D8.8

Governance model V1

ABSTRACT

This deliverable provides a first version of the Governance model for InteropEHRate. It describes different and applicable governance models to identified exploitable assets. It proposes an initial governance model for InteropEHRate based on the review of similar initiatives and describes the key defining characteristics, including principles, roles and responsibilities, organisational structures and processes.

Delivery Date	21st October 2020
Work Package	WP8 Impact, Standardization and Governance
Task	T8.4 Governance model
Dissemination Level	Public
Type of Deliverable	Report
Lead partner	EHTEL

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106.

This document has been produced in the context of the InteropEHRate Project which has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106.

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LOG TABLE

Version	**Date**	**Change**	**Author**	**Partner**
0.1	24-03-20	Table of contents	Tino Martí	EHTEL
0.2	29-05-20	Chapter 2 Governance models	Tino Martí	EHTEL
0.3	12-06-20	Chapter 3 Case studies	Tino Martí	EHTEL
0.4	26-06-20	Chapter 4 InteropEHRate resources	Tino Martí	EHTEL
1.0	07-07-20	First completed version	Tino Martí	EHTEL
1.1	16-07-20	Inclusion of comments and internal review	Stephan Schug Tino Martí	EHTEL
1.2	21-07-20	Technical review	Marc Lange Tino Martí	EHTEL
1.3	04-08-20	Technical review	Sofianna Menesidou Salima Houta	UBITECH ISST
1.4	30-09-20	Final version including comments from technical review and completing conclusions and next steps	Tino Martí	EHTEL
1.5	08-10-20	Final quality review	Marc Lange Argyro Mavrogiorgou	EHTEL UPRC
Vfinal	12-12-20	Final check and submission	Laura Pucci	ENG

ACRONYMS

Acronym	Term and definition
A7	A7 Software
API	Application Program Interface
BYTE	Byte Computer S.A. (Greece)
D2D	Device to Device
EHR	Electronic Health Record
EHTEL	European Health Telematics Association
ENG	Engineering – Ingegneria Informatica S.p.A. (Italy)
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
FRAU	Fraunhofer ISST – Institute for Software and Systems Engineering (Germany)
FTGM	Fondazione Toscana Gabriele Monasterio per la Ricerca Medica e di Sanità Pubblica (Italy)
GDPR	General Data Protection Regulation
HCP	Health Care Provider
HL7	Health Level 7
ICT	Information and Communication Technologies
IHS	InteropEHRate Health Services
IPR	Intellectual property rights
IRS	InteropEHRate Research Services
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
PSD2	Payment Services Directive
R2D	Remote to Device
SDO	Standards Development Organisations
S-EHR	Smart Electronic Health Record
SIVECO	SIVECO Romania S.A. (Romania)

SMEs	Small and Medium Enterprises
SRO	Self-regulatory organisation
UBIT	UBITECH Limited (Cyprus)
UNITN	University of Trento (Italy)
UPRC	University of Piraeus Research Center (Greece)
VZVZ	Association of Care Providers for Care Communication (from Dutch: Vereniging van Zorgaanbieders voor Zorgcommunicatie)
W3C	World Wide Web Consortium
WHO	World Health Organization

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1. INTRODUCTION

1.1. Scope and objective of the document

This document develops the first version of the governance model for InteropEHRate and it is linked to the first version of InteropEHRate exploitation plan [INTEROPEHRATE 2020]. It follows the guidelines set forth by the Document of Action to define an agile model of governance covering the following aspects:

(1) "The participation to the federation: rules to join the Electronic Health Record (EHR) federation and to guarantee the coexistence of different levels of interoperability.

(2) The evolution of Application Program Interfaces (APIs): new requirements regarding the evolution of APIs and how the members of the federation will agree on new versions of the interoperability APIs.

(3) The evolution of the reference meta-coding system: how the members of the federation will agree about the content of the European semantic coding system, the Interoperability HL7-FHIR profile and how to interact with involved standardization bodies.

(4) The collaboration with policy makers: how the federation may collaborate with policy makers to support the adoption of protocols and rules for the sharing of health data."

As a first version of the governance model, this document aims to identify and define the key components of governance including what is to be governed and how it will be governed, and provide options for InteropEHRate governance. A second and final version of the governance model is planned for December 2021 which will include feedback and guidance received through different mechanisms of stakeholder engagement.

1.2. Intended audience

This document is intended for stakeholders involved in the supply side and responsible for producing business impact and stakeholders on the demand side responsible for social and business impact. Supply side stakeholders include primarily healthcare Information and Communication Technologies (ICT) providers, privacy and security providers, SMEs and start-ups, healthcare standardization bodies. Demand side stakeholders include health authorities, institutions, providers and professionals. InteropEHRate partners and those organisations involved in the execution of the project are also part of the intended audience.

1.3. Structure of the document

This document is organised in five chapters:

- Chapter 1, introducing the scope and purpose of the document;
- Chapter 2, identifying and defining governance models that can be applicable to the endeavours of InteropEHRate;
- Chapter 3, seeking out relevant national and international experience, and policy frameworks that can inform the definition of InteropEHRate governance model;
- Chapter 4, describing the resources to be governed based on the Exploitation plan and the development of health data ecosystems;
- Chapter 5, approaching the first definition of InteropEHRate governance model;

- Chapter 6, drawing conclusions and future steps

1.4.Updates with respect to previous version (if any)

Not Applicable.

2. GOVERNANCE MODELS

2.1. Definition

A review of the term “governance” from different perspectives shows how its meaning and applications are very context specific. Thus, it is quite complex to come up with a one-size fit all definition. The function of governance is essential in determining how most organisations perform key activities. [GILL 2002] defines governance as "*the **processes**, **structures** and organisational traditions that determine how **power** is exercised, how **stakeholders** have their say, how **decisions** are taken and how decision-makers are held to **account***." Three building blocks for the development of a governance model emanate from this definition. First, the governance structures with their roles and responsibilities, second the processes of deliberation, decision-making and accountability and third the representation of actors or stakeholders.

