Breakout session report

EDITH-CSA Amsterdam meeting

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Overview breakout sessions

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Breakout sessions

- Digital health economics
  - Edwin Morley-Fletcher (Lynkeus); Enzo Fabiani (DigitalEurope)
- Use cases & proof-of-concept infrastructure
  - Sabato Mellone (University of Bologna)
- Standards
  - Martin Golebiewski and Gerhard Mayer (Heidelberg Institute of Theoretical Studies)
- Communication strategy & stakeholders
  - Davide Montesarchio, Martina Contin, Goran Stanic and Zita Van Horenbeeck (VPH institute)
- Balancing roles and responsibilities: how to define user profiles
  - Gökhan Ertaylan, Simon Denil, Frederic Jung (VITO); Frank Rademakers (UZ Leuven - KU Leuven)
- EU-AM-AP collaboration
  - Liesbet Geris (VPH institute)
- Unlocking research infrastructures to broader community
  - Marian Bubak, Piotr Nowakowski (Cyfronet); Marco Verdicchio, Sagar Dolas (SURF)

Breakout sessions: rooms

- Digital health economics: (8) Claus room
- Use cases & proof-of-concept infrastructure: (10) Queen Maxima Hall
- Standards: (6) Regents room
- Communication strategy & stakeholders: (2) Maurits room
- Balancing roles and responsibilities: how to define user profiles: (4) Council room
- EU-AM-AP collaboration: (7) Emma room
- Unlocking research infrastructures to broader community: (5) Board room

Use cases & PoC infrastructure

Sabato Mellone (UNIBO)

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Use cases & PoC infrastructure

- Clarify as much as possible the aim of the PoC in relation to the Roadmap
- Include in the Roadmap some “stories”/examples on how the mid-long term implementation of the VHT infrastructure will benefit the community
- Be more specific about the tools that should/will be available for the Community: data curation services, data standardization services, co-development tools, consensus processes, etc.
- Establish a inter-project board, with representatives of the projects funded in the call related to EDITH, to review the design choices based on the standard/requirements reported in the Roadmap. The aim is to take decision on the development and deployment of data and model. The board kick-off could be a workshop organised by EDITH in the fall.

Standards

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You cannot vote anymore

What are the gaps you still see in the standardization landscape?

Communication strategy & stakeholders

Davide Montesarchio, Martina Contin, Goran Stanic, Janaki Raman Rangarajan and Zita Van Horenbeeck (VPH institute)

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Stakeholder Engagement

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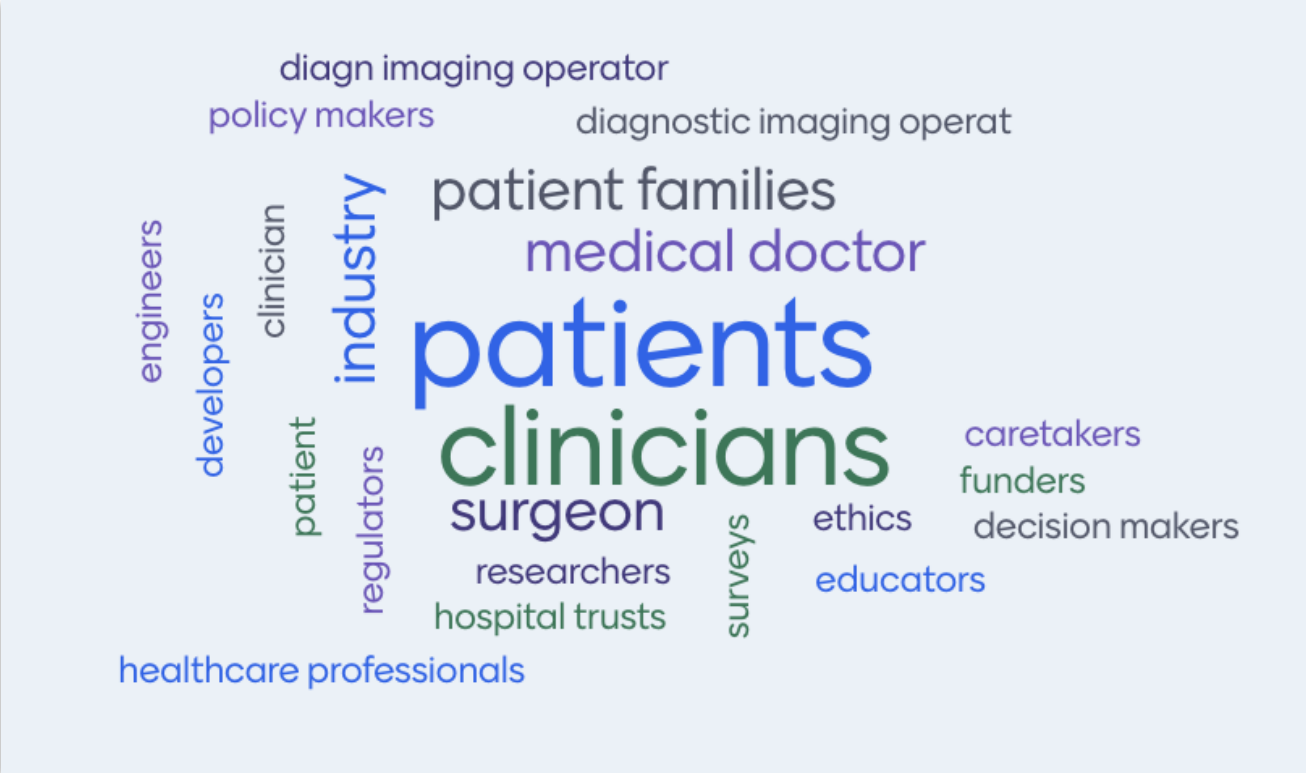
Action points



