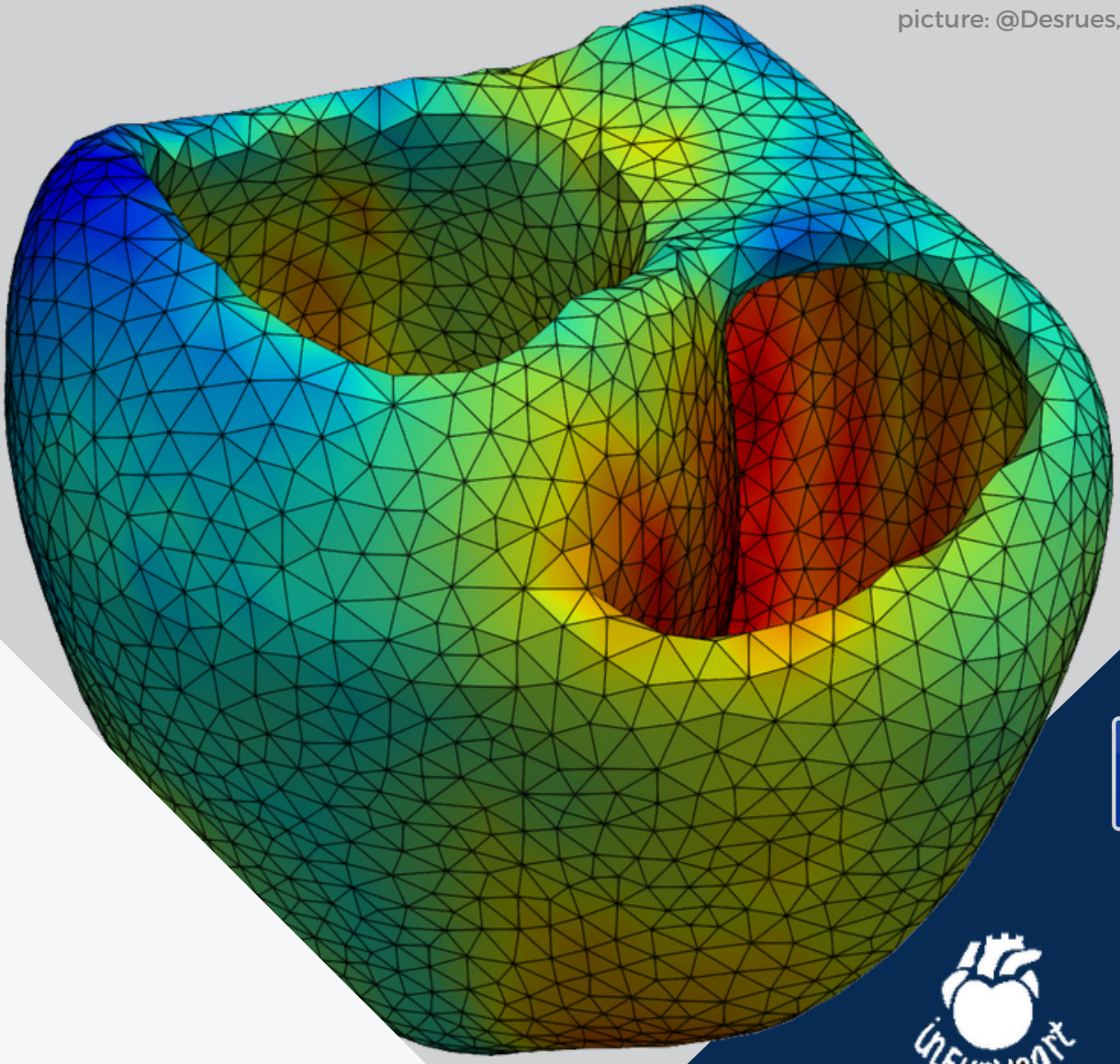

picture: @Desrues, Inria, 2022

MARCH · 22 · 2023

INNOVAHEART

A JOINT EUROPEAN WORKSHOP ON THE DIGITAL HEART

La Faïencerie

BORDEAUX - FRANCE

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 Faïencerie, 33300 Bordeaux, France

