

# Digital Health Economics breakout session

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# Digital Health Economics: an introduction

Edwin Morley-Fletcher  
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# The European Virtual Human Twins Initiative

The **European Virtual Human Twins Initiative** was launched in December **2023** by the European Commission, together with the Virtual Human Twin **Manifesto** supported by a large number of industries and research centres.

# The Manifesto

The Manifesto, among other things, states that:

- delivering the benefits of VHTs for human health requires a **robust ecosystem approach**.
- VHT research and innovation must be oriented towards **establishing VHTs as a platform technology**, generating evidence and value for healthcare and society as a whole, with an ecosystem ensuring **incentives for excellence, regulatory certainty and trust**.

# There is some engaging background

You are quite likely to have already come across the promise of a **European Health Data Space** (EHDS).

The EHDS is one of the central building blocks of the **European Health Union** and a milestone in **EU's digital transformation**.

Now there is even a **Manifesto for a European Health Union**, which is collecting signatures advocating a **Treaty change** for a European Health Union.

# Though still facing a difficult “problem tree”

As summarised in the **European Health Data Space Impact Assessment** on 03. 05. 2022



# It had all started some time ago

Already in **2017** the European Commission had recommended an increase in coordination efforts on the **digital transformation of health and care** in Europe, focusing on three priorities:

- support to **data infrastructures** to advance research, disease prevention and personalised medicine;
- facilitate **feedback and interaction between patients and healthcare providers**, supporting citizen empowerment and a better understanding of outcomes in healthcare systems;
- leverage the **advanced digital technologies** which can help improve citizens' health and address challenges in the healthcare systems of EU Member States.



# Virtual Human Twins

In the current context, where **scientific breakthroughs** are taking place in:

- medical imaging, molecular, biomarker and single cell analyses, genome sequencing and other omics domains,

in tandem with:

- scientific computing, advanced IT architectures, new data acquisition tools and techniques, and artificial intelligence,

**Virtual Human Twin (VHT)** based solutions have been understood as able to capitalise on these trends and **help realise significant benefits**.

The VHT signifies a **sciencebased, integrated, dynamic, reliable computational representation of human pathophysiological processes at different anatomical scales**.

It leverages **novel computational methods, advanced computing capacities, and health data drawn from various sources**.



# VHTs hold enormous potential in health and care

Being persuaded that VHTs can make a very significant contribution to achieving the goals of the European Health Union, the European Commission has launched **three initiatives**:

1. The **Coordination and Support Action EDITH**, started in October **2022** and terminating in December 2024, with the triple mission of:
  - defining a roadmap to go from separated single organ systems to a data-driven and knowledge-driven fully integrated multi-scale and multi-organ whole-body twin;
  - developing a federated and cloud-based repository gathering human digital twin resources;
  - outlining the architecture of a simulation platform to facilitate the transition towards the use of comprehensive Virtual Human Twin models in personalised medicine.
2. The already mentioned **European Virtual Human Twins Initiative**, launched in December **2023** with the Virtual Human Twin **Manifesto**.
3. A **procurement tender**, launched in April **2024**, for:
  - building a state-of-the-art platform to enable modelling across scales of human anatomy;
  - support the emergence of the next generation of VHT models;
  - in full compliance with EU values and rules (private, safe and secure).

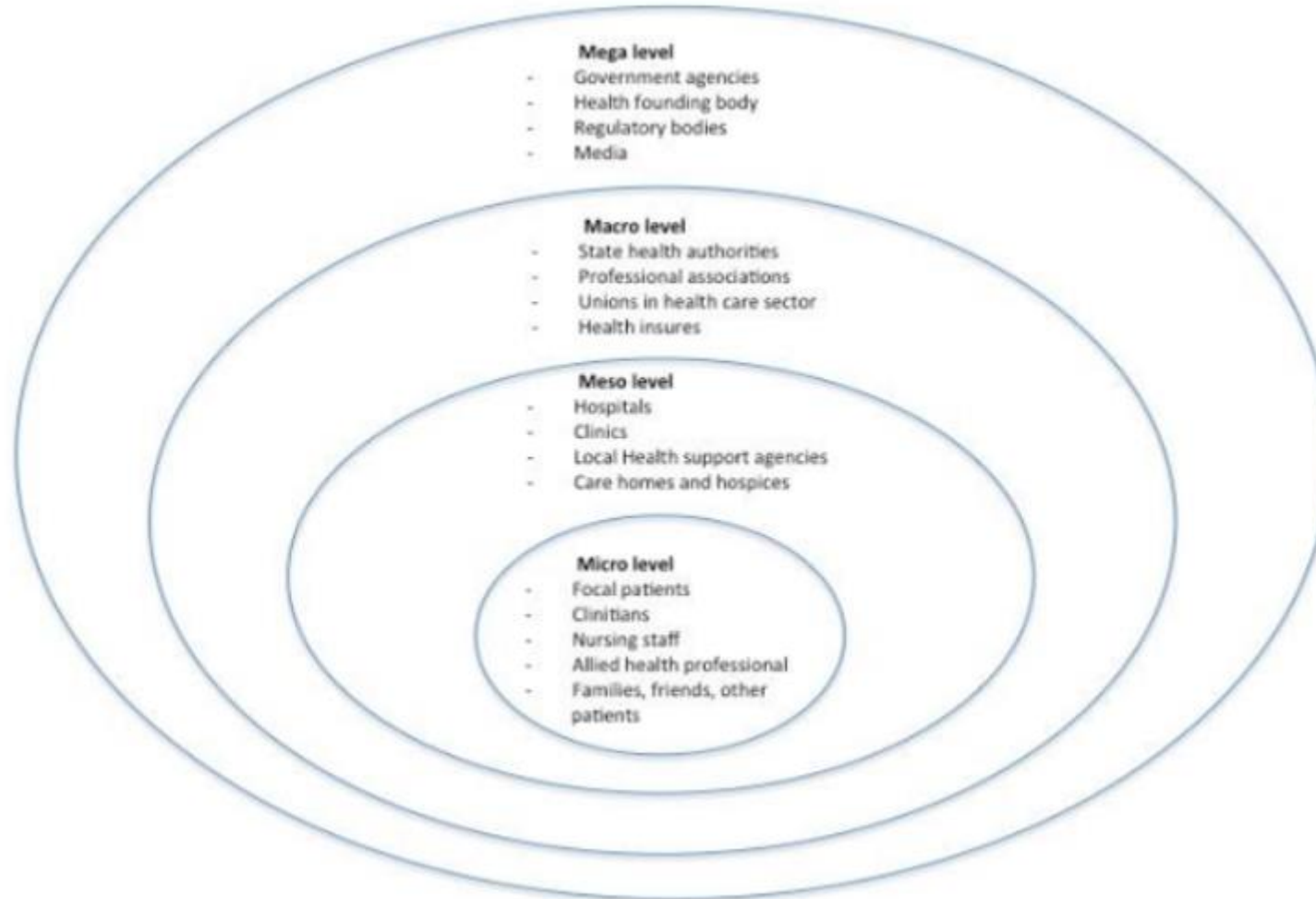


# Let's come back to the “robust ecosystem”

The Manifesto stated that “delivering the benefits of VHTs for human health requires a robust ecosystem approach”.

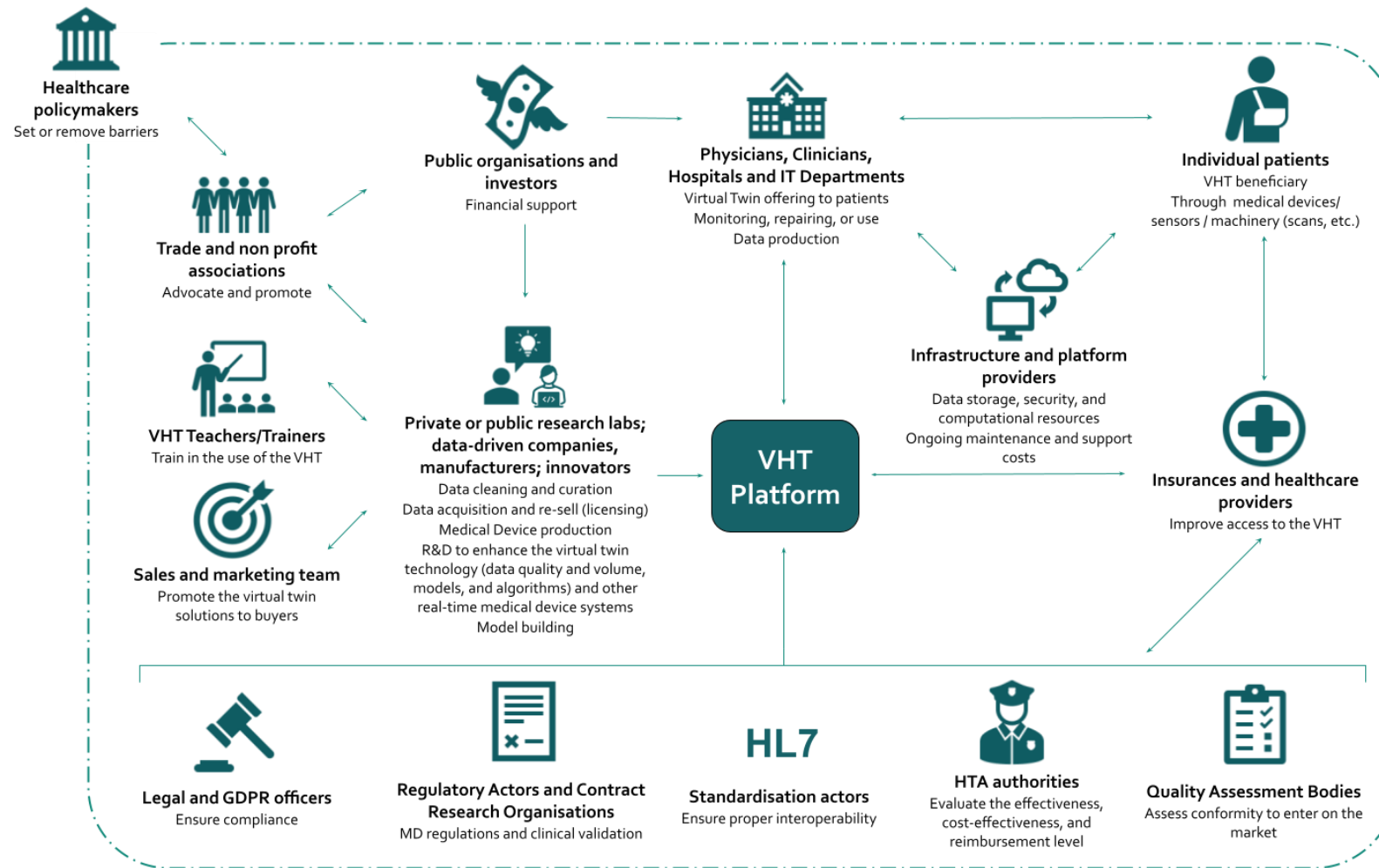
What does that mean?