- Feedback mechanism
- Joining forces
- Education
- Engage clinicians and lay people
- Tailor the language
- Stakeholder inclusion in R&I
- Constant feedback

Communication & Dissemination

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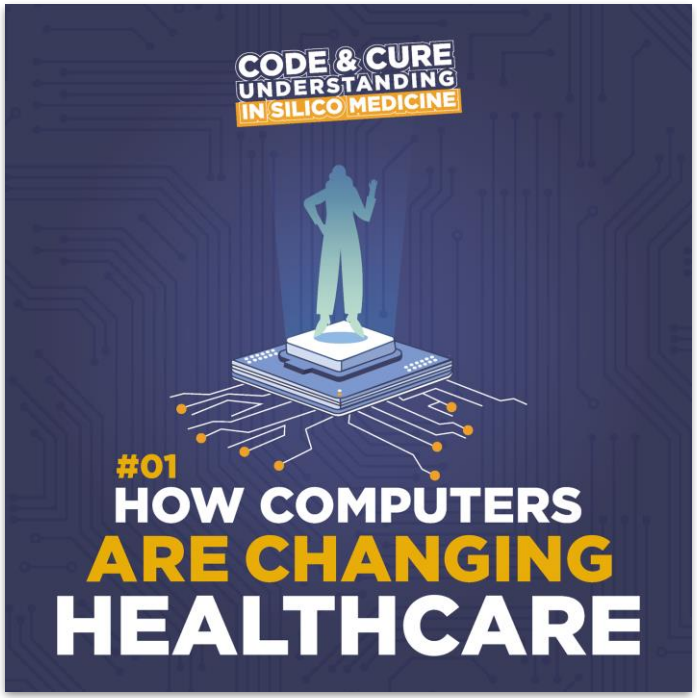
The importance of communication

The activities we conduct



Main points & Challenges

- Longer form content
- Tailor the language
- Finding the right balance engaging and not overselling
- Barriers as opportunities for growth
- How can we facilitate the flow between researches and communicators

You cannot vote anymore

How can we effectively empower and engage clinicians and patients?

You cannot vote anymore

How can we engage the VHT ecosystem in the communication process?

wooclap

100 %

57

Balancing roles and responsibilities: how to define user profiles

Gökhan Ertaylan, Simon Denil, Frederic Jung (VITO)
Frank Rademakers (UZ Leuven - KU Leuven)

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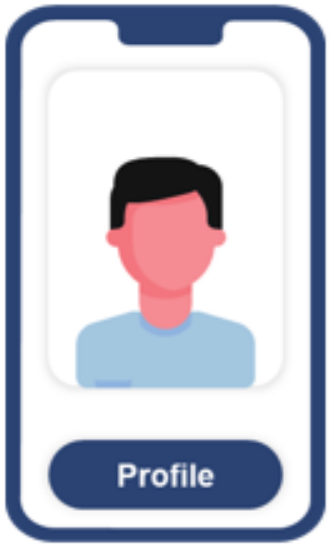
User Profile vs. Roles

