



## D3.1 Functional and technical requirements of GATEKEEPER platform

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## History

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## Abstract

D3.1 aims at providing a report on all functional and technical requirements of the Gatekeeper platform on different levels. After an initial collection of specifications, which also included an analysis of state-of-the-art platforms and technologies and a list of the innovative features of Gatekeeper, the first version of the deliverable was issued in Month 12. The current version of D3.1, version 2, provides an insight into the business aspect and the cooperation between the pilot and the platform cluster in separate chapters. More specifically, at this stage more information is available regarding the relevant business use cases. Furthermore, there is an update to the pilot needs, technological developments and technology integration based on effort done in T7.5. After gaining a comprehensive view of the current stage of the project and its progress, D3.1.2 features the updated list of the Gatekeeper platform requirements. The requirements are prioritised, evaluated in terms of difficulty and associated with reference components. Special focus is given on input from WP2 and WP5, which have now advanced in their development and decisions. Finally, the requirements reported are directly associated with the component interactions presented in the Gatekeeper reference architecture report.

## 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This deliverable contains original unpublished work except where clearly indicated otherwise.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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## 1 Introduction

Every year a release of the Gartner Hype Cycle for Emerging Technologies, highlights the technologies that will significantly change society and business over the next five to ten years. In 2020 version, 30 technology profiles were identified with the most unique trends to be: (a) Composite architectures, (b) Algorithmic trust, (c) Beyond silicon, (d) Formative artificial intelligence (AI), (d) Digital me.

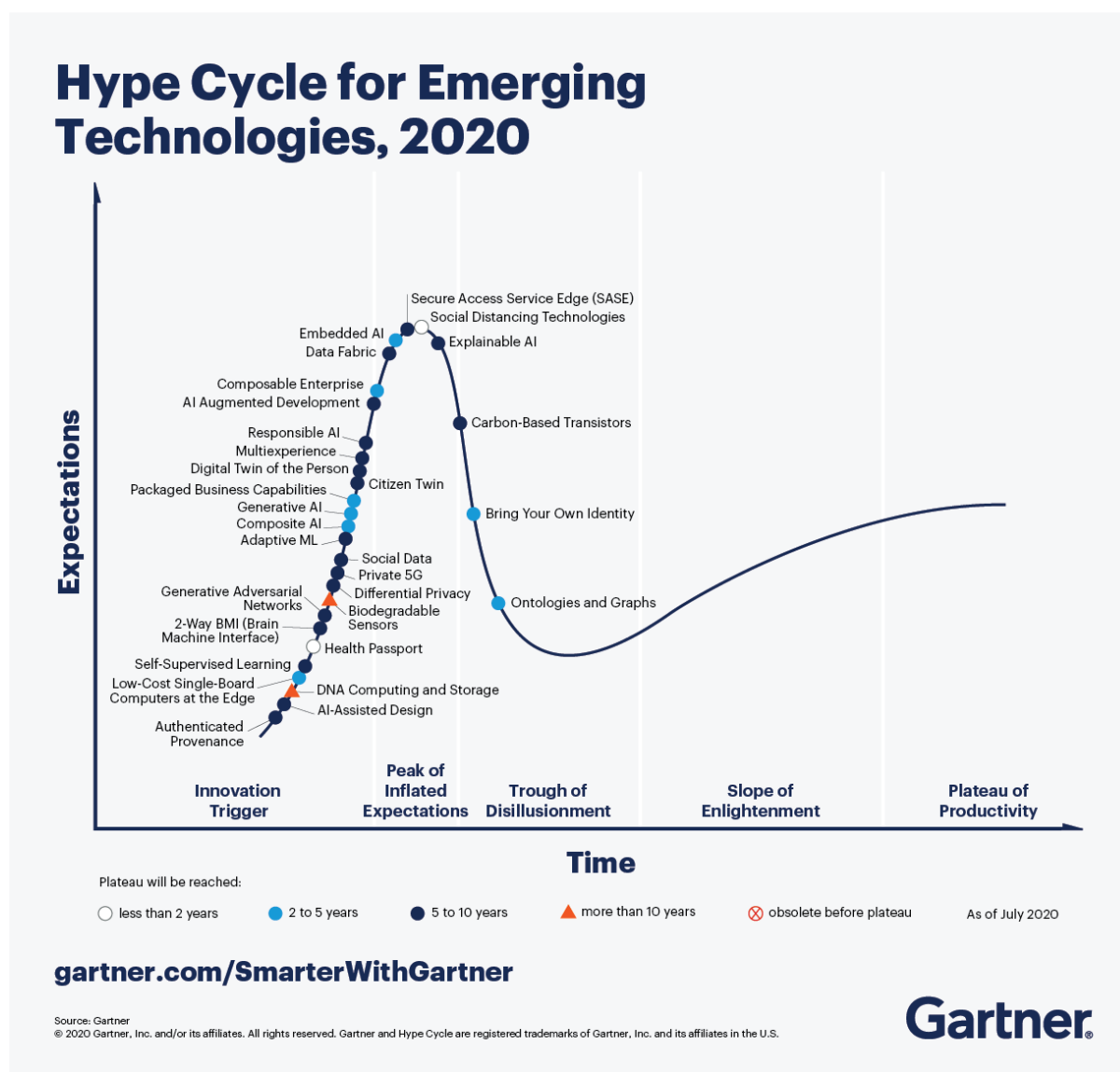


Figure 1 - Gartner 2020 Hype Cycle of emerging technologies.

- **Composite architectures** are flexible organisational structures, able to support the decentralised needs in several fields, and the need for increased resilience that result from flexible data fabric. These composite structures create innovation, reduced costs and develop the circumstances for better partnerships.

- **Algorithmic trust** is the framework where models ensure the privacy and security of data, provenance of assets, and the identities of people and things. Blockchain technologies hold a fundamental role in the achievement of the objective of algorithmic trust.
- **Beyond silicon** is related to advanced materials with enhanced capabilities designed to support smaller, faster technologies.
- **Formative AI** highlights the capability of AI to adopt into different use cases based on the continuous development of the content.
- **Digital me** is the representation of people through digital models in order to promote personalisation and immersive analytics.

The GATEKEEPER platform is designed based on the principles of the composite architecture (T3.2, Figure 2) and can be characterised as an ecosystems platform that supports the creation of and the connection to external ecosystems, marketplaces, and communities. In ecosystem platforms, the main elements are API management, control and security. However, GATEKEEPER enhanced this ecosystem platform approach by including components that support the objectives of algorithmic trust and formative AI. Furthermore, the design of the system can support the integration with technology and service providers that are aligned with the beyond silicon and digital me objectives. Thus, in this project a powerful platform has been designed and developed, able to support current trends and provide the technology needed for supporting decentralised healthcare sustainable models [D3.1.1].

