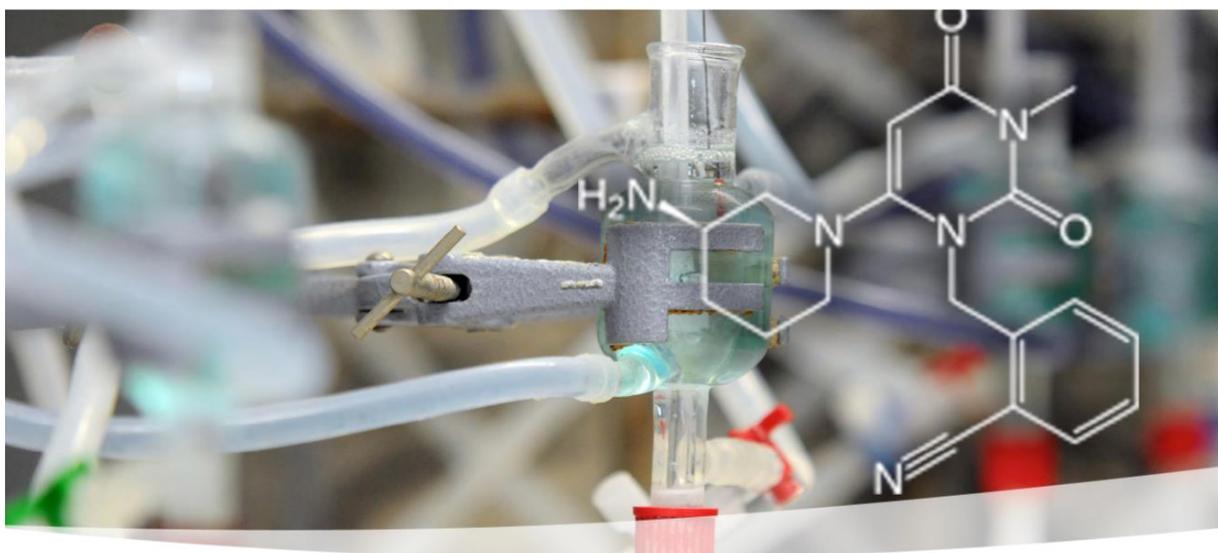# WELCOME BROCHURE

INSPIRE Summer School: Cardiovascular Safety Pharmacology in Drug Development | Antwerp Summer University
31 August – 5 September 2020
University of Antwerp, Belgium

www.uantwerpen.be/en/summer-schools/inspire/

www.inspire-safety-pharmacology.eu

Table of Contents

Welcome!

We are pleased to welcome you to the first digital edition of Antwerp Summer University.

The INSPIRE Summer School offers an intensive 5-days programme on Cardiovascular Safety Pharmacology in Drug Development. Built as a highly interactive and multidisciplinary training, it consists of theoretical lectures to provide an in-depth insight into Safety Pharmacology and its regulatory landscape provided by leading companies and associations in the sector. Furthermore, it is complemented with training in 'scientific writing' as well as hands-on sessions on how to develop strategies for achieving 'societal impact' and 'personal career development'.

In this brochure, we provide you with practical and substantive information regarding this summer school. For any additional questions, you can contact us via email to INFO.INSPIRE@uantwerpen.be or by phone T +32 3 265 27 07 (Mobile: +32 486 76 74 08, also via WhatsApp).

We wish you an interesting summer school and an unforgettable virtual experience!

1   Programme structure and contenCourse schedule (hours given in CET)

1.1   Course schedule (hours given in CET)

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 t o 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	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	

1.1.1. Theoretical courses

MONDAY, 31 AUG | 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.

TUESDAY, 1 SEPT | 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.

WEDNESDAY, 2 SEPT | Regulatory requirements in drug development and SP. *Lecturer: Xi Yang, The United States 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.

THURSDAY, 3 SEPT | 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.

FRIDAY, 4 SEPT | 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.

