

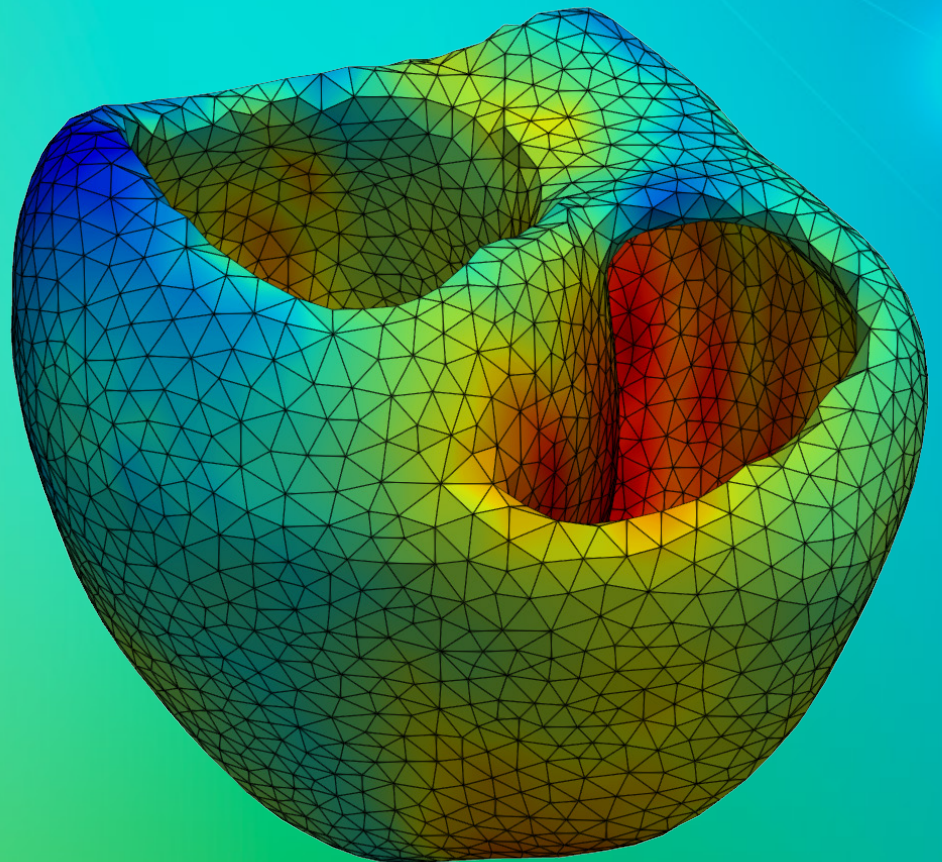
2nd EDITION

INNOVAHEART

A joint European workshop on the digital heart

Leuven, Belgium
6 — 7 February 2024

www.innovaheart.info



KU LEUVEN

INNOVAHEART 2024 at a glance

The 1st InnoVaHeart workshop, held in Bordeaux in March 2023, gathered a diverse group of **experts from academia, industry, regulatory and notified bodies** with the aim of discussing advancements, challenges, and outstanding issues in the field of **modelling and simulation in cardiovascular medicine**. A recurring topic emerged throughout these discussions: the persistent obstacles preventing the successful translation of in-silico models into clinical application.

The 2nd edition of InnoVaHeart will thus focus on the **challenges of efficiently transitioning in-silico models from a research environment to practical clinical applications**. The workshop will leverage **keynote talks** and a series of **working groups** on key open challenges and recent topics, giving the opportunity to delve deeper into specific barriers in the translation process.

InnoVaHeart 2024 is organised by the [SIMCor](#), [SimInSitu](#), [SimCardioTest](#) Horizon 2020 Research and Innovation Actions, the [EDITH](#) Horizon Europe Coordination and Support Action, and the [inEurHeart](#) EIT Health innovation project.

