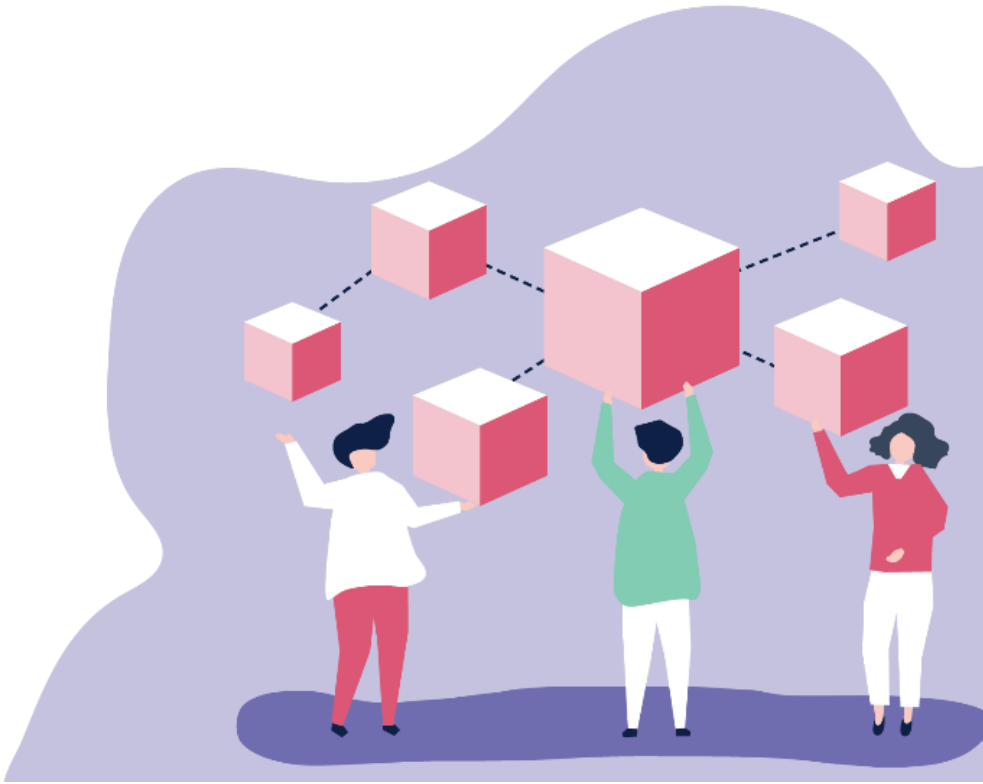
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 857223

D8.2 Initial Standardization Strategy

Deliverable No.	D8.2	**Due Date**	30/09/2020
Description	Synthetic report presenting the standardization strategy adopted by GATEKEEPER consortium		
Type	Report	**Dissemination Level**	PU
Work Package No.	WP8	**Work Package Title**	Standardization and certification mechanisms
Version	1.0	**Status**	Final



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History

Date	Version	Change
05.05.2020	0.1	Table of contents by MI
25.05.2020	0.2	State of the art analysis and literature review by MI
15.05.2020	0.3	Initial inputs by MI
20.09.2020	0.4	Additional Funka, UDGA, ERCIM inputs
25.09.2020	0.5	Final inputs
29.09.2020	0.6	Peer review by SAMSUNG, ENG
30.09.2020	1.0	Final version and submission

Key data

Keywords	Standardization, strategy
Lead Editor	Anna Brékine
Internal Reviewer(s)	Rohit Ail (SAMSUNG), Valentina Di Giacomo (ENG)

Abstract

The Initial Standardization Strategy delivers a steering map for coordinating and controlling standardization activities within the GATEKEEPER project. The strategy is centred on five standardization domains: The GATEKEEPER architecture, Interoperability enablers, FHIR implementation guides, Web of Things, Data protection, security and GDPR compliance. It presents the relevant SDOs and fora where standardization work can be carried out, as well as defines the partners and tasks which can support the activities.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Acronyms

Acronym	Meaning
AIOTI	Alliance for Internet of Things Innovation
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
DIN	Deutsches Institut für Normung
EC	European Commission
ECCP	European Centre for Certification and Privacy
EPHI	European Partnership for Healthcare Innovation
ETSI	European Telecommunications Standards Institute
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level Seven International
ICT	Information and Communications Technology
IDSA	International Data Space Association
IHE	Integrating the Healthcare Enterprise
IEEE	Institute of Electrical and Electronics Engineers
IoT	Internet of Things
ITU	International Telecommunication Union
ISO	International Organization for Standardization
KPI	Key Performance Indicator
SDO	Standards Developing Organization
SEIS	Sociedad Española de Informática de la Salud
SG	Study Group
SIS	Swedish Institute for Standards
SN	Standards Norway
WG	Working Group
W3C	World Wide Web Consortium

1 GATEKEEPER in a nutshell

GATEKEEPER is a European Multi Centric Large-Scale Pilot on Smart Living Environments. The main objective is enabling the creation of a platform that connects healthcare providers, businesses, entrepreneurs, and elderly citizens and the communities they live in, in order to originate an open, trust-based arena for matching ideas, technologies, user needs and processes, aimed at ensuring healthier independent lives for the ageing populations.

1.1 Objectives of Task 8.2 on standardization

Task 8.2 'GATEKEEPER platform standardization process and wide-spread adoption across Europe' is part of the WP8 'Standardization and certification mechanisms'. It seeks to coordinate and support the standardization process of relevant GATEKEEPER technologies, both at the European level and the global level. The standardization work carried out in this task aims at allowing the GATEKEEPER solution to be aligned with SDOs around legal and privacy aspects, healthcare, ageing, homes, cities and energies, IoT, Big Data and other Key Enabling Technologies, as well as value-based procurement.

As stated in the description of actions:

"Technological outputs of GATEKEEPER are communicated to SDOs leveraging on partners members already engaged in SDOs to relay and promote GATEKEEPER outputs for standardization. The strategy will be to pursue European standardization through such as CEN or ETSI and Global standardization through relevant SDOs such as ITU, W3C, ISO or IEC. Where applicable, it will leverage ongoing processes (such as the WoT at W3C, or the Reference architecture for IoT at ISO/IEC). Where needed, it will propose new and specific work items to be standardized. Considering the time required to get a norm formally standardized and adopted, this task will start early and provide a continuous support in parallel to the project life time. It will also synergise, where applicable with other H2020 research projects and with like-minded stakeholders to build support and consensus. The task will regularly hold telcos with relevant partners and support horizontal coordination among the various standardization tracks."

1.2 Objectives of D8.2

As per the Grant Agreement, the objectives of D8.2 are to deliver a 'Synthetic report presenting the standardization strategy adopted by GATEKEEPER consortium.'

This deliverable contains the Initial Standardization Strategy for GATEKEEPER. This primary standardization workplan can be adapted and enhanced based on future discussions, technological developments and inputs from the research partners. During the project, the standardization strategy may be revised to broaden the scope of contributions for the overall standardization process (see Figure 1 below).

First, the deliverable outlines the 'eHealth, healthy living and ageing' standardization priorities as defined by the European Commission. Next, it describes the methodology behind the plan, as well as the target key performance indicators in the field of standardization. The plan for standardization provides an overview of the foreseen standardization actions identified by the GATEKEEPER partners at the current stage (M12) of the project. Next, the document reports on the existing opportunities at target

Standards Developing Organizations, particularly CEN, CENELEC, ETSI, ITU, W3C, ISO or IEC, where the partners can contribute to within the scope of the research.

It is important to add that prior to initiating any standardization work, research projects must first concentrate on developing technological innovations. Hence, this task and deliverable seek to study the potential for standardization and suggest a coherent standardization plan to the partners. The identified opportunities for standardization take into account the work planned by the consortium partners and can contribute to align their research with the identified standardization opportunities. D8.2 analyses the standardization potential and formalizes the standardization strategy and plan for the project. It aims at coordinating and supporting the GATEKEEPER partners in their standardization initiatives. This preliminary deliverable will be complemented by another deliverable, D8.4 'Standardization report and recommendations' focused on reporting the standardization work achieved by the GATEKEEPER consortium, lessons learned and recommendations.

