

Balancing roles and responsibilities: how to define user profiles? (15/07/2024)

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Breakout session

Type/source data by initiator/generator

Clinical care Including prescribed wearables and questionnaires	by HCP	Clinical notes Labs, tests, genomics, ... Imaging Holter, BP 24hr Apps in EHR Social Biobank
Registries	by scientific organisations, others	Mostly linked to pathology ex ERN
Experiment Human	by researcher	Anything done xtra to normal clinical care (Cfr described in care program)
Personal	by individual	Data generated and stored by patient with own tool - weight, PoC data, ... - financial - social - economic - location information - diary - wellness apps
Personal	by individual with use of a tool from a third party	Data generated by patient with company tool - social media - wearables - financial - location information - diary - wellness apps
Employer	by HR collaborator	Personal - Social - Economic - Financial
Public	by public entity	General - Climate - Environment - Financial ...
Government	by governmental entity	General - Climate - Environment - Financial ...

11/07/2024

Faculty, department, unit ...



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Ecosystem for Digital Twins in Healthcare

Legal Status of Primary User

Legal Status of Primary User	IP - database: structure and/or content - copyright (ex images) - patent right (if present) NOT for INDIVIDUAL DATA		Physically residing	Legal Basis					
			(local or cloud)	Primary use	Secondary use with Purpose Limitation Always Registration, Privacy conserving, Transparent, Possibility for Opt-Out when FP party involved				
	Data creator unless contract = hospital or person	Data user	with adequate safety precautions	Clinical care	Q-control, Q-improvement, Safety, managerial by UZ Leuven, KU Leuven	HTA, ZIV, Government and legally required reporting	Research NonForProfit by UZ Leuven, KU Leuven, entity with similar research goal policy	Research ForProfit	Use ForProfit (improvement product)



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[illegible]

Overview

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Clinical care	Clinical notes Labs, tests, genomics, ... Imaging Holter, BP 24hr Apps in EHR Social Biobank	Custodian	nexuz vs UZ cfr contract	By contract: DTA - transfer - use - exclusivity	EHR Multiple copies see infra TTP? EHDS	GDPR	GDPR Public Interest	Public Interest Specific legislation	Public interest	Consent Legitimate interest Opt-out	Consent Legitimate interest Opt-out
Registries	Mostly linked to pathology ex ERN	Custodian	Organisation		Diverse Silo's Same info should be present in EHR? EHDS	NA	GDPR Public interest	Public Interest Specific legislation	Public interest	Legitimate interest Opt-out	Legitimate interest Opt-out



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A short intro on EU legislation and data

European Strategy for Data

A common European data space, a single market for data



GOAL: to ensure that more data becomes available for use in the economy and society, while keeping the companies and individuals who generate the data in control.

