

EDITH-CSA Ecosystem meeting

Royal Institute of the Tropics, Amsterdam (NL)
15-16/7/2024



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



Barry Fitzgerald

Meeting host

Peter Paul Verbeek & Alfons Hoekstra

Rector & EDITH-CSA local host
University of Amsterdam



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Margherita Fanos & Kyriacos Hatzaras

European Commission, DG CNECT



European Virtual Human Twins Initiative

EDITH-CSA Ecosystem meeting
15/07/2024

Margherita FANOS, Policy officer
CNECT.H3 eHealth, wellbeing and ageing
European Commission





What are virtual human twins?



- A digital representation of a human health or disease state, built using software models and data
- Designed to mimic and predict behaviors of their physical counterparts

Advancing personalised care – core EU priority

European
Leadership

Drug Discovery &
Clinical Trials

Leveraging HPC &
Quantum

Personalised
Medicine

Medical Education
& Training

Advancing Medical
Research





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



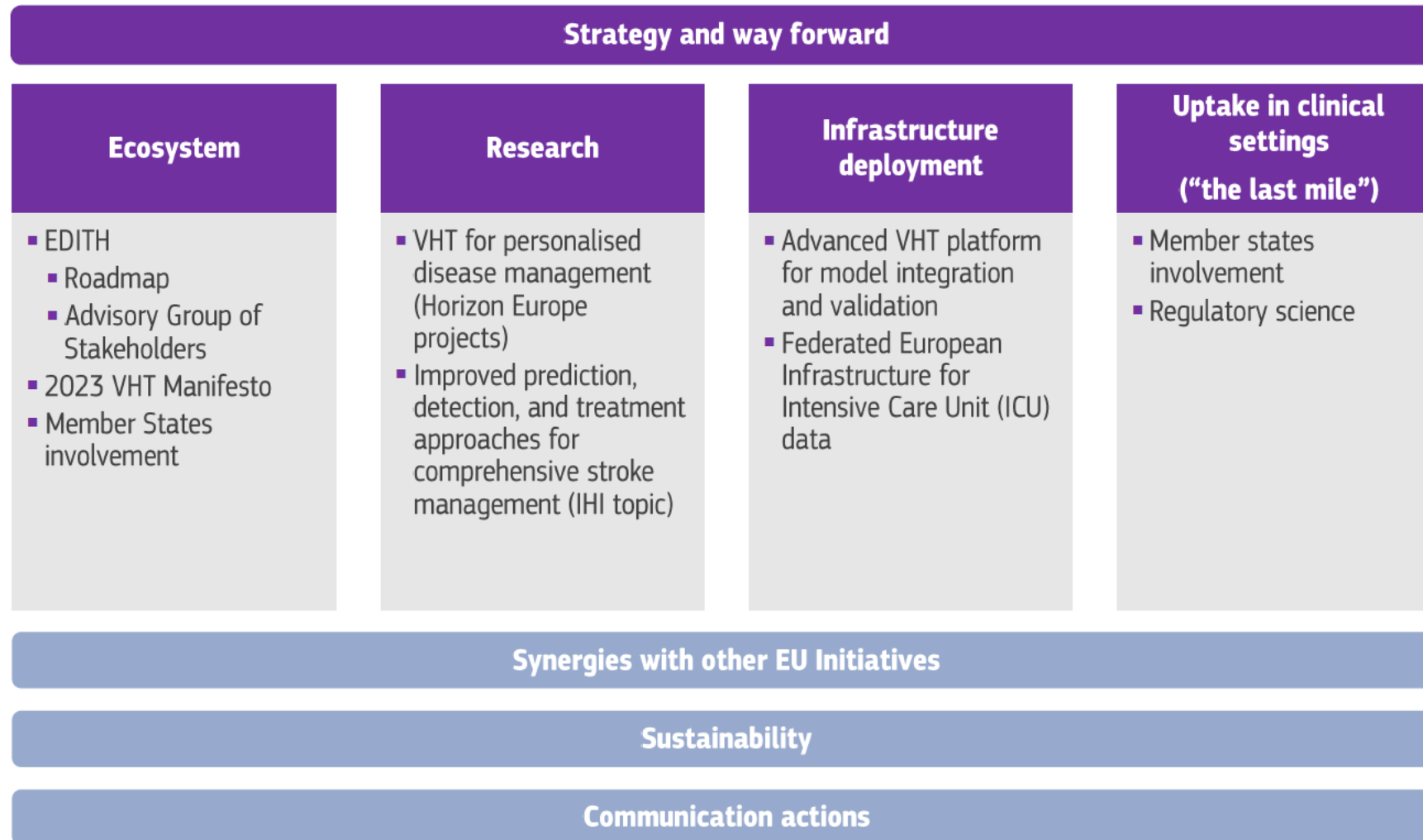
Leverage the **power of novel computational methods** and advanced computing capacities



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



The European Virtual Human Twins Initiative



Ecosystem-oriented actions





Ecosystem



Framing an inclusive **ecosystem** of digital twins in healthcare - mapping of the existing relevant actors, initiatives, resources and barriers

Roadmap



Identifying the necessary building blocks to ensure the VHT's clinical application and formulate clear short- and mid-term policy recommendations.