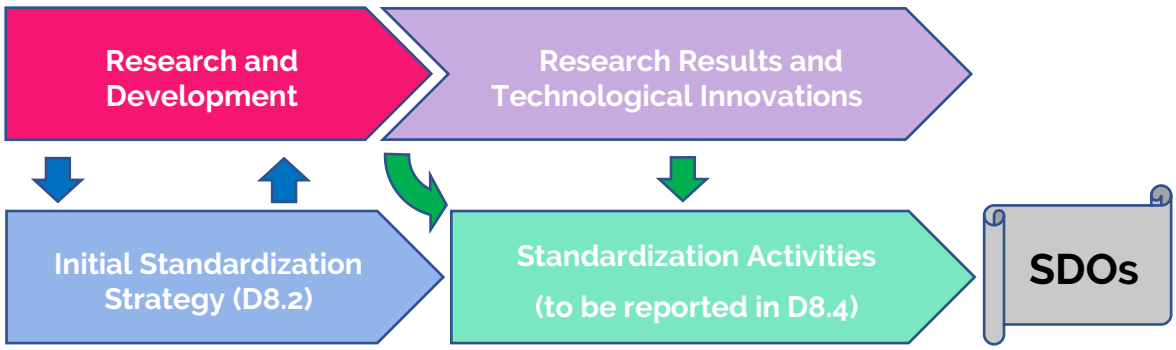

Figure 1: Standardization processes interdependencies and sequence

1.3 Results of gap analysis and follow-up in D8.2

The main finding in the gap analysis part of D8.1 'Overview of relevant standards in smart living environments and gap analysis' was that based on the overview of standards, there is good coverage of different standards in the various fields relevant for the GATEKEEPER project. The overview of pilots shows that the main needs of standards will concentrate on medical equipment and monitoring standards, besides data collection and communication related standards.

These responses further indicate that the standardization needs of the individual work packages will thus seem to concentrate on:

- Data management, data protection
- AI integration systems, eHealth technology and medical equipment.

The D8.2 elaborates on this and also on further reports and inputs from the project partners, to ensure that the proposals for new standardization initiatives support the technological development and business aspects of the project.

2 Overall methodology and strategy for standardization design approach

The following section presents the methodology behind the Initial Standardization Strategy. In order to elaborate the Standardization Strategy, task T8.2 has adopted the following methodology:

1. The deliverable details the key priorities identified by the European Commission's 2020 Rolling Plan for ICT standardization in the fields of 'eHealth, healthy living and ageing' and also looks into the European Data Strategy (section 3)
2. The deliverable presents and describes the GATEKEEPER identified results for standardization (WHAT) (section 4)
3. The deliverable studies the relevant Standards Developing Organizations (WHERE), with a special focus on CEN, CENELEC, ETSI, ITU, W3C, ISO/IEC, HL7, ECCP and TM Forum where the GATEKEEPER partners could perform standardization activities on matters that are connected to the GATEKEEPER project. (section 5)
4. The deliverable identifies GATEKEEPER lead partners in standardization (WHO) (section 6)
5. The deliverable presents a synthetic strategy for standardization (section 7)
6. The deliverable presents the upcoming timeline of standardization activities to be considered by the partners (section 8)
7. Finally, the conclusion provides a synthesis of the identified fora of high relevance to the GATEKEEPER project (section 9)

The upcoming section first describes the survey process that lead to the identification of standardization results. In a second stage, the section presents the five research results identified by the survey participants, relevant for standardization.

2.1 Internal survey and review of the GATEKEEPER potential for standardization

A formal survey has been elaborated to capture potential GATEKEEPER research results relevant for standardization. The survey was based on the "three Ws questions" below:

A. WHAT topics have the potential to be submitted to standardization?

B. WHERE (which SDOs and fora) will be most relevant and deliver the best impact ?

C. WHO can lead and support the standardization effort in the project?

The survey included both closed and open questions about future standardization and exploitation plans of each partner and was sent to all GATEKEEPER partners to complete. All the partners have submitted the results to the survey. The part A of the questionnaire was entitled "Partner perspective" and discusses exploitable results from GATEKEEPER, their value proposition, intellectual property strategy and possible partnerships. The part B "Partner's standardization activities" required the partners to indicate any standardization activities that they are involved in, express their views on the standardization processes

that GATEKEEPER should focus on, propose key elements that the project should push to standardization, and provide specific standardization information regarding their organization. Finally, part C "Exploitable result description" further addressed each partner's exploitable results in the framework of GATEKEEPER. The detailed survey used for collecting inputs form the partners is in Appendix A.

Due to the early stage of the project, partners could not necessarily identify all upcoming research results relevant for standardization, but the most important actions could be identified. Task T8.3 will of course keep continuously monitoring and identifying potential complementary research results to be certified in parallel to the research activities.

2.2 Target outcomes and KPIs

In order to better monitor the progress of the T8.2, the following KPIs have been defined for standardization according to the priority of the consortium members:

Table 1: KPI and targets

KPI	Target
Number of contributions to SDOs	10
Percentage of joint contributions	50%
Percentage of identified innovations brought to standardization succeeding to be taken into account in draft standards	50%

It is worth specifying that the 'contributions to SDOs' not only allude to new draft recommendations and contributions to existing standards but also include other forms of collaborations with SDOs including presentations, demos, tutorials and participations in target events.

3 Relevant EU frameworks for GATEKEEPER standardization

The following section focuses on two relevant EU frameworks relevant in the context of the GATEKEEPER Initial Standardization Strategy. First, it delves into the EU Rolling Plan for ICT Standardization and looks into the EU priorities for eHealth, healthy living and ageing. Next, it addresses the European Data Strategy.

3.1 EU Rolling Plan for ICT Standardization and EU priorities for eHealth, healthy living and ageing

Guaranteeing the sustainability, efficiency and quality of the healthcare system is one of the biggest challenges that the European Union currently faces. The ageing population, increasing prevalence of chronic diseases, the re-emergence of infectious diseases and the recent developments in line with the covid-19 pandemic call for modern, harmonized and efficient solutions.

The European Commission's White Paper on the Future of Europe highlights key drivers of Europe's future and specifies that by 2030, Europe will be the oldest region in the world.[1] While this development comes in hand with new challenges, it also grants new opportunities for ICT technologies to support this transition. Indeed, the efficient and responsible use of digital technologies can play a prominent role in improving the health and wellbeing of European citizens and providing a modern response to these emerging challenges.

In this line, in 2018, the European Commission released a Communication (COM(2018) 233) on enabling the digital transformation of health and care in the Digital Single Market, which lists the following objectives for the eHealth and digital care:

- *"Citizens´ secure access to electronic health records and the possibility to share it across borders.*
- *Supporting data infrastructure, to advance research, disease prevention and personalized health and care in key areas including rare, infectious and complex diseases.*
- *Facilitating feedback and interaction between patients and healthcare providers, to support prevention and citizen empowerment as well as quality and patient-centred care, focussing on chronic diseases and on a better understanding of the outcomes of healthcare systems"* [2]

[1] European Commission, 'White Paper on the Future of Europe and the Way Forward'. Text. Accessed 10 September 2020. https://ec.europa.eu/commission/future-europe/white-paper-future-europe-and-way-forward_en.

[2] EUR-LEX, 'EUR-Lex - 52018DC0233 - EN - EUR-Lex'. Accessed 10 September 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN.

In the past decade, the eHealth sector has significantly grown and matured in Europe. Digital technology deployments in the healthcare sector take place in all European member-states, often with the ambition to reform the health care system, offer original methods of healthcare delivery or enhance the current system process of exchange of medical data. In addition to that, eHealth offers fresh room of manoeuvre for European policymakers.

The 2020 European Rolling Plan for Standardization is the reference document of the European Commission for ICT standardization. It identifies 165 actions grouped into four thematic areas: key enablers and security, societal challenges, innovation for the single market and sustainable growth. In this context, 'eHealth, healthy living and ageing' are listed as one of the societal challenges that will benefit from standard setting.

According to the 2020 European Rolling Plan for Standardization, there is an evident urgency for progress in this field, *"by ensuring citizens' access to their own electronic health records anywhere in the EU, developing a secure EU-wide digital infrastructure that allows the pooling of electronic health records and other health data in compliance with data protection legislation and support the aggregation of investment plans across Member States and regions to deploy large scale digital health and care programmes (such as mobile health, telemedicine and connected care)."* Furthermore, amongst the core issues to be addressed are the need for interoperability between the solutions provided in both eHealth, active and healthy living and ageing domains.[3]

With regards to eHealth, interoperability is an important domain identified by the European Commission. Multiple processes have already been initiated at European level in order to facilitate cross-border access to health data for citizens (including Patient Summaries and ePrescriptions/eDispensations). The Recommendation for a European Electronic Health Record exchange format lays out base principles and coordination recommendations to support the further elaboration of the European EHR exchange format and to drive implementation. Another example is the European Interoperability Framework (EIF) adopted on 23 March 2017. The EIF provides support on how to deploy interoperable digital public services. The document delivers 47 concrete recommendations on how to enhance governance of their interoperability activities, establish cross-organizational relationships, streamline processes supporting end-to-end digital services, and guarantee that both existing and new legislation do not thwart interoperability initiatives.[4]

Overall, interoperability of ICT-enabled solutions and of data exchange appears as an indispensable milestone necessary for the improvement of the citizens' wellbeing and of the European healthcare services. Progress in this field supports the development of the EU digital single market and connects healthy living and ageing with ICT.