ICEBREAKER EVENT (Dinner): Le Café Maritime, 1 Quai Armand Lalande, 33300 Bordeaux - (arrival between 19h-19h30 ; dinner at 20h00)

Local Organizers

Nicolas Roussel, Inria centre at Université de Bordeaux
Yves Coudière, Univ. Bordeaux/IHU Liryc/Inria
Maxime Sermesant, Inria centre at Université Côte d'Azur
Philippe Gesnouin, Programme Director - eHealth, Inria
Michèle Barbier, Inria, European Project Coordinator

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SCIENTIFIC ORGANISING COMMITTEE

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Maxime Sermesant, Inria, France
Jan Brüning, Charité Universitätsmedizin Berlin, Germany
Nils Götzen, 4Realsim, The Netherlands
Claudio Capelli, University College of London, UK
Liesbet Geris, VPHi, international
Romano Setzu, Microport, France
Alessia Baretta, Insilicotrials, Italy
Anna Rizzo, Lynkeus, Italy
Michèle Barbier, Inria, France

INTRODUCTION

Cardiovascular diseases are the leading cause of death worldwide, with 15 million people living with heart failure in Europe alone[1]. 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.

[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.

THE PROGRAM

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.

As defined by Pappalardo et al (2019[1]), 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 healthcare[2] 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.

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[1] 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

THE PARTICIPANTS

The workshop will gather different sectors:

- **European Commission:** DG CNECT.H.3 – eHealth, Well-Being and Ageing
- **EITHealth France**
- **Academia:** Amsterdam UMC, Bordeaux University, Delft University of Technology, Deutsches Herzzentrum der Charité, Erasmus Universiteit Rotterdam, Grenoble Institut de Neurosciences, I3S-Université Côte d'Azur-CNRS, Institut du Cerveau (ICM), INSA Centre Val de Loire, IHU ICAN, IHU Liryc, INSERM, Inria, KU Leuven, Mines Saint-Etienne, Politecnico di Milano*, Simula Research Laboratory, Technical University Eindhoven, University Aix Marseille, University of Bologna, University College of London, University of Liège, Universitat Pompeu Fabra, Universitat Politècnica de València
- **Hospitals:** Bordeaux Hospital University, Charité Universitätsmedizin Berlin
- **Startups and demos*:** Bits2beat, CARANX MEDICAL, DESKi*, ELEM Biotech SL, ExactCure*, inHeart medical*, InSilicoTrials*, Noctua care*, Nurea*, PrediSurge*
- **Industries:** BIOTRONIK SE&Co.KG, Cortronik GmbH, Dassault System, Microport, RDS*, Siemens Healthineers, SimforHealth
- **SMEs:** Ansys, Lynkeus, 4RealSim Services BV, VOISIN CONSULTING LIFE SCIENCES
- **Non-profit organisations:** Avicenna Alliance, ECRIN, Fondation Inria, IT'IS Foundation, Virtual Physiological Human Institute
- **Hospitals:** Bordeaux Hospital University, Charité Universitätsmedizin Berlin
- **Regional organisations:** Aquitaine Science Transfert, Region Nouvelle Aquitaine

A **DEV Corner** will also show open source software developped at Inria : Fed-BioMed, medInria, primetimeIRE, Shanoir, Sofa, Clinica & Openvibe

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). **#Hinnovaheart2023!**

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

EVENT PROGRAM

MARCH · 22 · 2023

21 MARCH EVENING

19h00 – No later than 19h30 - Icebreaker event - Dinner at 20h, Le Café Maritime, Bordeaux

22 MARCH

9h - 9h30 - Welcome & Opening
Françoise Jeanson, Région Nouvelle Aquitaine
Kyriacos Hatzaras, European Commission - DG CNECT
Alexis Pacquit, EIT Health
Maxime Sermesant & Michèle Barbier, Inria