The domain specificity of governance to the context is significantly relevant between publicly or privately owned institutions. Public governance differs notably from corporate governance.

For publicly owned institutions, governance is primarily applied to define how they are organised and how they deliver public services. Public services used to be developed by the government in a strong hierarchical approach. In recently created public organisations, there is a growing trend towards governing on the edge where organisational limits are blurred, and shifting relationships between the private and public sector occur. In this evolving context, [RHODES 1996] provides the definition of public governance as “*self-organizing, inter-organisational networks, in which these networks complement markets and hierarchies as governing structures for authoritatively allocating resources and exercising control and co-ordination*.” The concept of networks emerges as an alternative organisational form in the continuum between hierarchies and markets, combining the roles of state and non-state actors [POWELL 1990]. This transition draws upon the belief that interaction generates new opportunities in terms of knowledge, asset, and capacity sharing, which cannot be achieved by one organisation acting alone [ANSELL 2016].

For privately owned institutions, a private sector perspective of business management defines how corporate governance is formed and executed. The European Central Bank refers to corporate governance as “*procedures and processes according to which an organisation is directed and controlled. The corporate governance structure specifies the distribution of rights and responsibilities among the different participants in the organisation – such as the board, managers, shareholders and other stakeholders – and lays down the rules and procedures for decision-making*.”

In the variety of definitions from different fields of inquiry some principles are shared. Indistinctly from the adopted perspective, governance is composed by structures, processes, decision-making, organising, managing and controlling, and actors. The terms and definitions of governance presented here will be used in the next sections as guiding principles to derive the governance definition of InteropEHRate.

Therefore, in the process of developing a governance model for InteropEHRate we start from a generic governance model that will be adapted for the specific use case of cross-border data sharing. In addition to the context specific circumstances and the characteristics of the organisational assets, four major components of a generic governance operating model require to be addressed: (1) structure; (2) oversight responsibilities; (3) talent and culture; and (4) infrastructure. The following table lists the attributes for each governance major component [BARET 2013].

Governance components	Attributes
Structure	- Organisational design - Reporting structure - Structure of the committees and charters
Oversight responsibilities	- Board oversight and responsibilities - Management accountability and authority - Authority and responsibilities of the committees
Talent and culture	- Performance management and incentives - Business operating principles - Leadership development and talent programs
Infrastructure	- Policies and procedures, - Reporting and communication - Technology

Table 1 – Governance components (Baret et al, 2013)

InteropEHRate services and solutions operate in the field of digital health innovation and can contribute to establishing a health data economy.

Person-centred cross-border healthcare is achieved in InteropEHRate through the development of open specifications and reference implementation enabled by digital health technologies. Digital health helping deliver cross-border healthcare cannot be realized unless it is introduced within a solid governance framework. Digital health systems based on data sharing cannot be managed in a transparent and accountable way without good governance. [MARCELO 2018] adapted the Good Governance Guide for local governments to identify eight principles of good digital health governance:

- **Accountable**: those making decisions and taking action on digital health need to be answerable and can be sanctions.
- **Transparent**: the decision-making process for digital health is clear to all stakeholders.
- **Aligned with the rule of law**: decisions on digital health are consistent with common law and legislation, and are not arbitrary.
- **Responsive**: digital health responds to the priorities of the health system, while balancing different stakeholders' competing needs.
- **Equitable and inclusive**: the interests of all stakeholders and segments of the community are considered when designing and implementing digital health, and is coalition building.
- **Effective and efficient**: making the best use of available resources, including human capital when implementing digital health.

- **Confidential**: data processes are managed in accordance with international best practices and health care regulations to ensure patient safety, and data security.

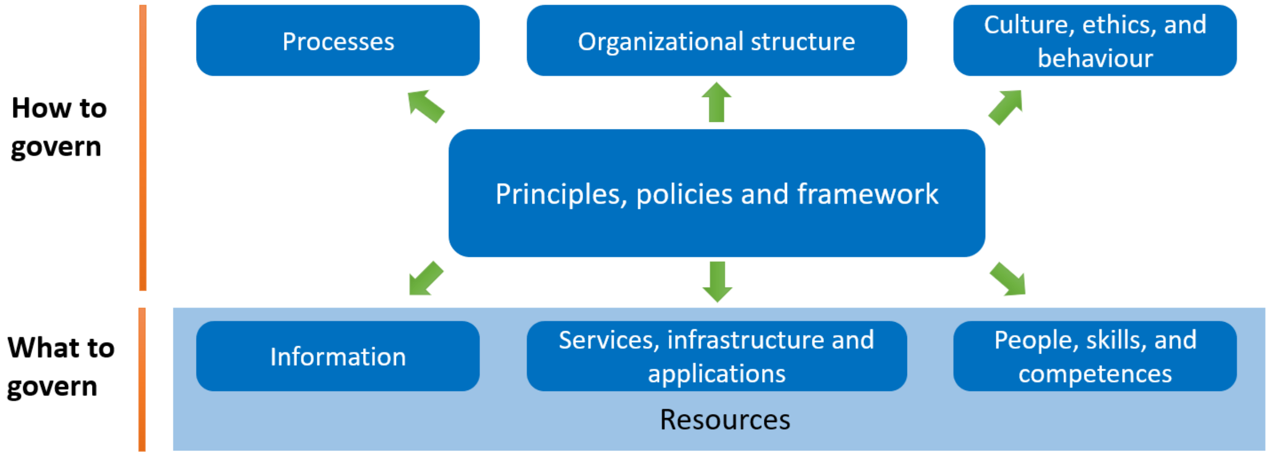

Figure 1 – Governance framework [MARCELO 2018]

These principles shape the governance policies and framework that defines how to manage the previously identified exploitable assets displayed under resources in Figure 1. The governance components are outlined in Table 2.