Repository



Developing a federated and cloud-based **repository** of digital twins (data, models, algorithms, and good practices) in healthcare, providing a virtual collaboration environment

Simulation Platform



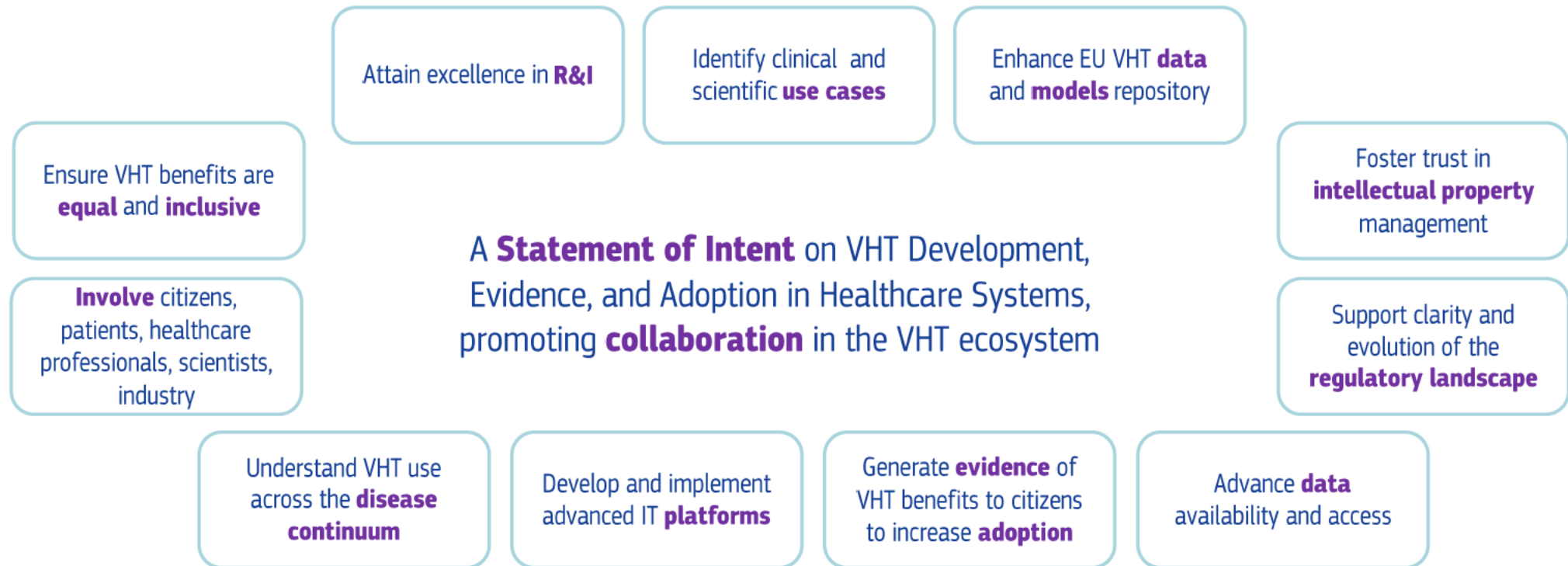
Developing the architecture of a **simulation platform** that will support the transition towards an integrated VHT, building on 5 use-cases (cancer, cardiovascular, intensive care, osteoporosis, brain) to be developed as prototypes



Virtual Human Twins Manifesto – launched December 2023



- Wide review by ecosystem: **132 organisations**
- More than **90 signatories** from industry, academia, research and clinical, and others TBC



Research Actions





Horizon Europe RIA projects



HORIZON-HLTH-2023-TOOL-05-03: Integrated, multi-scale computational models of patient pathophysiology (“virtual twins”) for personalised disease management – 80M EUR

GEMINI: a Generation of Multi-scale Digital Twins of Ischaemic and Haemorrhagic Stroke Patients

- Dec 2023–Nov 2029
- EUR 9.9M



CERTAINTY: A CELLular immunoTherapy virtuAl twin for personalised cancer treatment

- Dec 2023–May 2028
- EUR 9.9M



VIRTUAL BRAIN TWIN: Virtual Brain Twin for personalised treatment of Psychiatric Disorders

- Jan 2024–Dec 2027
- EUR 10M



SMASH-HCM: Stratification, management and guidance of hypertrophic cardiomyopathy patients using hybrid digital twin solutions

- Jan 2024–Dec 2027
- 8M



TARGET: Health virtual twins for the personalised management of stroke related to atrial fibrillation

- Jan 2024–Dec 2028
- EUR 7M



ARTEMIS: AcceleRating the Translation of virtual twins towards a pERsonalised Management of fatty liver patients

- Jan 2024–Dec 2027
- EUR 9.3M



dAlbetes: Federated virtual twins for privacy-preserving personalised outcome prediction of type 2 diabetes treatment

- Jan 2024–Dec 2028
- EUR 8.9M



VITAL: Virtual Twins as tools for personalised clinical care

- Jan 2024–Dec 2028
- EUR 8.7M





Actions under the Innovative Health Initiative (IHI)



Predictive computational models for preventive stroke management

- EU co-funding 20M EUR
- Projects expected to start by September 2024 latest



Develop innovative tools and approaches, **for example 'virtual human twin' model approaches** and AI/ML for enhanced computational modelling, optimised for transparency to users and non-users, federated data analytics, and visualisation for enhanced output/results view and interpretation. These tools aim at appropriate risk stratification, timely prediction of stroke and stroke recurrence, faster diagnosis, and treatment.

Propose approaches to improve implementation and scale-up of treatment in Europe relying on **multimodal clinical data capture** and their better interpretation and use in patient management and clinical decision-making. This should include consideration of the regional differences in stroke management and access to treatment options across Europe.

