COURSE OUTLINE

BIM303 Clinical Trials Management

School: School of Health - Biomedicine

2025 | 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 unisc.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 preclinical 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 – eModules for each course topic.	2hrs	Week 1	13 times
Tutorial/Workshop 1 – Delivered in an intensive format in weeks 1-4 (F2F on-campus).	3hrs	Week 1	13 times
Tutorial/Workshop 2 – Delivered in weeks 5-8 (F2F via Zoom).	2hrs	Week 5	4 times
Fieldwork – Excursion to the UniSC Clinical Trial Centre at Morayfield, scheduled in weeks 2, 3 or 4, depending on availability (F2F off-campus).	4hrs	Refer to Format	Once Only

1.3. Course Topics

1. Drug discovery, preclinical development and medical device development
2. Clinical research studies
3. Human research ethics and governance in clinical trials
4. Roles and responsibilities of clinical trial stakeholders
5. Clinical trial phases and participant eligibility
6. Patient communication and the informed consent process
7. Consumer involvement and engagement in clinical trials
8. Documentation and data collection during clinical trials
9. Auditing and monitoring in clinical trials
10. Clinical trial safety: monitoring and reporting
11. Regulation and pharmacovigilance
12. Clinical trials: special circumstances and what the future may hold
13. Principles of Good Clinical Practice (GCP)

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 On successful completion of this course, you should be able to...		GRADUATE QUALITIES 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 or BIM341 Biochemical 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.

5.5. Microcredential Information

Not applicable

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

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	Quiz/zes	Individual	30%	2-hour duration.	Week 3	In Class
All	2	Artefact - Technical and Scientific	Individual	35%	Varied throughout session	Refer to Format	Online Assignment Submission with plagiarism check
All	3	Examination - Centrally Scheduled	Individual	35%	2-hour duration.	Exam Period	Exam Venue

All - Assessment Task 1: Review Quiz

GOAL:	To provide you with an opportunity to demonstrate your knowledge of clinical trials, from drug discovery and preclinical testing through to regulatory approval.
PRODUCT:	Quiz/zes
AUTHORSHIP STATEMENT:	
FORMAT:	The review quiz will contain a combination of multi-choice and short answer questions. Please refer to our course Canvas site for more details.
CRITERIA:	**No.** — **Learning Outcome assessed** 1 — Apply theoretical knowledge about clinical trials, from drug discovery and preclinical testing through to regulatory approval, as per the course content. — 1 3 4 7
GENERIC SKILLS:	Problem solving, Applying technologies, Information literacy

All - Assessment Task 2: Theory Work Portfolio

GOAL:	To provide you with an opportunity to: 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 b). Demonstrate your knowledge of Good Clinical Practice (GCP).
PRODUCT:	Artefact - Technical and Scientific
AUTHORSHIP STATEMENT:	
FORMAT:	The following activities will make up the Task 2 Theory Work Portfolio: Task 2a. Human Research Ethics Assignment (1000 words +/- 10%) - 30%, week 6. Task 2b. Online Training Module Completion - 5%, week 7. Please refer to our course Canvas site for more details.
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	Understanding the importance of Good Clinical Practice (GCP) as it relates to clinical trials.	5

GENERIC SKILLS:	Communication, 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
AUTHORSHIP STATEMENT:	
FORMAT:	The exam will consist of a combination of multiple-choice and short answer questions. Please refer to our course Canvas site for more details.
CRITERIA:	

No.		Learning Outcome assessed
1	Apply theoretical knowledge about clinical trials, from drug discovery and preclinical testing through to regulatory approval, as per the course content.	1 3 4 7

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
Topic 1	Drug discovery, preclinical development and medical device development
Topic 2	Clinical research studies
Topic 3	Human research ethics and governance in clinical trials
Topic 4	Roles and responsibilities of clinical trial stakeholders
Topic 5	Clinical trial phases and participant eligibility
Topic 6	Patient communication and the informed consent process
Topic 7	Consumer involvement and engagement in clinical trials
Topic 8	Documentation and data collection during clinical trials
Topic 9	Auditing and monitoring in clinical trials
Topic 10	Clinical trial safety: monitoring and reporting
Topic 11	Regulation and pharmacovigilance
Topic 12	Clinical trials: special circumstances and what the future may hold
Topic 13	Principles of Good Clinical Practice (GCP)

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 an online training module 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

Eligibility for Supplementary Assessment

Your eligibility for supplementary assessment in a course is dependent of the following conditions applying:
(a) The final mark is in the percentage range 47% to 49.4%; and
(b) The course is graded using the Standard Grading scale

10.3. Assessment: Submission penalties

Late submissions may be penalised up to and including the following maximum percentage of the assessment task's identified value, with weekdays and weekends included in the calculation of days late:
(a) One day: deduct 5%;
(b) Two days: deduct 10%;
(c) Three days: deduct 20%;
(d) Four days: deduct 40%;
(e) Five days: deduct 60%;
(f) Six days: deduct 80%;
(g) Seven days: A result of zero is awarded for the assessment task.

The following penalties will apply for a late submission for an online examination:
Less than 15 minutes: No penalty
From 15 minutes to 30 minutes: 20% penalty
More than 30 minutes: 100% penalty

10.4. 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

10.5. 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.

10.6. 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

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