# A traditional image of the healthcare ecosystem



Frow et al, Co-creation practices: Their role in shaping a health care ecosystem, Industrial Marketing Management, Vol. 56, July 2016, pp. 24-39.

# The EDITH current image of the VHT ecosystem



# What is an ecosystem in digital economics ?

- Borrowed from biology, in economics the term ecosystem generally refers to a group of interacting entities that depend on each other's activities.
- These interdependent entities have varying degrees of complementarity, i.e. they can achieve some alignment though operating with significant individual autonomy.
- All together they form a **sybiotic community capable of converging** on the adoption of strategies by which:
  - each entity reinforces each other
  - collectively they can overcome multiple co-evolution challenges
  - decreasing risks
  - increasing certainties.
- This ecosystem is **an organisational structure which is different from both hierarchies and markets.**
- Its level of interaction depends on the flows of resources and information.

# Standards and ecosystems

- **Standards can be considered as institutions** that can be created through purposive actions and which play a fundamental role in supporting the success of ecosystems.
- The development of ecosystems faces **a key challenge**: the participating actors' existing work-practices and technological solutions cannot be spontaneously harmonised.
- For an ecosystem to succeed, **standards must be developed and implemented**, which is clearly highly challenging in the absence of an orchestrating leader.

# An ecosystem orchestrator

- Technological change requires coordinated responses, but decentralised ecosystems may face the **risk of creating inadequate decision-making structures** to manage complex interdependencies.
- A **crucial pre-condition** is the presence of an ecosystem orchestrator being, by design:
  - a central agent at the nexus of a distributed network of value creators,
  - tracking, monitoring, nudging and (when necessary) steering a fruitful use of resources without needing to own them.



# An apparent oxymoron

Ecosystems have been defined as **interdependent networks of self-interested actors jointly creating value**, under specific circumstances which need to be carefully analysed.

Ecosystems **do not just “emerge” spontaneously**. They are at least, in part, the result of deliberate experimentation and engineering from different parties.

In a way, whoever sets the goal of building an ecosystem, engages into an exercise of designing the **coexistence of emergence and intentionality**.

Planning the spontaneous attainment of an intentional outcome may seem an oxymoron.

In fact, what is meant is **designing appropriate preconditions** that allow the emergence of something that is intentionally pursued, though its effects, depending on multiscale nonlinear interactions, remain partially unpredictable.

Platforms leaders face the broad challenge of designing and orchestrating digital ecosystems.

# A non-hierarchical alignment

An innovation ecosystem aggregates all **actors whose contributions are essential to generate interrelated innovations.**

A platform ecosystem aggregates developers of **complementary and interdependent products** required to extend the value of a core platform technology.

Both are characterised by:

their “**generativity**”— i.e., the capacity for the continual creation of variant system components offering new affordances to the technology user.

a modular interorganisational architecture that enables **a non-hierarchical alignment** of actors' interests.

governance arrangements that are functional to **internalize the externalities** of these cooperation interdependencies.

# A new digital economy

The expansion of **digital technologies** and the proliferation of **modular production methods** have unlocked **opportunities for a completely different type of firm.**

In place of vertically and horizontally integrated corporate behemoths, or industrial conglomerates, there has been the emergence of **ecosystems orchestrators** with the ability of collaborating with a range of complementors to create and capture value.

# Hierarchies, markets, and ecosystems

Strong interdependencies in non-contractible decisions drive the emergence of integrated, hierarchical organisations, while weak or non-existent interdependencies are associated with a nonintegrated, market-like regime.

Modularization and the subsequent reduction of frictional transaction costs are more likely to lead to the emergence of ecosystems.

For ecosystems to be useful, there must also exist a significant need for coordination that cannot be dealt with in markets, but which also does not require the hierarchy structure of a central actor.

# Reduction of uncertainty

**The digital revolution has given rise to economies of a different nature:** it has made it possible to identify and exploit complementarities across users, machines, and sectors through the use of data, software, and networks.

Digital technologies enable individuals to connect with other individuals and organisations **with minimal friction**.

Because transactions are digitally mediated, we can observe behaviours which were previously unobservable and write contracts on them.

This **reduction of uncertainty helps reduce the need for ownership of resources**, which was previously compensating by hierarchical control excessive transaction costs.

# Transaction costs

Firms keep activities in-house when the transaction costs of using the market (including contracting) reduce value capture relative to in-house provision.

Similar transaction costs considerations apply to platform leaders in **deciding which activities to outsource and which activities to keep in-house.**

Firms have integrative capabilities, knowing how to integrate different activities and products within a vertical chain or across vertical chains.

When they possess comparative integrative capabilities, platform leaders can **orchestrate external complementary asset providers and users** on different sides of a platform and the costs of transacting with these partners is likely to be lower.

# Coordination without hierarchical governance

Ecosystems allow for some degree of coordination without requiring hierarchical governance precisely because of the ability to use some standards or base requirements that **allow complementors to make their own decisions** (in terms of design, prices, etc.), while still allowing for a complex interdependent product or service to be produced.

Ecosystems are groups of firms that must deal with complementarities requiring the creation of a **specific structure of relationships and alignment** to create value.

Platform ecosystems tend to emerge when there are **intermediate levels of interdependencies** making it possible for different ecosystem players to complement each other in order to bring added value and the required interaction **establishing win-win connections**.

This allows us to distinguish between ecosystems and supply chains since **in supply chains the hub has hierarchical control**—not by owning its suppliers, but by fully determining what is supplied and at what cost.



# Multi-sided platforms

A key aspect of Digital Economics is now the theory of Multi-sided platforms (MSPs)

MSPs have attracted a lot of attention for their indirect network effects, which, under certain conditions, have shown the capacity of driving competition between platforms to a “winner takes all” outcome.

MSPs cumulate mutually reinforcing network effects through the implicit support derived by each of the sides served by the platform, often needing to subsize at least one side to overcome the “chicken and egg” problem and enable growth and subsequent adoption on the other side.

MSPs thus appear to be the organisation model showing the greatest capacity to scale.

MSPs thus initially appear to go for growth, not for profits, since that is what markets value, turning traditional industry dynamics on their head.

Digital platform firms and their ecosystem are, for the time being, the emblematic organisational form of the digital age.

Platform ecosystems have proved to be a powerful force in reshaping industries and, in all likelihood, they should show a comparable potential of disrupting innovation also in healthcare

# How the EC tackles the VHT “chicken and egg” issue

It is highly to be commended that the European Commission has engaged in initiating such an ambitious and far-reaching transformation of the EU healthcare systems as implied by the Virtual Human Twins by squarely facing the chicken and egg issue of **fostering the VHT ecosystem while procuring a Platform for Advanced Virtual Human Twin Models**, and showing all willingness of **significantly funding new research and innovation projects** in this crucial area.

The expectation is therefore to trigger big changes in the next years, precisely leveraging the bold realisation of an essential precondition and **strategic orchestration vantage-point** as provided by this platform.

# An innovation procurement

**“The strategic use of public procurement to boost innovation is closely connected to the power to shape and create market conditions”** (Public Procurement in Healthcare Systems, Opinion of the Expert Panel on effective ways of investing in Health, 2021).

Decisions to adopt, use or reimburse new digital health services are ideally based on **evidence regarding their performance in the light of health systems goals, including quality, accessibility, efficiency and equity.** (Assessing the Impact of Digital Transformation of Health Services, Report of the Expert Panel on effective ways of investing in Health, 2019).

# An interesting policy riddle

Let me draw, therefore, your attention to the very recent procurement tender launched by the European Commission:

**the Platform for Advanced Virtual Human Twin Models.**

I think that its interpretation deserves a closer look, since it may possibly open the way to surprising policy consequences.

# Co-simulation

This procurement aims at setting in motion the **co-simulation paradigm**:

- enabling ecosystem member organisations and individuals to actively collaborate on a structured basis
- partner and cocreate the tools, methods and techniques to integrate and validate advanced models
- supporting productivity, ELSI compliance, evidence generation on advanced model efficacy, safety and usability with novel IT architectures closer to care and research use settings.

# Three distinct fully interoperable software products

The tender specifications for the Advanced Platform for VHT Models have been very detailed (107 pages) and have addressed three distinct goals:

- the **VHT Federated Repository** of VHT datasets, models, and other resources
- the reference implementation **Access Federator** for building and visualising simulations
- the **Orchestrator of computational services** for running these simulations on linked computing and storage resources.