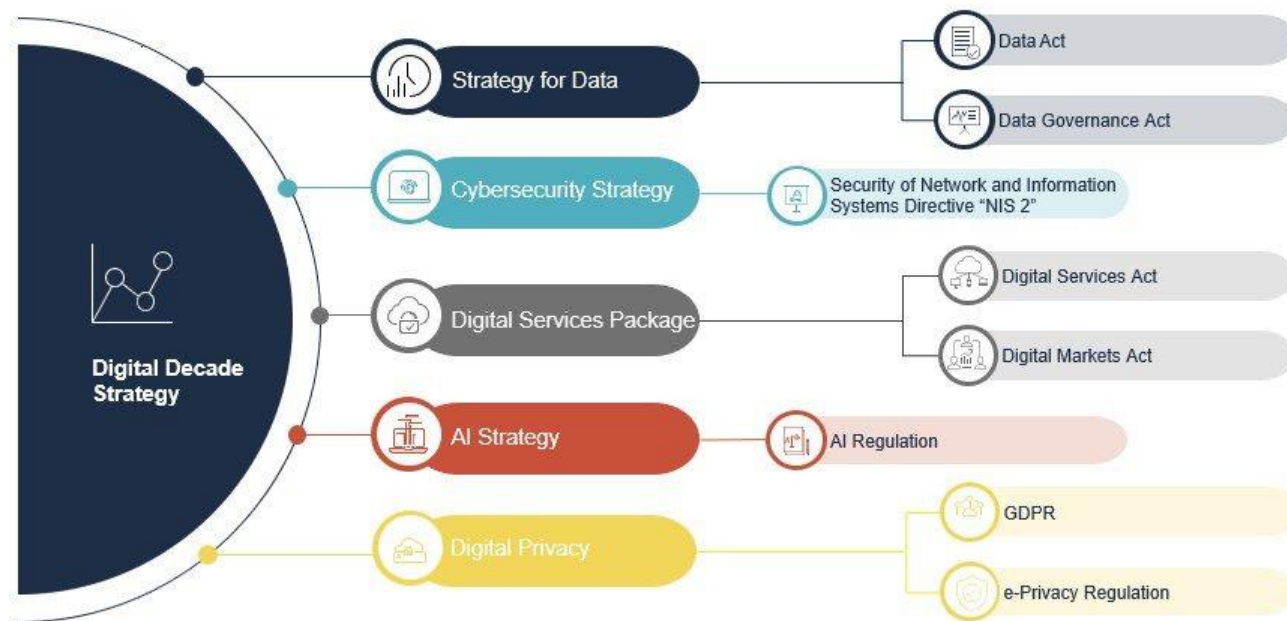


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European Data Strategy

Legislation



European Data Strategy, Data Spaces & Digital Twins

Quick overview of legislation

■ Data Act

Aims

- Harmonised rules on fair access to and use of data
- Who can create value and under which conditions
- E.g. IoT and data access rights

Topics

- Increase legal certainty
- Prevent abuse of contractual imbalances
- Allow public sector bodies to access and use data held by private sector
- Setting conditions for customers to effectively switch between providers
- Clarifying the Database Directive

European Data Strategy, Data Spaces & Digital Twins

Quick overview of legislation

- Data Governance Act

Aims

- Facilitate data sharing
- Make more data available
- Support set-up and development of European Data Spaces

Topics

- Conditions for re-use certain public sector data
- Data intermediaries and data altruism
- Cross-border data sharing – European Data Innovation Board

European Data Strategy, Data Spaces & Digital Twins

Quick overview of EHDS

Aims

- Support individuals to take control of their own health data
- Support use of health data for better healthcare delivery, research, innovation and policy making
- Safe and secure exchange, use and reuse of health data

Topics

- Primary use: healthcare
 - Access and transmission
 - Cross-border infrastructure
 - EHR systems and wellness applications
- Secondary use: research, innovation & policy
 - Governance and mechanisms based on Public Good
 - Data permissions
 - Cross-border access
 - Health data quality and utility

European Data Strategy

Data Act & Data Governance Act

EHDS



Health



Industrial &
Manufacturing



Agriculture



Finance



Mobility



Green Deal



Energy



Public
Administration



Skills

Personal
data spaces

- Driven by stakeholders
- Rich pool of data of varying degree of openness

- Sectoral data governance (contracts, licenses, access rights, usage rights)
- Technical tools for data pooling and sharing

High Value
Datasets
from public
sector

Technical infrastructure for data spaces



Edge
Infrastructure &
Services

Cloud
Infrastructure &
Services

High-Performance
Computing

AI on demand
platform

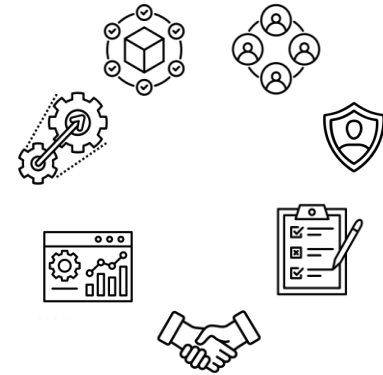
AI Testing and
Experimentation
Facilities



MOTIVATION - User Profiles and Access

Well-defined user profiles are crucial for the success of the EDITH platform and Virtual Human Twins (VHTs) overall, as they enable:

1. efficient resource allocation,
2. customized user experiences,
3. robust data privacy and security,
4. regulatory compliance,
5. streamlined collaboration,
6. improved monitoring and accountability,
7. overall scalability and flexibility of the system.



