

INSPIRE Summer School: Cardiovascular Safety Pharmacology in Drug Development

DAY 1 Monday	DAY 2 Tuesday	DAY 3 Wednesday	DAY 4 Thursday	DAY 5 Friday	DAY 6 Saturday
31 AUG	1 SEPT	2 SEPT	3 SEPT	4 SEPT	5 SEPT
Refresher on cardiovascular biology and cardiovascular pathologies Prof. Vincent Segers	Introduction to Drug Development, Safety Pharmacology and Toxicology Dr. Jean-Pierre Valentin	Time for assignment 4 2-3 slides introducing your research with focus on defining scientific goals. 10.30 - 12.00 Group dynamic to discuss the outcome.	3Rs in basic research and drug R&D Dr. Helen Prior	Introduction to Cardio-Oncology Dr. Constantijn Franssen	Time for assignments (No need to attend virtual sessions)
08.00 - 09.00 Part 1 - Hypertension	08.00 - 09.00 Part 1 - Drug Development		08.00 - 09.00 Part 1 - Ethical considerations for animal experimentation	08.00 - 09.00 Part 1 - Introduction Cardiology	
09.15 - 10.15 Part 2 - Coronary artery disease	09.15 - 10.15 Part 2 - Safety Pharmacology (SP) & Toxicology		09.15 - 10.15 Part 2 - How applying the 3Rs within animal research can improve welfare and scientific data quality	09.15 - 10.15 Part 2 - Cardio-Oncology	
10.30 - 11.30 Part 3 - Heart failure & cardiac remodeling	10.30 - 11.30 Part 3 - Cardiovascular Safety Pharmacology		10.30 - 11.30 Part 3 - 3Rs in SP and toxicology	10.30 - 11.30 Part 3 - Q&A	
Lunch break	Lunch break		Lunch break	Lunch break	
Interactive Session on Impact Dr. Bruno Hoste Paz Yanez	Career Development Plan Dr. Gábor Kismihók Prof. Pieter-Jan Guns	Regulatory requirements in drug development and SP Dr. Xi Yang	"Presenting with Impact" Hans Van de Water The Floor is Yours	Introduction to scientific writing Prof. Pieter-Jan Guns Prof. Guido De Meyer	
13.00 - 14.30 Communication & Dissemination Strategies	13.00 - 13.30 Interactive session on a Gap analysis, PCDP	13.00 - 14.00 Part 1 - Requirements for nonclinical and human studies	13.00 - 14.30 Part 1 - Incl. interactive exercise	13.00 - 14.00 First steps towards publishing	
14.45 - 15.30 Making the most of social media Brainstorm INSPIRE website Guidelines for assignment 1	13.30 - 14.15 Testimonial speech Q&A	14.15 - 15.00 Part 2 - Regulatory requirements for cardiovascular evaluation of drugs	14.45 - 16.00 Part 2 - Incl. Q&A	14.20 - 16.00 The case of the "Position Paper" Guidance assignment 5	
15.45 - 16.45 Group work activity assignment 2	14.30 - 16.00 Monitoring a CDP Guidance for assignment 3	15.15 - 16.00 Part 3 - Context of used of current methods in SP		16.00 - 17.00 Closing reception	

Theoretical courses

Refresher on cardiovascular biology and cardiovascular pathologies

Lecturer: Prof. 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.

Introduction to drug development and safety pharmacology (SP)

Lecturer: Dr. 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.

Regulatory requirements in drug development and SP

Lecturer: Xi Yang, The US Food and Drug Administration (FDA)

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.

3Rs in basic research and drug R&D

Lecturer: Dr. Helen Prior, The National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs)

Learning outcome: Position and regulations of animals experiments in basic research and drug R&D | Introduction to the 3Rs, i.e. Reduction Replacement and Refinement | Examples of implementations of 3Rs in safety pharmacology and toxicology | Which of the 3R's are applicable within your own research and/or how your work will influence animal use by others in the future.

Clinical cardiology and cardio-oncology

Lecturer: Dr. Constantijn Franssen, Antwerp University Hospital

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.

Workshop on transferable skills

Interactive Session on Impact

Lecturers: Prof. Pieter-Jan Guns, Paz Yanez and Dr. Bruno Hoste, University of Antwerp

Learning outcome: What is the impact of my research? Why is impact of research important? How can I increase the impact of my research? Tips and tricks for increasing the impact of your research.

Career Development Plan

Lecturers: Dr. Gábor Kismihók, Marie Curie Alumni Association, Prof. Pieter-Jan Guns, University of Antwerp | Testimonial speech by Dr. Muhammet Tanc, University of Antwerp

Learning outcome: How to develop a career development plan | Understanding which skills are required for becoming a successful researcher | What to do when reality is not

"Presenting with Impact"

Lecturers: Hans Van de Water, The Floor is Yours

Learning outcome: the participants learn to present their research or project in a clear and convincing manner, tailored to the needs of the target group.

Introduction to scientific writing

Lecturers: Prof. Pieter-Jan Guns, University of Antwerp

Learning outcome: An introduction to the process of academic publishing. 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.

Assignments, ECTS and course material

The successful completion of the summer school includes the submission of five assignments with due dates after the summer school. Only participants that have attended all the online sessions – social activities excluded – and delivered all the assignments in time are entitled to be awarded **3 ECTS** credits. In brief, participants shall submit the following tasks (more details will be provided on-the-spot):

1. Self-biography incl. project summary embodied in 1-min 'selfie-movie' or picture with a 10-lines story
2. Outreach material consisting of a social media post and an infographic (group work)
3. Personal Career Development Plan (PCDP)
4. Research project presentation in 3 slides
5. Scientific writing

Course material will be made available on VICE Blackboard, link provided upon registration.