# Support and Capacity Building Services (SCBs)

SCBs provide support to platform software and service development.

The full definition of the **VHT Framework** based on **data and models annotation, metadata, ontologies, supporting interoperability of data and model assets**, is part of SCBs.

SCBs involve ecosystem actors as users, and include the **Intellectual Property Rights Management policy** to design and implement and the development of a suitable **ethical, legal and societal (ELSI) governance framework** for advanced VHT models, and support for **legal and ethical compliance**.

This area implies taking into account what need to be “**an evolutionary ELSI basis**”, also because “in a future phase not in scope of this procurement, the platform may federate with EU healthcare data and other infrastructures”.



# What types of data can be used on the platform?

Only **data for enabling the identification of users accessing the platform** and **anonymous** or **non-identifying synthetic** human health and disease data are allowed for use.

**Human health and disease data** and datasets utilised in model integration and validation, co-simulations, workflows including pre- and post-processing and related activities as part of platform operations must be **either anonymised**, or **synthetically generated** human health and disease data that are **confirmed as anonymous**.

Any **anonymisation and synthetic data generation** processes and tools are within the **sole remit of the users**.

Any processing towards data anonymisation and synthesis shall take place within the user organisations' organisational and infrastructure boundaries and business processes, and not within or through any of the components and infrastructure of this platform system.

# Pseudonymised data shall not be admitted

Use of **anonymised and non-identifying synthetic** human health and disease data, as well as of anonymous statistics derived from human datasets, **do not fall within the scope of the GDPR.**

**In this first phase** of platform operations, **no personal data concerning health and genetic data**, collected and managed by user organisations for purposes they define, **shall be admissible to the platform.**

In the VHT and related domains, personal data concerning health may also be understood as pseudonymised personal health data. **Pseudonymised data shall also not be admissible to the platform within this procurement.**

**This approach** to the type of data admissible to the platform **may be revised in a later phase**, after the end of the Framework Contract.

# Anonymisation conditions

Regarding anonymised data use, all users, before uploading anonymised human health and disease datasets and making them available to other users with registered access, are subject to the following conditions:

1. any anonymised human health and disease datasets to be used within the advanced VHT platform complies with the EU and national laws and regulations and anonymisation requirements;
2. the user data provider must implement and ensure total, **irrevocable and definitive irreversible anonymisation** of any human health and disease dataset(s) intended for use on the platform.
3. in regard to synthetic data, a “**privacy assurance assessment**” will be mandatory for users to ensure that resulting synthetic dataset do not include personal data concerning health.

# Background intervention by the General Court of European Union

On 26 April 2023, the **General Court of European Union** has adopted a crucial decision regarding the issue of data pseudonymisation, in the case **SRB v. EDPS (T-557/20)**.

By this decision, **whenever re-identification is practically unfeasible for an entity receiving pseudonymised data**, because it is not provided with the additional information or other means necessary for reidentification, then specifically and solely for this entity the pseudonymised information is not to be considered as constituting personal data. Therefore, data protection legislation would not apply, and such **pseudonymised data would be de facto sharable as anonymous data**.

The **EDPS has brought an appeal to the General Court**, and the final ruling is certainly going to have a marked impact on the regulation of all situations in which the re-identifiability of data subjects is at issue in relation to pseudonymous data.

# A conservative approach

For the moment, it is worth noting that in this VHT platform procurement the European Commission is still adopting the approach stemming out of the **interpretation of anonymisation dating from WP29's Opinion 05/2014** ("total, **irrevocable and definitive irreversible anonymisation**") without questioning whether this should be compatible with the more flexible criterion of '**reasonable re-identification**' established by Recital 26 of the GDPR.

Furthermore, the European Commission follows the novel rules of the Artificial Intelligence Act, where (at Articles 10. 5 and 59.1,b) **synthetic data** are explicitly considered as **equivalent to anonymous (or other non-personal) data**, but additionally requests the mandatory implementation of a **Privacy Assurance Assessment**.

# How to interpret this (initial) restriction ?

The (provisional?) restriction to anonymised data and synthetic data marks a significant **differentiation** with what had been indicated as **Legitimate basis for Data Processing** in relation to the projected uses of the Simulation Platform, as initially designed within EDITH in its first dedicated report in **January 2024**.

Possibly, **changes** are expected with the **European Health Data Space**, which is the strategic initiative aiming to establish a secure and interconnected platform for the exchange and utilisation of healthcare data across EU member states.

But we've seen already the difficulties this still has to face, according to the EHDS Impact Assessment.

For sure, the **VHT transformation relies on health data** as a fundamental source of its realisation, development and implementation.

Defining the essential issue of health data makes **EHDS** of **pivotal importance to VHT** technology to move forward and beyond.

# Further data economy implications

1. The “European strategy for data” highlights **Personal Data Brokers (PDBs)** and **Personal Information Management Systems (PIMS)** as **building blocks of a fair and transparent data-driven digital economy supported by the right for data portability.**
2. PDBs and PIMS are important new intermediaries to empower consumers in the personal data economy.
3. PDBs should also enable personal data markets by offering consumers financial rewards for the data that they have created at online **content and service providers (CSPs)** as a by-product of their usage of these services.

# Data portability

- Data portability rights allow users to access the data stored about them at any CSP free of charge and in a machine-readable format, and to transfer that data to a third party of their choice.
- **Article 20 GDPR** demands explicitly that **CSPs shall transfer the respective user data directly to a third party if instructed to do so by a user.**
- Consequently, user data can be transferred to the PDB at relatively low transaction costs and even if consumers are not very technology-savvy.



# Data altruism

- The Data Governance Act (DGA) formalises the concept of **data altruism**, whereby individuals or businesses give their **consent or permission to make available data** that they generate – **voluntarily and without reward** – to be used **in the public interest**.

# An ongoing policy debate

- How will the EHDS encompass the operational functioning of entities being qualified as EU recognised data intermediaries and EU recognised data altruism organisations?



- How will these important developments be reflected in the way in which the VHT ecosystem is analysed in EDITH's roadmap?

# There is also the possibility of a more radical interpretation

Of course, the indication of using **“synthetically generated human health and disease data that are confirmed as anonymous”** may be interpreted as an unexpectedly conservative provisional first step, aimed at ensuring that the innovation procurement of VHT platform can operationally start to function without incurring in any data protection issue.

Conversely, it **could also be seen as a significant strategic choice**, motivated by the persuasion that **synthetic data will define the future of artificial intelligence** (AI), allowing machine learning (ML) models to use enormous amounts of training data to discern patterns, make decisions, and render predictions, triggering **a recursive loop, where AI systems generate synthetic data, which then train other AI systems.**

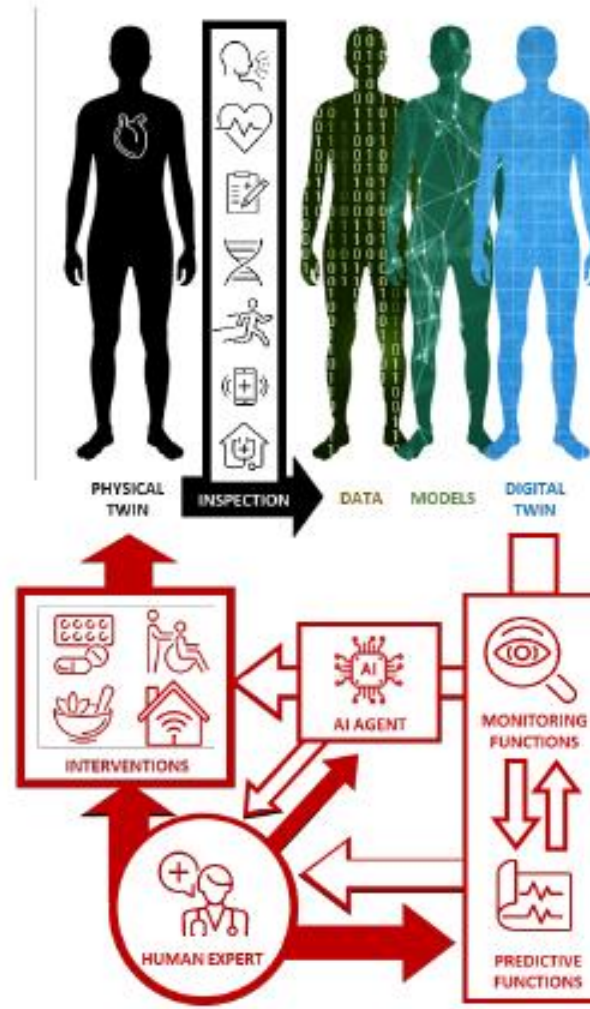
# An apparent paradox

In this hypothesis, such an iterative process, based on the interaction of AI and data synthesis, would be precisely and paradoxically launched **in a domain like VHT**, in which, **by definition, each virtual human twin personalised prediction will eventually need to be applied to concrete specific Real World individuals.**

Following this line of thought, should we presume that, considering the VHT transformation a general key objective which must not to be missed, the European Commission has **boldly decided to procure a platform** which will initially operate with great **abundance of synthetically generated and low-cost data**, where the complex EU regulatory framework is leveraged to move to synthetic data-based AI?

Or is this, more likely, just **a potential outcome** on which the Commission has eventually stumbled, **by trying first to be cautious and becoming then constrained to be bold?**

# A take-away image



Barresi et al.. Digital Twins and Healthcare: Quick Overview and Human-Centric Perspectives. mHealth and Human-Centered Design Towards Enhanced Health, Care, and Well-being, 120, Springer Nature, pp.57-78, 2023, Studies in Big Data.

# Thank you

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



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



# Business Models in a digital health context for the VHT

# EDITH: Foster a sustainable ecosystem

- How to ensure sustainability?
- Who will be the stakeholders in the ecosystem?

