SIMCor

In-Silico testing and validation of Cardiovascular IMplantable devices

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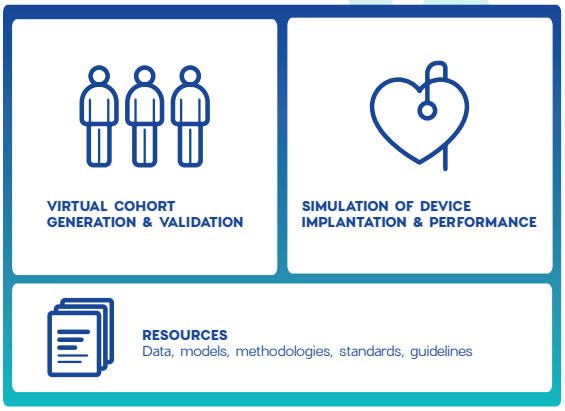
Why SIMCor?

Verification and validation represent critical activities in the development lifecycle of implantable medical devices, due to the need to meet increasing **clinical safety and performance standards** set by constantly evolving regulations.
In-silico methodologies, such as computer-based simulation and virtual patient cohorts, represent a promising opportunity for **enhancing safety, efficacy, time and cost effectiveness of medical devices**, but agreed standards and protocols are still needed for their full integration into the product cycle.

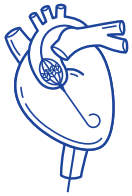
SIMCor aims to establish **a computational platform for in-silico development, validation and regulatory approval of cardiovascular implantable devices**, as a collaborative environment among device manufacturers, researchers, medical authorities and regulatory bodies.
The platform is composed of **(1) a virtual cohort generation and validation domain** and **(2) a device implantation and effect simulation domain**, and is equipped with **a variety of in-silico modelling resources**, including synthetic data, models and standard operating procedures.



Strategic objectives

- **Provide proof-of-validation for virtual cohorts and computer-based simulation of cardiovascular device implantation and performance**
- **Develop standards and protocols for in-silico testing and validation of cardiovascular devices**
- **Quantify the benefits of in-silico testing for healthcare, industry and society as a whole**
- **Accelerate the integration of in-silico testing into the medical device regulatory approval process, the market and the clinics**
- **Contribute to the European Open Science Cloud with data, virtual cohorts, simulation models, methodologies, standards and guidelines**

Clinical focus



Transcatheter aortic valve implantation (TAVI)

TAVI is a less-invasive procedure, alternative to surgical replacement, for the treatment of aortic valve diseases, conditions where the valve cannot open and close properly, putting an extra strain on the heart.

Transcatheter aortic valves are made of cow or pig tissue, re-engineered and attached to a flexible expanding mesh frame. The valve is implanted by **squeezing it around/inside a catheter**, which is inserted and guided to the aortic valve. Once the new valve is implanted within the existing one, the catheter is removed and the new valve starts working.

Pulmonary artery pressure sensors (PAPS)

Heart failure is a medical condition where the heart muscle is unable to pump blood around the body properly, as it has become too weak or stiff due to narrowed arteries, high blood pressure, diabetes, obesity or other damaging conditions.

PAPS are implantable, wireless monitoring systems able to transmit information on the patient's blood flow dynamics and intra-cardiac pressure to caregivers. By enabling earlier intervention, PAPS have been shown to reduce hospitalisation and improve patients' quality of life.

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