PhD program in Pharmaceutical Sciences

- Advanced courses -

Faculdade de Farmácia
Universidade de Coimbra

Coordinator

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ADVANCED COURSE

"Pharmacological trends in drug discovery and development**"**

6-9 March, 2023

Registration until 1st March 2023: https://forms.gle/5cSth9xWjaCcQSUn7

OBJECTIVES AND SIGNIFICANCE

Strong efforts are made during drug Research and Development (R&D) to attain new effective and safe drugs. However, clinical failure rates for treatments that slow or stop disease progression is extremely high, attaining, for example, nearly 100% of major neurodegenerative disorders with numerous compounds failing in expensive and time-consuming clinical trials for lack of efficacy. Pharmacology is a core discipline that underpins research in drug discovery and development. Encompassing fundamental and clinical pharmacology, Pharmacology is the branch of biomedical science that studies the interactions between chemicals and living beings directed to prevent, ameliorate or cure the deleterious consequences of their diseases. DDD is an incredibly complex process that involves multiple rounds of assays and tests to assess drug pharmacokinetics, efficacy and safety, from the screening of therapeutic candidates to the design of clinical trials in humans.

This course is based on a Research-inspired teaching provided by current practitioners in pharmacology laboratory research, pharmaceutical industry, and other areas of science including molecular biology, drug development, clinical trials and pharmacometrics.

Firstly, *in silico*, *in vitro* and *in vivo* quantitative and qualitative methods will be covered for identification of novel mechanisms of action and evaluation of compounds pharmacokinetics and efficacy. High throughput *in silico/in vitro* screening assays for pharmacodynamic and pharmacokinetic characterization and the use of small-animal models in research pharmacology will be specified during this course, discussing successful protocols and projects in neurodegenerative, psychiatric and oncological diseases. Application of pre-clinical imaging techniques (e.g., Magnetic Resonance Imaging, Nuclear Molecular Imaging & Positron Emission Tomography) in small rodent animals will be also exploited when used for the assessment of new chemical entities safety and efficacy.

Translational Research will be also explored based on practical examples of translating basic laboratory biomedical research into commercially drugs for diagnosing and treating patients. Students will be able to apply basic science knowledge and skills to experimental study design, data analysis, and modeling and simulation of pharmacokinetic/pharmacodynamic (PK/PD) data to support drug development and personalized pharmacotherapy.

Through innovative coursework and independent research opportunities, the program instills the student with strategic reasoning to drive preclinical R&D productivity and develop innovative therapeutic drugs. Students are strongly encouraged to participate interactively during classes and will complete a final test on the exposed topics.

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The course will be online, in Portuguese, English and Spanish language.

PROGRAM

6th March

9.30h- Introduction

Ana Fortuna
Faculty of Pharmacy of University of Coimbra
Centro de Imagem Biomédica e Investigação Translacional (CIBIT)

10h-12h30- Fundaments on drug pharmacokinetics and pharmacodynamics

Ana Fortuna
Faculty of Pharmacy of University of Coimbra
Centro de Imagem Biomédica e Investigação Translacional (CIBIT)

14h30-15h30- Pharmacology and toxicology of new chemical entities

Nuno Pires
Bial Laboratories

16h - 19h- Pharmacokinetic R&D of New Chemical Entities

Joana Bicker
Faculty of Pharmacy of University of Coimbra
Centro de Imagem Biomédica e Investigação Translacional (CIBIT)

7th March

09.30h-11h15 - Screening of antidepressant drugs

Catarina Gomes
Faculty of Pharmacy of University of Coimbra
Centre for Neuroscience and Cell Biology (CNC)
Centre for Innovation in Biomedicine and Biotechnology (CIBB)

11h30-13h30- Cancer pharmacology: from hallmarks to cellular therapy

Teresa Rosete
Faculty of Pharmacy of University of Coimbra
Centre for Neuroscience and Cell Biology (CNC)
Centre for Innovation in Biomedicine and Biotechnology (CIBB)

15h-16h30- Seminar: *The Delivery of Nanomedicines to the Lung and the Nose*

Fabio Sonvico
Department of Pharmacology and Neuropharmacology, Faculty of Pharmacy and Food Science, University of Barcelona, Spain

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8th March

9.30h-10h30 Seminar: *Alzheimer's disease: how to investigate new pharmacological targets and drugs?*

Miren Ettcheto
Department of Pharmacology and Neuropharmacology, Faculty of Pharmacy and Food Science, University of Barcelona, Spain