Infrastructure-deployment actions





Federated European Infrastructure for Intensive Care Unit (ICU) Data

- DIGITAL, WP 2023-2034, 5 MIO EUR co-funding – *GAP phase*
 - Data intensive computational model-based tools for decision support and risk prevention
 - Goal to identify personalised interventions in real-time
 - 6 clinical use cases, including one involving VHT creation
- Demonstrate ICU dataset integration and use with VHT models in 4+ clinical domains



Advanced Platform for VHT Models Integration & Validation

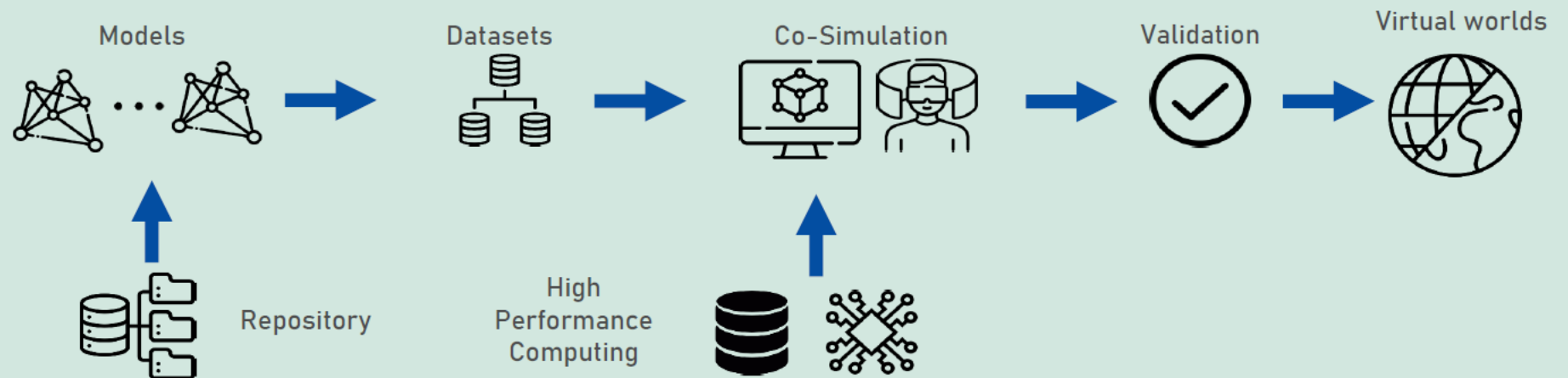


Procurement action, DIGITAL EUROPE Work Programme 2023-2024

Develop a distributed platform making available to users:

- a federated repository of VHTs related resources;
- a combined set of open-source software toolkits;
- access to computational services to develop, test and integrate VHT models

Platform used for developing, testing and integrating VHT models; fully interoperable with augmented and virtual reality environments



Uptake of VHTs in clinical settings – *the “last mile”*





Uptake of VHTs in clinical settings – *the “last mile”*



Focus on the **uptake** of integrated VHT technologies in health and care, to benefit patients, promote **personalised medicine**, foster equal **access** to healthcare, **speed-up** pharma and medical device developments and clinical trials



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Strengthening synergies with other EU initiatives



European Health Data Space
Regulation (**EHDS**)

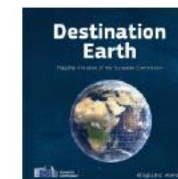
Cancer Imaging Initiative
Cancer Image Europe Platform



1+ Million Genomes Initiative
Genomic Data Infrastructure



DestinE Platform



European Virtual Human Twins Initiative

Commission Communication on boosting **startups**
and **innovation** towards **trustworthy AI**

