Building the European Virtual Human Twin

Call: Accelerating best use of technologies (DIGITAL-2021-DEPLOY-01)
Work program year: DIGITAL-2021-2022
Topic: ID DIGITAL-2021-DEPLOY-01-TWINS-HEALTH
Grant Agreement No: 101083771

Minutes of the Deep Thinkers Meeting Rome, May 16th – 17th 2023

Start of the project: 01 October 2022
End date: 30 September 2024

Executive summary

On May 16th and 17th 2023, the EDITH consortium organised a Deep Thinkers Meeting on the Virtual Human Twin in Rome. This document contains the agenda and the notes from this meeting. It is complemented by the slides of the different plenary and break-out sessions.

Table of contents

Acronyms

Acronym	Full name
1+MG	1 million genome
AI	Artificial Intelligence
AR	Augmented reality
ASME	American Society of Mechanical Engineers
B2B	Business-to-Business
CellML	Markup language for mathematical models
CoU	Context of Use
CSA	Coordination and Support Action
Csv	Comma-separated values
CWL	Common workflow language
DCJSC	Data Contract JSON Serializer
Dicom	Digital imaging and communications in medicine
doi	Digital object identifier
DT	Digital Twin
DTH	Digital Twin in Healthcare
DTM	Deep Thinkers Meeting
EATRIS	European infrastructure for translational medicine
EC	European Commission
EHDS	European Health Data Space
EHR	Electronic healthcare record
ELIXIR	European life sciences infrastructure
EMA	European Medicine Agency
EOSC	European Open Science Cloud
EU	European Union
FAIR	Findable, Accessible, Interoperable, Reproducible
FEM	Finite Element Modeling
FHIR	Fast healthcare interoperability resources
GDI	European Genomic Data Infrastructure
GDPR	General Data Protection Regulation
GSP	Goos simulation practice
HTA	Health Technology Assessment
ICD	International Classification of Diseases
IPR	Intellectual Property Rights
ISO	International standards organisation
ISW_CoP	In Silico World Community of Practice
IT	Information Technology
JSON	JavaScript Object Notation
MDR	Medical Device Regulation
ML	Machine learning
nD	n-dimensional
NIfTI	Neuroimaging Informatics Technology Initiative
OA	Open access
Q1	Quarter 1
RDM	Research Data Management
SaMD	Software as a Medical Device
SBML	Systems biology markup language
SED-ML	Simulation experiment description markup language
SNOMED	Systematized Nomenclature of Medicine
SOP	Standard Operating Procedure
Stl	Stereolithography file format
TEF	Testing and Experimentation Facilities
UQ	Uncertainty quantification
USP	Unique selling proposition
VHT	Virtual Human Twin
VR	Virtual reality
VV-40	Verification and Validation 40

1 Purpose of the meeting

1.1 Meeting objective

The meeting saw the participation of 90 experts, both from the consortium and external experts with a mix of representatives from industry, academia, clinicians, research infrastructures, patient organisations. It was a very interdisciplinary group with backgrounds in engineering, mathematics, medicine, biomedical sciences, social sciences, communication sciences, legal sciences. Most experts were based in the EU.

The purpose of the meeting was to discuss the vision of the Virtual Human Twin (VHT), developed by the consortium with the help of a wide range of experts with the goal of ensuring all elements relevant for the realisation of a successful VHT are captured into the roadmap. This includes research challenges (of any kind), infrastructure needs and other requirements. The meeting was not intended to provide definitive answers to all the challenges but rather the ensure all relevant questions were identified.

1.2 Agenda

Day 1: May 16th

12:30 - 13:30 Welcome buffet lunch, networking
13:30 - 14:00 Welcome addresses by the Host (Isabelle Andrieu, Translated and Pi School), the CSA Coordinator (Liesbet Geris) and the European Commission Representatives (Kyriacos Hatzaras & Margherita Fanos)
14:00 - 15:45 Presentation of vision and roadmap for the Virtual Human Twin
15:45 - 16:15 Coffee break
16:15 - 18:15 Breakout sessions

