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Statement on General Regulations

In the event of any conflict or inconsistency between the General Regulations published in the University Calendar and information contained in programme or local handbooks, the provisions of the General Regulations in the Calendar will prevail.
https://www.tcd.ie/calendar/graduate-studies-higher-degrees/complete-part-III-hl.pdf

Accessibility
Alternative formats of the Handbook can be made on request.
1. Introduction

Welcome to the postgraduate courses in pharmaceutical medicine, which are run by the Department of Pharmacology and Therapeutics, School of Medicine, Trinity College Dublin. We look forward to meeting you on Monday 23rd September for Module 1.

The 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 to acquire a proper understanding of each topic covered in the course. They review each topic from a European and international perspective and therefore are designed to cater for the needs of both EU and non-EU students.

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 is a member of the PharmaTrain Federation (www.PharmaTrain.eu). These courses have been accredited by PharmaTrain and Trinity has been designated as a PharmaTrain Centre of Excellence for pharmaceutical medicine training.

2. Aim of the Courses

The aim of the courses is to provide suitably qualified healthcare professionals with specialist knowledge and skills in pharmacology, therapeutics and pharmaceutical medicine to enable them to extend their professional role within the pharmaceutical industry and healthcare system.
3. Learning Outcomes of the Courses

On successful completion of the courses, students 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

4. General Information and Course Structures

Students should familiarise themselves with University General and Graduate regulations which are described in detail in the University Calendar Parts I and III – Graduate Studies and Higher Degrees (www.tcd.ie/calendar). In the event of any conflict or inconsistency between the General Regulations published in the University Calendar and information contained in this handbook, the General Regulations in the Calendar will prevail.

Information regarding data protection is available on https://www.tcd.ie/info_compliance/data-protection/student-data/

The European Credit Transfer and Accumulation System (ECTS) is an academic credit system based on the estimated student workload required to achieve the objectives of a module or programme of study. It is designed to enable academic recognition for periods of study, to facilitate student mobility and credit accumulation and transfer. The ECTS is the recommended credit system for higher education in Ireland and across the European Higher Education Area.

The ECTS weighting for a module is a measure of the student input or workload required for that module, based on factors including the number of contact hours, the number and length of written or verbally presented assessment exercises, class preparation and private study time and examinations. There is no intrinsic relationship between the credit volume of a module and its level of difficulty.
The Postgraduate Diploma course is equivalent to 60 ECTS and the MSc is equivalent to 90 ECTS.

Both courses are part-time and will be run together. They will be in a modular format spread over two academic years. The taught part of both courses consists of 12 modules (5 ECTS per module) run over 18 months.

MSc students must complete a research project and submit a dissertation (equivalent to 30 ECTS) at the end of the second year. A preliminary research project proposal must be submitted to the course co-ordinator before the start of the second academic year (e.g. by the 31st August).

Ten of the modules require student attendance (See section 10.1) and each module will typically be of 2-3 days duration (so-called taught modules). The remaining two modules are “blended learning” i.e. part-time distance learning and part-time on-site workshops, which will be taught via an interactive web-based system (Blackboard) – (See Section 7).
5. Learning outcomes of the modules

The learning outcomes of each of the modules are as follows:

YEAR 1

5.1 PM7011: Module 1: Introductory Programme; Principles of Discovery of Medicines and Development Planning

Module Overview:
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.

Learning Outcomes:
On successful completion of this module students should be able to:

- Outline the process of drug development and identify the critical factors and decision points.
- Explain the importance of the patient in drug development.
- Describe the background to the development of the regulation of medicines and the role of the competent authorities.
- Outline the monitoring of drug safety.
- Describe the principles and practice of medical marketing.
- Outline the role of pathophysiology and molecular biology-based pharmacology in drug development.
- Describe the principal steps in discovering, modifying, assessing and patenting new chemical and biological compounds (including advanced therapies) according to their therapeutic indication.
- Discuss the resource planning (in terms of project management, budgeting and cost-control) involved in the management of a drug development programme.
- Describe the principles of translational research and its role in drug development.
- Outline the functions and elements (including business aspects) involved in the integrated development of a new drug.
Module Overview:

The aim of this module, which is run in parallel with module 3, 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. 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 also describes the strategy behind drug development within the pharmaceutical industry and in particular the basis for assessing continuing viability of development projects.

Learning Outcomes:

On successful completion of this module students should be able to:

- Describe the early studies in patients: dose-finding / proof of concept studies and their impact on drug development plan.
- Outline the clinical trial design (including legal, regulatory, ethical and practical aspects and GCP).
- Discuss the principles and application of statistics in clinical trials.
- Describe the procedures for clinical trial data collection (paper and electronic) and data management (including validation processes) to ensure optimal quality data.
- Identify the key strategic and operational issues in the clinical trial process, in terms of legislative requirements and Good Clinical Practice (GCP).
- Describe the role of the investigator drug brochure (IDB).
- Discuss the principles and practical relevance of ethical issues in biomedical research.
- Outline the legal and ethical provisions for protection of clinical trial subjects.
5.3 PM7014 Module 3: Clinical Trials

Module Overview:
This module, which is run in parallel with module 2, 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 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.

Learning Outcomes:

On successful completion of this module students should be able to:

- Describe the various types of clinical studies and the methods used to choose the appropriate design.
- Describe the main statistical methods used in clinical research.
- Identify the key issues involved in the conduct of a clinical study including investigator and site recruitment, investigative site management and conflict resolution.
- Discuss the collection, evaluation and reporting of adverse event data in clinical trials.
- Outline the various quality management issues in clinical trials.
- Describe the impact of emerging results on the drug development plan.
- Outline the key operational and strategic issues in the clinical development plan.
- Explain the evaluation of the outcome of drug development: final therapeutic profile / usage of a medicine.
- Describe the role of the Target Product Profile (TPP) and Target Product Claims (TPC).
- Explain the role of the Drug Safety Monitoring Board (DSMB) and other relevant study committees.
- Discuss the statistical issues in statistical report writing.
- Describe the evaluation and interpretation of clinical trial results.
- Illustrate the principles and practical application of critical appraisal.
Module Overview:

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 (pharmacotoxicology testing) and how these findings are used to plan early exploratory development in man, as part of the overall R & D plan.

Learning Outcomes:

On successful completion of this module students should be able to:

- Discuss the choice and predictive value of the non-clinical testing programme as part of the overall drug development plan for chemical and biological compounds.

- Describe the integration of non-clinical tests into the overall drug development plan (including scheduling of toxicology tests with respect to clinical trials).

- Outline the steps in the pharmaceutical development of a drug substance and final drug product (including chemical and biological compounds).

- Describe the planning of clinical trial supplies for test substance(s) and comparators (active and placebo).

- Provide an overview of non-clinical study requirements prior to First-in-Man studies.

- Discuss the molecular and cellular basis of toxic reactions.

- Outline the principles and practical application of pharmacokinetics and toxicokinetics.

- Outline the early exploratory development in man.

- Discuss the principles of clinical pharmacology and their application to clinical development.

- Describe the influence of genetic factors in drug development and drug response.
Module Overview:
This module provides the student with the opportunity to develop competence in the logistical aspects of R & D, from the initial planning stage, through all aspects of organisation and management of the ongoing trial to its completion.