Day 1 — Tuesday 6 February 2024 (12:00 – 22:00)

12:00 | 13:00 *Welcome lunch and registration*

13:00 | 13:15 *Introduction and greetings*

13:15 | 14:15 **WG1 - Translation of industry problems**

The use of in-silico models in industry is diverse. It can range from research, aiding clinicians, regulatory compliance, marketing, to speeding up new device market entry. This will differ based on the company profile: large industry vs specific small and medium enterprises bridging academia and industry; tool developers vs service providers. Hence, determining a realistic complexity level for these models is crucial to balance practical applicability and scientific rigor.

Moderator: **L Geris** (Virtual Physiological Human Institute)

Speakers: **M Cox** (Xeltis BV): Restorative cardiovascular implants - potential role for in-silico trials

P Favre (Zimmer Biomet): From virtual design iterations to in-silico-clinical-trials - computational modelling and simulation in the orthopaedic device industry

14:15 | 15:15 **WG2 - From the basics of clinical trials to the development of in-silico clinical trials**

Preclinical and clinical trials (CTs) evaluate medical device safety and performance, being costly and subject to strict regulations. In-silico trials (ISCT) aim to replace CTs with computer models, providing physical property insights but facing challenges in predicting clinical endpoints. This group discusses ISCT frameworks and their development challenges.

Moderator: **J Brüning** (Charité – Universitätsmedizin Berlin)

Speakers: **J Colombel** (Dassault Systèmes SE), **S Levine** (Dassault Systèmes SE), **T Battisti** (Dassault Systèmes SE): ENRICHMENT in silico clinical trial study

PE Verde (Heinrich Heine University Düsseldorf): An introduction to patient-based clinical trials

15:15 | 15:45 *Coffee break and poster presentations*

15:45 | 17:15 **WG3 - Assessing the credibility of in-silico models – Part 1**

In-silico tools and models' credibility, crucial for trust, is assessed in sectors like aerospace through verification, validation, and uncertainty quantification (VVUQ). Hierarchical model development and VVUQ approaches are advantageous. Credibility, subjective to specific uses or interests, is vital, especially beyond the validation domain. A key challenge is assessing credibility in these scenarios and the reliability of models as in-silico tools under such conditions.

Moderator: **N Götzen** (4RealSim)

Speakers: **N Götzen** (4RealSim): VVUQ strategies and credibility assessment for medical devices

L Geris (Virtual Physiological Human Institute): Towards good simulation practice: a community-driven initiative

O Camara (Universitat Pompeu Fabra): Expectations, frustrations and hopes when adapting V&V40 guidelines to left atrial appendage occluder devices

17:15 | 18:00 **Start-up live session**

Moderator: **M Barbier** (National Institute for Research in Digital Science and Technology)

Speakers: **D Perrin** (Predisurge): A clinically relevant application for planning endovascular repair based on in-silico models


A Baretta (InSilicoTrials): InSilicoTrials: Hyper-accelerate drug and medical device development

N Cedilnik (inHeart): inHEART - A digital twin of the patient's heart to plan and guide interventions on patients with arrhythmia

18:00 | 19:00 *Aperitif and poster presentations*


19:00 | 22:00 *Dinner*


Day 2 — Wednesday 7 February 2024 (9:00 – 13:00)

9:00 | 10:00 **WG3 - Assessing the credibility of in-silico models - Part 2** 

The present SimInSitu consortium members will present their VVUQ approach for an patient-specific in-silico platform and outline its implementation and challenges at all relevant complexity levels. Afterwards the work-group participants can engage in a discussion about the applicability and feasibility to assess the credibility of complex in-silico models.


Moderator: **N Götzen** (4RealSim)
Speakers: **SimInSitu consortium members**

10:00 | 10:30 *Coffee break* 

10:30 | 11:30 **WG4 - Mapping engineering metrics with clinical endpoints** 

Computational models (CM) are key in predicting physical properties and medical device performance. The aim is to use CM in in silico clinical trials (ISCT) to foresee safety and performance before clinical trials, like predicting thrombosis from flow markers. However, linking clinical outcomes to engineering metrics remains challenging. Our framework will address this, discussing its limitations and potential solutions.