9h30 - 10h - Virtual cohort generation and multi-level validation for in-silico trials - Wouter Huberts, Technical University Eindhoven

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10h - 10h30 - IT'IS Foundation Virtual Population: a successful example of Virtual Cohort - Bryn Lloyd, IT'IS Foundation

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10h30 - 11h - Coffee Break

11h - 12h - Virtual cohorts : practical use-cases and tools
Chairmen Jan Brüning, Charité Universitäts-medizin Berlin and Maxime Sermesant, Inria with Guilhem Fauré, Microport, Gaëtan Desrues & Josquin Harrison, Inria and Wouter Huberts, Technical University Eindhoven

12h - 14h - Lunch with demos from companies and academics

14h - 14h30 - Clinical databases, AI & Evaluation
Introduction - Pierre Jaïs, IHU Liryc
Clinical evaluation of AI-based Digital Medical Devices - Sarah Zohar, INSERM

14h30 - 15h -Causal AI for in-silico trials - Irene Balelli, Inria

15h - 15h30 - ASME V&V40 Working Group #3 - Patient-Specific Modelling - Tiered Validation Approach, Nils Götzen, 4RealSim Services BV

15h30 - 16h - Coffee break with demos from companies and academics

16h - 16h30 - Regulatory bodies, medical devices & in-silico trials - Cécile Rousseau, VCLS/Avicenna Alliance

16h30 - 17h30 - Roundtable. From technological readiness to evidence requirements: what is still needed to implement in-silico clinical trials (iSCT) in regulatory practice?
Chairman: Claudio Capelli, University College London; Jan Brüning, Charité – Universitätsmedizin Berlin
Speakers: Dassault System (TBC), Jérôme Fabiano (EIT Health), Raphaelle Lesage (VPHi), Cécile Rousseau (VCLS/Avicenna Alliance), EMA (TBC), FDA (TBC)

17h30 - 17h45 - Concluding remarks - Maxime Sermesant & Michèle Barbier, Inria

18h - 21h - Cocktaïl

SCIENTIFIC PROGRAM

Participants will have the opportunity to hear from experts who are using virtual cohorts and in-silico trials to address some of the biggest challenges in the healthcare industry. Whether you're a researcher, clinician, or a healthcare professional, this workshop is an excellent opportunity to stay up-to-date on the latest developments in virtual cohorts and in-silico trials and their impact on improving patient outcomes. Don't miss out on this opportunity to network with peers and gain valuable insights into this exciting field

09:30 - 10:00: Virtual cohort generation and multi-level validation for in-silico trials

Speaker: Wouter Huberts, Technical University Eindhoven

Virtual cohorts are an essential pre-requisite for in-silico trials, as they allow to investigate large populations that could otherwise only be achieved with severe personnel and financial efforts or not at all. Furthermore, virtual cohorts are an ideal approach for providing standardised cohorts, as they are not affected by data privacy regulations and can therefore be shared freely between research, industries and regulatory authorities. For virtual cohorts to be accepted as substitutes for real patient-cohorts, they have to match real patients as closely as possible.

In this session, a general approach for the generation of virtual cohorts for in-silico assessment of implantable cardiovascular devices is presented. Relevant aspects such as uncertainty quantification and sensitivity analysis, but also different filtering strategies allowing to tailor the generated virtual cohorts to a given context of use are discussed. Finally, a three-level validation strategy is presented that can be used to ensure that the virtual cohorts are meeting the specific demands for their subsequent use in in-silico trials.

10:00 - 10:30: IT'IS Foundation Virtual Population: a Virtual Cohort success story

Speaker: Bryn Lloyd, IT'IS Foundation

The Virtual Population (ViP) models are a set of detailed high-resolution anatomical models created from magnetic resonance image (MRI) data of volunteers.