Learning Outcomes:

On successful completion of this module students should be able to:

- Define a project; define differences in organisational structures as well as their impact on leading a clinical development project.
- Define, plan, manage and verify the scope of medicinal product development.
- Review the Project Management Body of Knowledge (PMBOK) framework.
- Identify the processes required to plan successfully, execute, monitor and control as well as close-out a complex clinical trial.
- Estimate the resource needs and sequencing activities to produce a project schedule (Network Diagram and Gantt Chart).
- Estimate and control budgets for the medicines development plan.
- Discuss human resources management and communication in complex clinical trial projects.
- Evaluate risk management and contingency planning in medicines development.
- Analyse clinical study inspection findings and relate these to project monitoring, controlling, risk management and quality management.
- Identify and assess factors in failing clinical trials; discuss the concept of project rescue.
Module Overview:

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.

Learning outcomes:

On successful completion of this module students should be able to:

- Relate life-time changes in body composition and function to drug effects in different age groups.
- Create a drug development programme tailored to medical needs, age-specific physiological differences, ethical issues, legal and regulatory requirements.
- Assess the influence of the changed body composition on the pharmacokinetic behaviour of drugs and the effects of drugs on the developing new organism.
- Plan the non-clinical and clinical drug development programme considering the specific conditions of pregnant and lactating women and of the breast-fed baby.
- Compare pharmacokinetic behaviour and pharmacodynamic effects of drugs in the elderly and those observed in the normal adult population.
- Consider the need to develop drugs with elderly specific strength, combinations and drug containers, making a drug application easier in old patients.
- Assess and balance the therapeutic needs of elderly patients with the specific legal and ethical issues relating to trials involving this specific population.
- Evaluate the scientific, socio-ethical, pricing and reimbursement problems related to developing and marketing orphan drugs.
- Design a clinical drug trial protocol considering scientific goal(s), target patient population, suitable methods and feasibility.
- Create an ethics committee review considering the scientific goal(s), target patient population, suitable methods and feasibility.
- Appraise the suitability of traditional trial designs or develop possible new approaches for emerging technologies.
SECOND YEAR

5.7 PM7020 Module 7: Medicines Regulation

Module Overview:

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.

Learning outcomes:

On successful completion of this module students should be able to:

- Describe the background to the development of medicines regulation at a global level & discuss the similarities & differences between the current regulatory systems in the major regions (EU, US, Japan, ROW).
- Describe the role & importance of the practical input from expert international bodies including WHO, CIOMS, WMA, in the oversight of medicines regulation.
- Critically review & evaluate the similarities & differences in legislation relating to drug development in the different regions & explain the impact on the various stakeholders, including regulators, pharmaceutical companies, healthcare professionals & patients.
- Compare & contrast the legal requirements regarding the provision of product information between the major regulatory regions.
- Synthesise the post-marketing activities undertaken by the marketing authorisation holder & the regulatory agencies, & their associated interaction, as part of the life-cycle management of an authorised medicine.
- Explain the background to the development of the International Conference on Harmonisation (ICH) & evaluate its role & main activities, including the Common Technical Document (CTD).
- Describe & appraise the medicines legislation underpinning therapeutic areas, including paediatric use, orphan drugs, advanced therapies & biosimilars in the EU & other major region.
- Explain the principles & practical application of the Medical Devices regulations in the EU & other major regions.
Module Overview:

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.

Learning outcomes:

On successful completion of this module students should be able to:

- Describe the general principles of medicines regulation (both pre- and post-approval) at EU and global level.
- Discuss the impact of medicines legislative requirements on regulatory activities within a pharmaceutical company.
- Explain the role of national agencies and international bodies in medicines regulation.
- Describe the national provisions for management of (1) off-label / unlicensed use of medicines; (2) controlled drugs.
- Discuss the place of International Conference on Harmonisation (ICH) in medicines regulation (including Common Technical Document [CTD]).
- Explain the regulatory processes in the EU / EEA areas.
- Describe the regulation and legal considerations of Product Information.
- Outline the principles and practical application of medical devices regulation.
- Discuss the roles of the various stakeholders (including pharmaceutical and other healthcare professionals, investigators, regulatory authorities) in drug safety and pharmacovigilance.
- Outline the classification of adverse events / adverse drug reactions.
- Describe the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval.
- Discuss the ongoing management of drug safety issues pre- and post-approval (including Risk Management Plans [RMPs], Periodic Safety Update Reports [PSURs]); ongoing benefit / risk assessment throughout the life-cycle of a medicine.
- Discuss the role of pharmacoepidemiology in the life-cycle management of a medicine.
- Describe the factors influencing medication safety from the perspective of each stakeholder.
5.9 PM7017 Module 9: Drug Safety: Pharmacoepidemiology, Pharmacovigilance and Risk Management

Module Overview:

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.

Learning outcomes:

On successful completion of this module students should be able to:

• Explain the role of pharmacovigilance in monitoring of drugs in non-clinical and clinical research and in the marketplace.

• Appraise common nomenclature associated with pharmacovigilance (incl. AE & ADR, listedness, expectedness, causality etc).

• Demonstrate the sources of safety data: methods for collection, analysis, interpretation and reporting drug safety data, including electronic safety data reporting.

• Evaluate the assessment of causality.

• Analyse the application of signal generation and handling of drug safety data in pre-marketing (clinical trial) and post-marketing (pharmacovigilance) contexts, including automated methods.

• Explain the principles of pharmacoepidemiology and examine the different types of pharmacoepidemiological studies used in evaluating drug safety including the choice of the most appropriate study design.

• Describe pharmacovigilance aspects of medicines regulation throughout the lifecycle of a medicine.

• Critically appraise the principles of risk-benefit analysis and management using qualitative and quantitative approaches.

• Evaluate the background and purposes of Risk Management Plans (RMPs) and Risk Evaluation and Mitigation Strategies (REMS).

• Describe the role of the EU Qualified Person in Pharmacovigilance (QPPV).

• Describe major routes for reporting and communication of pharmacovigilance data.

• Evaluate the aetiology, mechanisms and pathology of major classes of adverse drug reactions and interactions.
5.10 PM7018 Module 10: Biologicales and Advanced Therapies

Module Overview:
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.

Learning Outcomes:

On successful completion of this module students should be able to:

- Demonstrate an understanding of the regulatory, ethical and legal issues that are peculiar to biological and advanced therapies.
- Demonstrate an understanding of the challenges presented in constructing a package of non-clinical data to support the clinical development and marketing of biological and advanced therapies.
- Recommend a clinical trial plan that is appropriate for the different types of products and technologies represented by biological and advanced therapies.
- Demonstrate an understanding of the technical and manufacturing issues that are peculiar to biological and advanced therapies.
- Critically review general articles on new or prospective biological or advanced therapies, and published papers describing the clinical trials of biological and advanced therapies.
- Describe the new technologies now available and those in development; describe the therapeutic opportunities that might arise from the technology.
- Critically analyse the differences between natural and modified proteins.
- Describe the global need for new and improved vaccines and the barriers to their development.
- Describe what a therapeutic vaccine is and how it could influence therapy in a common disease area.
- Discuss the history and future prospects for gene therapy, and the technical difficulties developing a gene therapy product.
- Describe the concept of stem cell therapy, what opportunities it might present, and the ethical issues that are unique to this technology.
- Describe the particular ethical and regulatory issues of advanced therapies and how The Advanced Therapy Directive is addressing these.
Module Overview:

The aim of this module, which is run in parallel with module 12, is to provide a higher understanding of the importance of health economics in contemporary healthcare management. It gives a comprehensive overview of the principles of health economics, economic modelling, QALY’s and sensitivity analysis. It provides practical examples of how economic principles are used to measure the cost-effectiveness of medicines and how this impacts on the pharmaceutical industry in terms of pricing and reimbursement.