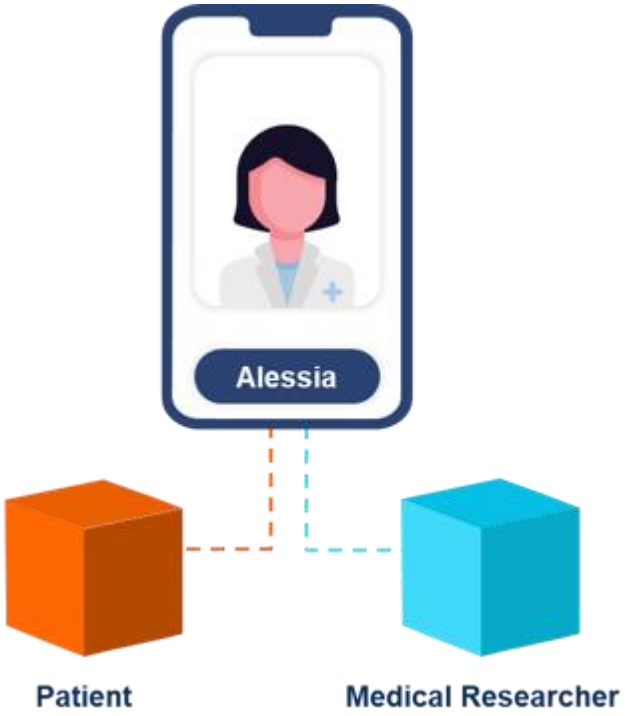
A user **profile** is a **collection of settings** and **information** associated with a user. It contains critical information that is used to **identify an individual**, such as their name, age and individual characteristics such as knowledge or expertise. The profile can be linked to external IDP (Identity provider) and thus authentication mechanism can be extracted to third party service.

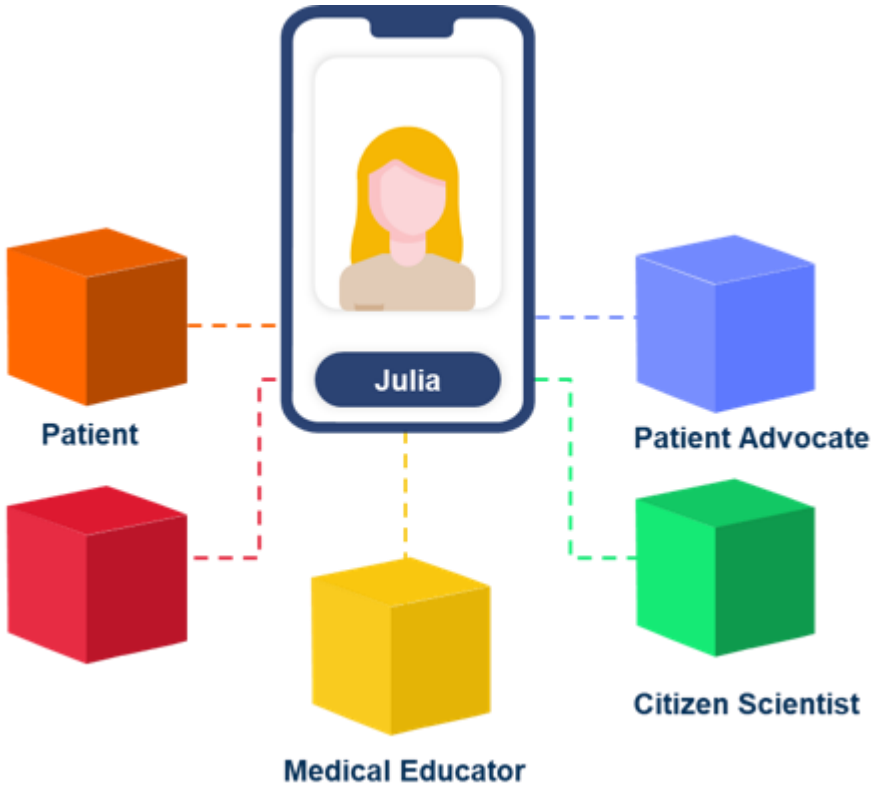


The **profile does NOT distinguish the role** of the user in the system.

User **roles** is a collection of capabilities that can be used to give access to concrete part of the system.

User Profiles vs Roles





Additions to the proposed roles system

- **Grants**: Facilitates dynamic allocation of resources (HPC, Data or other) to profiles based on agreements such as funded projects (EU, national) or institutional agreements or Affiliations (See below).
- **Affiliations**: Identifies the profile with affiliation with EU Institutions. Multiple affiliations are possible. (Can provide Grants to User Profiles for resource access).
- **Purpose**: Defines the explicit reason of use of certain data in the system. The data descriptor (metadata) is machine readable. Essential as it defines the workflow/pathway to access to a data resource.

Grants, Affiliations and Purpose compliment Roles and Profiles in a dynamic way to facilitate quick(er) dynamic access without creating multiple roles.

