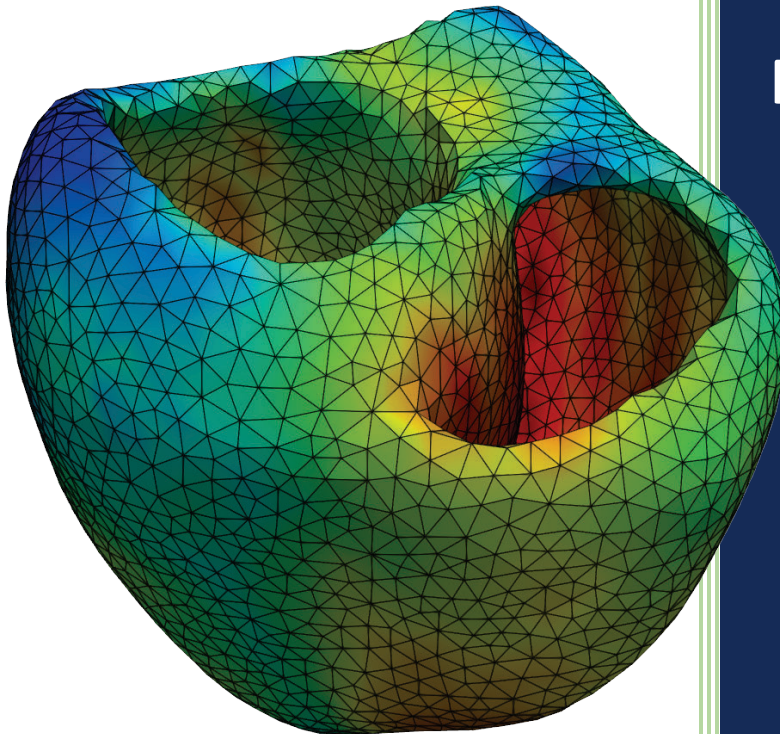


22 March 2023

INNOVAHEART

A joint European workshop on the digital heart



Bordeaux

France



SIM
CARDIO
TEST



EDITH



SIMCor



IneurHeart



Co-funded by the
European Union



SUMMARY

The European Commission ambitions to develop an integrated human digital twin in Europe, as well as to create a diverse ecosystem in modelling and simulation approaches with a coherent roadmap. Cardiovascular diseases are identified as one strategic use case of interest for clinical trials supported by digital twinning technologies.

Within this framework, a one day-workshop on the Digital Heart, initiated by the EU funded project [SimCardioTest](#), and co-organised by the EU-funded Research and Innovation Actions [SIMCor](#), [SimInSitu](#), the Coordination and Support Action [EDITH](#) and the EIT Health project [inEurHeart](#) will gather the European scientific community, start-ups, SMEs and industrial companies working on the digital heart, **on the 22nd of March in Bordeaux.**

This one-day workshop is a combination of lectures, roundtables and live demonstrations, with opportunities for knowledge exchange and discussion on state of the art, exploitation and regulatory approval perspectives, contributing to the creation of an e-health ecosystem dedicated to the heart well-being and cardiovascular diseases.

The participation to this workshop is open to all, cardiologists, regulatory bodies, engineers, scientists from academia, SMEs and industries with registration fees.

REGISTRATION

WEBSITE: [SimCardioTest](#)

LOCATION: [La Faiencerie](#), 24 Rue de la Faiencerie, 33300 Bordeaux, France

Local Organizers

Nicolas Roussel, Inria centre at Université de Bordeaux
Yves Coudière, Univ. Bordeaux/IHU Liryç/Inria
Maxime Sermesant, Inria centre at Université Côte d'Azur
Philippe Gesnouin, Programme Director - eHealth, Inria
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SCIENTIFIC ORGANISING COMMITTEE

Yves Coudière, Université de Bordeaux, France
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Jan Brüning, Charité Universitätsmedizin Berlin, Germany
Nils Götzen, 4Realsim, The Netherlands
Claudio Capelli, University College of London, UK

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Romano Setzu, Microport, France
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Anna Rizzo, Lynkeus, Italy
Michèle Barbier, Inria, France

Cover picture: @Desrues, Inria, 2022



INTRODUCTION

Cardiovascular diseases are the leading cause of death worldwide, with 15 million people living with heart failure in Europe alone¹. Among those, the prevalence of heart failure alarmingly continues to rise. While new solutions are urgently required, it is especially difficult to discover new drugs or devices. Despite significant investments in R&D, the number of new drug approvals is not increasing and development cycles for novel devices remain lengthy due to the high costs and difficulty in commercialisation. Furthermore, the regulatory requirements for approval of novel devices are ever increasing.

The power of digital technology and data exchange is known to support innovation: artificial intelligence, high-performance computing, cloud computing, along with the internet of things, all of which continue to impact our everyday lives. Our health data is no exception, as it can significantly contribute to enhance disease prevention, early diagnosis, and the development of personalised care strategies.

