

Printed on 18 January 2023

| Short Title | Long Title | Subject Area | College | School/Unit | Last Modified |
|-----------------|-----------------|-------------------|-----------------------|-------------|---------------|
| Clinical Trials | Clinical Trials | Medicine Clinical | Health & Agricultural | Medicine | 16 Jan 2023 |
| | | Science | Sciences | | |

| UCD Level | Credits (ECTS) | Semester/Trimester | Grade Scale | VLE Setup | Module Coordinator | Status |
|-------------|----------------|--------------------|---------------|-------------|--------------------|--------|
| 4 - Masters | 10.0 | Autumn | Letter grades | Module in | Deborah Wallace | Active |
| | | | | Brightspace | | |

| Mode of Delivery | Internship Module | Clinical / Fieldwork / Placement |
|------------------|-------------------|----------------------------------|
| Face-to-Face | No | Other |

| Overall Places | Core/Option | General Elective | First Year Elective | International | Open |
|----------------|-------------|------------------|---------------------|---------------|----------|
| | | | | | Learning |
| 40 | 40 | 0 | 0 | 0 | 0 |

Purpose & Overarching Content

This module forms part of the graduate programme in clinical and translational research. This module introduces students to drug discovery & development and introduces critical concepts in clinical trial design. In this module students will be introduced to clinical trials, from new drug discovery to how trials of medicines are completed.

Specific areas of focus in this module includes

1) Introduction to Pharmacology

2) New drug discovery

3) Preclinical Testing

4) Clinical Trial Designs

5) Trial Endpoints

6) Trial periods and interventions

7) Trial populations

8) Phases of Trials

Learning Outcomes

On completion of this module students will develop a comprehensive understanding of clinical trials, how they are designed and completed.

Specifically, students will be able to:

Understand clinical trial principles, including study design

Understand regulatory and legal environment in which clinical trials are completed

Analyse the design of clinical trials

Understand how emerging technologies are directly enhancing clinical trials

Appreciate how Good Clinical Practice guides trial design, development and implementation

Indicative Module Content

This modules includes content on the following key areas

1) Drug Discovery and Development

2) Clinical Trial Designs

3) Clinical Trial Applications

Approaches to Teaching and Learning

Lectures Online lectures of clinical trials in focus Additional reading

Student Effort Hours

| Student Effort Type | Hours |
|-------------------------------|-------|
| Contact Time | |
| Seminar (or Webinar) | 11 |
| Lectures | 57 |
| Total Contact Time | |
| Specified Learning Activities | |
| Specified Learning Activities | 42 |



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Student Effort Hours (continued)

| Student Effort Type | Hours |
|-------------------------------------|-------|
| Total Specified Learning Activities | 42 |
| Autonomous Student Learning | · |
| Autonomous Student Learning | 90 |
| Total Autonomous Student Learning | 90 |
| Total | 200 |

Assessment Details

| Assesment Type | Description | Timing | Open Book? | % of Final Grade | Component Scale | Must-Pass? | In-module Component Repeat Offered? |
|----------------|-------------|---------------------------------|------------|---------------------|--------------------|------------|---|
| Examination | Exam | 2 hour End of Trimester Exam | No | 100 | Graded | Yes | Yes |
| Total | | | | 100 | | | |

| Carry Forward |
|---------------|
| of Passed |
| Components |
| Yes |

Feedback Strategy

| Feedback Strategies | Sequence of Feedback |
|---|---|
| - Group/class feedback, post-assessment | Feedback provided at end of assessment |
| | In class instant feedback by way of quizzes |

Remediation Strategy

| Remediation Type | Remediation Timing |
|------------------|-----------------------|
| Resit | Within Two Trimesters |

Associated Staff

| Name | Role |
|--------------------------|------------------------|
| Dr Marie Galligan | Lecturer / Co-Lecturer |
| Ms Helen Campion | VLE Access Only |
| Miss Denise Gosling | Module Assistant |
| Mr Martin Heduan | VLE Access Only |
| Mrs Allison Kacperski | VLE Access Only |
| Professor Patrick Murray | VLE Access Only |

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