

## About the University of Melbourne

The University of Melbourne is among the oldest and largest universities in Australia. It is a research intensive, comprehensive institution with a strong postgraduate commitment. It aims to be one of the finest universities in the world - a proud institution of higher learning producing graduates, scholarships and research that matters to the nation and beyond.

## About ARCS Australia Ltd

ARCS Australia Ltd is a professional development association for people working in the development of therapeutic goods. Founded in 1984, ARCS is a "not for profit" company governed by an elected Board. ARCS has approximately 2,500 members who are involved in regulatory affairs, clinical research, health economics, medical devices, diagnostics, medical devices, data management, statistics, medical writing, pharmacovigilance, and the provision of medical information in the Australian pharmaceutical and health care industries.

# More Information

**For information on University enrolment, please contact the Program Manager.  
For all other enquires, please contact the Subject Coordinator.**

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**For further information please go to our websites**

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#### DISCLAIMER

The information in this brochure was correct at the time of printing. The University reserves the right to make changes as appropriate. Changes may be made to such things as course content and presenters. Students will be advised of changes as soon as practicable.

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THE UNIVERSITY OF  
MELBOURNE



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Professional Development for the Therapeutics Industry™

2009

# Specialist Certificate in Clinical Trials (Clinical Trials Monitoring)

## A Clear Pathway For Your Career

**Are you new to clinical trial monitoring and ready to take control of your career?**

ARCS Australia in partnership with the University of Melbourne have developed a new program for clinical research professionals. The Specialist Certificate in Clinical Research (Clinical Trials Monitoring) provides an opportunity for ARCS members to combine structured learning with workplace application and coaching. This program will provide you with the information, requirements, techniques, tips and inside knowledge you need to effectively monitor and manage investigational trial sites. A program which will take you from clinical trial monitoring to the project management of investigational trial sites.

For employers, this new course will provide your new clinical trial monitoring staff with all the technical knowledge required to understand their roles, responsibilities and obligations under the regulations, ICH-GCP and company procedures.

Using flexible delivery to meet the needs of busy clinical research professionals, each student will work with ARCS Australia to develop a personalised program to meet their learning needs. Modules can be undertaken nationally through ARCS Australia and are combined with relevant professional work experience in your workplace.

Students who successfully complete this program will understand:

- The drug development pathway and its link to clinical research
- The role of the CRA in clinical research
- The purpose and operational responsibilities of a CRA in maintaining the quality standards defined by Australian legislation and international Good Clinical Practice guidelines
- The purpose and role of regulatory documents necessary for initiating and running a clinical trial
- How to effectively manage clinical research sites
- How to manage risk when working with clinical research sites
- The role of project management in good clinical practice
- How to provide input in the implementation of clinical research studies within Australia

### Who should attend:

This program is designed for clinical research professionals wanting to improve their capabilities in clinical trial site monitoring. This includes science graduates, nurses and allied health workers involved in studies that must comply with ICH-GCP and relevant Australian legislation.

### All students must meet the following Entry Requirements:

- Be a full member of ARCS Australia Ltd
- Have an undergraduate degree or equivalent qualification in medicine, nursing, an allied health profession, science or social science which is recognised by the University of Melbourne
- Have documented evidence of at least 6 months full-time relevant professional work experience
- Have documented evidence that they will be able to undertake relevant professional work experience during the course



# Course & Subject Details

**This Specialist Certificate in Clinical Trials (Clinical Trials Monitoring) will prepare new CRAs to undertake clinical trial monitoring and enable them to play a more substantial role in the management and operations of clinical trials. The success of the program relies on the identification of a coach or mentor who will provide support for you and continue the learning back in the workplace for the duration of the course.**

## PROGRAM STRUCTURE

- **Subject 1: Clinical Trial Site Monitoring**
- **6 months relevant work experience**
- **Subject 2: Clinical Trial Site Management**

## SUBJECT 1 CLINICAL TRIAL SITE MONITORING

During this subject, students will be provided with an overview of drug development and the critical role the CRA plays in this process. Structured lectures and practical workshop sessions will provide the opportunity to learn the fundamentals of monitoring a clinical trial effectively. There are three workshops in this subject which are compulsory for all students.

### Subject 1 Assessment

- One open book test representing 20% of the total mark
- Two 1000 word assignments, each representing 25% each of the total mark
- One 1500 word workplace assignment representing 30% of the total mark.

