COURSE OUTLINE

# BIM303 Clinical Trials Management

**School:** School of Health - Biomedicine

2023 | Session 8

UniSC Sunshine Coast
UniSC Moreton Bay

BLENDED LEARNING

Most of your course is on campus but you may be able to do some components of this course online.

*Please go to usc.edu.au for up to date information on the teaching sessions and campuses where this course is usually offered.*

## 1. What is this course about?

### 1.1. Description

Clinical trials are research studies in humans that evaluate the effect of a behavioral, medical or surgical intervention. This course introduces you to the principles of clinical research, including Good Clinical Practice (GCP), as well as pre-clinical drug development, regulatory affairs, and human research ethics. As part of this course, you will complete an internationally recognized accredited GCP certificate, which is a requirement for any professional working in clinical trials.

### 1.2. How will this course be delivered?

| ACTIVITY | HOURS | BEGINNING WEEK | FREQUENCY |
|---|---|---|---|
| **BLENDED LEARNING** | | | |
| **Learning materials** – A series of e-modules on clinical trial coordination, which includes six (6) training modules offered through Praxis. (Online) | 2hrs | Week 4 | 6 times |
| **Tutorial/Workshop 1** – Tutorials covering theoretical concepts of clinical trials. Please note - there will be three tutorials in week 1 and three tutorials in week 2; there will then be one tutorial in week 3 and one tutorial in week 7. (F2F on-campus) | 3hrs | Week 1 | 8 times |
| **Tutorial/Workshop 2** – Discussion sessions to assist with completing the Praxis Australia modules. Please note - these will be scheduled in weeks 4, 5 and 6. (F2F - optional on-campus or via Zoom) | 1hr | Week 4 | 3 times |
| **Fieldwork** – Field trip to the USC Clinical Trial Centre at Morayfield. (F2F off-campus) | 4hrs | Week 3 | Once Only |

### 1.3. Course Topics

1. Drug discovery and preclinical development
2. Overview of the clinical trial process
3. Human research ethics
4. Patient communication and informed consent
5. Data collection during clinical trials
6. Principles of Good Clinical Practice (GCP)
7. Regulation of drugs and devices
8. Essential documentation in clinical trials
9. Research monitoring and audit
10. Safety monitoring and reporting
11. Principles of research governance
12. Role and responsibilities of clinical trial stakeholders

## 2. What level is this course?

300 Level (Graduate)

Demonstrating coherence and breadth or depth of knowledge and skills. Independent application of knowledge and skills in unfamiliar contexts. Meeting professional requirements and AQF descriptors for the degree. May require pre-requisites where discipline specific introductory or developing knowledge or skills is necessary. Normally undertaken in the third or fourth full-time study year of an undergraduate program.

## 3. What is the unit value of this course?

12 units

## 4. How does this course contribute to my learning?

| COURSE LEARNING OUTCOMES<br>On successful completion of this course, you should be able to... | | GRADUATE QUALITIES<br>Completing these tasks successfully will contribute to you becoming... |
|---|---|---|
| 1 | Capably and confidently demonstrate knowledge of the process of drug development, from preclinical testing to regulatory approval. | Knowledgeable |
| 2 | Identify and apply professional responsibilities according to appropriate national decision making frameworks for human research ethics. | Ethical |
| 3 | Describe the current regulatory and ethical environment for clinical trials with unapproved therapeutic goods and the role of the different stakeholders involved in this process. | Knowledgeable |
| 4 | Demonstrate proficiency in documentation practices required in the commencement of a clinical trial. | Empowered |
| 5 | Explain and describe the principles of Good Clinical Practice (GCP) in consent processes, quality data collection and compliance with reporting requirements. | Empowered |
| 6 | Develop tools to interact with various stakeholders involved in the conduct of clinical research. | Engaged |
| 7 | Critically evaluate technical documentation required to effectively commence and manage a clinical trial. | Creative and critical thinker |

## 5. Am I eligible to enrol in this course?

Refer to the UniSC Glossary of terms for definitions of “pre-requisites, co-requisites and anti-requisites”.

### 5.1. Pre-requisites

BIM263 Introduction to Pharmacology.

### 5.2. Co-requisites

Not applicable

### 5.3. Anti-requisites

Not applicable

### 5.4. Specific assumed prior knowledge and skills (where applicable)

It is recommended that students have some prerequisite knowledge of pharmacology, research methods and basic statistics.

## 6. How am I going to be assessed?

### 6.1. Grading Scale

Standard Grading (GRD)

High Distinction (HD), Distinction (DN), Credit (CR), Pass (PS), Fail (FL).