The ViP project first started in 2005 when the mobile phone industry launched the development of the Virtual Family, a joint project between the IT'IS Foundation and the US Food and Drug Administration (FDA). Additional models were gradually generated to broaden the population coverage.

ViP V3.x models, available since mid-2015, elevated computational simulations in 3D anatomies to an unprecedented level of detail and accuracy, with more than 300 tissues and organs per model, a resolution of 0.5 mm^3 throughout the entire body, and specific physical, physiological, and biological properties for all segmented tissues.

Model quality and consistency is based on stringent quality assurance guidelines, quality control procedures performed by team members. Quality guidelines were developed to ensure that differences between models are due to real interpersonal differences and not segmentation errors. All ViP3.x models come with an anatomical verification report issued by a professional anatomist.

IT'IS also maintains an online Database of Tissue Properties, in order to provide the computational life science community with values for electro-magnetic (EM), thermal, fluid, acoustic and MR properties of biological tissues.
The database collects the most up-to-date and comprehensive estimates for tissue material parameter values available in literature, including statistical information about the spread and standard deviation per tissue.

Since their inception, the ViP models have become the gold standard for in silico biophysical modeling for applications ranging from EM to thermal, fluid, and acoustic. A recent example is the area of implant safety during MRI examination: using simulations of EM field distributions inside the ViP models, induced by MRI radio-frequency (RF) coils, active implant manufacturers have been able to qualify their products as MRI-compatible. The IT'IS Foundation has pre-computed two large libraries of RF-induced EM fields inside the human body, resulting from a representative set of RF birdcage coils for 1.5T and 3T MRI scanners. In 2019, that library and its associated software tool, MRIxViP & IMAnalytics, together became the first Medical Device Development Tool (MDDT) to be qualified by the US FDA for assessment of implant RF compatibility with MR examinations.
IT'IS continues to extend the ViP and their application, and has been pushing towards developing state-of-the art computational techniques for invasive and non-invasive EM-induced neuro-modulation modelling.

11:00 - 12:00: Virtual cohort workshop practical use-cases and tools

This workshop brings together speakers from industry and academia that share their expertise in the field of virtual twins and cohorts and showcase their latest developments. Through several talks and demonstrations, attendees will gain insight on different applications of virtual cohorts and how those technologies might impact and transform clinical research. These technologies offer the opportunity to study large populations in a simulated environment, allowing for faster and more cost-effective research. Thus, they provide a safe and efficient way to test new treatments and evaluate their safety and efficacy before moving to expensive and time-consuming in-vivo trials.

The talks will cover different aspects of both technologies, ranging from the methodological approaches for generation of virtual anatomies, which are a common requirement for many in-silico models, the validation of virtual cohorts, as well as show-casing exemplary application in in-silico clinical trials for device evaluation.

Final list of topics and speakers and talks:

1. Gaëtan Desrues, Inria: Generation of virtual cohorts for patient-specific electromechanical cardiac simulations
2. Guilhem Fauré, Microport: Towards Patient Anatomy Personalisation for Heart Digital Twin.
3. Josquin Harrison, Inria: Atrial Shape Analysis for Patient Stratification and Virtual Cohort Generation.
4. Wouter Huberts, Eindhoven University of Technology: A clinically driven filtering approach for generation of virtual cohorts of aortic stenosis patients

14:00 - 14:30: Clinical databases, AI and evaluation

Speaker: Sarah Zohar, INSERM

Health-related interventions and their evaluation have been revolutionised by advances in biotechnology and digitization and expectations are high. To support the acceleration of drug development and other medical interventions through the use of artificial intelligence (AI) and data from a variety of sources, there is a need for a clear understanding of the appropriateness of this use and for robust trial evaluation methods. The need to adapt the methods used and to propose robust innovative approaches to clinical trials is increasingly critical, and for example, the proliferation of new digital medical devices using AI alone requires specific methods to evaluate their ultimate impact on health. In this presentation the PEPR Digital Health "SMATCH" project will be presented as well as the scientific challenges associated with the clinical evaluation of Digital Medical Devices. In addition, links with the regulatory requirements and initiatives will be presented.