1.1.2. Workshop on transferable skills

MONDAY, 31 AUG | Interactive Session on Impact. *Lecturers: 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.

TUESDAY, 1 SEPT | 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

THURSDAY, 3 SEPT | "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.

FRIDAY, 4 SEPT | 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.

1.2   Course material

All the supporting material for participants and the presentations will be shared on the section 'Course Materials' on the digital learning environment VICE Blackboard. More details on how to access VICE Blackboard in section 2.1. of this brochure.

1.3   Assignments

All participants with interest in being awarded 3 ECTS credits for the completion of the INSPIRE Summer School shall deliver the five following assignments on due date. Additional guidance to complete the assignments will be given during the virtual sessions.

Assignment 1. Website content – INDIVIDUAL WORK

Description: each participant will prepare a 1-minute short 'selfie-movie' or picture with a 10-lines story to introduce themselves and their own research project. This 'selfie movie' can be recorded with the own smartphone. However, audiovisual material recorded and edited by other means will also be accepted.

Delivery: to be submitted to info.INSPIRE@uwanterpen.be no later than September 20.

Assignment 2. Outreach material – GROUP WORK

Description: in the afternoon of Monday, Aug 31 (DAY 1), all participants will take part in an Interactive Session on the importance of Impact of research and strategies to increase the impact. It will provide guidance and tools to elaborate communications and dissemination material. In this context, the participants will work in groups of 4-5 persons to draft the following outreach material:

1. One post for the social media (Twitter or LinkedIn)
2. One infographic addressing one of the five clusters:
   a) hiPSC CM assays
   b) Hardware/software innovation for non-invasive haemodynamic evaluation.
   c) Alternative haemodynamic markers.
   d) Mass Spectroscopy Imaging (exposure – PBPK modelling)

e) Cardio-oncology / long-term toxicology

Delivery: the resulting material shall be either posted on social media during the Summer School (for N°1) or sent to info.INSPIRE@uwanterpen.be before September 7 (for N°2).

Assignment 3. Personal Career Development Plan – INDIVIDUAL WORK

Description: in the afternoon of Tuesday, Sept 1 (DAY 2), the participants will take part in a workshop on Personal Career Development, which will include: (1) guidance to perform a gap analysis and to build a career strategy; (2) testimonials; and (3) 'coaching' insights to get prepared for failure. Several resources will be provided allowing the participants to develop a good and actionable (i.e. S.M.A.R.T.) personal career development plan (PCDP), which will include the future career steps.

Delivery: the complete PCDP must be sent to info.INSPIRE@uwanterpen.be before Monday, September 21. PCDPs of the ESR fellows of INSPIRE shall be reviewed and approved by their respective supervisory teams before delivery.

Assignment 4. Presentation of 1-3 slide about the ESR research project – INDIVIDUAL WORK

Description: on Wednesday morning, Sept. 2, the Early Stage Researchers of INSPIRE will have 2 hours (8.00 – 10.00 CET) to prepare 2-3 slides summarizing their ESR project. This presentation should contain a clear definition of the scientific goals. In the last hour and a half (from 10.30 to 12.00), all participants will take part in a group dynamic in order to discuss the outcome in a group of 4-5 persons.

Delivery: the slides shall be sent to info.INSPIRE@uwanterpen.be in the evening of the same day, Wednesday, September 2. During the workshop 'Presenting with Impact' on Thursday afternoon, the trainer will provide comments for improvement on some of these presentations.

Assignment 5. Scientific writing – INDIVIDUAL WORK

Description: the session 'Introduction to scientific writing' on Friday afternoon will offer the participants basic learning on the first steps toward the peer-reviewed articles drafting process. Building on the knowledge acquired, all participants will need to draft a text that provides a comprehensive overview of the start-of-the-art and the specific research objectives (knowledge gaps) addressed by each ESR research project.

Delivery: the Word document must be sent to info.INSPIRE@uwanterpen.be before October 12.

