

Building the Virtual Human Twin: from an engaged ecosystem to an incipient infrastructure

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EDITH is a coordination and support action funded by the Digital Europe program of the European Commission under grant agreement n° 101083771



The Virtual Human Twin



Digital Twins



DT = virtual representation of a physical object or system across its life-cycle. It uses real-time data and other sources to enable learning, reasoning, and dynamically recalibrating for monitoring, diagnostics and prognostics



Concept from Industry 4.0

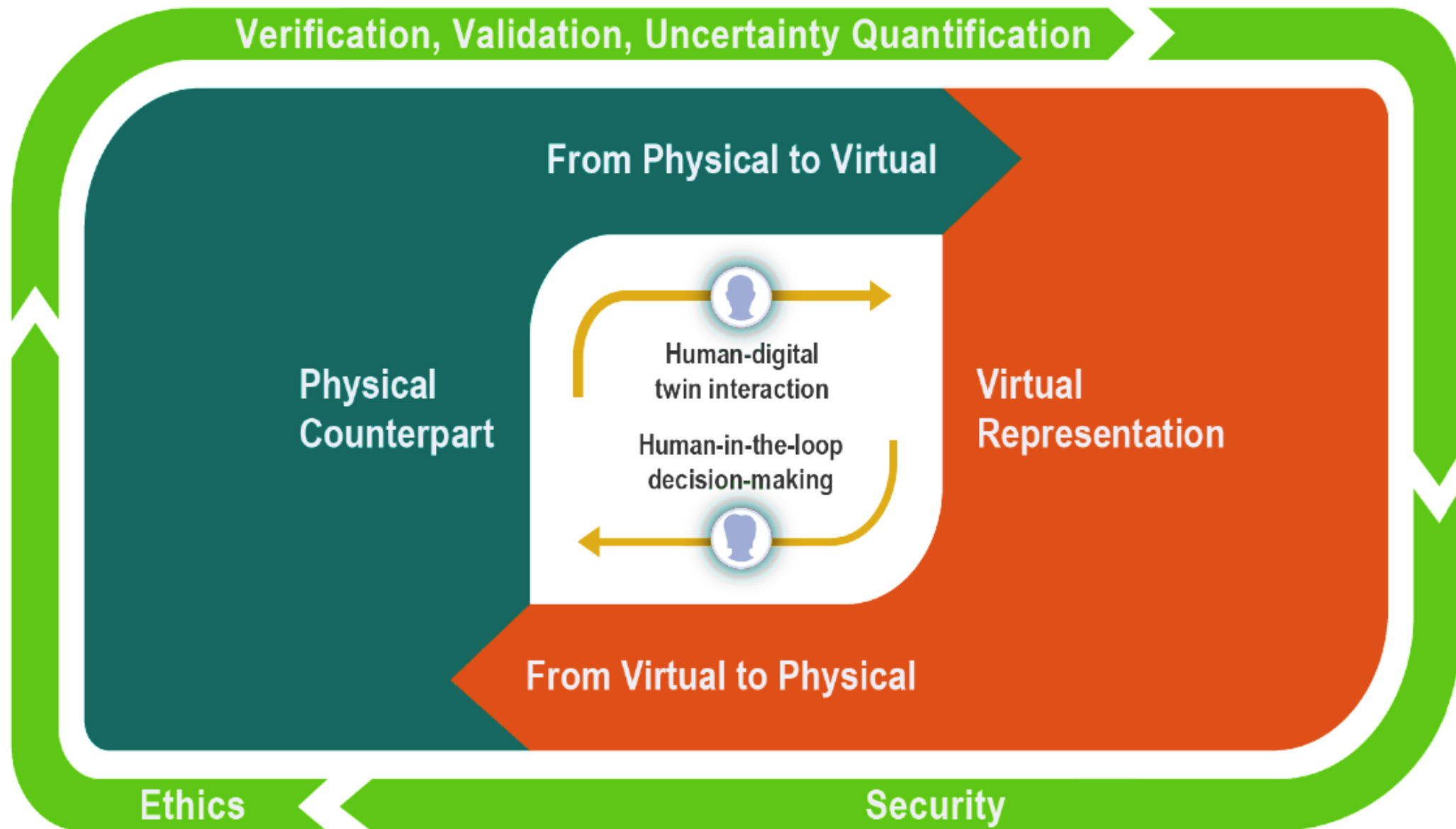


Digital Twins in Healthcare

The direct use of individual-specific models for the prevention, prediction, screening, diagnosis and treatment of a disease, as well as the evaluation, optimization, selection and personalisation of intervention options

Consensus definition from EC workshop on human digital twin

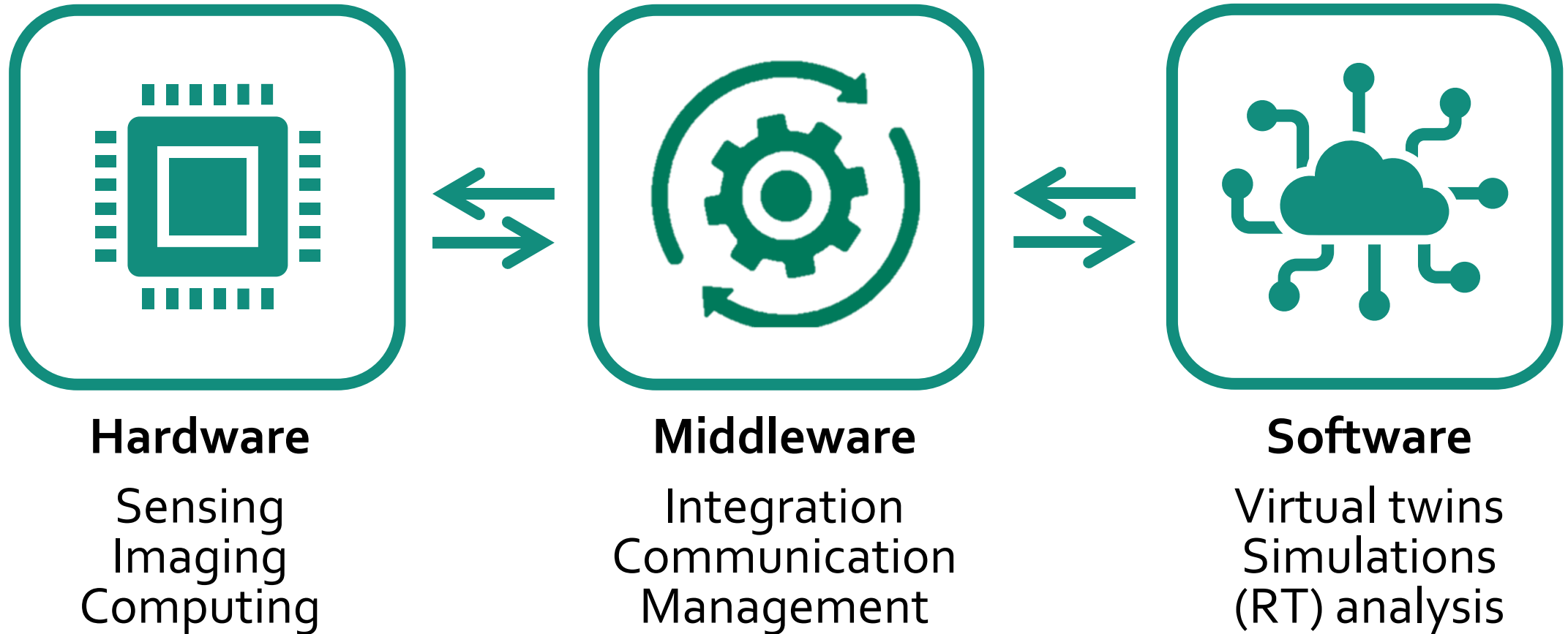




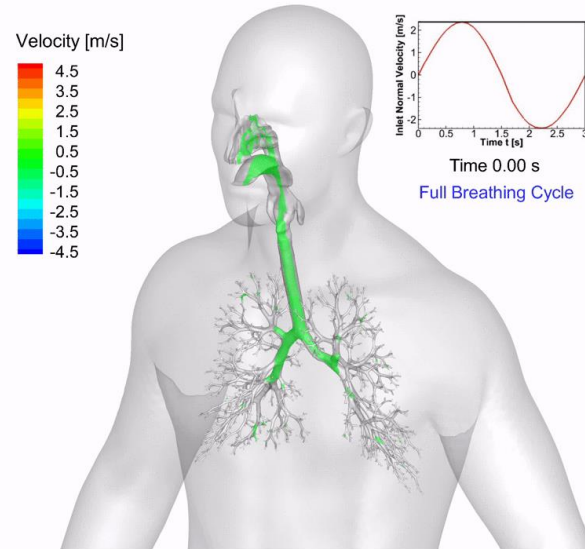
NASEM report on DT 2024



Components of a Digital Twin

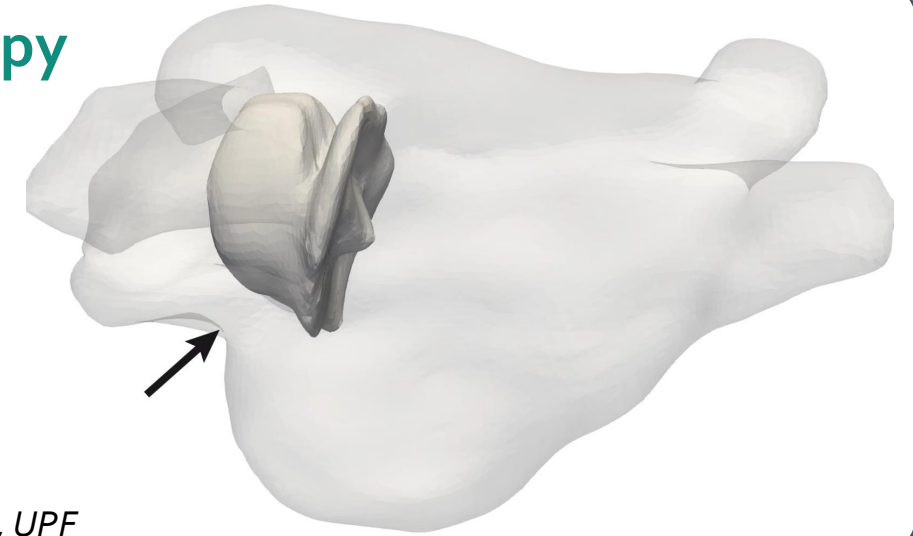


Cell Tissue Organ System



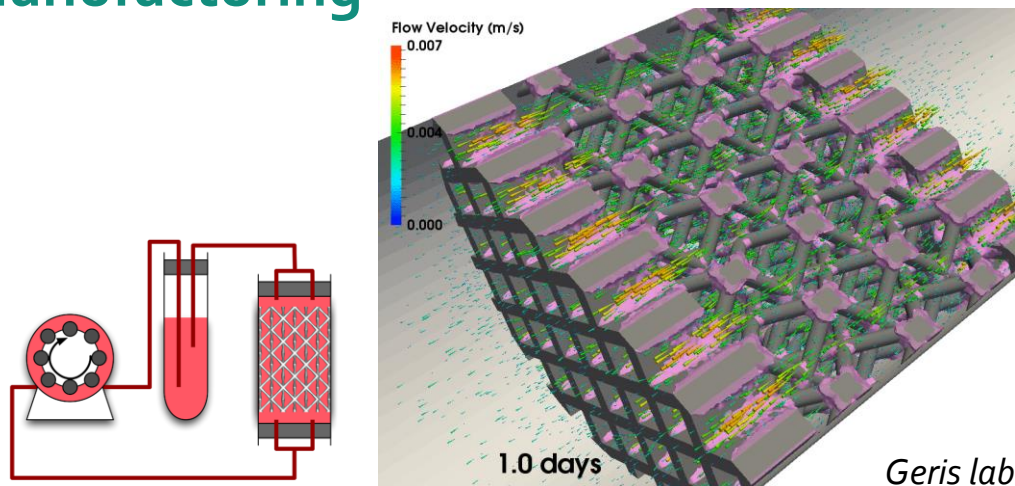
Y. Feng, OSU

Therapy



O. Camara, UPF

Manufacturing

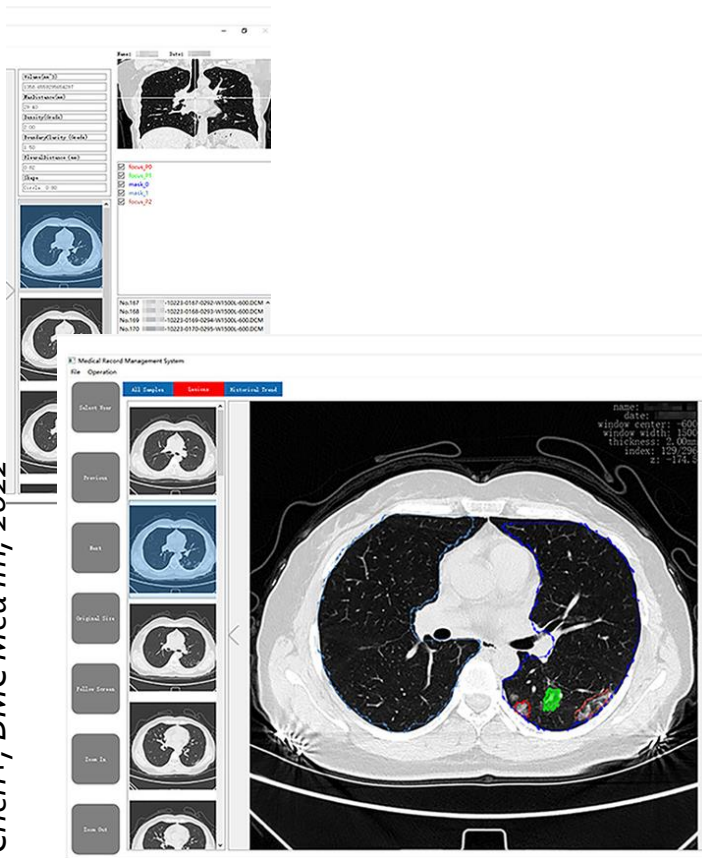


Medical Facility

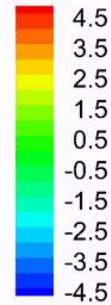


In Silico technologies for Digital Twins

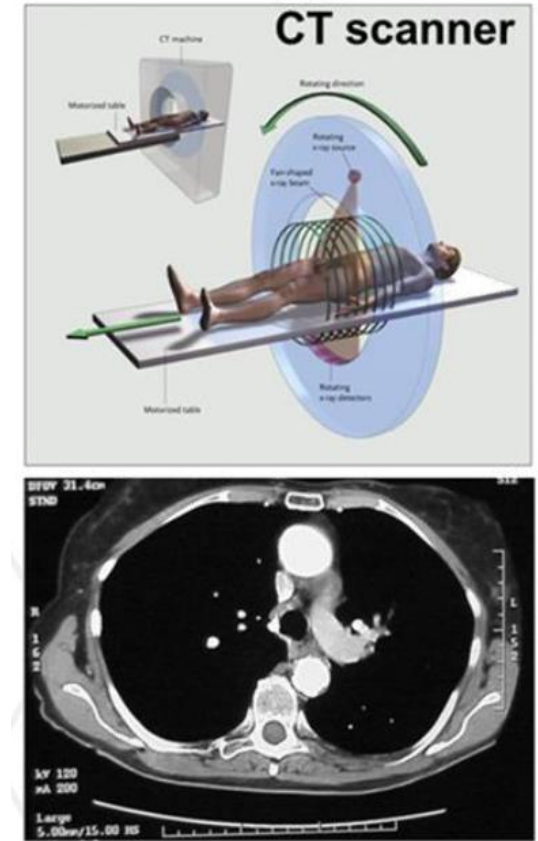
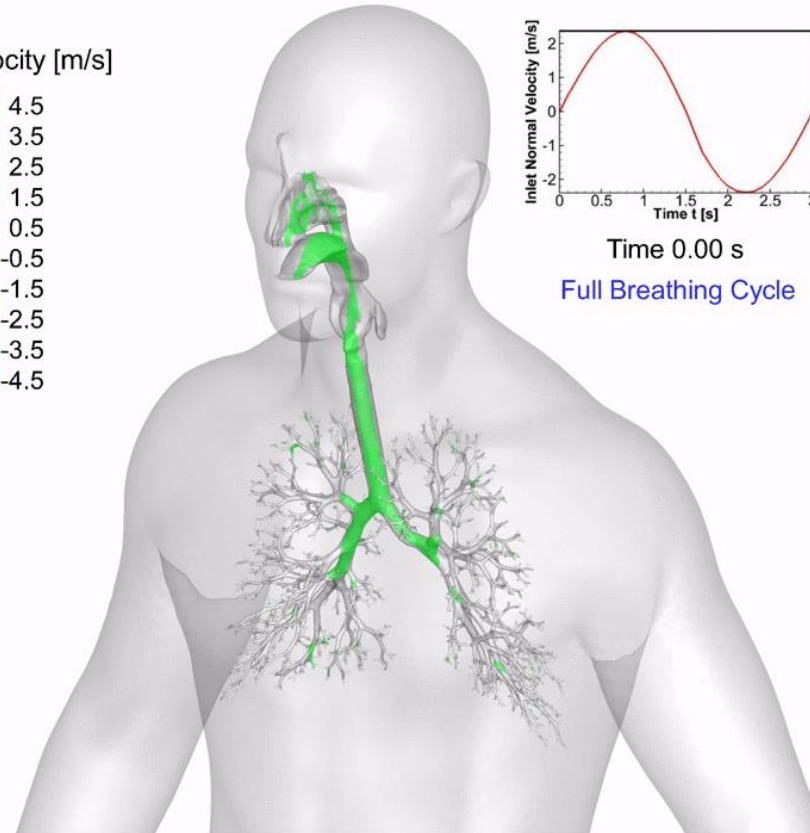
Chen+, BMC Med Im, 2022