Commission Communication on **Virtual** Worlds



Thank you

CNECT.H3



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Liesbet Geris

University of Liège, KU Leuven, VPHi
EDITH-CSA coordinator



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EDITH-CSA objectives

Ecosystem



Roadmap



Repository



Simulation Platform



Ecosystem
for Digital Twins
in Healthcare

Amsterdam 15/7/2024

EDITH WP leaders



Edwin Morley-Fletcher
Lynkeus

Mapping / Ecosystem



Sabato Mellone
UNIBO

Repository



Amaryllis Raouzaïou
ATHENA

Simulation Platform



Enzo Fabiani
Pi School

Sustainability

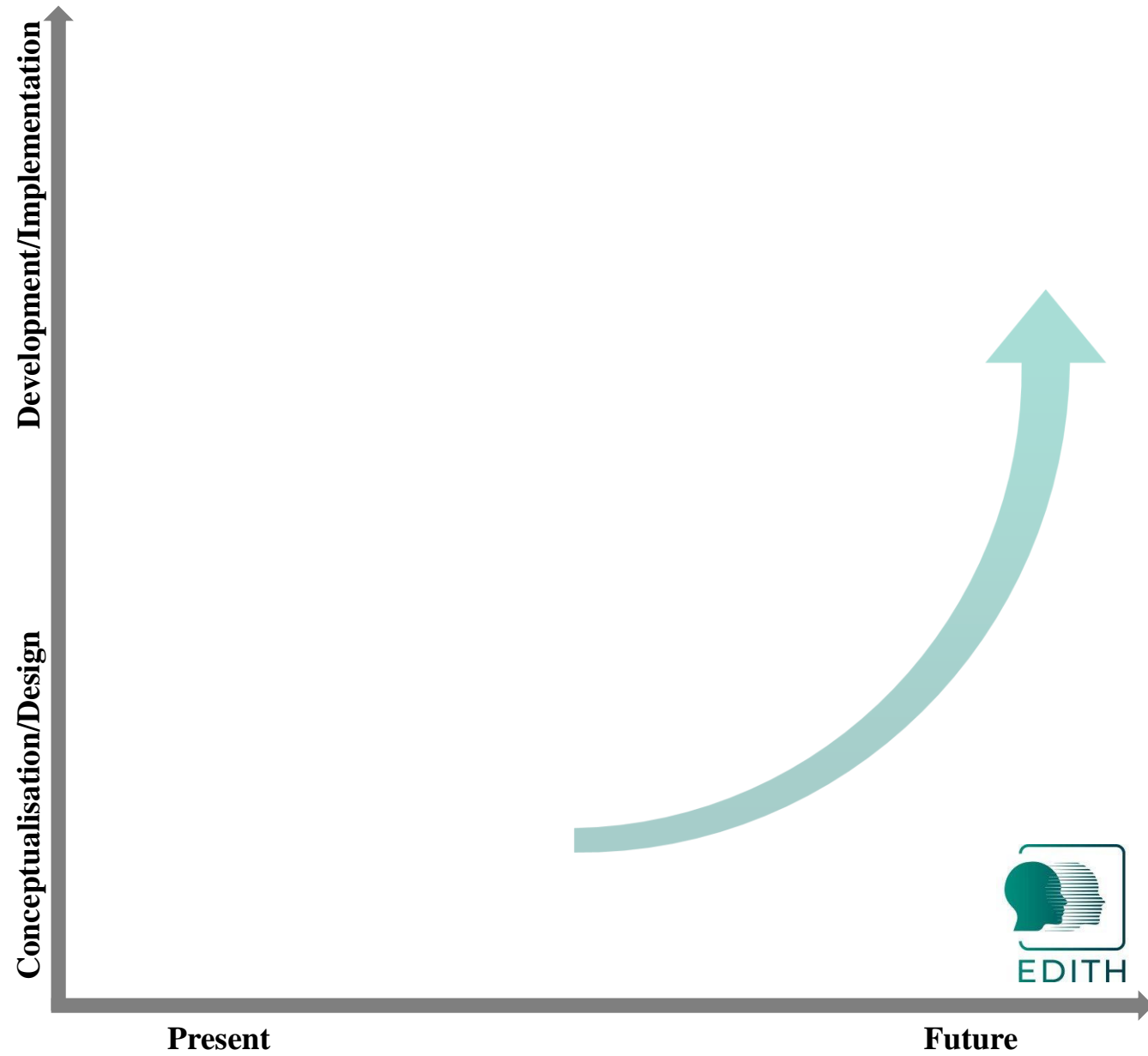


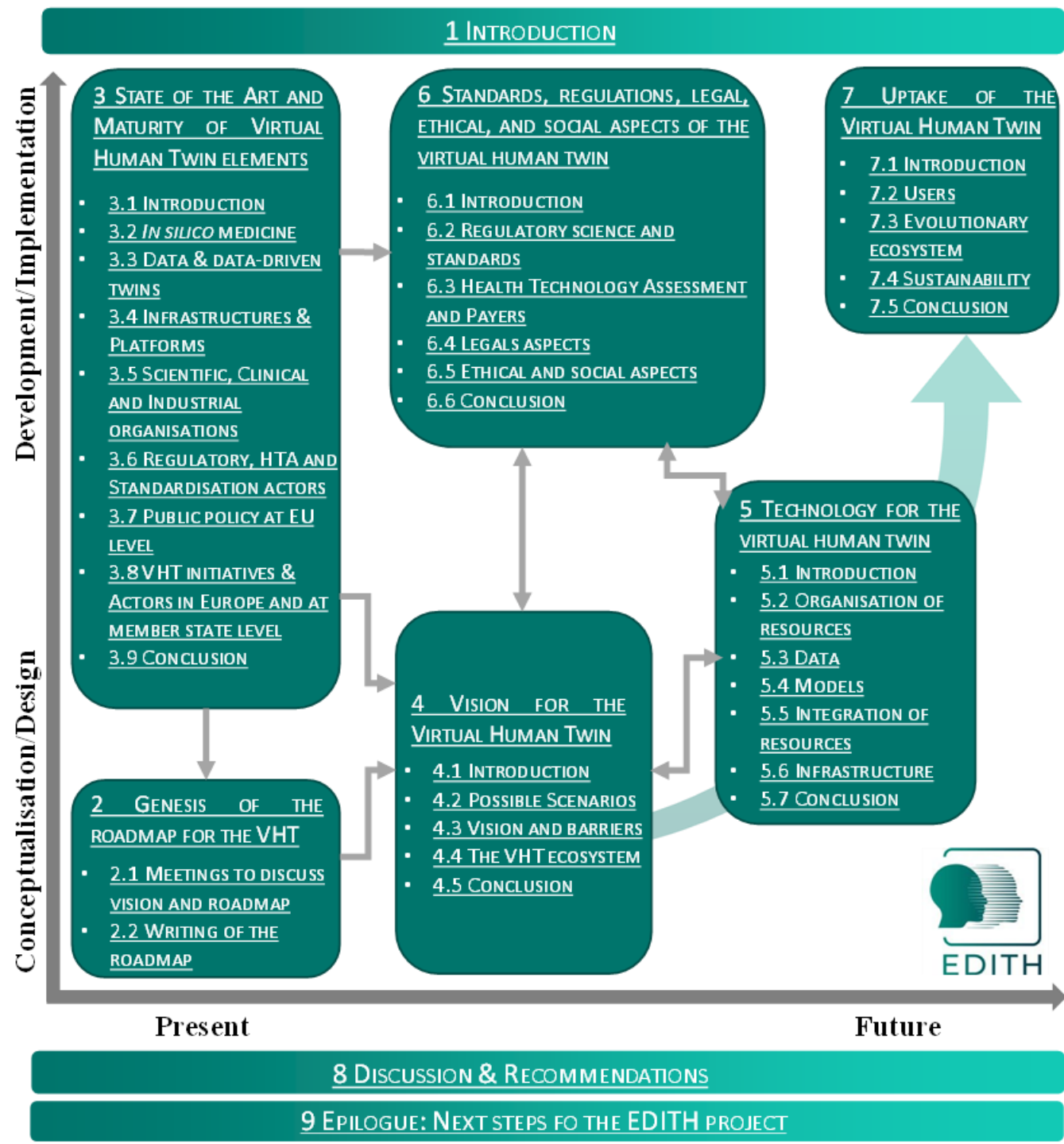
Liesbet Geris
VPHi, U.Liège, KU Leuven

Vision

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
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 - 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







Open Access Resources of the EDITH Coordination and Support Action

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.

