



Building the European Virtual Human Twin

Call: Accelerating best use of technologies (DIGITAL-2021-DEPLOY-01)

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Advisory Group of Stakeholders Meeting Minutes Online, May 13th 2024

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Executive summary

On May 13th 2024, the first meeting of the EDITH Advisory Group of Stakeholders took place online. This document contains the introduction to the Advisory Group of Stakeholder and its composition, the meeting agenda and the main discussion as well as further steps.

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Acronyms

Acronym	Full name
AGS	Advisory Group of Stakeholders
AI	Artificial Intelligence
CSA	Coordination and Support Action
EC	European Commission
ELSI	Ethical, Legal and Social Issues
EU	European Union
HPC	High Performance Computing
MDR	Medical Device Regulation
WP	Work Package

1 Purpose of the meeting

1.1 Advisory Group of Stakeholders: goal & composition

The Advisory Group of Stakeholders (AGS) is one of the advisory boards of the EDITH Coordination and Support Action (CSA)¹. The EDITH-CSA is working on facilitating an ecosystem-driven creation of the roadmap for the Virtual Human Twin (VHT). The Virtual Human Twin (VHT) is envisioned as 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, assess their credibility and facilitate their uptake in industry and clinical practice. It entails the development of a federated public infrastructure and the collection of appropriate resources, driven by the engagement of a collaborative ecosystem.

The AGS is an important component for strengthening the VHT ecosystem, providing high level feedback and validation, and supporting its further development going forward. The AGS members informed input to the VHT Roadmap, elaborated by the EDITH consortium and the wider ecosystem through public activities onsite and online, carries an important weight in its validation, wide dissemination, and acceptance. AGS members will then discuss orientations for future research beyond the EDITH CSA and ongoing initiatives.

The AGS is composed of high level experts from academia, clinics, industry (large companies and start-ups), trade associations, regulatory agencies and notified bodies. The expertise of the AGS members covers the technological, ethical, legal and social (ELSI) aspects related to VHT.

1.2 Meeting objective

The European Virtual Human Twins (VHT) Initiative was officially launched by the European Commission on the 22 December 2023². In 2024 the EU VHT Initiative activities kicked off with a core set of 12 ongoing actions supporting advanced VHT technology development, from foundational research through to evidence generation and deployment. A VHT Manifesto³, summarizing the core elements and key challenges of the VHT was signed by over 80 organisations (academia, industry, hospitals, trade organisations, HPC centres, patient organisations and civil society organisations).

In the meantime, work on the EDITH-CSA led to the publication of the first draft of the VHT roadmap⁴ in July 2023 and a further elaboration of its content since then, through a range of public activities and expert meetings. In light of the preparation of the final draft of the VHT roadmap, the AGS has been invited to meet and discuss the progress.

¹ www.edith-csa.eu (10/6/2024)

² [https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins#:~:text=Launch%20of%20the%20Virtual%20Human,Human%20Twins%20\(VHTs\)%20Initiative.-](https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins#:~:text=Launch%20of%20the%20Virtual%20Human,Human%20Twins%20(VHTs)%20Initiative.-) (10/6/2024)

³ www.virtualhumantwins.eu (10/6/2024)

⁴ <https://zenodo.org/records/8200955> (10/6/2024)

2 Agenda of the meeting

The first general AGS meeting took place online on Monday 13th May between 16:00-18:00 (CEST), with the following **agenda**:

- 16:00: Welcome & Introduction (Liesbet Geris)
- 16:05: The EU VHT Initiative and its strategic importance (Saila Rinne)
- 16:15: Participants' introductions (All)
- 16:30: EDITH Roadmap: approach, structure & subject matter (Liesbet Geris)
- 17:00: Roadmap review: open discussion, review & validation perspectives (All)
- 17:45: Roadmap review: chapters allocation and next steps (Liesbet Geris)

The meeting was **attended** by the majority of the AGS members (representing academia, industry, trade organisations, notified bodies, clinics and patient organisations), as well as the work package leaders of the EDITH-CSA (Amaryllis Raouzaïou, ATHENA; Sabato Melloni, UNIBO, Enzo Fabiano, PI School; Edwin Morley-Fletcher, Lynkeus), its coordinator (Liesbet Geris, VPHi) and representatives of the European Commission (DG CNECT H3 – eHealth, Wellbeing and Ageing).

3 Content of the meeting

The meeting started with an introduction of the EU VHT Initiative and its strategic importance by the interim Head of Unit of DG CNECT H3 (Saila Rinne). This introduction was followed by a tour de table of the meeting participants.

Next, a general introduction was given into the EDITH project, its consortium and main goals. This was followed by a discussion of the VHT roadmap approach, structure & subject matter.

3.1 Approach

The roadmap preparation and validation followed a three-phase approach.

- Design phase (1/10/2023-31/7/2023)
 - Consortium, industry advisory board (IAB), 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
 - Patient organisations: patient endorsement

The activities in the different phases were discussed in greater detail, along with the results of the stakeholder interactions. Finally, the subjects of further elaboration of the roadmap were discussed.