[3] European Commission, 'EHealth, Healthy Living and Ageing | Joinup'. Accessed 10 September 2020. https://joinup.ec.europa.eu/collection/rolling-plan-ict-standardization/ehealth-healthy-living-and-ageing.

[4] Idem.

3.2 The European Data Strategy

The European Union strongly correlates data-driven innovation with competitiveness and strives to become a role model of a society empowered by data. On February 19th 2020, the European Commission published the European Data Strategy – a manifesto calling for the creation of a single market for data in order to encourage government-to-business, business-to-business and business-to-government data sharing. The European Data Strategy is underpinned by the observation that the data produced by the public and private sector is continuously increasing and that it is changing the existing production, consumption and societal patterns.

The main objectives of the European Data Strategy are to set up European Data Spaces, the creation of a single market for data and the development of an attractive, secure and dynamic data economy. The Data Strategy puts an emphasis on the problems and existing challenges which are holding the EU back from realizing its potential in the data economy. Amongst the identified problems is 'data interoperability and quality', which should be encouraged through the ICT Rolling Plan for Standardization.

In order to achieve its objectives, the European Data Strategy is focused on four pillars:

1. A cross-sectoral governance framework for data access and use: this pillar should develop incentives for data sharing and create fair and transparent rules on data access and use, in line with European principles and regulations such as the GDPR, consumer protection and competition rules.[5]

   In terms of standardization, the Strategy will seek to *'strengthen the governance mechanisms at EU level and in the Member States relevant for cross-sector data use and for data use in the common sectoral data spaces, involving both private and public players. This could include a mechanism to prioritise standardization activities and to work towards a more harmonised description and overview of datasets, data objects and identifiers to foster data interoperability (i.e. their usability at a technical level) between sectors and, where relevant, within sectors. This can be done in line with the principles on Findability, Accessibility, Interoperability and Reusability (FAIR) of data taking into account the developments and decisions of sector-specific authorities'*

2. Investments in data and strengthening Europe's capabilities and infrastructures for hosting, processing and using data, interoperability: this pillar will facilitate investments in European High Impact projects on European data spaces as well as in trustworthy and energy efficient cloud infrastructures.[6] According to the Strategy,

   'In order to open up key public sector reference data sets for innovation, it shall start the procedure for the adoption of an Implementing act on high-value data sets (Q1 2021) under the Open Data Directive, making these data sets available across the EU

[5] European Parliament, 'Legislative Train Schedule | European Parliament'. Accessed 29 September 2020. https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-european-data-strategy.

[6] Idem.

for free, in machine-readable format and through standardised Application Programming Interfaces (APIs).[7]

3. Empowering individuals, investing in skills and in SMEs: this pillar will improve the portability right for individuals under Article 20 of the GDPR, granting them more control over who can access and use machine-generated data.[8]
4. Common European data spaces in strategic sectors and domains of public interest: this pillar strives to build European data spaces in various domains of high importance, such as industrial manufacturing, the Green Deal, mobility, finance, energy, agriculture, public administration, health and skills.[9]

[7] EUR-LEX, 'EUR-Lex - 52020DC0066 - EN - EUR-Lex'. Accessed 29 September 2020. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593073685620&uri=CELEX%3A52020DC0066.

[8] European Parliament, 'Legislative Train Schedule | European Parliament'. Accessed 29 September 2020. https://www.europarl.europa.eu/legislative-train/theme-a-europe-fit-for-the-digital-age/file-european-data-strategy.

[9] Idem.

4 GATEKEEPER identified results for standardization (WHAT)

4.1 Identified elements by the partners to be considered for standardization

As part of the Standardization survey, the partners expressed their opinions, aspirations and priorities regarding the possible topics and assets that can be brought to standardization. The following list compiles the results gathered from the survey:

- Accessibility and universal design aspects of equipment and services connected to the pilot projects.
- Standards at Organizational level (e.g. IHE)
- Standards at Semantic level (e.g. CIE, LOINC, ICD-10, SNOMED)
- Standards at Syntactic level (e.g. DICOM, HL7, FHIR)
- Standards at Technical level (e.g. REST, EDI)
- Pilot to validate the system
- Software for clinicians
- Usability of the whole system in clinical practice
- Standard access to patient monitoring devices marketed by different vendors, with specific emphasis on wearable/IoT-based ones, in order to address the needs mentioned under item (2) above (e.g. for measurement of glycaemia, BP, body composition, physical activity, sleep quality, etc.)
- Standard access to data visualization and interpretation dashboards, for HCPs to benefit from the availability of the above data
- Standard access to e-coach/patient empowerment components for conditions typical of active and healthy aging (e.g. frailty, MCI, T2D, HF, HT, COPD)
- Intelligent services for early risk detection and care plans
- Ecosystem co-creation framework
- GATEKEEPER Core components
- Technologies and innovations applied in Pilots
- Produced datasets from pilot implementations
- Operational standards for data-flows and data usage within the GK ecosystem
- Evaluation frameworks (impact, effectiveness, cost-effectiveness…)
- GATEEKEPER platform architecture
- GATEEKEPER platform interface (API)
- GATEKEEPER standard for consumer device interface
- FAIRification of things (W3C standards)
- Definition of a common (wide adopted) HL7 FHIR Profile

- HL7 FHIR International Patient Summary IG
- HL7 FHIR Point-of-Care Device Implementation Guide
- HL7 FHIR Personal Health Device Implementation Guide
- Extract database from Health Cap and WeRISE App to test OCR technology
- UI for easier recognition
- Knowledge from clinician regarding clinical notes and appointment format, expand OCR technology for users to capture appointment details and prompt reminders
- The questionnaires and datasets collected from the patients by each pilot site
- Research criteria for comparable outputs
- Standardized datasets as a result of pilots implementation
- Data federation framework (T4.4), Semantic models (T3.4), FHIR implementation guide (T3.5), because of they are the main tasks involved in the definition of a common healthcare data space
- Thing Management System (T4.2) because of it is implementing a broker service based on Web of Things following the intermediary Web of Thing component architecture published by W3C
- GATEKEEPER Trust Authority (T4.5) because of its promoting the compliance with the incoming IDSA architecture
- Standard processes and regulations to use ML and AI in Healthcare and in digital health
- Cross-border exchange and provision of digital healthcare services and products
- Citizen-Individual oriented usage and exploitation of data in health care and prevention

4.2 Description of identified elements to be considered for standardization

The results provided by the GATEKEEPER partners in the standardization survey have been analysed and further classified into five categories: GATEEKEPER reference architecture, interoperability enablers, FHIR implementation guides, Web of Things and Data protection, security and GDPR compliance. The following section provides a description of each of them.

4.2.1 GATEKEEPER reference architecture

The GATEKEEPER platform is a web-based platform designed to offer interdisciplinary healthcare and smart home services in the respective creation spaces: Healthcare, Consumer, Business and Ecosystem; in order to accelerate the setup of new business solutions to providers (B2B/B2G) and consumers (B2C). It is composed of a set of core services and several components that enable the creation of the different spaces of services in order to bring innovations and added value in healthcare at different level in the architecture, infrastructure, technology and business domain. At the architectural level GATEKEEPER improves the Web of Things layer architecture with a new layer and a proposal for networked things architecture. The current Web of Thing layer architecture

includes 4 layers: ACCESS (provide access to a Thing), FIND (discover things), SHARE (enables things exchange) and COMPOSE (enables Things creation from existing ones).Within GATEKEEPER we foresee the additional CERTIFY layer, on the top of ACCESS layer and before the FIND layer, that will build the concept of trustiness in the GATEKEEPER platform through certification of Things, and a way to securely share data across services using technologies such as Blockchains. From an architectural point of view, the GATEKEEPER architecture is mindful of components that it needs to comply with (like EHR, other existing eHealth platforms, Health Management Information Systems for supporting use cases & tools, standards) but also input/output parameters (APIs, Adaptors) specification.

