Ecosystem
for Digital Twins
in Healthcare

Project Coordinator:
Liesbet Geris, VPH Institute, U.Liège, KU Leuven
Contact:
director@vph-institute.org - info@edith-csa.eu

EDITH – CSA

Building an Ecosystem for Digital Twins in Healthcare

The European Union's competitiveness depends on its ability to embrace digital innovation, particularly in healthcare.

Artificial intelligence (AI) holds immense potential to revolutionize personalized medicine and clinical trials, but this requires robust support from the European Parliament through upcoming legislation, such as the **European Health Data Space (EHDS)**, the **Medical Device Regulation (MDR)**.

AI represents a double-edged sword for EU industries: it can drive competitiveness and leadership, but failure to integrate it swiftly risks falling behind global counterparts.

THE EU
VIRTUAL HUMAN TWIN

A consortium of approximately **100 organizations** - including patient advocacy groups, industry leaders, and research centers - demonstrates Europe's readiness for **AI adoption in healthcare**.

VHT supporters assert that the tools and infrastructure are already in place, offering tangible benefits for patients and healthcare practitioners. However, policy and regulatory frameworks lag behind technological progress. Without alignment, these advances cannot be effectivbe implemented, undermining the potential impact on EU healthcare.

AI

Proven Benefits of AI in EU Healthcare

The EU VHT initiative has already provided concrete examples of AI's potential:

- **Efficiency Gains:**
  - A Belgian SME, Insilicare, developed AI software to monitor and adjust glucose levels in **ICU patients**. This reduced ICU stays by 1.1 days, saving €1.2 million annually for a medium-sized hospital
- **Improved cancer care:**
  - Personalized tumor models offer more **accurate prognosis** scoring and improved outcomes in breast cancer care, while also providing an average cost saving of €6,000 to €13,000 per patient.

Supportive European Commission Actions

The European Commission has demonstrated its commitment to digital health innovation:

- **Europen Digital Infrastructure Consortium (EDIC):**
  Supporting research and innovation in digital health
- **VHT Platform:**
  A €24 million tender launched in 2023–2024 to establish advanced VHT models
- **European Cancer Imaging Initiative (EUCAIM):**
  Leveraging AI to improve cancer diagnosis and treatment

Regulatory Hurdles: Learning from the US

Currently, AI integration in the EU is constrained by conservative regulatory approaches; as per their mandate, the European Medicines Agency (EMA) and notified bodies limit AI applications primarily to preclinical trials for medicines and medical devices. In contrast, the US Food and Drug Administration (**FDA**) has embraced AI in both **preclinical** and **clinical** trials, setting a model for innovation.

Case Study: US Success with AI in In Silico Trials

Medtronic utilized AI-driven simulation-based clinical trials to gain FDA approval for an MRI-compatible pacemaker.

This approach saved approximately **$250 million** in costs and significantly reduced timelines compared to traditional methods.

The Urgent Need for Legislative Action

The EU healthcare system stands at a pivotal moment. With AI adoption at just **11%** among EU companies (far below the 2030 target of **75%**), regulatory inertia risks stalling progress.

Meanwhile, the global digital twins' market in healthcare is projected to grow from $1.63 billion in 2023 to $21.11 billion by 2028, underlining the economic stakes.

Call to Action: Promote the EDITH Roadmap

To harness AI's potential, the European Parliament shall support and promote the EDITH roadmap as a blueprint to empower EU citizens through AI in healthcare, ensuring safe and effective deployment under updated EHDS and MDR.

Exchange of views in the SANT committee 1st semester 2025 to showcase the benefits of EDITH on AI in healthcare.

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