1.4 Credits and certificates

Successful completion of the INSPIRE Summer School can be awarded with 3 credits according to the European Credit Transfer System (ECTS). Credits will be awarded upon delivery of the five assignments proposed assignments. Recognition of the credits in your home curriculum should be agreed upon with your home institution.

If you have a motivation to be absent at one or more virtual sessions, please inform us by sending an email to info.INSPIRE@uwanterpen.be as soon as possible.

2   Practical Information

2.1   VICE Blackboard

The INSPIRE Summer School will make use of VICE Blackboard, the digital learning environment of the University of Antwerp, to post announcements, facilitate communication, share resources and facilitate group works and interaction. Participants who already have UAntwerp account can access the course via their regular Blackboard environment (http://blackboard.uantwerpen.be), using their regular log-in. Other participants can access Blackboard via http://vice.uantwerpen.be.

1. Choose your preferred language
2. Log on with
    a. Username: email address used for your application
    b. Password: vice9512

This password can be changed after the first login via Settings > personal information > change password. Students currently enrolled at the University of Antwerp can access the course via their regular blackboard environment.

2.2   Blackboard Collaborate Ultra and Microsoft Teams

We will use the Collaborate Ultra module within Blackboard. In order to use this interactive module, participants need to have a stable internet connection, a headset, a computer and a webcam. All sessions will be held "live" to enable interaction and debate.

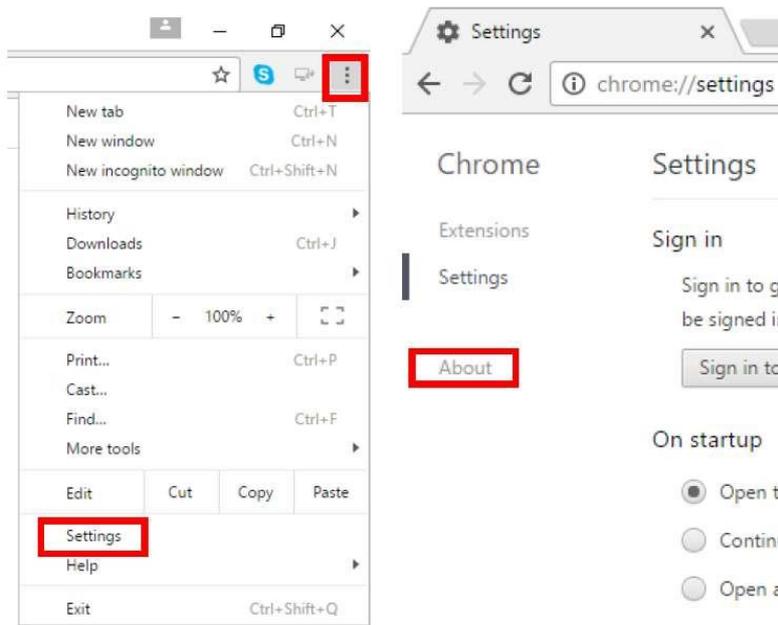Link to the virtual classroom: https://eu.bbcollab.com/guest/a96431dda642467a9151fa8670e6391f

We invite all paticipants to take part in an <u>open session to test the platform</u> on Friday, August 28 from 9h.15 to 10.15 (CET). Please access the virtual classroom on Blackboard Collaborate Ultra (link above).