4.2.2 Interoperability enablers

Data interoperability is very important as it allows using software components provided by multiple organizations and thus, to extending the possibilities of interactions between these software components, including new business relationships. Interoperability reduces the time of development of such software components and the time of data processing, while facilitating the efficient data management. Yet, it also requires strong security. Indeed, the exchanged data can contain personal or sensitive information which must be protected to avoid any data leakage during the transmissions between the interoperable software components.

Interoperability is one of the key preoccupations of GATEKEEPER. In the context of the project, multiple interoperability enablers have been identified including semantic interoperability, user centric optimization, open API for service integration, the data federation framework, secure data sharing mechanisms, risk assessment and risk detection, and GDPR and data protection by design compliance assessment of eHealth solutions.

Examples of topics to be raised for standardization in the field of interoperability include:

- Standard access to patient monitoring devices marketed by different vendors, with specific emphasis on wearable/IoT-based ones, in order to address the needs mentioned under item (2) above (e.g. for measurement of glycaemia, BP, body composition, physical activity, sleep quality, etc.)
- Standard access to data visualization and interpretation dashboards, for HCPs to benefit from the availability of the above data
- Standard access to e-coach/patient empowerment components for conditions typical of active and healthy aging (e.g. frailty, MCI, T2D, HF, HT, COPD)

4.2.3 FHIR implementation guides

The FHIR (Fast Healthcare Interoperability Resources) Specification is a standard developed by HL7 for exchanging healthcare information electronically. FHIR aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications.

FHIR implementation guides contribute to the definition of a common healthcare data space. Based on the results of the standardization survey, in the context of GATEKEEPER, topics relevant to the following FHIR implementation guides can be considered for standardization:

- Point-of-Care Device Implementation Guide: this Implementation Guide defines the use of FHIR resources to convey measurements and supporting data from acute care point-of-care medical devices (PoCD) to receiving systems for electronic medical records, clinical decision support, and medical data archiving for aggregate quality measurement and research purposes. It could be considered "deep metadata for device observations". Key goals include supplementing the measurement values with full provenance for traceability, and with further details of device architecture and dynamically changing attributes such as calibration history and battery state than is provided for in a FHIR Observation resource.[10]
- Personal Health Device Implementation Guide: this Implementation Guide defines the use of FHIR resources to convey measurements and supporting data from communicating Personal Health Devices (PHDs) to receiving systems for electronic medical records, clinical decision support, and medical data archiving for aggregate quality measurement and research purposes. In most cases there is a Personal Health Gateway (PHG) that handles the PHD communications.[11]
- International Patient summary Implementation Guide: The goal of this Implementation Guide is to specify how to represent in HL7 FHIR the International Patient Summary (IPS). Indeed, an International Patient Summary (IPS) document is an electronic health record extract containing essential healthcare information about a subject of care.[12]
- FHIR Profile: A profile specifies a set of rules that the content of a resource must adhere to. Moreover, a resource is allowed to describe required behavior for applications that conform to the profile.[13]

4.2.4 Web of Things

Web of Things (WoT) describes a set of standards by the W3C for solving the interoperability issues of different Internet of Things (IoT) platforms and application domains. In the context of GATEKEEPER, the following topics can further be explored and considered for standardization:

- Web of Things Management System as it is implementing a broker service based on Web of Things following the intermediary Web of Thing component architecture published by W3C.
- Web of Things standard over multiple smart and healthy living at home domains: W3C's architecture for the Web of Things as an abstraction layer to connect suppliers and consumers of services, decoupling developers from the need to

[10] HL7, Point-of-Care Device Implementation Guide, Accessed 14 September 2020. http://hl7.org/fhir/uv/pocd/2018Sep/.

[11] HL7, Personal Health Device Implementation Guide Home Page - FHIR v4.0.0'. Accessed 14 September 2020. http://hl7.org/fhir/uv/phd/2019May/.

[12] HL7, International Patient Summary Implementation Guide - FHIR v4.0.1'. Accessed 14 September 2020. http://hl7.org/fhir/uv/ips/.

[13] HL7, 'Profile - FHIR v0.0.82'. Accessed 14 September 2020. https://www.hl7.org/fhir/DSTU1/profile.html.

work at a lower level and the challenges of directly dealing with the myriad and fragmented technologies and standards at the network edge. The Web of Things associates things with URIs that can be used as identifiers for Linked Data descriptions, and dereferenced to obtain proxies for things in the form of software objects with properties, actions and events.

- The use of W3C's standards for Web of Things and Linked Data enables rich descriptions of the kinds of things and their relationship to other things including both static concepts and interactive things with affordances for properties, actions and events. The links form a Web of Things. W3C's Web ontology language (OWL) is commonly used for ontologies, whilst W3C's RDF shape constraint language (SHACL) is convenient for validation.
- Experience within Gatekeeper will be shared with the W3C across multiple areas, including security and privacy, marketplaces of services, and semantic interoperability.

4.2.5 Data protection, security and GDPR compliance

Data protection and security is regulated not only by primary norms approved and enforced by States or international organizations, it is also important to take into account the efforts which have been done and which are currently in place in regional and global SDOs. Standards are first of all important in order to achieve a common level playing field among the different stakeholders involved in the elaboration of e-health solutions. Lack of appropriate standardization can result in inaccurate and incomplete data collection, patient matching issues and slower organizational workflows. Standardization therefore brings improved quality, safety and health outcomes. In the context of GATEKEEPER this activity will be closely connected to the work on data protection being done in WP 1 and WP 8 in certification.

Of particular relevance for this field are the following initiatives:

- CEN/TC 251 – Health informatics
- ITU-T Focus Group on "Artificial Intelligence for Health" (FG-AI4H)
- FHIR Infrastructure Group (Fast Healthcare Interoperability Resources)
- ISO/TC 215: Health informatics
- ISO/IEC JTC 1/SC 27: Information security, cybersecurity and privacy protection

4.3 Summary of identified assets to be considered for standardization

The following table below summarizes the identified elements to be considered for standardization. The assets have been classified in five categories. The synthetic table gives a brief description of the elements and the relevant tasks which may support the standardization efforts.

Table 2: Summary of identified assets to be considered for standardization

Standardization assets	Description	GATEKEEPER tasks
GATEKEEPER reference architecture	GATEKEEPER WoT architecture	T3.1, T3.2
Interoperability enablers	Semantic interoperability (Ontologies, terminologies, value sets, etc.)	T3.3, T3.4
	User centric optimization	T3.5
	Open API for service integration	T3.5, T4.1, T5.1, T5.6, T5.7
	Data federation framework	T4.4
	Secure data sharing mechanism	T4.5, T4.6
	Risk detection and risk assessment	T5.3, T6.2
	Bluetooth profile for FHIR observation resource (under discussion)	T3.5.2
	Point-of-Care Device Implementation Guide	T3.3, T3.4, T3.5
FHIR implementation guides	Personal Health Device Implementation Guide	T3.3, T3.4, T3.5 T4.2
	International Patient summary Implementation Guide	
	FHIR Profiles	
Web of Things	Web of Things standard over multiple smart and healthy living at home domains	T3.3
	Market place standardization	T4.6
	Web of Things Management System	T4.2
Data protection, security and GDPR compliance	GDPR and data protection by design compliance assessment of eHealth solutions	T1.3, T1.4
	Standardized medical data exchange process in the health sector	T1.3, T1.4

5 Relevant Standards Developing Organizations (WHERE)

5.1 SDOs and fora identified by the partners relevant for GATEKEEPER standardization

As part of the survey, the GATEKEEPER partners were asked to list the SDOs that, in their opinion, the project should focus on. Based on the results, the following organizations have been identified, at the regional and global levels.

At the global level, the following SDOs and fora have been identified:

- ISO (International Organization for Standardization)
- IEC (International Electro Technical Commission), ISO-IEC-JTC1 (Joint Technical Committee for Information Technology)
- ITU (International Telecommunication Union)
- W3C (The World Wide Web Consortium)
- IEEE (Institute of Electrical and Electronic Engineering)
- HL7 Organization / FHIR (Health Level Seven International)
- IDSA (International Data Spaces Association)
- TM Forum

At the regional level, the following SDOs and fora have been identified:

- CEN (European Normalization Committee)
- CENELEC (European Committee for Electro-technical standardization)
- ETSI (European Telecommunications Standards Institute)
- AIOTI (Alliance for Internet of Things Innovation)
- EPHI (European Partnership for Health Innovation)
- IHE-Europe (Integrating the Healthcare Enterprise Europe)
- HL7-Europe (Health Level Seven Europe)
- ECCP (European Centre for Certification and Privacy)

Thanks to the diverse consortium representation, we also have the privileged access to the following SDOs and fora at the national level:

- SEIS (Sociedad Española de Informática de la SALUD / Spanish Society of Health Informatics)
- SIS (Swedish Institute for Standards)
- SN (Standards Norway)

- DIN (Deutsches Institut für Normung)

5.2 Detailed overview of relevant SDOs and fora for GATEKEEPER standardization

The following section provides an overview of the relevant SDOs and fora identified for GATEKEEPER standardization.