3K
VIEWS

2K
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	All versions	This version
Views ⓘ	3,336	3,230
Downloads ⓘ	2,493	2,422
Data volume ⓘ	8.4 GB	8.2 GB

More info on how stats are collected....

Versions

Roadmap writing & validation

- **Design phase** (1/10/2023-31/7/2023)
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- **Develop phase** (1/8/2023-16/7/2024)
 - Manifesto, advisory boards, expert meetings, ecosystem meetings, EDITH PoC infrastructure
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Develop phase – expert meetings

- **Vision & VHT science/technology**: multi-level & multi-organ integration/computing, Knowledge graphs, AI, hardware (imaging, sensing)
- **VHT Infrastructure**: Platform/repo (technical elements), Large (public) infrastructures (interoperability), HPC, data, Hospital networks & IT
- **ELSI for VHT**: Regulatory, standards, Patient perspective, Ethics, Social acceptance & trust, IPR
- **Uptake & sustainability**: Economics perspective, Public investments (member state strategy), Education, Incentives for stakeholders, Clinical community

Goal of this meeting

- Inform on the progress of the Virtual Human Twin (VHT) roadmap and the proof-of-concept EDITH infrastructure
- Obtain input from you on the last open parts of the VHT roadmap
- Start process of ecosystem validation for VHT roadmap

12 - 1 Lunch

1- 1.40 PLENARY SESSION: Welcome

Introduction by the meeting host: **Barry Fitzgerald**

Welcome address by the local hosts:

UvA rector **Peter Paul Verbeek**, host **Alfons Hoekstra**

Welcome address by the European Commission:

Margherita Fanos & Kyriacos Hatzaras

Introduction to EDITH, VHT roadmap & purpose of the meeting:

Liesbet Geris

1.40 - 2.55 STRATEGIC SESSION 1: Healthcare-related infrastructures

Keynote: Jens Habermann

(BBMRI-ERIC and European Life Science Research Infrastructures)

Panel:

- **Kyriacos Hatzaras** (European Commission - DG CNECT)
- **Jeroen Beliën** (Amsterdam UMC)
- **Claire Biot** (Dassault Systèmes)
- **Christopher Esterhuyse** (University of Amsterdam)

2.55 - 3.15 Coffee Break

3.15 - 4.30 PLENARY SESSION:

EDITH proof of concept infrastructure from user perspective

Researchers: connecting resources in the VHT

Caroline Roney, Laura Bevis & Elisa Rauseo

(Queen Mary University of London)

Amaryllis Raouzaïou (Athena Research and Innovation Center)

Communities: federated nature of the VHT

Martin Golebiewski (Heidelberg Institute of Theoretical Studies)

Sofia Karvounari (Athena Research and Innovation Center)

Industry: interactions of company services/activities with VHT (ELEM - Athena)

Mariano Vázquez (ELEM)

Evita Mailli (Athena Research and Innovation Center)

Healthcare providers: deployment at bedside in clinical workflows

Vincent Uyttendaele (Insilicare)

Konstantinos Triantos (Athena Research and Innovation Center)

Patient: functionality to upload own data in the VHT

Sabato Mellone (University of Bologna)

Amaryllis Raouzaïou (Athena Research and Innovation Center)

4.30 - 4.40 INTRODUCTION OF THE BREAKOUT SESSIONS Liesbet Geris

4.40 - 5 Coffee break

5 - 7 BREAKOUT SESSIONS

- **1. Digital health economics:**
Edwin Morley-Fletcher (Lynkeus); **Enzo Fabiani** (Pi School)
- **2. Use cases & proof-of-concept infrastructure:**
Sabato Mellone (University of Bologna)
- **3. Standards:** **Martin Golebiewski** and **Gerhard Mayer**
(Heidelberg Institute of Theoretical Studies)
- **4. Communication strategy & stakeholders:**
Davide Montesarchio, Martina Contin, Goran Stanic
and **Zita Van Horenbeeck** (VPH institute)
- **5. Balancing roles and responsibilities:** defining user profiles
Speakers: Gökhan Ertaylan, Simon Denil, Frederic Jung (MITO);
Frank Rademakers (UZ Leuven - KU Leuven)
- **6. EU-AM-AP collaboration:** **Liesbet Geris** (VPH institute)
- **7. Unlocking research infrastructures to broader community:**
Marco Verdicchio, Sagar Dolas (SURF), **Amaryllis Raouzaïou**
(Athena Research and Innovation Center)

7 - 9 Dinner

Coffee at 8am !