14:30 - 15:00: Causal AI for in-silico trials

Speaker: Irene Balelli, Inria

Digital health's current evolution heavily relies on the massive development and deployment of data-driven machine learning and deep learning methods, which has already shown impressive results in several clinical applications, ranging from oncology, cardiology, genetics, and many more. Nevertheless, in order to ensure reliability, robustness and generalizability of such models, their parameters need to be learned from a sufficiently large curated dataset, representative of the whole data distribution. In addition, pure data-driven methods may fail in inferring the causal structure underlined by the training data, especially in an observational context, which makes it impossible to control the variables of interest. To address these issues and try to improve the interpretability and trustworthiness of algorithmic prescriptions in the medical domain, I will discuss about causal data analysis and in-silico trials, and focus on the need of further exploring the “how?”, “why?” and “what-if?” questions.

15:00 - 15:30: ASME V&V40 Subcommittee - Working Group #3 - Patient-Specific Modeling

Speaker: Nils Götzen, 4RealSim Services BV

The ASME V&V40 subcommittee harbours several working groups that meet regularly to progress in several fields ranging from “Using historical clinical data as comparator”, via “End-to-End Example”, to “Patient-Specific-Models''. The workshop presentation will report about the activities within the working groups, especially about WG3, which has sub-teams focussing COU and Risk Assessment / Tiered-Validation-Approach / Clinical Validation.

The objective of WG3 is: Demonstrate the application of ASME V&V40 standard and IMDRF (International Medical Device Regulators Forum) guidance documents for a patient-specific computational model used as, or embedded within, a Software as a Medical Device (SaMD); Identify and discuss the challenges of applying the above documents to a patient-specific computational model considered as a SaMD; Assess the level of computational model credibility commensurate with the model risk for a specific context of use (i.e. when a clinician uses the predictive power of the model in their practice to help make clinical decisions, such as a patient's treatment plan).

16:00 - 16:30: Regulatory bodies, medical devices, and in-silico trials

Dr. Cécile F. Rousseau, PhD, Voisin Consulting Life Sciences (VCLS)

Medical device development has been customarily relying on prototypes, in vitro / ex vivo testing (a.k.a bench testing), and in vivo (animal) testing prior conducting clinical trials to demonstrate safety and performance of the device. Such conventional approach still faces the immense cost to bring these devices to market, that can exceed $100 million, and can also take over 10 years. At the same time, many of these medical device developers failed in the process, and only less than 20% make it to regulatory approval. With the new EU and US regulations, regulatory requirements increased. The rise of in silico methods and, in particular of in silico trials, will therefore change the development process by optimizing and derisking preclinical & clinical development while generating scientific data that will be part of the evidence supporting the regulatory approval.

16:30 - 17:30: Round-Table: From technological readiness to evidence requirements: what is still needed to implement in-silico clinical trials in regulatory practice

Chairmen: Claudio Capelli, University College London & Jan Brüning, Charité – Universitätsmedizin Berlin

Speakers: Dassault System (TBC), Jérôme Fabiano (EIT Health), Raphaelle Lesage (VPHi), Cécile Rousseau (VCLS/Avicenna Alliance), EMA (TBC), FDA (TBC)

Establishing an iSCT requires compliance with ethical, scientific, and regulatory quality standards, which are also mandatory in traditional clinical trials. However, iSCT also presents unique challenges, such as validating virtual patients, addressing procedural variability, and bridging in-silico results to real-world outcomes.

So, where are we currently in this ongoing journey to implement iSCT in regulatory practice? How do we assess iSCT technologies? Which evidence do we need to trust both the process and the results of it?