Session summary (1/3)

- **Overall**
  - National identity providers (later EU ID) preferred way for authentication in the platform, this might leave some non-EU citizens out. How to address this ?
  - How do we interface with other health infrastructure. Is this a new role or a new function in an existing role ?
  - Who assigns the roles initially ? How do we initialize and keep synced with reality in a federated infrastructure? Some professions have well organized national bodies, others not. Have a board for this purpose?

- **Quality assessment**
  - Who's job will it be to assess the quality of data ? Role : Simulation Engineer or a missing role ?
  - What about model's credibility ? What is the precise mechanism of keeping track of model credibility in relation to the roles ?
  - Who evaluates the platform ? Should not this be an independent agent/actor ?

Session summary (2/3)

- **Roles missing or Incomplete coverage**
  - Role of a data curator – who should be able to understand the model requirements / biology?
  - We need to be more sensitive and avoid use umbrella terms – important to be aware of the semantic differences (e.g. healthcare professional vs. clinical professional)
  - What is the intended purpose of giving citizens access? Make it clear the suggested *evolution of these roles* in the roadmap.
  - The patient/ citizen under the same category currently, which is ok in the early phase – Eventually these roles have different motivation, interest – how does this translate to level of access?
  - ELSI roles, where do they fit ?
  - Can we have role categories for *Health Data Access agencies*, *healthcare representatives – Patient association*, *service providers* …
  - Role of Industry related roles could be fleshed out better as their purpose of data access could be different than academic roles. Private industry actors with similar roles to academic user with different level of access? Through affiliations? Subset by purpose? (commercial vs public good/pre-competitive)

Session summary (3/3)

- **Data & Data-access procedure (Potential Road Block)**

  - Anonymization vs Pseudonymization of data
  - Data access bodies – by EHDS declared to decide on access for secondary use raises concerns about consistency across and within borders
  - Different from the DT/VHT simulation workflows – we need to create a data access procedure (we first need to know the purpose) to ask for permission. Create the workflow with a specific purpose and go through health data agencies to ask for the specific data.
  - Challenges are expected in data sharing & data-quality: even with great effort for the data access procedures it will be difficult to ensure the data quality in this entire ecosystems.


European Data Strategy

EU-AM-AP collaboration

Liesbet Geris (VPHi); Thiranja Prasad Babarenda Gamage (ABI); Anna Niarakis (Univeristy of Toulouse); Gary An (University of Vermont VT)

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Overview

- EU, funding opportunities – Liesbet Geris
- AP, lessons from 12 Labours, Sparc, VITAL – Thiranja Prasad Babarenda Gamage
- Example of bottom-up collaboration: the immune digital twin – Anna Niarakis & Garry An

Discussion points

- Sharing roadmaps & recommendations
  - Strategic documents
  - Key learnings, knowledge base, …
  - Aligning on vision & key-elements > interoperability-by-design
  - Mapping between standards

- For all stakeholders : Industry, academia, clinicians, patients, policy makers, regulatory, HTA, payers
  - Patients as drivers? Rare diseases, pediatrics,…
  - inter sectoral collaboration

Discussion points

- Communication
  - Success stories to help show progress: IDT
  - failures & lessons learnt
  - Find relevant project calls > overview?

- Facilitate collaborations across continents
  - Find relevant partners across the globe
  - find collaboration opportunities
  - Find collaborative platform

- VHT ecosystem is a success story: keep it alive!

You cannot vote anymore

What is the biggest challenge in collaborating with partners/organisations from other continents?

Unlocking research infrastructures to the broader community

Marco Verdicchio, Sagar Dolas (SURF);
Marian Bubak, Piotr Nowakowski (Cyfronet)

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Main barriers related to performing research on EU funded infrastructures:

- There is insufficient dissemination of information regarding the available infrastructures ("*we don't know about these possibilities*")
- There should be a well-defined outreach methodology, with KPIs - benchmarking - otherwise most infrastructures are used only internally
- "Proposal within a proposal" - the process of applying for access to infrastructure is tedious; perhaps the grant agency could apply to the infrastructure provider on our behalf while deciding to fund your proposal?
- Unclear if research infrastructure is certified for medical research
- Physicists/astronomers know how to apply for/use HPC because they tend to have longstanding experience - this is less true for life science researchers. Funding is biased towards established communities.