8.30 - 9.30

PLENARY SESSION:

Reporting of breakouts

Interactive session with questions for entire audience (breakout session chairs)

9.30 - 10.45

STRATEGIC SESSION 2:

Regulatory science and policy update

Keynote 1: Aldo Badano (USA-FDA)

Keynote 2: Kelly Brown-Plueschke (EMA)

Keynote 3: Nada Alkhayat
(European Commission, DG SANTE)

10.45 - 11.15

Coffee break

11.15 - 12.30

STRATEGIC SESSION 3:

Healthcare professionals & patients

Keynote:

Folkert W. Asselbergs
(Amsterdam UMC & University of Amsterdam)

Panel:

- Gernot Marx (Uniklinik Aachen)
- Job Leenen (Isala Hospital)
- Valentina Strammiello (European Patient Forum)
- Frank Rademakers (UZ Leuven – KU Leuven)

12.30 - 1.30

Lunch

1.30 - 2.45

STRATEGIC SESSION 4:

Bringing the VHT to society

Keynote:

Signe Mežinska (University of Latvia)

Panel:

- Jolien Roovers (Department Economy, Science & Innovation of the Flemish government)
- Rossana Alessandrello (AQuAS)
- Frank van Praat (KPMG-NL/AMdEX)
- Marco Verdicchio (SURF)

2.45 - 3.45

PLENARY SESSION:

Recommendations & validation

Short presentations of different aspects, public discussion, active participation **Liesbet Geris**

3.45 - 4

NEXT STEPS & WRAP-UP

Liesbet Geris and Barry Fitzgerald


Household announcements

- Wifi
 - Events
 - Key: welcometokit
- Dietary needs: please inform Antonella
- Taxi's for tonight/tomorrow: see sign at entrance
- Any other questions: Emily & team



Public questions

- Questions for audience



- 1 Go to wooclap.com
- 2 Enter the event code in the top banner

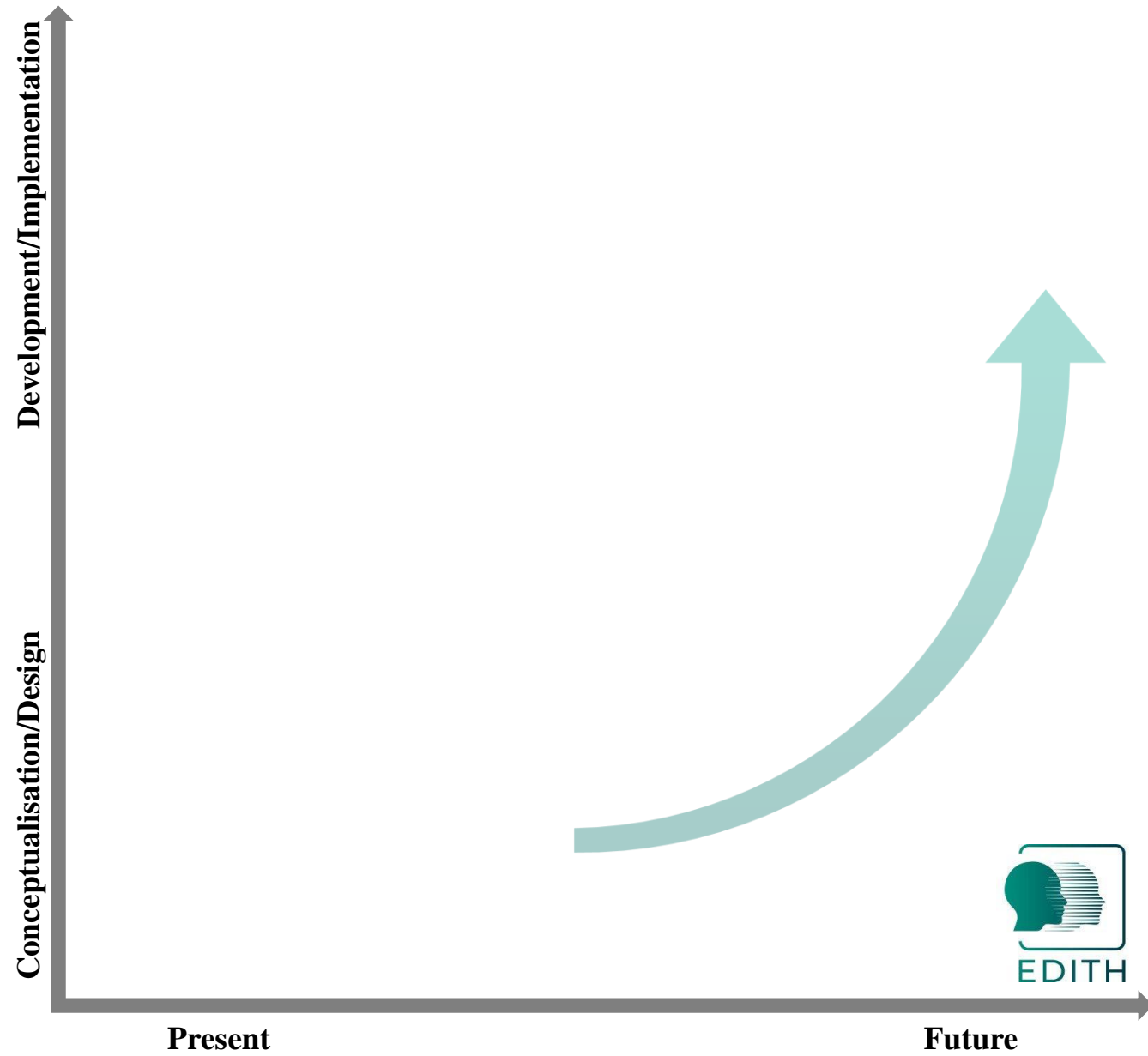
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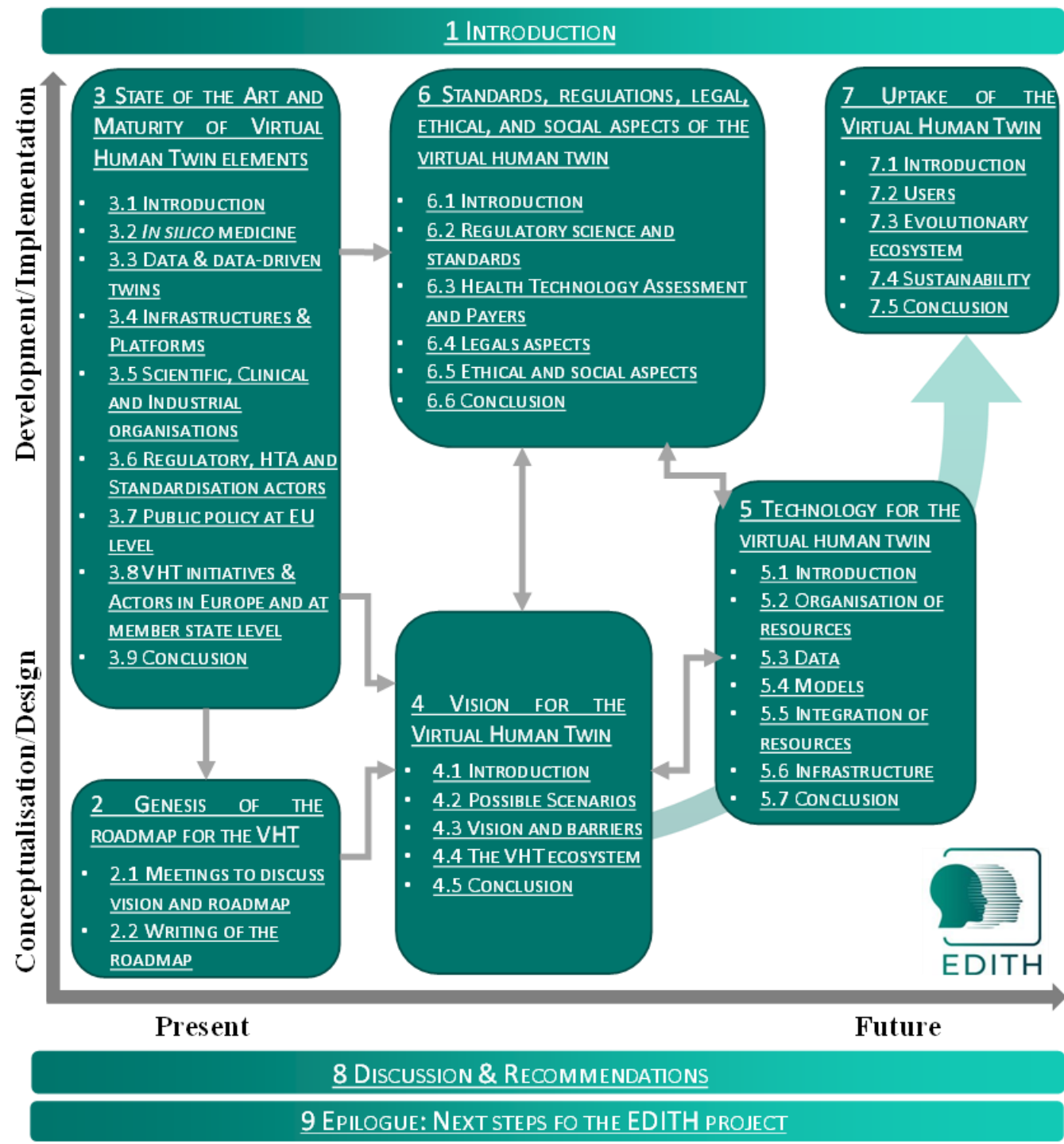