Learning Outcomes:

On successful completion of this module students should be able to:

- Explain the multidisciplinary nature of pharmacoeconomics and ethical boundaries, and the need for integration of knowledge from a range of health science disciplines in the management of sustainable health service challenges in the 21st century.
- Use in an appropriate manner the fundamental scientific theories underlying the application of health economic techniques to a range of healthcare interventions.
- Recognise and be capable of utilising basic relationships and techniques of healthcare management to maximise benefits from a given resource.
- Explain and present information associated with economic appraisal and assessment of new medicines carried out by NICE or similar agencies.
- Explain the role of the agencies which police the economic viability of existing and new medical technologies.
- Compare and contrast the different challenges of healthcare expenditure presented in different economies.
- Outline the structure of the global drug development and regulatory framework with emphasis on risk management in the context of benefit/risk assessment and the role of pharmacoeconomics and quality-of-life, and be capable of explaining its evolution, strengths and weaknesses.
- Explain methods utilised in clinical trials for examining cost-effectiveness of new pharmaceutical products.
Module content:

This module, which is run in parallel with module 11, 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.

Learning Outcomes:

On successful completion of this module students should be able to:

- Illustrate the life-cycle management (clinical, regulatory and marketing).
- Describe the processes of production and review of product information to ensure adherence to ethical and legal principles pertaining to marketing activities (Good Promotional Practice).
- Discuss the role of patient organisations.
- Discuss the principles and practical application of health economics and patient-reported outcomes within the pharmaceutical industry.
- Outline the principles of health technology assessment (HTA) and its role in the supply of medicines to the marketplace.
- Discuss the principles and practice of marketing within the pharmaceutical industry.
- Discuss drug budget control; pricing mechanisms.
5.13 The provisional timetable for the taught modules is as follows:

<table>
<thead>
<tr>
<th>Module</th>
<th>Course Code</th>
<th>Title</th>
<th>Dates</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PM7011</td>
<td>Introduction - Principles of Discovery of Medicines and Development Planning</td>
<td>23\textsuperscript{rd} – 25\textsuperscript{th} September 2019</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>PM7013</td>
<td>Exploratory and Confirmatory Clinical Development*</td>
<td>4\textsuperscript{th} – 8\textsuperscript{th} November 2019</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>PM7014</td>
<td>Clinical Trials*</td>
<td>4\textsuperscript{th} – 8\textsuperscript{th} November 2019</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>PM7012</td>
<td>Non-Clinical Testing, Pharmaceutical and Early Clinical Development</td>
<td>6\textsuperscript{th} – 8\textsuperscript{th} January 2020</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>PM7022</td>
<td>Project Management in Medicines Development</td>
<td>10\textsuperscript{th} – 12\textsuperscript{th} February 2020</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>PM7019</td>
<td>Special Populations: Clinical Trial Practice and Regulation</td>
<td>9\textsuperscript{th} – 11\textsuperscript{th} March 2020</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Exam</td>
<td>First Year examination</td>
<td>27\textsuperscript{th} April 2020</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>PM7020</td>
<td>Medicines Regulation*</td>
<td>October 2020 (to be confirmed)</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>PM7015</td>
<td>Regulatory Affairs; Drug Safety &amp; Pharmacovigilance*</td>
<td>October 2020 (TBC)</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>PM7017</td>
<td>Drug Safety: Pharmacoepidemiology, Pharmacovigilance and Risk Management*</td>
<td>November 2020 (TBC)</td>
<td>2</td>
</tr>
<tr>
<td>10</td>
<td>PM7018</td>
<td>Biologics and Advanced Therapies*</td>
<td>November 2020 (TBC)</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>PM7021</td>
<td>Health Economics / Pharmacoeconomics*</td>
<td>January 2021 (TBC)</td>
<td>2</td>
</tr>
<tr>
<td>12</td>
<td>PM7016</td>
<td>Healthcare Marketplace; Economics of Healthcare*</td>
<td>January 2021 (TBC)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>PM8000</td>
<td>Research Project Workshop**</td>
<td>April 2021 (TBC)</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Exam</td>
<td>Second Year examination</td>
<td>March 2021 (TBC)</td>
<td>2</td>
</tr>
</tbody>
</table>

* These modules are run in parallel; **MSc students only (lectures will also take place in first year on this module)
6. Course procedure

6.1 Details of each module, including content, draft programme and pre-module reading will be forwarded to the students prior to the module. It is obligatory for all students to read the pre-module material prior to each module (excluding Module 1). Each of the taught modules will consist of formal teaching sessions and interactive workshops; students will be given assignments for electronic submission in a Word document (which will form part of the continuous assessment). It is anticipated that students will spend an average of **10-15 hours** study per week for the duration of the courses.

The students of both the postgraduate Diploma and MSc courses must attend at least 8 of the 10 taught modules. **Students are required to attend at least 5 modules each year in order to sit the examination at the end of each year.**

See section 10 for practical information on the course including venue. There are also a number of students support services available (see appendix II)

6.2 Assessment

6.2.1 Assessment

Students are assessed by way of continuous assessment of personal assignments and written examinations. The continuous assessment portion of the course consists of assignments which will be given to the students at the end of the face to face contact of each module and will include student interaction on Blackboard. Students will be expected to complete the assignment for each module, irrespective of attendance at the module. When completing the assignments, students should make themselves aware of college policy on plagiarism (See section 6.2.5)

The current external examiner is Dr Annette Mollet.

6.2.2 Assignments and attendance at examinations

Continuous assessment assignments should be returned to Geraldine Crowther course executive officer (see Course Faculty, Section 10) within the allocated time frame, which will be specified in the relevant module.

**Late assignments will be subject to a penalty.** Late submission of assignments will only be accepted if there are extenuating circumstances and if the extension is applied for **before** the due date of submission. Otherwise the following penalties will apply:

- up to 1 week late 10% reduction in marks
- up to 2 weeks late 15% reduction in marks
- up to 3 weeks late 25% reduction in marks
- up to 4 weeks late 45% reduction in marks
- no marks for assignments submitted after 4 weeks

September 2019
The assignments are to be submitted electronically in a Word document from your Trinity e-mail. Please ensure that one assignment document for each module is submitted with a page break between each assignment and that your student number (not your student name) and the module number appear as a header on each page (documents that are not in this format will be returned to the student for resubmission). You will receive an e-mail acknowledging receipt of your assignment – please contact the course co-ordinator if you are experiencing any problems with this and if you do not receive an acknowledgement of receipt of your assignment within two weeks. Please note that Geraldine Crowther works part-time and is in the office 2 days per week. Please keep a copy of your assignment on file.

Students who consider that illness may prevent them from attending an examination (or any part thereof) should consult their medical advisor and request a medical certificate for an appropriate period. If a certificate is granted, it must be presented to the student’s Course Co-ordinator within three days of the beginning of the period of absence from the examination. Such medical certificates must state that the student is unfit to sit examinations. Medical certificates will not be accepted in explanation for poor performance; where an examination has been completed, subsequent withdrawal is not permitted.

Students who consider that other grave cause beyond their control may prevent them from attending an examination (or any part thereof) must consult and inform their Course Co-ordinator. The Course Co-ordinator will then make representations to the Dean of Graduate Studies requesting that permission be granted for absence from the examination.