MOTIVATION (1/3)



Efficient Allocation of Resources: Well-defined user profiles enable the system to allocate resources, such as computational power and storage, more efficiently based on the specific needs and usage patterns of different user groups.



Customized User Experience: By understanding the unique needs of different user profiles, the platform can provide a tailored user experience, ensuring that each user group can access the most relevant features and data easily and quickly.



Data Privacy and Security: Clearly defined user profiles are essential for implementing robust access control mechanisms, ensuring that users only have access to the data and functionality that is relevant and necessary for their roles. This helps maintain data privacy and prevents unauthorized access or misuse of sensitive information.



MOTIVATION (2/3)



Compliance with Regulations: Healthcare data is subject to strict privacy and security regulations, such as GDPR in Europe. By establishing well-defined user profiles, the platform can more effectively enforce compliance with these regulations and ensure that user access to data is in line with legal requirements.



Streamlined Collaboration: Well-defined user profiles facilitate collaboration among different stakeholders in healthcare, such as healthcare professionals, researchers, and regulatory agencies. This allows for a more efficient exchange of information, expertise, and resources, ultimately leading to improved patient outcomes and accelerated medical advancements.



MOTIVATION (3/3)



Monitoring and Accountability: With clear user profiles, it becomes easier to monitor user activity, track performance, and identify areas for improvement. This also enables better accountability and helps identify any unauthorized or suspicious activities.



Scalability and Flexibility: As the VHT concept evolves and expands, well-defined user profiles will allow the platform to scale more efficiently and adapt to new user groups and requirements. This ensures the long-term viability and sustainability of the EDITH platform and VHTs in general.



Authentication via user identity providers

Each EU country has a dedicated authentication mechanism for citizens. E.g.:

- Poland: <https://login.gov.pl>
- Belgium : <https://www.itsme-id.com/en-BE>
- Estonia: <https://e-estonia.com/solutions/e-identity/id-card/>
- Italy/Germany/France...

The benefits are obvious: **security**, **trusted IDP provider** (EU/EU country), **user verification**, etc.

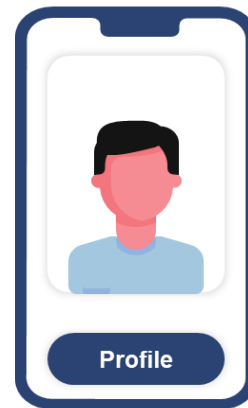
Disadvantages: not all applications can be integrated with such IDPs (e.g. in Poland only institution from specific category listed in the Act)

For the long run the EU is going to deploy **European wide citizens identification system**, aka: a [personal digital wallet for EU citizens](#) and residents thanks to the trust framework created by the eIDAS Regulation. EDITH and other EU initiatives (EHDS, EOSC, DARWIN, OPENAIRE,...)



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.

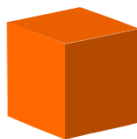
User **roles** is a collection of capabilities that can be used to give access to concrete part of the system.



