



**Trinity College Dublin**

Coláiste na Tríonóide, Baile Átha Cliath

The University of Dublin

Department of Pharmacology and Therapeutics

**Postgraduate Diploma/MSc in**

# **Pharmaceutical Medicine**

**Prospectus 2022–2024**



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Centre of Excellence

## WELCOME

Pharmaceutical medicine is the *'medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines and medical devices for the benefit of patients and public health'* as detailed by the Association of Pharmaceutical Physicians of Ireland.

These established training courses have been designed to improve the knowledge and skills of healthcare professionals in the area of pharmaceutical medicine. They provide comprehensive information to enable students acquire a proper understanding of each topic covered in the course. It looks at each topic from a European and international perspective and therefore is designed to cater for the needs of EU and non-EU students.

The course is aimed at the broad range of health science professionals working in the pharmaceutical/healthcare area who want to deepen their understanding of medicines, biopharmaceuticals and medical device development, regulation and marketing. The module content is in line with the current syllabus of the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom. Trinity College Dublin is a member of the PharmaTrain Federation ([www.pharmatrain.eu/](http://www.pharmatrain.eu/)) and these courses are accredited by PharmaTrain. Trinity has been designated as a PharmaTrain Federation *Centre of Excellence* for pharmaceutical medicine training.

### KEY FEATURES OF THE COURSE:

- To provide suitably qualified healthcare professionals with specialist knowledge and skills in all aspects of pharmaceutical medicine.
- To enable graduates to assume positions in, or extend their current role within the pharmaceutical industry, regulatory authority, and other relevant areas within the healthcare system.
- Engages teaching and educational support from academic staff members of the Faculty of Health Sciences, Trinity; experts from the National Centre for Pharmacoeconomics and National Centre for Medicines Information; and experts from national and international regulatory authorities and pharmaceutical organisations.

## INTENDED PARTICIPANTS

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Prospective students for the Postgraduate Diploma and MSc should hold:

- primary honours degree in either medicine or another relevant health science subject
- minimum of 2 years' practical experience in their area of qualification/pharmaceutical industry.

Candidates from within and outside the EU will be eligible for enrolment onto each course, providing their primary degree is from a recognised institution and of equivalent grading.

### **COURSE LEARNING OUTCOMES**

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On successful completion of the pharmaceutical medicine course, you should be able to:

- Outline and critically appraise the principal steps in drug discovery
- Explain the rationale for the complete development plan (pharmaceutical, pre-clinical and clinical) according to the proposed therapeutic indication
- Critically review the issues (including legal, ethical and clinical) involved in the undertaking of clinical research
- Appraise and compare the regulation of medicines in the various global markets
- Assess and compare the management of drug safety issues pre-and post-marketing authorisation
- Develop and critically appraise product-related information to ensure adherence to ethical and legal provisions
- Explain the principles of health economics and discuss their application in the development and marketing of medicines
- Critically review and interpret the literature relating to drug research and usage
- Demonstrate competence in the management of all lifecycle activities (regulatory and marketing) of a medicine

## COURSE STRUCTURE AND TIMETABLE

### POSTGRADUATE DIPLOMA PROGRAMME

The course is a part-time taught program, run over 18 months for a total of 12 modules. Each module typically has 3 days face-to-face teaching which consists of a combination of formal teaching sessions, workshops, and interactive/practical sessions.

Pre-module reading lists and self-directed learning material will be provided and form part of the module teaching. In addition, all registered students will have access to Trinity's web-based virtual learning environment facility. Students will be expected to interact with other class members and the course coordinators via the e-learning platform.

Completion of each module is obligatory. Students are recommended to attend all of the taught modules but must attend at least 10 of the 12 face-to-face modules.

Assessment will consist of personal assignments (continuous assessment) and end of year examinations. Continuous assessment assignments must be completed by the students for each module and submitted at designated time points. Students must submit continuous assessment assignments for all modules.

### MSc. PROGRAMME

Students must complete the postgraduate diploma course modules, as outlined above. In addition, students will be assigned a research project (in primary research), which should be submitted as a dissertation (with the possibility of an oral examination) by the 31<sup>st</sup> August of the second year.

