MSc Model-based Drug Development Programme Handbook 2025/26

Description

MSc MODEL-BASED DRUG DEVELOPMENT

PROGRAMME HANDBOOK

2025-26

Division of Pharmacy and Optometry

School of Health Sciences

Faculty of Biology, Medicine and Health

Welcome to the Programme

MSc Model-based Drug Development

Welcome to the Model-based Drug Development postgraduate programme.

This student handbook provides details of the University of Manchester Programme leading to the MSc in Model-based Drug Development and the Diploma/Certificate (exit awards). Please read this handbook in conjunction with the School of Health Sciences Student Handbook, which contains general information about postgraduate study at this University and within the School. It is important for you to be aware of the general support and resources that the University provides. You also need to be aware of the University regulations (such as those related to â€œacceptable use of computersâ€•, academic integrity, and policies on late work, sickness, and much more).

In this handbook you will find information about the programme aims and learning outcomes, structure, content, admissions, assessment and programme management.

Please make yourself familiar with the content and keep this handbook for future reference. We hope you will find it a useful resource as you progress through the programme. If anything remains unclear, please donâ€™t hesitate to ask me or my colleagues for more information or advice.

Section **A** is a summary of how the course is structured.

Section **B** is a description of each of the course units.

The students enrolled in this course bring a great range of experience into the programme. Some of you may already have a PhD or years of experience in industry or research. Others will have recently completed an undergraduate degree in a relevant area. Some of you will have detailed knowledge of analytical biochemistry or pharmacology; others will be more knowledgeable about statistical methods or data science and mathematical models. Sharing that knowledge and experience with your tutors and other students in person and through the online discussion boards will significantly enhance the learning experience. Above all, we aim to provide a structure that allows you to develop and demonstrate your ability to provide intelligent guidance to the drug development process.

We have made every effort to provide you with the most up-to-date and accurate information. However, some minor details may change during the course of your studies. All changes and additions will be brought to your attention. If there is anything not answered within the handbook please do not hesitate to contact us.

We hope that your time here in Manchester will be enjoyable and successful.

General information about the Division of Pharmacy and Optometry, staff listings and research interests are contained in this handbook, but more information can be obtained from the following web sites:

- The Pharmacy home page: https://www.bmh.manchester.ac.uk/pharmacy/
- The Faculty of Biology, Medicine and Health home page: https://www.bmh.manchester.ac.uk/
- The University of Manchester home page: http://www.manchester.ac.uk/

Programme Director:

Kayode Ogungbenro, PhD
Division of Pharmacy and Optometry
Stopford Building, Room 3.123
Email: kayode.ogungbenro @manchester.ac.uk

School Administrative Teams:

Student Hub: shs.hub@manchester.ac.uk

Wellbeing: shs.wellbeing@manchester.ac.uk

Attendance monitoring: shs.attendance@manchester.ac.uk

Disability support: shs.dc@manchester.ac.uk

Mitigating Circumstances: shs.mitcircs@manchester.ac.uk

Programmes team: shs.programmes@manchester.ac.uk

Assessments team: shs.assessment@manchester.ac.uk

Section A: Programme Structure

Rationale and General Description

This blended learning Masters course was originally designed for scientists already working within the pharmaceutical industry who wish to qualify as modellers with hands-on experience. In response to ever-increasing demand for modellers in the industry, we have developed a full-time option suitable for recent graduates who wish to begin a career related to drug development.

Given the above, we expect two categories of student:

- Type one, the Part-Time, Distance-Learning student. You are currently working for a pharmaceutical company, a regulatory authority, a contract research organisation or another research body. Your employer is supportive of your participation in the course and recognises its value for your further training and development. Ideally you will be able to identify a research project with your employer when time comes to begin your research dissertation. The distance learning aspect of the course means that you can fit your study around other commitments. However, you should also recognise that balancing your employment and academic workloads will require good self-discipline and time-management skills.
- Type two, the Full-time student in attendance at Manchester. You have completed an undergraduate degree in a pharmacy, pharmacology, medical and biological sciences related disciplines, mathematics or engineering discipline, and you are sure that you want to follow a career involving drug development. Ideally, you have some research or work experience that allows you to be confident that this is the right choice for you. As a full-time student in residence at Manchester, you will benefit from the resources and academic environment here. Your research dissertation will likely be carried out at the University but may involve placement with a company.

In brief, what you can expect to get out of the course:

- **Familiarity with the language and common scientific/technical principles fundamental to the profession.** This includes pharmacokinetic concepts (*e.g.*, bioavailability, volume of distribution, clearance), physiological/biochemical mechanistic concepts (e.g. phase 1 metabolism, types of inhibition, Kd), statistical/mathematical concepts (e.g. covariates, goodness of fit) and clinical/legal concepts (e.g., types of trials, regulatory authorities, endpoints and biomarkers).
- **Awareness of current research and state of the art of modelling and simulation for drug development**, including a sense of where the technology is headed.
- **Exposure to common software packages used in the industry, including hands-on experience.** The extent of your experience will depend on your eventual choice of dissertation project. Note: If your main aim is to get intensive training in a particular package, such as NONMEM, you might be better advised to take one of the specialist short-courses offered by the software publishers.

Aims of the MSc Programme

The overall aim of the programme is to provide specialist knowledge and skills that are highly relevant for a career linked to drug development and pharmaceutical industry. The programme is designed for science, engineering or mathematics graduates who want to acquire 1) awareness of the commercial and regulatory factors in drug development, and 2) understanding of the physiological, chemical, and

mathematical foundations used to define the safe and effective use of potential medicines.