5.2.1 International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) is an independent, non-governmental international organization involving 164 national standards bodies. The SDO facilitates knowledge sharing and seeks to present voluntary, consensus-based, and competitive international standards supporting innovation and responding to global challenges. ISO's work is carried out by technical committees. In the scope of GATEKEEPER, multiple technical committees have been identified.

Table 3: Relevant Technical Committees at ISO/IEC

Technical Committee	Relevance
ISO/TC 124: Wearable electronic devices and technologies	High
ISO/TC 173 : Assistive products	High
ISO/TC 210: Quality management and corresponding general aspects for medical devices	High
ISO/TC 215: Health informatics	High
ISO/TC 314: Ageing societies	High
ISO/IEC JTC 1/SC 27: Information security, cybersecurity and privacy protection	High
ISO/IEC JTC 1/SC 6: Telecommunications and information exchange between systems	High
ISO/TC 159: Ergonomics	Medium
ISO/TC 268: Sustainable cities and communities	Medium
ISO/TC 304: Healthcare organization management	Medium
ISO/PC 317: Consumer protection: privacy by design for consumer goods and services	Medium
ISO/IEC JTC 1/SC 31: Automatic identification and data capture techniques	Medium
ISO/IEC JTC 1/SC 32: Data management and interchange	Medium

Technical Committee	Relevance
ISO/IEC JTC 1/SC 35: User interfaces	Medium
ISO/IEC JTC 1/SC 41: Internet of Things and related technologies	Medium
ISO/TC 299: Robotics	Medium
ISO/IEC JTC 1/WG 11: Smart cities	Low
ISO/IEC JTC 1/SC 38: Cloud Computing and Distributed Platforms	Low
ISO/IEC JTC 1/SC 40: IT Service Management and IT Governance	Low

5.2.2 International Telecommunication Union (ITU)

The International Telecommunication Union (ITU) is the United Nations agency for information and communication technologies, which works as one of the three international standards developing organizations as designated by WTO. ITU develops international standards (also known as ITU-T Recommendations) within its technical groups known as Study Groups. Currently, the ITU is composed of 11 Study Groups, out of which the following ones are of high interest to the scope of the GATEKEEPER project: ITU-T Study Group 13: Future networks and cloud, ITU-T Study Group 16 on "Multimedia", ITU-T Study Group 17 on "Security", ITU-T Study Group 20 on "Internet of things (IoT) and smart cities and communities" (SC&C). Additionally, we can identify two focus groups: ITU-T Focus Group on "Artificial Intelligence for Health" (FG-AI4H) and ITU-T Focus Group on Machine Learning for Future Networks including 5G (FG-ML5G).

The table below gives an overview of the existing work items that can be contributed to on behalf of the project.

Table 4: Relevant Working Groups at ITU

Target Working Group / Question	Study Group	Relevance
Q28/16: Multimedia framework for e-health applications	SG16: Multimedia	Medium
Q2/17: Security architecture and framework	SG17: Security	High
Q4/17: Cybersecurity		High
Q7/17: Secure application services		High
Q10/17: Identity management architecture and mechanisms		High

Target Working Group / Question	Study Group	Relevance
Q1/20: End to end connectivity, networks, interoperability, infrastructures and Big Data aspects related to IoT and SC&C	SG20: Internet of things (IoT) and smart cities and communities (SC&C)	High
Q3/10: Architectures, management, protocols and Quality of Service		Medium
Q5/20: Research and emerging technologies, terminology and definitions		Medium
Q6/20: Security, privacy, trust and identification for IoT and SC&C		High
ITU-T Focus Group on "Artificial Intelligence for Health" (FG-AI4H)	SG16: Multimedia	High
ITU-T Focus Group on Machine Learning for Future Networks including 5G (FG-ML5G)	SG13: Future networks and cloud	Medium

5.2.3 World Wide Web Consortium (W3C)

The World Wide Web Consortium (W3C) is an international community, developing Web standards. W3C's vision for the Web involves participation, sharing knowledge, and thereby building trust on a global scale. Most W3C work revolves around the standardization of Web technologies. W3C is a Web focused SDO with a broad suite of standards for web browsers, internationalization, accessibility, privacy, the Semantic Web and Linked Data. The W3C comprises the Web of Things Interest Group, which brings together stakeholders interested in the Web of Things to discuss ideas prior to standardization together with collaboration with external groups, e.g. standards development organizations and industry alliances. Additional work is carried out in the Web of Things Working Group.[14]

JSON-LD is a serialization for RDF based upon JSON, and used for Thing Descriptions in the Web of Things. The Decentralized Identifier Working Group focuses on Web identifiers that do not need to be leased and don't require a central authority. The Privacy Interest Group focuses on privacy issues that affect the Web. The RDF-DEV Community Group is

[14] W3C, 'W3C Web of Things at W3C'. Accessed 14 September 2020. https://www.w3.org/WoT/.

a forum for discussion of potential extensions to the suite of RDF related standards, including the Easier RDF initiative for making RDF easier to use for average developers. The Cognitive AI Community Group seeks to enable AI solutions that mimic human memory and reasoning, inspired by advances in the cognitive sciences and over 500 million years of evolution. W3C Community Groups are free to join and offer an opportunity for Gatekeeper to share experience and insights with a view to incubating future standards.

Table 5: Relevant Groups at W3C

Groups	Relevance
Web of Things Interest Group	High
Web of Things Working Group	High
JSON-LD Working Group	Medium
Privacy Interest Group	Medium
Cognitive AI Community Group	Medium
Decentralized Identifier Working Group	Low
RDF-DEV Community Group	Low

5.2.4 Health Level Seven International (HL7)

Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms.[15]

Table 6: Relevant Work Groups at HL7

Work Group	Relevance
FHIR Infrastructure Group (Fast Healthcare Interoperability Resources)	High

[15] HL7, 'About Health Level Seven International | HL7 International'. Accessed 14 September 2020. https://www.hl7.org/about/index.cfm?ref=nav.

5.2.5 International Data Spaces Association (IDSA)

The International Data Spaces Association (IDSA) was founded in 2016 and gathers over 101 companies and institutions involved in major industries, software development and research. IDSA seeks to secure data sovereignty by an open, vendor-independent architecture for a peer-to-peer network which provides usage control of data from all domains. Its objectives are:

- To foster the general conditions and governance of a reference architecture for International Data Spaces and interfaces with the aim of achieving an international standard
- To develop and continue to work on the standards for International Data Spaces based on use cases
- To support certifiable software solutions and business models.[16]

5.2.6 TM Forum

TM Forum is a neutral, non-profit member organization and global industry association that drives collaboration and collective problem-solving to maximise the business success of communication and digital service providers and their ecosystem of suppliers. The TM Forum ambition is to help companies to adapt and excel in the digital era by providing solutions and expertise in the fields of digital transformation, Open API, and innovation. TM Forum has developed IoT architecture & API Component Suites, as standards for the ease of management of IoT (multi-protocol) devices.[17]

5.2.7 European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC)

The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are European standardization organizations. CEN and CENELEC provide a platform for the development of European Standards and other technical specifications across a variety of sectors. Both collaborate with the European Commission to guarantee that standards follow EU legislation.[18]

In the context of the GATEKEEPER project, the following technical committees for standardization have been identified.

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[16] IDSA, International Data Spaces Association. 'Our Approach'. Accessed 22 September 2020. https://www.internationaldataspaces.org/our-approach/

[17] TM Forum. 'About TM Forum - TM Forum'. Accessed 14 September 2020. https://www.tmforum.org/about-tm-forum/.

[18] CEN-CENELEC, 'About Us - CEN-CENELEC'. Accessed 14 September 2020. https://www.cencenelec.eu/aboutus/Pages/default.aspx.