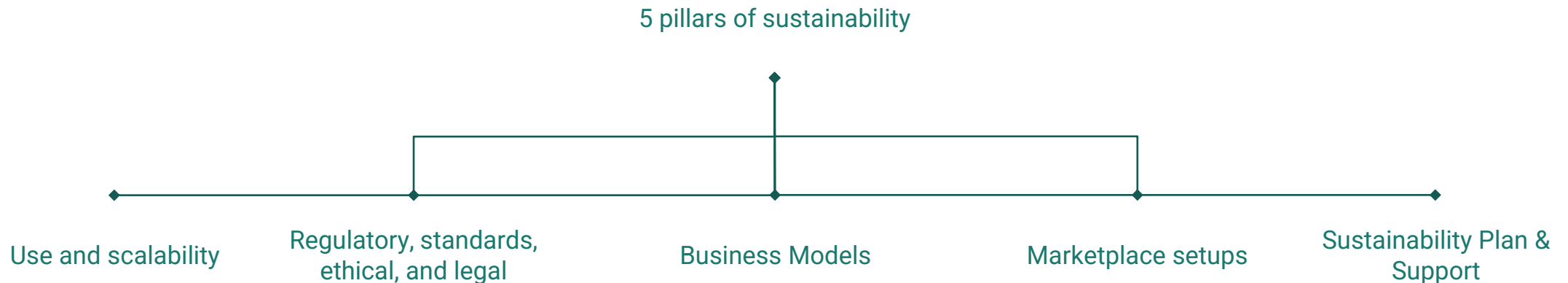
We have divided the analysis in 5 pillars

We have identified who will take part in the VHT ecosystem



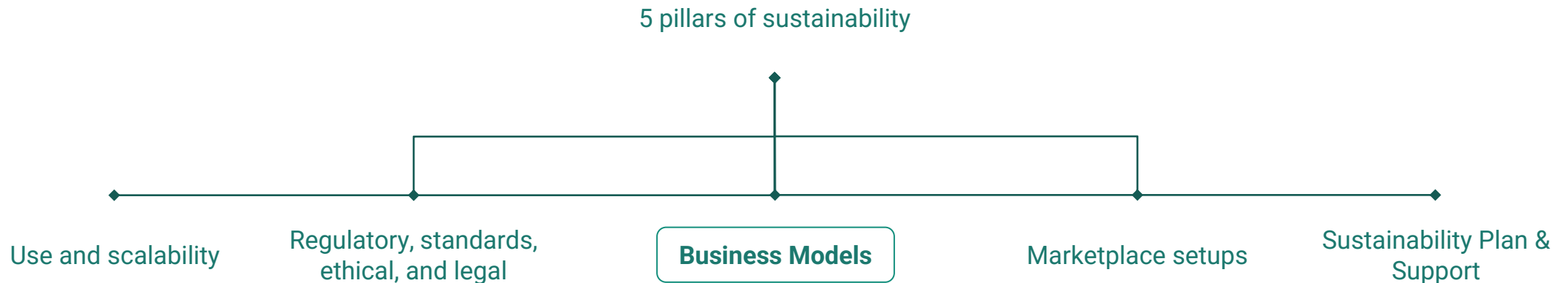
# VHT Sustainability — Main objectives

- Early prototype demonstrators of the simulation platform by means of the pre-selected use cases
- Develop recommendations on regulatory, standards, ethical and legal elements (simulation platform).  
Develop code-of-conduct.
- Ensure EDITH Sustainability through exploration of business models, marketplace options and sustainability.

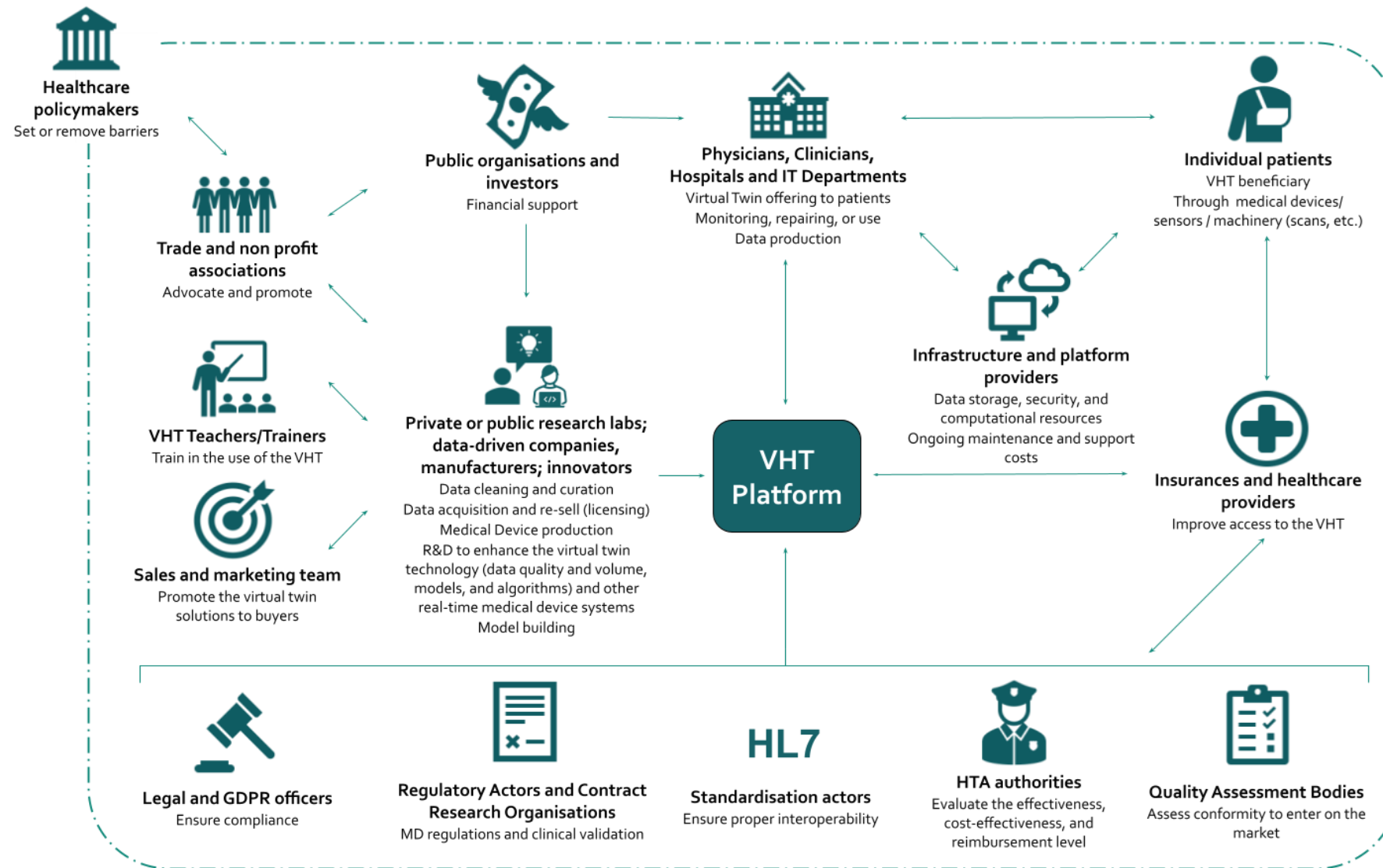


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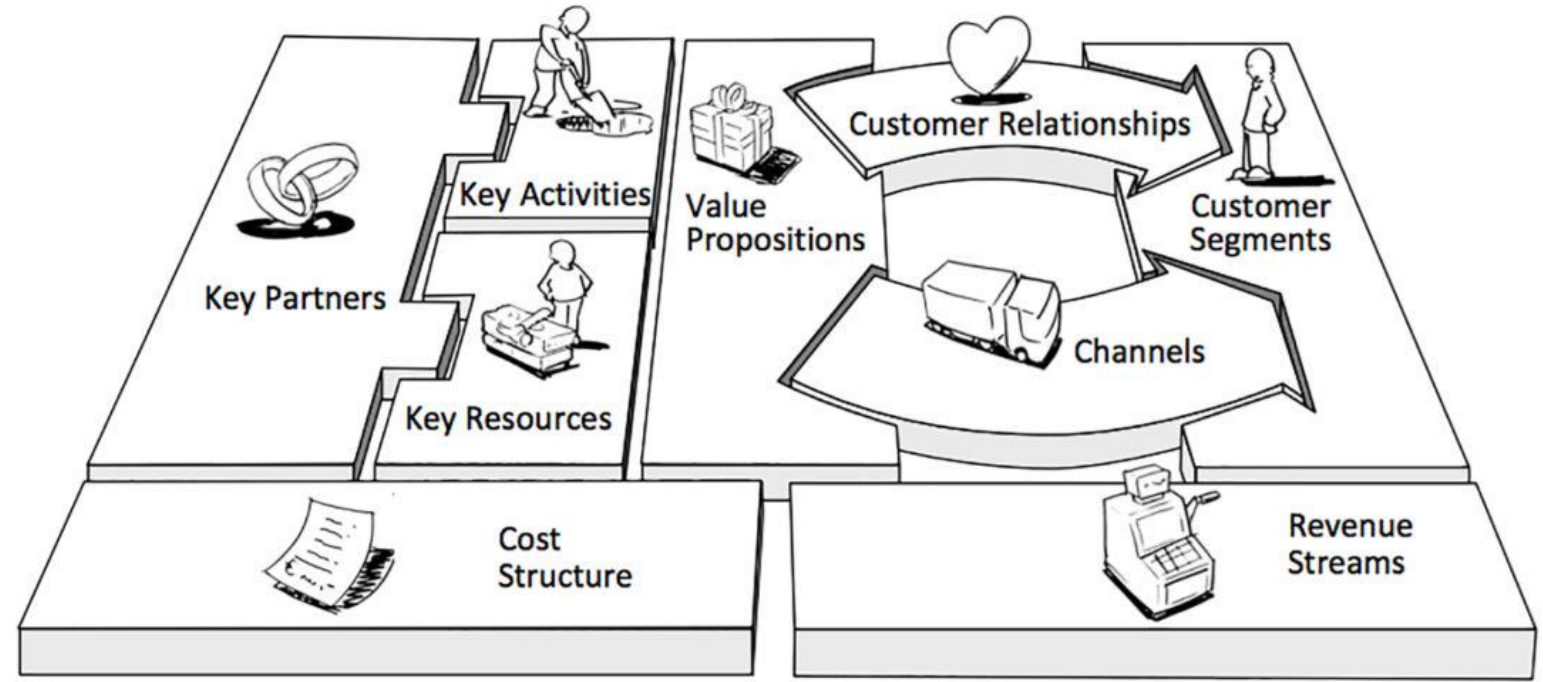