In-silico computational approaches can be used to predict complex clinical scenarios

The European Commission supports the use of digital technologies and health data in the digital transformation of health and care. Along this line, the Commission has funded, *inter alia*, three Horizon 2020 research and innovation actions, namely [SimCardioTest](#), [SIMCor](#), and [SimInSitu](#) to support the development and application of in-silico testing technologies in cardiology to sustain the development of new drugs and medical devices. Besides such projects, the Commission has recently funded, a new coordination and support action, namely [EDITH](#), to coordinate European efforts for the creation of digital twins in healthcare. EIT Health supported by the European Commission is also funding the project [inEurHeart](#) aiming at revolutionizing catheter ablation, a procedure performed in certain cardiac pathologies.

With these projects, methods for testing **medical devices and medicines on virtual populations are developed and made available**. Those models allow to meet the rigour of regulatory demands, so that the associated risks and flaws can be addressed before substantial investments in t in clinical trials.

Innovative ideas could emerge from large-scale simulations. For instance, **outliers within patients' cohorts or minority groups** that are not usually considered in standard clinical trials (e.g., children) can be identified. Furthermore, costs and efforts for extending the scope of existing medical devices and therapies to additional patient (sub-)groups can be reduced significantly.

THE PROGRAMME

In the recent years, new approaches to modelling and simulation have begun to provide important insights into biomedical perspectives: in-silico models are used in various clinical decision support systems and in the development and testing of medical products and devices.

The *Virtual Human Twin* (VHT) is a technological and methodological framework dedicated to the sharing of experimental observations, derivation of predictive hypotheses and their integration for a continuous improvement of our understanding of human physiology and pathology, by regarding it as a single system. VHT has been designed to enable collaborative investigations of the human body, particularly for the clinical translation of patient-specific model predictions to support clinical decision-making.

¹ Dickstein, K. et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2008. Eur Heart J 29, 2388-2442.



As defined by Pappalardo et al (2019²), in the context of in silico medicine, the term “*in-silico clinical trials*” refer to the development of patient-specific models to form virtual cohorts that enable the testing of the safety and/or efficacy of new drugs and medical devices.

This one-day workshop will focus on the added value that in-silico technologies can have in healthcare³ for several dimensions:

- Availability of reliable mechanistic knowledge, including open-source software
- Quality and quantity of cardiac-relevant data
- Credibility of predictions and result standardisation
- Health policy and regulatory frameworks.

Appropriate time and space will be dedicated to discussions for creating a cross-sector ecosystem, as well as for exchanging tips on methodological tools to generate virtual cohorts and specific challenges of regulatory bodies in Europe and the US for in-silico clinical trials or for accessing clinical data.

Will be included also the technological aspect of digital health care open source platform and software. And a live survey will also be organised to collect opinions of the community on challenges and solutions needed to further develop in-silico technologies for cardiac care.

THE PARTICIPANTS

Participation to this workshop is upon invitation; however, those who wish to attend please [contact us](#)
The workshop will gather different sectors:

Academic scientists	Cardiologists	SMEs	Companies	Intal / European organisations, National initiatives, Task forces
Confirmed participants				
Inria, IHU Liryc, INSERM, Univ. Bordeaux, VPHI, UPF, UPV, Simula, Charité, UCL, VITO	CHU Bordeaux	ExactCure, InSilicoTrials, inHeart medical Noctua care	Microport	Avicenna Alliance It’IS Foundation
Invitation of further scientists/companies from the in-silico cardiovascular ecosystem...and you!				
Engineers from institutions will have the opportunity to present digital health open source software and platforms...	IRCCS Med. Institute for Transplantation and Advanced Specialized Therapies (ISMETT), European Clinical Research Infrastructure Network (ECRIN) ...	Bitsbeat, Cardiologs, Implicity, Medrik-dynamic, Novadiscovery, Nurea...	Abbott, ANSYS, Biosense Webster, Biotronik, Boston Scientific, Dassault System, General Electric, Medtronic, Microsoft, Philips Netherlands BV, Roche, Servier, Virtonomy...	EMA, FDA, European Society of Cardiology, EIT Health, European Commission, European taskforces

Educational materials/demos will also be collected (Images, caption and videos, demos) for further scientific communication: dissemination to students and for popularizing the topic to the general public. This day includes also social media & media coverage (Inria, IHU Liryc, Univ. Bordeaux and all partners).