### COURSE TIMETABLE 2022 - 2024<sup>+</sup>

Module	Module Title	Date (DD/MM/YYYY)
1	Introduction - Principles of Discovery of Medicines and Development Planning	19/09/2022 – 21/09/2022
2 & 3	Exploratory and Confirmatory Clinical Development; Clinical Trials*	14/11/2022 – 18/11/2022
4	Non-Clinical Testing, Pharmaceutical and Early Clinical Development	4/01/2023 – 6/01/2023
5	Project Management in Medicines Development	6/02/2023 – 8/02/2023
6	Special Populations: Clinical Trial Practice and Regulation	6/03/2023 – 8/03/2023
7 & 8	Medicines Regulation and Regulatory Affairs; Drug Safety & Pharmacovigilance*	5/10/2023 – 6/10/2023
9 & 10	Drug Safety: Pharmacoepidemiology, Pharmacovigilance and Risk Management; Biologicals and Advanced Therapies*	20/11/2023 – 24/11/2023
11 & 12	Health Economics (Pharmacoeconomics) & Healthcare Marketplace; Economics of Healthcare*	15/01/2024 – 19/01/2024

<sup>+</sup> Provisional timetable dates

\* note – these 2 modules are run in parallel

## COURSE MODULES<sup>+</sup>

<b>Year 1</b>		
Principles of Discovery and Development Planning	Exploratory and Confirmatory Clinical Development	Clinical Trials
Non-Clinical Testing, Pharmaceutical and Early Clinical Development	Project Management in Medicines Development	Special Populations: Clinical Trial Practice and Regulation
<b>Year 2</b>		
Medicines Regulation	Regulatory Affairs; Drug Safety & Pharmacovigilance	Drug Safety: Pharmacoepidemiology Pharmacovigilance and Risk Management
Biologicals and Advanced Therapies	Health Economics / Pharmacoeconomics	Healthcare Marketplace; Economics of Healthcare
Research Project		<b>Only MSc</b>

<sup>+</sup> See Appendix for full module details

## COURSE VENUE



The course will be held in the Trinity Centre for Health Sciences Building at the St. James's Hospital campus, Dublin 8 and online using Trinity's virtual learning environment. Enrolled students will be notified of the exact venue in advance of each module.

## COURSE MATERIALS

- Comprehensive course materials will be available on Blackboard for each module.
- Students will be provided with pre-module reading to review before each of the taught modules.
- Personal assignments for each module must be completed by each student and returned within the designated time frame. Late assignments will be subject to penalties.
- Students will be expected to provide their own computer and online access for the modules undertaken by distance learning.

## COURSE FEES FOR 2021/2022\*

		EU (€)	Non-EU (€)
<b>Postgraduate Diploma</b>	Year 1	6,130	12,867
	Year 2	5,491	11,506
<b>MSc</b>	Year 1	6,130	12,867
	Year 2	6,130	12,867

\*Fees shown include tuition fees, sports levy, USI levy and commencement fees. Academic Year 2022/23 fees have yet to be finalised. Above fee schedules are indicative of the tuition fee and other charges.

## COURSE FACULTY

### HEAD OF THE DEPARTMENT



Prof. Michael Barry is a Consultant Clinical Pharmacologist and Head of the Department of Pharmacology & Therapeutics at the University of Dublin, Trinity College. He is the clinical director of the National Centre for Pharmacoeconomics which conducts pharmacoeconomic evaluations on medicines prior to reimbursement under the Community Drugs schemes in Ireland. He is Past-President (2010-2011) of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). He was a board member of the Health Information and Quality Authority (HIQA) and is a member of a number of National Committees on pricing and reimbursement of medicines. Prof. Barry chairs the New Drugs Committee and the Medication Safety Committee at St. James's Hospital, Dublin. In 2013 he was appointed as Clinical Lead for the new HSE Medicines Management Programme. He is a fellow of the Royal College of Physicians in Ireland and is a specialty trainer for Pharmacology & Therapeutics. His research areas include the cost-effectiveness of high cost drugs including chemotherapeutic agents and biologic drugs, pricing and reimbursement and performance based risk sharing schemes. He has published widely on the cost-effectiveness of medicines in the Irish healthcare setting.

### COURSE DIRECTOR



Dr Mary Teeling is a specialist pharmaceutical physician with over 30 years' experience in the areas of pharmacology and pharmaceutical medicine. She was part of the development team for the courses in Pharmaceutical Medicine in 2004, while working in Trinity College Dublin, and is currently adjunct assistant professor in the Dept. of Pharmacology and Therapeutics. Prior to working in Trinity College Dublin, Mary worked in the Irish Medicines Board (now Health Products Regulatory Authority) for 12 years and was its medical director for 6 years. She was the Irish member of the EU Committee for Human Medicinal Products (CHMP) in the European Medicines Agency (EMA) and served as its vice-chair for 3 years. She was part of the educational team that developed the higher speciality training (HST) programme in pharmaceutical medicine with the Royal College of Physicians in Ireland. The programme achieved approval from the Medical Council of Ireland in 2016 and she served as its first national speciality director (NSD) until 2021.