The programme focuses on these key concepts:

Pharmacokinetics, addressing how a drug dose is administered to the body and the fate of drug molecules that enter the body.

Pharmacodynamics, addressing the chemical and physiological response of the body to drug.

Pharmacometrics, â€œthe science that quantifies drug, disease and trial information to aid efficient drug development and/or regulatory decisionsâ€• (definition used by the US FDA)

Systems pharmacology, â€œanalysis of interactions between drug and a biological system, using mathematical models and aiming to understand the behaviour of the system as a wholeâ€•

Modelling and simulation, use mathematical models to guide drug development and learn how models are improved and validated.

Specific aims of the MSc programme:

01. Provide background information on the theory and methods for quantitative assessment of drug absorption, distribution and elimination (ADME) in the human body.

02. Provide an understanding of the role of pharmacometrics in the process of drug development, including scientific, regulatory and commercial perspectives.

03. Provide background information on *in vitro* assays used to characterise ADME properties of new drug entities.

04. Indicate the mathematical framework (physiologically-based pharmacokinetics) that is capable of integrating *in vitro* information with knowledge of the human body to predict pharmacokinetics.

05. Understand a major and current programming language (R language) for modelling and simulation and conduct statistical analysis with this language.

06. Provide familiarity and experience of using different software platforms related to pharmacometrics data analysis including R, Phoenix, NONNEM, MATLAB, Simcyp and MONOLIX.

07 Equip students to reflect upon influential research publications in the field, to critically assess recent published literature in a specific area.

08. Provide students an opportunity to undertake a project and carry out original research in the field of applied pharmacokinetics, pharmacodynamics and modelling and simulation.

Programme Learning Outcomes

Students will be able to:

- Display knowledge of historical development and rationale for clinical trials; drug development process; basic requirements for conducting clinical trials; ethical and regulatory aspects of the proper conduct of clinical trials

- Describe the detailed mechanisms involved in drug absorption, distribution, metabolism and excretion (ADME).
- Explain the crucial roles of pharmacometric methods in developing and gaining regulatory approval for a medicine.
- Describe the details of in vitro systems used to characterise drug absorption, distribution, metabolism and excretion.
- Describe the relationships (scaling) between data obtained from in vitro systems and in vivo observations on ADME.
- Give examples of how modelling and simulation methods are currently transforming the processes of drug development and regulation.
- Use the biostatistical concepts and language employed in the design and interpretation of clinical data.
- Evaluate the capability of different tools to perform relevant data analysis.
- Critically analyse the observations on plasma drug concentration-time profiles and characterise them quantitatively for the purpose of making inferences between different drugs, different patients, different conditions etc.
- Be able to design appropriate studies in delineating effects of co-variates on pharmacokinetics (including drug-drug interactions)
- Gain scholarly knowledge in a focused area of pharmacometrics, modelling and simulation.
- Deliver effective oral presentation of research findings and research proposals.
- Critically assess reports in the literature describing use of modelling and simulation to guide drug development. Identify examples of important innovations as well as examples where inconsistencies exist in the methods of analysis or representation of the outcome.
- Design and outline the details of appropriate projects to investigate including the articulation of research aims and methodology.
- Identify the reasons for differences in the time-courses of drug effect and plasma drug concentration.
- Make informed predictions of the behaviour of drugs in body with respect to plasma drug concentration-time profile.
- Make informed choices on using various models to be used for fit data obtained from studies involving Enzyme Kinetics, Pharmacokinetics, Pharmacodynamics
- Demonstrate the effective use of professional writing skills required in preparing the reports relevant to the subject area
- Execute and complete a piece of research which is narrowly focused on specific area of pharmacometric modelling and simulation.
- Debate the outcome of research and argue for validity of the methods used in the study and the conclusions drawn from the results.

A copy of the programme specification is available on the MBDD Virtual Common Room on Canvas.

Timetable

Please note: exam dates and deadlines for submitted work given below are approximate.

Please check Canvas for the actual dates.

Date (week of),	Full-time and Part-time, year 1	Full-time and Part-time, year 2
23 September 2025, 6 weeks	Unit: Basic PK/PD **(PHAR69921)**	Unit: Statistics for Health Data Science **(IIDS67631)**
November 2025	Due: Report & Basic PK Calculations	Due: Statistics for Health Data Science Coursework
November,6 weeks	Unit: Introduction to clinical trials **(PHAR72010)**	Unit: Physiologically-based PK &IVIVE 1 (basic concepts) **(PHAR69922)**
December 2025/ January 2026	Due: Clinical Trials Coursework Exams: Basic PKPD	Due: PBPK1 report & presentation Exams: PBPK1
February 6 weeks	Unit: Data analysis in PK/PD, **(PHAR69923)** part 1	Unit: Physiologically-based PK & IVIVE 2, part 1 (advanced concepts and applications) **(PHAR69932)**
March	Due: Data analysis in PK/PD Coursework 1	Due: PBPK2 presentation
March 6 weeks	Unit Data analysis in PK, part 2	Unit: Physiologically-based PK & IVIVE2, part 2 (advanced concepts and applications) **(PHAR69932)**
May	Due: Data analysis Coursework 2	Due: PBPK2 Coursework
May/June	Exam: Data analysis	Exam: PBPK2
June14 weeks	PT only â€“ summer break in year 1	Project
September	FT only: Due â€“ Oral presentation	/
September	FT only: Due â€“ Dissertation	/
December 2025	FT only: Graduation	/
January 2026	/	PT only: Due: Dissertation and oral presentation
July 2026	/	PT only: Graduation

Programme Staff

The core teaching staff on the course are listed below:

Kayode Ogungbenro, *BPharm, PhD*

- Course Director
- PHAR69923 Data Analysis in PK &PD (Unit Leader)
- PHAR69921 Basic Pharmacokinetics & Pharmacodynamics (Unit Leader)
- PHAR69920 Dissertation Project (Unit Leader, Supervision and Assessment)

Dr Kayode Ogungbenro is a Senior Lecturer in Cancer Pharmacometrics in the Division of Pharmacy and Optometry. He is also an Honorary Clinical Scientist at the Christie NHS Foundation Trust, Manchester.

