



CLASSROOM COURSES



Please see the calendar for all course dates. Our website provides further Course Registration & Information.

GCP for Research Professionals

About the Course Good Clinical Practice for Clinical Research Professionals is an intensive training course designed to boost knowledge and understanding of good clinical practice and locally applicable regulations and guidelines. Such training will translate into a reduction in the volume of data queries and minimize the time and expense associated with getting investigational products to patients. The goal is to help participants conduct cleaner, safer, and more efficient trials. [Course Certificate provided.](#)

Who should apply Whether you are a clinical research physician, investigator, study coordinator, or other member of the study team, this course will provide you with the intensive training needed to improve your trials and ensure compliance with Good Clinical Practice, TGA Regulations, EU Directives and ICH Guidelines. This course is designed for those who have either less than two year's experience conducting clinical trials on human subjects or who require a comprehensive up-to-date refresher course for local and international regulatory requirements.

GCP for Physicians & Investigators

About the Course This is a workshop based course which focuses on the basics of conducting clinical research trials within the Australian and International regulatory requirements. This includes principles of Good Clinical Practice (GCP), the drug development process, comparison and contrast drug and device research, current regulatory and ethical issues in clinical research, legal and insurance issues and adverse experiences as they affect the investigators perspective. [Course Certificate provided.](#)

Who should apply This course is designed for investigators who have either less than two year's experience conducting clinical trials on human subjects or who require a comprehensive up-to-date refresher course for local and international regulatory requirements.

Certification Exam Review Course (CRC and CRA)

About the Course CRA & CRC certification exam review courses are offered each winter and summer to prepare candidates for the annual March and September certification exams. The purpose of each exam review course is to help prospective candidates assess their level of preparation and identify regulatory information resources.

Who should apply The Association of Clinical Research Professionals (ACRP) exam review courses are designed for CRAs and CRCs involved in the conduct of clinical research who meet the eligibility requirements for the certification examination. Participants should plan to sit for the certification examination within a year of taking the exam review course.

“I wish I knew about it when I first started!”

CERTIFICATION



ACRP Certification for Research Professionals (EXAM: CPI, CRC and CRA)

About the EXAM Certification is the formal recognition of clinical research professionals who have met professional eligibility requirements and demonstrated at least a minimal level of job-related knowledge and skills. ACRP's certification is granted in recognition of documented and verified work experience and successful performance on a multiple-choice exam. ACRP offers three certification exams, one for Clinical Research Associates/CRAs, one for Clinical Research Coordinators/CRCs and one for Clinical Trial Investigators/CPIs. The exams are based on the industry job analysis to ensure the exams reflect CRAs, CRCs, and CPIs responsibilities & tasks.

Please see the ACRP website www.acrpn.org for exam dates, eligibility information and application forms: CRI, CRA, CRC

Who should apply To be eligible to take the ACRP exams, each candidate must fulfil one of the following two combinations of education and working experience as a research professional. For the purpose of meeting the working experience requirement, a minimum of 35-40 hours per week qualifies as full-time employment and a minimum of 20 hours per week qualifies as part-time employment, completed prior to the exam date.

“We all found the process very useful professionally”



CLASSROOM SEMINARS



Attend these seminars with or without the online courses

Seminar Certificate provided.

GCP Case Study Seminar

Seminar Objectives	This seminar provides a series of case study opportunities to examine the typical challenges faced in daily clinical trials. Learn to apply newly gained knowledge to real life situations. In addition, gain useful working resources.
Target Audience	Clinical researchers working in any area who wish to review and apply their knowledge gained in formal GCP training.

SOP Writing Seminar

Seminar Objectives	The SOP Writing Seminar is a unique opportunity to gain efficiency in this sometimes overwhelming task. Ranging from understanding where to begin, what format, minimum requirements and gaining a full appreciation of the process and its components, attendees will benefit from a day with handy templates and resources.
Target Audience	Clinical researchers responsible for creating their SOP and Quality System.

