

CHARTERED 
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

CERTIFIED UK GOOD CLINICAL PRACTICE MANAGER™

CGCP™

**Fully Accredited
By:**

Chartered Institute of
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CPD
Certification Service



PROGRAM OVERVIEW



UK firms continue to fail Medicines and Healthcare products Regulatory Agency (MHRA) GCP inspections due to systemic gaps in documentation, data integrity, and oversight. Inspection data shows that **nearly 100% of sponsor inspections and around 60–65% of investigator sites report major or critical findings, with about 25% facing critical deficiencies.** Top-performing organizations avoid these pitfalls by embedding robust quality management systems, ensuring real-time data integrity, and maintaining continuous inspection readiness – rather than relying on reactive compliance.

This live program delivers a comprehensive, end-to-end command of the UK clinical trials ecosystem, equipping you to lead compliant and inspection-ready studies from concept through close-out. You will gain authoritative expertise navigating key regulatory frameworks including **MHRA, HRA, REC approvals, IRAS submissions, and NHS site setup processes,** while building strong capabilities in **feasibility assessments, protocol development, study approvals, and site activation strategies.** The program also strengthens your command of sponsor-investigator responsibilities, delegation practices, and governance oversight across multidisciplinary research teams.

Throughout the program, you will build hands-on operational expertise in informed consent, participant

ACCREDITATIONS



4.8



4.6



PROGRAM OVERVIEW



eligibility, recruitment and retention strategies, and compliance with UK's clinical regulations. Strong emphasis is placed on **ALCOA+ data integrity principles, Trial Master File (TMF) and Investigator Site File (ISF) management, source documentation standards,** and maintaining audit-ready records under intensifying regulatory scrutiny. You will also gain practical expertise in safety and pharmacovigilance processes, including AE, SAE, and SUSAR reporting requirements. The program further explores advanced GCP management areas such as **risk-based monitoring, CAPA implementation, protocol deviation management, and inspection readiness.** By the end, you will be fully equipped to manage compliance risks, strengthen governance frameworks, and lead high-quality, ethically sound, and regulation-compliant clinical trials across the UK clinical research environment.

Upon completing the program and passing the Chartered exam, you will earn the **Certified Good Clinical Practice Manager (CGCP™)** designation – a credential that demonstrates your expertise in overseeing ethical, high-quality, and inspection-ready clinical trials in the UK. This CGCP™ designation distinguishes you as a trusted leader in driving compliant, high-performing clinical research internationally.

ACCREDITATIONS



4.8



4.6



KEY SKILLS YOU WILL GAIN

From This Program



**ADVANCED ICH GCP R3 COMPLIANCE
UK CLINICAL TRIALS GOVERNANCE
MHRA INSPECTION STRATEGY
HRA & REC APPROVALS MASTERY**

**IRAS SUBMISSION EXCELLENCE
NHS SITE SETUP & CCC APPROVALS
END-TO-END TRIAL LIFECYCLE LEADERSHIP
PROTOCOL & CIP DESIGN EXPERTISE**

**STRATEGIC FEASIBILITY & EOI PLANNING
INVESTIGATOR & SPONSOR OVERSIGHT
HIGH-PERFORMANCE SITE MANAGEMENT
INFORMED CONSENT EXCELLENCE**

**PATIENT RECRUITMENT OPTIMIZATION
RETENTION STRATEGY EXECUTION
ALCOA+ DATA INTEGRITY LEADERSHIP
TMF & ISF EXCELLENCE
AUDIT-READY DOCUMENTATION SYSTEMS**

**SOURCE DATA GOVERNANCE
PHARMACOVIGILANCE & SAFETY REPORTING**

YOUR FACULTY DIRECTOR



Karl Ward

Clinical Research Education & GCP Governance Leader

Karl Ward is a distinguished clinical research leader, educator, and GCP specialist **with over 27 years of healthcare experience, including 18 years in clinical trials across NHS** and academic environments.

He is the **Educational, Operational, and Strategic Lead** at the Leeds Research and Innovation Academy, where he designs and delivers high-impact training in GCP, clinical trials governance, and research delivery for multidisciplinary teams. With **more than 19 years of teaching experience**, Karl has delivered extensive face-to-face and virtual GCP programs and has **served as a National Institute for Health and Care Research (NIHR) GCP facilitator** for over 13 years, including leading regional train-the-trainer initiatives.

Karl holds postgraduate qualifications in Education, Clinical Research, and Healthcare Leadership and **is a Fellow of the Higher Education Academy (FHEA)**. He also brings over 9 years of consulting experience with leading UK institutions. A **published researcher and innovative educator**, he is widely recognized for advancing clinical research capability through practical, evidence-based, and technology-enabled learning.