Velocity [m/s]

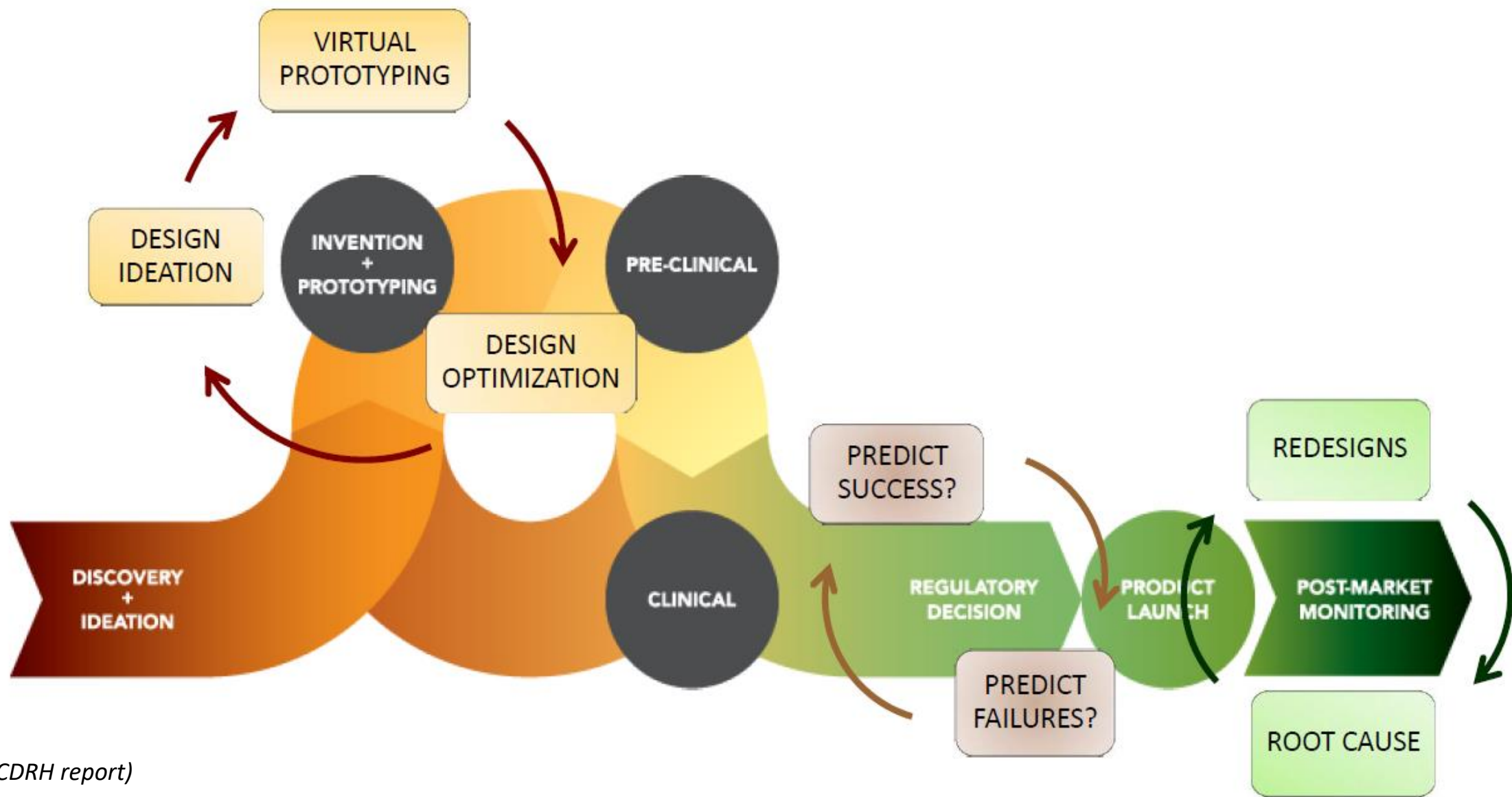


Y. Feng, OSU

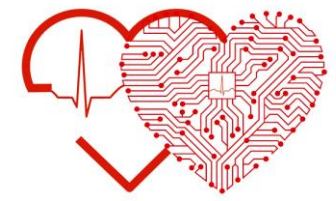


Black box, driven by data
AI, machine learning

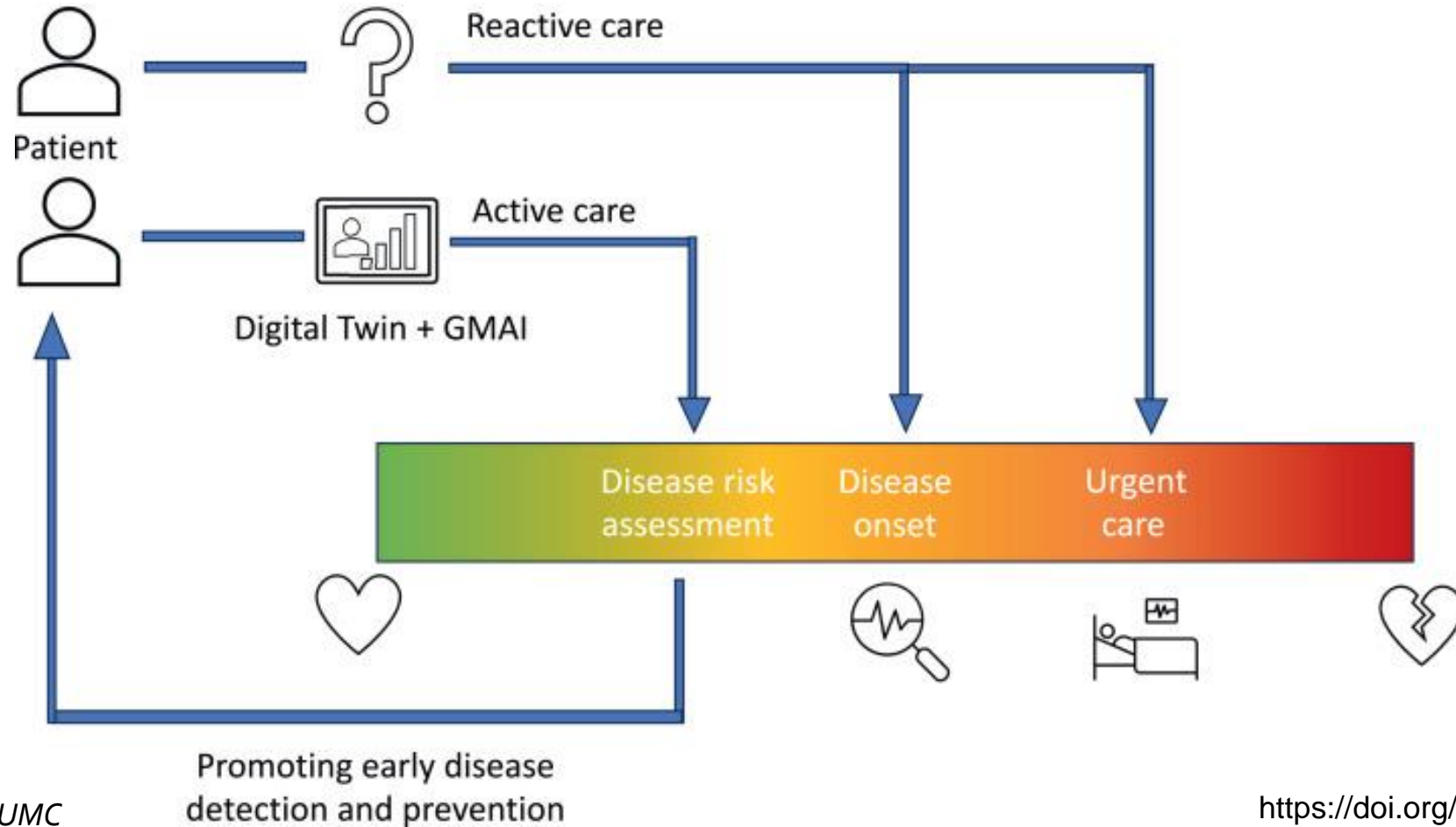
White box, driven by knowledge
Physics/physiology-based models







Example 1: MyDigitwin



V. Asselberghs, Amsterdam UMC

<https://doi.org/10.1016/j.hjc.2024.06.001>

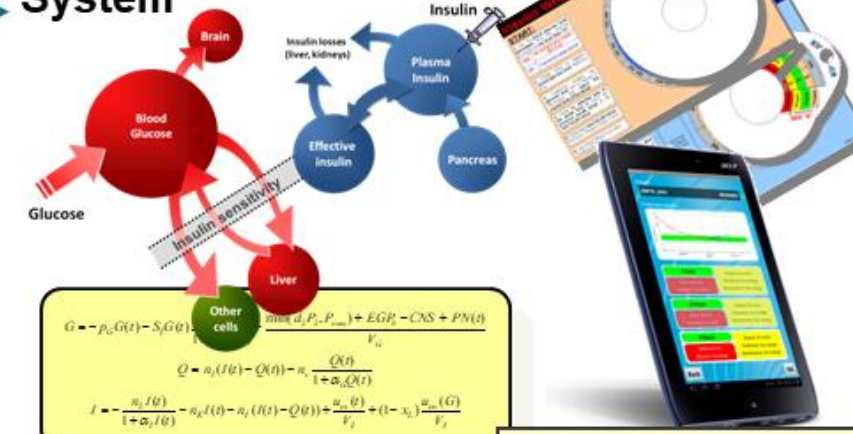
Example 2: ICU

Measured data



Patient management

Decision Support System



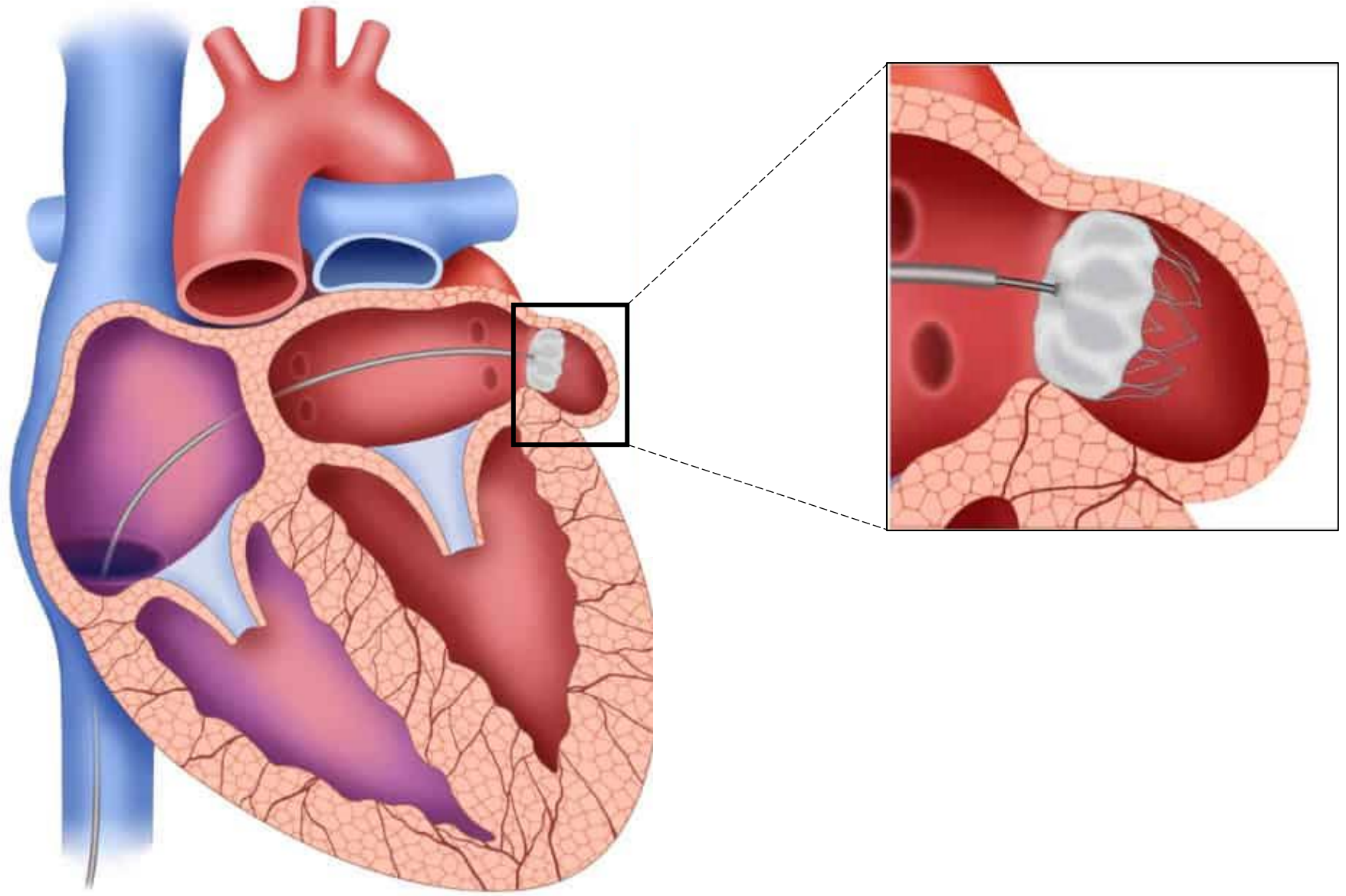
Identify and utilise
“immeasurable”
patient parameters

For insulin
sensitivity (SI)