² F. Pappalardo, G. Russo, F. Musuamba Tshinanu, M. Viceconti (2019) In silico clinical trials: Concepts and early adoptions. Briefings in Bioinformatics 20(5): 1699-1708. <https://doi.org/10.1093/bib/bby043>

³ The role of AI within in silico medicine white paper, Published August 2022, © Avicenna Alliance and VPH Institute. [Link](#)



PROGRAMME AT A GLANCE (Draft agenda)

21 MARCH EVENING	
19h30 – Icebreaker event, Diner at Le Café Maritime , Bordeaux downtown (TBC)	
22 MARCH – La Faiencerie, Bordeaux	
9h-9h30	Official opening (TBD) Introduction of the European Commission (DG CNECT, TBC) Introduction on the digital heart (Maxime Sermesant, Inria)
9h30-10h00	Virtual cohort generation and multi-level validation for in-silico trials (Jan Brüning, Charité Universitätsmedizin Berlin or Wouter Huberts, Technical University Eindhoven)
10h10h40	IT'IS Foundation Virtual Population: a successful example of Virtual Cohort (Byrne Lloyd, IT'IS Foundation)
10h40-11h30	Coffee break with demos/booth from SMEs/partners/engineers/companies
11h30-12h00	Causal AI for in-silico trials - Irene Balelli (Inria)
12h00-12h30	Regulatory bodies, medical devices & in-silico trials (Cécile Rousseau, Avicenna Alliance)
12h30-14h00	Lunch with demos from SMEs/partners/engineers/companies
14h-14h30	Clinical evaluation of AI based Digital Medical Devices (Sarah Zohar, INSERM UMRS 1138)
14h30-15h30	Virtual cohort generator hands-on workshop (Chairman Jan Brüning, Charité Universitätsmedizin Berlin or Wouter Huberts, Technical University Eindhoven)
15h30-16h00	Coffee break with demos/booth from SMEs/partners/engineers/companies
16h-17h	16h00-17h00 Workshop on anatomical geometries for virtual cohort (Chairman Maxime, Sermesant, Inria, Guilhem Faure, Microport & Josquin Harrison, Inria (Deformetrica software))
17h-17h30	Roundtable. From technological readiness to evidence requirements: what is still needed to implement in-silico clinical trials (iSCT) in regulatory practice? (Claudio Capelli, University College London; Jan Brüning, Charité – Universitätsmedizin Berlin) <i>Brief introduction on Technology Readiness Levels (TRL) and discussion on required TRL for different in-silico approaches using exemplary use-cases.</i>
17h30-18h	live survey - Concluding remarks: scientific challenges and needs to be taken into account for the EC - future calls)
18h-21h	Cocktail reception and demos



REGISTRATION FEES

This day will be partially funded by VPHi and the EU projects SimCardioTest, SIMCor and SimInSitu, but a modest contribution from participants is requested (in particular for a dinner) to ensure the success of this day.

	Early birds before 22 February 2023 (excl. VAT)	Late birds after 22 February 2023 (excl. VAT)
Access to the Workshop* on 22 March	100 €	200 €
Access to the workshop* on 22 March plus Dinner on 21 March at night	150 €	300 €

* This includes access to the conferences, round tables, demonstrations, technical workshops plus coffee break, lunch & cocktail.

Demos from start-ups will be organised around bar-tables (mange-debout) and seats (stool). If you wish a booth, please contact us (extra fees will be applied).

Companies willing to sponsor the event are welcome. Please [contact us](#) to know the sponsorship opportunities.

A space will be dedicated to digital health open source platform and software. Please [contact us](#) if you wish to present a software.



EUROPEAN PROJECTS PRESENTATION

SimCardioTest aims to design new predictive tools in cardiac pathologies and aims to accelerate the uptake of computer simulations for testing medicines and medical devices. **One objective is to provide a framework and wide approach of in-silico methods** (Computer modelling and simulation) where generic and standardized elements can be used for other applications. **The second one aims to demonstrate that such approach can help develop devices and drugs** as well as reduce the cost and time to market and to **gain the trust of scientists, companies, regulatory bodies, physicians, patients**. **The final objective is to impact the whole clinical trials**, since this approach can replace some invasive aspects of these trials, and maybe provide novel biomarkers for more accurate clinical trials.

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, composed of **(1) a virtual cohort generation and validation domain, (2) a device implantation and effect simulation domain**, and equipped with a **variety of in-silico modelling resources**, will represent **an open environment for collaborative R&D among device manufacturers, researchers, medical authorities, and regulatory bodies**.

SimInSitu is aiming to develop a sophisticated in-silico method to predict the short- and long-term behavior of in-situ tissue engineered heart valves (TEHV) by combing advanced tissue re-modeling algorithms with a personalized virtual heart modelling approach. The method will be specifically developed to predict the complex transformation process of biodegradable heart valves from the initially synthetic scaffold into a fully re-modeled & functional valve.

EDITH CSA aims to foster an inclusive ecosystem for Digital Twins in healthcare in Europe and to prompt the convergence of such an ecosystem towards a common strategy conducive to its further development. This will be achieved by mapping and analyzing the status of the fields which are crucial for the growth, uptake and use of digital twins in healthcare, including in silico medicine, health data, HPC, etc.

inEurHeart is an innovation project in Artificial Intelligence, Digital Twin & Clinical Trial for a Disruption in Catheter Ablation for Ventricular Tachycardia, making ablation therapy accessible to most patients. inEurHeart is funded by EIT Health supported by the European Commission.





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for a future where personalised cardiac care and healthcare innovations accelerate thanks to in-silicotrials & computational cardiology.

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Deadline for registration: 22 February 2023
bit.ly/innovaheart