Roadmap & recommendations

Liesbet Geris

16/7/2024






Recommendations for final RM

- Research & use cases
- Infrastructure
- ELSI, standards & regulatory
- Users & inclusiveness
- Sustainability





- 1** Go to wooclap.com
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Event code

ZUDRGJ

Research & use cases

- R&I in the development, testing, validation, and verification of advanced VHT technologies
 - In synergy with existing digital services and capabilities
 - Basic research defined on identified knowledge gaps
 - Continuum of basic to translational research
 - Includes lower TRL work
 - Covering generic / population-specific and personalized digital twins

Research & use cases

- Advancing the understanding of how VHT solutions, products, and services can be used **across the disease continuum**
 - prevention, treatment and follow-up
 - biomedical studies, clinical studies
 - therapy development, diagnostics, remote care and self-care
- **Generation of clinical, experimental and digital evidence** for the (future) development of VHT solutions, methods, and tools and technologies.

Research & use cases

- Identification, development and delivery of high-impact clinical and scientific use cases
 - diagnostics, medical education, training, decision support, therapy development and intervention planning.
 - credibility / risk-informed credibility



Infrastructure

- Designing, building, and enhancing the VHT resource repository and simulation platform
 - in full compliance with applicable laws and regulations in Europe
 - incentivize adoption of VHT in new developments
- Support development, testing and implementation of advanced and interoperable IT platform architectures combining technology advances
 - computational infrastructure, cybersecurity, HPC, cloud services and edge infrastructure

Infrastructure

- Advancing the availability of and access to high quality, annotated and interoperable digital health data
 - standardised in terms of format and semantics
 - safeguarding patients' privacy, personal data, health and safety.
- Include co-evolution with other initiatives
 - Global vision for (life sciences) research infrastructure
 - Links to existing platforms
 - Longevity of support