Governance components	Attributes
Structure	• Governance setup and organisational structures • Roles and responsibilities (mandates) • Relationships between actors • Oversight and accountability
Processes	• Planning • Policy and decision-making • Coordination • Monitoring, reporting and evaluation
Stakeholders	• Public and private stakeholders • Health and non-health stakeholders • Citizens, patients and civil society

Table 2 – Digital health governance components

In the context of the data economy, institutional arrangements, organisational structures, roles and responsibilities ensure effective and efficient processes and operational implementation. Information technologies, standardization and healthcare innovations have to reckon social, economic, political and legal dimensions in cooperation with all stakeholders. Despite the proliferation of businesses of data economy, especially in digital health innovation, practical large-scale examples of data governance are still missing according to the Organisation for Economic Co-operation and Development (OECD) [OECD 2013].

Three main principles define governance of businesses in the data economy: (1) trust and engagement; (2) effectiveness; and (3) efficiency. Trust and engagement are composed of mechanisms for integrity and transparency, stakeholder engagement and monitoring and evaluation. Effectiveness is achieved through a clear definition of roles and responsibilities, policy coherence and capacity. Efficiency is built upon data and information, financing, regulatory framework and innovative governance.

In a successful governance model, the governing body will be therefore responsible for creating a vision, securing resources, defining clear roles and responsibilities, establishing benchmarks for performance and monitoring them, and being accountable to key stakeholders.

As it does not exist a gold standard for governance of data economy businesses, experience from other sectors such as fintech, environment or education can inform health data economy initiatives.

2.2. Types of governance models

As described by the varied definitions of governance, there is no a one-size fits all standard for developing a governance model. However, a review of the different types of governance in relation to the context of non-profit organisations can provide some additional guidance for selecting InteropEHRate governance.

For the non-profit sector, [GILL 2002] identifies eight different types of governance which are listed and described in Table 3. They provide a notion of organisational structures such as board of directors, functional committees, federations, executive director or advisory boards.

Governance models	Description
Operational Model	The **board** manages, governs and performs the work of the organisation.
Collective Model	The **board and staff** operate as a single team when making decisions about governance and the work of the organisation. Board members may work with either or both service operations or management functions.
Management Model	The board manages operations through **functional committees** that may or may not have a staff coordinator.
Constituent Representational Model	An approach used by publicly elected officials. **Federations** or other constituency-elected boards have the primary responsibility of balancing the interests of their constituents with the best interests of the organisation.
Traditional Model	The board governs and oversees operations through **committees** established along functional lines (finance, human resources, programs) but delegates the management functions to the **executive director**.
Results-based Model	The **executive director** is a non-voting member of the board, carries substantial influence over policy making, and is viewed as a full partner with the board. **Committees**, organized around board responsibilities and lead planning, would guide governance, and monitor and audit performance of the board, executive

	director and organisation.
Policy Governance (Carver) Model	The board governs through **policies** that establish organisational aims (ends), governance approaches, and management limitations. These policies also should define the relationship of the board with the executive director. The executive director has broad freedom to determine the means that will be used to achieve organisational aims.
Advisory Board Model	A **board** selected and dominated by the executive director. This board provides *prima facie* legitimacy to the organisation but governs only in a nominal sense. Board members provide **advice** and may rubber-stamp the executive director's recommendations.

Table 3 – Types of governance models [GILL 2002]

Given the intangible nature of InteropEHRate exploitable resources, namely open source protocols and reference implementations, it is worth exploring specific governance types developed in the open source software community. In these initiatives, the community is the originator and resulting recipient of ownership. [O'MAHONY 2007] typifies a specific governance called "community managed governance model" based on the study of mature open source software communities of Apache, Debian, GNOME, and Linux Standards Base.

Community managed governance is underpinned by five core critical principles:

- **Independence**: it is free of financial sponsorship dependencies
- **Pluralism**: it preserves multiple and potential competing approaches.
- **Representation**: it includes contributing members in community-wide decisions
- **Decentralized decision-making**: some degree of decision-making is decentralized.
- **Autonomous participation**: it welcomes participation and allows members to contribute on their own terms.

3. CASE STUDIES

This section examines several examples of digital health ecosystems and health data sharing experiences in Europe in recent years. Through the review of these experiences, it is intended to extract the principles and practical insights in the development of their governance model and structures as well as how they have evolved. The following initiatives are reviewed and synthesized: MedMij in the Netherlands, the IHAN project in Finland, Salus Coop in Spain and aNewGovernance in France.

3.1. MedMij

MedMij[1] is a governmental initiative in the Netherlands that makes possible to combine health data safely and reliably in **personal health environments**. These emergent personal health environments differ from single-provider portals.

Provider portals are built and accessed by one care provider, and provide information from the care provider. Patients have no freedom of choice and there is no option to share information with third parties. Unlike provider portals, personal health environments are accessed by many care providers, patient information is also available, patients can choose their own personal health environment and information can be shared with third parties. Tables 4 summarises the differences between personal health environments and provider portals.