**Students must achieve a mark of at least 50% in each assessment to achieve a pass grade for this subject.**

### Overview of Drug Development (7 hours)

- The process of discovering and developing new pharmaceutical products
- Description of the organisation of the Australian regulatory authority, their requirements and interactions with sponsor companies
- The activities associated with conducting clinical research and reporting the results and responsibilities of various departments in accomplishing these activities
- Ethical considerations underpinning clinical studies
- Knowledge about concepts and functions associated with ensuring overall quality of studies

### CRA1: Essential GCP Training for New CRAs (14 hours)

- Therapeutic goods and their regulation and access to unapproved therapeutic goods
- Critical concepts in clinical development, including protocol development
- The role of the CRA in research
- Good Clinical Practice
- Getting a study started and putting together an ethics submission
- Clinical trial approvals
- Adverse event management
- Clinical trial monitoring - the whole story...
- Audit and common quality findings

### Managing Regulatory Documents (3 hours)

- The purpose and value of regulatory and essential documents
- The principles which make documents 'acceptable' in clinical trials
- Levels of control of documents
- Best practice for essential/regulatory document management

## SUBJECT 2 CLINICAL TRIAL SITE MANAGEMENT

During this subject, students will build up the knowledge and requirements to more effectively manage investigational sites. Student will have the option to select a minimum of 10 hours of electives, depending on their needs, followed by the compulsory capstone topic.

### Subject 2 Assessment

- One assignment for each elective, with a combined word count of at least 2000 words and a total contribution of 40% of the marks for the subject.
- One 2000 word assignment for the capstone module, representing 40% of the total marks
- One 1000 word overall workplace assignment representing 20% of the marks

**Students must achieve a mark of at least 50% in each assessment to achieve a pass grade for this subject.**

## FEES

For the Specialist Certificate are AS\$4,200. (\$2,100 per subject)

## TIME COMMITMENT

Each subject of the specialist certificate involves 24 hours of lectures. In addition to face-to-face teaching time, students should expect to undertake a minimum of 120 hours research, reading, writing assignments and general study to complete this subject successfully.

# Electives & Capstone

## Fundamentals of Project Management (7 hours)

- Decide when work effort should be treated as a project
- Use a simple model to manage projects
- Apply motivational and team building techniques to gain support and buy-in
- Employ practical leadership and communications skills to ensure coordination and collaboration during the project

## How to Effectively Select Investigational Sites (3 hours)

- Identify the typical steps and phases in an effective investigational site selection
- Risk management during site selection
- Outline challenges and strategies during investigator site selection

## Effective Management of GCP Issues (3 hours)

- Deconstructing clinical processes and GCP issues
- Using evidenced based problem solving and causality assessment
- Developing appropriate corrective and preventative actions

## Research Ethics and Governance (3 hours)

- Overview of human ethics system
- Site specific assessment
- Roles of key stakeholders
- Resources and strategies to facilitate the approval process

## Introduction to Pharmacovigilance (3 hours)

- How adverse events are defined and managed
- The difference between Causality, Seriousness and Expectedness
- Local regulations and reporting requirements for adverse events

## Clinical Statistics for Non-Statisticians (14 hours)

- Basic statistical concepts
- Hypothesis testing
- Study designs
- Analysis plan
- Survival analysis
- A trial for superiority
- A trial for equivalence
- Meta analysis

## Managing Laboratories in Clinical Research (14 hours)

- Pre-analytical factors – sample collection
- Standards and Quality Control
- Quality Assurance and Laboratory Accreditation
- Reference Ranges
- Lab Tour (half day)
- Sample Logistics
- Managing Data

## Either Assertiveness in the Workplace (7 hours) Or Managing and Resolving Conflict in Teams (7 hours)

### Assertiveness in the Workplace

- Assertiveness: what is it and why it matters
- Aggressive v. Submissive v. Assertiveness
- Learning to be assertive
- Manipulation v. Influencing
- How to give feedback
- Sticking to the bottom line
- Negotiating as equals

### Managing & Resolving Conflict in Teams

- What is conflict? Identifying levels of conflict
- Appropriate conflict management style
- Barriers to effective communication
- Improving active listening skills
- Checking for understanding
- Being empathetic

## CAPSTONE

### CRA2 – Managing your Trial Sites More Effectively (14 hours)

- Things to consider when planning your study
- Importance of study feasibility assessments
- Site selection: how to apply risk minimising strategies in an actual site selection visit
- Managing the informed consent process
- Recruitment strategies and contingencies
- Investigational product (IP) management
- Supporting your sites - applying management strategies that work
- Investigator training - what can I do to stand out from the crowd?
- Fraud and misconduct