### 6.2. Details of early feedback on progress

Students may seek guidance from the course coordinator on the structure and content of their Human Research Ethics Assignment (Task 1a). Also, students will have a revision session prior to the Review Quiz (Task 2), which will be based on theory covered during Workshops 1 to 6.

### 6.3. Assessment tasks

| DELIVERY MODE | TASK NO. | ASSESSMENT PRODUCT | INDIVIDUAL OR GROUP | WEIGHTING % | WHAT IS THE DURATION / LENGTH? | WHEN SHOULD I SUBMIT? | WHERE SHOULD I SUBMIT IT? |
|---|---|---|---|---|---|---|---|
| All | 1 | Portfolio | Individual | 40% | Varied throughout session | Throughout teaching period (refer to Format) | Online Assignment Submission with plagiarism check |
| All | 2 | Quiz/zes | Individual | 20% | 1-hour duration; multi-choice questions. Total 50 marks. | Week 3 | In Class |
| All | 3 | Examination - Centrally Scheduled | Individual | 40% | 2-hour duration; multiple-choice and short answer questions. Total 100 marks. | Exam Period | Online Test (Quiz) |

**All - Assessment Task 1:** Theory Work Portfolio

| | |
|---|---|
| **GOAL:** | To provide you with an opportunity to:<br>a). Demonstrate your understanding of the human research ethics process in Australia and your ability to make ethical decisions in relation to clinical research, and<br>b). Demonstrate your knowledge of Australian regulatory requirements and Good Clinical Practice (GCP). |
| **PRODUCT:** | Portfolio |
| **FORMAT:** | The following activities will make up the Task 1 Theory Work Portfolio:<br>Task 1a. Human Research Ethics Assignment (1000 words +/- 10%) - 30%, week 4.<br>Task 1b. Online Training Module Completion - 10%, week 7. |
| **CRITERIA:** | |

| No. | | Learning Outcome assessed |
|---|---|---|
| 1 | Identification of the key ethical issues presented in the case study. | 2 |
| 2 | Analysis and decision making related to the ethical issues in the case study. | 2 4 6 |
| 3 | Quality of the overall structure of the assignment, including introduction, main body and conclusion. | 4 |
| 4 | Use of primary and secondary sources of literature selected for the assignment. | 5 |
| 5 | Overall presentation of the assignment, including word count, structure and formatting, quality of written expression (sentence structure, spelling and grammar), citations and referencing. | 5 |

| | |
|---|---|
| **GENERIC SKILLS:** | Communication, Problem solving, Applying technologies, Information literacy |

**All - Assessment Task 2:** Review Quiz

| | |
|---|---|
| **GOAL:** | To provide you with an opportunity to demonstrate your knowledge of the drug development process, from preclinical testing through to regulatory approval. |
| **PRODUCT:** | Quiz/zes |
| **FORMAT:** | The review quiz will contain 50 multiple-choice questions. It will examine the material covered during Workshops 1 to 6. |
| **CRITERIA:** | |

| No. | | Learning Outcome assessed |
|---|---|---|
| 1 | Apply theoretical knowledge about the drug development process and study design for clinical trials as identified in the course face-to-face tutorials. | 1 |
| 2 | Use evidence-based reasoning from your knowledge and understanding of the course content to provide correct answers to multiple-choice questions. | 1 7 |

| | |
|---|---|
| **GENERIC SKILLS:** | Problem solving, Applying technologies, Information literacy |

**All - Assessment Task 3:** End-of-Session Exam

| | |
|---|---|
| **GOAL:** | In this assessment task, you will be able to demonstrate, apply and evaluate your theoretical and practical knowledge of the principles of clinical research and regulatory affairs as they relate to clinical trials. |
| **PRODUCT:** | Examination - Centrally Scheduled |
| **FORMAT:** | The exam will consist of multiple-choice and short answer questions for a total of 100 marks and will be based on the materials covered in the course workshops and field trip as well as the course learning materials including the online Praxis Australia training modules. |
| **CRITERIA:** | |

| No. | | Learning Outcome assessed |
|---|---|---|
| 1 | Demonstrate and apply knowledge of the principles of clinical research and regulatory affairs. | 1 3 5 7 |
| 2 | Analyse information and explain important elements involved in the conduct of clinical research. | 2 4 5 7 |
| 3 | Use evidence-based reasoning from your knowledge and understanding of clinical trial coordination to provide correct answers to the multiple-choice and short answer questions. | 3 |

| | |
|---|---|
| **GENERIC SKILLS:** | Problem solving, Applying technologies, Information literacy |

# 7. Directed study hours

A 12-unit course will have total of 150 learning hours which will include directed study hours (including online if required), self-directed learning and completion of assessable tasks. Student workload is calculated at 12.5 learning hours per one unit.