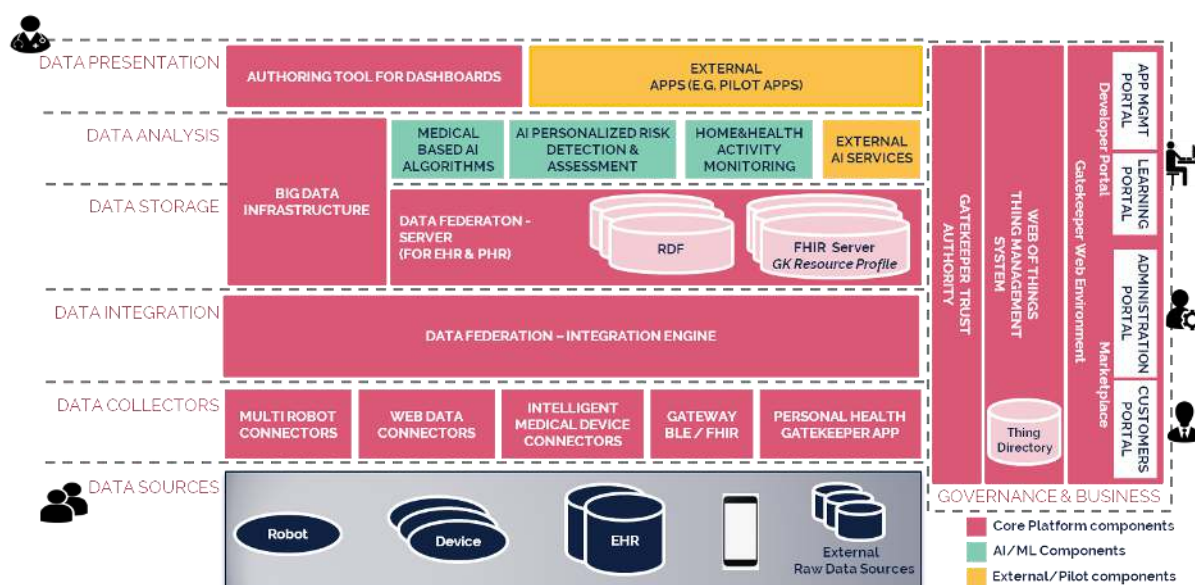


Figure 2 – GATEKEEPER Platform logical view

D3.1 aims at providing a report on all functional and technical requirements of the Gatekeeper platform on different levels. After an initial collection of requirements, which also included an analysis of state-of-the-art platforms and technologies and a list of the innovative features of Gatekeeper, the first version of the deliverable was issued in Month 12. The current version of D3.1, D3.1.2, provides an insight into the business aspect, namely the business use cases, and the pilot technology developments based on pilot reports

and on the COVID-19 survey implementation efforts in separate chapters. After gaining a comprehensive view of the current stage of the project and its progress, the deliverable features the updated list of the Gatekeeper platform requirements sorted into levels introduced in D3.1.1. These requirements are the outcome of communication among partners in the scheduled biweekly work package calls, in bilateral calls and while co-editing the deliverable. They are prioritised, evaluated in terms of difficulty and associated with reference components.

This deliverable is **structured** in the following way:

- [Section 2](#) offers the context of the work done, referring specifically to the interaction among Tasks (T), Work Packages (WP) and Clusters to determine the requirements.
- [Section 3](#) includes definitions so that the reader can have a clear understanding of the users of the GK platform, its technical components and the abbreviations or technology terms used across the document.
- [Sections 4 and 5](#) summarise the business aspect of the platform and of the (implemented/expected) cooperation between the pilots and the platform. The needs arising from these two sections are then analysed in the following section.
- [Section 6](#), where not only these, but also the updated platform reference component requirements are presented. Special focus is given on input from WP2 and WP5, which have now advanced in their development and decisions.
- [Appendix A](#) associates the component interactions with requirements from all pertinent levels.

## 2 Relationship with other work packages

This deliverable is closely related to the rest of WP3 tasks and also most of the WPs of the project, as it is one of the basic steps towards the development of the platform.

In Figure 3, a representation of the main interactions and expected outcomes is presented. WP2, WP8 and WP9 provided insights for the setting of requirements in D3.1, while in the cases of the remaining WP3 tasks, WP4, WP5, WP6 and T7.5 the approach was bi-directional. The lighter arrows refer to the input to D3.1, whereas the darker arrows show the effect of the requirements identified to the work of the other packages.

In Figure 4, the contribution of each cluster to set requirements for each level is represented. Each cluster is involved in multiple levels and the levels are affected by multiple clusters. The user level is the common ground of all three clusters, Platform, Business and Large-Scale Pilot (LSP).

The next subsections provide more details about the specific interactions for each WP.

