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CERTIFIED AUSTRALIA CLINICAL TRIALS PROJECT MANAGER™

CCT ™

Fully Accredited By:

Chartered Institute of Professional Certifications

CPD Certification Service

CCT™
CERTIFIED AUSTRALIA CLINICAL TRIALS PROJECT MANAGER™

PROGRAM OVERVIEW

Despite Australia's reputation for high-quality research and a robust healthcare system, nearly **50% of clinical trials experience delays due to fragmented ethics review processes and inconsistent approval timelines across states**. Additionally, inconsistent interpretation of regulatory requirements among HRECs and study sites frequently results in repeat submissions and extended review cycles.

This certified program will provide you with the regulatory clarity, operational structure, and practical tools needed to navigate these challenges and deliver trials on time and in full compliance. You will gain a clear understanding of the **TGA CTN/CTX pathways, the National Statement on Ethical Conduct, HREC expectations, and the practical application of ICH-GCP E6(R2)/E6(R3)** across Australia. The curriculum covers the full **clinical trial lifecycle—including planning, feasibility, budgeting, contracting, site initiation, monitoring, safety oversight, quality management, and close-out**—ensuring you can manage every stage with confidence.

Through real-world examples, you will build practical competency in **Quality-by-Design, risk-based quality management (RBQM), and structured risk mitigation**, including identifying critical data, critical processes, and quality tolerance limits. You will also learn how to coordinate cross-functional teams in **Clinical Operations, Data Management, Biostatistics, Pharmacovigilance, and Medical Affairs**, while addressing common challenges such as data integrity issues, remote monitoring limitations, and cross-team delays.

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PROGRAM OVERVIEW

The program will strengthen your expertise in **informed consent, adverse event reporting, safety reconciliation, and documentation excellence**—especially Trial Master File (TMF) integrity and TGA inspection readiness through strong oversight frameworks. You will also gain hands-on experience with monitoring plans, hybrid oversight models, KPI-driven performance management, and end-of-trial responsibilities such as Clinical Study Report (CSR) preparation, archiving, and regulatory notifications.

By integrating regulatory knowledge with operational and project-management best practices, this program prepares you to **deliver efficient, high-performing, and inspection-ready clinical trials** across Australia's complex research environment.

Upon successful completion, you will attain the **Certified Australia 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 HREC, and ICH-GCP (R3) standards. This industry-recognized certification has lifelong validity and positions you as a trusted leader in the Australia clinical research and project management.

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KEY SKILLS YOU WILL GAIN

From This Program

TGA CTN/CTX MASTERY
MULTI-HREC SUBMISSION MANAGEMENT
ETHICS REVIEW NAVIGATION
ICH-GCP E6(R2/R3) COMPLIANCE

RISK-BASED MONITORING (RBM)
QUALITY-BY-DESIGN (QBD) APPLICATION
RISK-BASED QUALITY MANAGEMENT (RBQM)
CRITICAL DATA IDENTIFICATION

PROTOCOL FEASIBILITY ASSESSMENT
TRIAL BUDGETING EXCELLENCE
SITE SELECTION STRATEGY
CONTRACT & CTA NEGOTIATION

VENDOR & CRO OVERSIGHT
RECRUITMENT & RETENTION PLANNING
INFORMED CONSENT MANAGEMENT
ADVERSE EVENT REPORTING
SAFETY DATA RECONCILIATION

TMF MANAGEMENT & INTEGRITY
AUDIT & INSPECTION READINESS

YOUR FACULTY DIRECTOR

Melinda Borrelli

Renowned Clinical Research and GCP Compliance Expert

Melinda Borrelli is a distinguished Clinical Research Professional with over 20 years of expertise in Australia's biotechnology industry. Her career encompasses a variety of roles that have cultivated a deep understanding of clinical research complexities, making her an expert mentor in the field.