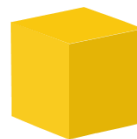
Role 1



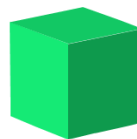
Role 2



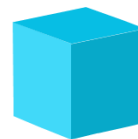
Role 3



Role 4



Role 5



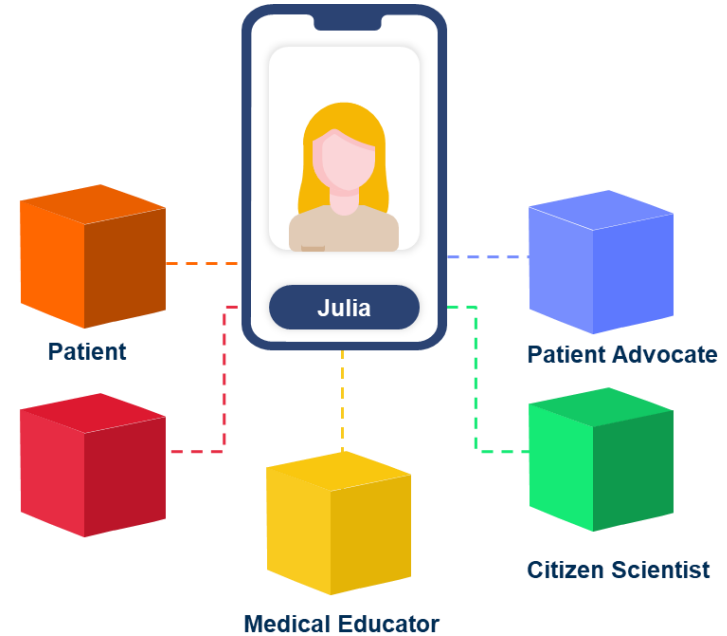
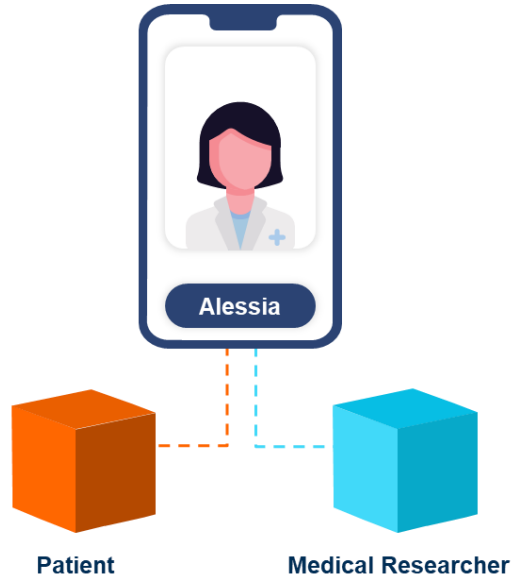
Role 6



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User Profile vs. Roles

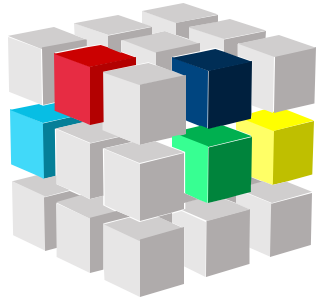


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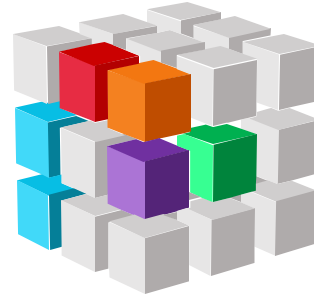
User Profile vs Roles: Access

Patient/Citizen



- 1 View personal health data
- 2 Access to applications
- 3 Submit personal data
- 4 Access to limited data storage and retrieval
- 5 Feedback and comments

Healthcare professional



- 1 View patient data
- 2 Perform cohort analysis and studies
- 3 Dedicated GUIs for Healthcare Professionals
- 4 Access to broader datasets
- 5 Feedback and comments

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User Profile vs. Roles

User roles is a collection of capabilities that can be used to give access to concrete part of the system. In the EDITH environment we can have following roles:

Patients/Citizens Category:

- *Patient*: Access to their own VHT, personal medical data, and treatment options, enabling them to better understand their health and make informed decisions about their care.
- *Patient Advocate*: Access to a specific patient's VHT and medical data with the patient's consent, allowing them to provide support and guidance in healthcare decision-making.
- *Citizen Scientist*: Limited access to anonymized data sets and research tools to contribute to community-driven medical research initiatives.



Role category: patient/citizen

The **patient/citizen category** encompasses end users who are primarily interested in the outcomes of medical therapy rather than in development of new treatment methods or direct processing of medical data.

- This category encompasses **the roles of patient, patient advocate and citizen scientist**.
- Persons who belong to this category may be interested in using applications which encapsulate computational models **as long as appropriate UIs are offered** by their respective developers.
- Patients/citizens may also want to submit their own personal data for processing, which implies the need for at least limited access to data storage and retrieval features.
- The ability to comment upon the features provided by the platform and submit feedback could be regarded as “nice to have” but is not regarded as essential for any prototype.



