The Role of Ecosystem Organisations in Advancing In Silico Medicine and Regulatory Science

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1. Advancing in silico medicine

In silico medicine includes all the practices of computer simulations for prevention, diagnosis, prognostic assessment, and treatment of a disease, as well as the development and de-risking of biomedical products. Currently, barriers still exist that delay the uptake of Computer Modeling & Simulation in all aspects of the health and care domain, including lack of (public) validation collections, incomplete regulatory context, insufficiently trained workforce and insufficiently informed stakeholders [1].

2. Need for united ecosystem

Overcoming barriers will require an ecosystem approach, bringing together all the relevant stakeholders from policymakers, regulators, healthcare professionals, industry and patients. A united ecosystem can facilitate the development of appropriate tools, infrastructure, standards and good practices, as well as the implementation of Responsible Research and Innovation concepts, building stakeholder trust and social acceptance.
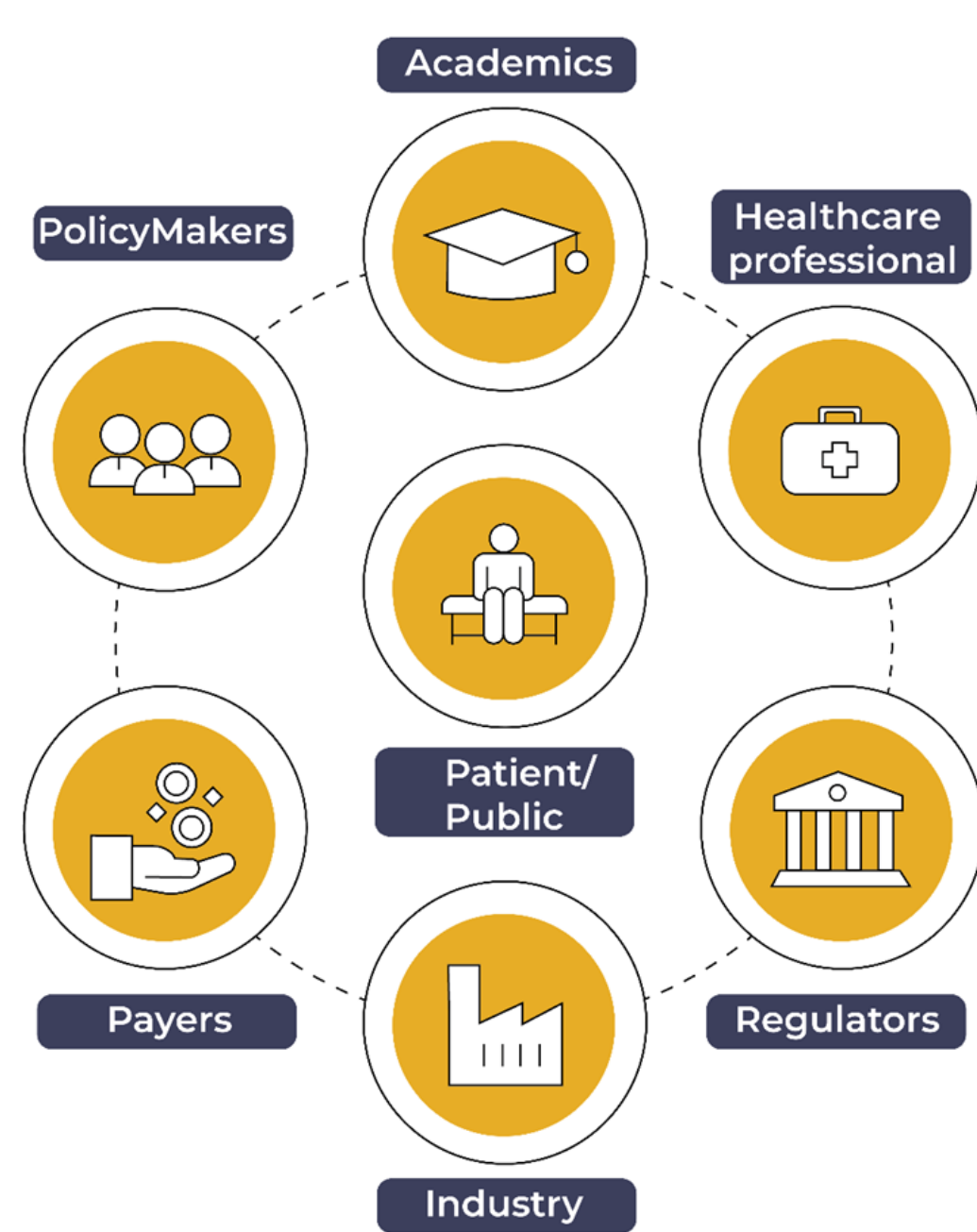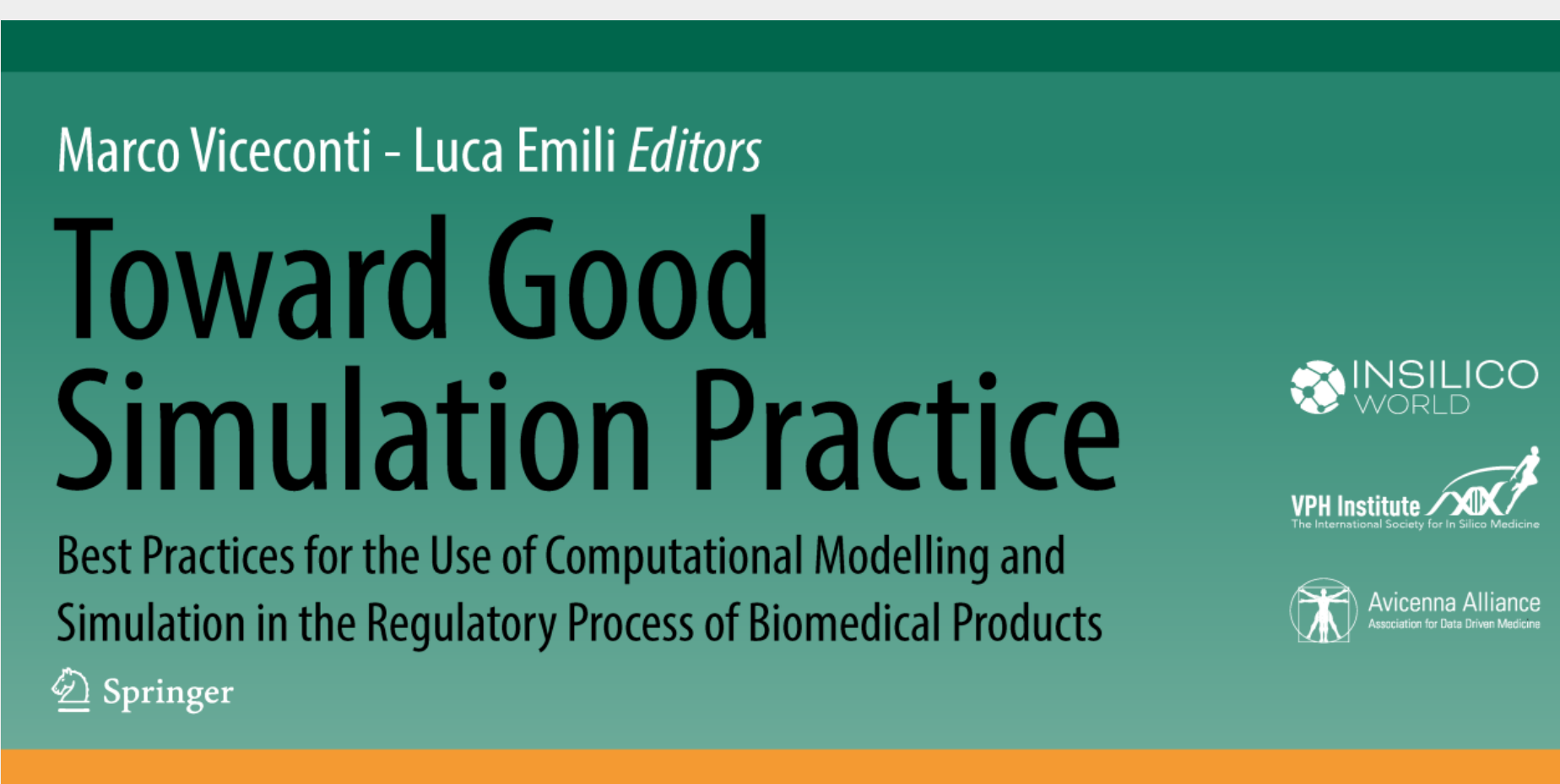
3. Ecosystem Organisations