- **BREAKOUT SESSION 1: Infrastructure** (Yannis Ioannidis, Amaryllis Raouzaiou, Sabato Mellone)
  - A distributed/federated architecture: flexible, adaptable, scalable, deployable across multiple locations, interoperable between different systems
  - What core elements need to be centralised
  - General platform and scientific services to be provided to the end-users
  - Domain-specific services ensuring easy onboarding for a variety of services and applications
  - Interoperable access to HPC
- **BREAKOUT SESSION 2: Tech stack** (Marco Viceconti, Alfons Hoekstra)
  - Data and Model objects within the six-dimensional VHT framework
  - Collection from multiple sources, integration across different systems, interoperability
  - Common Workflow Language
  - Quality/credibility assessment
- **BREAKOUT SESSION 3: Data Privacy and Security regulatory landscape** (Edwin Morley Fletcher, Francesca Conte, Lorenzo Cristofaro)
  - Legal scenario and regulatory boundaries
  - Health data reuse
  - Specificities of AI-driven approaches
  - Privacy-enhancing technologies to foster data sharing in virtual twins
  - Ways and recommendations to engage with regulatory bodies towards adoption

19:00 - 22:00 Networking social dinner

Day 2: May 17th

08:00 - 08:30 Arrival, coffee
08:30 - 08:45 Welcome, purpose of the day, the process so far (Liesbet Geris)
08:45 - 10:45 Breakout sessions

- **BREAKOUT SESSION 1: Industry collaborations, Clinical partnerships** (Michael Strübin, Liesbet Geris)
    - Collaborations and partnerships between health technology companies, healthcare providers,
    - and research institutions in the integration of multi-level and multi-organ models towards VHT
    - VHT Manifesto
    - Clinical uptake
    - Recruitment of medical technology experts by healthcare providers and their professional
    - recognition as co-decision makers
- **BREAKOUT SESSION 2: User Experience and co-creation** (Amarillys Raouzaiou, Sabato Mellone)
    - User-centred design
    - User-friendly interfaces
    - User engagement measurement
    - Incentives for sharing data and models
- **BREAKOUT SESSION 3: Sustainability** (Edwin Morley Fletcher, Minos Garofalakis, Sebastien Bratières)
    - Pre-competitive to competitive transition
    - Phases of Distributed Ledger Technology
    - IPR and licensing
    - Business cases
    - Governance roles and responsibilities

10.45 - 11:15 Coffee Break

11.15 - 12:30 Bringing breakout conclusions back to plenary

12.30 - 13:30 Buffet lunch

13.30 - 14:30 World café sessions

- Metaverse, AR/VR (Claudio Capelli)
- GPT (Sanjay Pant & Sebastien Bratières)
- Standardization of data, models, metadata and workflows (Martin Golebiewski & Gerhard Mayer)
- Incentivization (Liesbet Geris)
- Worst case scenarios (Raphaëlle Lesage)
- Training / retraining (Bernard Staumont)

14.30 - 15:30 Lessons learned from other initiatives

- ELIXIR (Niklas Blomberg)
- EATRIS (Gary Saunders)
- TEFs (Petra Ritter)

15:30 - 16.00 Next steps, timeline & prioritization, wrapping up (Sabato Mellone & Liesbet Geris)

2 Vision and Roadmap for the Virtual Human Twin

Slides: EDITH_DTM_Rome_master file

2.1 Presentation

The presentation discussed the vision of the EDITH consortium on the Virtual Human Twin, as it was articulated in detail in the public Deliverable 3.1[1] and discussed in a series of consortium meetings, public information meetings and communications at other events.

2.2 Discussion points

The participants brought up several elements to be further elaborated during the DTM itself or afterwards during further activities of the CSA.

- Data access & consent
- Legal elements related to VHT public infrastructure (access, liability)
- Interoperability (technological & conceptual)

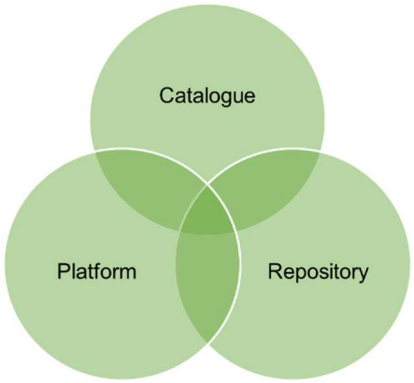
[1] https://zenodo.org/record/7791708

- Ontologies and taxonomy
- Existence of other communities and unique positioning of the VHT
- Existing platforms
- Integration of different resources

3 Breakout sessions

3.1 Infrastructure

Slides: EDITH_DTM_Rome_Breakout_Infrastructure



The discussion focused on the main elements of the infrastructure and the required services

- EDITH Ecosystem: Catalogue, Repository, Platform
- Catalogue: no storage, basic automated "validation"
- Repository: storage, services
- Platform: standard workflows (CWL), interactive computing, remote desktop

The main questions/work points addressed were the following.