Making research results sustainable on EU funded infrastructures

- What is needed is some kind of instrument for upkeep of research services.
- A standard to describe infrastructural requirements would be useful.
- The way forward for advanced platforms is to work towards a higher level of engagement of member state actors (ministries, etc.) to promote sustainability beyond the nominal end of EU support.
- Important Projects of Common European Interest (IPCEI) - funding instrument, incl. for cloud services (quite high on the EC's agenda)

Interoperability, data sharing and usage of commercial resources for scientific research

- Nowadays, we have catalogues, marketplace, containers etc. - technical challenges are going away
- OTOH platforms do not share authentication mechanisms and have few infrastructural commonalities (unlike commercial platforms - eg. Azure, where you can deploy services all around the world under a single contract with MS) - no shared APIs/billing systems/accountability in EU systems
- Legal issues (incl. data privacy and IPR)
- Incentivization is key - it cannot just be red tape and responsibility for the data provider
- Need a clear path for individual researchers/clinicians on how to become involved with EU infrastructures (EHDS, etc.)

You cannot vote anymore

How do we evolve our existing infrastructures to support advanced use cases and applications - technically, organizationally and socially?

Digital health economics

Edwin Morley-Fletcher (Lynkeus)
Enzo Fabiani (DigitalEurope)

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Ecosystem orchestrators

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.

Ecosystems can be defined as groups of firms that deal with interdependent complementarities requiring the creation of a **specific structure of relationships and alignment.**

A new digital economy

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.

Hierarchies and Markets

Platform ecosystems are **organisational structures which are different from both hierarchies and markets**.

High transaction costs lead to hierarchies and command economies, low transaction costs lead to market solutions.

Modularization and the subsequent reduction of frictional transaction costs are more likely to lead to the emergence of ecosystems, if there is at the same time a significant need for coordination that cannot be dealt with in markets, but which requires the **non-hierarchical alignment** orchestration provided by a platform.

Multi-sided platforms

Multi-sided platforms are ecosystems orchestrated by platforms which 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.

Digital platform firms and their ecosystems appear to be, for the time being, the organisation model showing the greatest capacity to scale, thanks to its capacity to internalise network effects by producing at loss on one side while eventually compensating it with profits on other sides.

They thus initially appear to go for growth, not for profits, gathering this way huge amounts of equity from investors who value this approach, turning traditional industry dynamics on their head.

The emblematic organisational form of the digital age

This phenomenon is so quick and intense that it may drive unregulated competition to a “winner takes all” outcome.

All in all, ecosystems and platform seem to represent until now 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, eventually bringing about the cost revolution implied by prioritising predictive medicine through the growing adoption of Virtual Human Twins.

Of course, such a transition risks to determine an immediate increase of costs while allowing for significant longer-term economies. This is another type of chicken and egg situation.

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 initiatives** 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.

What types of data can be used on the platform?

The platform is characterized by the choice of allowing for use only **data for enabling the identification of users accessing the platform** and **anonymous** or **non-identifying synthetic** human health and disease data.

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**.

Pseudonymised data shall also not be admissible to the platform within this procurement, but 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.

How to interpret this (initial) restriction ?

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.

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.

This apparently very restrictive choice can be seen as being 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 recoursive loop, where AI systems generate synthetic data, which then train other AI systems**.

This choice may appear as paradoxical considering that such an iterative process, based on the interaction of AI and data synthesis, would be precisely 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**.

Are we to think that the European Commission has **boldly decided to procure a platform** which will initially operate with great **abundance of synthetically generated and low-cost data** for training the algorithms to be applied outside the platform by clinical and research institutions making use of personalised and appropriately consented data of specific individuals?

Business models

Various business models can be implemented by a variety of stakeholders within a mature sustainable VHT ecosystem, based on mutual incentives and advantages deriving from the interaction through the the same platform.

Different incentives and strategies can be explored to facilitate the adoption of VHT tools in the clinical practice, such as:

a. Assessing the economic benefits of adopting VHT solutions compared to traditional ways of treating patients – on the basis of the known data about the costs of a given illness and of the relevant treatment; the target could be the payer of the health service (e.g., insurance companies, public and private providers) with a patient-centric focus on outcome instead of established DRG performances
b. Experimenting new patient management and onboarding strategies, so to offer incentives to care providers to adopt novel tools and technologies minimising costs and optimising treatment outcomes. The target could be decision makers managing the resources to be allotted to care providers for handling specific conditions (e.g. chronic disease patients);
c. Demonstrate superior treatment outcomes associated with the adoption of VHT tools if compared with standard practice; the target could be clinicians specialised in the area interested by the application of a given VHT approach.

Validation

Various models for applying VHT tools could be implemented, both locally (on premise at the hospital) and as a service – accessing the models directly within the platform.

The platform could facilitate the validation of novel tools and the sharing of relevant data by incentivising the offering of clinical expertise for validation, the availability of validated solutions and simulations to be accessed with appropriate IPR definition.

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