Standard infuser
equipment adjusted by
nurses

Example 3: LAAOD





**SIM
CARDIO
TEST**

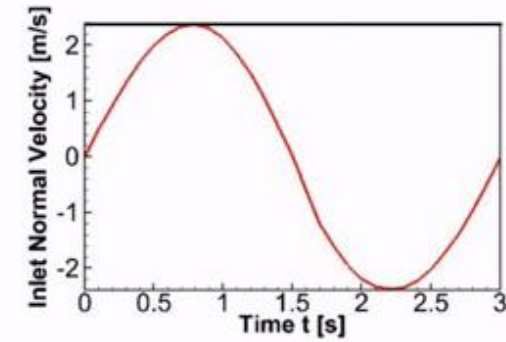
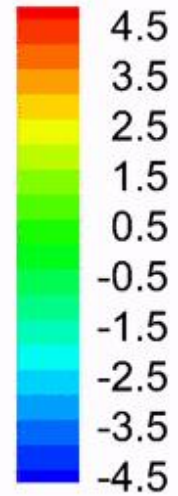


O. Camara, UPF



Ecosystem
for Digital Twins
in Healthcare

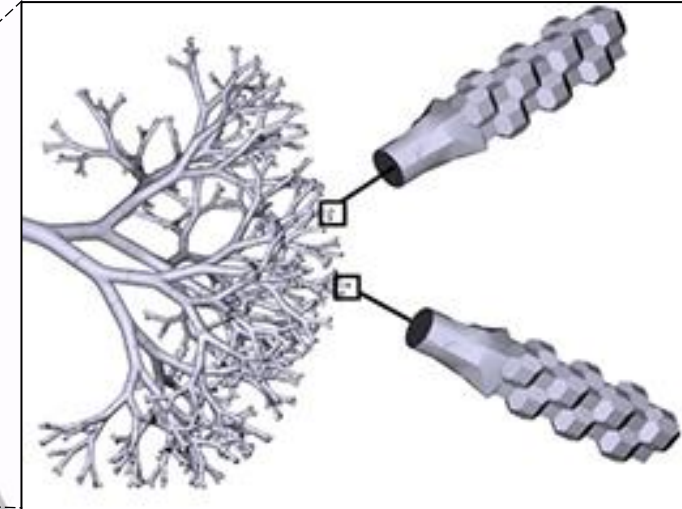
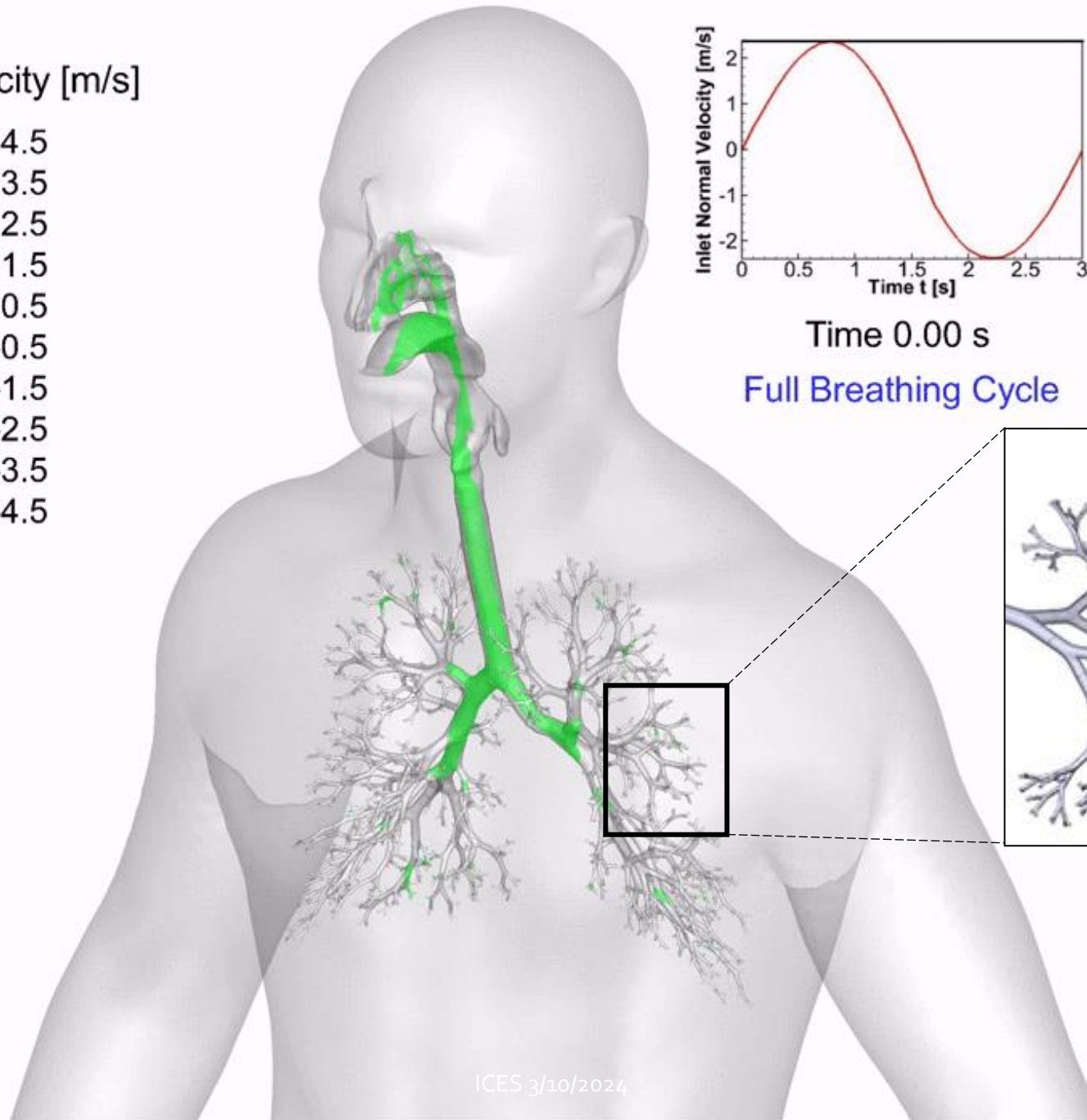
Velocity [m/s]



Time 0.00 s

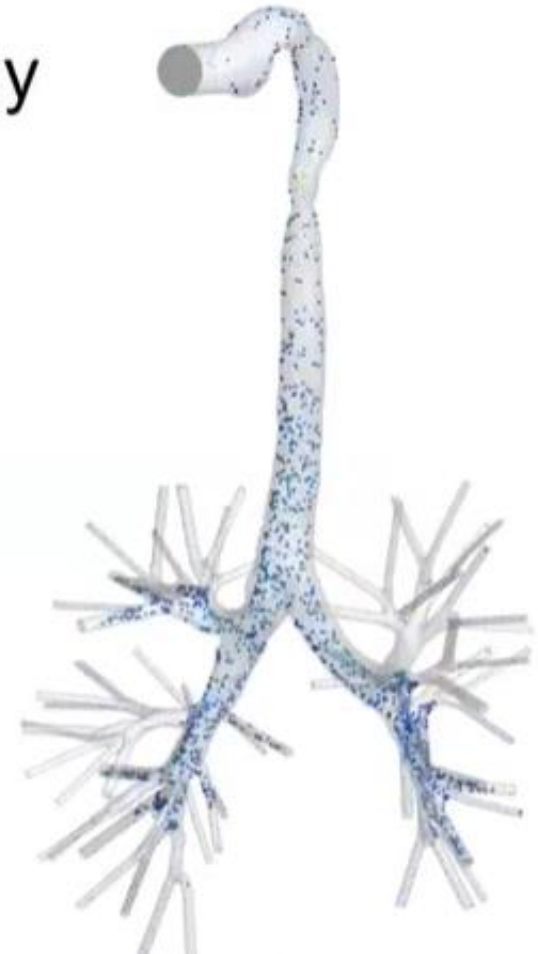
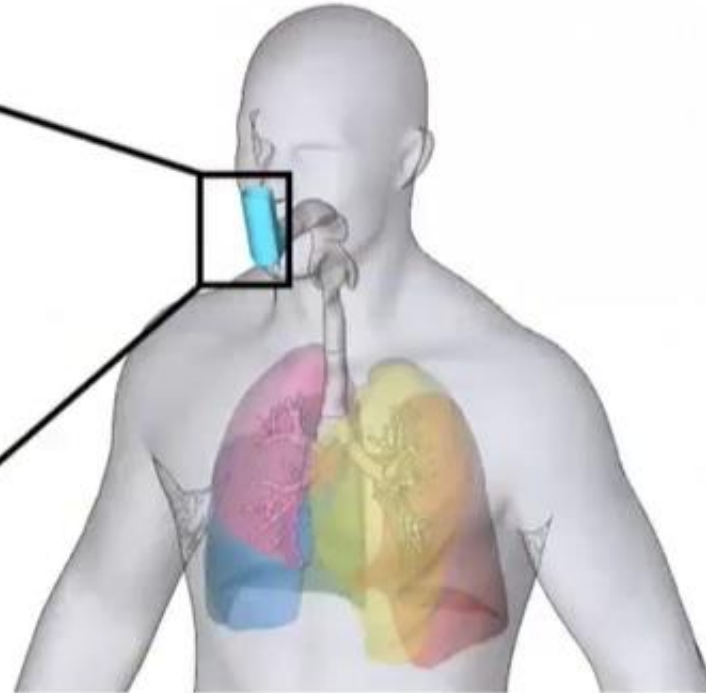
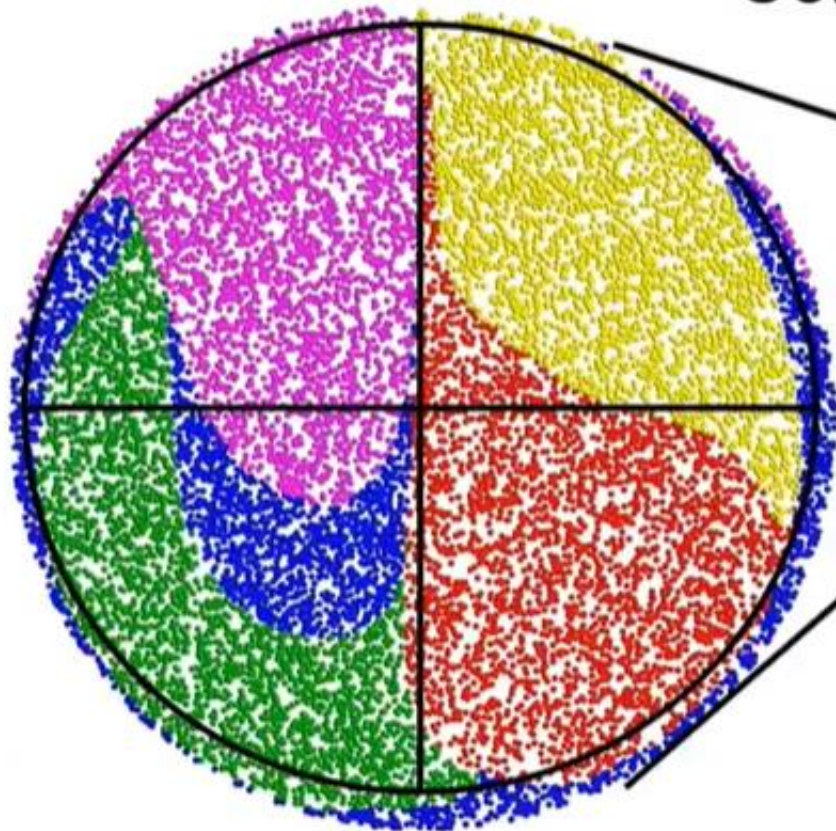
Full Breathing Cycle

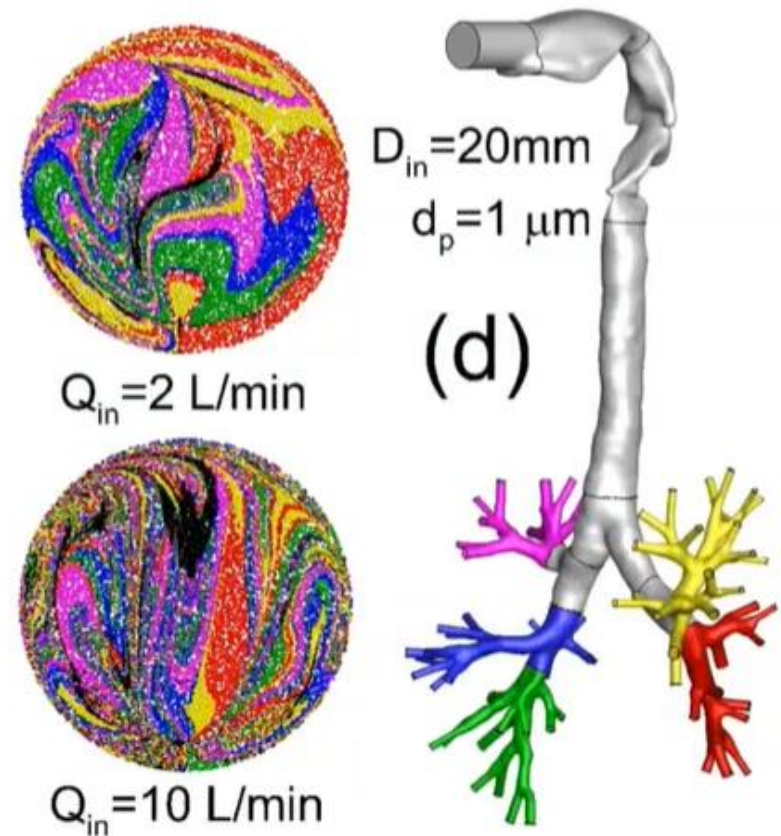
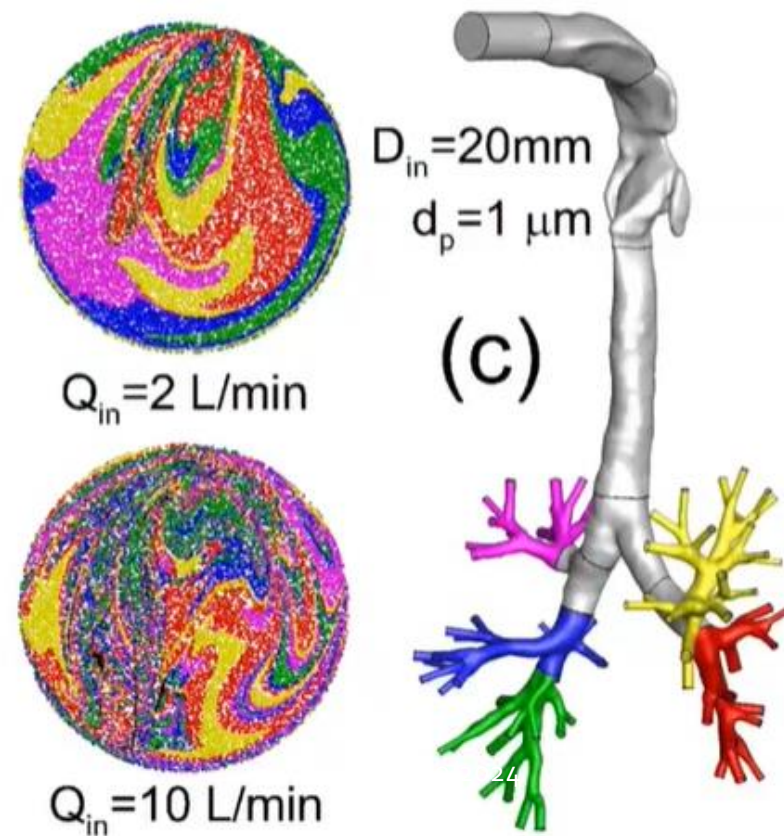
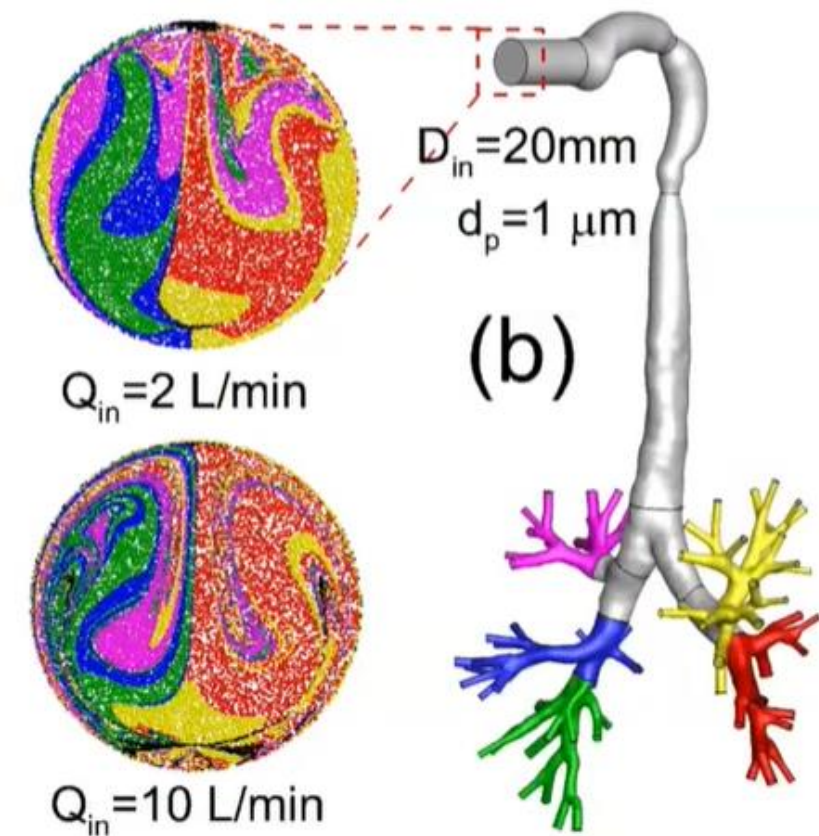
Example 4: Lung DT