# VHT Ecosystem: composition, roles and interactions



# Business Model Canvas (Osterwalder & Pigneur, 2010)

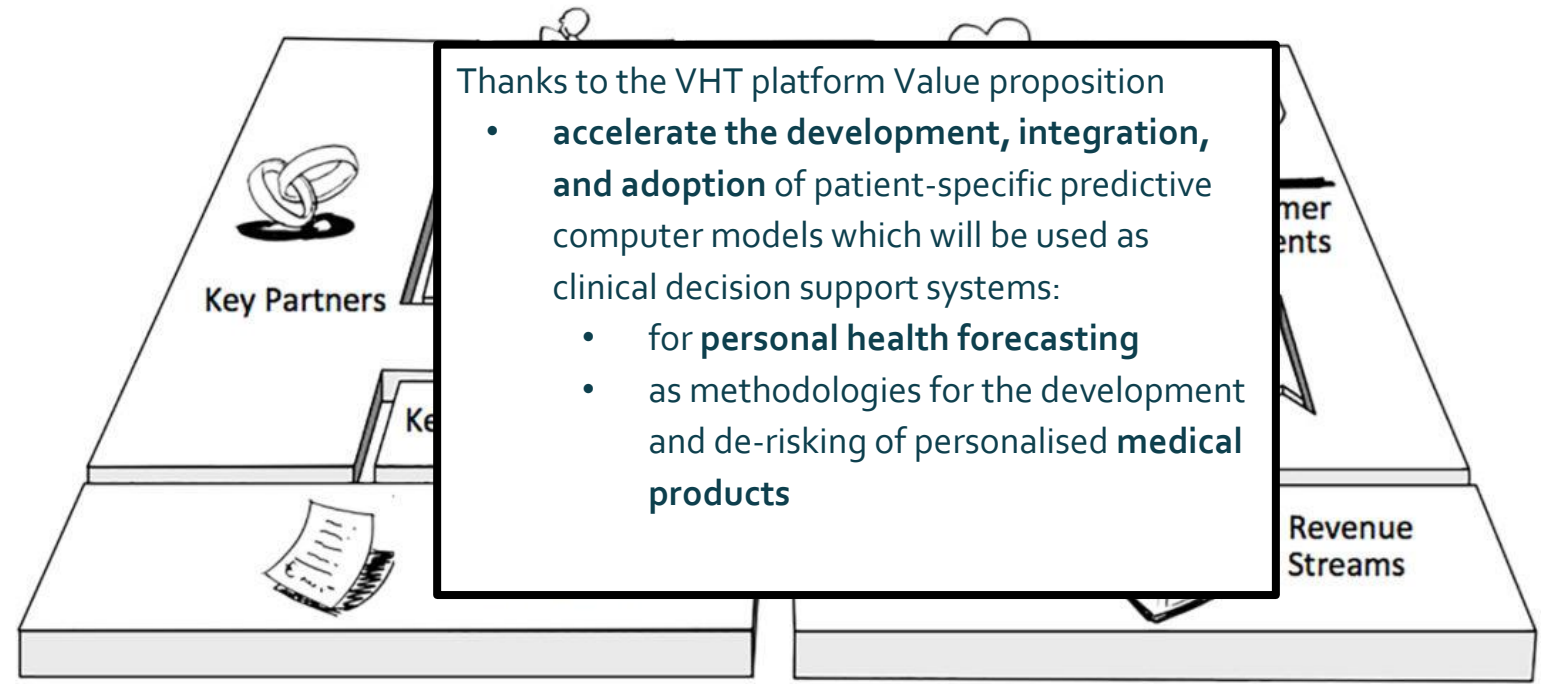
- Business Model Canvas analysis: a **widely used tool** in the startup environment that provides a broad vision of
  - incoming and outgoing cash flows,
  - the **value proposition** provided by a company,
  - its **customers and the relationship** with them,
  - the way in which **collaborations** can be made, and
  - the **key activities and resources** that can demonstrate the added value of the company/organization involved in VHT platform.
- Our initial approach has been to interview each UC partner about their respective Digital Twins and its foreseen use at TRL8+



Adapted from 'Business Model Generation', Alexander Osterwalder, Wiley 2012.  
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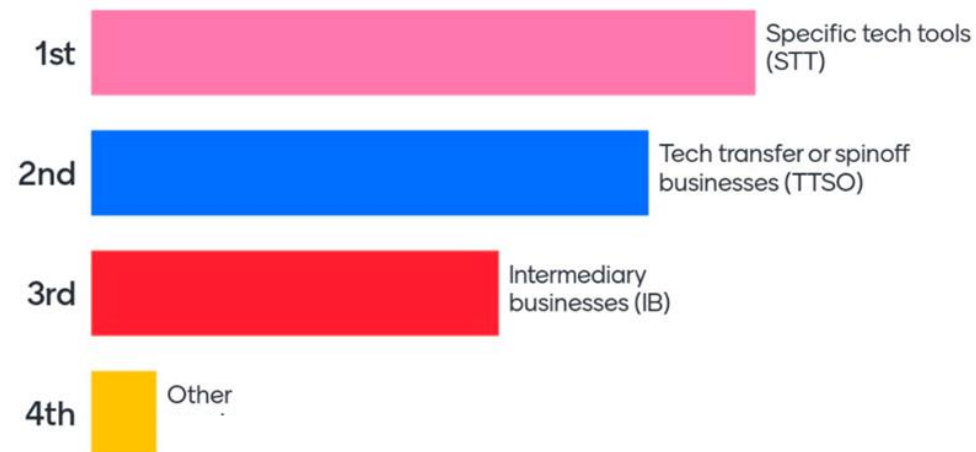
# Foreseen business model types

- A variety of business models are possible, depending on the maturity level of the specific Virtual Twin and on the economic situation:
  - **Tech transfer or spinoff businesses (TTSO):** starting from university and research lab, going towards ad-hoc created spinoffs and then (sometimes) to health industries
  - **Specific tech tools (STT):** from private deep tech companies specialized in specific fields that provide optimization or support in the use of a particular Virtual Twin
  - **Intermediary businesses (IB):** everything that brings assistance at each step of the VHT process, country and economy-dependant

# Last Survey in Paris meeting



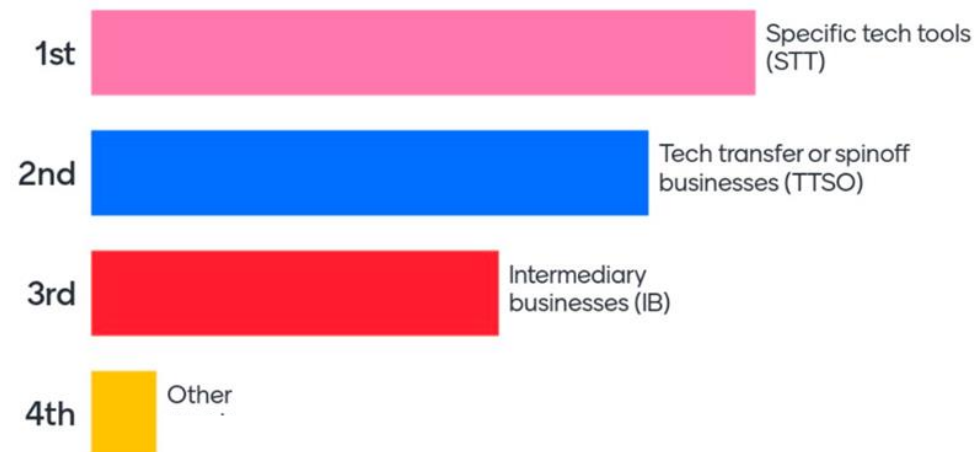
What do you think will be the predominant business model among these categories?