- Data Quality (and model validity): automatic *vs*. manual. Who does the data curation? What type of documentation/guarantees do we want to request? *E.g.,* research protocol with details about how the data was collected/verified. Adopt a rating model?
- Data Standardization: converters as a service? Who does it, the user (community) or the provider? Harmonization and mapping cannot be automated in most of the cases.
- Versioning as a service. Notify when a new version of a VHT resource is released.
- Visualization tools should be included
- Knowledge base/graphs for indexing, query, etc.
- Licenses: types and management. Contribute agreement to be included for composite workflows?
- Information about authorized uses and documentation associated with VHT resources as part of the metadata
- Central role of the Community

3.2 Tech stack

Slides: EDITH_DTM_Rome_Breakout_Tech Stack_data and model objects & EDITH_DTM_Rome_Breakout_Tech Stack_resources

At the start of the breakout, it was agreed that the session would focus on determining points requiring further discussion rather than discussing possible solutions in detail. The points discussed were the following.

- Clarification VHT vs DTH
- Influence of environment: exchange, exposome, risk profile
- Time: normalized, years, dates
- Space: moving quantities, anatomical. functional partitions
- Individuality: metadata
- Disease axis: disease vs illness, no axis but annotation
- Model object type: where to put in 6D space? Models are operators, credibility different depending on location
- Eager computing: why (not) > model brokering
- Trust: credibility > trueness & precision, discrete values, influence of CoU
- Validation: measurement chain or validation experiment, quality of data, calculation of trueness/precision in VHT
- Data provenance: learn from others (ELIXIR), curation-standardization-annotation
- Categories of resources: (1) model, (2) data, (3) data transformation services

- Additional resources: compute, storage & network (Géant)
- Integration: inside & between resource categories
- Workflows: managers, knowledge graphs, specificity of VHT vs other communities
- UQ campaigns
- Include clinical applications in VHT itself: technologically possible

3.3 Data Privacy and Security regulatory landscape

Slides: EDITH_DTM_Rome_Breakout _Legal_Health Data Reuse & EDITH_DTM_Rome_Breakout_Legal_Health Data

In the light of the currently applicable legislation, there are a number of gaps which need to be filled and issues that must be addressed. The debate started from 6 macro-questions.

- What are the privacy conditions and safeguards that must be fulfilled so that personal data can be lawfully used in the context of VHT?
- Is the reuse of health data permitted in the EU for the purpose of delivering Artificial Intelligence-driven medical solutions?
- Which obligations apply to the developers and the users of AI-based models? And what is still necessary to elaborate for VHT and relevant communities?
- Can specific Privacy-Enhancing Technologies help ensuring safe and compliant processing for the purpose of in silico medicine?
- Can clinically reliable VHT be generated thanks to anonymous, pseudonymous or synthetic data?
- Which regulatory recommendations can be made to policy-makers to ensure that the EU will soon be at the global forefront of the VHT sector?

The main areas of legislation which are relevant to *In Silico* Medicine and so to Virtual Human Twins ('VHT') are, to date, GDPR, Data Governance & reuse, AI Act, Medical Devices Regulation, Clinical Trial Regulation. Challenges and novelties of said legislation were analysed in the Breakout session, with a special focus on the roles and responsibilities of the parties involved in the reuse and/or sharing of personal and health data. VHT will always configure 'high-risk systems' under the AI Act, whenever they will qualify as Medical Devices (or SaMD, Software as Medical Devices). In other cases, a case-by-case assessment must be carried out to ascertain whether the VHT amounts or not to an AI high-risk system. Special attention was also paid to anonymisation and pseudonymisation, comparing the very complex scenarios and operational uncertainties deriving from the strict interpretation of these concepts, and the novel perspective offered by EU Court of Justice in a very recent landmark ruling (26/4/2023, Case T 557/20). Finally, privacy enhancing technologies were discussed.

3.4 Industry collaborations, Clinical partnerships

Slides: EDITH_DTM_Rome_Breakout_Industry Clinical collaborations

The session included a number of testimonies from industrial participants (Ger Jansen (Philips), Antoine Rimaud (TwinSight), Martha Cunha Maluf-Burgman (Edwards Life Sciences), Mariano Vasquez (ELEM), Vincent Uyttendaele (InSiliCare)) and clinical participants (Frank Rademakers (University Hospital Leuven), Gunther Deutschl (University Hospital Schleswig Holstein, campus Kiel)).