User Profile vs. Roles

Healthcare Professional Category (Doctors, Specialists, etc.):

- *General Practitioner* (can create new simulations for their patients): Access to their patients' VHTs and relevant medical data to monitor health, diagnose conditions, and recommend treatments.
- *Medical Specialist*: Access to group specific patients' VHTs and related data within their area of expertise (e.g., cardiologists accessing cardiac data) to provide specialized consultation and treatment recommendations.
- *Medical Researcher* (can run cohort analysis): Access to anonymized data sets and research tools to conduct studies and contribute to advancements in medical knowledge.
- *Medical Educator*: Access to VHTs for teaching and training purposes, allowing students and professionals to learn and practice in a simulated environment.



Role category: healthcare professional

A **healthcare professional** operates in a clinical setting and has a role in diagnosing and treating patients.

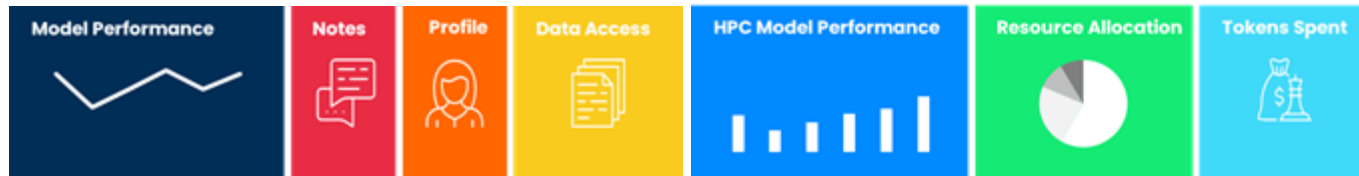
- This category encompasses **the roles of general practitioner, medical specialist, medical researcher and medical educator**.
- Features provided to this category largely overlap with those provided to patients/citizens; however, additional access may be required, e.g. to enable processing of broader datasets.
- Unlike a citizen/patient, a healthcare professional should be able to **review medical records of multiple patients** (depending on their specific area of responsibility) and be able to **perform cohort analyses and other studies** which depend on aggregation of data representing multiple individuals.
- We assume healthcare professionals possess a low to moderate level of IT expertise; accordingly, the platform should expose dedicated GUIs for this group.



User Profile vs. Roles

Creator/Model Developer Category (can upload new model version, train the models):

- *Data Scientist*: Access to anonymized data for developing models, as well as access to model training and evaluation tools.
- *Simulation Engineer*: Access to simulation tools, environments (HPC), and relevant data (*with permissions based on **purpose***) to design and validate virtual human twin simulations.
- *Model Developer/Owner*: Upload new model version, manage existing models (e.g. configuration, model access constraints, etc.)



Role category: creator/model developer

The **creator/model developer category** applies to experts who contribute computational artifacts and/or datasets to the platform.

- This category encompasses the roles of **data scientist, simulation engineer and model developer**.
- Individuals who belong to this category are typically experienced users of IT platforms, including HPC and cloud computing systems, and may **require lower-level access interfaces, or ways to interact with the platform/registry programmatically**.
- Creators **require guidelines or SOPs** showing how to integrate existing computational models with the EDITH platform, and the platform itself must support such integration.
- We also believe it is essential for the platform and the registry to expose APIs, enabling deployment of higher-order tools or extension of any core UIs offered by EDITH, as a step towards building an IT ecosystem.



User Profile vs. Roles

Platform Administrator Category:

- *System Administrator*: Low-level access to the catalogue, repository and platform infrastructures. Monitors applications, applies security fixes, respond to DoS attacks, etc.
- *Data Curator*: Access to the catalogue and repository. Handles data curation, oversees data quality and standardization to maintain data interoperability..
- *DevOps specialist*: Creates recipes to simplify application installations and integration of the new resources (e.g. cloud or HPC) with the platform.
- *Software Developer*: Access to platform APIs, documentation, and tools for integrating new features, improving user interfaces, and ensuring platform stability.