## 7.1. Schedule

| PERIOD AND TOPIC | ACTIVITIES |
|---|---|
| Drug discovery and preclinical development. | An overview of the drug development process.<br>Key stakeholders in drug development.<br>History of drug discovery.<br>Target identification.<br>Finding and optimising lead compounds.<br>Preclinical (nonclinical) development.<br>Pharmacological testing.<br>The Investigator's Brochure. |
| Overview of the clinical trial process. | Overview of the clinical trial process.<br>Phases I, II, III and IV clinical trials.<br>Research design for clinical trials. |
| Human research ethics in clinical trials. | What is human research ethics and why is it needed in clinical trials?<br>Fundamental principles in human ethics underpinning the National Statement.<br>Gaining ethics approval for human research.<br>Roles of the Human Research Ethics Committee.<br>Case studies in human research ethics. |
| Patient communication and informed consent. | Effective and compassionate patient communication<br>What is informed consent and why is it needed in clinical trials?<br>Obtaining informed consent<br>Limited disclosure<br>Importance of confidentiality |
| Data collection during clinical trials. | Importance of accurate data collection<br>Data collection tools<br>Source data verification |

| PERIOD AND TOPIC | ACTIVITIES |
|---|---|
| Principles of Good Clinical Practice (GCP) | Define Good Clinical Practice<br>Laws and guidelines that govern the conduct of clinical research<br>Roles and responsibilities of stakeholders involved in clinical research |
| Regulation of drugs and devices | Need for regulation of drugs and medical devices.<br>Regulatory framework for drugs and medical devices in Australia.<br>Funding of medicines and medical devices in Australia<br>Events in the later phases of the medicines lifecycle |
| Essential documentation in clinical trials | Essential Documents<br>Source Documentation<br>Storage requirements for different documents in clinical trials.<br>Safety form types, completion and maintenance<br>Safety reporting responsibilities |
| Research monitoring and audit | Monitoring a clinical trial, including the key stages<br>Risk Based Monitoring<br>Auditing a clinical trial |
| Safety monitoring and reporting | Adverse event<br>Adverse incident<br>Information included in a safety report<br>Expedited reporting based on seriousness, causality and expectedness |
| Principles of research governance | Ethical principles and guidelines for the responsible conduct of research in Australia.<br>Elements of research governance. What needs to be considered by Australian institutions when governing research conducted under their auspices?<br>What is site-specific assessment?<br>Establishing a clinical trial agreement.<br>The importance of insurance and indemnity in clinical trials. |
| Role and responsibilities of clinical trial stakeholders, including the clinical trial coordinator (CRC) and pharmacy. | Specific responsibilities of the CRC in relation to study set-up and conduct of the study.<br>Importance of Good Clinical Practice (GCP) for the CRC.<br>Scheduling challenges faced by CRCs.<br>Role of CRCs in overseeing quality assurance and safety in clinical trials, including minimising risk on treatment days.<br>General role of the pharmacist in clinical trials.<br>Pre-study activities of the pharmacist.<br>Shipment and receipt of the Investigational Medicinal Product (IMP).<br>Dispensing and accountability.<br>Monitoring and study conclusion responsibilities. |

## 8. What resources do I need to undertake this course?

Please note: Course information, including specific information of recommended readings, learning activities, resources, weekly readings, etc. are available on the course Canvas site– Please log in as soon as possible.

### 8.1. Prescribed text(s) or course reader

> There are no required/recommended resources for this course.

### 8.2. Specific requirements

There are no prescribed textbooks for the BIM303 course. You will be provided access to the online training modules offered by Praxis Australia via the BIM303 Canvas site. In addition, you will be referred to government websites that contain important documents that outline guidelines and information associated with monitoring and managing clinical trials in Australia. There also will be readings that you will need to download from the BIM303 Canvas site for the tutorial classes.

## 9. How are risks managed in this course?

Health and safety risks for this course have been assessed as low. It is your responsibility to review course material, search online, discuss with lecturers and peers and understand the health and safety risks associated with your specific course of study and to familiarise yourself with the University's general health and safety principles by reviewing the online induction training for students, and following the instructions of the University staff.

## 10. What administrative information is relevant to this course?

### 10.1. Assessment: Academic Integrity

Academic integrity is the ethical standard of university participation. It ensures that students graduate as a result of proving they are competent in their discipline. This is integral in maintaining the value of academic qualifications. Each industry has expectations and standards of the skills and knowledge within that discipline and these are reflected in assessment.