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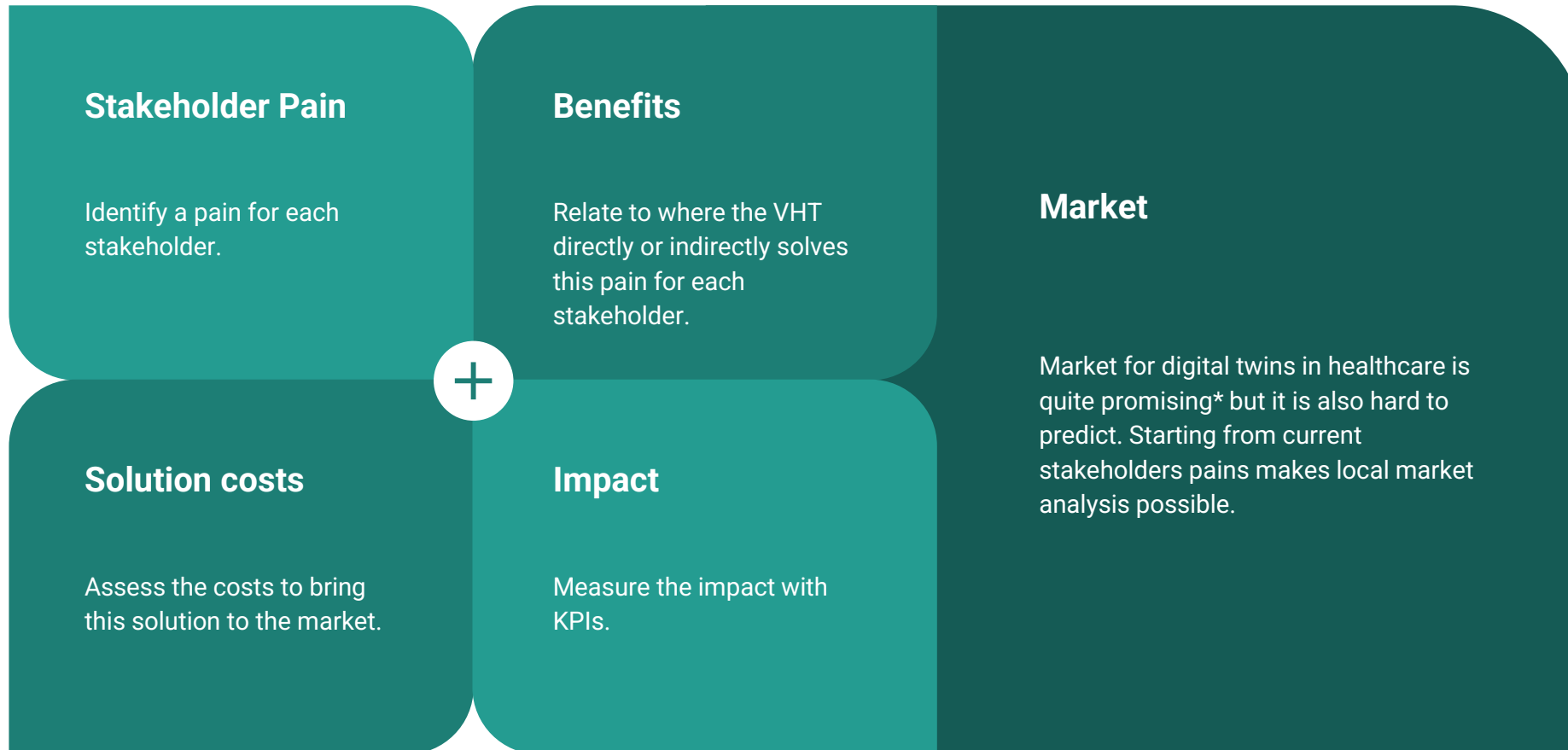


How to detect them?





# A common pattern



\*993 m€ for a 67% CAGR on 2023-2028, source: *Digital twins in HealthCare Market*, Markets&Markets



# Example: sleep disturbances

## Pain

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- National authorities cannot access reliable data
- Pharma/Health IT/Medical devices industries invests a lot in R&D
- Researchers access few reliable clinical trials data only based on straight collaboration

\*The case of Germany and England, source: *IDEA-FAST*, innovation medicine initiatives (imi)

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Stakeholder	Benefits	Costs
National competent authorities	<ul style="list-style-type: none"> <li>• Access to high-density, accurate, objective and reliable trial data and transparent information for rapid assessment and scientific evaluation of medical device</li> <li>• Efficient pre- and post-market surveillance</li> <li>• Promotion of digital health technologies</li> <li>• Potentially shorter clinical trials with fewer subjects needed for recruitment in the future</li> <li>• Access to high-density, accurate and reliable data on effectiveness, cost-effectiveness, benefits and harms of health technology</li> <li>• Market authorisation studies meaningful for HTA</li> <li>• Efficient pre- and post-market surveillance</li> <li>• Promotion of digital health technologies</li> <li>• Data for evidence-based reimbursement and pricing decision-making</li> </ul>	<ul style="list-style-type: none"> <li>• Administrative costs of authorisation procedure</li> </ul>
Pharmaceutical, health-IT and medical devices industries	<ul style="list-style-type: none"> <li>• Reduce operating costs (ex: setting up physical clinical trials)</li> <li>• Increase recruitment rates and inclusive diversity in trials</li> <li>• Accelerate drug discovery and development of new therapies</li> <li>• Create patient-centric approaches</li> <li>• Reduce participation burden</li> <li>• Accurate information on how therapy affects the disease</li> <li>• Opportunity to collaborate</li> </ul>	<ul style="list-style-type: none"> <li>• Costs of provision of devices</li> <li>• Security risk on collected participants' data</li> <li>• Data platforms, data analytics</li> <li>• Greater personnel needed to support patient's questionnaires and concerns.</li> </ul>
Research community	<ul style="list-style-type: none"> <li>• Enhanced health and disease knowledge</li> <li>• Opportunity to collaborate</li> <li>• Increase recruitment rates and inclusive diversity in trials</li> <li>• Access to high-density, accurate, objective and reliable trial data and transparent information for scientific evaluation</li> </ul>	<ul style="list-style-type: none"> <li>• Security risk on collected participants' data</li> <li>• Data platforms, data analytics</li> <li>• Greater personnel needed to support patient's questionnaires and concerns.</li> </ul>

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Pharmaceutical, health-IT and medical devices industries	<ul style="list-style-type: none"> <li>• Reduce operating costs (ex: setting up physical clinical trials)</li> <li>• Increase recruitment rates and inclusive diversity in trials</li> <li>• Accelerate drug discovery and development of new therapies</li> <li>• Create patient-centric approaches</li> <li>• Reduce participation burden</li> <li>• Accurate information on how therapy affects the disease</li> <li>• Opportunity to collaborate</li> </ul>	<ul style="list-style-type: none"> <li>• Costs of provision of devices</li> <li>• Security risk on collected participants' data</li> <li>• Data platforms, data analytics</li> <li>• Greater personnel needed to support patient's questionnaires and concerns.</li> </ul>
Research community	<ul style="list-style-type: none"> <li>• Enhanced health and disease knowledge</li> <li>• Opportunity to collaborate</li> <li>• Increase recruitment rates and inclusive diversity in trials</li> <li>• Access to high-density, accurate, objective and reliable trial data and transparent information for scientific evaluation</li> </ul>	<ul style="list-style-type: none"> <li>• Security risk on collected participants' data</li> <li>• Data platforms, data analytics</li> <li>• Greater personnel needed to support patient's questionnaires and concerns.</li> </ul>

Table 5. Quantified direct and indirect costs of fatigue and sleep disturbances in Germany and England.

Cost	Country	Value
Direct costs	Cost of illness (healthcare resource consumption)	DE €1.03 billion (ICD10-F41 and ICD10-G47 in 2015)
		GB €5630 million purchasing power parity (sleep disturbances in 2010); £3.3 billion (per year; chronic fatigue syndrome)
	Hospitalisation and inpatient days	DE 104,659 cases of hospitalisation (ICD10-G47) resulting in 205,721 inpatient days in 2018
		GB-ENG 32,035 finished consultant episodes (ICD10-G47 as primary diagnosis) in England in 2019/20
	Costs of inpatient care for patient	DE €20 taking the average of 2 inpatient days
		GB-ENG £0
	Drug bill for patients	DE €5-10 per outpatient prescription
		GB-ENG £9.15 outpatient prescription charge per item
	Doctor consultations	DE €31.78 - 42.45 per 10-minute consultation
		GB-ENG £43.434 per 10.33-minute consultation
Indirect costs	Cognitive-behavioural therapy	DE SHI patients: no OOP, payers reimburse therapists €86,90 per one-hour session OOP for private patients: €50-150/session £582 for six 55-minute sessions with NHS providers (no costs for the patient) £40-100 for private sessions
		GB-ENG
	Diagnostics	DE Costs for statutory health insurances: €500 per night spent in sleep laboratories 104,327 inpatient polysomnographies (2019) 61,912 inpatient cardiorespiratory polygraphies (2019) 4,536 inpatient MSLT/MWT tests (2019) 96,685 sleep studies (NHS England YTD 2019/20), costs unclear.
		GB-ENG
	Annual macro-economic loss (morbidity, loss in productivity at work and school)	DE \$60 billion USD (1.56% of GDP in 2015)
		GB \$50.2 billion USD (1.86% of GDP in 2015)
	Working time lost due to absenteeism and presenteeism	DE 209,024 working days and 1,672,192 working hours lost
		GB 207,224 working days and 1,657,792 working hours lost
	Days of sick leave	DE Total of 1.29 million days of sick leave per year with sleep disturbances as the documented reason

\*The case of Germany and England, source: *IDEA-FAST*, innovation medicine initiatives (imi)

# Example\*: sleep disturbances

## Pain

- National authorities cannot access reliable data
- Pharma/Health IT/Medical devices industries invests a lot in R&D
- Researchers access few reliable clinical trials data only based on straight collaboration

How to transform these benefits in business models? Foster innovation through the VHT ecosystem?