Budgeting, Feasibility & Finance Seminar

Seminar Objectives	This seminar provides an overall understanding of financial concepts. Learn how to identify the factors in determining if a trial will break even or make a profit. Methods of maintaining cash flow and identifying which the decision makers in the process should be involved.
Target Audience	Clinical researchers needing a system of financial management and project profit viability.

Research Governance Seminar

Seminar Objectives	Research Governance is intrinsic to patient safety and risk management. Understanding the comprehensive key regulatory responsibilities and managing them, along with building compliant sites is the challenge for site research offices. Gain knowledge and resources to achieve this end.
Target Audience	Clinical researchers responsible for research governance and compliance at their site.

These seminars complement the rigorous training of our extensive online program

Customise your learning

“Very informative, useful study material provided. Very useful for people considering a career in clinical research”

RESOURCES



Certification Exam Review Package (CPI, CRC and CRA)

About the Pack	The Exam Prep Package includes four (4) sections: a Certification Exam Preparation Guide, a Helpful Hints document, and a 50-question Self-Assessment Test. If you're comfortable with independent study, this comprehensive package will give you the guidance you need to make the most of your study time.
Target Audience	ACRP's exam review courses are designed for CRAs and CRCs eligible exam candidates comfortable with independent study. This comprehensive package will give you the guidance you need to make the most of your study time.

GCP Q&A Reference Guide

About the Book	Newly updated and expanded for 2009, this industry-leading GCP training and reference guide answers approximately 700 of the most common and difficult questions regarding the day-to-day interpretation and implementation of GCP standards for drugs and biologics. While having a U.S./FDA focus, this innovative reference pocket guide has now been expanded to provide even more information on not just US GCP, but also international GCP issues.
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ONLINE COURSES



Course AA. Site Personnel - Core GCP Training

Group AA.1. Introduction

- Topic AA.1.1. Introduction to Clinical Research
- Topic AA.1.2. Principles of GCP
- Topic AA.1.3. Ethical Considerations in Clinical Research
- Topic AA.1.4. Clinical Trials in Australia
- Topic AA.1.5. Investigator Responsibilities
- Topic AA.1.6. Phases of Clinical Trials

Group AA.2. Informed Consent

- Topic AA.2.1. Informed Consent – Elements & Documentation
- Topic AA.2.2. Informed Consent – Process and Exceptions

Group AA.3. Study Conduct

- Topic AA.3.1. Site Selection, Pre-Study and Initiation Visits
- Topic AA.3.2. Essential Documents in Clinical Research
- Topic AA.3.3. Study Drug Accountability
- Topic AA.3.4. Safety Reporting
- Topic AA.3.5. Routine Site Monitoring Visits
- Topic AA.3.6. Site Audits

Course AB. Site Personnel - Adv GCP Training 1

Group AB.1. Study Document Development

- Topic AB.1.1. Protocol Writing
- Topic AB.1.2. CRF Design

Group AB.2. Site Contract and Budget

- Topic AB.2.1. Site Contract & Budget
- Topic AB.2.2. Investigational Site Study Budget

Group AB.3. Ethical Review and Regulatory Applications

- Topic AB.3.1. HREC Ethical Review
- Topic AB.3.2. CTN / CTX Applications

Group AB.4. Additional Topics

- Topic AB.4.1. Subject Recruitment & Retention
- Topic AB.4.2. Data Management
- Topic AB.4.3. Electronic Records & Signatures

Course AC. Sponsor Personnel/CRA - Core GCP Training

Group AC.1. Introduction

- Topic AC.1.1. Introduction to Clinical Research
- Topic AC.1.2. Principles of GCP
- Topic AC.1.3. Ethical Considerations
- Topic AC.1.4. Clinical Trials in Australia