Table 7: Relevant technical committees at CEN

Technical Committee	Relevance
CEN/TC 251 – Health informatics	High
CEN/TC 450 - Patient involvement in person-centred care	High
CEN/SS S99 - Health, environment and medical equipment	High
CEN/CLC/TC 8 - Privacy management in products and services	High
CEN/WS 102 - CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care	High
CEN/TC 293 - Assistive products and accessibility	High
CLC/TC 62 - Electrical equipment in medical practice	Medium
CEN/TC 140 - In vitro diagnostic medical devices	Medium
CEN/TC 294 - Communication systems for meters and remote reading meters	Medium
CEN/TC 362 - Healthcare services - Quality management systems	Medium
CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices	Medium
CEN/CLC BT/WG 213 - Strategic Advisory Group Accessibility (SAGA)	Medium
CEN/CLC/ETSI/JWG eAcc - eAccessibility	Medium
CEN/CLC/JTC 3 - Quality management and corresponding general aspects for medical devices	Medium
CEN/CLC/JTC 16 - CEN/CENELEC Joint Technical Committee on Active Implantable Medical Devices	Medium
CEN/CLC/JTC 12 - Design for All	Low

5.2.8 European Telecommunications Standards Institute (ETSI)

The European Telecommunications Standards Institute (ETSI) is an independent European standards-developing organization that provides a platform for the development, ratification and testing of globally applicable standards for ICT-enabled systems, applications and services across all sectors of industry and society. ETSI supports European standardization efforts through the development of Harmonized European Standards. The table below presents the Committees of interest relevant to GATEKEEPER, where contributions can be made.

Table 8: Relevant Committees at ETSI

Committee	Relevance
eHealth	High
CYBER - Cybersecurity	High
Human Factors	High

5.2.9 European Partnership for Healthcare Innovation (EPHI)

The European Partnership for Healthcare Innovation (EPHI) is a public-private partnership set up to strengthen dialogue on the technical and scientific advances needed to address the challenges of healthcare in Europe. EPHI provides an opportunity for GATEKEEPER to contribute to case studies and coordination of research and innovation across Europe. As such EPHI provides an important forum for Horizon 2020 projects in respect to incubation of ideas for future healthcare related standards.

5.2.10 Alliance for Internet of Things Innovation (AIOTI)

The Alliance for Internet of Things Innovation (AIOTI) is a public-private partnership set up to strengthen the dialogue and interaction among Internet of Things (IoT) players in Europe, and to contribute to the creation of a dynamic European IoT ecosystem to speed up the take up of IoT. AIOTI has a number of horizontal and vertical Working Groups. Of particular note is the semantic interoperability task force within the IoT standardization Working Group.

Table 9: Relevant AIOTI Working Groups

Working Group	Relevance
WG 03 Standardization	High

5.2.11European Centre for Certification and Privacy (ECCP)

The European Centre for Certification and Privacy (ECCP) is in charge of the Europrivacy certification scheme management and licensing process. It assumes the function of the scheme owner with the support of the Europrivacy International Board of Experts. The

ECCP is particularly active in the following areas: Internet of Things, ICT certification, privacy and personal data protection and certification and labelling process.[19]

Table 10: Relevant Working Groups at ECCP

Working Group	Relevance
Europrivacy international Board of Experts - Specification working group	High

5.2.12 Integrating the Healthcare Enterprise (IHE Europe)

The Integrating the Healthcare Enterprise is a non-profit organization that gathers healthcare professionals and members of the industry to improve the sharing of information between computer systems in the healthcare sector. IHE endorses the coordinated use of standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. At the European level, IHE-Europe engages clinicians, health authorities, industry and users to improve healthcare interoperability by:

- Helping national and European stakeholders and policy-makers in adopting, promoting and implementing IHE specifications.
- Developing tools and services in support of interoperability testing.[20]

Table 11: Relevant committees at IHE Europe

Committee	Relevance
IT Infrastructure	High
Patient Care Coordination	High
Patient Care Devices	High
Quality, Research and Public Health	High

5.2.13 Sociedad Española de Informática de la Salud (SEIS)

SEIS – Sociedad Española de Informática de la Salud (Spanish Society of Health Informatics) is a national non-profit scientific society that embraces hundreds of professionals who are interested in the application of informatics to health. It is a common space of participation for medicine, computer science, nursery, pharmacy, veterinary science, psychology and other health sciences, and also for students of the related

[19] ECCP, 'ECCP - European Centre for Certification and Privacy | ECCP Is a Lead Organization in Tests, Labelling and Certification for Personal Data Protection and Internet of Things'. Accessed 14 September 2020. https://eccpcentre.com/.

[20] IHE Europe, 'About Us | IHE Europe'. Accessed 22 September 2020. https://www.ihe-europe.net/about-us.

disciplines. Its mission is to promote research, development and innovation, implementation and appropriate use of IT in the area of health for the sake of society, with full respect to person rights, specially to privacy.

Some of the activities that the Society holds are:

- the I+S Magazine. Electronic and paper magazine including information and scientific dissemination of eHealth contents;
- National awards of computer science and health. Six organizations, companies and professionals receive a prize each year to recognize their contribution to development and implementation of IT in health area;
- Yearly conferences on innovation, e-health, interoperability, security and data protection, IT Governance, and e-health;
- SEIS Index is a report about the real state of deployment and implementation of IT in the Spanish public healthcare system;
- SEIS reports are reference documents for professionals, services and health systems about IT and health systems;
- Master's degree on IT management for health.

The society also holds committees at national level that share experiences and knowledge from the different regions in Spain. The table below presents the relevant technical committee at SEIS. This committee is composed by one representative from each region and it is oriented to discuss on how standardization and interoperability contribute to the development of the national health system.

Table 12: Relevant technical committee at SEIS

Technical Committee	Relevance
Technical Interoperability Committee of National Health System of SEIS (Sociedad Española de Informática de la Salud / Spanish Society of Health Informatics).	Medium

5.2.14 Swedish Institute for Standards (SiS)

The Swedish Institute for Standards (SiS) is an international organization specialized in national and international standards. With SiS, private industry and public-sector stakeholders can take initiatives and collaborate on best practices that promote Sweden's competitiveness and encourage smart, sustainable development. SIS operates across all areas of Swedish society including industry, academia, the public sector and non-governmental organizations. SIS acts as project manager for Swedish efforts to develop standards. They strive to increase Sweden's influence on international collaboration and to ensure that best practices are shared and leveraged throughout Sweden.

Some relevant activities where SiS is active include:

- CEN/TR 15592:2007 Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance improvement
- EN 15224:2016 Quality management systems - EN ISO 9001:2015 for healthcare

The SiS is active in various aspects of relevant standardization, among others on assistive technology. The committees mentioned in the table has their secretariat in SiS.

Table 13: Relevant activities at SiS

Working Group	Relevance
CEN/TC 293 Assistive products and accessibility	High
CEN/TC 362 - Healthcare services - Quality management systems	High

5.2.15 Standards Norway (SN)

Standards Norway (SN) is a private and independent member organization, and is one out of three standardization bodies in Norway. Standards Norway is responsible for standardization activities in all areas except the electrotechnical field and the telecommunications field.

The organization was established the 24 June 2003 with roots dating back to 1923. Standards Norway has approximately 75 employees and is located at Lysaker in the western part of Oslo.

Standards Norway is the national member of the International Organization for Standardization (ISO) and the European Committee for Standardization (CEN). Standards Norway holds a seat on the boards of these organizations.

Each year, Standards Norway publishes about 1 200 new Norwegian Standards (NS). Norwegian Standards are established on the basis of national draft standards as well as on the basis of European and International Standards. Currently, more than 17 000 valid NS exist.

Some relevant activities where SN is active include:

- CEN/TC 293 WG 12 Accessibility
- CEN/TC 251 Health informatics
- ISO/TC 215 Health informatics
- CEN/CLC/JTC 12 - Design for All

SN will chair and have the secretariat for the new WG 12 accessibility in CEN/TC 293, to work on accessibility to medical technology and home appliances.

SN is also responsible for chairing and having the secretariat for the SAGA committee mentioned in the table, working for including accessibility aspects in mainstream standardization, among others the European standard EN 17161 Design for All - Accessibility following a Design for All approach in products, goods and services - Extending the range of users.

Table 14: Relevant activities at SN

Working Group	Relevance
CEN/CLC BT/WG 213 Strategic Advisory Group Accessibility (SAGA)	Medium

5.2.16 Deutsches Institut für Normung (DIN)

The 'Deutsches Institut für Normung' (DIN), the German Institute for Standardization, is the independent platform for standardization in Germany and worldwide. As a partner for industry, research and society as a whole, DIN plays a major role to supporting the marketability of innovative solutions through standardization - be it on topics around the digitization of business and society or in the context of research projects.