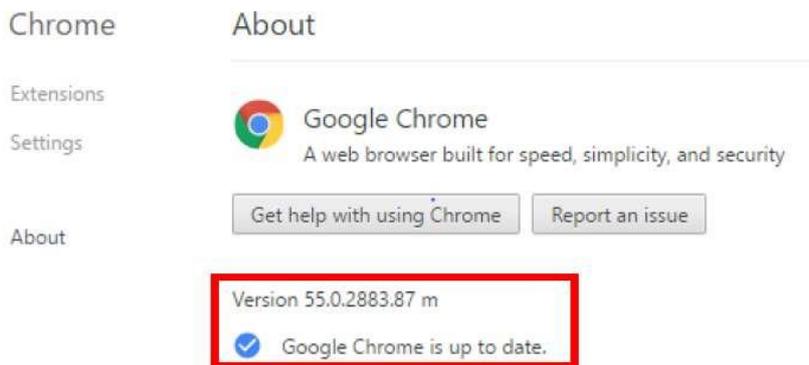### 2.2.1   Preparing for your first Blackboard Collaborate Ultra Session

Check your browser settings

Blackboard Collaborate Ultra requires the use of an internet browser that supports WebRTC. We suggest using <u>Google Chrome</u> for the best results, or Safari if you are using an Apple device. You will need to check that your Google Chrome browser is up to date on the computer you will use for the summer school:

1. Open the Chrome browser
2. Locate the three dots on the top right of the screen and click to open menu
3. Click on 'Settings'
4. On the settings page, locate and click the 'About' button

5. When you access the 'About' page, the browser will automatically check for updates and update automatically

Check your computer settings

Answer the following questions. If you answer no to any questions, please make sure that you are able to resolve the issue yourself or that you can receive help to resolve the issue.

1. Is your device audio turned on? (vital)
2. Is your device mic turned on? (vital)
3. Is your web-camera operational? (not vital, but ideal)
4. Do you have a headset? (not vital, but …. Actually, we consider it vital)

2.2.2 Best practices for the best experience

- Use a hard-wired (Ethernet) connection, if available. If not available, use a Wifi connection. If using Wifi, try to be as close to the router as possible. If possible, try to be the only one using WiFi during the session.
- Close other programmes. Close all programs and streaming services on your computer except for the browser you are using for your Collaborate session.
- Limit video use. Use video during the session only when necessary.
- Use supported mobile browsers. If on a mobile device, use a supported mobile browser. For the best experience, use Safari on iOS devices and Chrome on Android devices.
- Disable Adblockers. Browser Adblockers can turn off your audio and video and can cause buttons to not show up.
- When using video, make sure not to be seated behind a window or other light source.

2.2.3 Online etiquette

- Be on time. If you can't be early, be on time. Let us know if you are going to be late or absent.
- Mute yourself when not speaking.
- Raise your hand if there is no opening to speak. Type questions and feedback in the chat.

2.2.4 FAQs

I only see a black screen	Use Google Chrome; switch on "cookies".
My camera doesn't work	Home button "Windows" > Settings > Privacy > Camera. Switch on "Allow access to camera on this device". More information: https://bit.ly/3hghHrO
My micro doesn't seem to work	Use Google Chrome. Cancel "mute". If this doesn't work, check your audio settings in.
I can't hear anything. Can I change the volume?	Adjust your microphone and speaker volume in My Settings. Point to your avatar image to open My Settings. Select Audio and Video Settings.
I don't manage to share files	You don't have the right role to do so. Ask the moderator to change your role to "presenter".
My screen is not large enough	Double click on the screen to zoom, or use the zoom button at the upper left corner.
How can I switch of the sound/notifications of the chat?	Click on settings (right corner), then go to notifications settings and change the settings.
How can I ask a question?	Ask the question in the chat and/or use the icon "Raise hand". Wait to switch on your micro until the teacher gives you the floor.
More troubleshooting	https://bit.ly/2UrQHvG
Still don't find an answer to your question?	https://bit.ly/3fbdh3S or contact summeruniversity@uantwerp.be

3   Social programme

During this first digital edition of Antwerp Summer University, we don't want you to miss out on getting to know your classmates and fellow participants. That is why we're offering you an online social programme, full of fun, challenging and cultural activities to enjoy live or whenever it suits you. We want you to experience what life in Antwerp is about, but we also love to get to know all of you!

The overview of activities can be found from August onwards via www.uantwerp.be/asu-social-programme.