Group AC.2. Trial Preparation

- Topic AC.2.1. Phases of Clinical Trials
- Topic AC.2.2. Protocol Writing
- Topic AC.2.3. CRF Design
- Topic AC.2.4. Informed Consent I -- Elements & Documents
- Topic AC.2.5. Essential Documents in Clinical Research

Group AC.3. Trial Start-up

- Topic AC.3.1. Monitoring: Site Selection
- Topic AC.3.2. Monitoring: Pre-study Visits
- Topic AC.3.3. Monitoring: Site Initiation
- Topic AC.3.4. Informed Consent II -- Process & Exceptions

Group AC.4. Trial Monitoring

- Topic AC.4.1. Routine Site Monitoring
- Topic AC.4.2. Monitoring: CRF Review & SDV
- Topic AC.4.3. Monitoring: Safety Reporting
- Topic AC.4.4. Monitoring: Drug Accountability
- Topic AC.4.5. Site Close-out

Course AD. Sponsor Personnel/CRA - Adv GCP Training 1

Group AD.1. – Roles & Responsibilities

- Topic AD.1.1. Sponsor/Vendor Responsibilities
- Topic AD.1.2. Investigator Responsibilities

Group AD.2. – Drug Development & Design

- Topic AD.2.1 Drug Discovery & Development
- Topic AD.2.2. Clinical Trial Design

Group AD.3. – Regulatory Submissions

- Topic AD.3.1. CTN / CTX Application
- Topic AD.3.2. Clinical Study Report (CSR)

Group AD.4. – Compliance & Audits

- Topic AD.4.1. Clinical Quality Assurance (CQA)
- Topic AD.4.2. SOPs in Clinical Research
- Topic AD.4.3. Sponsor Compliance & Audits
- Topic AD.4.4. Site Audit
- Topic AD.4.5. Electronic Records & Signatures

Course AE. Site/Sponsor/CRA Personnel - Adv Training 2

Group AE.1. – Data Management & Biostatistics

- Topic AE.1.1. Data Management
- Topic AE.1.2. Biostatistics 1: Introduction to Biostatistics
- Topic AE.1.3. Biostatistics 2: Data analysis & reporting

Group AE.2. – Project Planning & Management

- Topic AE.2.1. Project Management Fundamentals
- Topic AE.2.2. Integrated Project Management

Group AE.3. – Vendor Selection & Management

- Topic AE.3.1. Vendor Selection
- Topic AE.3.2. Vendor Management

Group AE.4. – Additional Topics

- Topic AE.4.1. Medical Terminology
- Topic AE.4.2. IND Application
- Topic AE.4.3. NDA Application

“I have learnt a significant amount of new information despite 10 years of experience working as a research coordinator. The course has been delivered in a very informative way with many useful links.”

Course Certificate provided.

www.clinfosource.com/Australia



2010 COURSE CALENDAR

	VIC	NSW	QLD	SA	WA	NZ
GCP for Research Professionals	Mar 3-4 May 31-Jun 1 Jul 29-30 Oct 25-26	Mar 23-24 ! Nov 11-12 !	★	May 3-4 !	!	◆
GCP Seminars	Jun 23-24 Oct 20-21	Mar 22 ! Nov 8-9	★	May 6-7		
GCP For Investigators	Jun 02	Nov-10	★	May 5		◆
Certification Review Courses	Mar 01, 02 Aug 07					
! Subject to a minimum number of registrants						
★ Contact CNS	+61 7 3331 3933	info@clinical.net.au		www.clinical.net.au		
◆ Contact Beltas	+64 9 520 2410	training@beltas.com		www.beltas.com		

Fiona Wood, Australian of the year (2005), one of our previous course participants, made the following comment:

“As we progress medical care into the future we need to do so with an understanding of clinical evidence.

Research governance is essential in implementing GCP. The framework is one which protects patients, researchers, clinicians and providers.

Therefore education is key to ensuring our evidence is sound and Australia is a desirable environment to undertake clinical research.”



For more information contact



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Courses endorsed by