3.2 Structure & Subject Matter

The interactive content map of the roadmap was used to explain the content of the different chapters in the first draft of the roadmap. The chapters 4-7 were discussed in greater detail: approach, decisions made, overall strategy and open points.

4. Vision for the VHT
5. Technology for the VHT
6. Standards, regulatory & ELSI for the VHT
7. Uptake of the VHT

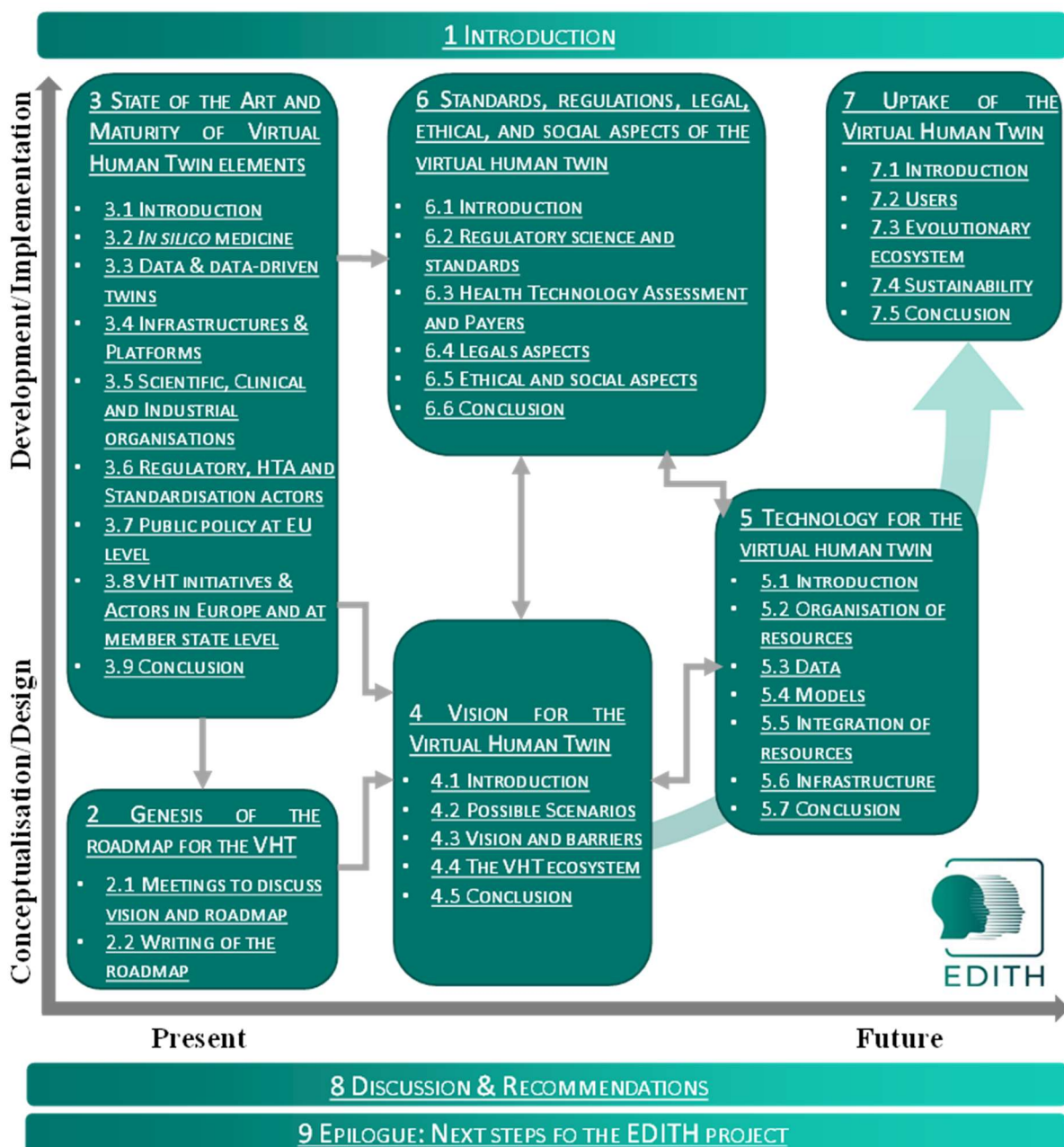


Figure: interactive map showing the structure of the first draft of the roadmap.

3.3 Open discussion

The presentation was followed by an open discussion, in which the following points were elaborated:

- Metadata, matching model & datasets
- Data availability
- Data curation & quality
- Verification & validation
- Bias in data sets but also in choices made for technologies
- IPR
- MDR Annex 17

4 Next steps

Given the large quantity of elements that require discussion, the AGS agreed to organise further meetings dedicated to specific topics, to allow a deeper dive into the subject matter. These deep dive meetings are the following:

- VHT science, technology & infrastructure: 25th of June, 1 – 2.30 pm
- ELSI for VHT: 26th June, 11.30 am – 1 pm
- Uptake, users & sustainability: 28th June, 2.30 – 4 pm