Next to these virtual events, the organisers of the INSPIRE Summer School have also scheduled a closing reception on Friday, September 4 at 16.00 (CET). More details will be provided during the training week.

4   Antwerp Summer University on social media

Participants are invited to follow @AntwerpSummerUniversity on Instagram and tag the account in their feed and/or stories. For those who may be intrigued or interested in taking over our Instagram account for one day, send us an email at summeruniversity@uantwerp.be. An Instagram takeover is when someone takes over another account to create and share content from their point of view - usually on behalf of a brand. A closed group on Facebook has been created as well for all participants of this year's edition. www.facebook.com/groups/2167360196906511/.

Connect with us during your online-experience by using the following hashtags on your social media channels: #ASUgoingdigital, #AntwerpSummerUniversity and for those joining the social programme #ASUdailychallenge.

Make sure to sign up to our social channels to get to know us and other participants, and to share with us your pictures and experiences related to the summer school and the social programme. We are looking forward to meeting you soon and discovering your posts and comments!

Facebook group

Instragram page

Antwerp Summer University

Antwerp Summer University 2020 ›

PRIVATE GROUP · 39 MEMBERS

144	424	644
Posts	Followers	Following

Antwerp Summer University
Experience a summer where new friendships and unforgettable learning experiences are made!
International speakers | ECTS | Lots of knowledge and fun!
www.uantwerpen.be/asu-overview

5 About…

5.1 … Your host: University of Antwerp

The University of Antwerp, which was founded in 2003, has about 20,800 students and scores extremely well in Young University Rankings. It is ranked 7th in the world in the Times Higher Education Millennials 2019, and 22nd of all universities younger than 50 years old in the Times Higher Education 250 under 50 2019. Up to 20% of our students are international, coming from all corners of the world: from the A of Argentina to the Z of Zambia. The University of Antwerp is characterised by its high standards in education, internationally competitive research and its entrepreneurial approach.

5.2 … Antwerp Summer University

Since 2010 Antwerp Summer University offers intensive, short term courses during the summer months within the areas of excellence of the University of Antwerp and its partners. Next to several interdisciplinary summer schools, summer school topics range from Law over Design Sciences to Health. Target groups are different for each summer school and may consist of students, researchers and/or working professionals.

As you will notice, summer schools consist of intensive full-time programmes in which a wide variety of teaching methods are used. Sessions are taught by international speakers and experts from both within and outside the academic world. An intensive learning experience with maximum impact is guaranteed thanks to the international composition of the classroom, the interactive set-up of the courses and the approachability of the lecturers.
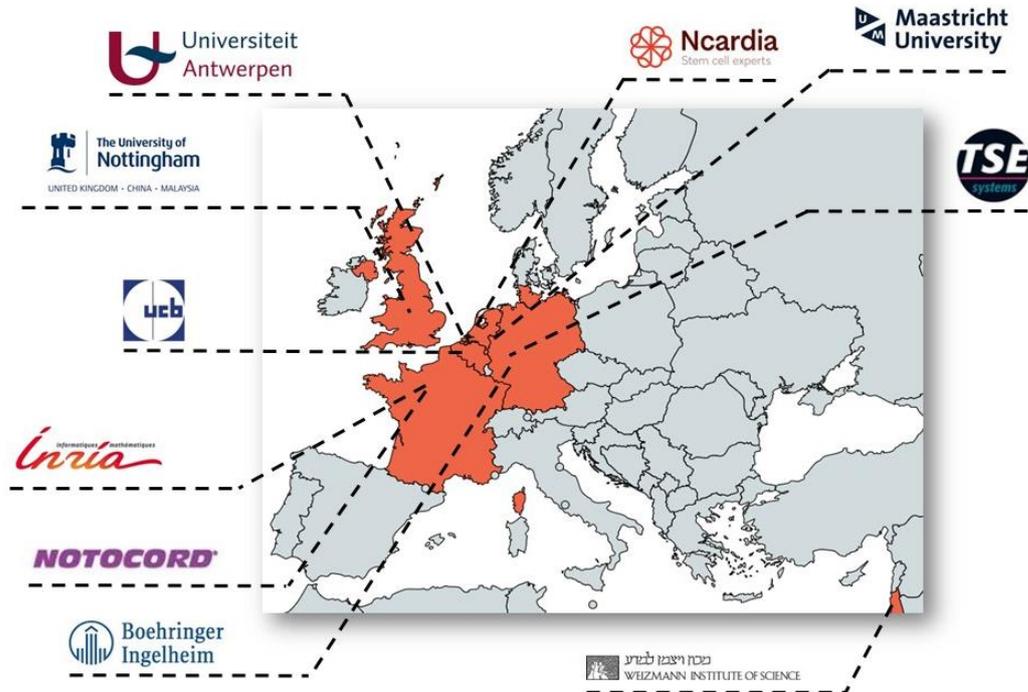
5.3 … INSPIRE Project