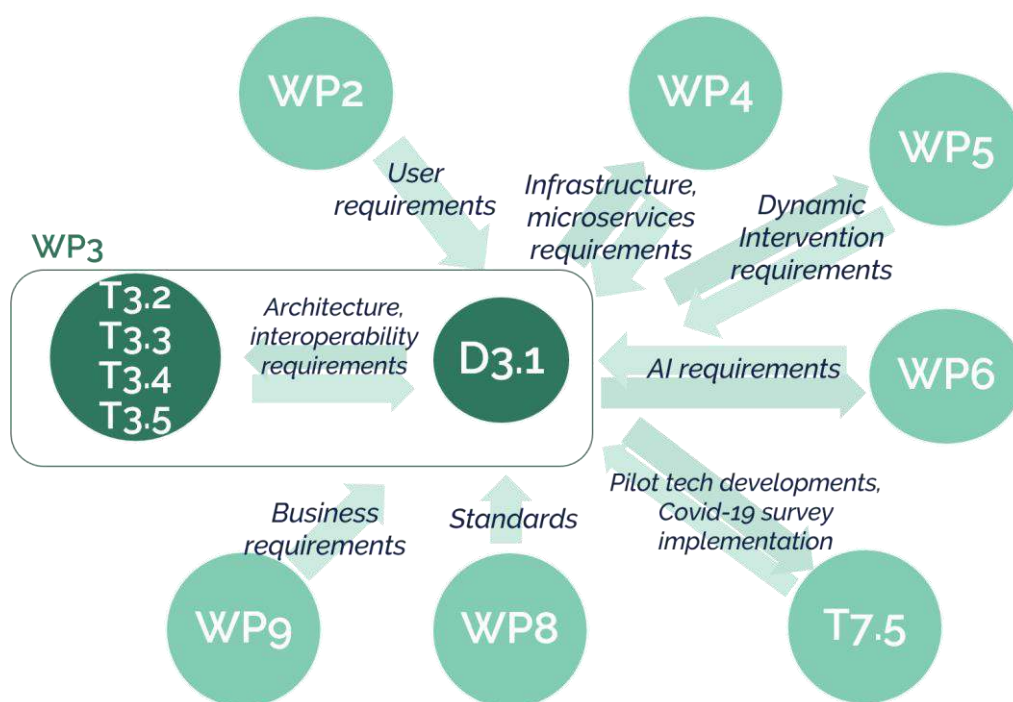


Figure 3 - Overview of the main interaction between D3.1 and other tasks and WPs

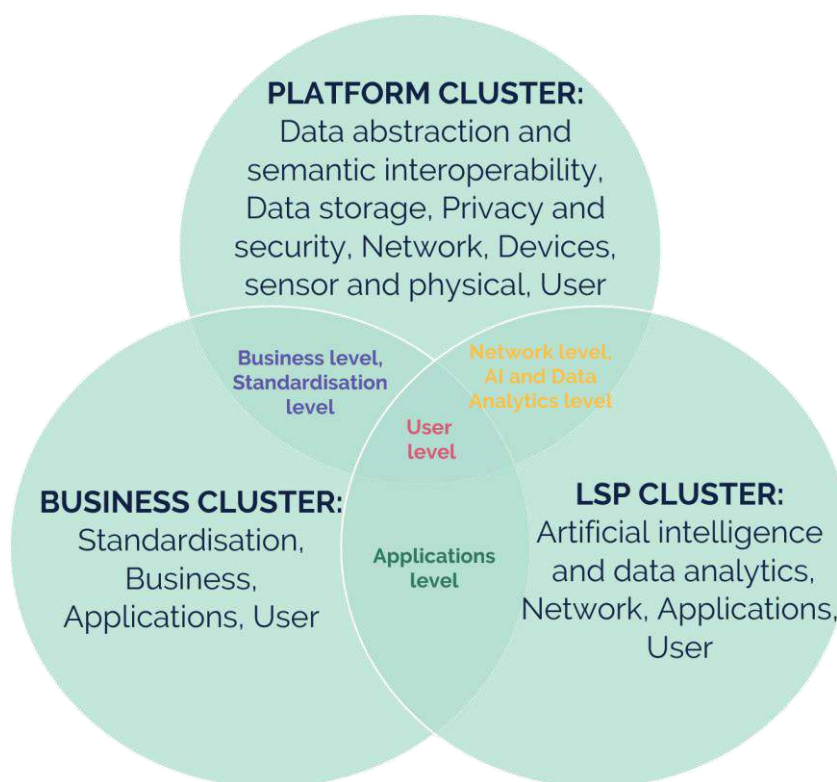


Figure 4 - Interaction among clusters for the setting of requirements in all levels

## WP2 – Ecosystem value co-creation, Open Calls and scaling-up twinning

The interaction between D3.1.2 and WP2 focused on the translation of the user requirements reported in D2.13 (D2.3 v2) into technical requirements. The needs and preferences of stakeholders in the project ecosystem, namely consumers (elderly, patients, families), health providers (informal and professional, home personal services etc.) and developers, which had been collected through focus groups questionnaires for D2.3, were mapped into system requirements, categorised in requirement levels and assessed in terms of priority and difficulty. The outcome of the analysis was then confirmed with the platform cluster partners. The mapped requirements are specifically mentioned in the requirement tables. Moreover, the interaction with WP2 as well as T3.2 contributed to identifying user types per platform component as reported in the current deliverable and in D3.2.2.

## WP3 – GATEKEEPER Web of Things (WoT) Reference Architecture

The aim of WP3 is to study state-of-the-art technology in terms of Web of Things (WoT) architecture, interoperability and semantics and expand the WoT concept while defining the GATEKEEPER platform architecture. The functional and technical requirements arising from this study were reported in D3.1.1 and updated for D3.1.2. Special focus should be made in the interaction with T3.2, since it led to the identification of Gatekeeper actors and



their classification, to input for the design of the architecture and to the association of requirements with the component interactions found in D3.2.2 as an update to the interactions mentioned in previous versions of both D3.1 and D3.2.

## **WP4 – GATEKEEPER Things management infrastructure and development,**

## **WP5 – Integrated Plug & Play GATEKEEPER Dynamic Intervention services,**

## **WP6 – Medical use cases, early detection and interventions**

The cooperation with WP4, WP5 and WP6 led to requirements for the infrastructure, the interventions and the devices to be incorporated in the GATEKEEPER environment, as well as the medical use case specifications and the Artificial Intelligence solutions to be offered. The tasks involved interact also with WP7 to study the pilot systems' architecture. Compared to the previous version of the deliverable, more details are offered on the implementation.

## **T7.5 – Technology developments**

T7.5 provided insight into the technical needs of the pilots and the collaboration with T3.1 led to prioritised functional requirements for the platform, each assigned to the partner responsible for the related component. In addition, T7.5 coordinates the implementation of the COVID-19 Task Force survey. The relevant time plans are reported here as well.

## **WP8 – Standardisation and certification mechanisms**

The platform should comply with relevant existing standards and legislation, as this will facilitate its integration into existing systems of its ecosystem and its trustworthiness as a solution. On the other hand, an effort to comply with too many standards hinders the development process and may set unnecessary limitations to the product capabilities. Therefore, T3.1 lists relevant standards based on the WP8 efforts and cooperates with the platform cluster partners to reach a decision on which ones are most suitable for the project, so that developers can build on them. The standards are also essential for the Things Validator System in order to validate compatibility. At a later stage, GATEKEEPER assets can be the basis of new standards to be established, as is the focus of WP8.

## **WP9 – Dissemination, communication, exploitation and sustainability**

An interaction with WP9 was made regarding the exploitation of the system. This explored the marketplace application featured, as well as a first approach to pricing requirements. Specifically for pricing, since the business cluster analysis is still at an early stage, future work will determine more relevant factors.



## 3 Definitions

### 3.1 User definitions

The GATEKEEPER (or GK) ecosystem includes a variety of interfaces aiming to interact with the stakeholders and support the corresponding needs and requirements.

By definition of the project, the stakeholders of the ecosystem can be separated according to their Space into:

- Healthcare: where intuitive and self-configuring dashboards, intelligent services for early risk detection and care plans, and a federated data infrastructure are provided to healthcare professionals and patients. It enables to build Business-to-Business (B2B) solutions and services from companies to healthcare providers.
- Consumer: where certified solutions, services and devices are provided to citizens for the management and prevention of health and social risks. It allows to build Business-to-Consumer (B2C) solutions and services to be used by end-users for health or life-style monitoring, as well as integrated with solutions from the Healthcare Space to combine services and provide a holistic health view and monitoring in return.
- Business: where certified companies are able to develop solutions, services and devices alone or in partnership, in order to reach end-users (Consumer Space) or health providers (Healthcare Space) following a set of standards in order to reach and boost the Digital Single Market.
- Ecosystem Transaction: where a large selection of applications and devices leveraging AI, Big Data, machine learning and IoT technologies; coupled with a variety of smart objects (e.g. wearables, sensors, robots) currently available in the market to support Data Sharing and Value-based healthcare are provided.