	Provider portals	Personal health environments
Access	Only one care provider	Many care providers
Information	From the care provider	From care providers and patients
Freedom of choice	Patients have no freedom of choice	Patients have freedom of choice
Information sharing with third parties	Not possible	Possible

Table 4 – Differences between provider portals and personal health environments

Personal health environments are citizen-centric putting citizens in charge of their own health, helping them to collect, manage and share health data and use applications. Therefore, a personal health environment comprises:

- Functional modules: appointments, reminders, caregiver access, e-consultation
- Data management from different sources: practitioners, hospitals, mental healthcare, medication and other caregivers
- Personal services: personal health plans, research data, data analytics, telemonitoring

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[1] MedMij: https://www.medmij.nl/en/

- Data exchange: eHealth data, images and videos, self-measurements, sport data, questionnaires

In this context, the core tasks of MedMij are facilitating the digital sharing of health data between Dutch residents and their caregivers, and creating trust that it is safe, sustainable, affordable and user-friendly. The MedMij Framework creates the trusted environment in which patients and caregivers securely exchange health data. Health products and services with MedMij label are compliant with the MedMij Framework, thus reducing the need for bilateral agreements between service providers.

To accomplish these goals, MedMij started as a national programme initiated by the Dutch Patient Federation and embraced by the Healthcare Information Council and the Ministry of Health, Welfare and Sport in 2015. The first endeavour was to develop the MedMij Trust Scheme and the information standards required to effectively exchange data.
In 2018, MedMij evolved from a national programme towards a Foundation as it enabled independence to evaluate compliance with participation rules. Table 5 illustrates the evolution of MedMij's governance, distinguishing structures of governance and management, and operations.

Organisation	MedMij programme	MedMij Foundation
Governance structures	Steering group	Board of Directors Members' Council
Management structures	Programme agency	Executive board
Operations	Projects MedMij support Communication Standards	Implementation organisation VZVZ Service Centre[2] Nictiz[3]

Table 5 – Evolution of MedMij's governance

As an implementation organisation, the new MedMij Foundation relies on VZVZ Service Centre and Nictiz to further develop the Trust Scheme – qualification and acceptance procedures - and the information standards.

3.2. Salus Coop

Salus Coop[4] is a citizen data cooperative for health research based in Barcelona and supported by Mobile World Capital since 2017. It was founded considering health data as common good and elaborating a participatory social model to devolve data ownership to citizens as a source of democracy and economic prosperity.

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[2] VZVZ - Association of Care Providers for Care Communication: https://www.vzvz.nl/

[3] Nictiz: https://www.nictiz.nl/

[4] Salus Coop: https://www.saluscoop.org/

As an initiative centred on citizen ownership as other self-data movements like MyData,[5] Salus Coop has the objective of exploring a citizen-driven model of collaborative governance and management of health data. This model should enable citizens to share their health data to accelerate research and innovation in healthcare, maximising social and collective benefits.

Salus Coop data ecosystem has four types of players. Citizens are data donors and self-administrators of their data. Public and private health care providers, including digital health, mobile health and medical devices, collect and store health data on behalf of the citizens. Finally, the act of data sharing renders raw material for data users whereas they produce personalized services or conduct health research.

Salus Coop reassures citizens with a common good data license for health research that frame data re-use. This license specifies that data will be only used for research of chronic and rare diseases by public or non-for-profit research institutions. It also establishes that data will be anonymised prior to use and the citizen will remain in control being able to cancel or change the conditions to access data. Finally, it defines that research results will be made accessible at no cost.

The governance of Salus Coop is based on cooperative governance models where a governing body representing citizens is in charge of steering activities.

Salus Coop is especially relevant for InteropEHRate as it applies to the third scenario of data sharing for improving health research.

3.3. IHAN project

In 2018, the Finnish Innovation Fund Sitra[6] initiated the project IHAN to develop a European data economy model based on the principles of a fair data economy: data sharing in exchange of trust, consent and value. Adherence to these principles may unleash more targeted services to improve the well-being of people and generate economic growth for companies of all sizes through data-driven innovation.

The set of values on which a fair data economy is based combines a human-centric approach, trust, a new sense of community and the principles of sustainable growth. The aim is a human-driven European data market, where companies that use data responsibly succeed with smart services.

In that direction, IHAN project aims to build the foundation for personalized wellbeing and healthcare services. It is a joint collaboration effort for European organisations. IHAN ensures trust for new digital services and is founded upon European values.

IHAN project builds upon the progress made in accelerating the use of cross-border and cross-sectoral online services. Data transfer between Finland and Estonia and between the social and healthcare sector were initially achieved through the Isaacus project. It focuses on secondary use of social and health data for research purposes and it served as the foundation of the operating model of Findata. As we move towards person-centred healthcare and well-being services, individual's data will become a crucial component.

Modelling governance for data sharing

According to IHAN, defining the governance model for a data economy is a challenging and complex task. At present, it exists limited amount of research and recommendations on governance of data ecosystems combining the interest of individuals and creating possibilities and tools for businesses. However, the governance model has the following objectives:

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[5] MyData: https://mydata.org/

[6] Sitra: https://www.sitra.fi/en/themes/about-sitra/

- ensuring trust, transparency and citizen-rights in accordance to the EU General Data Protection Regulation (GDPR)
- accelerating data sharing between companies
- balancing long-term solutions and interests between different government agencies
- providing neutrality, namely no risk for take-over by individual companies or other actors

One of the operating goals of the IHAN project is to define an effective, efficient and transparent governance model which ensures the trust and engagement of different stakeholders, and how it should be developed. One of the building blocks to achieve this goal is the Rulebook for fair data sharing.

Three types of governance models for fair data sharing are identified by IHAN.