The acceptance of medical disability is entirely at the discretion of the Dean of Graduate Studies, who may ask for a report from the medical officers in charge of the Student Health Service. The report will be strictly confidential to the Dean of Graduate Studies. Further details on regulations for absence from lectures and exams Calendar, Part II, General Regulations and Information http://www.tcd.ie/calendar/undergraduate-studies/general-regulations-and-information.pdf

6.2.3 Postgraduate Diploma

Students must pass 5 of the 6 modules taken in the first year in order to be permitted to proceed to the second year of the course. If a student fails to pass 2 or more modules then they must present for supplemental examinations and/or re-submission of required work in order to proceed to second year. The students will only be allowed one re-submission/repeat of the examination and the maximum mark to be awarded for the module is 50%.

To qualify for the award of the Postgraduate Diploma, students must achieve an overall mark of at least 50% which will be the credit-weighted average of all modules and students must pass individual taught modules amounting to 60 ECTS. Students may compensate failed modules accounting for not more than 10 ECTS by end of year two provided that they achieve an overall pass mark of 50% across the taught modules and get a mark of no less than 40% in the failed module(s).

Assessment will be by a combination of continuous assessment (50% of marks for each module) and a written examination (50% of marks for each module) at the end of the first academic year and in March of the second year. The only exception to this is the module on health economics.
(in the second year of the course) which is assessed entirely by continuous assessment. The students will only be allowed one re-submission/repeat of the examination and the maximum mark to be awarded for the module is 50%.

A distinction may be awarded to those students who achieve an overall credit weighted mark of ≥70%. A Postgraduate Diploma with Distinction cannot be awarded if a candidate has failed any component of any module during the period of study.

6.2.4 MSc

Students must pass 5 of the 6 modules taken in the first year in order to be permitted to proceed to the second year of the course. If a student fails to pass 2 or more modules then they must present for supplemental examinations and/or re-submission of required work in order to proceed to second year. The students will only be allowed one re-submission/repeat of the examination and the maximum mark to be awarded for the module is 50%.

For the taught part of the MSc, students will be assessed by continuous assessment and a written examination at the end of the first academic year and in March of the second year, similar to the Postgraduate Diploma. Students will be required to repeat the failed components of the modules which they have failed in supplementary examinations. The students will only be allowed one re-submission/repeat of the examination and the maximum mark to be awarded for the module is 50%.

To qualify for the award of the M.Sc., students must achieve an overall mark of at least 50% which will be the credit-weighted average of all modules including the research project/dissertation. They must pass taught modules amounting to 60 credits and achieve an average mark of at least 50% across the taught modules as well as in the research project/dissertation. Students may compensate failed modules accounting for not more than 10 ECTS by end of year two provided that they achieve an overall pass mark of 50% across the taught modules and get a mark of no less than 40% in the failed module(s).

6.2.4.1 Research Project

As part of the research project module (30 ECTS), students are required to work on their research project over the summer period between year 1 and 2. Lectures will also be provided during the first year on this module in addition to the research project workshop which takes place in April of the second year. A preliminary project proposal should be submitted to the course co-ordinator by the 31st August 2020. Feedback will be given on these preliminary proposals to the students. Students are expected to submit a final project proposal for their research project at the end of October 2020. Marks will be allocated for the project proposal as part of the overall marks of the research project module. Students will be allocated a supervisor for their research once the proposal has been approved by the management committee of the course. They will be expected to follow an agreed time-plan for their project and to submit a written dissertation (15,000 – 20,000 words) by the end of August 2021. An external examiner and internal examiner will be appointed to review the dissertation. The student may be required to attend an oral examination following submission of the dissertation, if one is deemed necessary. When writing-
up the dissertation, students should make themselves aware of college policy on plagiarism (See section 6.2.5 and appendix I)

The award of a MSc with Distinction shall require the achievement of a distinction (70% or above) for the dissertation, and an overall average mark for the taught part of the course of at least 70%. A MSc with Distinction cannot be awarded if a candidate has failed any component of any module during the period of study.

6.2.5 College Regulations regarding Plagiarism

Plagiarism is a serious offence in the academic setting and is punishable by severe penalties, including rejection of submitted work and even expulsion from College. Plagiarism is interpreted by the University as the act of presenting the work of others as one’s own work, without acknowledgement. Plagiarism can arise from actions such as:
   a) copying another student’s work
   b) enlisting another person or persons to complete an assignment on the student’s behalf
   c) quoting directly, without acknowledgement, from books, articles or other sources, either in printed, recorded or electronic format
   d) paraphrasing, without acknowledgement, the writings of other authors.

This is not an exhaustive list, and plagiarism can be intentional or unintentional. However whether it is intentional or otherwise is not considered relevant – both are equally serious and the student must be informed and proactive in avoiding plagiarism. In order to guard against this occurring, all students are expected to screen their work using TurnItIn software. Students are expected to have read and understood College policy regarding plagiarism and to ensure that none of their submitted work is plagiarized (see appendix I for more information on plagiarism).

In order to support students in understanding what plagiarism is and how they can avoid it, there is an online central repository hosted by the Library and located at http://tcd-ie.libguides.com/plagiarism. It includes the following:

- What Plagiarism is and how to avoid it
- Ready Steady Write Plagiarism Tutorial
- Coversheet Declaration
- Consequences of Plagiarism at Trinity
- Detecting Plagiarism
- Citation Styles
- Reference Management Apps

6.2.6 Turnitin

Trinity College Dublin has teamed up with Turnitin, the global leader in plagiarism prevention and online grading. (www.turnitin.com). All written assignments must be passed through Turnitin before the deadline for submission to the course administrator, giving the student an
opportunity to check that any material taken from other sources is referenced and acknowledged correctly.

Turnitin is now integrated into the College VLE, Blackboard Learn, which offers students and instructors a facility for checking academic integrity of online assignments and dissertations.

We regard Turnitin more as a proactive tool for educating students on academic writing as opposed to a means of uncovering plagiarism after the fact (however it will do both!). If you put an essay through Turnitin, it will highlight any paragraphs that match text from elsewhere e.g. online, journals, essays etc. The course coordinators will evaluate whether an item is plagiarized or just poorly referenced.

6.3 Course material

Course documentation including lectures, reading lists and assignment details will be uploaded to Blackboard (see section 9) for each module. Students will be directed to relevant texts depending on the content of the individual module. Students are also expected to keep up to date with current information and literature and should be competent at searching databases and the internet for up-to-date information.

A collection of dissertations submitted by former students is available in the Department for perusal by MSc students. Students may borrow dissertations from the Department on the condition that they

a) have permission from the Course Coordinators to remove the dissertation from the Department;
b) notify Course Executive Officer Geraldine Crowther by email, providing details of author, date and title of the dissertation, along with due date for return of dissertation;
c) return the dissertation to the Department within two weeks.

Students may request permission from the Course Coordinators if they wish to retain the dissertation for a longer period, and must notify Course Executive Officer Geraldine Crowther of amended due date for return of dissertation.
7. Student Registration & Orientation

The College website has useful information for new Trinity students on their website http://www.tcd.ie/orientation/. This includes details on how to register, which occurs on a rolling basis from mid-August and is done online. Once you have registered, you will need to collect your TCD student card in person from the main Trinity campus.

The Postgraduate Orientation Week is taking place from 26th – 30th August 2019. If you are unable to attend at this time you must make alternative arrangements to collect your student card. A copy of the Postgraduate Students Handbook is available to download on www.tcd.ie/students/orientation/postgraduates/handbook.php

The student information system (SITS) is accessible to students via the web portal my.tcd.ie. All communications from College will be sent to you via your online portal which will give you access to an ‘in tray’ of your messages. All fee invoices/payments, student levies and commencement fees will be issued online and all payments will be carried out online.

