PRESS RELEASE n.1/2021
15/01/2021 (for immediate release)

Horizon 2020 Research and Innovation Action kick-off: SIMCor (*In-Silico testing and validation of Cardiovascular IMplantable devices*)

Berlin, 15 January 2021

Today, 15 January 2021, the Charité – Universitätsmedizin Berlin has concluded the kick-off e-meeting of the new EU-funded research project SIMCor (*In-Silico testing and validation of Cardiovascular IMplantable devices*). The project will create an in-silico platform and simulation tools for the development, validation and regulatory approval of cardiovascular devices, providing tangible value to patients and clinicians, device manufacturers, clinical researchers, medical authorities and regulatory bodies.

Cardiovascular implantable medical devices are among the most life-sustaining treatments in cardiology. According to the Regulatory Affairs Professionals Society, verification and validation are amongst the most critical activities in the medical development lifecycle. Inadequate validation is one of the most common issues leading to clinical complications, warnings from the US Food and Drug Administration and subsequent device recalls which cost companies tens of millions of dollars.
In-silico methodologies for medical device testing and validation and the use of virtual cohorts of animal and human patients represent a clear opportunity for enhancing the quality of medical devices released into the market, increasing their efficacy and safety, meanwhile reducing costs and time-to-market, minimising the need for live testing on animal and human subjects.
However, the complexity and speed of technological innovation strongly demands the establishment of agreed protocols, standards and shared resources between device manufacturers, authorities and regulatory bodies, allowing for a standardised, reliable and integrated use of in-silico methodologies into the entire product cycle of medical device development, validation and regulatory approval.

To address this challenge, SIMCor aims to establish a computational platform for in-silico models development and validation as an open resource for collaborative R&D among cardiovascular device manufacturers, researchers, medical authorities.
SIMCor will specifically focus on two clinically and economically relevant cardiovascular procedures and devices: *transcatheter aortic valve implantation* (TAVI) and *pulmonary artery pressure sensors* (PAPS), having taken into account their large socio-economic impact, the wide range of pathophysiologic conditions and biomechanical parameters involved. SIMCor will also extrapolate best practices for in-silico trials that, through a strict collaboration with regulatory authorities, clinicians and the industry will be translated into *standard operating procedures* (SOPs) for the entire cardiovascular device manufacturing and clinical communities.

SIMCor will define a methodology for the generation of *virtual cohorts* for in-silico tests to lower the burden of preclinical test in animals, as well as of clinical I-III stage human trials. The virtual cohort technology will allow exposing new devices to a variety of geometries, pathophysiologic conditions and clinical parameters relevant to both adults and children, to meet the critical need of making new devices usable in young patients.

SIMCor will also elaborate a standardized framework for the virtual implantation of TAVI- and PAPS-devices on bench test environments, animal and patient cohorts, and then generalise the approach for other cardiovascular devices and clinical use cases.
The consortium will also develop device-specific models to predict device performance in terms of safety, efficacy and usability endpoints, utilising simulations of generic and individualised geometries assessing variability, uncertainty and sensitivity against anatomical and pathologic variations beyond current ISO norms.

SIMCor will assess and quantify the impact of virtual cohorts and computer simulations in “real world”. SIMCor will evaluate benefits on clinical research workflows, industrial development and business dimensions

at large, as well as on societal benefits. Expected value include increased treatment efficacy and patient safety through reduction of device failures and adverse events; more personalized clinical indications and implant strategies; reduced use of animal and human subjects; lower costs and time-to-market for medical device validation and regulatory approval; reduced costs and wider accessibility of device-based treatments; boosting innovation and creation of economic added value.

SIMCor will actively disseminate its results to the medical device industry, researchers, investors, authorities and regulatory bodies, healthcare professionals and patients. The Project Coordinator, Titus Kühne, commented *"We firmly believe that SIMCor will accelerate the adoption of in-silico technologies in the development, validation and approval of new and better cardiovascular devices through the use of computer simulations and virtual trials methodologies."*

SIMCor is a 3-year (1 January 2021 - 31 December 2023), 7.2 M€ Research and Innovation Action (RIA) funded under the topic SC1-DTH-06-2020 (*Accelerating the uptake of computer simulations for testing medicines and medical devices*) of the call H2020-SC1-DTH-2018-2020 (*Digital transformation in Health and Care*), in the Health, Demographic Change and Wellbeing area of the Horizon 2020 Framework Programme.

Consortium structure and participants
The Consortium consists of 12 partners from 8 countries, including clinical centres, academia, industry and small and medium-sized enterprises (SMEs):
Charité – Universitätsmedizin Berlin, Germany (*Coordinator*)
Lynkeus (LYN), Italy
Biotronik (BIO), Germany
European Clinical Research Infrastructure Network (ECRIN), France
Institut für Höhere Studien – Institute for Advanced Studies (IHS), Austria
Institut für ImplantatTechnologie und Biomaterialien e.V. (IIB), Germany
Philips Electronics Netherlands B.V. (PHI), Netherlands
Eindhoven University of Technology (TUE), Netherlands
Technical University Graz (TUG), Austria
Universitatea Transilvania Din Braşov (UTBV), Romania
University College of London (UCL), United Kingdom
Virtual Physiological Human Institute for Integrative Biomedical Research VZW (VPH), Belgium

Contact

Project Coordinator:
Prof. Dr. med. Titus Kühne
Deutsches Herzzentrum Berlin and Charité – Universitätsmedizin Berlin
Augustenburger Platz 1, 13353 Berlin
Email: titus.kuehne@dhzb.de
Phone: +49 30450553881

About the coordinating institution: Charité – Universitätsmedizin Berlin

Charité – Universitätsmedizin Berlin is one of the largest university hospitals in Europe. All its clinical care, research and teaching is delivered by physicians and researchers of the highest standards, and it is internationally renowned for its excellence in teaching and training. Charité extends over four campuses, and has close to 100 different Departments and Institutes, which make up a total of 17 different centres. Innovative capacity and responsible governance, for the benefit of patients and society, are the central tenets behind all of Charité research endeavours. At Charité, approximately 3,700 researchers are actively engaged in the development of pioneering innovations in the field of medicine. Committed to the highest standards of quality and sustainability, they work across 1,000 projects, working groups and collaborative projects.
The responsible Institute for Imaging Science and Computational Modelling in Cardiovascular Medicine (ICM) is the innovation driver in the field of digital transformation in cardiac medicine in Berlin. The institute combines modern imaging methods with data science methods (e.g., AI, visual analysis) and biophysical modelling (e.g., haemodynamics, metabolism) to develop methods for diagnostics, therapy planning and decision support systems. The work is therefore always in a direct clinical context (bench-to-bedside) and unites interdisciplinary teams of physicians, mathematicians, computer scientists, physicists and engineers.