	Description
Model 1. Focus on technology and standards	Standards are technological definitions, limits or rules approved and monitored by governmental authorities or professional bodies. Development of standards can be private, committee, network and organisational standardization. The results can be statutory enforced by law, proprietary standards or voluntary standards. Examples: International Organization for Standardization (ISO)[7]; World Wide Web Consortium (W3C).[8]
Model 2. Self-regulation based on common rulebook for data sharing ecosystem	Self-regulatory organisation (SRO) around data sharing practices, rules and guidelines. An SRO is an organisation that exercises some degree of regulatory authority over an industry or profession. There are softer forms of self-regulation as well. Industry self-regulation is the process whereby members of an industry, trade or sector of the economy monitor their own adherence to legal, ethical, or safety standards. Self-regulation may ease compliance and governance of standards, but it can also give rise to conflicts of interest. Self-regulation could be built around industries or around professional groups such as lawyers and journalists working according pre-defined set of ethical rules. Examples: US Securities and Exchange Commission (SEC); American Medical Association (AMA).
Model 3. Emphasis on regulation	The EU is acting in a broad range of areas to bring about new data re-use scenarios, using both hard legislation and soft instruments (like voluntary standardization or funding pilot projects). Data re-use and portability are not goals unto themselves, but means to achieve various policy ends. The basic regulatory building blocks already exists. Now governments (in collaboration with consumer groups and companies) need to put Europe's new rules for the data economy into practice in a way that promotes the widest possible data reuse and individual control. This requires major activity on adoption, clarification, support and enforcement. There is lots of

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[7] ISO: https://www.iso.org

[8] W3C: https://www.w3.org/

	uncertainty about how these regulations will play out in practice, and uncertainty reduces willingness to invest. For instance, simply mandating data portability and sharing is insufficient - to achieve an impact there is a need for machine readable and machine-speed data access. Examples: The Payment Services Directive (PSD2) shows some of the limitations of a top-down regulatory approach. It is a slow and expensive process. It has taken six years, from the legislation's proposal by the European Commission in 2013, for open banking standards to become law. And standardization in payment services is straightforward, with banks already highly regulated, working on fairly standardized processes and participating in a global standards organisation (SWIFT). Approaching every sectoral case of data sharing in the same manner would most likely take a decade or more.

Table 6 – IHAN governance models for fair data sharing

Rulebook for fair data sharing

IHAN's Rulebook[9] is the founding document that members of a data ecosystem sign to adhere to. It helps the ecosystem orchestrator to create the rulebook together with its ecosystem partners. It is structured with the following sections:

- Business: it provides the vision and mission for the ecosystem, and the business models for all participants in the ecosystem.
- Technical: it defines data formats, consent management, logging etc.
- Legal: it covers how different legislations enable or inhibit the activities in the ecosystem.
- Data: it describes different laws and regulations on different kind of data.
- Ethical: it clarifies how data is sourced and how services utilize data, how ecosystems thrive from sustainable and fair use of data and what kind of values are held by the ecosystem.

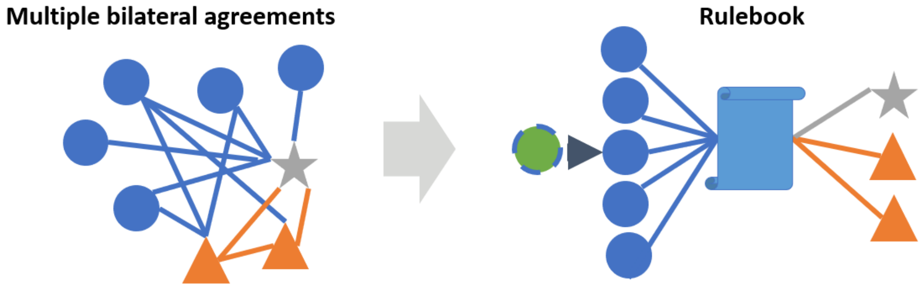

Figure 2 – The streamlining role of the ecosystem rulebook

Instead of multiple bilateral agreements, the rulebook streamlines agreement and build trust among the data ecosystem players. This collective process makes the ecosystem more cost efficient and eases access to join data ecosystems for companies, increasing know-how and trust, and ensuring fair, sustainable and ethically businesses within data ecosystems.

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[9] IHAN's Rulebook: https://data-economy.sitra.fi/ihan-project-material-rulebook

A critical aspect of the ecosystem rulebook is interoperability. A validation process ensures that the resulting rulebook conforms to set quality and content standards, and interoperability between data ecosystems.

3.4. aNewGovernance

aNewGovernance[10] is a public private partnership designed specifically to help deliver the free flow of data in a human centric way. Originated in France, it aims to break silos between countries, sectors and disciplines globally to ultimately build a governance body, an independent and international standard supporting organisation.

A ten rules manifesto for the use and flow of personal data under the control of citizens was published based on the PrivacyTech White Paper produced by more than 50 organisations from different European countries and presented at the French Parliament on 10 April 2019 [PRIVACYTECH 2019].

These rules pave the way to a data strategy for Europe that considers data sharing as an engine for social and economic wealth. Data sharing can only be based on trust where individuals can store their data, transfer easily and manage consents in a clear and concise way.

It also requires a cross-sectoral human-centric governance framework aiming at a fair, sustainable and prosperous digital society. To ensure the delivery of quality services, non-personal and personal data need to be governed within the same guidelines.

aNewGovernance advocates for investment in data to strengthen Europe's capabilities, including a European cloud. In this context, the European Commission's Digital Single Market is an accelerator.

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[10] aNewGovernance: https://www.anewgovernance.org/

4. INTEROPEHRATE GOVERNABLE RESOURCES

This chapter describes the range of resources that InteropEHRate is creating and which will form the object of future governance. InteropEHRate's resources include the exploitable assets identified in the Exploitation Plan (D8.4) as well as the potential health data ecosystem that the use of InteropEHRate solutions might derive.

4.1. Exploitable assets

As it has been detailed in the Exploitation Plan of InteropEHRate, eleven components have been identified as exploitable assets. They were described and typified according to their characteristics into two main categories: open specifications and applications and interfaces.

Open specifications include new EHR interoperability standards, vendor-neutral citizen-centred mobile and secure health interoperability protocols, FHIR profiles for EHR interoperability and knowledge management and data mapping tools enabling healthcare providers legacy systems to securely exchange health data with secure patients EHR. Applications and interfaces include the integration code of mobile and web apps, and protocols for healthcare and research data sharing enabling citizens to engage into cross-national research trials and retrospective studies and to receive health data from them.