Kayode obtained his PhD in 2005 from University of Manchester; he was appointed a Research Associate in 2005 at the Centre for Applied Pharmacokinetic Research (CAPKR), University of Manchester and a Research Fellow in 2009. He was subsequently appointed a Lecturer in 2014 and a Senior Lecturer in 2020. Kayode is a member of CAPKR where his research activity is currently on population pharmacokinetic and pharmacodynamic study design and data analysis, physiologically based pharmacokinetic modelling, optimal design of population pharmacokinetic and pharmacodynamic experiments, population pharmacokinetics in special population (children) and computer aided clinical trial simulation.

Aleksandra Galetin, *PhD*

- PHAR69922 Physiologically-based PK and *In vitro â€“ In vivo* Extrapolation 1
- PHAR69932 PBPK and *IVIVE 2*
- PHAR69921 Basic Pharmacokinetics & Pharmacodynamics
- PHAR69920 Dissertation Project (Supervision and Assessment)

Professor Galetin is a Professor of Translational Pharmacokinetics in the Centre for Applied Pharmacokinetic Research, School of Health Sciences, Division of Pharmacy & Optometry, University of Manchester, UK. Prof Galetin is the recipient of the 2012 ISSX European New Investigator Award and 2015 AAPS Meritorious Manuscript Award. She is appointed on the expert panels such as International Transporter Consortium (ITC) and AAPS Drug Transport Focus Group Steering Committee.

Prof Galetin has extensive experience in mechanistic *in vitro* characterisation of hepatic and renal transporters/metabolism, *in vitro-in vivo* extrapolation and development of physiologically-based pharmacokinetic (PBPK) models for prediction of transporter-mediated pharmacokinetics/drug-drug interactions in different patient population groups. She led the preparation of the ITC â€˜whiteâ€™ paper on the best practices in transporter *in vitro* kinetic studies and translational modelling. In 2016, Dr Galetin completed a sabbatical in the US FDA Office of Clinical Pharmacology where she provided expert advice on the PBPK modelling of drug-drug interactions /special populations. In addition to MPharm programme, she teaches drug disposition and pharmacokinetics on MRes in Experimental Cancer Medicine and MSc course for Independent Prescribers. She has published over 75 research papers in highly cited peer reviewed journals (H index 36) and supervised/mentored 30 PhD students and postdoctoral research associates.

Amin Rostami-Hochaghan, *PharmD, PhD, FCP*

- PHAR69922 Physiologically-based PK and *In vitro â€“ In vivo* Extrapolation 1
- PHAR69932 PBPK and *IVIVE 2*

Amin joined the University of Manchester in December 2009 as a Professor of Systems Pharmacology at the Centre for Applied Pharmacokinetic Research in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester.

Previously Amin held a chair in Systems Pharmacology at the University of Sheffield. He joined the University of Sheffield as Research Assistant to Professor Geoff Tucker in 1996 before progressing to Lecturer, Senior Lecturer, Reader and Full Professorship posts in 1997, 2002, 2005 and 2007, respectively.

As the Vice President of Research and Development at Simcyp Limited, Amin leads a team of over 30 scientists working on extrapolation of in vitro data on drug metabolism to predict in vivo pharmacokinetics and pharmacodynamics in â€œvirtual patient populationsâ€•.

A decade ago, Professor Rostami founded the postgraduate course in Modelling and Simulation in Pharmacokinetics & Pharmacodynamics, which has become this current course in Model-based Drug Development.

Daniel Scotcher, PhD

- Deputy programme director
- PHAR69922 Physiologically-based PK and *In vitro â€“ In vivo* Extrapolation 1 (Unit Lead)
- PHAR69932 PBPK and *IVIVE 2* (Unit Lead)
- PHAR69921 Basic Pharmacokinetics & Pharmacodynamics
- PHAR69920 Dissertation Project (Supervision and Assessment)

Dr Scotcher is a Lecturer in Applied Pharmacokinetics in the Division of Pharmacy and Optometry. Dan received his PhD from University of Manchester in 2016; he then visited the US Food and Drug Administration as an ORISE research fellow, and returned to University of Manchester as a post-doc, and subsequently appointed as Lecturer in 2019.

Danâ€™s expertise is in quantitative translation of in vitro data to predict pharmacokinetic outcomes. He draws upon direct and collaborative research experiences with pharmaceutical industry and regulatory institutions, to understand real-world practice and problems that can be addressed using combination of in vitro and in silico research methodologies. Dan is based within the Centre for Applied Pharmacokinetic Research (CAPKR), a consortium of academic researchers at The University of Manchester and industrial pharmaceutical companies.

Dissertations

The dissertation involves working closely with your supervisor to develop and implement an empirical research project. Details of what is involved, and of how and when to submit the dissertation are provided in the Dissertation Handbook. The Universityâ€™s Guidance for the presentation of Taught Dissertations can be found on the A-Z of Student Services. This guidance tends to change annually, so confirm the dissertation unit lead that you are using the correct version. It is useful to note that the Faculty no longer requires submission of a printed dissertation, although you may want to print and bind your own personal copy. Unlike PhD theses at the University, MSc dissertations are not routinely made â€œopen accessâ€•. We often deal with projects involving confidential data; if that is the case with your project, you should discuss with your supervisor measures to protect confidentiality.