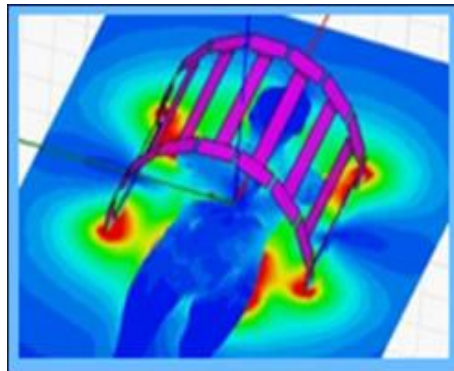
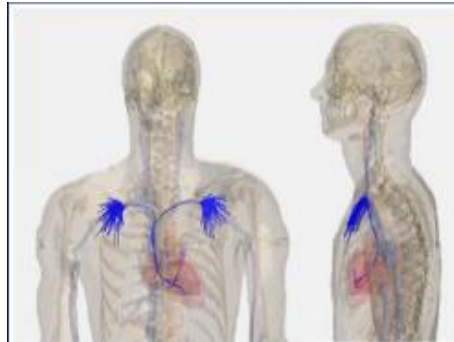


Conventional Drug Release Strategy





In silico clinical trials



2 years

The product was released 2 years earlier

256

Reduction of the number of patients involved in the clinical trial

\$10M

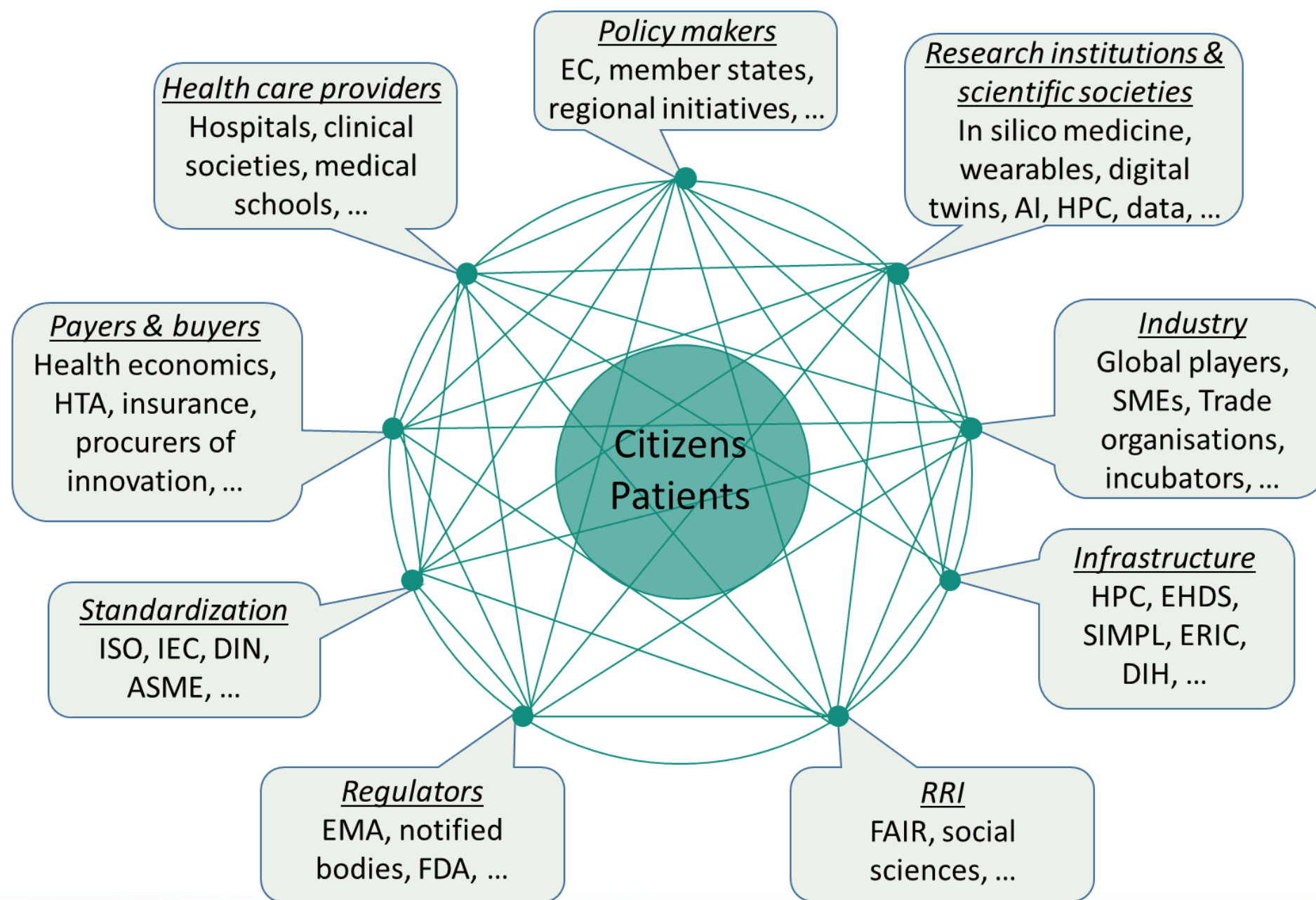
Cost reduction due to the reduced number of patients

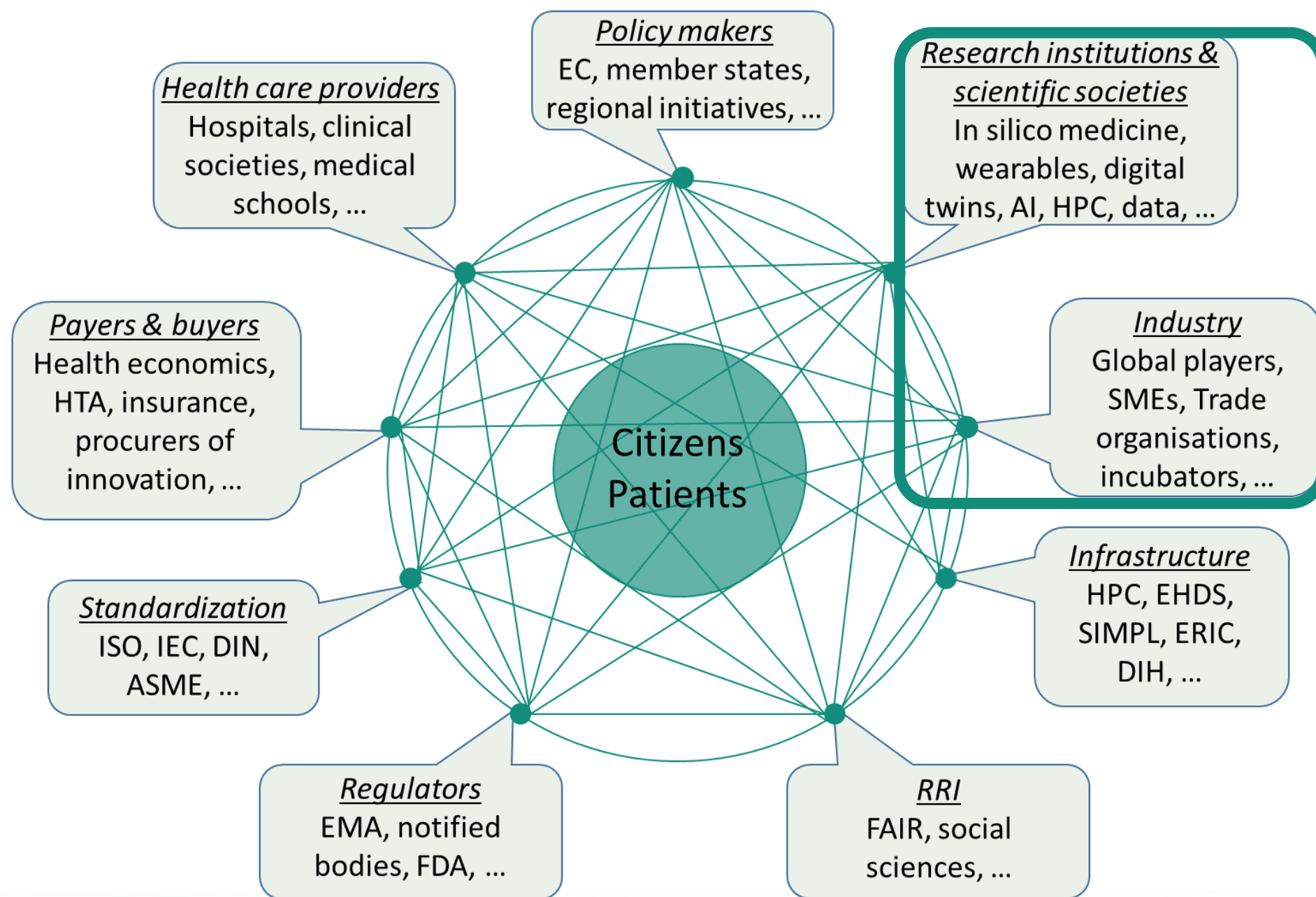
10,000

Number of patients treated during these 2 years with the product

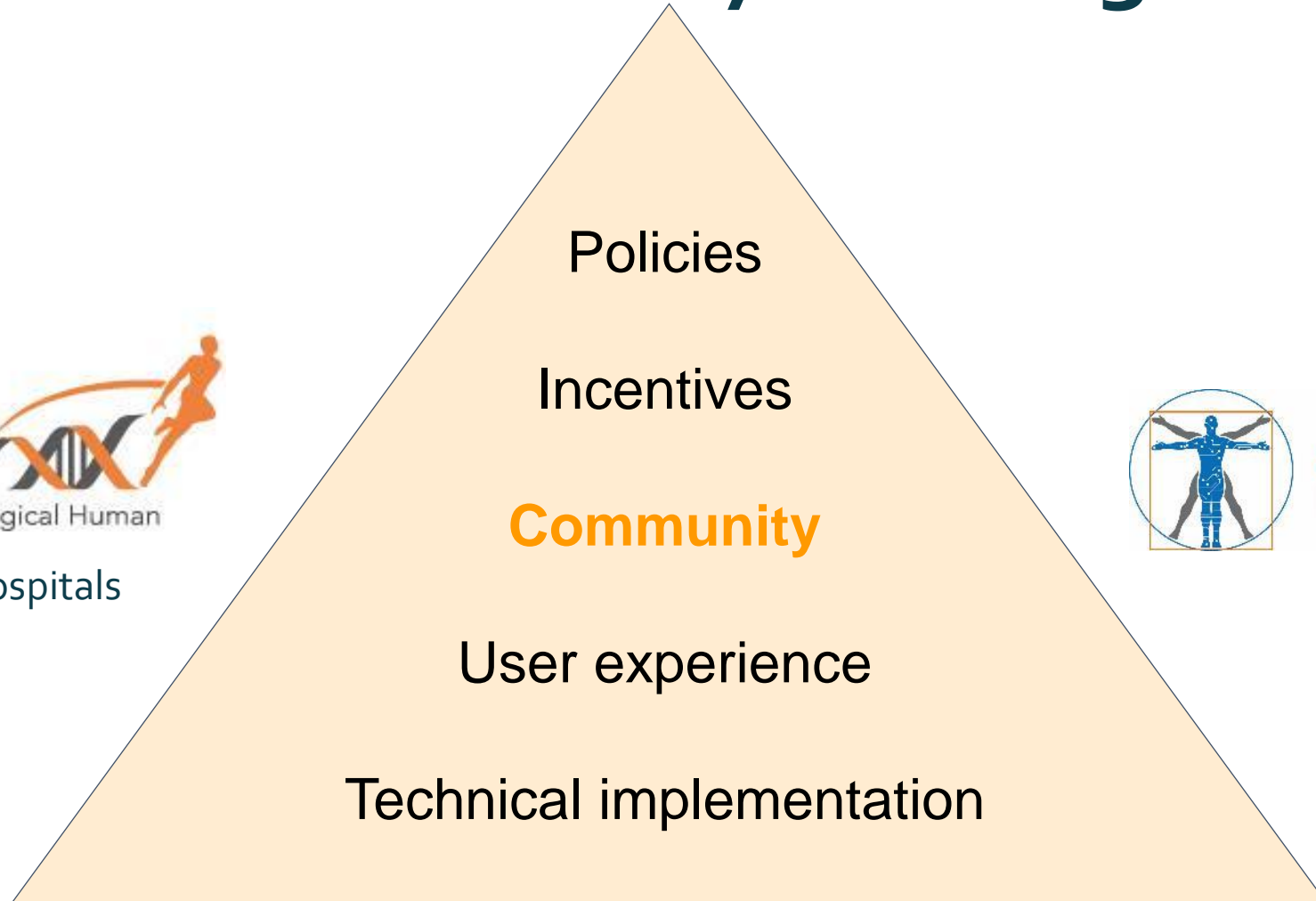
Courtesy of Medtronic

From an engaged ecosystem...