#	Exploitable Asset	IPR Owner	Software license
	OPEN SPECIFICATIONS		
1	FHIR profiles for EHR interoperability	FRAU	Open source
2	R2D protocol	ENG	Open source
3	D2D protocol	UPRC	Open source
4	Security libraries	UBIT	Open source
5	Research Data Sharing protocol	UNITN, FTGM, FRAU, UBIT, BYTE, A7	Open source
6	Knowledge Management Tools & Data Mapping Tool	UNITN	Data Mapping Tool: Open source Knowledge Management Tools: Proprietary
	APPLICATIONS & INTERFACES		
7	S-EHR mobile app	A7	Open source for integration code
8	S-EHR cloud	BYTE	Open source
9	HCP Web App	SIVECO	Open source for integration code
10	InteropEHRate Health Services (IHS)	UNITN, ENG	Open source
11	InteropEHRate Research Services (IRS)	UNITN, BYTE	Open source

Table 7 – Overview of InteropEHRate's exploitable assets

Table 7 lists all exploitable assets, their intellectual property rights (IPR) owner and the type of software license distinguishing between open source and proprietary.

With the exception of the component “Knowledge Management Tools” which licensing remains proprietary, the rest of exploitable assets are either entirely open source or their integration code is open source. Therefore, as open source components, are subject to the scope of InteropEHRate governance in terms of their maintenance, promotion and future evolution.

4.2. InteropEHRate health data ecosystem

According to the Document of Action, the governance model will define “simple rules to join the EHR federation and to guarantee the coexistence of different levels of interoperability”. InteropEHRate services aim to facilitate the exchange of health data for cross-border health care and health research purposes. The concept of federation has been discussed within the project and has evolved from EHR federation to platform and health data ecosystem.

Therefore, a potential resource that InteropEHRate contributes to develop are health data ecosystems in the fields of healthcare and health research. Through health data access and sharing at patient’s hands, data flows between health care and research actors and enables new forms of collaboration that bring value to the data ecosystem. A data ecosystem is defined as a “network of actors that directly or indirectly consume, produce, or provide data and other related resources” [OLIVEIRA 2018]. Ecosystems are complex interconnected components that require specific governance rules. As we have seen before in the IHAN project, these groups of entities aim to create new business by sharing data in exchange of services. Gartner categorizes data services by the level of insight they provide into three categories: simple data services, smart data services and adaptive data services [LANEY 2017].

In the health domain, these exchanges are specifically sensitive. The World Health Organization (WHO) defines “health data ecosystems” as environments where patients are encouraged to participate in their own care, delivering personalized information and integrating medicine with behavioural determinants of health. From a data perspective, it involves the integration of electronic health records with personal data captured from other sources such as medical devices, wearable devices, sensors and tools based on virtual reality (Figure 3) [VAYENA 2018].

In health data ecosystems, citizens are important stakeholders in the development, evaluation, implementation and monitoring of health data initiatives. Their role should extend far beyond the provision of informed consent for data use and include involvement in the governance of data initiatives and negotiations on the fair sharing of the benefits of data exploitation. More specifically, health services and digital health providers can seek better patient insights by tapping to third-party data generated around InteropEHRate health data ecosystem.

Figure 3 – Evolving health data ecosystem (Source: WHO 2018)

The interdependent nature of the relationships across health data ecosystem members also requires some form and degree of coordination and governance, whether decentralized or centralized, to encourage service and value creation [BOGERS 2019]. Health data ecosystem governance encompasses policies about data portability, data sovereignty, data ethics and data governance where the conditions of data access are defined, including appropriate safeguards, the responsibilities and roles of data users and the principles of benefit sharing.

Towards an InteropEHRate governance: preliminary role mapping

IHAN project helps to identify and develop a health data ecosystem following a four-steps methodology. First, identify the common vision and objectives of the ecosystem, describing roles (Table 8 and Figure 4), value and data exchanges. Second, it figures out business models where data and cash flows are depicted. Third, responsibilities, duties and roles are typified in a contract model (rulebook). And fourth, technical solutions such as interfaces, data contents and formats are defined in the technical section of the rulebook.

Roles	Description
End-user	Entities interested in consuming, utilizing, accessing the value that is created in the data ecosystem.
Service provider	Entities interested in creating value in the data ecosystem by providing services to end users.
Partner	Entities interested in creating value in the data ecosystem by providing services to other service providers.
Data source	Entities seek to create additional value in the data ecosystem and provide data to

	the ecosystem.
Technical enabler	Entities providing services for identity, consent management, logging, and service management for the data ecosystem. Can act as system integrators between ecosystem members if needed.
Business enabler	Entities that provide services to the data ecosystem but do not share data in the ecosystem.
Leader	Entities who drive the vision and realisation of the data ecosystem to function. Takes the lead role (can be temporary) in coordinating the data ecosystem.
External stakeholder	Entities that have a specific interest in the data ecosystem success.