Missing elements - infrastructure



ELSI & standards/regulatory

- Development of **common ground, trust, agreement and certainty on IPR management, and protection of Trade Secrets**
 - Forms basis for partner collaborations among stakeholders
 - [harmonization or at least] monitoring national laws
- HTA: analyzing effectiveness & efficiency
 - analyse impact , harmonize approaches

ELSI & standards/regulatory

- Identification of opportunities, approaches, standards, tools, and techniques that **enhance clarity of the regulatory landscape**
 - To enable efficacy, safety, trustworthiness, performance and risk management, from early stages of development
 - Evolutionary framework
 - Standards-based interoperability
 - Credibility-by-design
 - Best practices, community-driven standards, consensus procedures, link to credibility & interoperability

Missing elements - ELSI, standards & regulatory



Users & inclusiveness

- Ensuring the contributions, feedback, priorities, requirements, views, concerns and interests of citizens, patients, industry, healthcare professionals, and scientists are **proactively captured and addressed**
 - as part of the development, testing, verification, and validation of VHT tech
 - Active & outgoing ecosystem & user community
- **Building trust** amongst users of the VHT & its developments
 - Trustworthiness vs trust
 - Responsible research & innovation

Users & inclusiveness

- Ensuring that VHT technology **benefits people** of all ages, genders, ethnicities, socioeconomic statuses, and disabilities
 - fostering equitable and universal access to high-quality healthcare
 - Access to VHT: manage own health, personal health forecasting
- **Education & training** on use and developments of VHT
 - For all stakeholders
 - Training & re-training
 - Use of VHT as training platform



Sustainability

- Realising the **embedding of the VHT** as a European Digital Research Infrastructure
 - Co-evolution of existing infrastructure
 - Interoperable, federated, distributed
- Continuous source of support and ecosystem development
 - Top-down
 - Bottom-up
 - Incentivize adoption
 - Ecosystem & technology



Recommendations for final RM

- Research & use cases
 - Infrastructure
 - ELSI, standards & regulatory
 - Users & inclusiveness
 - Sustainability
-
- Elements cross-cutting previous topics

Elements cross-cutting previous topics

- Example: **health data** for building the VHT
 - Access to patient-specific data
 - Data pods
 - Link and access to EHDS
 - Federated
 - Cases where consent is there & data can be harvested
 - Synthetic data > allowed in all countries?

Discussion

Next steps & wrap-up

Liesbet Geris

Input / comments

- Strong basis for VHT
- VHT ecosystem is growing rapidly & thriving
- Collaborative mindset
- All stakeholders represented

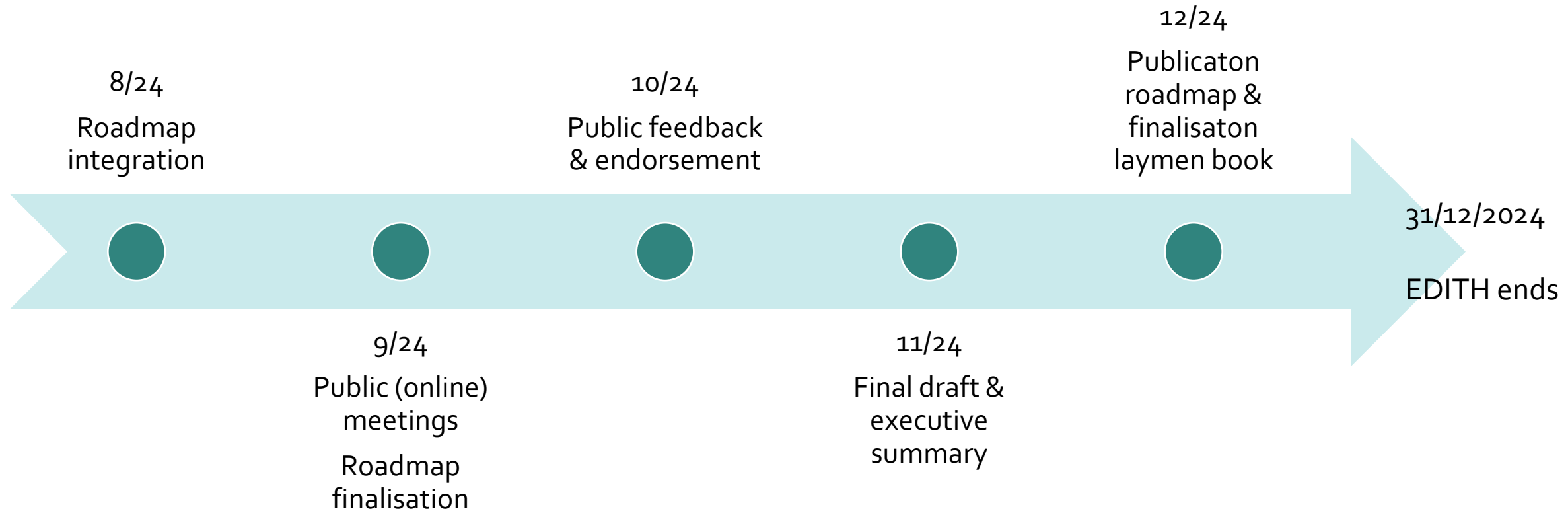
Building the VHT's Yorktown



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Timeline roadmap



Practical requests

- Add to the roadmap
 - www.edith-csa.org/roadmap
- Sign the manifesto
 - www.virtualhumantwins.eu
- Contribute use cases, resources
 - www.edith-csa.org/call-for-use-cases
- Tell your friends!
 - www.edith-csa.org/contact



Final word

Barry Fitzgerald