Role category: platform administrator

The **platform administrator category** applies to users whose primary concern is to ensure continued operation of the EDITH platform.

- This category encompasses the roles of **system administrator, DevOps specialist, data curator, software developer**.
- Administrators **require low-level access to the platform** and **dedicated monitoring tools**.
- Software developers who belong to this category may be tasked with **developing additional features** in the EDITH platform itself - they should not be confused with model providers (who perform software development work on computational models).
- Administrators may work to expand the platform with additional hardware resources (computational/data storage), which requires bilateral contacts with their operators thereof. Legal aspects of such collaboration should be acknowledged but are out of scope of this discussion.



Cross-border, Project-based Resource allocation (1)

- **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 compliment Roles and Profiles in a dynamic way to facilitate quick(er) dynamic access without creating multiple roles.



Cross-border, Project-based Resource allocation (2)

The screenshot displays the PLGrid Portal interface for a grant titled "Wytwarzanie modeli oraz narzędzi umożliwiający". The left sidebar contains navigation links: Profile, Affiliations, Services, Research team, Certificates, Projects, Subordinates, Grants (selected), List, New Grant, and Settlements. The main content area shows the grant's progress through five stages: 1 Draft, 2 Verification, 3 Active (current), 4 Grant settlement, and 5 Ended. Below the progress bar, the "Resources" section features a "CYFRONET" logo and the title "ACK Cyfronet Ares". A descriptive text states: "In 2021, the Ares supercomputer was launched at Cyfronet. It is built from computing servers with Int..." with a "Show more" link. A button labeled "CPU - Active" and "plgedith1-cpu" is visible. A note indicates "Resources available from 2022-10-25 to 2023-10-24" with a "Renegotiate resources" link. A table titled "FOLLOWING RESOURCES HAVE BEEN GRANTED" lists: Computation time (10 000 h) and Maximum job execution time (72 h).

PLGrid Portal / Grants / plgedith1 / Resources

Wytwarzanie modeli oraz narzędzi umożliwiający

1 Draft — 2 Verification — 3 Active — 4 Grant settlement — 5 Ended

Resources

CYFRONET **ACK Cyfronet Ares**

In 2021, the Ares supercomputer was launched at Cyfronet. It is built from computing servers with Int...
[Show more](#)

CPU - Active **plgedith1-cpu**

Resources available from 2022-10-25 to 2023-10-24
[Renegotiate resources](#)

FOLLOWING RESOURCES HAVE BEEN GRANTED

Computation time	10 000 h
Maximum job execution time	72 h



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Opportunities & Threats

Customized User Experience: By creating well-defined user profiles, the VHT infrastructure can provide a tailored user experience that caters to the specific needs of different user groups. This can lead to improved efficiency and user satisfaction.

Enhanced Security: Properly designed user profiles and access controls can strengthen the security of the VHT infrastructure, minimizing the risk of unauthorized access, data breaches, and insider threats.

Improved Collaboration: Clearly defined user profiles can facilitate collaboration among different stakeholders in healthcare, such as healthcare professionals, researchers, and regulatory agencies. This enables a more efficient exchange of information, expertise, and resources, ultimately leading to improved patient outcomes and accelerated medical advancements.

Accountability and Monitoring: By implementing well-defined user profiles and access controls, the VHT infrastructure can better monitor user activity, track performance, and identify areas for improvement. This also enables better accountability and helps identify unauthorized or suspicious activities.

Scalability and Flexibility: As the VHT concept evolves and expands, well-defined user profiles and access controls will allow the infrastructure to scale more efficiently and adapt to new user groups and requirements. This ensures the long-term viability and sustainability of the VHT infrastructure.



Opportunities & Threats

Unauthorized Access: The risk of unauthorized access to sensitive data due to compromised user credentials or misconfigured access controls can lead to data breaches and misuse of personal and medical information.

Mitigation: Implement robust authentication mechanisms, such as multi-factor authentication (MFA).

