF) AND DOCUMENTATION

- TMF Reference Model and Essential Document Management
- Best Practices in Good Documentation Practice (GDP)
- eTMF Systems and Real-time Audit Readiness
- Archiving and Record Retention Obligations
- Proportionate Documentation Management Under R3: Referencing DIA CDISC TMF Model

MODULE 14 - STUDY CLOSURE, REPORTING AND TRANSPARENCY

- Clinical Study Reports (CSR) and Lay Summaries
- Database Lock and Statistical Analysis Plan Execution
- Summary Results Posting and Public Disclosure
- Transparency Initiatives (e.g., EU CTR, UK HRA Expectations)

MODULE 15 - INNOVATIONS AND FUTURE OF UK CLINICAL TRIALS

- O'Shaughnessy Report and UK Strategy for Clinical Research Growth
- Decentralized and Hybrid Trial Models
- Digital Health Tools (ePROs, Wearables, Telemedicine)
- AI/ML Applications in Recruitment, Monitoring, and Risk Detection
- Influence and Application of Annex 2

EXAMINATION

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 completing the program and passing the Chartered exam, you will be awarded with the **Certified UK Clinical Trials Project Manager (CCT™) designation** that can be used in your resume, CV and other professional credentials. This certification is industry-recognized with lifelong validity.

Globally demanded and recognized, this certification demonstrates your expertise in navigating the UK's complex clinical trial regulatory landscape. It equips you the expertise to manage trial operations, ensure GCP compliance, and uphold the highest standards of ethics, safety, and data integrity. Developed by **Chartered Institute of Professional Certifications**, the content of this program has been independently accredited by **CPD Certification Service** as adhering to the highest standards of continuing professional principles.

ABOUT US

49,525 Business Leaders Have Attained Their Chartered Certifications Since 2009

390 Certified and Fully Accredited Programs

87% Chartered Leaders Have Reported Career Promotions and Enhancements

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

Singapore and Asia Pacific Enquiries

Email: advisor@charteredcertifications.com
Phone: +65 6716 9980
Address: Chartered Institute of Professional Certifications
1 Gateway Drive
#20-04 Westgate Tower
Singapore 608531

Australia and New Zealand Enquiries

Email: advisor@charteredcertifications.com
Phone: +61 3 9909 7310
Address: Chartered Institute of Professional Certifications
530 Little Collins Street, Level 1
Melbourne VIC 3000, Australia

UK, Europe and Middle East Enquiries

Email: advisor@charteredcertifications.com
Phone: +44 (020) 335 57898
Address: Chartered Institute of Professional Certifications
86-90 Paul Street
London, EC2A 4NE

USA Enquiries

Email: advisor@charteredcertifications.com
Phone: +1 888 745 8875
Address: Chartered Institute of Professional Certifications
99 Wall Street #3936
New York, NY 10005