The **Virtual Physiological Human institute (VPHi)** is the international non-profit organization representing the in silico medicine community. VPHi also represents the academic community inside the **Avicenna Alliance**, an industry-academia network promoting the use of in silico medicine technologies in healthcare. VPHi has been driving and/or participating in several initiatives in the last couple of years that aim to facilitate the transition from bit to bed side for all applications.

4. VPHi Initiatives

Here are a few initiates that foster the in silico ecosystem, by rallying the community:

(A) Good Simulation Practices (GSP) Grassroots movement, brought together 100's of experts in #InSilicoTrials working in academia, medical industry, regulatory bodies and hospitals. A proposal for the GSP [2] was formulated, capturing the essential elements for conducting credible in silico trials.

Marco Viceconti - Luca Emili *Editors*

Toward Good Simulation Practice

Best Practices for the Use of Computational Modelling and Simulation in the Regulatory Process of Biomedical Products

Springer

(B) Clinical survey
In 2021 a first survey was conducted amongst members of the clinical community to assess their opinion, knowledge and doubts regarding the use of in silico methods in clinical practice [3]. A new one is running now. Are you a clinician? **Scan the code and participate in the new survey!**

Trust
Medical doctors' **trust** level in CM&S results is **independent** of their experience with actually **using** it.

Clinical Survey:

(C) Card-based focus groups with patients, clinicians and in silico medicine experts to assess social implications of in silico technologies, towards fostering trust and social acceptance. The focus group used simplified scenarios, captured in easy-to-understand graphics to start the discussion.
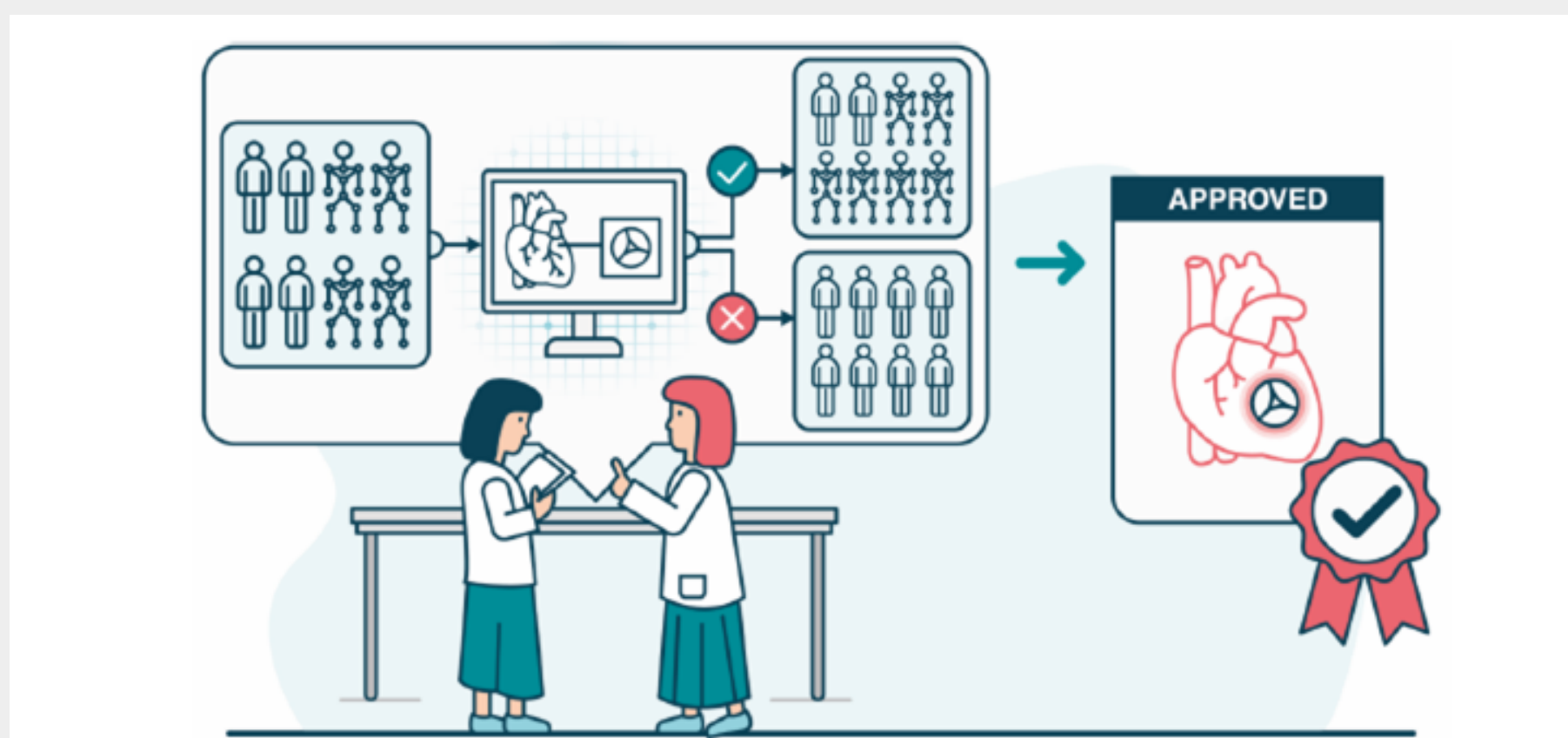
(D) Building an ecosystem for Digital Twins in Healthcare

EDITH

The European Commission has recently announced a new flagship program **Virtual Human Twin (VHT),** to facilitate the development, credibility assessment and uptake of digital twins in healthcare. VPHi is leading the **EDITH coordination and support action** that aims to bring together the ecosystem, write a comprehensive **Roadmap [4]** for the realization of VHT and provide the proof of concept implementation. A short **Manifesto [5] was created** to rally the support of all interested organizations within the ecosystem. In addition, the EDITH consortium developed a **FAIRsharing collection of standards & guidelines [6]**.

Objectives

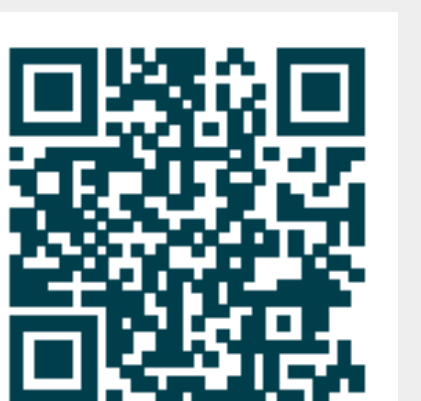Framing an ECOSYSTEM of digital twins in healthcare within the EU

Building a ROADMAP towards an integrated Virtual Human Twin (VHT)

Developing a FEDERATED and CLOUD- BASED REPOSITORY of digital twins in healthcare

Outlining a SIMULATION PLATFORM, supporting the transition towards an integrated VHT

European Virtual Human Twins

Virtual Human Twin Roadmap:

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