Supervisory Arrangements

Each studentâ€™s progress will be ultimately under the direction of the Programme Directors. At the beginning of the dissertation unit (PHAR69920) students will be provided with a list of available academic supervisors, their topic areas and potential projects. On the basis of this information, students will be encouraged to speak to individual members of staff to discuss project ideas. Students will be given a few weeks in order to select supervisors/projects/research areas of their choice. **Please note:** it is not always possible to allocate students to the academic supervisor of choice, but every attempt will be made to match students to a research area of their choice.

Supervisor

Each student will be supervised by an academic Supervisor within the programme and in the case of part-time students co-supervised by a work-based contact whenever possible. Supervision is governed by the University Manual of Academic Procedures, which outlines in more detail the responsibilities of the Supervisor and the Student. Briefly, the responsibilities of the Supervisor include: giving guidance about the nature of research and the standard expected; the planning of the research programme; and pointing the Student towards relevant literature and other sources of information.

The relationship between the Student and his/her Supervisor is of central importance. Both the Student and the Supervisor have a responsibility to ensure that the dissertation is completed within the prescribed period of the programme. Supervisors and students should establish at their initial meeting clear and explicit expectations of each other in order to minimise the risks and problems of misunderstanding, personality clashes, inadequate supervision and unsatisfactory work. Timetables for Progress Monitoring meetings must be closely observed.

Advisor

Each student will also be allocated an adviser. The role of the Advisor is not in any way meant to disturb the special relationship between Student and Supervisor. However, if a student feels the need to discuss matters, whether academic or otherwise, with another person, the Adviser will be available. Such discussions can be in the absence of the Supervisor outside of the framework of the formal meetings and confidential.

If you have any queries or concerns at any time during your period of study, there is a range of people you can approach:

- *Your Student Representatives*

- *The Course Administrator*
- *Your Supervisor*
- *Your Adviser*
- *The Student Support Officer*
- *The Programme Director*
- *The Consortium PGT Lead (Dr Ellen Schafheutle)*
- *The Head of Division (Prof. Jayne Lawrence)*

Course Assessments

Full details of modes of assessment for each Course Unit are provided in Section B.

The programmes contain a range of both formative and summative assessment tasks which have been designed to establish studentâ€™s knowledge and understanding of the stated learning outcomes for the course unit.

Formative assessments

- These are developmental assessments which assess your learning as you work through the unit and whenever possible form part of the preparatory work for, and link to the summative assessments.
- Formative assessments do not contribute towards the final mark but are an important form of your assessment in that feedback from these assessments will enable you to develop and improve before moving on to the summative assessment.
- Formative assessments are marked as a pass or fail, feedback will be offered to guide your learning.
- You must attempt all formative assessments within a course unit and if you do not pass you should discuss your learning needs with the course unit lead.

Summative assessments

- Each unit includes at least one summative assessment. These have been designed to assess your learning and the practice-based application of it.
- Each assessment task is allocated a percentage weighting towards the final mark.
- The minimum weighting of any individual summative assessment will be 10%.

Exemptions to the Postgraduate Taught Degree Regulations

Please be aware that the MSc in MBDD has some higher requirements to the University degree regulations and details of these are outlined below.

- ***The course unit pass mark for all levels (i.e. Postgraduate Certificate, Diploma and Masters) is 50%.***
- ***The programme will not apply any compensation rules***

Criteria of Levels of Achievement

To obtain a pass for the Postgraduate Certificate you are required to successfully pass 60 credits, Postgraduate Diploma â€“ 120 credits, and Masters you are required to successfully pass 180 credits.

You will be eligible for the award of a distinction at Masters level only, provided you achieve an average mark of 70% or more, based on the weighted programme as a whole. If credit has been awarded as a result of referral, you will not be eligible for the award of distinction.

You will be eligible for the award of a merit at Masters level only, provided you achieve an average mark of 60% or more, based on the weighted programme as a whole. If credit has been awarded as a result of referral, you may still be eligible for the award of merit.

Reassessment

Reassessment as a result of a fail is known as a â€œReferralâ€•. Reassessment as a result of approved and verified mitigating circumstances is known as â€œDeferralâ€• and may be permitted where students are reassessed as a first attempt, for which no penalty applies.

Students may be referred in up to half of the total taught credits. The combined total number of credits referred and compensated cannot exceed half the taught credits. Decisions with regard to which components should be reassessed are made by the Examination Board. When a student is referred they will normally be permitted to retake the assessment/exam on one further occasion.

At the recommendation of the Board of Examiners, students will normally be allowed one resubmission of a failed dissertation or project and this will normally be within four months of the date of the publication of the result.

The pass mark for a reassessment is the same as the first attempt (i.e. 50% for masters and 40% for Postgraduate Diploma/Certificate). When a reassessment is passed, the mark is capped at the lowest compensable fail mark, i.e. 50R. This mark is used in the weighted average/total mark for the final award. The capped mark is applied to the whole unit and not the failed component.

Please note that some programmes do not allow referrals. Please refer to the â€˜Programme Exemptions to PGT Degree Regulationsâ€™ section of the handbook where specific exemptions applicable to the programme will be listed.

Assignment Word Count (including Dissertations)

In accordance with accepted academic practice, when submitting any written assignment for summative assessment, the notion of a word count includes the following

- All titles or headings that form part of the actual text. This does not include the fly page or reference list.
- All words that form the actual essay.
- All words forming the titles for figures, tables and boxes, are included but this does not include boxes or tables or figures themselves.
- All in-text (that is bracketed) references.
- All directly quoted material.