Proficient in project management, **Melinda has demonstrated her expertise through her proficiency in Electronic Data Capture (EDC), Good Clinical Practice (GCP), Clinical Trials, and CRO management**. Now a **certified vocational Trainer and Assessor**, Melinda has transitioned to educating others, drawing on her extensive experience to guide peers through their professional development. She is a **compelling presenter, known for engaging and enlightening audiences at both local and international conferences**. Melinda Borrelli continues to be a catalyst for growth and excellence in the clinical research field, nurturing new talent and enhancing professional standards through her dynamic leadership and commitment to advancing clinical research practices.

OUR PARTICIPANTS

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

PROGRAM AGENDA

MODULE 1: INTRODUCTION TO CLINICAL TRIAL PROJECT MANAGEMENT IN AUSTRALIA

- Overview of the Australian clinical trials landscape
- Role of the Clinical Trials Project Manager (CTPM)
- Course structure, expectations, and certification requirements

MODULE 2: CLINICAL TRIAL REGULATIONS AND GOVERNANCE IN AUSTRALIA

- TGA regulatory framework (CTN vs CTX)
- National Statement on Ethical Conduct in Human Research
- GCP (ICH E6 R2/R3) compliance in the Australian context

MODULE 3: ETHICS AND HUMAN RESEARCH ETHICS COMMITTEE (HREC) SUBMISSIONS

- Navigating HREC approval processes
- Informed consent protocols and participant protections
- HREC query resolution

MODULE 4: PROJECT PLANNING AND TRIAL LIFECYCLE

- Trial phases and milestones
- Work Breakdown Structure (WBS) and Gantt chart planning
- Key performance indicators for trial success

MODULE 5: SITE SELECTION, FEASIBILITY, AND INITIATION

- Criteria for selecting trial sites in Australia
- Investigator/site contracts and budgets
- Site feasibility failure and lessons learned

MODULE 6: CLINICAL TRIAL MONITORING AND OVERSIGHT

- Monitoring plans and visit types
- Remote monitoring in a post-COVID environment

MODULE 7: CLINICAL DATA MANAGEMENT AND ALCOA+ PRINCIPLES

- Data collection and query resolution
- ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate + Completeness, Consistency, Enduring, Available)
- Data integrity breach and remediation

MODULE 8: CROSS-FUNCTIONAL CLINICAL TRIAL OPERATIONS

- Understanding cross functional stakeholders and their role

PROGRAM AGENDA

- Collaboration with cross functional leads (Clinical operations, data management, biostatistics, medical affairs, pharmacovigilance)
- Resolving delays caused by cross functional misalignment

MODULE 9: QUALITY RISK MANAGEMENT IN CLINICAL TRIALS

- Quality risk management & planning
- Critical Data & Processes
- Key risk indicators & quality tolerance limits
- Contingency planning
- Identifying critical data & processes and applying risk management

MODULE 10: LEADERSHIP AND STAKEHOLDER COMMUNICATION

- The mindset shift to project manager
- Building effective relationships
- Conflict resolution with a sponsor over data queries

MODULE 11: REGULATORY READINESS AND QUALITY OVERSIGHT

- Preparing for audits and inspections (TGA, FDA, EMA)
- CAPA (Corrective and Preventive Action) strategies
- Quality assurance system essentials

MODULE 12: SAFETY REPORTING AND PHARMACOVIGILANCE

- SAE/SUSAR reporting obligations in Australia
- Safety data reconciliation and communication with regulators
- Handling an urgent safety alert

MODULE 13: TRIAL REPORTING AND CLOSE-OUT

- Clinical Study Report (CSR) requirements
- End-of-trial notifications (TGA, HREC, sites)
- Archiving and record retention

MODULE 14: FUTURE TRENDS IN CLINICAL TRIAL PROJECT MANAGEMENT

- Decentralised Clinical Trials (DCTs) in Australia
- Digital health tools and remote patient monitoring
- Sustainability and diversity considerations in trial design

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 Australia 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 Australia'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.

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We Thank You for Your Ongoing Support of Our Programs

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