All registered students in Trinity College have an account on Blackboard Learn. You can access your modules by logging in from any device with internet access at mymodule.tcd.ie using your Trinity computer account username and password. For guides, support and video tutorials on using Blackboard Learn please click on the Help tab after you have logged in.

If you are having problems logging in to Blackboard contact the IT Service Desk by email itservicedesk@tcd.ie or in person on the ground floor of Aras an Phiarsaigh.

Full user helpline facilities, including emergency contact details, will be available from when you register to guide you through these new processes and to answer any queries that you may have.

Additional student services that are available are included in appendix II.

8. Library facilities

The John Stearne medical library in the Trinity Centre for Health Sciences at St James's Hospital has extensive facilities. A library workshop has been included in Module 1 to demonstrate the library facilities available to Trinity students.
9. Academic Registry

The Academic Registry provides central academic administrative services in support of the following key student life cycle activities:

- Undergraduate and Postgraduate Admissions
- Fees & Payments
- Annual Student Registration
- Lecture Timetables
- Erasmus & Study Abroad
- Examinations, Assessment & Progression
- Research Degrees
- Commencements & Graduation
- Seanad Éireann
- University Senate
- Statistical Reporting

The Service Desk is the public face of the Academic Registry. The team provides an integrated service for prospective students, current students and graduates of Trinity College. The Service Desk can assist with queries concerning application and admissions, registration and record management, student finance, postgraduate studies and examinations.

The Service Desk is located in the Watts Building at the East End of campus on the Upper Ground Floor. Please enter through the Panoz Building entrance and turn left up the stairs. Go through the red doors on your left and The AR Service Desk is straight ahead.

Service Desk Opening Hours: Monday to Friday: 9.30am – 5.30pm.

The AR can be contacted in the following ways:

- Log Student Queries: Click onto my.tcd.ie and click the 'ASK AR' button
- Phone: +353 (0) 1 896 4500
- Email: academic.registry@tcd.ie
- Postal Address: Academic Registry, Watts Building, Trinity College, Dublin 2, Ireland
- Social Media: www.facebook.com/TCDAcademicRegistry
- www.twitter.com/TCDAcadRegistry
10. Computer Use

Students are expected to have access to their own computer with online access.

Please review the Trinity IT Services [https://www.tcd.ie/itservices/](https://www.tcd.ie/itservices/). IT Services is the central provider of IT services for students and staff of Trinity College Dublin. This section of the site, which has a useful video, is intended as a guide for new students in getting started with the various College computer facilities available to them. There will be an IT induction session at the first module, facilitated by a member of the IT department.

Please note that all technical or support queries should be addressed only to the IT Service Desk. The IT Service Desk can be contacted in the following ways:

- Email: itservicedesk@tcd.ie (please ensure you fill in the 'Subject' for your email). Technical queries relating to the SITS service should be directed to asksusu@tcd.ie.
- Phone: ext. 2000 (+353-1 896 2000)
- In Person: Ground Floor, Áras An Phiarasgaigh (Mon-Thu: 9.00-17.30, Fri: 9.00-17.00)
- Web Portal: ask.tcd.ie

Training courses available include:

- Planning Thesis Production Using MS Word
- Effective Presentations using PowerPoint 2013
- Data Processing with Excel
- Survey Monkey courses

www.tcd.ie/itservices/training/index.php

There is a published IT Security Policy which all Trinity staff and students are obliged to adhere to. This document and a full range of supporting material with advice on practical ways that all members of the University can help to protect the confidentiality, availability, and integrity of Trinity information technology resources are available on the IT Security Website. The document and other useful information regarding IT Security is available on [www.tcd.ie/itservices/security/](http://www.tcd.ie/itservices/security/)

Students can avail of software under the Site Licenses College has purchased on behalf of students. This includes:

- Microsoft Office 365 ProPlus for Students
- SPSS (statistics package)

http://www.tcd.ie/itservices/software/kb/student_software.php

The course will be using an interactive web based system – Blackboard. It will be used to provide information and details about the course for the individual modules and will also be used for contact and discussions in between the modules.

Please note that in order to access webpages (including Blackboard and the electronic library) external to college, it is necessary to configure your web browser to use the web proxy server. Please review the IT Services website for instructions regarding this.
11. Course Faculty

Head of Department of Pharmacology and Therapeutics, School of Medicine

Professor Michael Barry

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 Pharmacoconomics 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 Pharmacoconomics 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

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 with overall responsibility for the postgraduate courses. 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 specialty 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 is the current national specialty director (NSD).

Course Co-ordinators

Mary Rafter

Mary Rafter is responsible for day-to-day running of the courses, since joining Trinity College Dublin as assistant professor in pharmaceutical medicine in 2017. With a background as a pharmacist, she has spent a considerable portion of her career as a pharmaceutical assessor at the Health Products Regulatory Authority (HPRA, formerly Irish Medicines Board), and
represented the board on various CPMP/CHMP/EMA committees as a pharmaceutical expert. This was interspersed with periods spent in the pharmaceutical industry, including as senior manager of a global regulatory affairs team at Pfizer Newbridge. She has worked as a consultant in the regulatory affairs arena and contributed to academic education programmes since obtaining her MSc in Pharmaceutical Medicine from Trinity College in 2010. [Email: rafterm1@tcd.ie]

Joanne Ramsey

Joanne Ramsey is also responsible for the day-to-day running of the courses. Joanne graduated from University of Ulster with a degree in Biomedical Science and obtained her Diploma in Professional Practice (DPP) working in the NHS. She carried out her PhD in the Centre for Cancer Research and Cell Biology at Queen’s University Belfast where she studied small molecule therapies in malignant diseases. Upon completion of her PhD in 2011 she took up a pharmaceutical research position in Royal College of Surgeons in Ireland developing ATMPs and is involved in two invention disclosures and one patented gene therapy. She became a lecturer and principal investigator in RCSI in 2015 and obtained her postgraduate diploma in Health Professional’s Education before joining Trinity College Dublin as assistant professor in pharmaceutical medicine in 2019. [Email: ramseyj@tcd.ie]

Course Executive Officer

Geraldine Crowther

Geraldine Crowther assists with the administration of the course. [E-mail: crowtheg@tcd.ie]

Speakers/ lecturers will primarily come from the:

- Dept. of Pharmacology and Therapeutics, Trinity College
- Specialist staff of the Trinity affiliated hospitals
- National Medicines Information Centre, St James’s Hospital
- National Centre for Pharmacoeconomics, St James’s Hospital

In addition each module will have contributions from national and international speakers, including experts from the Health Products Regulatory Authority (previously known as the Irish Medicines Board), the European Agency for the Evaluation of Medicinal Products (EMA) and the Pharmaceutical industry.

Details of the speakers for each module will be provided in the relevant module.
12. Practical Information

12.1 Venue

The course will take place in the Trinity Centre for Health Sciences, which is situated in the grounds of St. James’s Hospital. Please note that the James’s Street entrance is the designated entrance to the hospital grounds for the general public. There is no public access allowed via the Rialto Gate entrance. St James’s hospital is situated in Dublin 8, on the south side of the city. Please allow plenty of time to reach the hospital, if you are visiting for the first time, as the traffic in the vicinity is very heavy, especially in the mornings.

12.2 Emergency Procedure

In the event of an emergency, dial Security Services on extension 1999. Security Services provide a 24-hour service to the college community, 365 days a year. They are the liaison to the Fire, Garda and Ambulance services and all staff and students are advised to always telephone extension 1999 (+353 1 896 1999) in case of an emergency.