External Examiners

The External Examiner for this programme is: Dr Raj K. Singh Badhan
Name of Institution: Aston University
Position at current Institution: Lecturer in Pharmacokinetics (Pharmacometrics)

Please see the SHS Student Handbook for further information on External Examiners.

Section B: Syllabus, Course Units and Route through the Programme

Syllabus

Unit Sequence	Part-time	Full-time
		PHAR69921 (15 credits)
Semester 1 (Sept-Jan)	PHAR69921 (15 credits)	IIDS67631 (15 credits)
(Year 1)	PHAR72010 (15 credits)	PHAR72010 (15 credits)
		PHAR69922 (15 credits)
Semester 2 (Feb-May)		PHAR69923 (30 credits)
(Year 1)	PHAR69923 (30 credits)	PHAR69932 (30 credits)
Summer (June â€“ Sept)	/	PHAR69920 (Dissertation) (60 credits)
(Year 1)		
Semester 3 (Sept-Jan)	IIDS67631 (15 credits)	/
(Year 2)	PHAR69922 (15 credits)	
Semester 4 (Feb-May)	PHAR69932 (30 credits)	/
(Year 2)		
Summer + Year 2 (June to Sept)	PHAR69920 (dissertation) (60 credits)	/

Course Units

Study Method & Unit content

For each unit there is a unit description outlining what is required, these are listed below. Throughout your studies help and support is available from your Academic Advisor, the Programme Director and

the PGT Programmes Support team. All elements of each unit must be undertaken in order to complete the unit, they are all compulsory components.

The unit descriptions and handbook provide an overall outline for the course, any further details or advice on specifics of the programme should be sought from the unit leader. Students are advised to keep the unit leader and administrator up to date on the progress of their study, including any difficulties they are encountering. Regular updates between the students and unit leader will also take place through a series of tutorials based on specific essays and coursework questions and these will be available to Distance-Learning students through on-line virtual meetings.

PHAR69921 Basic Pharmacokinetics and Pharmacodynamics (PKPD)

Unit Lead: Dr. Kayode Ogungbenro

This introductory unit is designed to give the student an understanding of fundamental concepts in pharmacokinetics and pharmacodynamics, essentially how drugs get into the body, how they get around the body and how they get out of the body. Topics include the processes of absorption, distribution, metabolism and excretion (ADME), the concept of compartmental analysis, and basic statistical concepts.

Emphasis is given to explaining how chemical properties of drug interact with physiological aspects of the human body to affect the behaviour of different drugs and the variation between individual patients. Quantitative assessment of the processes (modelling and data analysis) is described with reference to drug discovery, drug development and therapeutic usage. The unit also provides experience in solving numerical problems relating the time-course of drugs and their metabolites in the body.

This unit is a prerequisite for subsequent units which focus on physiologically-based models and advanced approaches to data analysis.

Theoretical knowledge will be disseminated through a series of lectures and tutored workshops. Students will then work on a structured assignment that emphasises the application of theory by solving problems.

Topics outline:

- Introduction to pharmacokinetics
- Drug distribution concepts
- Drug elimination concepts
- Kinetics following an intravenous bolus dose
- Kinetics following an extravascular dose
- Drug Absorption concepts
- Pharmacological response concepts
- Kinetics following an Intravenous infusion dose
- Multiple dosing regimens concepts
- Pharmacokinetics in renal failure

Summary of Teaching

Contact time

Full-time students

Lectures 20 hours

Workshops/drop-in sessions 22 hours

Total 42 hours

Full-time students

Webinars 12 hours

Independent Study 90 hours
(reading, case study)

Assessment

Assignmentâ€“ Case study report and calculations 60%

Formal Examination (January exam period) 40%

Learning Outcomes

Knowledge:

- Describe the detailed mechanisms involved in drug absorption, distribution, metabolism and excretion (ADME).
- Explain the crucial roles of pharmacometric methods in developing and gaining regulatory approval for a medicine, and specifically the role of pharmacokinetics and biostatistics in guiding the design and conduct of clinical trials.

Skills:

- Make informed predictions on the influence of any change in (ADME) mechanism on plasma drug concentration-time profile for a given substance,
- Critically analyse observations on plasma drug concentration-time profiles and characterise them quantitatively for the purpose of making inferences between different drugs, different patients, different conditions etc.
- Identify the reasons for differences in the time-courses of drug effect and plasma drug concentration.
- Apply basic biostatistical concepts and interpret statistical information arising from clinical trials.

Transferable Skills:

- Perform calculations using fundamental pharmacokinetic equations
- Produce written reports on the pharmacokinetics of a given drug, making effective use of pharmacokinetic terminology.

Suggested Reading

Rowland and Tozerâ€™s clinical pharmacokinetics and pharmacodynamics : concepts and applications, Hartmut Derendorf, Stephan Schmidt, Malcolm Rowland, 5th edition, Wolters Kluwer, Philadelphia, 2020

PHAR69922 In Vitro- In Vivo Extrapolation (IVIVE) of ADME & Physiologically- Based Pharmacokinetics [PBPK1]

Unit Lead â€“ Dr Dan Scotcher

This unit provides a focused introduction to the use of *mechanistic* pharmacokinetic models, which use mathematical descriptions of physiological processes to predict the fate of drug molecules within the human body. Therefore, the unit addresses two key aspects of IVIVE: 1) developing mathematical representation of key chemical and physiological processes that affect drug molecules in the body, and 2) defining the relationships that link these processes. Implementation of this approach will be described in the following areas:

- Prediction of drug-drug interactions by extrapolating from *in vitro* laboratory tests before commencing clinical studies
- Prediction of oral absorption; guiding the design of oral drug formulations

Topics outline

Introduction to physiologically-based pharmacokinetics (PBPK) and systems pharmacology

Modelling of *in vitro* experiments

- metabolic assays
- permeability
- mDDI assay data

Quantitative prediction and IVIVE of metabolic clearance

- Physiology of hepatic and extrahepatic metabolism
- *In vitro-in vivo* extrapolation (IVIVE) of metabolism
- PBPK modelling and simulation (M&S)
- IVIVE in drug development

Predicting absorption

- Principles of drug absorption
- The evolution of PBPK absorption models
- PBPK M&S of oral formulation effects
- PBPK M&S in drug and formulation development

Drug distribution and binding

- Principles of drug distribution

- Models for predicting volume of distribution
- Whole-body PBPK M&S
- Drug binding and local tissue concentrations

Summary of Teaching

Lectures 12 hours

Workshops, seminars and webinars 22 hours

Tutorial, Academic advice (face-to-face or via teleconference) 6 hours

Total hours 40 hours

Assessment

Final exam 40%

Coursework, Case Study report 60%

Knowledge:

- Describe the details of *in vitro* systems used to characterise drug absorption, distribution, metabolism and excretion.
- Describe the relationships (scaling) between data obtained from *in vitro* systems and *in vivo* observations on ADME.

Intellectual Skills:

- Critically analyse observations on plasma drug concentration-time profiles and characterise them quantitatively for the purpose of making inferences between different drugs, different patients, different conditions etc.
- Identify the reasons for differences in the time-courses of drug effect and plasma drug concentration.
- Make informed predictions of the behaviour of drugs in body with respect to plasma drug concentration-time profile.

Practical skills

- Perform calculations using fundamental pharmacokinetic equations
- Use specialised computer software Simcyp to simulate and explore the effects of covariates on drug and metabolite concentrations in the body.

Transferable Skills:

- extracting key points from scientific literature
- effective written communication

Suggested Reading

Core textbook: â€œPhysiologically Based Pharmacokinetic (PBPK) Modeling and Simulations: Principles, Methods, and Applications in the Pharmaceutical Industryâ€• by Sheila Annie Peters, 2021; DOI:10.1002/9781119497813

Lecture notes cite key research articles and reviews, which includeâ€¦

Wienkers, L.C. and T.G. Heath (2005) Predicting in vivo drug interactions from in vitro drug discovery data. *Nat Rev Drug Discov* **4:**825-33.

Houston, J.B. and A. Galetin (2008) Methods for predicting in vivo pharmacokinetics using data from in vitro assays. *Curr Drug Metab.* **9:**940-51.

Rostami-Hodjegan, A. (2012) Physiologically Based Pharmacokinetics Joined With In Vitro-In Vivo Extrapolation of ADME: A Marriage Under the Arch of Systems Pharmacology. *Clin Pharmacol Ther* **92:** 50-61.

Jamei, M., S. Marciniak, K. Feng, A. Barnett, G. Tucker, and A. Rostami-Hodjegan (2009) The Simcyp population-based ADME simulator. *Expert Opin Drug Metab Toxicol.* **5:**211-23.

Rowland, M., C. Peck, and G. Tucker (2011) Physiologically-based pharmacokinetics in drug development and regulatory science. *Annu Rev Pharmacol Toxicol* **51:**45-73.

Zhao, P., M. Rowland, and S.M. Huang (2012) Best practice in the use of physiologically based pharmacokinetic modeling and simulation to address clinical pharmacology regulatory questions. *Clin Pharmacol Ther* **92:**17-20.

Tsamandouras, N., A. Rostami-Hodjegan, and L. Aarons (2013) Combining the â€œbottom-upâ€• and â€œtop-downâ€• approaches in pharmacokinetic modelling: Fitting PBPK models to observed clinical data. *Br J Clin Pharmacol*.

PHAR69932 Advanced topics in Physiologically-based PK models [PBPK2]

Unit Lead: Dr Dan Scotcher

This unit provides further training on the use of mechanistic pharmacokinetic models, which use mathematical descriptions of physiological processes to predict the fate of drug molecules within the human body. Completion of the introductory module (PHAR69922) is an essential prerequisite.

The unit addresses two key aspects of IVIVE and PBPK models: 1) developing mathematical representation of key chemical and physiological processes that affect drug molecules in the body, and 2) defining the relationships that link these processes.

Conceptual and theoretical understanding is developed through lectures. Hands-on workshops with flipped-classroom approach promotes independent and active learning as students gain hands-on experience with relevant software and enables parallel teaching and assessment of full-time (on-campus) and part-time/ CPD (distance learning) student cohorts. Implementation of this approach will be described in the following areas:

- Prediction of drug-drug and drug-disease interactions in special populations such as neonates, children, patients with kidney or liver impairment
- Special considerations for endogenous biomarkers, biologics, PBPK- pharmacodynamic models (PBPK-PD), and biopharmaceutics

Topics outline

- Complex drug interactions involving transporters and endogenous biomarkers
- PBPK modelling in special populations, including paediatrics and organ impairment
- PBPK M&S of biologics
- PBPK M&S for biopharmaceutics
- Regulatory considerations for PBPK modelling
- Best practices including sensitivity analysis and parameter estimation

Summary of Teaching

Full-time studentsâ€™ contact time

Lectures 31 hours

Workshops 29 hours

Journal club and drop-in 12 hours

Oral presentations (summative assessment) 3 hours

Part-time studentsâ€™ contact time

Webinars 24 hours

Independent study time

Coursework assignments, includes reading, formative problem sets, modelling assignment, preparation of written and oral report 225 hours