The purpose of this roundtable is to bring together stakeholders to discuss and progress the integration of iSCT into regulatory practice and to assess the technology. The discussion will focus on identifying the necessary evidence to establish trust in both the process and results of iSCT.

DEMOS

lifex-heart: an open tool for the simulation of the cardiac function

Company / Presenter: MOX, Department of Mathematics, Politecnico di Milano, Italy / Roberto Piersanti

In this demo we present lifex-heart, an innovative tool for the simulation of the cardiac function. In particular, we focus on three modules: lifex-fiber, for the myocardial fiber generation; lifex-EP, for simulating the electrophysiological muscular activity of the heart; lifex-CFD, for the simulation of the blood fluid dynamics inside the cardiac chambers. lifex-fiber, lifex-EP and lifex-CFD are publicly released modules for cardiac simulations based on lifex, an open-source, high-performance Finite Element solver for multi-physics, multi-scale and multi-domain problems. lifex is developed in the framework of the iHEART project, and it aims at making in silico experiments easily reproducible and accessible to a wide community of users, including those with a background in medicine or bio-engineering.

Noctua Care - Your companion for holistic health

Company / Presenter: Noctua Care / Hugo WEIDMANN, Alexander DMOCH

Noctua Care is a digital companion providing paramedical support for patients and caregivers after myocardial infarction. We are supporting individuals throughout all phases of cardiac care following a multidisciplinary care approach. Noctua Care strives to provide lifestyle management tools and programs based on self-guided education, self-management, as well as community and interaction modules.

HeartFocus

Company / Presenter: DESKi / Olivier Moal

DESKi team has developed HeartFocus, a software allowing any Healthcare professional to perform any cardiac. AI algorithms and intuitive UI indicate how to move the ultrasound probe in 3D in order to obtain cardiac quality images. DESKi will demonstrate live usage of HeartFocus and explain how 3D simulated images could be used to train such algorithms.

High-Fidelity ambulatory cardiovascular patient's monitoring

Company / Presenter: RDS SAS, Louis Mayaud

MultiSense® is a wearable device that can monitor heart rate, breathing rate, SpO2, temperature, activity, and posture in ambulatory patients every second for a full week. The device weighs 30g and is compatible with patients' lifestyle (shower, activity, …). It therefore allows the remote monitoring of patients and serves data to a web dashboard that clinicians can use to review their patients. The full resolution data (256Hz ECG, …) is uploaded to a data lake for future advanced analysis when used in the context of a clinical trial.

The first integrated cloud-based platform for in silico trials

Company / Presenter: InSilicoTrials - Alessia Baretta

InSilicoTrials is an emerging startup founded by a team of life science, cybersecurity and digital innovation experts, which aims to revolutionise Healthcare through an innovative digital simulation platform, where complex computational simulations run in an easy and cost-effective way to hyper-accelerate drug & medical device development.
We offer Pharma and MedTech companies a cloud platform combining state-of-the-art AI, simulation tools and patient data that can highly reduce the cost and time of drugs & medical device development. InSilicoTrials built up an ecosystem of more than 70 scientific collaborations, where computational models are developed with internationally recognized universities and research centres, offering access to the highest level of data security.
The demo will focus on the three solutions developed within the SimCardioTest project, as well as a computational tool for the in silico standard testing of self-expandable valves.

inHEART, a digital twin of the patient's heart

Company / Presenter: inHEART - Jean-Marc Peyrat / Luis Kabongo

inHEART's web-based, cloud-based, AI-based SaaS leverages medical images and electrocardiograms to deliver a digital twin of the patient's heart, allowing physicians to individualize and optimize each patient's treatment strategy and ablate with greater efficiency and efficacy. The company has gathered clinical data, received a CE mark and 510(k) clearance, and is rapidly growing its user base in Europe, the US, and Australia. In addition, inHEART uses its vast amount of annotated clinical data to develop powerful predictive AI to assess the risk of sudden cardiac death, stroke, heart attack, and heart failure in large patient populations.