Should you require any emergency or rescue services on campus, you must contact Security Services. This includes chemical spills, personal injury or first aid assistance. It is recommended that all students save at least one emergency contact in their phone under ICE (In Case of Emergency). The Security Services are located at the Security desk on the ground floor of the Trinity Centre in St James’s Hospital campus.

12.3 Parking

There are no parking spaces available in the Trinity Centre campus site in St James’s Hospital. There is an underground public car-park within St. James’s Hospital grounds; you are advised to follow the large “P” signs along the hospital’s main thoroughfare. Full day parking in this car-park is expensive (fee payable at hourly rate). It is likely that parking will be an issue with the proposed building of the children’s hospital and you are advised to use public transport where possible. Illegal parking is subject to clamping by the Security staff.

12.4 Public Transport

The Luas (Red line), which runs from Connolly Station to Tallaght, has a stop in St. James’s Hospital. Park and ride facilities are available at the Red Cow and at some other stops– please check www.luas.ie for up to date information including maps and fare details prior to planning your journey.

Bus number 123 also goes through the hospital grounds. It can be accessed in the city centre (bus stops in O’Connell Street, D’Olier Street and Dame Street). The 78a and 51b buses pass by the hospital entrance on James’s Street. These buses depart from Aston Quay outside the Supervalu shop, beside O’Connell Bridge in the city centre.
12.5 Refreshments/lunch

In general there will be morning/afternoon coffee breaks and a one-hour lunch break for the full day sessions, although it may occasionally be necessary to alter break times to accommodate the availability of lecturers. There is a coffee shop in the stone building opposite the Trinity Centre building and there are also coffee shops, restaurants and a juice shop, at the main hospital entrance. Participants are asked to respect the time-limits set for the refreshments break and lunch, in order to ensure that each lecturer has sufficient time to cover his/her topic within the allotted time.

12.6 Accommodation

St James's Hospital is close to the city centre where there is a wide range of different hotels. There are also bed and breakfast establishments close to the hospital. Please contact us if you require any further details.

13. Feedback

We hope that you enjoy the course and that it fulfills your expectations. We ask for feedback via anonymous questionnaires at the end of the first year and taught part of the course. We welcome your comments in relation to any aspect of the course and are open to suggestions on how you feel we can improve the course.

Course coordinators will be available at each of the individual modules and also can be contacted in between modules via e-mail.
Appendix I

College Regulations Regarding Plagiarism (see College Calendar Section 1.32)

1. General
   It is clearly understood that all members of the academic community use and build on the work and ideas of others. It is commonly accepted also, however, that we build on the work and ideas of others in an open and explicit manner, and with due acknowledgement. Plagiarism is the act of presenting the work or ideas of others as one’s own, without due acknowledgement. Plagiarism can arise from deliberate actions and also through careless thinking and/or methodology. The offence lies not in the attitude or intention of the perpetrator, but in the action and in its consequences.
   It is the responsibility of the author of any work to ensure that he/she does not commit plagiarism.

   Plagiarism is considered to be academically fraudulent, and an offence against academic integrity that is subject to the disciplinary procedures of the University.

2. Examples of Plagiarism
   Plagiarism can arise from actions such as:
   (a) copying another student’s work;  
   (b) enlisting another person or persons to complete an assignment on the student’s behalf;  
   (c) procuring, whether with payment or otherwise, the work or ideas of another;  
   (d) quoting directly, without acknowledgement, from books, articles or other sources, either in printed, recorded or electronic format, including websites and social media;  
   (e) paraphrasing, without acknowledgement, the writings of other authors.

   Examples (d) and (e) in particular can arise through careless thinking and/or methodology where students:
   (i) fail to distinguish between their own ideas and those of others;
   (ii) fail to take proper notes during preliminary research and therefore lose track of the sources from which the notes were drawn;
   (iii) fail to distinguish between information which needs no acknowledgement because it is firmly in the public domain, and information which might be widely known, but which nevertheless requires some sort of acknowledgement;
   (iv) come across a distinctive methodology or idea and fail to record its source.

   All the above serve only as examples and are not exhaustive.

3. Plagiarism in the context of group work
   Students should normally submit work done in co-operation with other students only when it is done with the full knowledge and permission of the lecturer concerned. Without this, submitting work which is the product of collusion with other students may be considered to be plagiarism. When work is submitted as the result of a Group Project, it is the responsibility of all students in the Group to ensure, so far as is possible, that no work submitted by the group is plagiarised.
4. **Self-Plagiarism**
No work can normally be submitted for more than one assessment for credit. Resubmitting the same work for more than one assessment for credit is normally considered self-plagiarism.

5. **Avoiding Plagiarism**
Students should ensure the integrity of their work by seeking advice from their lecturers, tutor or supervisor on avoiding plagiarism. All schools and departments must include, in their handbooks or other literature given to students, guidelines on the appropriate methodology for the kind of work that students will be expected to undertake. In addition, a general set of guidelines for students on avoiding plagiarism is available at https://libguides.tcd.ie/friendly.php?s=plagiarism

If plagiarism as referred to in paragraph (1) above is suspected, the Director of Teaching and Learning (Postgraduate) or his/her designate will arrange an informal meeting with the student, the student’s Supervisor and/or the academic staff member concerned, to put their suspicions to the student and give the student the opportunity to respond. Students may nominate a Graduate Students’ Union representative or PG advisor to accompany them to the meeting.

The student will be requested to respond in writing stating his/her agreement to attend such a meeting and confirming on which of the suggested dates and times it will be possible for them to attend. If the student does not in this manner agree to attend such a meeting, the Director of Teaching and Learning (Postgraduate), or designate, may refer the case directly to the Junior Dean, who will interview the student and may implement the procedures as referred to in Section 5 (Other General Regulations).

If the Director of Teaching and Learning (Postgraduate) forms the view that plagiarism has taken place, he/she must decide if the offence can be dealt with under the summary procedure set out below. In order for this summary procedure to be followed, all parties noted above must be in agreement and must state their agreement in writing to the Director of Teaching and Learning (Postgraduate) or designate. If one of the parties to the informal meeting withholds his/her written agreement to the application of the summary procedure, or if the facts of the case are in dispute, or if the Director of Teaching and Learning (Postgraduate) feels that the penalties provided for under the summary procedure below are inappropriate given the circumstances of the case, he/she will refer the case directly to the Junior Dean, who will interview the student and may implement the procedures set out in

If the offence can be dealt with under the summary procedure, the Director of Teaching and Learning (Postgraduate) will recommend one of the following penalties:

(a) **Level 1**: Student receives an informal verbal warning. The piece of work in question is inadmissible. The student is required to rephrase and correctly reference all plagiarised elements. Other content should not be altered. The resubmitted work will be assessed and marked without penalty;

(b) **Level 2**: Student receives a formal written warning. The piece of work in question is inadmissible. The student is required to rephrase and correctly reference all plagiarised elements. Other content should not be altered. The resubmitted work will receive a reduced or capped mark depending on the seriousness/extent of plagiarism;

(c) **Level 3**: Student receives a formal written warning. The piece of work in question is inadmissible. There is no opportunity for resubmission.

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Note: Plagiarism at postgraduate level is considered (at a minimum) an immediate Level 2 offence.

Provided that the appropriate procedure has been followed and all parties above are in agreement with the proposed penalty, the Director of Teaching and Learning (Postgraduate) should in the case of a Level 1 offence, inform the Course Director and, where appropriate, the Course Office. In the case of a Level 2 or Level 3 offence, the Dean of Graduate Studies must be notified and requested to approve the recommended penalty.