Stakeholder	Benefits	Costs
National competent authorities	<ul style="list-style-type: none"> <li>• Access to high-density, accurate, objective and reliable trial data and transparent information for rapid assessment and scientific evaluation of medical device</li> <li>• Efficient pre- and post-market surveillance</li> <li>• Promotion of digital health technologies</li> <li>• Potentially shorter clinical trials with fewer subjects needed for recruitment in the future</li> <li>• Access to high-density, accurate and reliable data on effectiveness, cost-effectiveness, benefits and harms of health technology</li> <li>• Market authorisation studies meaningful for HTA</li> <li>• Efficient pre- and post-market surveillance</li> <li>• Promotion of digital health technologies</li> <li>• Data for evidence-based reimbursement and pricing decision-making</li> </ul>	<ul style="list-style-type: none"> <li>• Administrative costs of authorisation procedure</li> </ul>
Pharmaceutical, health-IT and medical devices industries	<ul style="list-style-type: none"> <li>• Reduce operating costs (ex: setting up physical clinical trials)</li> <li>• Increase recruitment rates and inclusive diversity in trials</li> <li>• Accelerate drug discovery and development of new therapies</li> <li>• Create patient-centric approaches</li> <li>• Reduce participation burden</li> <li>• Accurate information on how therapy affects the disease</li> <li>• Opportunity to collaborate</li> </ul>	<ul style="list-style-type: none"> <li>• Costs of provision of devices</li> <li>• Security risk on collected participants' data</li> <li>• Data platforms, data analytics</li> <li>• Greater personnel needed to support patient's questionnaires and concerns.</li> </ul>
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# Finding the right business model

Formulate business models to highlight pain, resources & partnerships, channels and impact

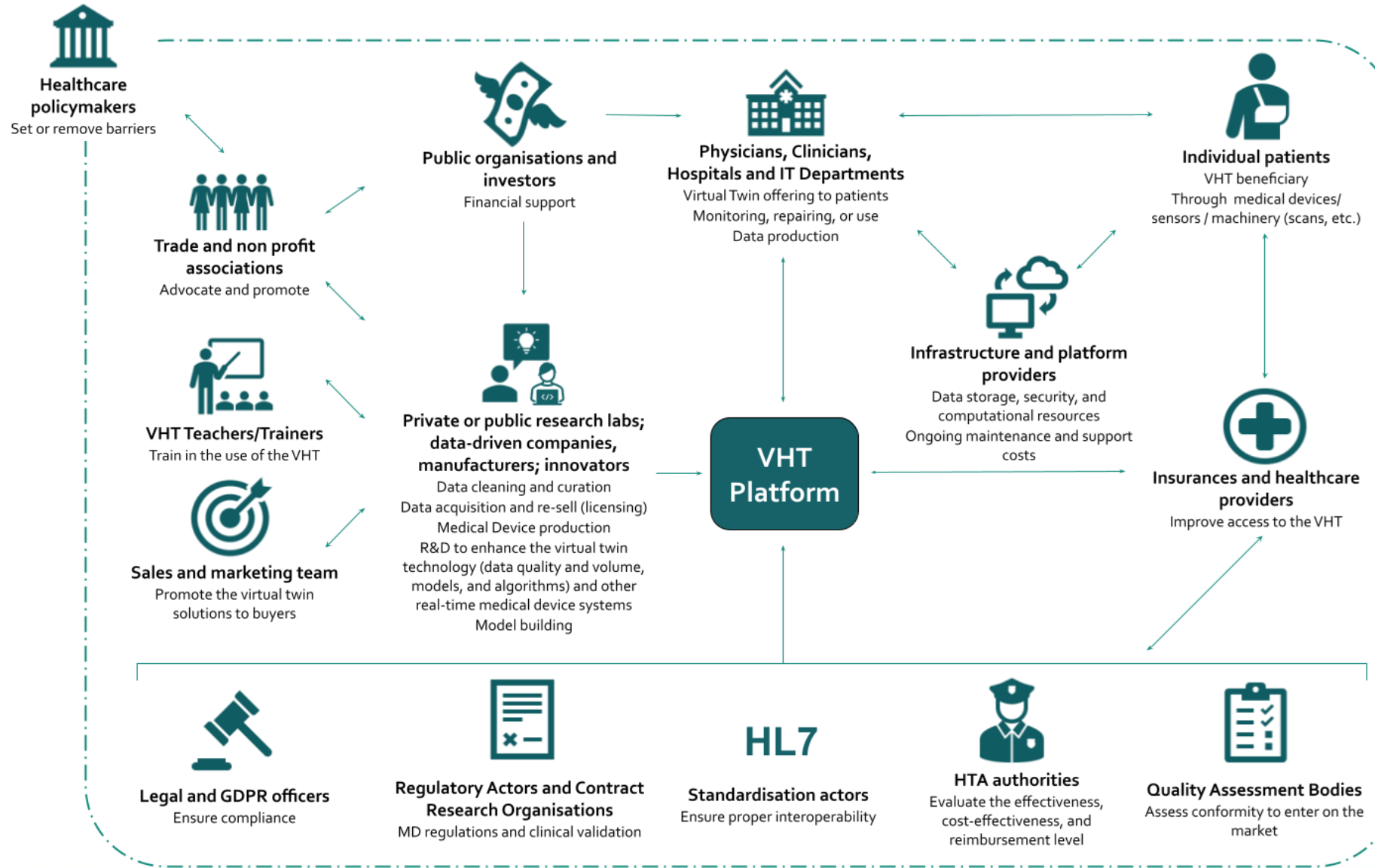
## STRUCTURE OF THE FORMULATION

- Company's name [WE]
- verb [HOW WE INTEND TO HAVE SOCIAL AND ECONOMIC IMPACT AND SUSTAINABILITY] + noun [WHAT]
- for [WHO]
- through [CHANNEL]
- in [EXPLAIN HOW] + (optional) with the help of [PARTNERS/RESOURCES]

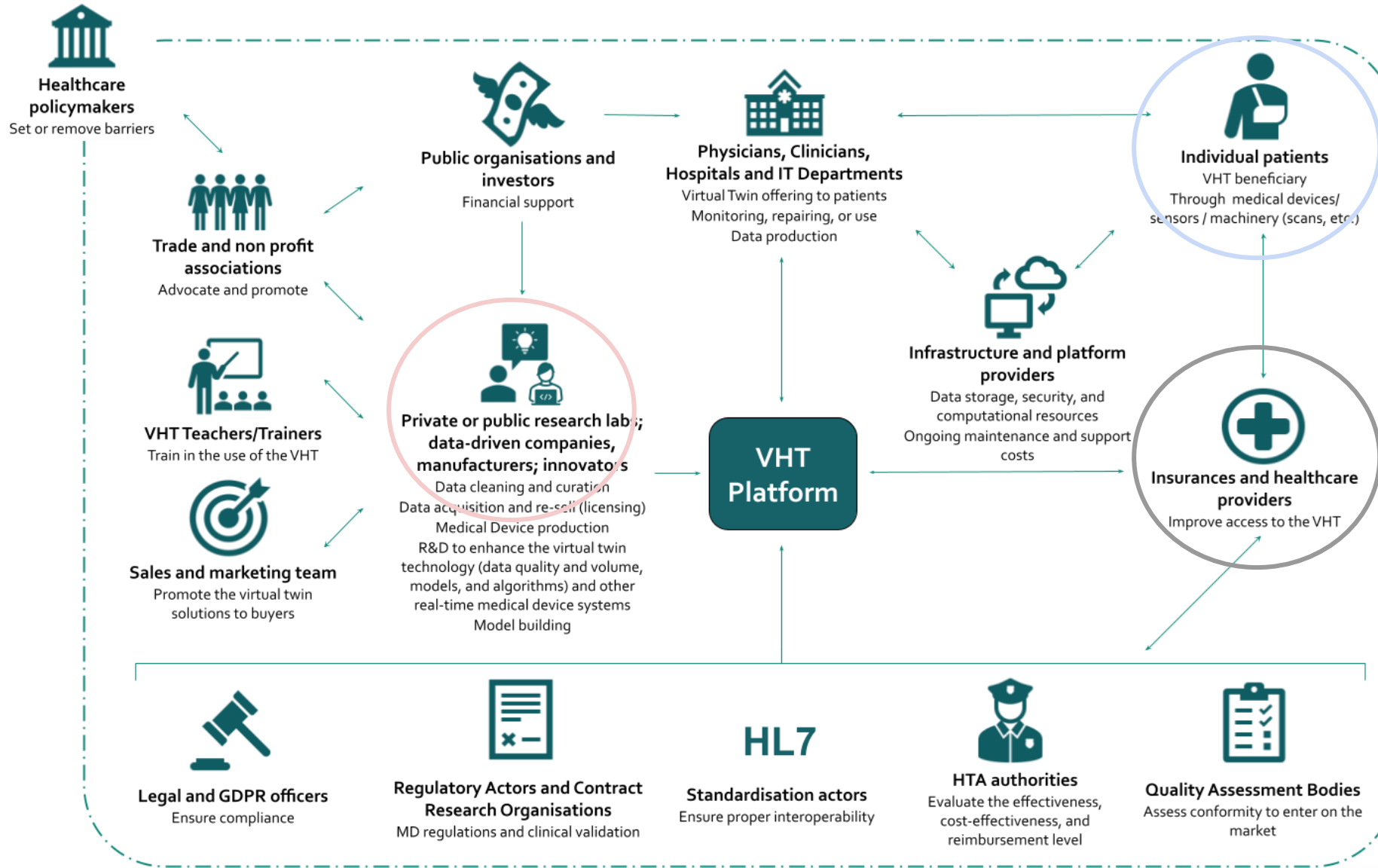
Example: [Cardiaconference] [organises] [networking events] for [VHT stakeholders], through [conferences] in [analysing cardiac european public data with healthcare advisors], enabling [awareness and partnerships based on key findings, strategic insights (reports, presentations)], with the helpt/support of partnerships with [public institutions].



# VHT Ecosystem: composition, roles and interactions



# VHT Ecosystem: composition, roles and interactions





# Modellathon

- Event organised: a hackathon to explore business models for the VHT



# A result from this experience

## Introduction

GemelosXSiempre develops a solution to prevent the advancement of rheumatoid arthritis (RA). Implementing sensorial gloves, we analyze hand movements in patients with early RA and keep the information on DataBase using Virtual Twins with the help of rehabilitation institutes.