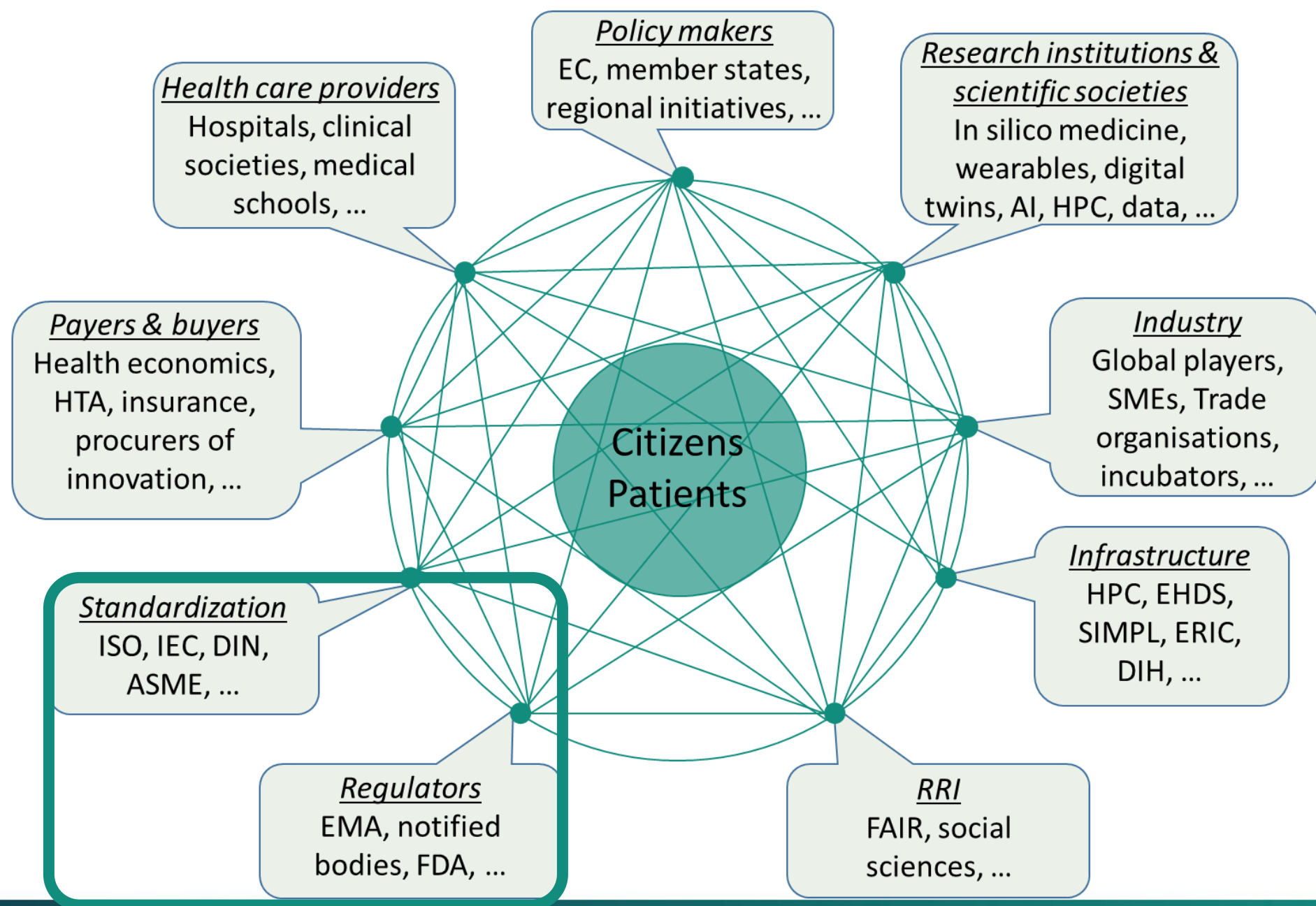




Important role for ecosystem organisations



Avicenna Alliance
Association for Predictive Medicine
VPHi + industry



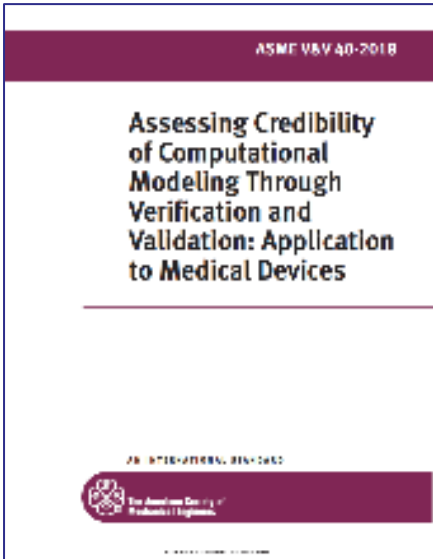
In silico medicine in regulatory science

Reduce, refine & replace traditional sources of evidence to establish safety and effectiveness



Tina Morrison, FDA

From the computer screen to the patient



Citation: CPT Pharmacometrics Syst. Pharmacol. (2020) 9, 195–197; doi:10.1002/psp4.12504



COMMENTARY

Verifying and Validating Quantitative Pharmacology and *In Silico* Models: Current Needs, Gaps, and Challenges

Flora T. Musuamba^{1,2,3,*}, Roberta Bursi⁴, Efthymios Manolis^{1,5}, Kristin Jean-Pierre Boissel⁷, Raphaële Lesage⁸, Cécile Crozatier⁹, Emmanuelle Rossana Alessandrello¹¹ and Liesbet Geris^{8,12}

The added value of *in silico* models (including quantitative systems pharmacology models) for drug development is now unanimously recognized. It is, therefore, important that the standards used are commonly acknowledged

CPT: Pharmacometrics & Systems Pharmacology

ARTICLE |  Open Access |   

Scientific and regulatory evaluation of mechanistic *in silico* drug and disease models in drug development: building model credibility



IEEE JOURNAL OF BIOMEDICAL AND HEALTH INFORMATICS, VOL. 25, NO. 10, OCTOBER 2021

3977

Possible Contexts of Use for *In Silico* Trials Methodologies: A Consensus-Based Review

Marco Viceconti¹⁰, Luca Emili¹⁰, Payman Afshari¹⁰, Eulalie Courcelles, Cristina Curreli¹⁰, Nele Famaey¹⁰, Liesbet Geris¹⁰, Marc Horner, Maria Cristina Jori¹⁰, Alexander Kulesza¹⁰, Axel Loewe¹⁰, Michael Neidlin¹⁰, Markus Reiterer, Cecile F. Rousseau, Giulia Russo¹⁰, Simon J. Sonntag, Emmanuelle M. Voisin, and Francesco Pappalardo¹⁰

Abstract—The term “*In Silico* Trial” indicates the use of computer modelling and simulation to evaluate the safety and efficacy of a medical product, whether a drug, a medical device, a diagnostic product or an advanced therapy

medicinal product. Predictive models are positioned as new methodologies for the development and the regulatory evaluation of medical products. New methodologies are qualified by regulators such as FDA and EMA through formal

Raphaële Lesage, Giulia Russo, Roberta Bursi, Luca Emili, Alexander Kulesza, Eulalie Courcelles, Jean-Pierre Boissel, Rossana Alessandrello, Nuno Curado, Enrico Dall'ara, Liesbet Geris ... See fewer authors ^

doi:10.1002/psp4.12669

This article has not undergone full peer review but has not been through the peer reviewing process, which may lead to differences between this pre-proof and the final version. Please cite this article as doi:10.1002/psp4.12669



Standards related to Digital Twins

STANDARDS

DATABASES

POLICIES

COLLECTIONS

ORGANISATIONS

ADD CONTENT

STATS

ACTIONS

GENERAL INFORMATION



EDITH standards collection for Virtual Human Twins in Health



Type

Collection

Registry

Collection

Description

Collection of standards recommended by the European EDITH (Ecosystem Digital Twins in Healthcare) consortium for virtual human twins (VHTs) in health.

Organisations

[Heidelberg Institute for Theoretical Studies](#) , [EDITH consortium](#) , [VPHi - Virtual Physiological Human Institute](#)

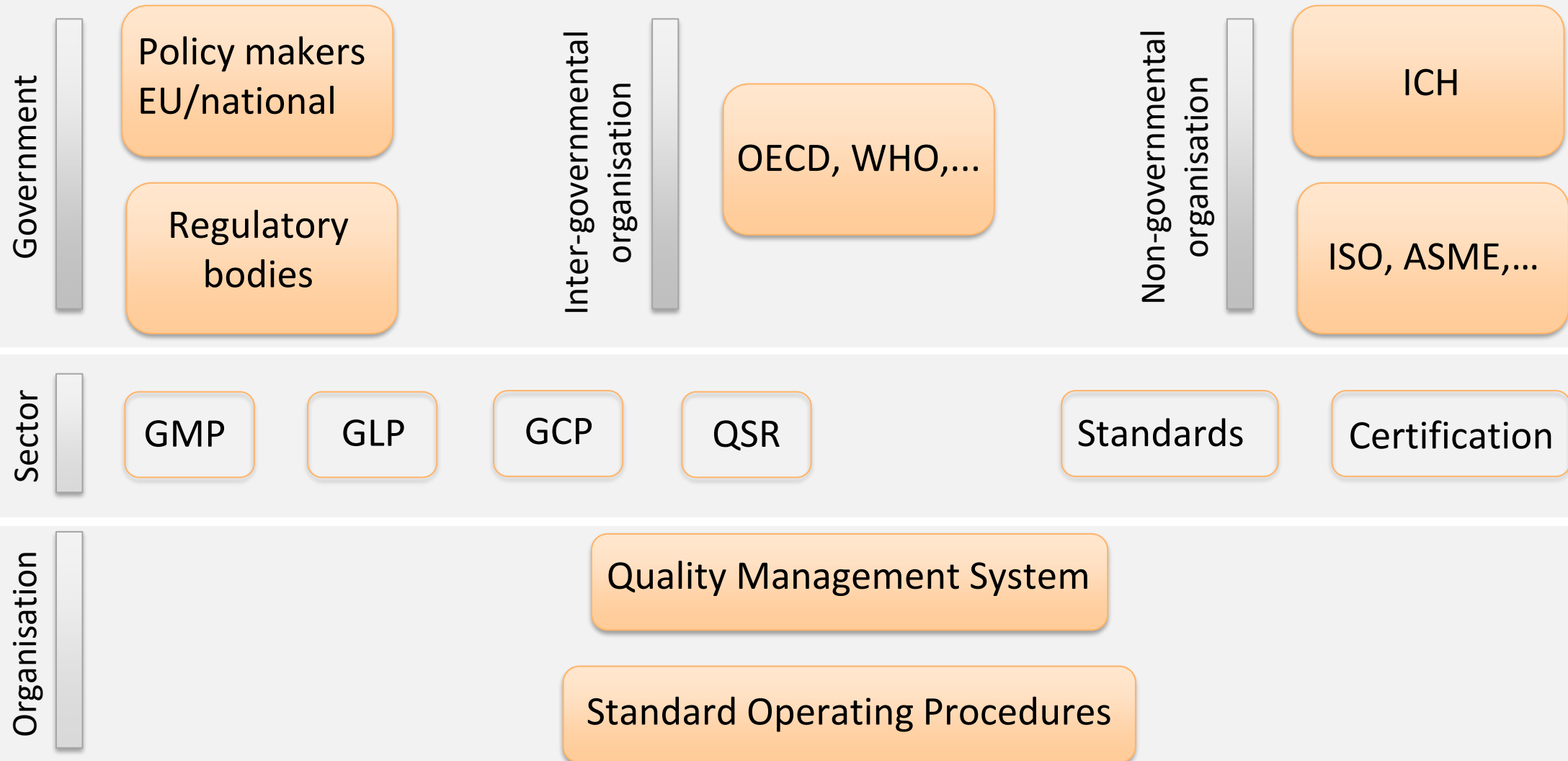
Homepage

<https://www.edith-csa.eu>

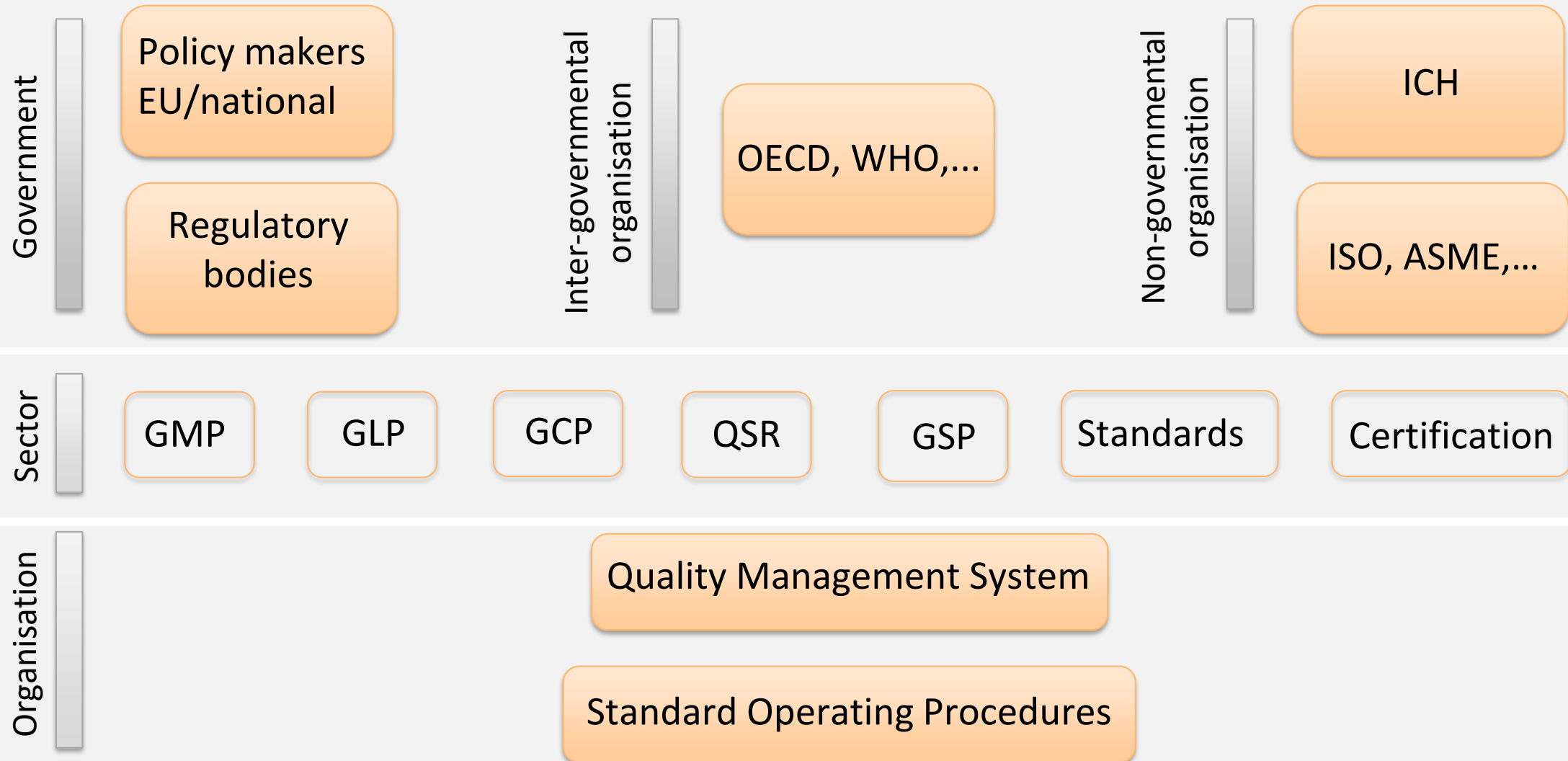
<https://fairsharing.org/4787>



Translation towards the patient



Translation towards the patient



Good Simulation Practice

- Community effort
 - Academia
 - Industry
 - Regulators
 - HTA
 - Ethics & social sciences
- Used GCP as basis
- Each chapter reviewed by FDA