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PROGRAM AGENDA



MODULE 1 - ICH GCP OVERVIEW AND UK CLINICAL TRIALS LANDSCAPE

- Background to GCP
- Importance of research
- National changes and updates
 - ICH GCP R3 Session
 - Increased United Kingdom (UK) commercial focus
 - Updates to Recruitment to Time and Target (RTT) metrics

MODULE 2 - THE CLINICAL TRIALS RESEARCH PROCESS

- Types of research
- New and adaptive trial design and decentralized trials
- CTIMPs, ATMPs & device studies

MODULE 3 - REGULATORY FRAMEWORKS, QUALITY STANDARDS AND STANDARDS

- Overview
- Medicines for Human Use (Clinical Trials) Regulations (2004) & ICH GCP R3 Updates 2025/26
- UK Policy Framework for Health and Social Care Research (2017)
 - IRMER
 - HTA

- Professional guidance and accountability

MODULE 4 - COMPETENT, REGULATORY AUTHORITIES AND RESEARCH ETHICS COMMITTEES

- Introduction to competent authorities and their role in regulation
- Medicines and Healthcare products Regulatory Authority (MHRA)
 - European Medicines Agency (EMA)
 - FDA
- Health Research Authority (HRA)
 - Study approvals
 - Research Ethics Committees (RECs)
- Other regulatory authorities
 - IRMER
 - HTA

MODULE 5 - PRINCIPAL INVESTIGATOR & RESEARCH DELIVERY TEAM (SITE) RESPONSIBILITIES

- Definitions
- Team and role specific roles and responsibilities
- The art of delegation
- Royal College of Physicians (2017) "Teams in Healthcare" report (2017)

PROGRAM AGENDA



- Key PI responsibilities
 - Oversight
 - Delegation

MODULE 6 - SPONSOR RESPONSIBILITIES

- Chief Investigator (CI)
- Finance / Funding
- Contract Research Organisations (CRO)
- Safety
- Data & medical safety committees

MODULE 7 - CLINICAL PROTOCOLS, CLINICAL INVESTIGATION PLANS (CIPs) AND AMENDMENTS

- Definitions
- Key elements of a protocol / CIP
- Modifications (Amendments)
- Deviations
- Violations

MODULE 8 - STUDY SET-UP AND APPROVALS

- Why do we need approvals?
- REC approval
- Integrated Research Application System (IRAS)

- NHS Site approvals
 - NHS Confirmation of Capacity and Capability (CCC)
 - Key Service Support (KSS) departments

MODULE 9 - EXPRESSION OF INTEREST (EOI) AND FEASIBILITY

- Key considerations during EOI and Feasibility
- Different types of feasibility
- Site level conduct of EOI and feasibility
 - “Top tips” and where it can go wrong

MODULE 10 - SCREENING, ELIGIBILITY AND INFORMED CONSENT

- Definitions
- Who can confirm eligibility in CTIMPs
- Different and alternative approaches to informed consent

MODULE 11 - RECRUITMENT AND RETENTION

- When to start planning recruitment and retention strategies
- 6 factor approach to recruitment and retention
- Factors that improve and hinder recruitment and retention

PROGRAM AGENDA



MODULE 12 - ESSENTIAL DOCUMENTATION

- Definitions - Source data
- Types of Medical Records - Electronic / Paper
 - Source data location sheets
 - Source data worksheets
- Annotations & standards of documentation
- CRF / eCRF
 - ALCOAC +
 - Corrections
- Trial Master File (TMF)
 - More regulatory scrutiny
- Investigator Site File (ISF)
- Note to file / File notes

MODULE 13 - ESTABLISHING, MAINTAINING AND FACILITATING OVERSIGHT

- Definitions of oversight
- Types of oversight
- Establishing and facilitating oversight

MODULE 14 - SAFETY AND ADVERSE EVENTS

- Key Adverse Event definitions (AE / AR / SAE / SAE / SUSAR)

- Expedited reporting
- Importance of follow up
- Investigator brochure
- SmPC
- Concomitant medication

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 successfully attending this program, you will be awarded the **Certified Good Clinical Practice Manager (CGCP™)** designation, which can be added to your resume, CV, and other professional credentials. This industry-recognized certification carries lifelong validity.

Globally recognized, this certification affirms your expertise in leading ethically sound, regulatory-compliant clinical trials in the UK. It demonstrates your authority to apply GCP principles within complex governance frameworks, oversee stakeholder responsibilities, and ensure participant safety and data integrity across diverse trial settings. Developed by the **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.

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CONTACT US TODAY

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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