

1. PROGRAMME STRUCTURE AND CONTENT

1.1. INTRODUCTION

The INSPIRE Summer School aims to provide participants with insight in Cardiovascular Safety Pharmacology and Cardio-Oncology. The programme starts with a refresher on cardiovascular physiology and pathophysiology. Next, speakers from leading pharma companies will provide insight in the process of drug development and the importance of clinical safety. The regulatory landscape of drug development and safety evaluation will be elaborated, as well as a description of key methods implemented in Safety Pharmacology to identify adverse effects of drug candidates early on. A few case studies of failed drug candidates will also be discussed. Further, clinical cases of drug-related cardiovascular complications presented by cardiologists will provide a wider perspective on the topic. More specifically, the discipline of cardio-oncology will be discussed in detail. With increasing survival rates of cancer patients, the long(er)-term effects of anticancer treatment (i.e. cardiac toxicity) are receiving more scrutiny. In this context, the programme will conclude by highlighting academic research to evaluate the detrimental effects of many anticancer drugs on endothelial cells. Endothelial cells are the inner lining of the vascular system and play a pivotal role in vascular physiology and pathophysiology. At the end of the programme, participants will have gained a comprehensive view of the topic of cardiovascular (patho)physiology and how these mechanisms should be taken into account during drug development.

1.2. COURSE SCHEDULE

DAY 1 – Thursday 27 AUGUST

MORNING (09:00 -12:30) Refresher on cardiovascular disease pathophysiology. Speaker: Vincent Segers, University of Antwerp

Learning outcome: Understand the physiology and pathophysiology of hypertension | Understand the pathophysiology of ischemic heart disease (including atherosclerosis) | Understand the pathophysiology of heart failure and cardiac remodeling.

AFTERNOON (13:30 – 17:00) Lecture: Insight in the process of drug development and safety pharmacology (SP). Speaker: Jean-Pierre Valentin, UCB Biopharma SRL

Learning outcome: Understand the process of drug development and the importance of clinical safety | Introduction to non-clinical safety testing | Principles and helicopter view on Safety Pharmacology and Toxicology.

DAY 2 – Friday 28 AUGUST

MORNING (09:00 – 12:30) Regulatory landscape of drug development and safety evaluation and case studies. Speaker: Jean-Pierre Valentin, UCB Biopharma SRL - Industry perspective

Learning outcome: Requirements for nonclinical studies and their relation to the conduct of human clinical trials | Regulatory requirements for cardiovascular evaluation of drug candidates | Advantages and limitations of the methods currently used for cardiovascular safety assessment.

AFTERNOON (13:30 – 17:00) Endothelial cells (EC) in cardio-oncology

Speaker: Stefan Chłopicki, Jagiellonian University in Kraków - Academic perspective

Learning outcome: Introduction to the important role of EC in maintaining cardiovascular homeostasis | Overview of methods state-of-the-art to study endothelial phenotype *in vivo* and their application to understanding pathomechanisms of endothelial dysfunction in various cardiovascular and non-cardiovascular diseases | Detrimental effects of anti-cancer drugs on endothelial function | Towards endothelial profiling of anti-cancer drug.

DAY 3 – Monday 31th AUGUST

MORNING (09:00 – 12:30) PartA: strategies for evaluation of teratogenicity during drug R&D.

Speaker: Steven Van Cruchten, University of Antwerp Learning outcome: Physiological signals analysis and interpretation | Displays , graphs and charts: how to choose the right ones | Data acquisition requirements depending on analysis objectives | Regulatory framework.

PartB: Signal processing / data visualization. Speaker: Pieter-Jan Guns, University of Antwerp

Learning outcome: Physiological signals analysis and interpretation | Displays , graphs and charts: how to choose the right ones | Data acquisition requirements depending on analysis objectives | Regulatory framework.

AFTERNOON (13:30 – 17:00) Hands-on echocardiography / organ baths

Organisers: Physiopharmacology Research Group, University of Antwerp

Description: Follow the researchers of the laboratory during live experiments | Gain insights on methodologies to investigate cardiovascular function *in vivo* and *ex vivo* | Practical insight in data handling and analysis | Introduction in good laboratory practices.

DAY 4 - 27 Tuesday 1 SEPTEMBER

MORNING (09:00 – 12:30) Clinical cardiology and cardio-oncology (and case reports)

Speaker: Constantijn Franssen, Antwerp University Hospital - Cardiologist perspective

Learning outcome: Introduction to cardiology | Understand the main cardiovascular pathologies and methods used for diagnosis and treatment | Introduction to cardio-oncology | Understand challenges and best practices in cardio-oncology.

AFTERNOON (13:30 – 17:00) hiPSC technology in drug R&D

Speaker: Brigitta Rita Szabó, MSCA doctoral researcher, Maastricht University

Learning outcome: Basic introduction to hiPSC, general principles of generation, differentiation, and applications in Safety Pharmacology | Advanced integrated hiPSC-based assays: validation and challenges | Large scale production and associated ethical aspects | Future perspectives of hiPSCs in drug development

DAY 5 – Wednesday 2 SEPTEMBER

FULL-DAY WORKSHOP & CLOSING (09:00 – 15:00) **Career development, strategic thinking, and proposal writing. Speaker: Pieter-Jan Guns, University of Antwerp**

Learning outcome: Tools to develop a career development plan | Understanding which skills and strategies are useful to become a successful researcher | Tips and tricks for writing a research proposal | How can we measure the quality of scientific output? | What are the ingredients of a good scientific publication? | Tips and tricks for writing your first publication

An career in pharmaceutical industry – what are the opportunities. Speaker: Khuram Chaudhary, Bristol Myers Squibb

1.3. ECTS AND CERTIFICATES

A certificate of attendance will be awarded at the end of the training.

Participants are expected to attend all classes. Successful completion of the INSPIRE Summer School by 100% participation in the lectures and hands-on sessions can be awarded with a certificate of completion providing 3 credits according to the European Credit Transfer System (ECTS). Recognition of the ECTS credits in your home curriculum should be agreed upon with your home institution. We can provide a course information sheet if necessary.

1.4. COURSE MATERIAL

Supporting and class materials will be shared via Blackboard, the digital learning environment of the University of Antwerp. Participants already in possession of an UAntwerp account (i.e. UAntwerp students and staff members) can access the course via their regular Blackboard environment (blackboard.uantwerpen.be) using their regular log-in credentials. Non-UAntwerp participants will receive log-in information by email a few days before the start of the summer school. Students can also use this platform to communicate informally with each other.

The Blackboard learning environment is accessible through <https://lms.uantwerpen.be/>