Assessment

Written exam 40%

Written assignment (inc essay) 30%

Oral assessment/presentation 30%

Suggested Reading

Core textbook: â€œPhysiologically Based Pharmacokinetic (PBPK) Modeling and Simulations: Principles, Methods, and Applications in the Pharmaceutical Industryâ€• by Sheila Annie Peters, 2021; DOI:10.1002/9781119497813

Lecture notes cite key research articles and reviews, which includeâ€¦

- Houston, J.B. and A. Galetin (2008) Methods for predicting in vivo pharmacokinetics using data from in vitro assays. Curr Drug Metab. 9:940-51.
- Rostami-Hodjegan, A. (2012) Physiologically Based Pharmacokinetics Joined With In Vitro-In Vivo Extrapolation of ADME: A Marriage Under the Arch of Systems Pharmacology. Clin Pharmacol Ther 92:50-61.
- Rowland, M., C. Peck, and G. Tucker (2011) Physiologically-based pharmacokinetics in drug development and regulatory science. Annu Rev Pharmacol Toxicol 51:45-73.
- Zhao, P., M. Rowland, and S.M. Huang (2012) Best practice in the use of physiologically based pharmacokinetic modeling and simulation to address clinical pharmacology regulatory questions. Clin Pharmacol Ther 92:17-20.
- Tsamandouras, N., A. Rostami-Hodjegan, and L. Aarons (2013) Combining the â€œbottom-upâ€• and â€œtop-downâ€• approaches in pharmacokinetic modelling: Fitting PBPK models to observed clinical data. Br J Clin Pharmacol. 79:48-55
- Chu, X., et al. (2022) Clinical implications of altered drug transporter abundance/function and PBPK modeling in specific populations: an ITC perspective. Clinical Pharmacology & Therapeutics 112:501-526.

PHAR69923 Data Analysis in PKPD

Unit Lead: Dr. Kayode Ogungbenro

Data analysis in PKPD studies is a specialised area of modelling that combines mathematical and statistical knowledge in data fitting with the sound knowledge of the human body as a system to choose more mechanistic models. Analysis can describe the observed data but also it can be used for the purpose of prediction. The mathematical background provided in this module relates to linear and non-linear fitting, optimisation procedures that are applied to objective function(s), Statistical input relates to finding inferences and covariates application of non-linear mixed effect modelling. This unit also provides information on available tools for simulation and data analysis and their applications. Commonly used platforms for data analysis such as NONMEM, MONOLIX, Phoenix, MATLAB and R (rxode/nlmixr), are explored within this module where students analyse some data and learn the advantages and disadvantages of these platforms/packages, as well as their limitations.

Summary of Teaching

Contact time (hours)

Full-time students

Lectures: 38

Workshops: 30

Drop-in sessions: 20

Part-time students

Webinars: 24

Assessment

Examination (end of year 1) 40%

Coursework (2 equally weighted assignments) 60%

Learning Outcomes

Knowledge:

- Understand different types of models that exist in pharmacokinetics and pharmacodynamics
- Understand basic concepts and mathematical principles associated with parameter estimation in pharmacokinetic and pharmacodynamic modelling
- Understand how to choose between different software and methods available for parameter estimation depending on the situation in pharmacokinetics and pharmacodynamics
- Understanding limitations of common packages for modelling and simulation
- Understand the role of modelling and simulation in drug development

Skills:

- Implement basic models in pharmacokinetics and pharmacodynamics for estimation and simulation purposes
- Use common software that are available for parameter estimation and simulation in pharmacokinetics and pharmacodynamics
- Interpret results obtained from different software and methods in pharmacokinetics and pharmacodynamics
- Describe the theory of parameter estimation in non-linear mixed effects modelling
- Use modelling and software for dose optimisation during drug development

Transferable Skills:

- Extracting key point from scientific literature for a pharmacokinetic and pharmacodynamic model
- Effective communication of pharmacokinetic and pharmacodynamic modelling results

IIDS67631 Statistics for Health Data Science

Unit Lead: Hui Guo

Currently, there is a large amount of health and related data that is not analysed in order to provide insights into healthcare delivery. A core skill required of a health data scientist is to be able to analyse various forms of health data; the unit will cover the fundamental knowledge required to do this including understanding data, pre-processing steps, key analytical skills, and a suitable statistical programming language. The unit will introduce students to what can be achieved through the analysis of health data. Key research questions will be drawn from teaching staff and their networks to illustrate these techniques.

The unit aims to introduce students to a range of mathematical and statistical techniques that are widely used when analysing health data, and to demonstrate what can be achieved when using health data.

The focus is on explaining which techniques are available and how best to use them, rather than going into details of how a method works (it is more useful to know how a method could be implemented and when to use rather than understand theoretical principles). On completion students should be aware of a range of techniques and have experience of writing scripts and executing them in R.

Summary of Teaching

Scheduled activity hours

Lectures 18

Practical classes & workshops 24

Tutorials 2

Assessment

Summative assignments include one long report at 1500 words counting for 80%, and one short report at 750 words counting for 20%.

Each assignment should include statistical scripts demonstrating the analysis of data and a written report (in paper style) to justify methods and explanation of work.

Formative assignments will be delivered through a wide range of interactive exercises and supervised practical exercises.