The key-points discussed were the following.

- Different outlooks & perspectives (patients, healthcare providers, industry,…)
- Hybridization of people/profiles, shadowing (brining engineers into the clinics, have clinicians spend time in engineering school)
- Collaboration from the get-go rather than in the end stage of the project. 'Self-validation' is an important component of uptake (*i.e.*, what can I do with the model, how does it work for me?)
- VHT uptake in whole ecosystem: involve all stakeholders – including hospital IT departments

- Clinical data: electronic health records are very different geographically (format, centralisation)
- Open science: incentives, USP, IPR
- Monetization: what are the business models? A validated and clinically useful model is no guarantee for translation into practical use.
- Reimbursement of in silico services > HTA discussions
- Regulatory – MDR: clear regulatory guidances are lacking at level of EMA and notified bodies (for latter it depends on the notified body)
- Clinical value proposition: not only to improve patient care but also to help reduce the impact of staff shortage as well as use in training of clinicians & healthcare providers.

3.5 User Experience and co-creation

Slides: EDITH_DTM_Rome_Breakout_UI_UX

Mock-ups of what the VHT environment could look like were prepared and the breakout participants were taken on a tour of the VHT, while different options for several of the services were elaborated and discussed. Major elements:

- Login module
- Provider perspective: upload resource in the repository
    - Semantics
    - Ontologies: list major existing ones to be included in VHT. What if the dataset does not follow an ontology?
    - Standardization: metadata crosswalk, guided procedure for standard mapping
    - Licensing: OA vs specific conditions (accept/decline conditions, signature on the document, warranties, other documentation needed): how to adopt this strategy?
    - Data object pose:
        - Body: how to represent a data set in the 6-dimensional framework[2]? How to represent datasets with different variables?
        - Time: how to represent a dataset with different subjects?
        - Credibility: different procedures were discussed on standardizing the procedure to reach a certain credibility rating and inserting a third-party process for its evaluation.
        - Clustering: how to generalize the concept (also in relation to previous questions on multi-subject datasets)
- User perspective
    - Strategies of selecting resources
        - Based on visual representation of the body / organ system of interest: with or without preselection of type of resource and scale?
        - Query based on metadata information
    - Build the workflow
        - Technical validation: system checks for actionable nature of selected resources, for HPC connections (and credits), for input-output compatibility and required inputs.
        - What about a «logical validation», i.e. if the datasets and models used are coherent with each other?

3.6 Sustainability

Slides: EDITH_DTM_Rome_Breakout_Sustainability

In this breakout, various elements related to long-term stability and evolution of the VHT ecosystem were discussed.

- Ecosystem - a model different from market and hierarchy
    - The role of Distributed Ledger Technology: track, transaction, provenance, trust, transfer, efficiency
    - Phases of the evolutionary ecosystem[3]: honour ledger, token ledger, money marketplace
- Governance models: by consortium (honour ledger), by third party (token phase)

[2] https://zenodo.org/record/7791708
[3] https://zenodo.org/record/8070381

- Ensuring long-term sustainability:
  - partnership between EC and EU industrial partners
  - non-for-profit part of the infrastructure funded by EC
  - fully commercial services/segments
- Valuation mechanisms:
  - how can incentive linked to automated assignment and distribution of value and quality validation be determined by ML mechanisms?
    - Resource valuation, Shapley values, DTH model valuation
    - What about unforeseen uses?
    - Is value determined by the person using the resource?
  - IPR and licensing
    - Models created in VHT space > build services around them
    - In software, solutions exist for common IPR
    - Why IPR: comply with regulations, contractualise resources, allow translations
    - Guide users to identify correct license > cfr Github
- Business models
  - Relatively few computational clinical models on market (difficult to predict what business models will function)
  - Future drivers: clients are hospitals, diagnostic centres, patients, B2B, multi-platform model libraries
  - Roadblocks: performance, accuracy, trust, amount of resources
- Money marketplace
  - Growing community: (1) scientific /academic (exploration) & (2) industry & entrepreneurs (private use)
  - With procurement process included in the Digital Europe work program (end 2023), quid evolutionary ecosystem approach and correlative incentives?
- Other elements
  - Involve payers & HTA
  - Provide guidance for the standard process

4 World Café Sessions

During the world café sessions, a variety of topics were addressed in a highly dynamic and interactive manner. All sessions were running in parallel with a duration of 20 minutes and all sessions were repeated 3 times.

