PPCT8000

Foundations of Clinical Trials

Session 1, Online-flexible 2024

Macquarie Medical School

Contents

General Information

Unit convenor and teaching staff
Unit Convenor
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By appointment only (online or in-person consultations)

Credit points
10

Prerequisites

Corequisites

Co-badged status

Unit description
This foundation unit introduces you to the role of clinical research and different trial phases in the development process of therapeutics and other interventions. This unit focuses on the core knowledge and skills which underpin a career in clinical trial operations through an overview of the Australian and international regulations governing clinical trials, the breadth of trials being undertaken and the impact of trials on the economy. You will explore the different roles and responsibilities of clinical trial professionals in ethically designing, implementing, and monitoring safe and efficient patient-centred clinical trials according to the Good Clinical Practice (GCP) guidelines. The role of ethical guidelines and the necessity of protocol compliance in generating quality data, protecting study participants, and answering the clinical research question will be discussed. You will learn about the key concepts of identifying appropriate trial design, recruitment strategies, cultural safety, data security and confidentiality and preserving integrity of the clinical research. This unit is co-designed with industry and offers a range of online learning activities including pre-recorded industry expert lectures, real-world case studies, and industry relevant assessments. You will receive a GCP certification upon successful completion of this unit.

Important Academic Dates

Information about important academic dates including deadlines for withdrawing from units are available at https://www.mq.edu.au/study/calendar-of-dates

Learning Outcomes

On successful completion of this unit, you will be able to:

ULO1: Recognise the role and impact of clinical trials research and its design on clinical practice and product development. (Capability 1 - Scientist and Scholar)

ULO2: Define the Australian and the global regulatory environment and its impact on clinical research integrity and patient safety. (Capability 3 - Engaged Global Citizen)

ULO3: Discuss roles and responsibilities in designing, implementing, and monitoring safe and efficient patient-centred clinical trials according to the Good Clinical Practice guidelines. (Capability 2 - Clinical Trial Practitioner)

ULO4: Recognise the role of ethical guidelines and the necessity of protocol compliance in protecting study participants, data security and confidentiality and preserving integrity of clinical research. (Capability 4 - Professional)

ULO5: Interpret study protocol requirements and aspects of the participant consent process, expectations, rationale of clinical equipoise and therapeutic misconception, diverse needs, privacy requirements, and continuance of post-trial care. (Capability 2 - Clinical Trial Practitioner)

ULO6: Consider cultural and diverse ethical issues that arise for minority and vulnerable groups participating in clinical trials and identify strategies that encourage regional and cultural diversity in clinical trials, including engaging Aboriginal and Torres Strait Islander peoples in trials. (Capability 3 -Engaged Global Citizen)

General Assessment Information

Grade descriptors and other information concerning grading are contained in the Macquarie University Assessment Policy.

All final grades are determined by a grading committee, in accordance with the Macquarie University Assessment Policy, and are not the sole responsibility of the Unit Convenor.

Students will be awarded a final grade and a mark which must correspond to the grade descriptors specified in the Assessment Procedure (clause 128 and 129).

To pass this unit, you must demonstrate sufficient evidence of achievement of the learning outcomes, meet any ungraded requirements, and achieve a final mark of 50 or better.

Further details for each assessment task will be available on iLearn.

Late Submissions

Unless a Special Consideration request has been submitted and approved, a 5% penalty (OF THE TOTAL POSSIBLE MARK) will be applied each day an assessment is not submitted, up until the 7th day (including weekends). After the 7th day, a grade of '0' will be awarded even if the assessment is submitted. Submission time for all written assessments is set at 11.55pm. A 1-hour grace period is provided to students who experience a technical concern.

For example:

Number of days (hours) late	Total Possible Marks	Deduction	Raw mark	Final mark
1 day (1-24 hours)	100	5	75	70
2 days (24-48 hours)	100	10	75	65
3 days (48-72 hours)	100	15	75	60
7 days (144-168 hours)	100	35	75	40
>7 days (>168 hours)	100	-	75	0

For any late submissions of time-sensitive tasks, such as scheduled tests/exams, performance assessments/presentations, and/or scheduled practical assessments/labs, students need to submit an application for Special Consideration.