Learning Outcomes

Knowledge:

- Identify and describe the steps required to analyse a set of health data
- Describe and explain key ideas and concepts in statistics
- Know how to prepare data sets for analysis
- Appreciate the key concepts in study design
- Understand the ideas behind building mathematical models

Intellectual Skills:

- Represent problems mathematically, in a way in which allows statistical scripts to be written to solve them
- Identify and apply appropriate mathematical and statistical methods to analyse/model a given health data set

Practical Skills

- *Execute and write statistical scripts to compute basic statistical measures and analyse data*
- *Prepare a data set for analysis*

Transferable Skills:

- Demonstrate statistical programming skills
- Demonstrate experience of solving applied problems
- Communicate analyses and interpretation of results of health data

PHAR72010 Introduction to Clinical Trials

This introductory unit provides an overview of the basic requirements and procedures employed in planning and conducting clinical trials. It also provides guidance on ethical, regulatory and statistical aspects as well as the managerial requirements.

Aims:

- Acquire and develop an advanced knowledge and in depth understanding of the theory of setting up and running clinical trials
- Acquire and develop the advanced skills to make an effective contribution to clinical trial practice
- Demonstrate the ability to analyse the different clinical trial phases and the purpose of each
- Identify their own learning needs, develop themselves as critically reflective practitioners and advance their own learning to sustain continuing professional development
- Critically evaluate literature, theories and methodologies and apply approaches to creating a clinical trials project plan

Summary of Teaching

This unit is delivered entirely through distance learning. A printed manual consisting of ten chapters is issued to the student on registration and receipt of payment. Each chapter is designed to contain ten hours of assessed learning.

Additional learning activities are directed which, together with the assessment, require 50 hours of self-directed learning and assessment

Assessment

Assignment (3000 words) 100%

Learning Outcomes

Knowledge

Demonstrate an advanced knowledge and detailed understanding of the:

- historical background of how clinical trials have developed
- and evolved to modern standards
- drug development process
- basic requirements for developing and conducting clinical trials
- practical and theoretical aspects of the design, conduct,
- analysis of outcomes and reporting of clinical trials
- ethical and regulatory aspects of the proper conduct of trials

Skills

Critically analyse, evaluate and where appropriate formulate an informed opinion about:

- Clinical trial reporting
- Impact of poor practices in clinical trial conduct
- Effectiveness of current systems and processes
- Analyse approaches to project management
- Offer guidance on Project Management in Clinical Trials, including Project Management Tools and how to use them effectively, and how to
- Plan approaches to manage when things donâ€™t go as planned, for example when there are unexpected outcomes or accidents in the conduct of clinical trials
- Complete practical exercises to demonstrate an understanding of the application of knowledge derived from the course material
- Engage in critically reflective practice as a process of continuous personal development
- Network with key stakeholders in own organisation to drive processes forward based on knowledge gained through course participation

Transferable skills

- The ability to critique information from a range of sources to formulate opinions
- Project manage in accordance with organisational requirements, demonstrating high level knowledge on a process driven approach
- The ability to assess current working practices based on knowledge and experience gained and adapt working practices as necessary
- The ability to prioritise and effectively manage time to complete work by required deadlines

PHAR69920 Dissertation / Supervised Research Project

Unit Lead: Dr Kayode Ogungbenro

This is a research unit and follows on directly from the literature review and research protocol in modelling and simulation (PHAR69924). Students carry out the research project proposed in PHAR69924, i.e. on a topic of current interest that addresses the issues raised in their review project. The research should have elements of data analysis, modelling or simulation and is supervised by one academic supervisor. The dissertation should be written as an MSc thesis and the major results should be worthy of publication in pharmacokinetic journals.

The total time spent on the research and writing the dissertation should be based on 10 notional learning hours per credit (i.e. a total of 600 hours teaching for this 60-credit unit). The projected hours of independent study are intended as guidelines only, but are important to ensure a balanced workload between the units.

Supervisory Sessions (10T x 2H) = 20 h

Independent Study (P x 560H) = 560 h

Assessment

Dissertation (10,000 words) 90%

Oral Presentation (via Web Link for part-time students) 10%

(The oral presentation will normally take place before the final Dissertation submission.)

Learning Outcomes

This unit aims to give the opportunity and environment where the students take a leading edge piece of research work and employ the knowledge that is gathered through other modules of the course. The research must be an applied PKPD or M&S project and it should add to the existing knowledge in the area.

Knowledge:

- Knowing how to identify an appropriate research question in the field of pharmacokinetic and pharmacodynamic M&S.
- Understand relevant research methodologies
- Show awareness of a wide range of applications of pharmacometric modelling
- Gain the knowledge and understanding to be able to produce a report that is publishable in a peer reviewed journal relevant to the area
- Design and outline the details of appropriate projects to investigate including the articulation of research aims and methodology.

Intellectual and Practical Skills:

- Gain scholarly knowledge in a focused area of M&S
- Construct a project plan showing awareness of important objectives, possible limitations and dependencies, time and resource constraints
- Critically assess reports in the literature describing use of modelling and simulation to guide drug development. Identify examples of important innovations as well as examples where inconsistencies exist in the methods of analysis or representation of the outcome
- Apply the knowledge and skills gathered in other modules within a well-defined research project
- Execute and complete a piece of research which is narrowly focused on specific area of M&S
- Construct a focussed critical review of scientific literature in a specific area, exhibiting good writing and referencing skills
- Deliver effective oral presentation of research findings and research proposals

Transferable Skills:

- Extracting key points from scientific literature
- Effective written communication
- Project planning
- Develop the ability to debate the outcome of research and argue for validity of the methods used in the study and the conclusions drawn from the results.

Progress Committee

The MSc Programme Board, and ultimately the Pharmacy and Vision Sciences Postgraduate Consortium Committee, considers issues of poor student progress, student dissatisfaction with academic supervision and other mitigating circumstances that may be influencing progress.

Failure to submit progress forms or assessments on time will result in investigation.