- 3'-5' to introduce the topic
- 11'-13' for free discussion or live polls
- 2' to wrap up with main conclusions for further development in VHT/roadmap
- 2' to move from one space to another

The topics chosen are relevant topics for the VHT and, if not addressed in the first draft of the VHT roadmap, will be discussed in year 2 of the EDITH project and included in the final VHT roadmap.

4.1 Metaverse, AR/VR

Possible implementation for AR/VR in the VHT is through planning, training and patient interaction (as first targets).

Planning

- Patient-specific model: anatomical visualization, slicing/clipping, cutting, labelling, virtual imaging
- Increased confidence
- Advantages over conventional imaging
- Advantages over 3D visualizations

Training

- Topics: anatomy, imaging, procedure, scenarios
- Training tool for residents and medical students: immerse trainees in a virtual rendering of a range of different procedures, particularly with laparoscopic procedures. Previous studies have shown that trainees who use these VR simulators in their surgical curriculum face shorter times to completion of their learning tasks compared with their counterparts who did not use VR. The use of VR for surgical planning has been demonstrated in plastic and orthopaedic surgery wherein surgeons created VR models of their surgical sites and simulated the planned procedure.
- Simultaneous training across globe

Patients

- Can increase understanding
- Reduce the anxiety
- Used for rehabilitation
- Increased compliance

Can VR/AR facilitate the uptake of VHT?

- Benefits in all areas of management of complex procedures
- Technological developments (e.g., new platform and applications) will expedite VR/AR progresses
- Gather clinical evidence on the benefits
- Support training programmes
- Facilitate the patients' involvement
- Need for a cost/benefits analysis

4.2 GPT

Slides: EDITH_DTM_Rome_World Café_GPT

During this session, the use of large language models (LLM) was discussed in the context of EDITH and the VHT. This included the following points, complemented by short online questionnaires.

- VHT repository: large body of scientific, legal, regulatory, and other relevant documents
- Large language models can be used to summarise literature (individually and collectively) and answer any question from the literature
- Chat-GPT: caution from WHO, banned in Italy

4.3 Standardization of data, models, metadata and workflows

In this session, the state of the art was discussed for a range of topics related to standards for the different VHT resources.

- Data formats, integration & input
    - DICOM, NIfTI, stl, omics, identifier mapping, csv + controlled vocabulary, xml + controlled vocabulary, JSON, DCJSC, electronic HR (openEHR)
    - Physiology data, biosignal data, wearables
    - Ontologies/semantic
    - FEM
- Modeling: SBML, CellML, COMBINE standards, hdf5, SED-ML, guidance documents, GSP, ISO 9491-1:2023
- Metadata
- Data provenance: ISO 23494 series
- Interoperability: FHIR, terminologies (SNOMED, …), ICD-10
- Workflows: CWL, protocols
- Record linkage
- Model quality & validation: needs to be developed specifically for VHT models. Based on VV40, upcoming ISO 9491-1:2023 & GSP
- Standardization initiatives, committees & drivers: TransCelerate

4.4 Incentivization

For academia

- Reputation rewards
- Citations / doi / publication (cfr Physiome)
- Align with institutional requirements on data management systems
- Facilitate the process: user-friendly interfaces, automated annotation services, automatic extraction from Zenodo, …
- Success stories & information campaigns
- Use of VHT environment as non-public personal/lab sand-box to minimize effort of translation later on
- Why should EU care & fund > added value of open science, cfr ELIXIR

For industry

- Should industry be treated differently (less services, pay more, …)? Cfr EHDS > no discrimination between actors, only between purposes. How to evaluate?
- Sharing data might be ok. Sharing models much more tricky > Intellectual Property. Cfr FDA: qualification of tool is not enough incentive to convince company making model publicly available

For patients

- Get them involved early if you want to go towards co-decision making. Having others sell your message is 10x more powerful.
- Impact pathways: show stories about how this might work. Match them with top-down & bottom-up expectations. Communication on early wins to show value.
- Alternative use of models as science communication tool > workflows can be created to facilitate the process targeting different audiences (cfr New Zealand 12 labours project's citizen portal). Interfaces can be created for visualization from models where only text needs to be added. Help targeting different audiences / cater to different cultural views (world lenses)

4.5 Worst case scenarios

In this session, possible non-intentional malfunctions & intentional malicious use were discussed. Identifying the risks from the beginning allows to consider the possible solutions early.