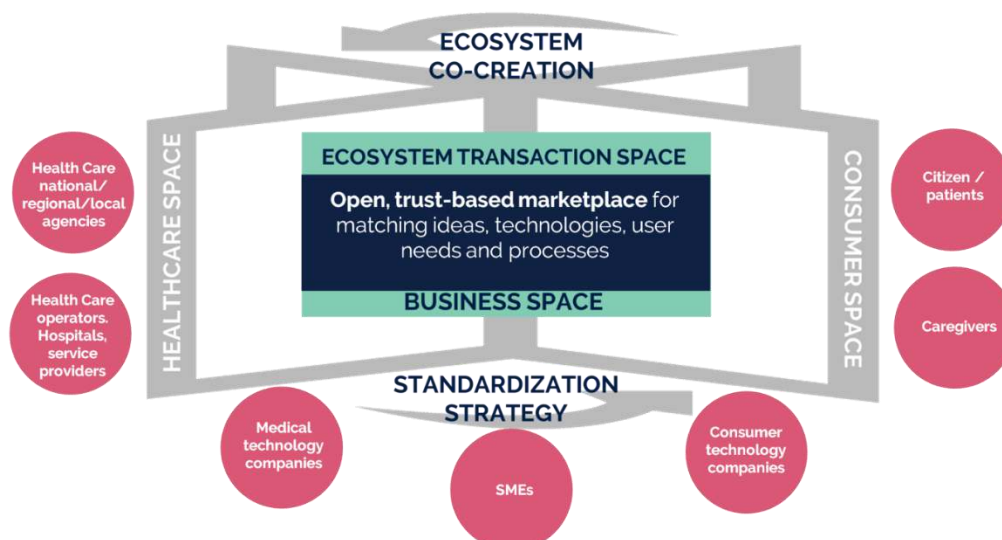


Figure 5 - The GATEKEEPER CONCEPT

The detailed WoT Architecture (D3.2) identified three interfaces that the project provides to the spaces in order to better interact with the system in the aim of supporting the

individual requirements. These interfaces are: (a) the GATEKEEPER Marketplace (D4.6) that is mainly linked with the Business space, (b) the GATEKEEPER Authoring tool (D5.5) that is supporting the needs of the Healthcare space, and the GATEKEEPER Developers portal (D5.1), that can be used to modify and inject technologies building a transaction space. The links between applications and spaces are indicative and can be extended based on individual requirements. For example, a representative for the Healthcare space can use the GK Developers portal to modify an application that supports the requirements of a hospital.

The GK stakeholders, who are identified and reported in D3.2.2, combining the analysis of D2.1, D2.3, the domain knowledge expressed in D6.2 and WP9 at the time of writing, are visualised as extending GK actors in Figure 6. A more detailed list of the roles they are assigned to, the GK Space(s) they belong to and their most indicative user stories per space are presented in Table 1.

In this document, users are associated with the requirements as GK actors or as user types per component.

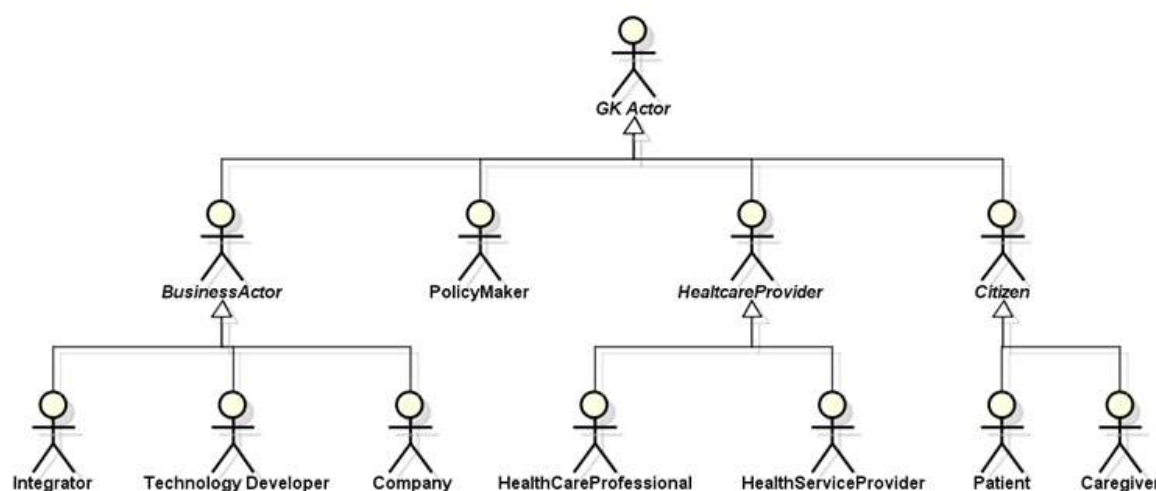


Figure 6 - GATEKEEPER actors (D3.2.2)

Table 1: GK actors and user types in GATEKEEPER platform

GK actors	Role in GK architecture	Space	User story	User type/ Component
Patient	Citizen-patient	Healthcare	A user receiving or registered to receive medical treatment, in this way being the owner of personal health and wellbeing data	End-user of Pilot KETs
		Consumer	A user that is using the KETs suggested/	End-user of Pilot KETs

GK actors	Role in GK architecture	Space	User story	User type/Component
			provided by Healthcare professionals	
Caregiver	Citizen-caregiver	Healthcare	A user providing formal or informal care to one or more patients	End-user of Pilot KETs
		Consumer	A user that is using the KETs suggested/ provided by Healthcare professionals or supports a Patient in using the applications	End-user of Pilot KETs
Healthcare Professional	Healthcare-professional	Healthcare	A user that wants to visualise data collected from integrated KETs and make decisions	Advanced User in Authoring Tool
		Consumer	A user that wants to use an application/service from the GATEKEEPER Marketplace	Consumer in Marketplace
Health Service Provider	Healthcare-coordinator	Healthcare	A user that provides primary healthcare services at local/regional scope, in some cases coordinating healthcare professionals	Simple User in Authoring Tool
		Consumer	A user that wants to use an application/service from the GATEKEEPER Marketplace	Consumer in Marketplace
Technology Developer	System-viewer	Business	A user that develops KETs which exploit the existing GATEKEEPER services.	Developer in Developers Portal
Company	System-manager	Business	A user that produces and markets technology health and wellbeing KETs.	Vendor in Marketplace
Integrator	System-viewer	Business	A user that provides local support and deploys services such as maintenance and system integrations, supporting Consumer Space actors.	Provider in Marketplace

GK actors	Role in GK architecture	Space	User story	User type/ Component
Policy Maker	Healthcare-regulator	Ecosystem Transaction	A user that wants to interpret case-specific data in order to manage governance policy decision-making and acts and as an administrator of the GK Platform and also as a promoter	Consumer in Marketplace

## 3.2 System, device and application definitions

The Gatekeeper platform consists of components responsible for its wide range of services, as reported in the WP3, WP4 and WP5 deliverables, and will offer integration with devices and applications including but not exclusively those produced by the technical partners of the consortium and those used by the pilots of the project.

In order to offer a clear view of the component each requirement refers to, a definition of the terms used is offered in Table 2:

Table 2: Definition of technology component terms

Term	Definition
System	The Gatekeeper platform
Device	Physical device offered by a technology provider/technical partner of the consortium that is integrated or aiming to be integrated
GK-enabled platform	Platform integrated with the Gatekeeper platform to be used by healthcare providers and citizens
GK-enabled application	Application integrated with the Gatekeeper platform to be used by healthcare providers and citizens
Pilot Key Enabling Technology/-ies [Pilot KET(s)]	Devices and applications selected by the pilots to serve their needs during pilot execution

## 3.3 Glossary

Table 3: D3.1.2 glossary

Term	Definition
<b>API</b>	Application Programming Interface - An interface that allows the user to access information from another service and integrate this service into their own application. Through a set of defined requests, the asking application is allowed to access limited pieces of the called upon application's functionality. APIs are used to share limited functionality between programs.
<b>Accessibility</b>	The design of products, devices, services, or environments so as to be usable by people with disabilities
<b>B2B</b>	Business-to-Business (B2B), also called B-to-B, is a form of transaction between businesses, such as one involving a manufacturer and wholesaler, or a wholesaler and a retailer. Business-to-business refers to business that is conducted between companies.
<b>B2C</b>	The term Business-to-Consumer (B2C) refers to the process of selling products and services directly between a business and consumers who are the end-users of its products or services.
<b>B2G</b>	Business-to-Government (B2G) is the sale and marketing of goods and services to federal, state or local agencies.
<b>Big Data</b>	A broad term used to describe unconventional data sets which are either too large or too complex to be dealt with using traditional data-processing techniques and are typically characterized by the 4 Vs: Volume, Variety, Velocity and Veracity.
<b>Cloud Computing</b>	Cloud computing is the delivery of information technology services over a network, usually the internet. In the cloud computing model, infrastructure, data, and software are hosted by the vendor and delivered to the user as a service.
<b>Enterprise Application</b>	An enterprise application is an application (or software) that is intended for large scale use by a (large) business.