### COURSE COORDINATOR



Prof Joanne Ramsey is responsible for the day-to-day running of the courses. Joanne trained as a Biomedical Science and worked in the NHS. She carried out her PhD in the Centre for Cancer Research and Cell Biology at Queen's University Belfast studying small molecule therapies in malignant diseases. Upon completion of her PhD she took up a pharmaceutical research position in Royal College of Surgeons in Ireland (RCSI) developing ATMPs and is involved in two invention disclosures and one patented gene therapy. She became a pharmaceuticals lecturer and principal investigator in RCSI in 2015 and obtained her postgraduate certificate in Health Professional's Education before joining Trinity College Dublin as assistant professor in Pharmaceutical Medicine in 2019. She is a member of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP™) and sits on the IFAPP™ education working group and the IFAPP™ communications working group.

## COURSE FACULTY

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In addition to the faculty members from the academic staff of the Faculty of Health Sciences, Trinity College, the course will include contributions from experts from the National Centres for Pharmacoeconomics and Medicines Information, and experts from national and international regulatory authorities and pharmaceutical organisations.

## CONTACT INFORMATION

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Contact the Course Co-ordinator (Joanne Ramsey) at:

Email: [ramseyj@tcd.ie](mailto:ramseyj@tcd.ie)

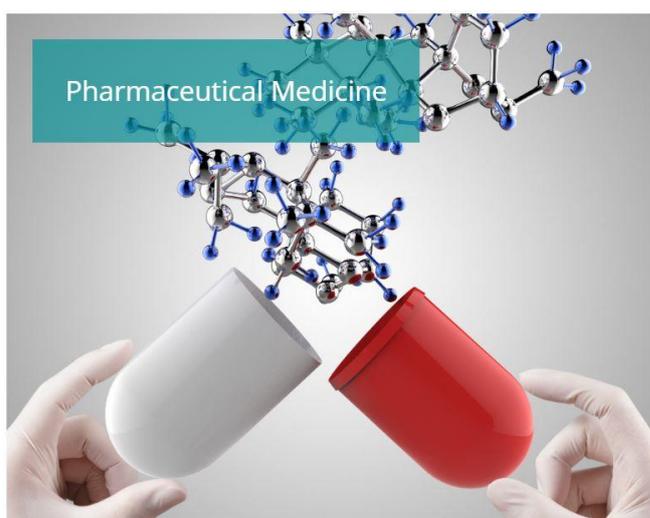
Phone: + 353 1 8961568

**or visit:**

<https://www.tcd.ie/medicine/pharmacology-therapeutic/postgraduate>

**Applications for this course should be made online via:**

<https://www.tcd.ie/courses/postgraduate/az/course.php?id=DPDMD-PMED-1P09>



# YEAR 1

### **MODULE 1: PM7011 - INTRODUCTORY PROGRAMME: PRINCIPLES OF DISCOVERY OF MEDICINES AND DEVELOPMENT PLANNING**

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This module introduces the aims and objectives of the course. It discusses the principles of pharmaceutical medicine. It describes the philosophy behind new drug development and how this impacts on the activity of a pharmaceutical company. It describes the various factors which have an impact on the life-cycle of a drug.

### **MODULE 2: PM7013 - EXPLORATORY AND CONFIRMATORY CLINICAL DEVELOPMENT\***

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The aim of this module is to provide a comprehensive overview of the main types of studies used in clinical research and the legal, methodological and ethical issues involved in the undertaking of biomedical research (including Good Clinical Practice). It will detail the principles and practical application of statistics in clinical trials and the role and responsibilities of the statistician as part of the R & D team. It will outline the early studies in patients and describe the strategy behind drug development within the pharmaceutical industry and in particular the basis for assessing continuing viability of development projects.

### **MODULE 3: PM7014 - CLINICAL TRIALS\***

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This module provides comprehensive information on the clinical development of new medicines. It describes the choice of clinical trial design and target populations, according to the proposed indication for use. It examines in detail the key issues involved in the conduct of a clinical trial and describes their statistical analysis and reporting. It describes the handling the safety data in clinical trials and how it impacts on drug development. It highlights the importance of evaluation in at-risk populations and explores the concept of benefit / risk assessment in clinical development. The aim of this module is to ensure comprehensive knowledge in the area of clinical development and how the clinical development programme interacts with the overall R & D programme.