Example of business use case idea from Yanis Diallo, Thibault Boyer, Alan Velazquez Isidro



# A result from this experience

## Socio-economic impact

In France **314,900** people have rheumatoid arthritis

Annual incidence of early inflammatory arthritis (EIA):  
**115 to 271 per 100,000 adults**

**Etarnecept :**

- second-line treatment
- prescribed when arthritis is too active

**Our goal : Save 13.950€**

(of therapy costs) by preventing from being in an advanced stage of Rheumatoid arthritis

Source : Coût de la polyarthrite rhumatoïde en France : comparaison léflunomide/étanercept - ScienceDirect

<https://www.sciencedirect.com/science/article/pii/S1297319X22001208>

Dénomination Commune Internationale	Nom de spécialité	Prix unitaire*	Coût annuel par patient*
léflunomide	Arava®	14,9€	964€
		2,5€	
étanercept	Enbrel®	143,4€	14 914€

x11.3

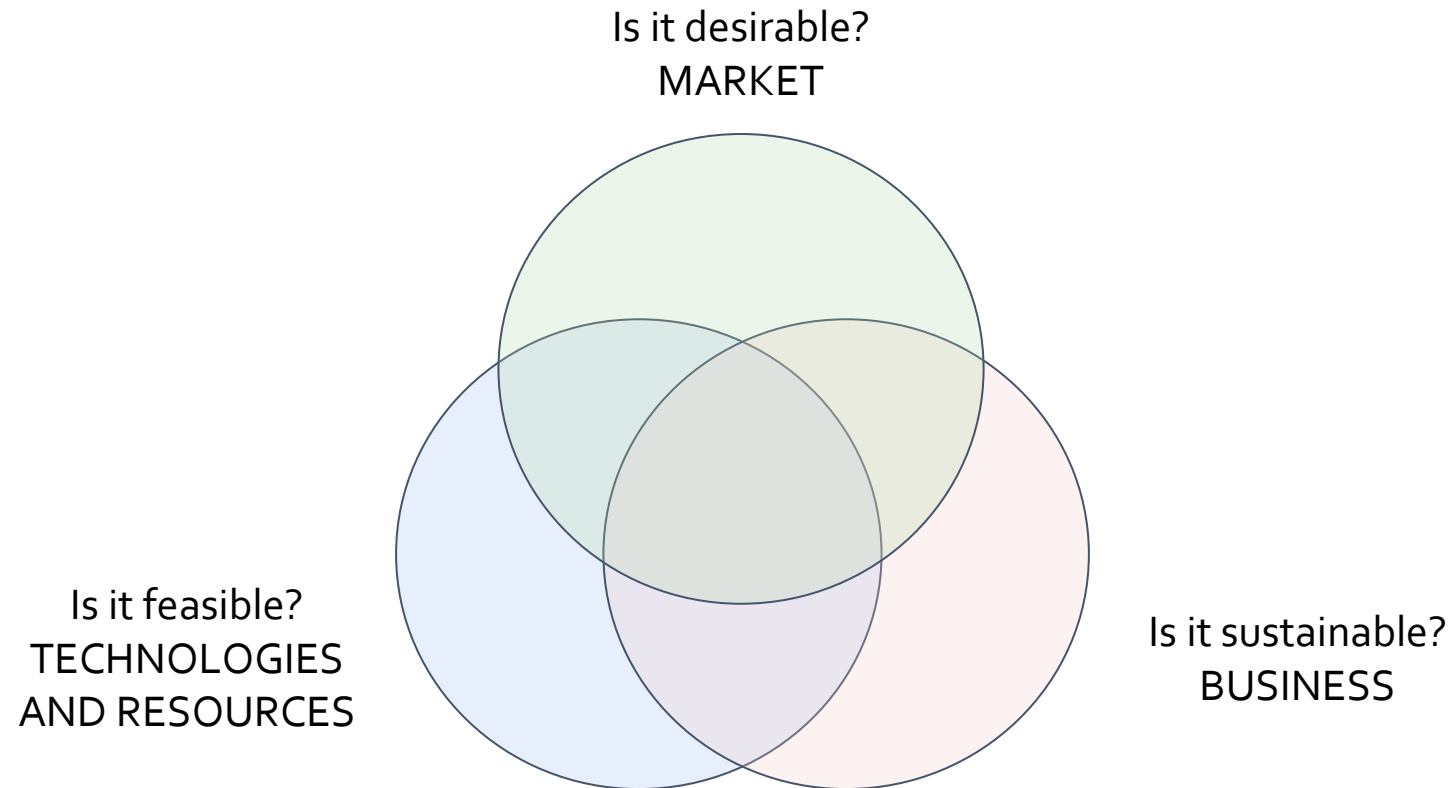
\* Figurant dans le Résumé des Caractéristiques du Produit.

\*\* Estimation théorique basée sur la posologie mensuelle usuelle pendant 12 mois.

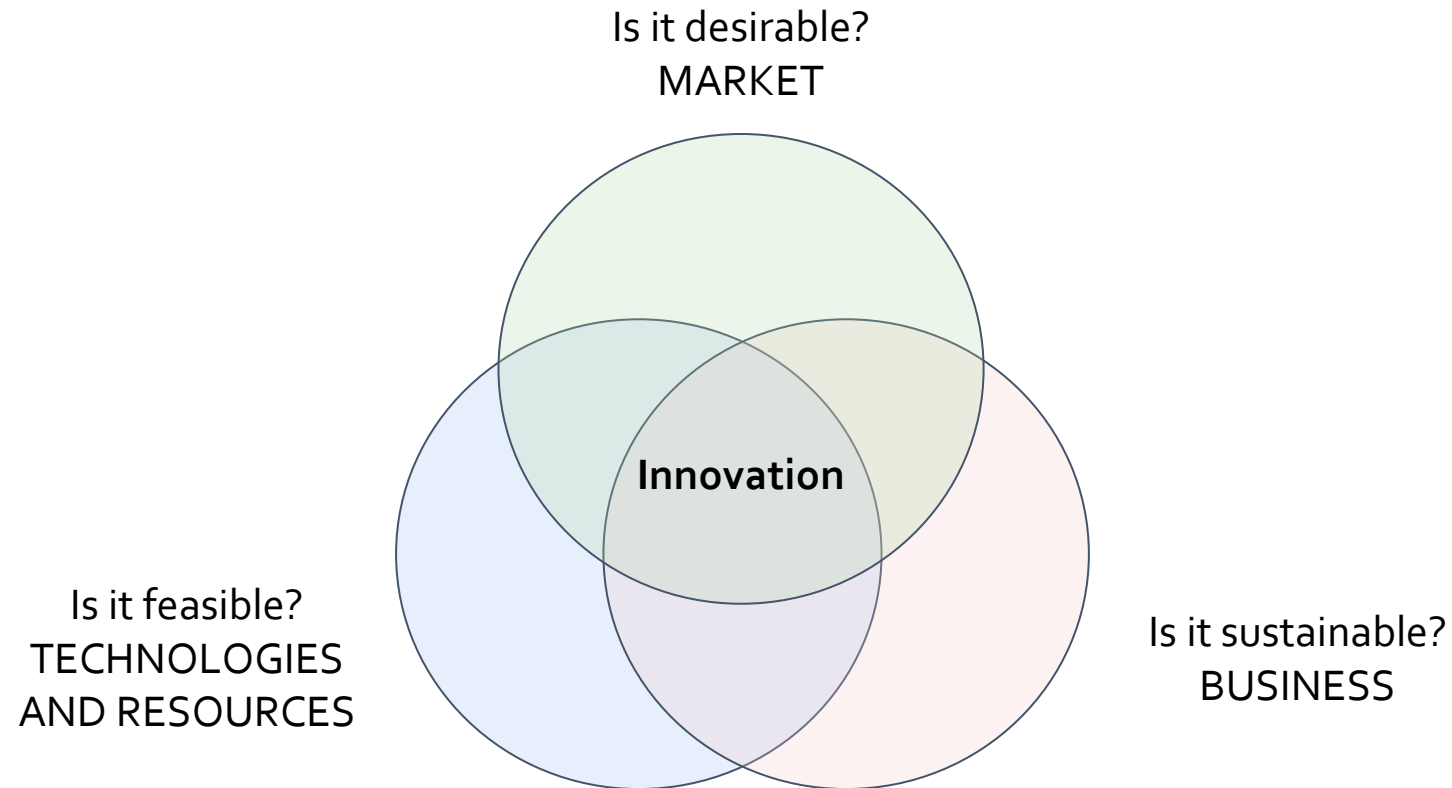
Example of business use case idea from Yanis Diallo, Thibault Boyer, Alan Velazquez Isidro



# Innovation and competitive advantage



# Innovation and competitive advantage



# Ecosystem Sustainability: key metrics

## Identified key metrics

- Size of potential market and quantification of the VHT benefits
- Number of target customers and user adoption rates
- Revenue generated from virtual twin platforms
- Customer and user satisfaction / feedback
- Accuracy and performance metrics of Virtual Twin models
- Return on investment for healthcare organisations utilising the VHT

# Revenue streams, added value, opportunity

- Take part in the VHT Marketplace through licensing or subscription fees (e.g., pay-per-use or annual subscription access) — healthcare industries
- Consultancy services for customising virtual twin solutions to specific healthcare VHT use cases
- Data analysis services for the VHT
- Integration for medical devices with real time record systems
- Enhance semi-automatic processes for certification, standardisation, compliance
- Make collaboration even easier between healthcare industries (SMEs, corporations)
- Reduce costs and time (clinical trials, certifications, curate data, access data, others)



# Thank you

[www.edith-csa.eu](http://www.edith-csa.eu)