Academic integrity means that you do not engage in any activity that is considered to be academic fraud; including plagiarism, collusion or outsourcing any part of any assessment item to any other person. You are expected to be honest and ethical by completing all work yourself and indicating in your work which ideas and information were developed by you and which were taken from others. You cannot provide your assessment work to others. You are also expected to provide evidence of wide and critical reading, usually by using appropriate academic references.

In order to minimise incidents of academic fraud, this course may require that some of its assessment tasks, when submitted to Canvas, are electronically checked through Turnitin. This software allows for text comparisons to be made between your submitted assessment item and all other work to which Turnitin has access.

### 10.2. Assessment: Additional Requirements

Your eligibility for supplementary assessment in a course is dependent of the following conditions applying:
- The final mark is in the percentage range 47% to 49.4%.
- The course is graded using the Standard Grading scale.
- You have not failed an assessment task in the course due to academic misconduct.

### 10.3. Assessment: Submission penalties

Late submission of assessment tasks may be penalised at the following maximum rate (the rates are cumulative):
- 5% (of the assessment task's identified value) per day for the first two days from the date identified as the due date for the assessment task.
- 10% (of the assessment task's identified value) for the third day
- 20% (of the assessment task's identified value) for the fourth day and subsequent days up to and including seven days from the date identified as the due date for the assessment task.
- A result of zero is awarded for an assessment task submitted after seven days from the date identified as the due date for the assessment task.

Weekdays and weekends are included in the calculation of days late.
To request an extension you must contact your course coordinator to negotiate an outcome.

### 10.4. SafeUniSC

UniSC is committed to a culture of respect and providing a safe and supportive environment for all members of our community. For immediate assistance on campus contact SafeUniSC by phone: 07 5430 1168 or using the SafeZone app. For general enquires contact the SafeUniSC team by phone 07 5456 3864 or email safe@usc.edu.au.

The SafeUniSC Specialist Service is a Student Wellbeing service that provides free and confidential support to students who may have experienced or observed behaviour that could cause fear, offence or trauma. To contact the service call 07 5430 1226 or email studentwellbeing@usc.edu.au.

### 10.5. Study help

For help with course-specific advice, for example what information to include in your assessment, you should first contact your tutor, then your course coordinator, if needed.

If you require additional assistance, the Learning Advisers are trained professionals who are ready to help you develop a wide range of academic skills. Visit the Learning Advisers web page for more information, or contact Student Central for further assistance: +61 7 5430 2890 or studentcentral@usc.edu.au.

### 10.6. Wellbeing Services

Student Wellbeing provide free and confidential counselling on a wide range of personal, academic, social and psychological matters, to foster positive mental health and wellbeing for your academic success.

To book a confidential appointment go to Student Hub, email studentwellbeing@usc.edu.au or call 07 5430 1226.

## 10.7. AccessAbility Services

Ability Advisers ensure equal access to all aspects of university life. If your studies are affected by a disability, learning disorder mental health issue, injury or illness, or you are a primary carer for someone with a disability or who is considered frail and aged, AccessAbility Services can provide access to appropriate reasonable adjustments and practical advice about the support and facilities available to you throughout the University.

To book a confidential appointment go to Student Hub, email AccessAbility@usc.edu.au or call 07 5430 2890.

## 10.8. Links to relevant University policy and procedures

For more information on Academic Learning & Teaching categories including:

- Assessment: Courses and Coursework Programs
- Review of Assessment and Final Grades
- Supplementary Assessment
- Central Examinations
- Deferred Examinations
- Student Conduct
- Students with a Disability

For more information, visit https://www.usc.edu.au/explore/policies-and-procedures#academic-learning-and-teaching

## 10.9. Student Charter

UniSC is committed to excellence in teaching, research and engagement in an environment that is inclusive, inspiring, safe and respectful. The Student Charter sets out what students can expect from the University, and what in turn is expected of students, to achieve these outcomes.

## 10.10. General Enquiries

**In person:**

- **UniSC Sunshine Coast** - Student Central, Ground Floor, Building C, 90 Sippy Downs Drive, Sippy Downs
- **UniSC Moreton Bay** - Service Centre, Ground Floor, Foundation Building, Gympie Road, Petrie
- **UniSC SouthBank** - Student Central, Building A4 (SW1), 52 Merivale Street, South Brisbane
- **UniSC Gympie** - Student Central, 71 Cartwright Road, Gympie
- **UniSC Fraser Coast** - Student Central, Student Central, Building A, 161 Old Maryborough Rd, Hervey Bay
- **UniSC Caboolture** - Student Central, Level 1 Building J, Cnr Manley and Tallon Street, Caboolture

**Tel:** +61 7 5430 2890

**Email:** studentcentral@usc.edu.au