Assessment Tasks

Name	Weighting	Hurdle	Due
Online quiz	30%	No	Check unit iLearn site
Written Assignment	35%	No	Check unit iLearn site
Simulation/Role Play	35%	No	Check unit iLearn site

Online quiz

Assessment Type [1]: Quiz/Test
Indicative Time on Task [2]: 20 hours
Due: **Check unit iLearn site**
Weighting: **30%**

Multiple online quizzes throughout the session, comprising partial fulfilment of the GCP certification requirements.

On successful completion you will be able to:
• Recognise the role and impact of clinical trials research and its design on clinical practice

and product development. (Capability 1 - Scientist and Scholar)

- Define the Australian and the global regulatory environment and its impact on clinical research integrity and patient safety. (Capability 3 - Engaged Global Citizen)

- Discuss roles and responsibilities in designing, implementing, and monitoring safe and efficient patient-centred clinical trials according to the Good Clinical Practice guidelines. (Capability 2 - Clinical Trial Practitioner)

- Recognise the role of ethical guidelines and the necessity of protocol compliance in protecting study participants, data security and confidentiality and preserving integrity of clinical research. (Capability 4 - Professional)

- Interpret study protocol requirements and aspects of the participant consent process, expectations, rationale of clinical equipoise and therapeutic misconception, diverse needs, privacy requirements, and continuance of post-trial care. (Capability 2 - Clinical Trial Practitioner)

- Consider cultural and diverse ethical issues that arise for minority and vulnerable groups participating in clinical trials and identify strategies that encourage regional and cultural diversity in clinical trials, including engaging Aboriginal and Torres Strait Islander peoples in trials. (Capability 3 -Engaged Global Citizen)

Written Assignment

Assessment Type [1]: Practice-based task
Indicative Time on Task [2]: 25 hours
Due: **Check unit iLearn site**
Weighting: **35%**

Critically evaluate a Participant Information & Consent Form (PICF).

On successful completion you will be able to:

- Recognise the role and impact of clinical trials research and its design on clinical practice and product development. (Capability 1 - Scientist and Scholar)

- Define the Australian and the global regulatory environment and its impact on clinical research integrity and patient safety. (Capability 3 - Engaged Global Citizen)

- Discuss roles and responsibilities in designing, implementing, and monitoring safe and efficient patient-centred clinical trials according to the Good Clinical Practice guidelines. (Capability 2 - Clinical Trial Practitioner)

- Recognise the role of ethical guidelines and the necessity of protocol compliance in

protecting study participants, data security and confidentiality and preserving integrity of clinical research. (Capability 4 - Professional)

- Interpret study protocol requirements and aspects of the participant consent process, expectations, rationale of clinical equipoise and therapeutic misconception, diverse needs, privacy requirements, and continuance of post-trial care. (Capability 2 - Clinical Trial Practitioner)

Simulation/Role Play

Assessment Type [1]: Viva/oral examination
Indicative Time on Task [2]: 20 hours
Due: **Check unit iLearn site**
Weighting: **35%**

Online oral examination format in which you will respond to a broad range of questions, including some questions relating to short scenarios of clinical trials e.g. responding to potential study participant's queries.

On successful completion you will be able to:

- Recognise the role and impact of clinical trials research and its design on clinical practice and product development. (Capability 1 - Scientist and Scholar)
- Define the Australian and the global regulatory environment and its impact on clinical research integrity and patient safety. (Capability 3 - Engaged Global Citizen)
- Discuss roles and responsibilities in designing, implementing, and monitoring safe and efficient patient-centred clinical trials according to the Good Clinical Practice guidelines. (Capability 2 - Clinical Trial Practitioner)
- Recognise the role of ethical guidelines and the necessity of protocol compliance in protecting study participants, data security and confidentiality and preserving integrity of clinical research. (Capability 4 - Professional)
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in trials. (Capability 3 -Engaged Global Citizen)

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[1] If you need help with your assignment, please contact:

- the academic teaching staff in your unit for guidance in understanding or completing this type of assessment
- the Writing Centre for academic skills support.

[2] Indicative time-on-task is an estimate of the time required for completion of the assessment task and is subject to individual variation

Delivery and Resources

PPCT8000 Foundations of Clinical Trials is an online unit. As a student enrolled in this unit, you will engage in a range of online learning activities, including readings, videos, online modules, etc. Details can be found on the iLearn site for this unit.

Technology Used

Active participation in the learning activities throughout the unit will require students to have access to a tablet, laptop or similar device.