Term	Definition
<b>FAIR</b>	(for data) Findable, Accessible, Interoperable, Reusable <sup>1</sup>
<b>FHIR</b>	Fast Healthcare Interoperability Resources (FHIR) specification is a widely adopted, fully computable standard by HL7 for exchanging healthcare information electronically.
<b>GTA</b>	The Gatekeeper Trust Authority (GTA) is the component responsible for certifying the Things of the GATEKEEPER platform. It also offers mechanisms to secure the connections between components and manages authentication, authorisation and auditing. GTA is Blockchain-based. More information can be found in D4.5.
<b>IaaS</b>	Infrastructure as a Service (IaaS) is a model of cloud computing in which the vendor hosts virtualised computing resources, as well as network and storage resources, and provides them to the user as a service via the internet.
<b>IDE</b>	An Integrated Development Environment (IDE) is a software application that provides comprehensive facilities to computer programmers for software development. An IDE normally consists of at least a source code editor, build automation tools and a debugger.
<b>IoT</b>	Internet of Things - A network of objects (such as sensors and actuators) that can capture data autonomously and self-configure intelligently based on physical world events, allowing these systems to become active participants in various public, commercial, scientific, and personal processes.
<b>IoT Cloud Platform</b>	A cloud platform that provides a set of services that simplify the integration process between the services provided by cloud platforms and IoT devices. Some platforms include development tools and data analytics capabilities.
<b>JSON-LD</b>	JavaScript Object Notation for Linked Data (JSON-LD) is a modification of the JSON file format to allow encoding of linked data.

<sup>1</sup> "FAIR Principles - GO FAIR", GO FAIR, 2021. [Online]. Available: <https://www.go-fair.org/fair-principles/>. [Accessed: 29-Mar- 2021].

Term	Definition
<b>MSPs</b>	Multisided platforms (MSPs) are technologies, products or services that create value primarily by enabling direct interactions between two or more customer or participant groups.
<b>PaaS</b>	Platform as a Service (PaaS) is a model of cloud computing in which a vendor provides the hardware and software tools necessary to create, deploy and manage applications at scale to the user via the internet, as a service.
<b>RDF</b>	Resource Description Framework (RDF) is W3C's framework for metadata. It describes objects in terms of graphs composed from vertices and focuses on the individual edges <subject, label, object>. RDF simplifies integration across heterogeneous information sources. <sup>2</sup>
<b>SaaS</b>	Software as a service (SaaS) is a model of cloud computing in which applications (software) are hosted by a vendor and provided to the user as a service. SaaS applications are licensed on a subscription basis and are made available to users over a network, typically the internet.
<b>SAREF</b>	Smart Applications REference ontology (SAREF) is a family of standards that enable interoperability between solutions from different providers and among various activity sectors in the IoT. It started as Smart Appliances REference ontology and then evolved to cover application domains such as ageing well and wearables.
<b>SDK</b>	A Software Development Kit (SDK) is a collection of software development tools in one installable package. They ease creation of applications by having compiler, debugger and perhaps a software framework. They are normally specific to a hardware platform and operating system combination. An SDK can take the form of application programming interfaces (APIs) in the form of on-device libraries of reusable functions used to interface to a particular programming language, or it may be as complex as hardware-specific tools that can communicate with a particular embedded system.
<b>SLA</b>	A Service Level Agreement (SLA) is a contractual agreement between a customer and a service provider

<sup>2</sup> Deliverable 3.3 "Interoperability within Gatekeeper" v1.0.

Term	Definition
	which defines the level of service, availability and performance guaranteed.
<b>SPARQL</b>	SPARQL is an RDF query language recognised as one of the key technologies of the Semantic Web. It can be used to express queries across diverse data sources, both when the data is stored natively as RDF and when it is viewed as RDF via middleware. <sup>3</sup> The queries can range from simple graph pattern matching to complex queries.
<b>TD<sup>4</sup></b>	A Web-of-Things Thing Description or Thing Description (TD) is structured data that describes a Thing. It includes general metadata, domain-specific metadata, Interaction Affordances (which include the supported Protocol Bindings), and links to related Things.
<b>TMS</b>	The Thing Management System (TMS) is the central gateway that orchestrates all the interactions to, from and within the Gatekeeper platform. More information can be found in D4.2.
<b>TSS</b>	A Transaction Space Service (TSS) is a special software environment which allows management of internal and external transactions. TSSs are often implemented on Multi-sided platforms (MSPs) playing an intermediation or a matchmaking role. All operational transactions can be weighted depending on different scenarios and data mining focus.
<b>WoT</b>	Web of Things (WoT) is an abstraction layer for digital twins that aims at addressing the fragmentation of the IoT. According to it, virtual digital objects stand for physical and abstract entities that are exposed to client applications as local software objects and are used as part of semantic descriptions.

<sup>3</sup> "SPARQL 1.1 Query Language", W3.org, 2021. [Online]. Available: <https://www.w3.org/TR/sparql11-query/>. [Accessed: 9-Mar- 2021].

<sup>4</sup> "Web of Things (WoT) Architecture", W3.org, 2021. [Online]. Available: <https://www.w3.org/TR/wot-architecture/%23dfn-thing-description>. [Accessed: 10- Mar- 2021].



## 3.4 Reference Use Cases

Table 4: List of Reference Use Cases

Reference Use Case (RUC)	Target
RUC#1	Lifestyle-related early detection and interventions
RUC#2	COPD exacerbations management
RUC#3	Diabetes: predictive modelling of glycemic status
RUC#4	Parkinson's disease treatment Decision Support System
RUC#5	Prediction readmissions and decompensations in heart failure
RUC#6	Primary and secondary stroke prevention
RUC#7	Multi-chronic elderly patient management including polimедication
RUC#8	eHealth solutions for the management of High Blood Pressure
RUC#9	eHealth solutions for the management of COVID-19

## 4 Business use cases of the Gatekeeper platform

At the time of writing this deliverable, the Business Cluster's tasks have started working on the definition of Gatekeeper Products and Services, the market consultation through interviews of more than 100 stakeholders (Med-tech companies, SMEs, Hospitals, Health agencies, individual health professionals, business accelerators, venture capital, and more), and the functional design of the GK marketplace. The first formal conclusion of these activities will be published by Month 24. These activities will permit the design of realistic and actionable business cases for GK that shall include the platform along with other important project outcomes.