Role Creep: Over time, users may accumulate excessive access rights beyond their original roles, increasing the risk of unauthorized data access.

Mitigation: Conduct regular audits and reviews of user access rights.

Misaligned User Profiles: Poorly designed or outdated user profiles can result in users having insufficient or excessive access to data and services.

Mitigation: Continuously update and refine user profiles to align with evolving user needs and requirements.

Compartmentalized access (no SSO for EU-wide frameworks): Without a Single Sign-On (SSO) solution that spans the EU, users may have to manage multiple sets of credentials and login procedures for different parts of the VHT infrastructure.

Mitigation: Implement a secure SSO solution that spans across the EU, streamlining access and improving security while reducing the risk of credential misuse.

Complicated and poorly maintained UIs: If the user interfaces (UIs) for the VHT infrastructure are not well-designed, intuitive, or properly maintained, users might struggle to navigate and access the necessary data and services.

Mitigation : Invest in user-centric design and regular maintenance of user interfaces, ensuring intuitive navigation and efficient access to the necessary data and services.

GUI work typically not funded by research programmes: Graphical User Interface (GUI) development and maintenance are often not prioritized in research funding, which can result in outdated or suboptimal user interfaces.

Mitigation: Advocate for research funding to prioritize GUI development and maintenance, enabling a more effective and user-friendly VHT infrastructure that fosters user adoption and collaboration. Design VHT design system - similar to e.g. <https://design-system.service.gov.uk/>

No uniform standards regulating programmatic access to frameworks: Absence of uniform standards for programmatic access.

Mitigation: Establish and enforce uniform standards for programmatic access to VHT frameworks, promoting interoperability, seamless data exchange, and consistency in user experiences across the infrastructure.



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Envisioned VHT Platform Access



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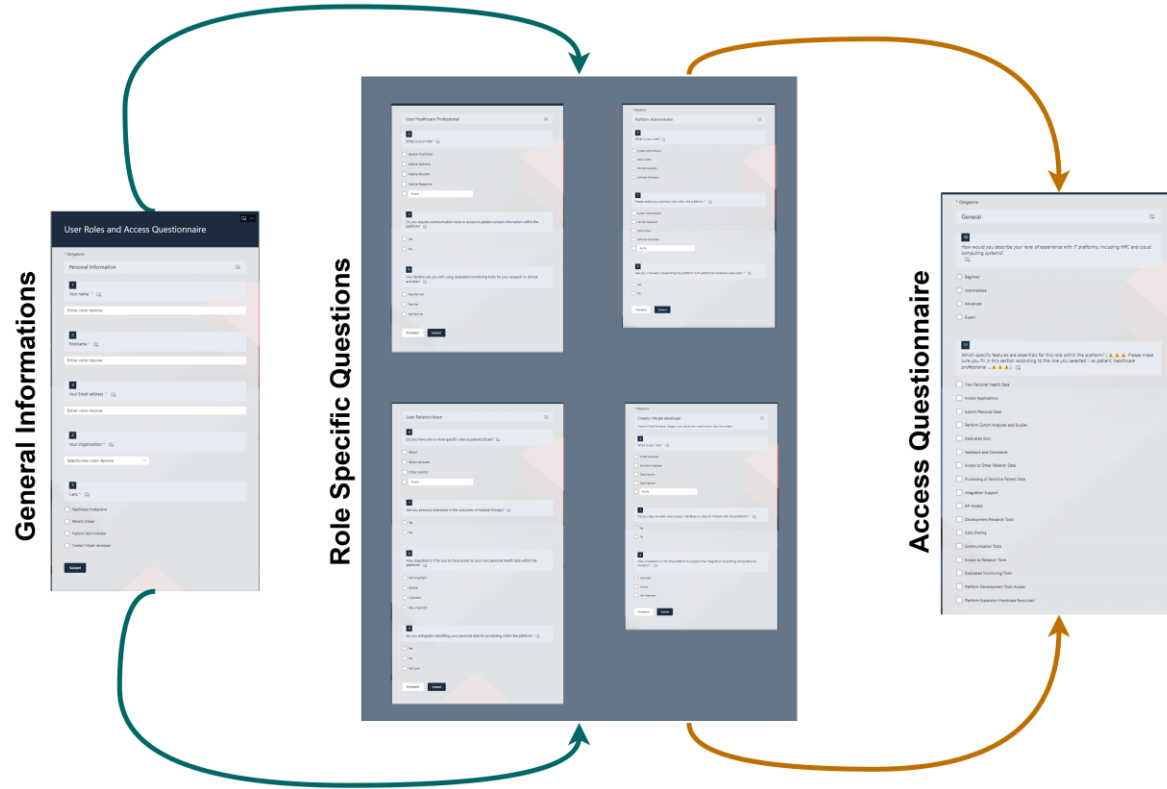
User Access & Restrictions