- Malicious use by insurance companies: usage for risk assessment without permission. Is it justified? Political choice? Is this a global worry or is this geographically constraint?
- Using scientific components for pseudo-scientific claims : *e.g.* white supremacist groups, stigmatization, anti-vaxxers, homeopathy
- Unsupervised use of twin technologies/output by people who are not trained and might have limited understanding/knowledge (*e.g.* patients to make predictions with their data). To what extent should patients have access? Is it ethical to receive health information through messages from a platform? The easier it is for untrained people to work on the platform, the easier the interpretation/conclusions might be wrong.
- Faulty output
- Increasing gap in healthcare access & support (EU-context & globally)
- (re)use of data without consent: transparency in database (different consent forms). Differences between member states, institutions, etc. Patients want to come back on consent: (im)possible? [cfr discussions in the legal breakout]
- Industry: reverse-engineering: *e.g.* bioweapons, misuse for own benefits, use VHT to kill patient faster
- Manipulation of clinical trial or data for own benefit (bias): what actors/processes can/should prevent manipulation of output? Which questions are (not) allowed? Conscience researcher?
- Hackers/malware
- Reuse of data, validation will decrease (developed for a purpose and used in another one)
- Sold by social media platforms
- If you don't pay for it, you are not the client, but the product

Solutions/considerations moving forward:

- Social engagement crucial in projects
- Projects focusing on data (EHDS)

- Involvement of social scientists
- Create awareness, educate citizens (> knowledge)
- Open event: include general public
- Transparency of governance/ decision-making
- Transparency of model interpretation, where results expected.
- Define purpose of tools (because open access for different stakeholders!)
- Have a responsible person for questions around imaging data, understanding model, etc.
- Biased data is a normal case scenario (inherent to research)
- Every model application should have a definition/description of what it is supposed to be doing
- Include legal disclaimers on platform

4.6 Training / retraining / skills development

Who needs training? Diverse profiles – Regulators, clinicians, modelers, researchers, HTAs, notified bodies

- Training the regulators : train and retrain, profiles of candidates at the regulatory agencies. To reduce the barriers that block *in silico* trials, we need to build necessary competencies at various levels. Possible approach through internship/exchanges: Possibility to facilitate short-term movement of *in silico* experts. Thus, steer internal push. Likewise, possibility for regulatory experts to spend time and gather know how from academia.
- Training the clinicians : Need for specialization courses within the medical school. Need to teach them on standards and the value it brings.

Training areas and modes

- Training & Validation
  - Training is often only related to development while validation is seen as less interesting. Training on validation process is passed on to end-user.
  - Validation is a multi-disciplinary element, where communication between the engineers and biologists, is not straightforward.
  - We need to build competencies not only on "*How to validate*" but "*Why validation is critical*".
- Can an independent validator profile help?
  - Can we build a dedicated set of experts, who champion and carry out validation?
  - Inspiration: Testing teams within software companies.
  - Approach: Sub-groups within the research labs, who have the necessary competencies on validation. Barter system: each researcher to validate the models of fellow researcher.
- Training modelers on ontologies and validation as part of summer schools
  - Theory and hands-on workshop
  - Training the younger generation on the value of "validation" is rewarding, as they move up to industry/clinics/regulatory agencies.
  - Training is also needed for how to use the platform

Incentive & measures of success :

- Accreditation +++
- Certifications
- Continuous professional development (works well with clinicians)
- Course credit points

Learnings from ELIXIR

- "Train the trainers" has been very successful and scalable. Thanks to:
  - Accreditation
  - Formal peer-to-peer push
  - Performance management strategy
- Federated infrastructure with node coordinator, given the responsibility of professional manager role.
  - Classifying training into generic *vs.* transferable skills
  - Overseeing the execution of the above training modules

Why training and capacity building is critical for VHT?