*\* - these modules are run in parallel*

### **MODULE 4: PM7012 - NON-CLINICAL TESTING, PHARMACEUTICAL AND EARLY CLINICAL DEVELOPMENT**

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The objective of this module is to develop a higher understanding of the types of pharmaceutical and non-clinical testing carried out on new drug substances and how these fit into the overall development programme. It discusses the principles of early pharmaceutical development of drug substance and how the choice of formulation is made with reference to the proposed indication for use. It provides background information on how potential candidates are tested for bioequivalence, stability, impurity and incompatibility in order to produce the final product specification. It describes in detail the different stages of non-clinical (pharmaco-toxicology testing) and how these findings are used to plan early exploratory development in man, as part of the overall R & D plan.

## **MODULE 5: PM7022 - PROJECT MANAGEMENT IN MEDICINES DEVELOPMENT**

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This module provides the student with the opportunity to develop competence in the logistical aspects of R & D (project management). It details how to define, plan, manage and verify the scope of the development of a medicine. It promotes in-depth knowledge of how to identify factors in failing clinical trials and discusses the concept of project rescue.

## **MODULE 6: PM7019 - SPECIAL POPULATIONS: CLINICAL TRIAL PRACTICE AND REGULATION**

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This module provides in-depth knowledge into the impact of the specific target population on the undertaking of clinical research. It details the importance of taking physiological profile, disease characteristics into account and provides practical examples of how to conduct clinical research in vulnerable populations. The aim of the module is to enable the student develop competence in the area of clinical research, appropriate to the target patient profile, particularly in vulnerable populations.

# YEAR 2

## **MODULE 7: PM7020 - MEDICINES REGULATION\*\***

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This module, run in parallel with module 8, provides comprehensive information on the role of drug regulation before and during the authorisation of medicines. It details the current national and international regulatory requirements for the authorisation of medicines. It looks at the guidelines which are published to aid new drug development by the various regulatory agencies and evaluates the importance of practical input from expert international organisations. The aim of the two modules is to enable the student gain competence in the handling of all regulatory lifecycle issues of a medicine both pre- peri- and post-authorisation in the various jurisdictions.

## **MODULE 8: PM7015 - REGULATORY AFFAIRS; DRUG SAFETY & PHARMACOVIGILANCE\*\***

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This module, run in parallel with module 7, provides comprehensive information on the role of drug regulation with a particular emphasis on the regulation of drug safety during and after the authorisation phase of drug development. It details the current national and international requirements for the regulatory aspects of the authorisation of medicines. It details the regulation and management of drug safety issues, both pre-and post-approval. The aim of the two modules is to enable the student gain competence in the handling of all regulatory lifecycle issues of a medicine both pre- peri- and post-authorisation in the various jurisdictions

*\*\*These modules will be undertaken by way of blended learning in parallel*

## **MODULE 9: PM7017 - DRUG SAFETY: PHARMACOEPIDEMIOLOGY, PHARMACOVIGILANCE AND RISK MANAGEMENT §**

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This module provides comprehensive information on pharmacovigilance and the existing regulatory requirements for the pharmaceutical industry and regulatory authorities at EU and international level. It explains the principles of pharmacoepidemiology and how these are used to evaluate drug safety in practice. It discusses drug interactions and how they can be avoided; medication errors and their prevention +/- management and provides information on research methodology in pharmacovigilance. The aim of this module is to promote a higher understanding of the benefit/risk evaluation of drugs and the importance of safety monitoring throughout the lifecycle of a medicine.

## **MODULE 10: PM7018 - BIOLOGICALS AND ADVANCED THERAPIES §**

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This module provides comprehensive information on medicines derived from biological sources, including those defined as advanced therapies. It details the legal, ethical, regulatory and practical issues relating to the development of such medicines and provides practical application of the regulatory provisions. The aim is to enable the student to be able to work as part of a team in the lifecycle management of a biological agent or advanced therapy.

*§ - these modules may be run in parallel*

## **MODULE 11: PM7021 - HEALTH ECONOMICS / PHARMACOECONOMICS #**

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The aim of this module is to provide a higher understanding of the importance of health economics in contemporary healthcare management. It will give a comprehensive overview of the principles of health economics, economic modelling, QALY's and sensitivity analysis. It will provide practical examples of how economic principles are used to measure the cost-effectiveness of medicines and how this impacts on the pharmaceutical industry.

## **MODULE 12: PM7016 - HEALTHCARE MARKETPLACE; ECONOMICS OF HEALTHCARE #**

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This module focuses on the lifecycle management of medicines. It describes the legal and ethical principles governing communication between the pharmaceutical industry and healthcare professionals and. It examines the provision of product information within the healthcare marketplace by a pharmaceutical company and the role of educational versus promotional activities relating to the use of medicines. It discusses the developing role of health technology assessment within the pharmaceutical arena. The aim of the module is to enable the student to be competent in the management of all aspects of the lifecycle management of a medicine.

*# - these modules are run in parallel*