11h-13h- *In Silico* Phamacological Studies

Nuno Vale
Faculdade de Medicina da Universidade do Porto
Departamento de Medicina da Comunidade, Informação e Decisão em Saúde (MEDCIDS)
Centro de Investigação em Tecnologias e Serviços de Saúde (CINTESIS)

14h30- Clinical development of new chemical entities

Andreia Guimarães
Bial Laboratories

16h-17h30 - Clinical Pharmacology and Pharmacometrics in drug development

Paulo Magalhães
Menarini Group
Centro de Imagem Biomédica e Investigação Translacional (CIBIT)

9th May

9h30-10h45 – Seminar: *Pharmacometrics and Populational Pharmacokinetics: from theory to practice*

Helena Colom
Pharmacy and Pharmaceutical Technology Department, Universitat de Barcelona
Institut d'Investigació Biomèdica de Bellvitge (IDIBELL)

11h-12h Brain immaging approaches in drug discovery and development

Miguel Castelo-Branco
Faculdade de Medicina da Universidade de Coimbra
Centro de Imagem Biomédica e Investigação Translacional (CIBIT), Coordenador Científico

12h-13h – Final Remarks and Evaluation

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Professor Fabio Sonvico – Biosketch

Fabio Sonvico graduated in Chemistry and Pharmaceutical Technologies in 1999 at the University of Pavia (Italy) with a Master Thesis carried out in Bayer Italia, then received his Ph.D. in 2004 form University of Parma (Italy) and University of Paris XI (France) with a co-tutorial research project under the supervision of Prof. P. Colombo and Prof. Patrick Couvreur. After an experience as researcher at the National Institute of the Physics of the Matter (INFM, Parma) joined Pharmaceutical Department of the University of Parma as Assistant Professor. In 2012 he moved to Australia at the Graduate School of Health of the University of Technology Sydney, where he was involved in setting up a new Master Course in Pharmacy.

Since January 2015 he is Associate Professor at the Department of Pharmacy of the University of Parma following several research projects on drug administration of nanomedicines by nasal and pulmonary routes and innovative delivery systems for the treatment of lung tumors.

Since 2016, he is Member of the Executive Committee and Treasurer for the European Federation for Pharmaceutical Sciences (EUFEPS).

He authored more than 100 papers (H-index 29), 6 book chapters and 6 patents on novel dosage forms.

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Professor Miren Ettcheto – Biosketch

Miren Ettcheto Arriola studied biology specialized in health in the University of Barcelona. Last year of her degree, she obtained an Erasmus grant to go to Paris where she spent 10 months working in the "ICM Institute for brain and spinal cord", located in the heart of the "Pitié Salpêtrière Hospital", a reference center in neurology. Later, she came back to Barcelona where she obtained her MSc degree in biomedicine from the University of Barcelona in 2012.

She completed her PhD in the group of aging and neurodegeneration from Department of Pharmacology, Toxicology and Therapeutic Chemistry, in the Faculty of Pharmacy and Food Science from the same University where she is currently an Assistant Professor.

Ettcheto has performed several internships including reference centers from Germany and Netherlands.

Her research is focused on the study of cognitive decline and associated molecular pathways in neurological disorders including Alzheimer´s disease with the objective to find new targets involved in the development of the pathology. Moreover, she is involved in the evaluation of not only natural compounds but also new promising molecules in order to stop the cognitive decline, contributing significantly to the field of neuropharmacology.

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Professor Helena Colom – Biosketch

Associate Professor of the Pharmacy and Pharmaceutical Technology and Physical Chemistry Department of the School of Pharmacy and Food Sciences. University of Barcelona. Spain.

Traditional pharmacokinetic (PK) studies require a sufficient number of data per subject, using whether the non compartmental analysis or non linear regression methods. However, if difficulties exist to obtain a sufficient number of samples per subject, sparse data designs are required. This led to the development of the non-linear- mixed- effects models (population PK approach, POPPK). This approach has a broad applicability in drug development to Support Regulatory decisions but also in informing therapeutic individualization. In the first case, data from many subjects of the population are analysed simultaneously. This allows to account for differences in PK parameters between individuals and that's why POPPK is defined as "the integration of all relevant PK information to identify factors that can affect a drug's exposure in an individual". The second application is to support dose individualization during the therapeutic drug monitoring, from few samples in a particular patient. The prior typical values of PK parameters in the population of the patient from which sparse data are obtained, are assumed. Then, bayesian estimates of the most likely individual PK parameters are obtained and used for dose tailoring.
This seminar aims to show the applicability/advantatges of POPPK through real examples developed from Clinical practice data.