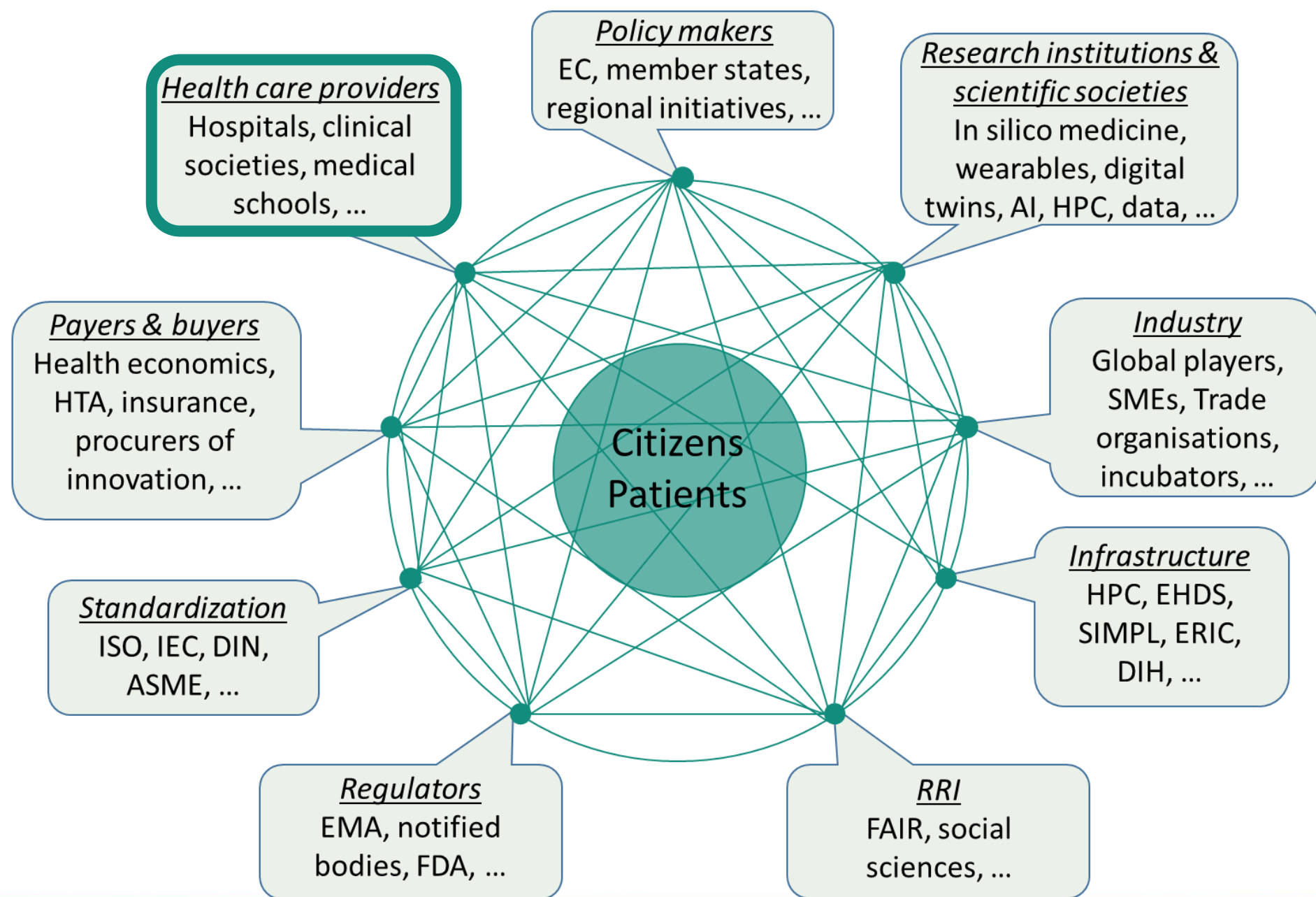
Marco Viceconti · Luca Emili *Editors*

Toward Good Simulation Practice

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

OPEN ACCESS

 Springer



Clinical survey on in silico medicine



Mapping the use of computer modelling and simulation in clinics

Report of the 1st VPHi
Clinical Community survey
2021



Objective 1

Mapping the use of
computer modeling
& simulations
(CM&S).



Objective 2

Assessing the
current level of
acceptance.



Objective 3

Identifying the
barriers.



Objective 4

Highlighting future
opportunities.

Lesage+, Front. MedTech, 2023

Clinical survey on in silico medicine

Lesage+, Front. MedTech, 2023



Strengths:

- Awareness in concepts
- Perception of positive role played by CM&S in planning procedures
- Positive impact on confidence
- Accuracy to provide patient-specific results
- Trust



Weaknesses:

- Required technical expertise
- Low access to computing resources
- Perceived slow turnaround time of simulations
- Limitation to a few medical area
- Familiarity with CM&S technologies



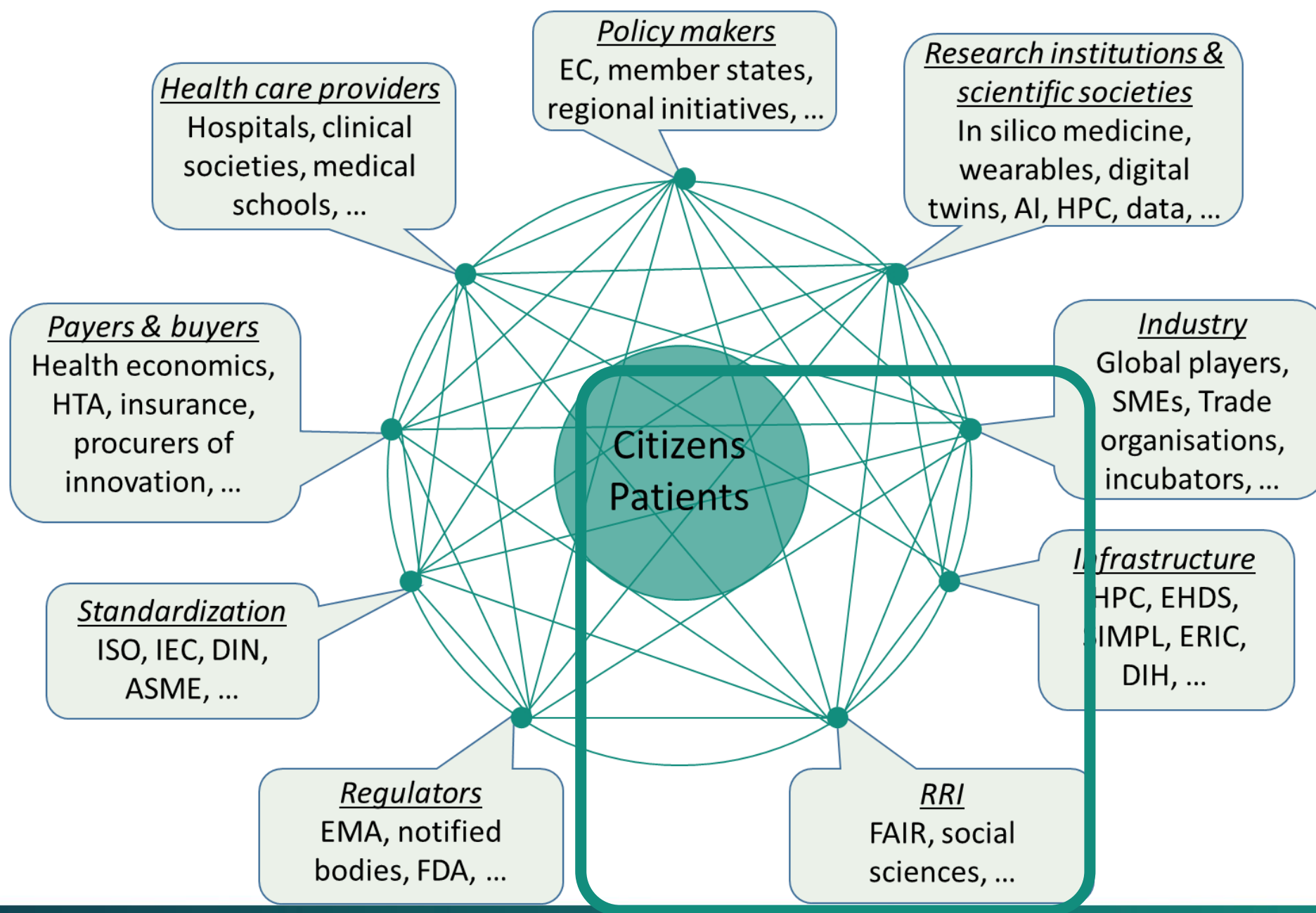
Opportunities:

- Trust
- Role for CM&S profiles & expertise considered
- Existence of interdisciplinary collaborations
- Applications in teaching, planning



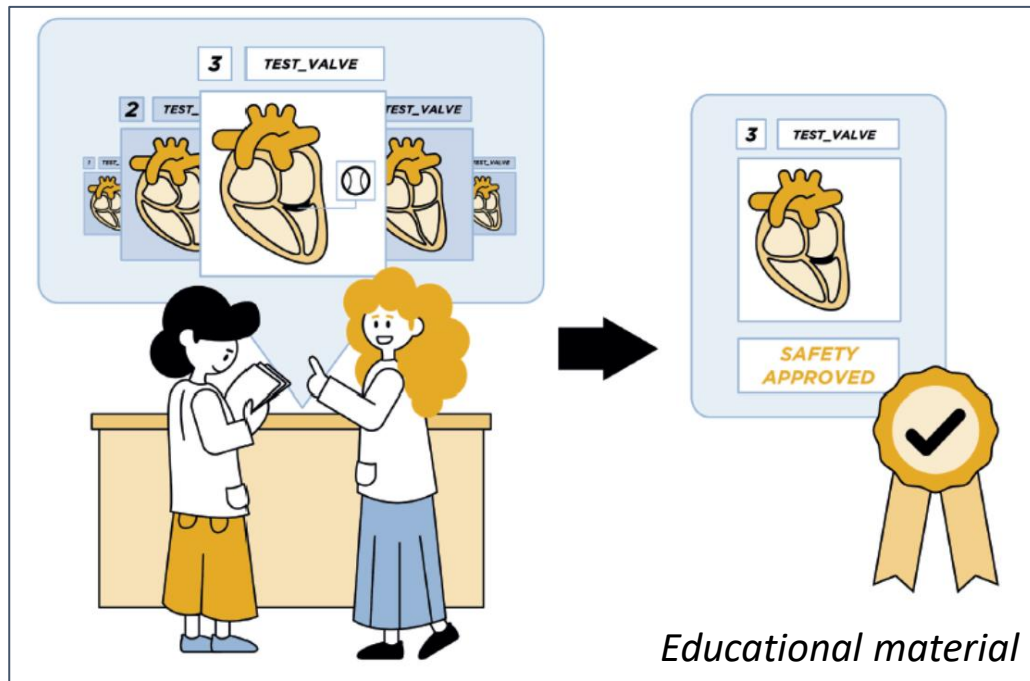
Threats:

- Recognition of regulatory approval by clinicians
- Level of awareness in certain terms
- Mistrust/over expectations
- Lack of funding for CM&S expertise



ELSI challenges: social acceptance & trust

- Trustworthiness vs trust
- Important role for clinician



Educational videos



All material combined

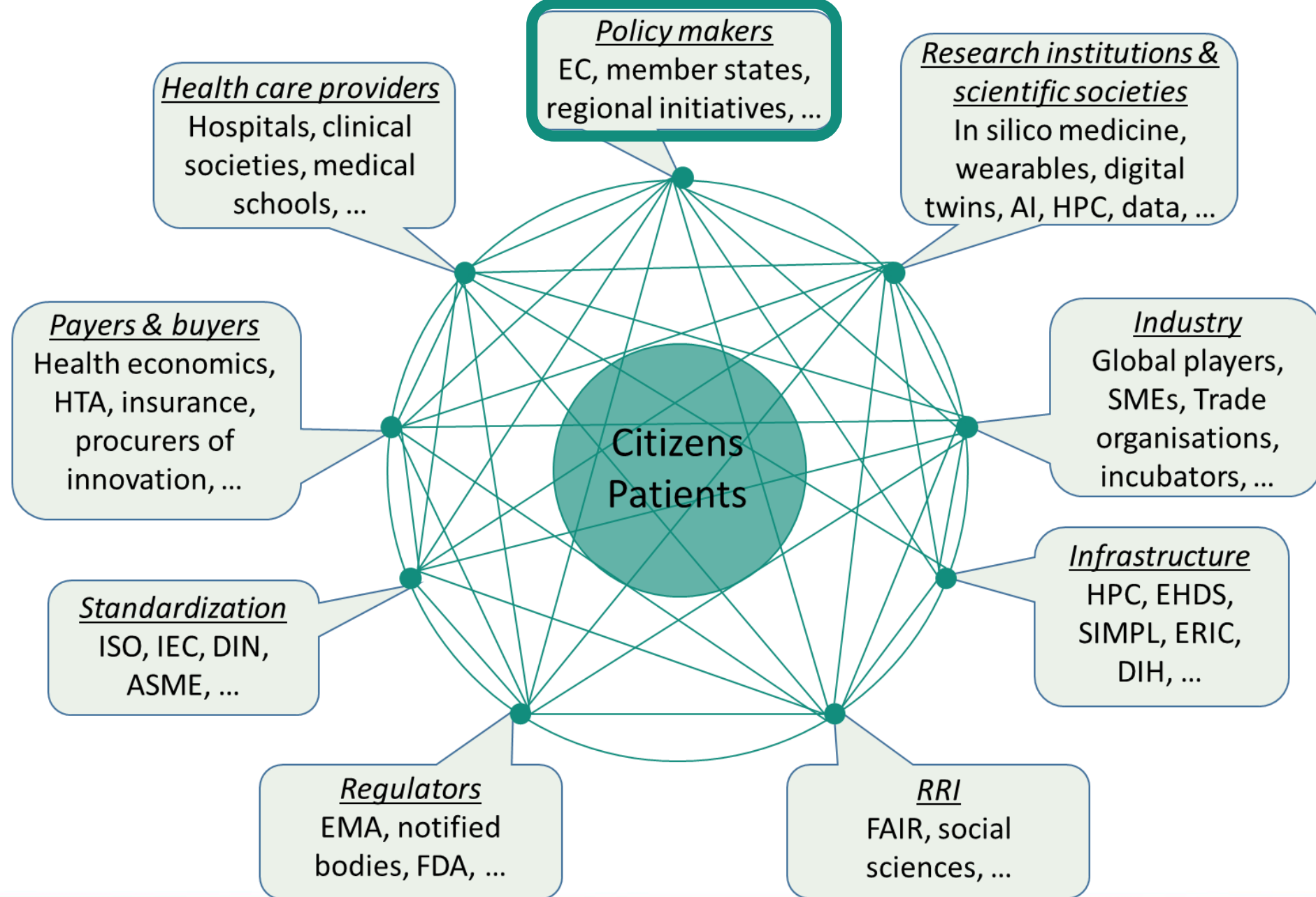
Coming soon!

VPHi Info Kit

A DIY guide for
stakeholder engagement
and outreach
on In Silico Medicine

VPH Institute





... to an incipient infrastructure



European
Commission

European Virtual Human Twins

An EU framework supporting the emergence and adoption of the next generation of virtual human twin solutions in health and care

The European Virtual Human Twins Initiative aims to accelerate personalised care with tangible benefits for citizens and patients, while sustaining and advancing EU science and technology in the Digital Single Market.



