Module Descriptor for MDCS41900 in 2022/2023

Short Title	Long Title	Subject Area	College	School/Unit	Last Modified
Clinical Protocol Development	Clinical Protocol Development	Medicine Clinical Science	Health & Agricultural Sciences	Medicine	08 Sep 2022

UCD Level	Credits (ECTS)	Semester/Trimester	Grade Scale	VLE Setup	Module Coordinator	Status
4 - Masters	10.0	Spring	Letter grades	Module in Brightspace	Marie Galligan	Active

Mode of Delivery	Internship Module	Clinical / Fieldwork / Placement
Blended	No	Other

Overall Places	Core/Option	General Elective	First Year Elective	International	Open Learning
80	50	0	0	30	0

Purpose & Overarching Content

This module forms part of the MSc in Clinical & Translational Research. The goal of this module is to provide students with an in-depth understanding of clinical trial protocols including their structure and how a scientifically appropriate protocol is developed.
Students will build on previous content as they design their own clinical research protocol. Students will
1) Formulate a research question
2) Choose a suitable study design
3) Complete a study summary, defining study population, endpoints etc...
4) Pre-specify study activities such as monitoring, data management, statistical analysis
5) Write a protocol using the HPRA protocol template
Students will receive feedback throughout the protocol development process

Learning Outcomes

On completion of this module, students will be able to design, develop and deliver a clinical trial protocol that is ethically, legally and regulatorily sound and statistically valid.
Specifically students will:
Propose a research question applicable to a clinical, occupational or scientific setting
Design a methodologically sound study to address their research question
Develop a clinical research protocol within a specified framework
Choose the study design most appropriate to the research question, including definition of endpoints and determination of sample size requirements
Understand the most appropriate control and intervention groups
Write up the clinical research protocol

Indicative Module Content

In this module, students will be guided through the stages of protocol development, from research question to initial PICO and from study summary to completed protocol

Approaches to Teaching and Learning

Lectures
Active learning activities
Tasks
Group work
Peer review and feedback

Student Effort Hours

Student Effort Type	Hours
Contact Time	
Tutorial	8
Seminar (or Webinar)	12
Lectures	24
Total Contact Time	**44**
Specified Learning Activities	
Specified Learning Activities	60
Total Specified Learning Activities	**60**
Autonomous Student Learning	
Autonomous Student Learning	100
Total Autonomous Student Learning	**100**
Total	**204**

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Assessment Details

Assesment Type	Description	Timing	Open Book?	% of Final Grade	Component Scale	Must-Pass?	In-module Component Repeat Offered?
Assignment	Protocol	Coursework (End of Trimester)		55	Graded	No	No
Assignment	Research Question (PICO)	Throughout the Trimester		15	Graded	No	No
Assignment	Study Summary	Throughout the Trimester		30	Graded	No	No
Total				**100**			

Carry Forward of Passed Components
Yes

Feedback Strategy

Feedback Strategies	Sequence of Feedback
- Feedback individually to students, on an activity or draft prior to summative assessment - Peer review activities - Self-assessment activities	Feedback is provided on a continuous basis to students, throughout this module. Students also engage in peer review and feedback

Remediation Strategy

Remediation Type	Remediation Timing
Resit	Within Two Trimesters

Prior Learning

Requirement	Details
Learning Requirements	Prior to undertaking this module, students should have a detailed knowledge of biostatistics and data management

Module Requisites

And/Or	(	Module Code	Module Title	Type	)
		MDCS41950	Biostatistics &Data Management	Prereq	

Associated Staff

Name	Role
Ms Helen Campion	VLE Access Only
Miss Denise Gosling	Module Assistant
Mr Martin Heduan	VLE Access Only
Dr Sinead Holden	Tutor
Professor Patrick Murray	Tutor
Dr Deborah Wallace	Tutor

Associated Majors

Programme	Major	Stage	Module Type
MTMED001 - Master of Science-Medicine	X789 - MSc Clinic&Transl Research FT	1	Core Module
MTMED001 - Master of Science-Medicine	X427 - MSc Clinic&Transl Research PT	1	Option Module

For help with the information on this report, please email curriculum@ucd.ie