Moderator: **A Arndt** (Technische Universität Dresden)
Speakers: **J Brüning** (Charité – Universitätsmedizin Berlin), **M Stiehm** (Institut für ImplantatTechnologie und Biomaterialien e.V.),
J Mill Tena (Universitat Pompeu Fabra)

11:30 | 12:30 **WG5 - Assessing the socioeconomic impact of in-silico technologies** 

The potential of in-silico technologies in bolstering the development and evaluation of medical devices is widely acknowledged. Yet, there exists a gap in accurately quantifying the socioeconomic impacts these technologies pose on various stakeholders and society at large. This session will explore both the open challenges and the potential impacts of in-silico technologies. It will culminate in an interactive discussion, where we will introduce a comprehensive framework designed to facilitate the effective quantification of their impact, encouraging collaborative insights and shared expertise.

Moderator: **T Czypionka** (Institut für Höhere Studien)
Speakers: **C Rousseau** (Voisin Consulting Life Sciences), **D Rösler** (Institut für Höhere Studien), **C Zech** (Institut für Höhere Studien)

12:30 | 13:00 **Conclusions and farewell**

SimCardioTest (*Simulation of Cardiac Devices and Drugs for in-silico Testing and Certification*) aims to design new predictive tools in cardiac pathologies and accelerate the uptake of computer simulations for testing medicines and medical devices. It provides a generalised framework for in-silico methods applicable for device and drug development, helping to reduce costs and time to market, replace most invasive aspects and provide novel biomarkers for clinical trial design and patient stratification.

SIMCor (*In-silico testing and validation of Cardiovascular Implantable devices*) aims to establish a computational platform for in-silico development, validation, and regulatory approval of cardiovascular implantable devices. The platform is composed of a virtual cohort generation and validation domain and a device implantation and effect simulation domain, and is equipped with standard operating procedures, virtual cohorts, models and tools for collaborative research and development.

SimInSitu (*In-silico Development- and Clinical-Trial-Platform for Testing in-situ Tissue Engineered Heart Valves*) aims to develop a sophisticated in-silico method to predict the short- and long-term behaviour of in-situ tissue engineered heart valves by combining advanced tissue re-modelling algorithms with a personalized virtual heart modelling approach. The method aims to predict the transformation process of biodegradable heart valves from the synthetic scaffold into a fully re-modelled and functional valve.

EDITH (*Ecosystem of Digital Twins in Healthcare*) capitalises on the developments of digital technologies, high performance computing, and healthcare data in Europe, with the mission of defining a vision of the integrated **virtual human twin** and developing a roadmap to implement this vision. EDITH will build an evolutionary ecosystem driven by a consensus among the relevant European communities, and implemented through practical tools, such as a data and model repository, and a simulation platform.

inEurHeart is an innovation project in artificial intelligence, digital twin and clinical trial for a disruption in catheter ablation for ventricular tachycardia, making ablation therapy accessible to most patients.

The venue

KU Leuven, Faculty of Medicine

Onderwijs en Navorsing (ON 2) building
Herestraat 49, 3001 Leuven, Belgium

Workshop sessions: ON 2, room BMW6

Welcome lunch - coffee breaks: ON 2, entrance hall (Day1); GA0, entrance hall (Day 2)

Dinner: ALO – Alma Gasthuisberg (ALMA)



By car - Drop off: there is a kiss + ride zone next to the ON 2 building. Follow the arrows 'Parking Onderwijs en Navorsing' to access the car park. It is closed by a barrier. The code to enter and leave is 10228#.

By public transport - The campus is located 4 km from Leuven train station. Buses leave from the train station to campus about every 10 mins. Bus 3 stops right next to the ON 2 building, make sure to remain seated until you reach the very last stop called 'Leuven Gasthuisberg Campus'. Alternatively, you can take any bus that stops at the main entrance of the University Hospital and ask for directions at the welcome desk.

By bike - There is bicycle parking available for visitors across the street from our building (tunnel access). Once the bicycle is parked, you cross the street by the stairs.

Hotels

Begijnhof Hotel Leuven, Tervuursevest 70, 3000 Leuven, Belgium

Martin's Klooster, O.L.Vrouwstraat 18, 3000 Leuven, Belgium