New drug candidates often have off-target effects resulting in adverse events, thus representing a major limitation for drug R&D. Safety Pharmacology (SP) aims to detect, understand and reduce undesirable pharmacodynamic effects early-on. Especially, cardiovascular (CV) toxicity is problematic, as it is the most prevalent reason for failure during preclinical development and remains a key reason for drug attrition during clinical development and beyond. This indicates current SP screens fail to detect a number of (late-onset) functional or structural CV toxicities. Additionally, SP uses a significant number of laboratory animals, thereby creating opportunities for a better implementation of the 3Rs. The vision of INSPIRE is to advance and "inspire" SP by exploring new technological capabilities to addressing emerging CV safety concerns.

Hereto, INSPIRE unites expertise from academic teams, technology-providers, pharmaceutical companies, regulators and hospitals to create a European training platform for 15 Early Stage Researchers (ESRs). This EU-leading Network is composed of 5 academic beneficiaries and 5 industry R&D teams with complementary expertise and skills in the field of safety pharmacology. Additionally, 10 partner organisations complement the training programme.

INSPIRE consortium: an interational team

Key innovative aspects of INSPIRE include: i) in vitro humanized cardiomyocytes assays, ii) unparalleled in vivo hardware/software solutions, iii) in silico predictions of haemodynamics, iv) mass spectroscopy imaging of drug exposure, v) exploration of mechanisms of late-onset CV toxicity, as observed in cardio-oncology, and vi) early integration of feedback from industry and regulators.

Overall, INSPIRE constitutes a multidisciplinary and intersectoral training programme with a balanced combination of hands-on research training, intersectoral secondments, local courses and network-wide events on scientific and transferable skills, enabling future R&I collaborations. Hence, INSPIRE will equip the future generation of SP scientists with a wide range of scientific knowledge and the ability to adapt to a dynamic industry.

More information: www.inspire-safety-pharmacology.eu

6 Organising committee and contact details

Prof. Pieter-Jan Guns
Coordinator of the INSPIRE Project
Assistant Professor Physiopharmacology
GENCOR Research Unit | Faculty of Medicine
and Health Sciences,
University of Antwerp
Email: pieter-jan.guns@uantwerpen.be
Tel. +32 3 265 27 84

Paz Yanez
Project Manager of the INSPIRE Project
Grants Officer | Department of Research
Affairs & Innovation
University of Antwerp
Email: paz.yanez@uantwerpen.be
Tel. +32 3 265 27 07
Mobile: +32 486 76 74 08 (also via WhatsApp)

Antwerp Summer University Team
Wannes Gijsels I Sara Bervoets | Anneleen ibens I Ana Laura Inclán Velázquez
Email: summeruniversity@uantwerpen.be
Tel. +32 3 265 43 82| +32 3 265 48 23 | +32 3 265 42 41 | +32 3 265 49 80

We wish you an enriching and pleasant virtual experience at Antwerp Summer University!