The Dean of Graduate Studies may approve or reject the recommended penalty, or seek further information before making a decision. If he/she considers that the penalties provided for under the summary procedure are inappropriate given the circumstances of the case, he/she may also refer the matter directly to the Junior Dean who will interview the student and may implement the procedures as referred to under conduct and college. Notwithstanding his/her decision, the Dean of Graduate Studies will inform the Junior Dean of all notified cases of Level 2 and Level 3 offences accordingly.

The Junior Dean may nevertheless implement the procedures as set out in Section 5 (Other General Regulations). If the case cannot normally be dealt with under summary procedures, it is deemed to be a Level 4 offence and will be referred directly to the Junior Dean. Nothing provided for under the summary procedure diminishes or prejudices the disciplinary powers of the Junior Dean under the 2010 Consolidated Statutes.

All students will be required to submit a cover sheet with the declaration completed confirming that the Ready Steady Write plagiarism tutorial has been completed (see below)
In order to support students in understanding what plagiarism is and how they can avoid it, there is an online central repository hosted by the Library and located at https://libguides.tcd.ie/plagiarism. It includes the following:

(i) The 2018-19 Calendar entry on plagiarism for undergraduate and postgraduate students;
(ii) The matrix explaining the different levels of plagiarism outlined in the Calendar entry and the sanctions applied;
(iii) Information on what plagiarism is and how to avoid it;
(iv) ‘Ready, Steady, Write’, an online tutorial on plagiarism which must be completed by all students - https://libguides.tcd.ie/plagiarism/ready-steady-write;
(v) Details of software packages that can detect plagiarism, e.g. Turnitin.

I have read and I understand the plagiarism provisions in the General Regulations of the University Calendar for the current year, found at http://www.tcd.ie/calendar/

I have also completed the Online Tutorial on avoiding plagiarism ‘Ready Steady Write’, located at https://libguides.tcd.ie/plagiarism/ready-steady-write

I declare that the assignment being submitted represents my own work and has not been taken from the work of others save where appropriately referenced in the body of the assignment.

Signed:______________________  Date:_________________________
Appendix II

Additional student information and support

1. Student Services

Student services make a crucial contribution to the student experience at Trinity College. The mission of student services is to provide opportunities of the highest quality for student development in an inclusive, caring and cost effective way, consistent with the academic mission of College. The Student Services website provides information on the services available to Trinity students

www.tcd.ie/students/orientation/services/

Further information is available on each service's website.

2. Student Learning and Development (SLD)

SLD provides learning support to help students reach their academic potential. They run workshops, have extensive online resources and provide individual consultations.

www.tcd.ie/Student_Counselling/student-learning/postgraduate/

3. Explanation of ECTS Weighting

The European Credit Transfer and Accumulation System (ECTS) is an academic credit system based on the estimated student workload required to achieve the objectives of a module or programme of study. It is designed to enable academic recognition for periods of study, to facilitate student mobility and credit accumulation and transfer. The ECTS is the recommended credit system for higher education in Ireland and across the European Higher Education Area.

The ECTS weighting for a module is a measure of the student input or workload required for that module, based on factors such as the number of contact hours, the number and length of written or verbally presented assessment exercises, class preparation and private study time, laboratory classes, examinations, clinical attendance, professional training placements, and so on as appropriate. There is no intrinsic relationship between the credit volume of a module and its level of difficulty.

The European norm for full-time study over one academic year is 60 credits. 1 credit represents 20-25 hours estimated student input, so a 10-credit module will be designed to require 200-250 hours of student input including class contact time, assessments and examinations.
ECTS credits are awarded to a student only upon successful completion of the programme year. Progression from one year to the next is determined by the programme regulations. Students who fail a year of their programme will not obtain credit for that year even if they have passed certain component. Exceptions to this rule are one-year and part-year visiting students, who are awarded credit for individual modules successfully completed.

4. Graduates Students’ Union

Trinity’s Graduate Students’ Union (GSU) established in 1973 is the representative body for all postgraduate students in Trinity College Dublin, the University of Dublin. The two sabbatical officers of the GSU work full-time and represent postgraduate students on all major committees including Board, Council, Student Life, Graduate Studies Committee and Research Committee. The Union’s executive committee which includes representatives from all faculties convene on a monthly basis and more often when required. The objective of the Union is to effectively represent postgraduate students within the University, advocate on behalf of Union members on issues that impact your education internally and nationally; and to protect the interests of our union members during their studies.

Activities of the Union include: providing social and recreational facilities for postgraduate students; monitoring and developing the study and recreational facilities of the 1937 Postgraduate Reading Room; providing a Graduate common room for postgraduate students (located in house 7) and to provide and manage lockers for students in the 1937 Reading Room (rental is organised through the front office in house 6).

The GSU produces an academic and peer-reviewed journal on an annual basis, the Trinity Postgraduate Review (http://trinitypostgradrev.wixsite.com/tcd-ie), and a literary magazine, College Green (www.collegegreenmagazine.com/). It also produces a postgraduate handbook for students with information on supports and services available to postgraduate students.

The GSU President works in the area of policy and strategy. The GSU Vice-President acts as the Welfare and Education Officer for postgraduates in TCD and provides confidential one-to-one advice, advocacy and support in areas such as student supervisor relationships and financial hardship. The GSU Communications Officer informs you on a weekly basis of information, postgrad events and updates from the university and the wider metropolitan community through the medium of a digital newsletter titled The Postgrad Weekly.

The GSU website www.tcdgsu.ie provides the latest updates from the Union, information on elections, campaigns and connections to the Union’s social media platforms. Students can arrange meetings with the sabbatical officers via emailing either the GSU President Oisin Vince Coulter at president@tcdgsu.ie or the GSU Vice-President Gogoal Falia at vicepresident@tcdgsu.ie or by contacting the office landline at (01) 896 1169.

Students in the Health Sciences faculty may also contact the Union’s Health Sciences Officer at hsofficer@tcdgsu.ie with any faculty-specific questions or concerns.
5. Postgraduate Advisory Service

The Postgraduate Advisory Service, commonly referred to as PAS, is the frontline support for postgraduate students at Trinity. PAS is coordinated by the Postgraduate Student Support Officer who acts as a first point of contact for any postgraduate student needing support or guidance. We also have a panel of academics to act as Postgraduate Advisors to assist on more complex cases. PAS is based in the Senior Tutor’s Office.

How we can help

We are here to provide support on any matter that may impact upon your time as a postgraduate at Trinity.

Some of the most common issues students come to PAS to discuss include: study-related stress or worry; concerns about academic progress; supervisor-relationship concerns; extensions and going off-books; queries regarding regulations and academic appeals; bullying; plagiarism and disciplinary cases and financial hardship.

We support students by:

- Providing frontline confidential and free support, information, and referral via the Postgraduate Student Support Officer
- Providing, on referral, named academics to provide advice, advocacy, and assistance via a panel of Postgraduate Advisors
- Providing a suite of complementary supports including informal mediation, workshops and training to postgraduates
- Administering the Postgraduate Student Assistance Fund and other financial assistance to postgraduate students.

PAS also provides representation for postgraduates in the event of disciplinary and/or academic appeals. PAS is located on the ground floor of House 27, Library Square. Appointments are available from 10am to 3pm, Monday-Friday. If in doubt get in touch!

Contact info:

+353 896 1417
pgsupp@tcd.ie
https://www.tcd.ie/Senior_Tutor/students/postgraduate/
6. Careers Advisory Service

Postgraduate study opens the doors to many opportunities, but the market is competitive and you will need to differentiate yourself clearly from other candidates.