Table 8 – Data ecosystem roles (Source: IHAN project)

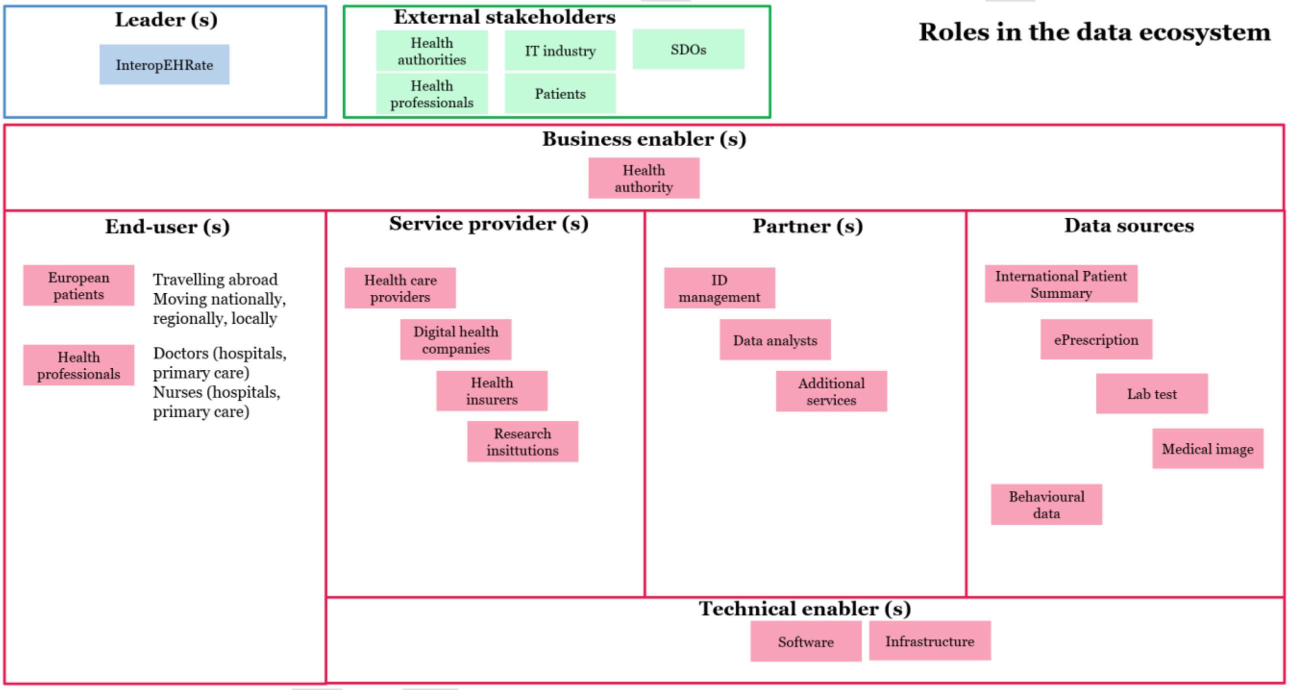

Figure 4 – Data ecosystem roles applied to InteropEHRate scenario 1 (Source: IHAN project)

In the next version of this deliverable, the results of the health data ecosystem development exercise with the InteropEHRate consortium will be reproduced. This exercise will be accomplished through workshops to identify the roles of all stakeholders in the three scenarios: healthcare, emergencies and research.

5. APPROACH TO THE GOVERNANCE MODEL OF INTEROPEHRATE

In the previous chapters, different governance models have been identified, defined and analysed. Derived key governance components have been reviewed in selected similar international and national experiences, political and analytical frameworks, all related to personal health data sharing. Resources identified in the exploitation plan of InteropEHRate have been listed together with the potential generation of health data ecosystems in the healthcare, emergency care and research scenarios.

InteropEHRate supports an open source approach that is modular, agile, bottom-up, decentralised and citizen-centric. Modularity is achieved through single specifications or software components that can be exploited independently. Agility means that InteropEHRate results can be developed and exploited in different ways without changing EU policies or infrastructure. A bottom-up approach represents that end-users (citizens, health organisations and research centres) can benefit from InteropEHRate results in the short-term while developing long-term impact to EU health policy. Decentralisation is related to the independence from National Contact Points as single source of EHR data. Citizen-centredness assumes that data is at patient's hands and citizens are in control of the use of their health data with the capabilities of sharing data for primary and secondary use.

EU policy endorsement of InteropEHRate results is fundamental. Cross-border data exchange has a multiplier effect when more companies and organisations adopt the same standards for different use cases. This can be achieved in the context of European, national, and regional health data ecosystems where health organisations and data service providers agree with specific rules and comply with international standards. With the overarching support to InteropEHRate results, EU policies will increase the value of health data sharing across Europe and will boost implementation and exploitation.

Collaboration with policymakers for promoting the adoption of InteropEHRate protocols and rules for health data sharing, and the approach to a socio-economic impact analysis will be addressed in the second version of the governance model.

Against this backdrop, the main goal of this chapter is to define how to govern these resources (Figure 5) through an agile and evolving model of governance that will respond to the following aspects:

(1) Establishing the principles and values

(2) Identifying stakeholders' roles

(3) Defining organisation structures and processes

InteropEHRate governance model defines a framework to structure and describe the governance elements and relationships including candidate organisational structures, processes, roles and responsibilities for the governance and management of an operational environment that follows the governance framework (Figure 5).