More than 35,500 experts from industry, research, consumer protection and the public sector bring their expertise to work on standardization projects managed by DIN. The results of these efforts are market-oriented standards and specifications that promote global trade, encouraging rationalization, quality assurance and environmental protection as well as improving security and communication. DIN was founded in 1917 and celebrated its 100 year anniversary in 2017.

Some relevant activities where DIN is active include:

- IEC 113/33/NP New work Item Proposal on Terminology for medical, health and personal care applications of nanotechnologies
- IEC 82304-1: Health Software - Part 1: General requirements for product safety
- ISO/AWI TR 24288 Health informatics - An Indicative Outcome Framework for HI Standardization
- ISO/AWI TR 24305 Health informatics - Guidelines for implementation of HL7/FHIR based on ISO 13940 and ISO 13606
- ISO/AWI TS 17975 Health informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information
- ISO/CD TR 11633-2 Health informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 2: Implementation of an information security management system (ISMS)

DIN is also responsible for proposed new projects on Terminology for medical, health and personal care applications of nanotechnologies (IEC 113/33/NP), under the committee as mentioned in the table.

Table 15: Relevant technical committee at DIN

Technical Committee	Relevance
DKE German Commission for Electrical, Electronic & Information Technologies of DIN and VDE	Medium

6 GATEKEEPER lead partners in standardization (WHO)

The contribution to standardization activities often necessitates a membership or official affiliation to a SDO as a pre-requirement. Luckily, GATEKEEPER can leverage several partners actively involved in standardization. Some partners serve as chairs and rapporteurs in SDOs. This is the case of Mandat International, whose representative is Rapporteur on Research and Emerging Technologies for at the ITU SG20.

After consultation with the partners, it has appeared that GATEKEEPER may leverage a variety of connections and affiliations to various SDOs and fora at the global, regional and national levels, thus allowing the project to engage in multi-level standardization activities. The partners which are able to contribute to the standardization activities within this project are listed in the table below with their respective SDOs access.

Table 16: Identified partners for standardization work

Partners involved in standardization	SDO	Focal point
Mandat International	ITU, ISO, ECCP, IEEE	Sébastien Ziegler, Anna Brékine
FUNKA	CEN, CENELEC, ETSI, SN, SIS, DIN	Susanna Laurin, Rudolph Brynn
CERTH	IDSA	Konstantinos Votis, Eleftheria Polychronidou
HL7 Europe	HL7, CEN, IHE, ISO, W3C	Catherine Chronaki, Giorgio Cangioli
ERCIM	W3C, IETF, ETSI, AIOTI, EPHI	Dave Raggett
UPM	W3C, HL7	Eugenio Gaeta, Giuseppe Fico
UDGA	ECCP, IETF, ITU	Pasquale Annicchino, Eunah Kim

6.1 Identified partners' ongoing standardization activities relevant to GATEKEEPER

Partner	Organization	Working Group / Study Group	Topic	Relevance to GK (High – Low)	Status
FUNKA	ISO	ISO/TC 314	Ageing society	Medium	Draft soon out for hearing
	CEN	CEN/TC 293	Assistive technology	High	Ongoing, new WG on welfare technology soon to start
	CEN/CENELEC	CEN/CLC BT/WG 213 (SAGA)	Accessibility in standardization	Medium	Ongoing, advising TCs on accessibility inclusion in standardization
	ETSI	STF 536	ICT Accessibility	High	Published version 2.1.2 presumed conformance to WAD
	CEN/CLC/ETSI /JWG eAcc eCommittee	Joint Working Group	Coordination on accessibility requirements for EU legislation	High	Ongoing
	SIS	TK504	Digital accessibility	High	Mirror committee
	SIS	TK536	Coordination of accessibility topics in all standardization	Medium	Recommendations out
	SIS	TK445	Character codes, symbols, programming languages and interfaces	Low	Ongoing

Partner	Organization	Working Group / Study Group	Topic	Relevance to GK (High – Low)	Status
ERCIM	W3C	Web browsers Web of Things Web of Data Cognitive AI	ERCIM is the European host for W3C, which is a global SDO focusing on web technologies.	High	Mix of existing standards and ongoing incubation and standardization activities
SALUD Aragon	Spanish Society of Health Informatics	Technical Interoperability Committee of National Health System of SEIS	This committee is composed by one representative from each region and it is oriented to discuss on how standardization and interoperability contribute to the development of the national health system.	High	Continuous report
	Spanish Society of Health Informatics	Technical Security Committee of Health Informatics of SEIS	This committee is composed by one security responsible from each region and it is oriented to share experiences and knowledge for the secure and safe use of IT for the provision of quality healthcare in an efficient way and with a special respect for the citizens' rights.	High	Continuous report

Partner	Organization	Working Group / Study Group	Topic	Relevance to GK (High – Low)	Status
DCCG		SRSS/SC2019/164 "Design and Implementation of National eHealth Interoperability Framework" of the Greek Ministry of Health in collaboration with IHE-Europe	Design and Implementation of National eHealth Interoperability Framework" of the Greek Ministry of Health	High	Ongoing
HL7 Europe	HL7	Several	HL7 FHIR and HL7 FHIR implementation Guides	High	Normative / STU
	HL7, ISO, IHE, CEN, SNOMED, JIC	Several	International Patient Summary	High	Normative / STU
	HL7 European Affiliates	Several	HL7 FHIR Implementation Guides	High	Normative / STU

Partner	Organization	Working Group / Study Group	Topic	Relevance to GK (High – Low)	Status
	HL7, IHE, PCHAlliance	HL7 Health Care Devices WG Integrating the Healthcare Enterprise (IHE), and the Personal Connected Health Alliance (PCHAlliance) / Continua	Personal Health Device Implementation Guide http://build.fhir.org/ig/HL7/PHD/	High	STU ballot reconciliation
	HL7, IHE, PCHAlliance	HL7 Health Care Devices WG Integrating the Healthcare Enterprise (IHE), and the Personal Connected Health Alliance (PCHAlliance) / Continua	Point-of-Care Device Implementation Guide http://build.fhir.org/ig/HL7/uv-pocd	High	STU ballot reconciliation
	HL7	Several	Other HL7 standards (see list at http://www.hl7.org/implement/standards/product_matrix.cfm)	Low-Medium	Normative / STU
	W3C-HL7	HL7 ITS WG W3C FHIR/RDF subgroup	HL7/W3C - FHIR/RDF R5 (based on JSON-LD 1.1)	High	Ongoing

Partner	Organization	Working Group / Study Group	Topic	Relevance to GK (High – Low)	Status
MI	ITU-T	Study Group 20	Rapporteur for Research on Emerging Technologies (SG20 for Internet of Things and Smart Cities and Communities)	High	Ongoing
	ECCP	Europrivacy international Board of Experts - Specification working group	Extension of Europrivacy certification scheme criteria of GDPR compliance towards eHealth domain	High	Ongoing
UDGA	ECCP	Europrivacy international Board of Experts - Specification working group	Extension of Europrivacy certification scheme criteria of GDPR compliance towards eHealth domain	High	Ongoing

7 Synthetic strategy for standardization

Standardization requires a continuous effort and contributions over time. Consequently, for a standardization strategy to be successful determining the priority fora to be considered in the project is indispensable. Additionally, having a clear overview of the effort distribution is also essential to have effective impact.

On the basis of the identified research results to be standardized, the partners' memberships and capability to contribute to SDOs, as well as the relevance of the SDOs, the synthetic strategy below summarizes the priority standardization activities to be considered in the course of the project. Unquestionably, any additional contributions to other venues identified in section 5 will be welcome too and appropriately described in D8.4.