Patient pharmacological Digital Twin

Company / Presenter: ExactCure / Sylvain Benito.

ExactCure develops a medical device for helping patients in better taking their drugs. It is based on the concept of patient pharmacological Digital Twin which consists in a mathematical model that 1/ can be personalised from patients characteristics and 2/ can predict pharmacological endpoints informing about patient response.
Through this demo we will show how our product works presenting a dedicated use case.

PlanOp Structural Heart - Cardiovascular digital

Company / Presenter: PrediSurge / Raphael Doustaly & David Perrin

PrediSurge has been developing cardiovascular digital twin solutions for physicians and MedTech for the last 6 years. After a first focus in the aortic space, where PlanOp Vascular has been already used for the planning of more than 400 interventions, PrediSurge is now extending its patient-specific digital twins skills towards the Heart and in particular towards the mitral valve.

Nurea - Cardiovascular diseases quantifications

Company / Presenter: Nurea / Donatien Le Liepvre & Florian Bernard

Nurea is a software company that offers a unique suite of tools specifically designed for vessels analysis. Our software provides fully automated extraction of geometrical measurements from CT scans, which helps surgeons make informed decisions prior and after procedures. With more than a dozen university hospitals already installed across the world, we are now moving to the more specific cardiac segment to initiate the research of new predictive criteria to improve patient outcomes and optimize surgical practices.

Patient-specific cardiac simulations

Company / Presenter: INRIA - Microport CRM

Three demos are presented at this stand:

- Use of shape models for the generation of patient-specific cardiac models - Gaëtan Desrues
- Guilhem Fauré - In this demo, some numerical tools will be presented to personalise/deform human body surface meshes and generate patient-specific torso geometries for cardiac simulations.
- Atrial Shape Analysis for Patient Stratification and Virtual Cohort Generation - Josquin Harrison.

DEV CORNER

SOFA

Company / Presenter: SOFA Framework, Hugo Talbot, Inria

SOFA is an open-source framework for interactive physics simulation, with an emphasis on soft body dynamics. Further to 17 years of research and development, the framework is made up of a stable core providing state-of-the-art models and numerical methods. Its LGPL v2.1 open-source license (permissive and non-contaminating) and its plugin architecture foster the development of prototypes and products under any commercial license. Today, SOFA benefits from a large international community made up of research centers and companies.
Engineering simulation software has become invaluable within many industries. The role of simulation in all medical curricula to safely learn and rehearse surgical procedures significantly increased in the last decade. Research centers and companies rely on SOFA to build realistic simulations for surgical training and planning. For device manufacturing, SOFA can be a strategic approach to reduce the duration of the design process and its costs, by predicting the interaction between the product and its physical environment.

Fed-BioMed: a federated learning framework for healthcare

Company / Presenter: Fed-BioMed team - Sergen Cansiz // Marc Vesin, Inria

Fed-BioMed is an open source framework for translating federated learning into real-world medical applications. The community of Fed-BioMed gathers experts in medical engineering, machine learning, communication and security. We all contribute to provide an open, user-friendly, and trusted framework for deploying the state-of-the-art of federated learning in sensitive environments, such as in hospitals and health data lakes.
Federated learning enables hospitals to jointly train an aggregated machine learning model, while addressing data privacy and security issues: data never leaves the hospitals and only model parameters are shared.
This demo uses Fed-BioMed to train a 3D U-Net model for the segmentation of 3D medical MRI images of brains, using the publicly available IXI dataset from 3 separate centers.

OpenViBE

Company / Presenter: Thomas Prampart, Inria

OpenViBE is a free open-source software for neurosciences and real-time brain data processing allowing to create Brain-Computer-Interfaces (BCI) and Neurofeedback applications.
Its graphical and non-programming interface makes it a great tool in many projects across various topics: research, disability, health, entertainment, robotics, sports, neurosciences, etc.
OpenViBE is compatible with 30+ EEG equipment and contains nearly 90 functional boxes resulting from research work. Common devices that can be integrated into OpenViBE pipelines, alongside EEG data are Galvanic Skin Response and also Heart Rate signals.