- Value addition: key for sustainability
  - It's an act of engagement with community.
  - Having training material/platform is a good sales pitch element for the VHT infrastructure.
  - Fosters adoption.
  - Key element and foundation for sustainability.
- VHT platform as a "mode" of training
  - Encompass all components required for training within the VHT platform.
  - Library of validated models, data, SOPs.
  - Use the platform to give training and develop competences: where the examples of how the models can be validated is made obvious (*e.g.* coursework, ready-to-follow topic). Thus, empower the users to embrace the validation workflow and emulate it for their own models.
  - Strive to use training as a means to enrich the platform
- How to measure the success of training?
  - Job retention
  - Satisfaction of employees
  - Fostering transnational collaboration

5 Lessons learned from other initiatives

Niklas Blomberg (ELIXIR), Gary Saunders (EATRIS) and Petra Ritter (TEFs) presented their respective European large scale infrastructures/organisations.

5.1 ELIXIR

Slides: EDITH_DTM_Rome_other initiatives_BLOMBERG ELIXIR

Main message: analyse what is available, what can be used in the context of ELIXIR/VHT and what needs to be developed. The presentation showed many examples of synergies between ELIXIR and other initiatives (RDM toolkit, EOSC, 1+MG, GDI) that can serve as examples for further development and implementation of the VHT and its infrastructure.

5.2 EATRIS

Slides: EDITH_DTM_Rome_other initiatives_SAUNDERS-EATRIS

Main message: understand the Unique Selling Proposition of the initiative and its place in the landscape. Combine bottom-up (starting from user needs) and top-down (vision-driven – within the niche) actions. Understand impact pathways. Explain vision to others.

5.3 TEFs

Slides: EDITH_DTM_Rome_other initiatives_RITTER_TEF

Main message: pragmatic solutions for data access & management in accordance with regulations. Interaction/alignment with other initiatives, after evaluation of readiness, driven by use cases. Interaction with notified bodies, regulators & standards organisations. Provide AI regulatory sandboxes.

6 Next steps, timeline & prioritization

Slides: EDITH_DTM_Rome_master file

6.1 General conclusions

- Proposed vision and roadmap elements cover the major topics related to VHT and its implementation in broad lines. Further refinement necessary in second phase of EDITH project and implementation in follow-up EC programme.
- Continue to investigate what is available, what can be exploited and what needs to be developed specifically for the VHT and its infrastructure.
- User needs are key. Most users are already on board > intensify interactions. Add hospitals (management & IT departments) and innovation procurement.
- Community support is crucial. VHT is starting to live within the community. Year 2 of the EDITH project will focus on further widening the reach (cfr section 6.3).

6.2 EDITH use case contributions

The proof of concept implementation of the EDITH repository will include selected use cases from consortium partners: from the integration with other platforms to the interconnection between models developed by different research groups.
External contributors are expected too and will be reached through the EDITH database (with contact details of community members having indicated an interest in the EDITH project), Advisory Board Members, synergies with the ongoing research projects, coordinated activities with relevant stakeholders, and other EU networking initiatives.

To invite in external contributors, we will release a structured form and procedure by the end of summer. The external use cases will require:

- a narrative description, e.g. intended use of the model, users involved, brief description of inputs/outputs of the model.
- the full dataflow: the flow of information for any process/step in the pipeline.
- a detailed description and a sample of input/output data for each computational block.
- a detailed description of each single computational block in the pipeline, models and tools.
- the computational requirements for each block in the pipeline.
- the additional functional requirements; e.g. the need for dedicated user interfaces.
- the legal requirements for both models and data; e.g. who is the data controller, the lawful basis for the processing, the need for an ISO certified data hosing service, etc.

6.3 Next steps

Following activities are foreseen to widen the reach of the EDITH project before the end of the first project year

- Presentations to different communities: AR/VR coalition (22/5), European Society of Cardiology/Radical Health Festival (14/6), European Society of Biomechanics/ESB2023 (12/7)
- VHT Manifesto : expression of intent by entire ecosystem > pre-signature process facilitated by EDITH
- Public discussion session online: June 1: 12-1pm
- Public discussion phase of the first draft of the VHT roadmap[4]: mid June – July 15th (via google docs, ISW_CoP slack or offline)
- Deliverable: first draft of roadmap to be submitted on 31/7/2023
- Publication of call for use cases/resources (cfr. previous section): early September 2023

Activities to widen the reach of the EDITH project during the second project year

- Dedicated meetings with specific communities to investigate synergies
- Community writing (via google docs & slack)
- Public meetings : Paris Q1 2024 & Amsterdam 14-15/7/2024
- …

[4] https://zenodo.org/record/8070381