Ecosystem
for Digital Twins
in Healthcare



The European Virtual Human Twins Initiative



An EU framework supporting the emergence and adoption of the next generation of virtual human twin solutions in health and care

The Initiative will:



Foster an **inclusive and collaborative multi-stakeholder ecosystem**



Breakdown silos and support **interoperability**, integration and scaling up of VHT-based solutions



Build a **state-of-the-art platform** to enable modelling across scales of human anatomy



Facilitate **advanced research and technology** development on virtual human twins, including AI foundational models



Leverage the **power of novel computational methods** and advanced computing capacities



Fully comply with **EU values and rules: private, safe and secure**

EDITH-CSA objectives

Ecosystem



Roadmap



Repository



Simulation Platform



Ecosystem
for Digital Twins
in Healthcare

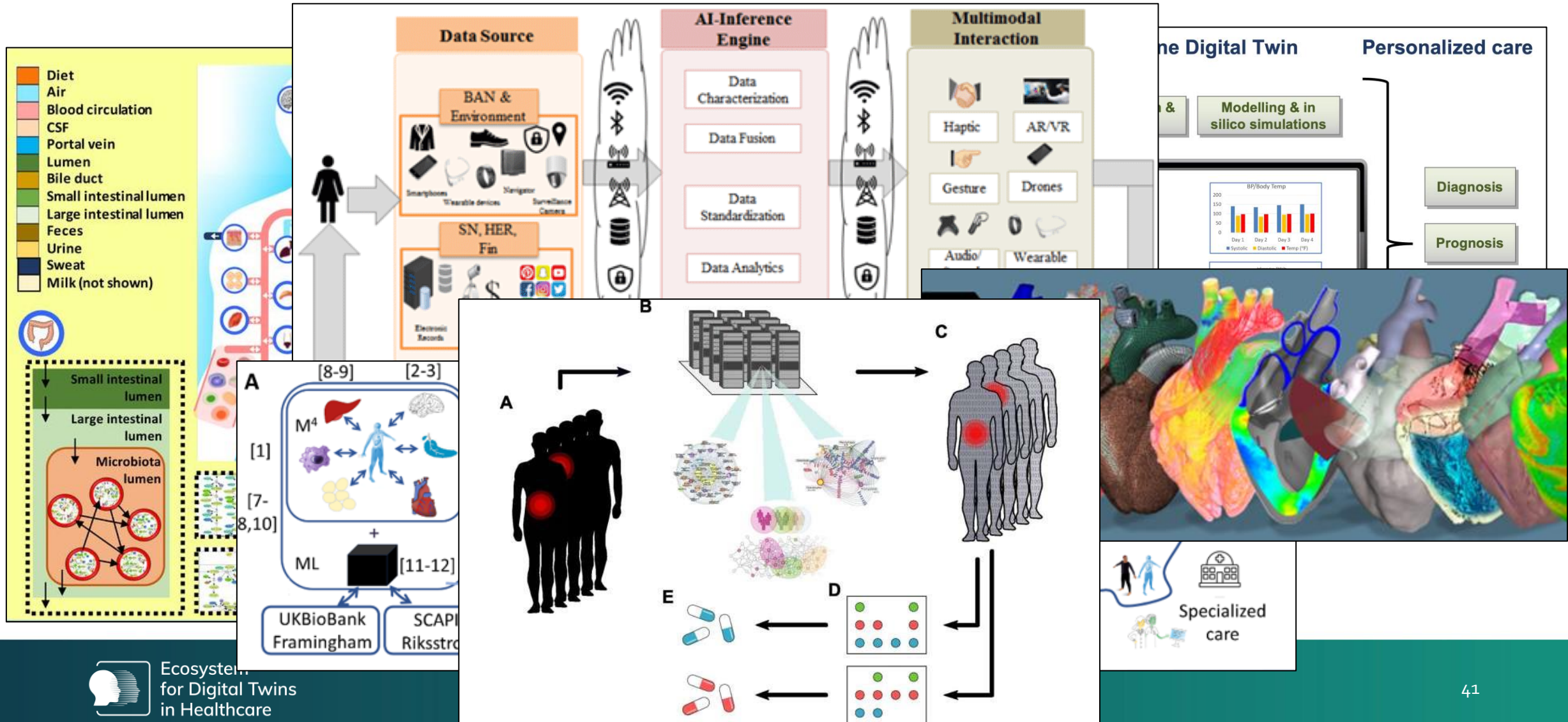
Virtual Human Twins – pragmatic definition

The Virtual Human Twin (VHT) is
a systematic, ever-growing **digital and quantitative representation** of
the actionable knowledge available on human pathophysiology.

The European VHT platform will enable
the **pooling of resources** and assets (data, models, algorithms,
computing power, storage etc.) to **develop digital twins** in healthcare and
assess their credibility.

It entails the development of a **federated public infrastructure** and the
collection of appropriate resources, driven by the engagement of a
collaborative ecosystem.

Virtual Human Twins



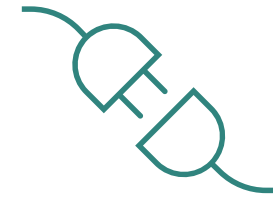
What could the VHT look like?



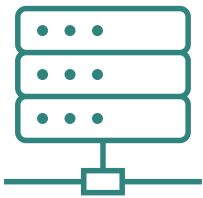
you can **search catalogue** by data type, anatomical location, age of the patient, and many other attributes

$$I(x, t) = \int_0^1 xy^{\ln(t)} dx$$

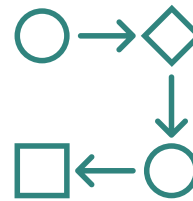
you can **access** every digital twin developed so far by anyone in Europe, including your own



you can **match** any digital twin with any available dataset that is a valid input for that model



you can **run** all those models on every digital dataset available in Europe on human health



you can **orchestrate** multiple digital twins to build multiscale or multisystem models

```
# Program adds two numbers  
num1 = 1.5; num2 = 6.3  
sum = num1 + num2
```

You can **script** the whole VHT, and save your scripts for automation or reuse by you or others

Uptake in Industry & Clinics

• Industry

- Access to resources (data, models, compute infrastructure, storage networks,..)
- Sand box
- Benchmark
- Technology development
- ELSI clarity & certainty
- Find partners
- New commercial opportunities

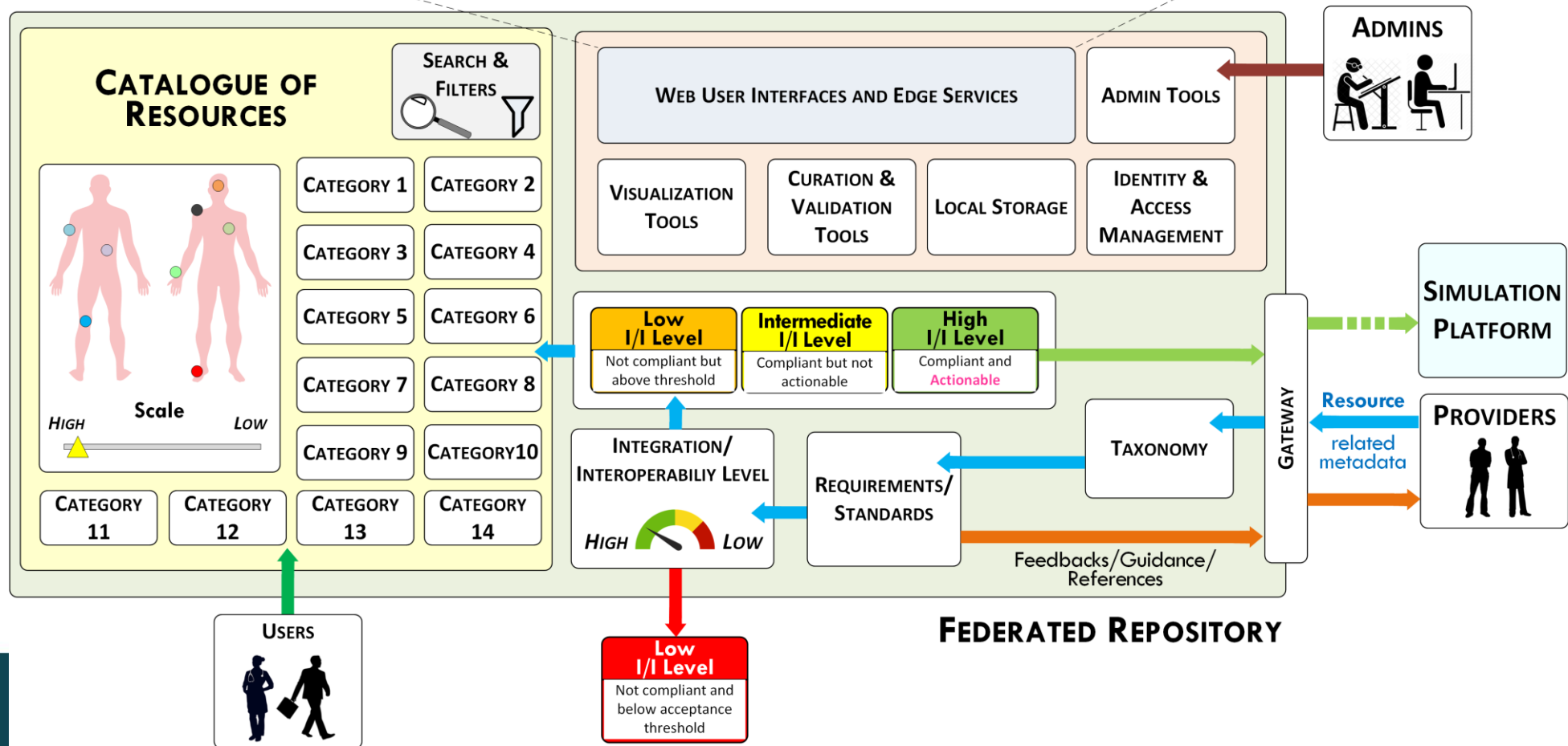
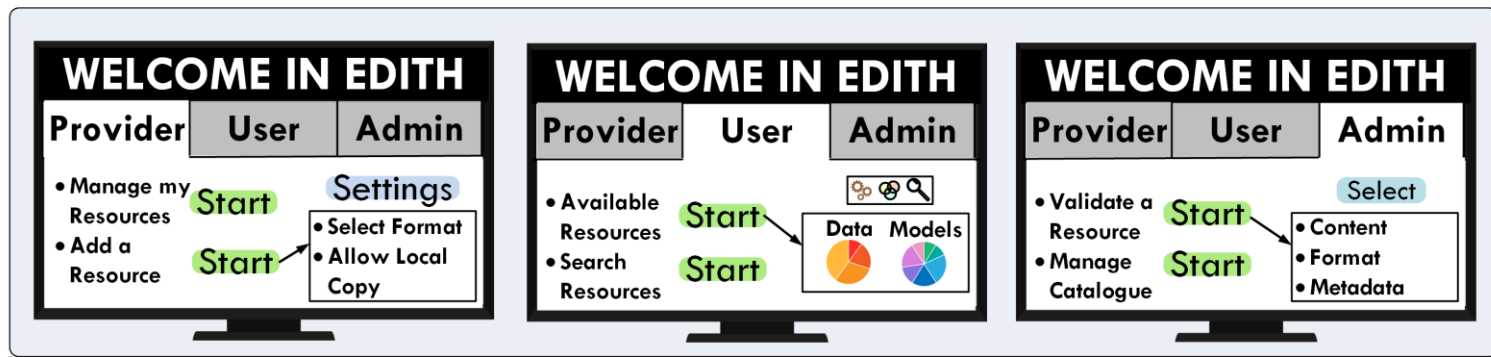
• Clinicians

- Train on virtual patients
- Test hypotheses on pathologies
- Clinical decision support
- Investigate comorbidities

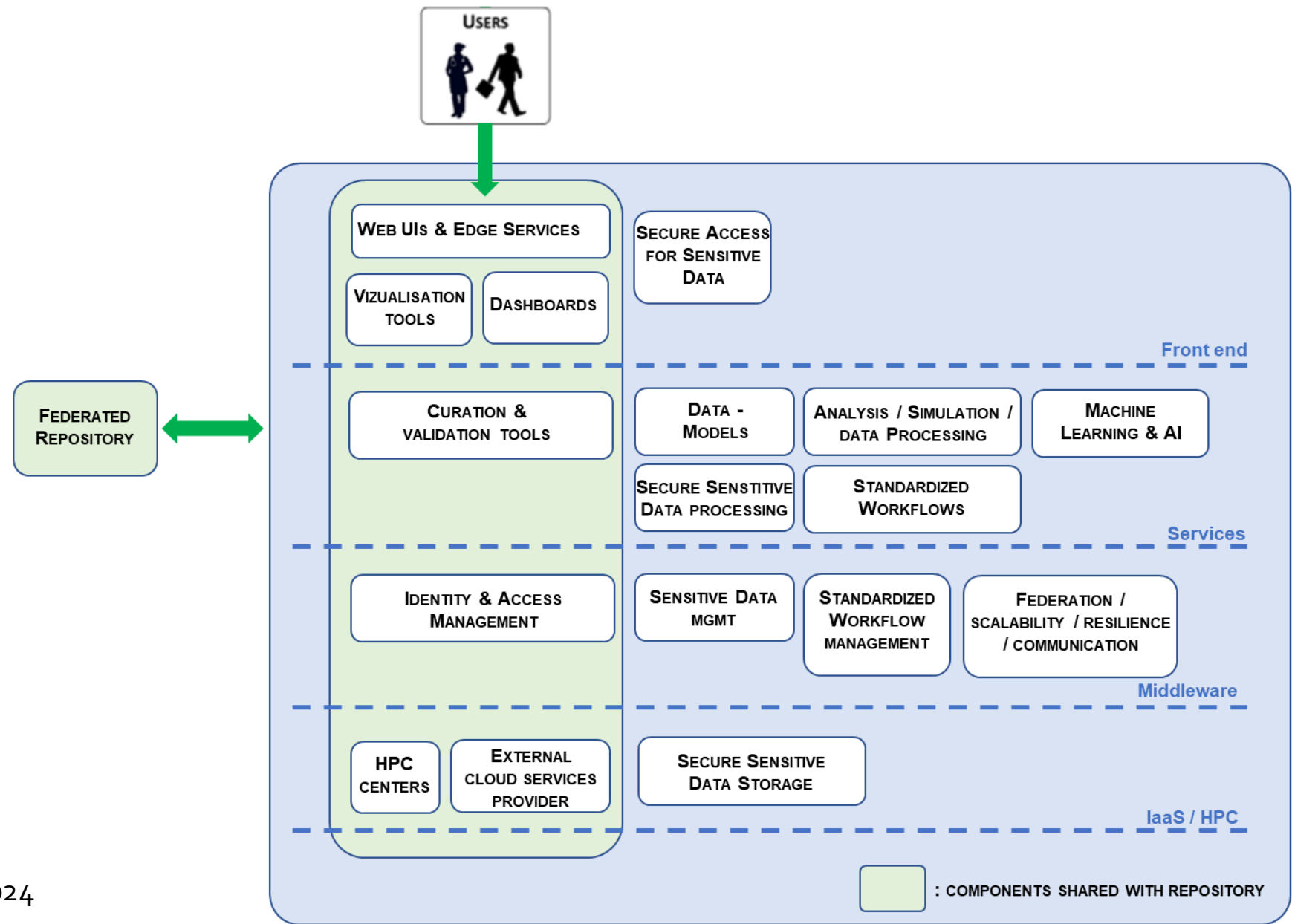
- Integration in clinical workflow
- Access
- Data & annotation

Pre-selected use cases

Partner	Topic	Model	Data	Computation	Integration	Use case(s)
BSC	Cancer (<i>PerMed Coe</i>)	Multiscale, agent-based	Single cell sequencing, images	HPC	Workflow in development	Personalised health forecast
U.Liège & UKA	Intensive Care (<i>Mill, STAR</i>)	Pharmaco- dynamics	Nutrition intake, glucose measurements, mechanical ventilation	Bedside, realtime	Parameter sensitivity	In silico clinical trials, Personalised treatment
QMUL & EPFL	Cardio-vascular (<i>CVDHub</i>)	mechanistic electromechanical model + with ML algorithm	Medical images (CT, MRI), electroanatomic mapping	HPC, GPU	Single-organ workflow established; integration with cancer use case	In silico clinical trials, Personalised treatment planning
UNIBO	Osteo-porosis (<i>BBCT</i>)	Mechanical model	Medical images	HPC	Single-organ workflow established	Personalised health forecast
JFZ + QMUL	Brain (<i>BigBrain</i>)	Data-driven model	Very large data-sets (1TB)	Distributed	Single-organ workflow established, integration with CV use case	Personalised treatment planning
HITS	Platform (<i>SEEK</i>)	Repository	Repository	Cloud	Development of API to link to EDITH repository	Linking EDITH to existing repositories