Resources:
The Careers Service provides a wide range of resources and services to help you make and implement informed choices about your future career direction.
The Careers Information Centre at 7-9 South Leinster Street contains a range of free, career-related booklets and employer materials for you to take away. You will also find information, resources and advice on our website www.tcd.ie/careers to guide you through making applications and career decisions.

Services:
Individual appointments to meet a Careers Consultant are available throughout the year. Your Careers Consultant is available to work with you to help you identify how best to approach the next step in your career. They can also review your applications for jobs or further study and provide coaching to ensure maximum impact at interview.
Job opportunities from employers currently recruiting Trinity graduates as well as postgraduate courses and funding are available via our MyCareer portal.

MyCareer
An online service that you can use to:
- Apply for opportunities which match your preferences - vacancies including research options
- Search opportunities - postgraduate courses and funding
- View and book onto employer and CAS events
- Submit your career queries to the CAS team
- Book an appointment with your Careers Consultant

Simply login to MyCareer using your Trinity username and password and personalise your profile.

Careers Advisory Service
Trinity College Dublin, 7-9 South Leinster Street, Dublin 2
01 896 1705/1721 | Submit a career query through MyCareer

MyCareer: mycareerconnect.tcd.ie
TCD.Careers.Service
www.tcd.ie/Careers/
@TCDCareers
7. Centre for English Language Learning and Teaching (CELLT)
http://www.tcd.ie/slscs/english/
English for Academic Purposes
CELLT provides English Language Learning Support for prospective and accepted students of Trinity College who are not native-speakers of English, as well as offering specialized courses for the general public. Located in the School of Linguistic, Speech and Communication Sciences, the centre delivers pre-sessional (summer), in-sessional, and pathway English for Academic Purposes courses within the college.

8. College Health Centre
www.tcd.ie/collegehealth/

The health service was founded in 1965. It aims to take a holistic approach to Student Health and in addition to providing on campus, primary health care for all full-time students it focuses on the psychological and occupational aspects of Student Health and Health Education. Student consultations are free of charge with modest charges for additional services.

Absolute confidentiality is maintained. All medical records are retained in the Health Centre and do not form part of the University's Student Records. Information is only given to third parties with the patient's consent.

The Health Centre is located in a modern, purpose built premises situated on Trinity Campus in House 47, a residential block adjacent to the rugby pitch. Emergency clinics available at 9:00am and 2pm. Emergency patients must be present at the above times. If demand is heavy, lists may be closed early. To make an appointment, please call 01 8961591 or 01 8961556.
9. Student Supports: Quick Glance

Trinity welcomes all its students and as a TCD student you have many supports available to you. Please see below for a list of relevant supports. We hope you find this Quick Glance Page useful. If you find a site is missing, please contact us and we will add it to this list.

- **Academic Registry** | www.tcd.ie/academicregistry/
- **Academic Policies and Procedures** | www.tcd.ie/teaching-learning/academic-policies/
- **Careers Advisory Service** | www.tcd.ie/Careers/students/postgraduate/; www.tcd.ie/careers
- **Chaplaincy** | www.tcd.ie/Chaplaincy/
- **Complaint Procedures** | www.tcd.ie/about/policies/160722_Student%20Complaints%20Procedure_PUB.pdf
- **Disability Service** | www.tcd.ie/disability/
- **Data Protection** | www.tcd.ie/info_compliance/data-protection/student-data/
- **Dublin Uni. Central Athletic Club (DUCAC)** | www.tcd.ie/Sport/student-sport/ducac/?nodeId=94&title=Sports_Clubs
- **Dignity and Respect Policy** | www.tcd.ie/equality/policy/dignity-respect-policy/
- **Graduate Student’s Union (GSU)** | www.tcdgsu.ie
- **Guidelines on Plagiarism** | http://tcd-ie.libguides.com/plagiarism
- **Health and Safety Statement** | www.tcd.ie/medicine/local/staff/health-safety.php
- **Health Centre** | www.tcd.ie/collegehealth/; www.tcd.ie/College_Health
- **IT Services** | www.tcd.ie/itservices/
- **Maths Help Centre** | www.maths.tcd.ie/Info_for_Schools/Maths_Helproom.php
- **Mature Students Office** | www.tcd.ie/maturestudents/
- **Online tutorial Ready Steady Write** | http://tcd-ie.libguides.com/plagiarism/ready-steady-write
- Orientation Programme | www.tcd.ie/students/orientation/
- Postgraduate Advisory Service | www.tcd.ie/Senior_Tutor/postgraduateadvisory/
- Student Services | www.tcd.ie/corporate-services/structure/student-services/
- Student Counselling Services | www.tcd.ie/Student_Counselling/
- Student societies | http://trinitysocieties.ie/
- Student Representation Structures | www.tcdgsu.ie/becomearep/
- Senior Tutor Services | www.tcd.ie/seniortutor/
- TCD sports | www.tcd.ie/Sport/
- TCD Student’s Union (TCDSU) | www.tcdsu.org
Appendix III

Support Provision for Students with Disabilities

Trinity has adopted a Reasonable Accommodation Policy that outlines how supports are implemented in Trinity. Student seeking reasonable accommodation whilst studying in Trinity must applying for reasonable accommodations with the Disability Service in their student portal my.tcd.ie. Based on appropriate evidence of a disability and information obtained from the student on the impact of their disability and their academic course requirements, the Disability Staff member will identify supports designed to meet the student’s disability support needs. Following the Needs Assessment, the student’s Disability Officer prepares an Individual Learning Educational Needs Summary (LENS) detailing the Reasonable Accommodations to be implemented. The information outlined in the LENS is communicated to the relevant School via the student record in SITS.

Examination accommodation and deadlines

Students should make requests as early as possible in the academic year. To ensure the Assessment, Progression and Graduation Team can set your accommodations for examination purposes the following deadlines are applied:

- End of Year assessments: the last Friday in January (24th January 2020)

Student responsibilities for departmental assessments/course tests

- Students are required to initiate contact with the School/Department and request reasonable accommodations as per their LENS report, or email received following their needs assessment for particular assessments for School/ Department administered assessment. Students are advised to make contact at least two weeks prior to the assessment date to enable adjustments to be implemented.
**Professional Learning Education Needs Summary - PLENS**

Students with disabilities on professional courses in receipt of reasonable accommodation provided by College the Disability Service will be issued a PLENS report and are provided with supports such as examination and academic reasonable accommodations. In the background section of the PLENS the following text is included:

<table>
<thead>
<tr>
<th>Boxed Text</th>
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<tbody>
<tr>
<td>Student is encouraged to discuss any disability supports required on professional course and placement with the Academic contact and/or Placement Co-ordinator of their course. Student can be referred back to Disability Service for placement planning supports - Level 2 - Placement Planning, if and when required.</td>
</tr>
<tr>
<td>Students are encouraged to speak with the placement co-ordinator if they are unsure of any needs for placement supports. Students can be referred back to Disability Service for placement planning supports, if and when required. More Information on placement supports offered are linked <a href="https://www.tcd.ie/disability/services/placement-planning.php">here</a>.</td>
</tr>
</tbody>
</table>

Please note: no reasonable accommodation can be provided outside the procedures outlined in the Trinity Reasonable Accommodation Policy.

More detailed text on placement planning and supports can be found at the following link:

[https://www.tcd.ie/disability/services/placement-planning.php](https://www.tcd.ie/disability/services/placement-planning.php)