Therefore, the use cases described below must be taken as very preliminary, not yet subjected to any formal analysis and benchmarking with stakeholders.

### Preliminary Business Case of GK Platform

- 1- The GK Platform is a suite of software components that orchestrate the generation and delivery of different type of services to external connected systems. The GK platform responds to the definition of Open Platform, i.e. "*open platform as enabling applications from multiple vendors to be orchestrated to work together to meet an individual user's needs*". The five characteristics of open platforms as proposed by the **universAAL IoT consortium**<sup>5</sup> are:
  - a. **OpenAPI:** A platform's Application Programming Interface (API) specifies the interfaces available for developing applications on top of the platform, along with guidelines on how to use them. *Control question: Does the platform implement published and fully documented external application programming interfaces?*
  - b. **OpenScope (extensibility):** Open Scope refers to the capability of using the platform for purposes it was not planned for, resulting in extensible systems. The scope of a platform determines the extent of the platform's applicability, in the sense of degree of freedom in the development of applications on top of it. *Control question: To what extent can a third party use the Open API to add not a-priori planned functionality without requiring modification of the source code?*
  - c. **Open Source:** Open Source refers to the availability of the source code of a piece of software in a given programming language with a license in which the copyright holders provide the rights to study, change, and distribute the software to anyone and for any purpose. There are different open-source licenses which approach commercialisation differently. An open platform does not mean it is open source, however most Open APIs have also open source implementations, resulting in open source platforms. *Control question: Is the source code of the platform available with a recognized open source licensing model?*

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<sup>5</sup> "What is an open platform", PlatformUptake.eu, 2020. [Online]. Available: <https://www.platformuptake.eu/2020/12/03/what-is-an-open-platform-according-to-universaal/>. [Accessed: 24- Feb- 2021].

- d. **OpenUsage (adoptability):** Adoptability refers to enabling others to use the open platform while bypassing specific business development negotiations. This does not necessarily mean that usage has to be royalty free; it is rather about published, clear, and generally applicable (non-discriminatory) terms and conditions, usually known as the license. *Control question: Does usage necessitate a specific business development negotiation?*
  - e. **OpenAdaptation (adaptability):** Assuming that the specifications are publicly available, adaptability of an open platform refers to the possibility of changing existing functionality of the platform itself as opposed to adding new functionality (which is addressed under Open Scope). *Control question: Does the platform allow developers to change existing functionality?*
- 2- Regarding services that the platform must provide to stakeholders:
- a. Remote monitoring. Stakeholders using such services might be, but are not limited to: hospitals of any type and size, outpatient clinical offices, nursing homes, well-being institutions, individuals (non-patient) and more. Remote monitoring services enable the user (customer) to build a program of patient remote monitoring for any disease or medical condition. The platform must be medical condition / disease agnostic in the sense that it enables data acquisition from subjects through different types, brands and models of sensor devices in the market, and connectivity conditions. The more devices and connectivity conditions are supported the more universal use of the platform will be. GK must fit this condition broadly.
  - b. Data standardisation. All acquired data from whatever data source are supplied must be converted into a standard data format. In GK this standard of data representation is HL7-FHIR.
  - c. Data storage and accessibility. Data must be stored in a secure repository. Data must be accessible without restriction by applications that work with real-time data. For example, application of arrhythmia monitoring, detection of exacerbations, etc. Additionally, the GK platform must provide long- term data aggregation capabilities and generation of FAIR data sets that can be of two types. i) non-anonymised (identifiable) data belonging to each individual patient, and ii) anonymised data for other no-patient linked usage.
  - d. Standard interface (1). GK platform must provide standardised API for external medical applications to use data on any of the above-described conditions. These applications, using AI or other data-processing technologies, may use real-time-identified data along with anonymised data sets for their internal processing algorithms.
  - e. Standard interface (2). GK platform must provide standardised API for application developers to use anonymised data sets for training and testing of AI algorithms and big data.
  - f. Productivity tools. GK platform must provide productivity tools to facilitate data cleaning, data adequacy, data visualisation, AI environment, application deployment and more, providing support to developers along the AI development pipeline.

- g. Trustworthiness. GK platform must provide a framework for security and privacy based on blockchain technology to guarantee the full respect of European and national regulations on privacy and data security.

## 5 Pilot development and deployment

At the time of writing, pilot execution has just started or is ready to start, depending on the pilot site. Following the methodology described in section 5.1, pilot development and deployment strategies are presented in section 5.2 for both European and Asian pilots. Section 5.3 reports the technology developments for the implementation of the COVID-19 survey as documented in the scope of T7.5.

### 5.1 Pilot report methodology

In order to have a clear view of the progress in pilot development and deployment, a form was distributed to all pilots and filled in by their respective technical partner in the scope of T7.5. The form (Table 5) included information about pilot architecture and its components, the expected integration of Pilot KETs with the system and the planned steps for the implementation process to run smoothly. Foreseen risks were also included. The overall time frame for the technology developments was finally summarised in a Gantt chart for each pilot (Table 6).

Furthermore, a spreadsheet about technology developments needed by the pilots was completed by Pilot Leaders and/or technical partners. The pilots were requested to submit the requirement description and the KET it refers to, as well as the partner and the pilot submitting the requirement. Each requirement was then associated with the existing Gatekeeper platform component that could work on its implementation in the scope of T7.5. Next, in a joint effort with T3.1, the original requirements were translated into user stories, prioritised and assigned to a specific partner, taking into account also the estimated effort for their fulfilment.

All European pilot reports originating from the forms are presented in section 5.2. Asian pilots are still early in their development, so no concrete development steps could be provided at the time of writing. Requirements reported in the aforementioned spreadsheet were incorporated into the section 6 tables according to the level-based approach followed in the document.

Table 5: Distributed form for development and deployment strategy

<b>Partner responsible</b>
<b>Pilot figure</b>
[Add the updated pilot figure we presented at the review meeting]
<b>Pilot components</b>
[list the components available and the ones that need to be developed for your pilot]
<b>Expected integration with Gatekeeper</b>

[Describe how integration with Gatekeeper component is foreseen in your pilot]
<b>List of needed tasks for development and integration of pilot components</b>
[list the activity that you need to carry out for development and deployment of your pilot, development of missing components (e.g. Authentication and authorisation system) or expected integration (e. g. data transformation for EHR into Data Federation, integration of devices)]
<b>Expected partner interactions</b>
[Describe the interaction with other partner that you have identified, for instance ENG for EHR integration, Samsung for Samsung Health integration, etc..]
<b>Risks and criticisms</b>
[Describe any risk related to preparation, implementation, and deployment of your pilot]