Table 17: Synthetic strategy for standardization

WHAT	WHO			WHERE	
Research result to be standardized	**Related tasks**	**Lead expertise / Contributors**	**Lead SDO facilitator**	**SDO**	**Working Group**
GATEKEEPER architecture	T3.1, T3.2, T5.3	CERTH, ENG	FUNKA	CEN	CEN/TC 251: Health informatics
			ERCIM	AIOTI	WG 03: Standardization
			MI	ITU	SG20: Internet of things (IoT) and smart cities and communities (SC&C)
					ITU-T Focus Group on "Artificial Intelligence for Health" (FG-AI4H)
Interoperability enablers	T3.3, T3.4, T3.5, T4.1, T4.4, T4.5, T4.6, T5.3, T5.6, T5.7, T6.2	ERCIM, MYS, HL7, HPE, ENG, CERTH, MUL, OU, UPM	MI	ITU	SG20: Internet of things (IoT) and smart cities and communities (SC&C)
					SG16: Multimedia
				ISO	ISO/IEC JTC 1/SC 6: Telecommunications and information exchange between systems
			FUNKA	CEN	CEN/TC 293: Assistive products and accessibility

WHAT	WHO			WHERE	
Research result to be standardized	**Related tasks**	**Lead expertise / Contributors**	**Lead SDO facilitator**	**SDO**	**Working Group**
FHIR Implementation guides	T3.3, T3.4, T3.5, T4.2	HL7, ERCIM, MYS, UPM	HL7	HL7	FHIR Infrastructure Group
Web of Things	T3.3, T4.6, T4.2	ERCIM, UPM, CERTH	ERCIM, UPM, HL7 Europe	W3C	Web of Things Interest Group Web of Things Working Group
Data protection, security and GDPR compliance	T1.3, T1.4	UDGA	MI, UDGA	ECCP	Europrivacy international Board of Experts - Specification working group
			HL7	ISO	ISO/IEC JTC 1/SC 27: Information security, cybersecurity and privacy protection
			MI	ITU	SG17: Security
			ERCIM	ETSI	CYBER
			FUNKA	CEN	CEN/CLC/TC 8: Privacy management in products and services
					CLC/TC 62: Electrical equipment in medical practice
			HL7	HL7	FHIR Infrastructure Group

8 Upcoming timeline

Keeping track of the deadlines for contributions in each of the relevant for standardization is essential for effective work management and prioritization.

Due to the recent developments related to the coronavirus pandemic, not all SDOs have yet confirmed their agendas for the upcoming periods. Therefore, GATEKEEPER partners wishing to engage in standardization activities should regularly follow up on the updates of their target SDOs. Deadlines may fluctuate between 2 weeks and a month before the event, depending on the SDO.

The table below shows the timing of the relevant events identified in 2020 and provides a tentative calendar for the future standardization contributions.

Table 18: Upcoming timeline

SDO	Study/Working Group	Date	Location
CEN/CENELEC	All	Ongoing	Virtual
ETSI	eHealth	TBC	Virtual
	CYBER		
	Human factors		
ITU	SG13	7 December 2020	Virtual
	SG16	TBC	Virtual
	SG17	TBC	Virtual
	SG20	6 November 2020	Virtual
	FG-AI4H	30 Sep. - 2 Oct. 2020	Virtual
	FG-ML5G	TBC	Virtual
HL7	FHIR Infrastructure Group	TBC	Virtual
ISO	ISO/TC 124: Wearable electronic devices and technologies	9 Nov. – 13 Nov.2020	Virtual
	ISO/TC 159: Ergonomics	21 October 2020 5 November 2020	Virtual
	ISO/TC 173 : Assistive products	TBC	TBC
	ISO/TC 215: Health informatics	21 November 2020 14-18 June 2021	Virtual Arlington, USA

SDO	Study/Working Group	Date	Location
	ISO/TC 268: Sustainable cities and communities	16-20 November 2020	Virtual
	ISO/TC 299: Robotics	14-18 June 2021	Norrmalm, Sweden
	ISO/TC 304: Healthcare organization management	5 November 2020	Virtual
	ISO/TC 314: Ageing societies	23 November 2020	Virtual
	ISO/PC 317: Consumer protection: privacy by design for consumer goods and services	TBC	TBC
	ISO/IEC JTC 1/WG 11:Smart cities	TBC	TBC
	ISO/IEC JTC 1/SC 6: Telecommunications and information exchange between systems	19-30 October 2020 July-August 2021 March-April 2021 October-November 2022	Virtual
	ISO/IEC JTC 1/SC 27: Information security, cybersecurity and privacy protection	18-29 September 2020 April 2021 April 2022	Virtual
	ISO/IEC JTC 1/SC 31: Automatic identification and data capture techniques	June 2021 June 2022	TBC
	ISO/IEC JTC 1/SC 32: Data management and interchange	May-June 2021 May-June 2022	TBC
	ISO/IEC JTC 1/SC 35: User interfaces	18-22 January 2021	TBC
	ISO/IEC JTC 1/SC 38: Cloud Computing and Distributed Platforms	21-25 September March 2021 September-October 2021 March 2022	Virtual

SDO	Study/Working Group	Date	Location
		September 2022	
	ISO/IEC JTC 1/SC 40: IT Service Management and IT Governance	8-24 June 2021 May-June 2022 May-June 2023	TBC
	ISO/IEC JTC 1/SC 41: Internet of Things and related technologies	16-20 November 2020 May 2021 November 2021 May 2022 November 2022	Virtual Montreal, Canada Canada TBC Germany
W3C	Web of Things	TBC	Virtual
ECCP	Specification working group	On-going	Virtual
AIOTI	WG 03: Standardization	On-going	Virtual
SEIS	Technical Interoperability Committee of National Health System of SEIS	TBC	TBC
SIS	CEN/TC 293	On-going	Virtual
SN	CEN/CLC BT/WG 213	On-going	Virtual
	CEN/TC 293 WG 12	On-going	Virtual
DIN	IEC 113/33/NP	On-going	Virtual

9 Conclusion

The Initial Standardization Strategy intended to deliver a steering map for coordinating and controlling standardization activities within the GATEKEEPER project. The standardization activities will be guided by the key performance indicators for standardization defined in the strategy, designed in consultation with and according to the priority of the consortium members.

Based on the results of the standardization survey and discussions with the partners, five standardization domains have been identified:

- The GATEKEEPER architecture
- Interoperability enablers
- FHIR implementation guides
- Web of Things
- Data protection, security and GDPR compliance

The initial standardization strategy has also allowed identifying the relevant standardization developing organizations and fora at the global, regional and national levels, where activities can be carried out. At the global level, standardization work may be performed at ISO, IEC, ITU, W3C, IEEE, HL7, IDSA, TM Forum. At the regional level, CEN, CENELEC, ETSI, AIOTI, EPHI, IHE-Europe HL7-Europe and ECCP will be prioritized. Finally, thanks to the diverse consortium representation, we also have the privileged access to the following SDOs and fora at the national level: SEIS, SIS, SN, DIN.

Finally, the initial standardization strategy allowed identifying the potential partners and tasks in the projects that can support the standardization activities in the identified topics.

Reporting on the progress of the standardization activities will be further provided in D8.4 'Standardization report and recommendations'.

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Appendix A

GATEKEEER Standardization Survey (T8.2. Lead: MI)

Survey on standardization potential to be returned by ALL partners before August 30th 2020

Dear partners, in order to pave the way to a successful standardization and exploitation plan of the GATEKEEPER results, we need your inputs. We are aware that as a research project, not all results are identified yet, but we would like to get from each partner a clear description of your expected standardization plans out of the project. The results of this survey will be used to analyze and report on the standardization strategy. The form has to be sent to: abrekine@mandint.org

Partner name:

Person of contact name:

Person of contact email:

Person of contact phone number:

Part A – Partner perspective

1. Please define which exploitable results your organization is planning to get from GATEKEEPER? (Please fill in multiple categories if applicable and provide a clear description)

❑ Open source technology enablers:

❑ Proprietary technology enablers:

❑ Products:

❑ Online services:

❑ Consulting service and/or technology transfer:

❑ Other (please specify):

2. What is, according to you, the value proposition of what we are developing in GATEKEEPER?

Part B - Partner's Standardization Activities

1. **Please indicate any standardization activities that your organization is involved in (organization and working group/study group):**

Organization	Working Group / Study Group	Topic	Relevance to GK (High – Low)	Status

2. **What standardization process should the project focus on?**

3. **What are the key elements (standardizable assets, research outputs, knowledge) that the project should push to standardization?**

- …
- …
- …

4. **What are the target Standards Developing Organizations (SDOs) that GATEKEEPER should focus on? (please be as detailed as possible: name of organization and if possible, working group, question/subcommittee. This will help us build the standardization plan)**

- …
- …
- …

5. **Are you a member of a Standards Developing Organization? Please specify.**

6. **Are you aware of any standards that you would need for your work ?**

7. **Are you interested in making a joint contribution to standardization with another GK partner?**

8. **If you are not a member of a Standards Developing Organization, would you be interested to collaborate with a partner who already has a membership and make a joint contribution?**

9. **Please fill in the following table with the relevant standardization information about your organization. Please identify a focal point in your organization that we can contact to follow up with and update on the standardization activities.**

Partner	Name of lead(s)	E-mail(s)	Ready to lead new (yes/no)	Ready to collaborate (yes/no)	SDO(s)	Existing work items

10. **Other remarks**

Thank you for your answers!