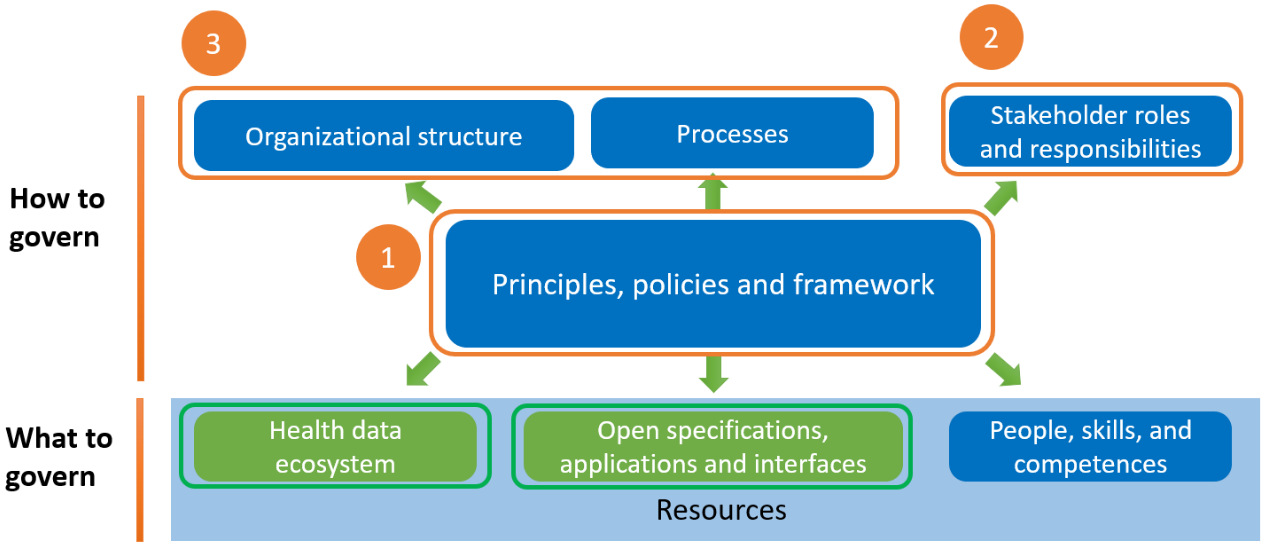

Figure 5 – Governance components for InteropEHRate adapted from Marcelo et al, 2018

5.1. Principles and values

As a citizen-centric, cross-border digital health open source solution, InteropEHRate generates open specifications and reference implementations. These solutions are a building block capable of facilitating the generation of health data ecosystems that provide value to all players. Therefore, its open source character and its capacity of developing health data ecosystems leads to a governance model based on the principles of community managed digital health and the fair data economy.

As described by Marcelo et al, good digital health governance is based on the principles of accountability, transparency, legality, responsiveness, equity and inclusiveness, effectiveness and efficiency, and confidentiality. Complementarily to those, the principles of a fair data economy are human-centredness, trust, sense of community and sustainability. The community managed governance described by O'Mahony for open source software endeavours adds the values of independence, pluralism, representation, decentralized decision-making and autonomous participation.

All these principles apply to InteropEHRate and are in line with the TAPIC model supported by the WHO [GREER 2019]. The TAPIC model combines five domains of governance for health institutions: transparency, accountability, participation, process integrity and policy capacity. Trust, transparency and participation are three key principles whose consequences will be further developed to define InteropEHRate governance model.

5.2. Roles and responsibilities

Identifying all stakeholders in the InteropEHRate enterprise is an evolving process that will culminate in the development of the different health data ecosystems. At present, core players are identified in relation to the productions, consumption and enablement of InteropEHRate exploitable assets. The following table lists all identified key stakeholders and their roles in the generic InteropEHRate ecosystem.

Stakeholder	Role (as defined in Table 8)
Citizens	End-user and external stakeholder
Healthcare providers	End-user, service provider and external stakeholder
Research centres	End-user and service provider
Technology industry	Service provider, technical enabler and external stakeholder
Health authorities	Business enabler and external stakeholder
SDOs	External stakeholder

Table 9 – Stakeholders and roles in InteropEHRate ecosystem

More actors will be identified in the development of health data ecosystems addressing the health and care innovation environment and the health research environment.

Besides identifying the role of actors, how leadership will endure after the end of the project is a key element of the governance model that will be further analysed in the final version.

5.3. Organisational structures and processes

Different modalities of public private partnership, adopting varied steering committees or similar bodies, and different legal entities will be explored in the final version of InteropEHRate governance model. Under this digital health governance framework, the role of European, national and subnational levels will be discussed depending on the decentralization and public-private healthcare provider mix of each country.

The key functions of the governance body of InteropEHRate are:

- Establishing and updating the participation rules to join the federation or ecosystem
- Updating the governance framework according to changing requirements of InteropEHRate with advancing technological adoption
- Evolving the exploitable assets: open specifications, APIs and interoperability profiles
- Identifying performance measures and monitoring processes for the adopted framework to ensure accountability and promote improvement towards person-centred integrated care.

A first formal leadership role can be assigned to InteropEHRate steering committee composed initially by a public-private partnership. Under this steering committee, different technical steering groups related to the services and access mechanisms can be defined. These technical steering groups will hold responsibility for defining the agreement process on new versions of open specifications and how to adopt and adapt interoperability standards.

6. CONCLUSIONS AND NEXT STEPS

InteropEHRate approach to health data sharing is unique in the current context of health information exchange in Europe. Modularity, agility, decentralisation, citizen-centredness and a bottom-up orientation are the key features of its innovative approach. Consequently, defining InteropEHRate governance model is an interactive process that involves many actors including health authorities at European, national and regional level, adopters represented by citizens, healthcare providers, health research centres, technology services providers and other external stakeholders such as Standards Development Organisations.

This first version laid the foundation of InteropEHRate governance model addressing two types of resources. On one hand, InteropEHRate technological exploitable assets represented by open specifications, reference implementations and interfaces that enable health data sharing between citizens, healthcare providers and researchers. On the other hand, health data ecosystems that InteropEHRate results enable in the three chosen scenarios: healthcare, emergencies, and research access. Informed by the review of governance models and case studies, this initial version of InteropEHRate governance model has defined the principles and values, identified stakeholders and their potential role and responsibilities, and succinctly described the key functions of the governance bodies.

The second and final version of InteropEHRate governance model will define the formal structure of governing, the level of representation and participation of identified stakeholders. Health data ecosystems development for InteropEHRate healthcare and research scenarios will describe roles, business models and governance requirements. Further analysis of the selected case studies and underlying governance structures will provide additional insights to governing InteropEHRate resources considering long-term sustainability. In this respect, special emphasis will be paid to the role of European, national and subnational health actors in supporting and adopting InteropEHRate results aligned with the general and individual exploitation plans.

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