PPCT8003

Advanced Clinical Trial Skills

Session 2, Online-flexible 2024

Macquarie Medical School

Contents

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General Information

Unit convenor and teaching staff
Unit Convenor
Rania Salama
rania.salama@mq.edu.au
By appointment only (online or in-person consultations)

Credit points
10

Prerequisites

Corequisites
PPCT8000, PPCT8001 and PPCT8002

Co-badged status

Unit description
This unit brings together a deeper understanding of the essential skills and responsibilities of the different roles in initiating, managing and operating effective, ethical and safe clinical trials. You will explore innovative approaches of designing clinical trials and their impact on participants, sources of bias and balancing risks and benefits. You will gain an appreciation of the dynamics of teamwork and conflict management skills required in this industry. In addition, you will explore how clinical research findings are interpreted and reported in scientific disseminations and how you could present them to different audiences. Completing this unit will allow you to reflect on different self-care strategies to maintain a healthy balance between your role responsibilities and your own wellbeing. Learning activities in this unit are co-designed with industry experts and offer pre-recorded lectures and interviews, real-world case studies, knowledge check quizzes and industry relevant assessments.

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:** Analyse the components of, and effectively communicate, the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientific community. (Capability 1 – Scientist and Scholar)

ULO2: Explain the fundamental and innovative approaches of designing clinical trials with reference to the study research question, impact on participants, sources of bias and balancing risks and benefits. (Capability 3- Engaged Global Citizen)

ULO3: Appraise the responsibilities of Clinical Trial Coordinators and Clinical Research Associates in ensuring participants safety, integrity, accuracy and verifiability of documented trial data. (Capability 2 - Clinical Trial Practitioner)

ULO4: Evaluate the role of clinical trials pharmacists in interpreting applicable government and regulatory authority guidelines, laws, common policies and requirements of pharmacy manual for investigational products. (Capability 2 - Clinical Trial Practitioner)

ULO5: Determine effective communication and conflict management strategies, and negotiating and influencing skills in the workplace. (Capability 4 - Professional)

ULO6: Reflect on own practice and self-care strategies suitable for clinical trial professionals' roles. (Capability 4 - Professional)

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.

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
Presentation of Study Results	35%	No	Check unit iLearn site
Reflection	35%	No	Check unit iLearn site
Online Oral Examination	30%	No	Check unit iLearn site

Presentation of Study Results

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

Based on a published study, you will communicate trial results in written and/or video format(s) suitable to a variety of different audiences.

On successful completion you will be able to:
• Analyse the components of, and effectively communicate, the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientific community. (Capability 1 – Scientist and Scholar)

- Explain the fundamental and innovative approaches of designing clinical trials with reference to the study research question, impact on participants, sources of bias and balancing risks and benefits. (Capability 3- Engaged Global Citizen)
- Determine effective communication and conflict management strategies, and negotiating and influencing skills in the workplace. (Capability 4 - Professional)

Reflection

Assessment Type [1]: Reflective Writing
Indicative Time on Task [2]: 25 hours
Due: **Check unit iLearn site**
Weighting: **35%**

You will reflect on the professional and graduate capabilities fulfilled in your learning in the course. You will plan for your next steps in your professional career through identifying gaps and suggesting future opportunities to fulfil these competencies for a role in the clinical trial industry.

On successful completion you will be able to:

- Analyse the components of, and effectively communicate, the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientific community. (Capability 1 – Scientist and Scholar)
- Appraise the responsibilities of Clinical Trial Coordinators and Clinical Research Associates in ensuring participants safety, integrity, accuracy and verifiability of documented trial data. (Capability 2 - Clinical Trial Practitioner)
- Evaluate the role of clinical trials pharmacists in interpreting applicable government and regulatory authority guidelines, laws, common policies and requirements of pharmacy manual for investigational products. (Capability 2 - Clinical Trial Practitioner)
- Determine effective communication and conflict management strategies, and negotiating and influencing skills in the workplace. (Capability 4 - Professional)
- Reflect on own practice and self-care strategies suitable for clinical trial professionals' roles. (Capability 4 - Professional)

Online Oral Examination

Assessment Type [1]: Viva/oral examination
Indicative Time on Task [2]: 25 hours
Due: **Check unit iLearn site**
Weighting: **30%**

You will respond to short answer questions/scenarios relevant to all unit content. You will demonstrate core skills required for when working in a clinical trial professional role and interacting with other team members and stakeholders.

On successful completion you will be able to:

- Analyse the components of, and effectively communicate, the content and relevance of clinical research findings to colleagues, advocacy groups and the non-scientific community. (Capability 1 – Scientist and Scholar)
- Explain the fundamental and innovative approaches of designing clinical trials with reference to the study research question, impact on participants, sources of bias and balancing risks and benefits. (Capability 3- Engaged Global Citizen)
- Appraise the responsibilities of Clinical Trial Coordinators and Clinical Research Associates in ensuring participants safety, integrity, accuracy and verifiability of documented trial data. (Capability 2 - Clinical Trial Practitioner)
- Evaluate the role of clinical trials pharmacists in interpreting applicable government and regulatory authority guidelines, laws, common policies and requirements of pharmacy manual for investigational products. (Capability 2 - Clinical Trial Practitioner)
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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

PPCT8003 Advanced Clinical Trial Skills 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 laptop, tablet, 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 and 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, 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 2024.03 of the Handbook