Possible architecture simulation platform



Digital Europe program: procurement for simulation platform (24 mio€) – DL 7/6/2024

To realise the VHT, work is required on:

- **Technology**

- Individual resources: data, models, algorithms
- Integration of resources
- APIs
- Infrastructure, networks
- Hardware: imaging, sensing...
- Connection EHDS, SIMPL

- **ELSI**

- Access, privacy
- Ethics, code of conduct
- Legal & policy aspects
- Regulatory considerations
- Standardization

- **Users**

- Different profiles
- Access & workflows
- Interaction with other platforms & repositories

- **Sustainability**

- Clinical uptake
- Large companies
- Start-ups
- Marketplace
- business modelling
- ERIC, EDIH

Integration

- Integration of models
 - Different levels (tissue & intracellular)
 - Different organ systems (e.g. heart & lung)
 - Orchestration : strongly vs loosely coupled
- Integration of data
 - Different types of data (e.g. images & wearables, omics & wearables)
- Integration of model & data [when data and models are not co-located]
 - Bring data to the model > data replication services
 - Bring model to the data > model containerization

Complementary to existing RIs



+ VHT



Roadmap for the Virtual Human Twin

Roadmap writing & validation

- **Design phase** (1/10/2023-31/7/2023)
 - Consortium, industry advisory board, expert meetings (covering all elements of ecosystem)
 - Public writing 1st draft
- **Develop phase** (1/8/2023-16/7/2024)
 - Manifesto, boards, expert meetings, ecosystem meeting
 - Public writing 2nd draft
- **Deliver phase** (17/7/2024-31/12/2024)
 - Ecosystem: public endorsement
 - Advisory boards: expert / political endorsement
 - EPF: patient endorsement



Published July 31, 2023 | Version v1

Project deliverable

Open

EDITH CSA Deliverable 3.2: first draft of the VHT roadmap

EDITH consortium

The VHT Roadmap is due – in its final version – by the end of the EDITH Coordination and Support Action (i.e., September 2024). The present document is the first draft of the Roadmap. This preliminary version of the Roadmap was planned in EDITH's Grant Agreement as an initial contribution to the internal decision-making process of the European Commission. It has the declared purpose of allowing the Commission to start specifying already at an early stage **by what steps the goal of pursuing the development of a VHT-based healthcare will be likely to trigger an effective engagement of Europe's researchers, clinicians, industries, and regulators.**

This interim version is therefore meant to highlight what is currently the **envisioned structure** of what will be in a year time the **final roadmap** and its main contents, leaving open the possibility that these contents can still be subject to both substantial and formal changes, in response to suggestions coming from both the European Commission and from different sectors of the broadening community of practice that the EDITH CSA is addressing.

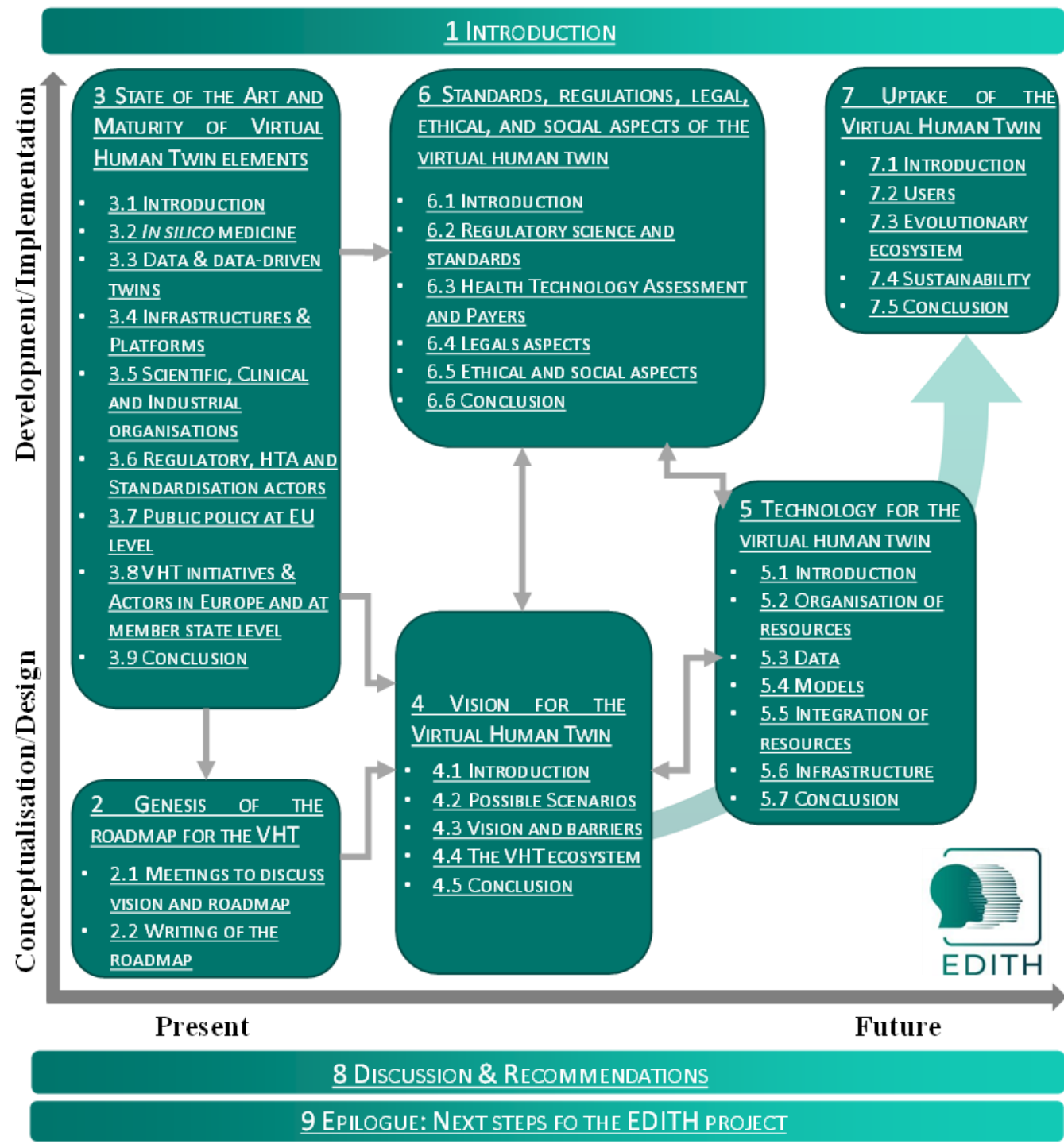
In consideration of these double-edge purposes, this preliminary draft aims to capture the **main concepts and the overall approach of the VHT Roadmap**, while also **identifying relevant challenges** (from the perspective of research, infrastructure, and other specific aspects) that need to be addressed in the remaining year of the EDITH CSA (and beyond) and which will require further analysis, with the support of the whole VHT Community. For the technology, standards, regulatory, and legal aspects, the draft provides an overview of the state of the art and an analysis of VHT-specific needs, without determining as yet any conclusive choice.

4K
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Downloads	2,625	2,554
Data volume	8.8 GB	8.6 GB

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Versions



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 - Ecosystem: public endorsement
 - Advisory boards: expert / political endorsement
 - EPF: patient endorsement



Manifesto for the Virtual Human Twin

- Driven by EC, facilitated by EDITH
- Why?
 - Way of demonstrating support from ecosystem
 - Increase visibility of VHT-related activities
 - High-level entry into the VHT
- <http://www.virtualhumantwins.eu>



 Centre for Advanced Research Computing	 ALMA MATER STUDIUM UNIVERSITÀ DI BOLOGNA	 Instituto Universitario de Investigación en Ingeniería de Aragón Universidad Zaragoza	 4RealSim	 Ansys	 aussie ergonomics	 ATHENA Research & Innovation Information Technologies	 FOUNDATION FOR RESEARCH AND TECHNOLOGY - HELLAS
CARC UCL - UK	UNIVERSITA DI BOLOGNA - ITALY	I3A UNIVERSIDAD ZARAGOZA - SPAIN	4REALSIM - THE NETHERLANDS	ANSYS - BELGIUM	AUSSIE ERGONOMICS - AUSTRALIA	ATHENA - GREECE	FORTH - GREECE
 Fraunhofer	 University of Sheffield INSIGNEO	 ΕΠΙΣΤΗΜΟΝΙΚΟ ΚΕΝΤΡΟ ICCS	 BioIRC	 BIOMAPAS Clinical, Regulatory & Pharmacovigilance	 BIOTRONIK excellence for life	 IMC inovatyvios medicinos centras	 Inria
FRAUNHOFER - GERMANY	INSIGNEO - UK	ICCS ATHENS UNIVERSITY - GREECE	BIOIRC - SERBIA	BIOMAPAS - LITHUANIA	BIOTRONIK - GERMANY	IMC - LITHUANIA	INRIA - FRANCE
 LINKÖPING UNIVERSITY	 Maastricht University	 POLITECNICO MILANO 1863	 Computational Life	 DASSAULT SYSTEMES	 Edwards Lifesciences	 BSC Barcelona Supercomputing Center Centro Nacional de Supercomputación	 CINECA
LINKOPING UNIVERSITY - SWEDEN	MAASTRICHT UNIVERSITY - THE NETHERLANDS	POLITECNICO DI MILANO - ITALY	COMPUTATIONAL LIFE - USA & ITALY	DASSAULT SYSTEMES - FRANCE	EDWARDS LIFESCIENCES - SWITZERLAND	BARCELONA SUPERCOMPUTING CENTER - SPAIN	CINECA - ITALY
 Tampere University	 Technische Universiteit Eindhoven University of Technology Where innovation starts	 upf. Universitat Pompeu Fabra Barcelona	 ELEM THE VIRTUAL HUMANS FACTORY	 HC SIMULATION, LLC	 healthskouts	 sano	 Salut/ Agència de Qualitat i Avaluació Sanitàries de Catalunya
TAMPERE UNIVERSITY - FINLAND	TECHNISCHE UNIV. EINDHOVEN - THE NETHERLANDS	UNIVERSITAT POMPEU FABRA - SPAIN	ELEM BIOTECH - SPAIN	HC SIMULATIONS - UNITED STATES	HEALTHSKOUTS - BELGIUM	SANO - POLAND	AQUAS - SPAIN
 UCL Lyon 1	 UNIVERSITEIT VAN AMSTERDAM	 UCD DUBLIN University College Dublin	 "Initiatives for Bio-Materials Behaviour" ISMB Site	 insilicare	 InSilicoTrials	 COCIR Advancing healthcare	 DIGITALEUROPE
UCLB LYON1 - FRANCE	UNIVERSITEIT VAN AMSTERDAM - THE NETHERLANDS	UNIVERSITY COLLEGE DUBLIN - IRELAND	ISMB - ITALY	INSILICARE - BELGIUM	INSILICOTRIALS - ITALY	COCIR - BELGIUM	DIGITALEUROPE - BELGIUM
 IsiTwin In silico Twin Solutions	 LYNKEUS STRATEGY CONSULTING BLOCKCHAIN & SMART CONTRACTS DATA ANALYTICS	 MDSim Predict Excellence	 UNIKLINIK RWTHAACHEN	 UNIVERSITY OF BERGEN	 University of Cyprus	 Amsterdam UMC Universitair Medische Centra	 CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN
ISITWIN -FRANCE	LYNKEUS - ITALY	MDSIM - LUXEMBOURG	UNIKLINIK RWTH AACHEN - GERMANY	UNIVERSITY OF BERGEN - NORWAY	UNIVERSITY OF CYPRUS - CYPRUS	AMSTERDAM UMC - THE NETHERLANDS	CHARITE - GERMANY
 Mediolanum Cardio Research	 nova DISCOVERY	 numericor	 UNIVERSITY OF LIVERPOOL	 UNIVERSITY of NICOSIA	 UNIVERSITY OF OXFORD	 JÜLICH Forschungszentrum	 VPH Institute Building the Virtual Physiological Human
MEDIOLANUM CARDIO RESEARCH - ITALY	NOVA DISCOVERY - FRANCE	NUMERICOR - AUSTRIA	UNIVERSITY OF LIVERPOOL - UK	UNIVERSITY OF NICOSIA - CYPRUS	UNIVERSITY OF OXFORD - UK	JULICH - GERMANY	VPH INSTITUTE - BELGIUM
 PHILIPS	 SANOFI	 SERVIER	 UNIVERSITY OF WEST BOHEMIA	 VRIJE UNIVERSITEIT AMSTERDAM	 VRIJE UNIVERSITEIT BRUSSEL	 eatris European infrastructure for translational medicin	 IAC
PHILIPS - THE NETHERLANDS	SANOFI - FRANCE	SERVIER - FRANCE	UNIVERSITY OF WEST BOHEMIA - CZECH REPUBLIC	VRIJE UNIV. AMSTERDAM - THE NETHERLANDS	VRIJE UNIV. BRUSSEL - BELGIUM	EATRIS - EU/THE NETHERLANDS	IAC CNR - ITALY
 SIEMENS Healthineers	 SIMA GmbH	 twinsight twinsight-medical.com	 GHENT UNIVERSITY	 KIT Karlsruher Institut für Technologie	 KU LEUVEN	 Erasmus MC Universitair Medisch Centrum Rotterdam	 vito
SIEMENS HEALTHINEERS - GERMANY	SIMA GMBH - GERMANY	TWINSIGHT - FRANCE	GHENT UNIVERSITY - BELGIUM	KIT - GERMANY	KU LEUVEN - BELGIUM	ERASMUS MC - NETHERLANDS	VITO - BELGIUM
 Virtonomy.io	 VCLS Voisin Consulting Life Sciences	 ISPPA INTERNATIONAL SPINAL PAIN PATIENTS ASSOCIATION	 Transilvania University of Brasov	 SERVIZIO SANITARIO REGIONALE EMILIA - ROMAGNA Istituto Ortopedico Rizzoli di Bologna Istituto di Ricovero e Cura a Carattere Scientifico	 ELPA European Liver Patients' Association	 DIN	 PANETTA law firm
VIRTONOMY - GERMANY	VOISIN CONSULTING - FRANCE	ISPPA - UK	UNIVERSITY OF BRASOV - ROMANIA	IRCCS RIZZOLI - ITALY	EU LIVER PATIENTS' ASSOCIATION - BELGIUM	DEUTSCHES INSTITUT FÜR NORMUNG - GERMANY	PANETTA LAW FIRM - ITALY

Sustainability & Ecosystem involvement

- Develop and promote specific (**policy**) **recommendations** to further the development of the VHT ecosystem, infrastructure and uptake.
- Develop **incentive mechanisms** for developers/researchers for uploading and/or making their resources available on the federated infrastructure.
- **Promote buy-in** in the community, targeting resource developers (modellers, infrastructure providers, data collections) and users, but also regional & national initiatives in EU27.

EDITH-CSA Ecosystem Meeting

15 & 16 July 2024 | KIT Royal Tropical Institute, Amsterdam



Roadmap writing & validation

- **Design phase** (1/10/2023-31/7/2023)
 - Consortium, industry advisory board, expert meetings (covering all elements of ecosystem)
 - Public writing 1st draft
- **Develop phase** (1/8/2023-16/7/2024)
 - Manifesto, boards, expert meetings, ecosystem meeting
 - Public writing 2nd draft
- **Deliver phase** (17/7/2024-31/12/2024)
 - Ecosystem: public endorsement
 - Advisory boards: expert / political endorsement
 - EPF: patient endorsement



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Deliverables available under tab 'dissemination/material'

Sign up for updates under 'get involved/contact form'

Access roadmap files for providing input/feedback under tab 'roadmap'



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