Policies and Procedures

Macquarie University policies and procedures are accessible from Policy Central (https://policies.mq.edu.au). Students should be aware of the following policies in particular with regard to Learning and Teaching:

- Academic Appeals Policy
- Academic Integrity Policy
- Academic Progression Policy
- Assessment Policy
- Fitness to Practice Procedure
- Assessment Procedure
- Complaints Resolution Procedure for Students and Members of the Public
- Special Consideration Policy

Students seeking more policy resources can visit Student Policies (https://students.mq.edu.au/support/study/policies). It is your one-stop-shop for the key policies you need to know about throughout your undergraduate student journey.

To find other policies relating to Teaching and Learning, visit Policy Central (https://policies.mq.edu.au) and use the search tool.

Student Code of Conduct

Macquarie University students have a responsibility to be familiar with the Student Code of Conduct: https://students.mq.edu.au/admin/other-resources/student-conduct

Results

Results published on platform other than eStudent, (eg. iLearn, Coursera etc.) or released directly by your Unit Convenor, are not confirmed as they are subject to final approval by the University. Once approved, final results will be sent to your student email address and will be made available in eStudent. For more information visit ask.mq.edu.au or if you are a Global MBA student contact globalmba.support@mq.edu.au

Academic Integrity

At Macquarie, we believe academic integrity – honesty, respect, trust, responsibility, fairness and courage – is at the core of learning, teaching and research. We recognise that meeting the expectations required to complete your assessments can be challenging. So, we offer you a range of resources and services to help you reach your potential, including free online writing an d maths support, academic skills development and wellbeing consultations.

Student Support

Macquarie University provides a range of support services for students. For details, visit http://stu dents.mq.edu.au/support/

The Writing Centre

The Writing Centre provides resources to develop your English language proficiency, academic writing, and communication skills.

- Workshops
- Chat with a WriteWISE peer writing leader
- Access StudyWISE
- Upload an assignment to Studiosity
- Complete the Academic Integrity Module

The Library provides online and face to face support to help you find and use relevant information resources.

- Subject and Research Guides
- Ask a Librarian

Student Services and Support

Macquarie University offers a range of Student Support Services including:

- IT Support
- Accessibility and disability support with study

- Mental health support
- Safety support to respond to bullying, harassment, sexual harassment and sexual assault
- Social support including information about finances, tenancy and legal issues
- Student Advocacy provides independent advice on MQ policies, procedures, and processes

Student Enquiries

Got a question? Ask us via AskMQ, or contact Service Connect.

IT Help

For help with University computer systems and technology, visit http://www.mq.edu.au/about_us/offices_and_units/information_technology/help/.

When using the University's IT, you must adhere to the Acceptable Use of IT Resources Policy. The policy applies to all who connect to the MQ network including students.

Inclusion and Diversity

Social inclusion at Macquarie University is about giving everyone who has the potential to benefit from higher education the opportunity to study at university, participate in campus life and flourish in their chosen field. The University has made significant moves to promote an equitable, diverse and exciting campus community for the benefit of staff and students. It is your responsibility to contribute towards the development of an inclusive culture and practice in the areas of learning and teaching, research, and service orientation and delivery. As a member of the Macquarie University community, and when on external placement representing Macquarie University, you must not discriminate against or harass others based on their sex, gender, race, marital status, carers' responsibilities, disability, sexual orientation, age, political conviction or religious belief. All staff and students are expected to display appropriate behaviour that is conducive to a healthy learning environment for everyone including when on external placement activities.

Professionalism

In the Faculty of Medicine, Health and Human Sciences, professionalism is a key capability embedded in all our courses.

As an adult learner, we respect your decision to choose how you engage with your learning, but we would remind you that the learning opportunities we create for you have been done so to enable your success, and that by not engaging you may impact your ability to successfully complete this unit. We equally expect that you show respect for the academic staff who have worked hard to develop meaningful activities and prioritise your learning.

Another dimension of professionalism is having respect for your peers. It is the right of every student to learn in an environment that is free of disruption and distraction. Please communicate respectfully when interacting on discussion forums and in group assignments (when

applicable). Please treat your fellow students with the utmost respect. If you are uncomfortable participating in any specific activity, please let the relevant academic know.

Unit information based on version 2024.02 of the Handbook