Table 6: Distributed form requesting the pilot time plan as a Gantt chart

	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec

## 5.2 Pilot reports

### 5.2.1 Aragon

Table 7: Aragon pilot development and deployment strategy

Partner responsible					
SALUD					
Pilot Figure					
DEVICES	GATEWAY	GATEKEEPER APIs COMPONENTS	BACK-END APPLICATIONS	FRONT-END APPLICATIONS	USERS
 <p>Standard devices HR, BP, SpO2, ECG, Temperature, Glucose</p> <p>Multi-parameter sensor (tbd)</p>	 <p>Mobile Gateway</p> <div> <p>Green – KETS ready</p> <p>Orange – KETS ready, but willing to include new elements</p> <p>Red – KETS to be developed / acquired</p> <p>Pink – KETS to be developed in GATEKEEPER</p> </div>	<p>Data Federation</p> <p>AI Personalized Risk Detection &amp; Assessment - Predictive modelling Exacerbations/ decompensations Health risk Frailty risk</p>	<p>Telemonitoring Back-end</p> <p>GUHARA EHR Data Extraction</p> <p>Integrated Care Back-end</p> <p>Mobile app Back-end Educational content, PROMs and data from integrated devices</p>	<p>Telemonitoring Front-end</p> <p>GUHARA FRONT-END</p> <p>Professional Dashboard</p> <p>Integrated Care Front-end</p> <p>Mobile app Educational content, PROMs and data from integrated devices It could be integrated with the mobile gateway</p>	 <p>Healthcare Professionals</p> <p>Contact center</p> <p>Social Care Professionals</p> <p>Patients</p> <p>People with risk factors,</p>
Pilot components					
<ul style="list-style-type: none"> <li>- <b>Available (elements in green in the diagram)</b> <ul style="list-style-type: none"> <li>o Telemonitoring platform for RUC#2, RUC#5 and RUC#7 mid-complexity</li> </ul> </li> <li>- <b>New elements (to be validated in the pilot)</b> <ul style="list-style-type: none"> <li>o Telemonitoring platform for RUC COVID-home</li> <li>o Telemonitoring platform for RUC COVID-centre</li> <li>o Telemonitoring devices (patches) for high complexity</li> </ul> </li> <li>- <b>Need to be developed</b> <ul style="list-style-type: none"> <li>o App for RUC#1 (Healthy habits promotion)</li> <li>o Predictive models for exacerbations / acute conditions / hospitalisations</li> <li>o Dashboards for professionals</li> </ul> </li> </ul>					
Expected integration with Gatekeeper					

The main route for integration in our pilot will be data federation to feed the predictive models that may be deployed in the project context. This may include, but not be restricted to vital signs data, demographics information and EHR information.

#### List of needed tasks for development and integration of pilot components

- Development/adaptation of an app for healthy habits
- Federation of data to feed the predictive models
- Predictive models development
- Dashboards for professionals

#### Expected partner interactions

- o Development of an app for healthy habits (UPM / BIOSENSE)
- o Federation of data to feed the predictive models (ENG)
- o Predictive models development (UoI)

#### Risks and criticisms

RUC	Risk	Probability	Impact	Mitigation action
RUC#1	App definition takes longer than expected	high	high	Concern and continuous work at several levels (internal and with tech provider) to reach project objectives Work on several phases
RUC#1	App TRL is low	medium	high	Tests and validation before pilot
RUC#1	Difficulty to reach target number of patients	high	high	Recruitment campaign
COVID-H COVID-C	Number of patients decreases a lot (vaccine) and it is difficult to reach target number of patients	medium	high	Re-definition of the RUC# for other profile (e.g. elderly homes, chronic patients) to validate service and technology
Predictive models	Number of data is not enough to achieve results from the predictive models	high	medium	The model will be built at the local premises (federated approach) so as to maximise the



				number of data that can be used
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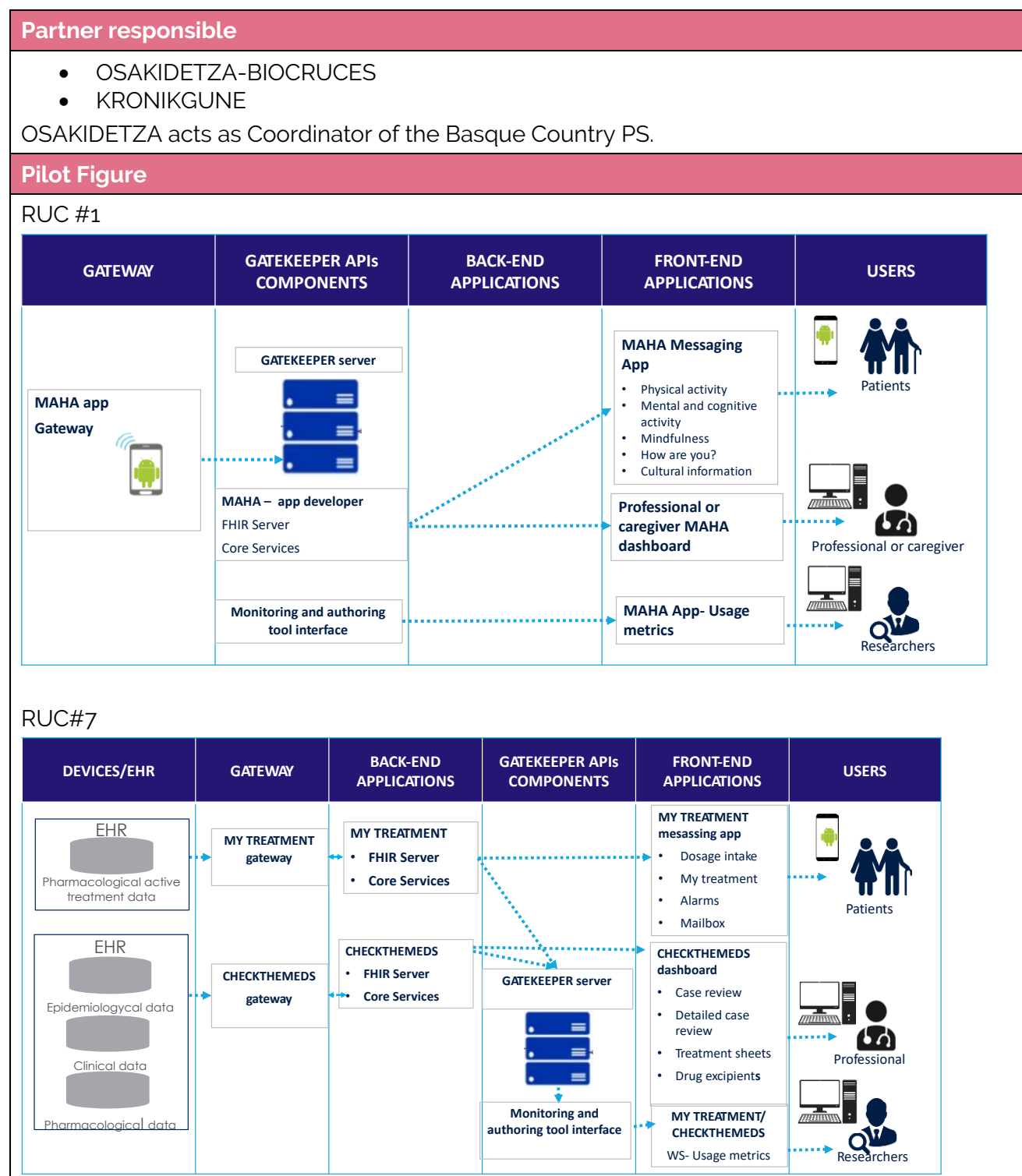
## Time plan (GANTT)