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User Questionnaire v1



User Role & Access Questionnaire v2

This questionnaire wants to collect feedback on user expectations regarding access to the future Virtual Human Twin (VHT) platform, particularly in the context of personal health data and computational models.

The end goal is to help to identify the features and access levels that are relevant to various roles and profiles.

<https://forms.office.com/e/v1DqQ2gkCx>



Healthcare Professional example

Feature	General Practitioner	Medical Educator	Medical Specialist
View Personal Health Data	8	7	3
Access Applications	1	5	5
Submit Personal Data	3	9	4
Perform Cohort Analyses and Studies	3	2	10
Dedicated GUIs	6	1	7
Feedback and Comments	9	3	9
Access to Other Patients' Data	3	8	4
Processing of Sensitive Patient Data	3	1	7
Integration Support	9	2	10
API Access	10	9	8
Development/Research Tools	6	5	7
Data Sharing	5	7	3
Communication Tools	8	3	2
Access to Research Tools	9	4	5
Dedicated Monitoring Tools	8	4	2
Platform Development Tools Access	5	9	7
Platform Expansion (Hardware Resources)	4	4	8



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Conclusion & Discussion



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Moving forward...

- We envision a EU citizenship based access to the VHT platform.
- The profiles and roles are defined based on individual needs.
- Each role category calls for a **dedicated set of access tools**.
- They are complemented by **Grants** and **affiliations** to allow customization and dynamical allocation.
- Ultimately, **distinct access interfaces** would need to be exposed by an EDITH-inspired catalogue/repository/platform infrastructure, each tailored to a specific user group
- The purpose of this presentation was to present our vision and get your valuable feedback.

Comments are welcome in the discussion!



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General Discussion

- Pathways/Workflows towards data import – hospital / EHR / Patient via their roles and allowed purpose.
- European Identity provider for authentication of Profiles (EU Wallet ?)
- Road Blocks ?
- ...



Thank you for your attention!



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Features List

#	Feature	Description
1	View Personal Health Data	Users can view their own personal health data.
2	Access Applications	Users have access to applications using the computational models.
3	Submit Personal Data	Users can voluntarily submit their personal data for processing.
4	Perform Cohort Analyses and Studies	Users can perform cohort analyses and studies.
5	Dedicated GUIs	Users have access to dedicated Graphical User Interfaces (GUIs).
6	Feedback and Comments	Users can provide feedback and comments on platform features.
7	Access to Other Patients' Data	Users can access to other patients' data.
8	Processing of Sensitive Patient Data	Users have permission to process sensitive data.
11	Integration Support	Users receive support for integrating computational models.
12	API Access	Users have access to Application Programming Interfaces (APIs).
13	Development/Research Tools	Users have access to tools for development and research.
16	Data Sharing	Users are allowed to share data.
17	Communication Tools	Users have access direct communication tools and/or have access to patient contact informations.
19	Access to Research Tools	Users can access research tools.
23	Dedicated Monitoring Tools	Users have access to dedicated monitoring tools.
24	Platform Development Tools Access	Access to software developmetn tools for the platform development.
25	Platform Expansion (Hardware Resources)	Authorized access for expanding the platform with additional hardware resources.



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