Shanoir

Company / Presenter: Michael Kain, Inria

Shanoir is a web application developed to import, share, archive, search and visualise all kind of medical imaging data (BIDS, MR, CT, PT, EEG, Bruker).
The principal usage is destined for multi-centric studies that want to easily collect and share datasets among multiple centers in France or internationally. The data can be visualised, and re-downloaded in multiple formats (principaly nifti or dicom).
Shanoir proposes configurable quality control over dicom metadata and dicom content during import or at the end of the import phase.
Shanoir proposes a conversion from its data to a BIDS format for a study. This format can be configured by the user.
Shanoir Uploader is a little software that allows to send dicoms from a clinical PACS directly to Shanoir. This can be done patient by patient or using batches.

MedInria

Company / Presenter: Florent Leray, Inria

Clinica

Company / Presenter: Mauricio Diaz // Ghislain Vaillant, Inria

Clinica is a free open-source software for clinical research studies involving patients with neurological and psychiatric diseases and the acquisition of multimodal data (neuroimaging, clinical and cognitive evaluations, genetics, etc.), most often with longitudinal follow-up.
This demonstration will show how Clinica can be used to make the link between a database in a clinical environment (XNAT) and the tools used in medical imaging, without losing the structure and organisation of the original data.

SPONSORS

The organisation of this day is supported by VPHi, the EITHealth project inEurHeart and the EU projects SimCardioTest, SIMCor and SimInSitu, Institut de Mathématiques de Bordeaux UMR 5251, Bordeaux University and Inria centre de l'université de Bordeaux.

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 isto 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.

Inria is the French national research institute for digital science and technology. World-class research, technological innovation and entrepreneurial risk are its DNA. In 215 project teams, most of which are shared with major research universities, more than 3,900 researchers and engineers explore new paths, often in an interdisciplinary manner and in collaboration with industrial partners to meet ambitious challenges. As a technological institute, Inria supports the diversity of innovation pathways, from open source software publishing to the creation of Deeptech startups.

The Inria centre at the University of Bordeaux has 19 joint project-teams with the university, Bordeaux INP, CNRS, Inserm, INRAE, Naval Group, Airbus Central R&T and Cerfacs. Two joint project-teams with the University of Pau and the Pays de l'Adour, CNRS and TotalEnergies are also attached to this centre.

The Inria centre at Université Côte d'Azur has developed along with Université Côte d'Azur on the Sophia Antipolis and Nice sites. It has 35-project teams at Sophia Antipolis, Nice,and Montpellier, half of which are joint-teams.

The Institut de Mathématiques de Bordeaux (IMB) is a joint research unit (UMR 5251) CNRS - Université de Bordeaux - Bordeaux INP. The IMB is the host laboratory of l'Ecole Doctorale de Mathématiques et Informatique, brings together most of the mathematical research on the Bordeaux site. It brings together the scientific activities of numerous researchers, teacher-researchers, doctoral students and post-doctoral fellows, who are hosted by 7 teams.

The VPHi is an international non-profit organisation incorporated in Belgium, whose mission is to ensure that the Virtual Physiological Human is fully realised, universally adopted, and effectively used both in research and clinic.

Liryc, the institute for heart rhythm disorders, is one of the first six university hospital institutes created in France in 2011 as part of the “National Investment Programme”, with the aim of boosting medical research and innovation. University hospital institutes were the pioneers of an original method of innovation, combining basic and clinical research, training and promotion in specific health fields. The ambition of the programme is to invent the health of tomorrow and to distribute biomedical innovations more quickly to patients and the economy.

With the support of the Region Nouvelle Aquitaine

Simula Research Laboratory is an internationally-leading Norwegian research institute in the key ICT areas of communication systems, scientific computing and software engineering, based in Oslo, Norway.