Table 8: Aragon pilot time plan

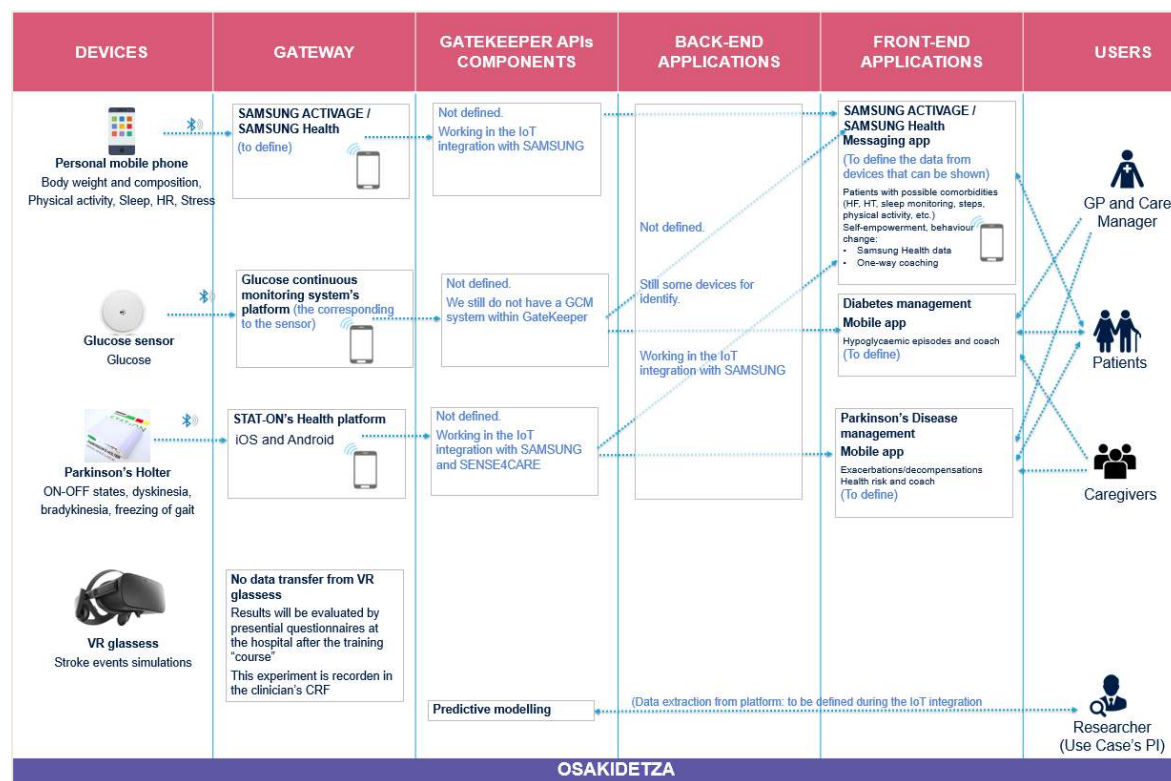
#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Mid complexity -> Pilot running (deployment)												
2	COVID-home -> Setup and preparation												
3	COVID-home -> Pilot running (deployment)												
4	COVID-centre -> Setup and preparation												
5	COVID-centre -> Pilot running (deployment)												
6	High complexity -> Setup and preparation												
7	High complexity -> Pilot running (deployment)												
8	RUC#1 (healthy habits) -> App development (first iteration)												
9	RUC#1 (healthy habits) -> Setup and preparation												
10	RUC#1 (healthy habits) -> Pilot running (deployment)												
11	Data Extraction and data federation												
12	Predictive Models Training												

## 5.2.2 Basque Country

Table g: Basque Country pilot development and deployment strategy



RUC#3, RUC#4, RUC#6



### Pilot components

- MAHA Mobile health application**, to:
  - Promote healthy lifestyle habits that enhance independence, autonomy and improve the well-being of elderly people, promoting their physical, cognitive and mental activity and social participation, in the RUC#1 low complexity interventional study. This component is available but must be adapted.
- MAHA dashboard**, to:
  - Visualise and monitor patient's data in the RUC#1 low complexity interventional study. This dashboard is available for professionals and caregivers. This component is available but should be adapted.
- Monitoring and authoring interfaces** to:
  - Visualise and analyse usage metrics of the application UCs#1 (MAHA app) and #7 (Checkthemeds and My treatment). This dashboard is available for clinical researchers. This component is planned to be developed in T5.5.
- MY TREATMENT Mobile application**, to:
  - Improve adherence to pharmacological treatment in patients with chronic diseases and polypharmacy, in the RUC#7 moderate complexity interventional study. This component is available and no adaptation is required.

5. **CHECKTHEMEDS web application**, to:
  - Optimise the detection of inappropriate pharmacologic prescription. It is a computer-based tool for professionals, in the RUC#7 moderate complexity interventional study. This component is available but must be adapted.
6. **EHR**
  - Local Information system queried by dedicated web services in the RUC#7 moderate complexity interventional study
7. **GK-adapted ACTIVAGE platform**, connected to Gatekeeper platform, to:
  - Support health promotion in elderly citizens, in the RUC#3, RUC#4 and RUC#6.
  - Follow up patients in the RUC#3, RUC#4 and RUC#6.

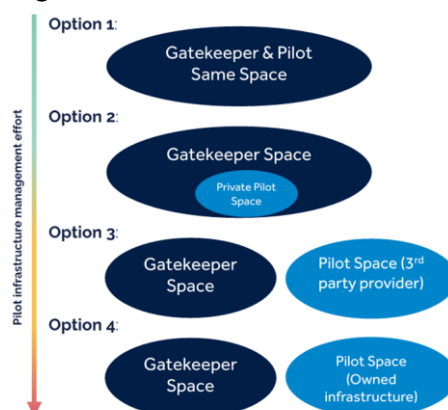
This component is available but must be adapted.
8. Integration of **ACTIVAGE SmartThings kit** for the RUC#6 Stroke.
  - SmartThings Hub
  - Samsung SmartThings Motion Sensor
  - SmartThings Smart Plug
  - SmartThings Multipurpose Sensor
  - Temperature/Humidity sensor
  - SmartThings Tracker
9. **T5.5 Dashboards** to visualise:
  - Patient data to GPs in the RUC#3, RUC#4 and RUC#6.
  - Patient data to clinical researchers in the RUC#3, RUC#4 and RUC#6.

This component is planned for development in T5.5.
10. **Integration of selected data from EMRs** with the GK Data Federation.
11. Integration of a **Continuous Glucose Monitoring (CGM) system (to define)** for UC #3 Diabetes.
12. Integration of the **STAT-ON Holter** for the Parkinson's Disease UC #4.
13. Integration of a **Blood Pressure monitor** for supporting RUC#3, RUC#4 and RUC#6.
14. **Virtual Reality glasses** for visualisation of videos in 360° (no need integration).

#### Expected integration with Gatekeeper

1. We expect the **ACTIVAGE application** to be able to store data in the GK Data Federation, including data collected through Samsung Health.
2. We expect the **T5.5 Dashboards** to be able to visualise data stored in the GK Data Federation to GPs and to clinical researchers, on both a patient-by-patient as well as aggregated form. We also need that such Dashboards are coupled with an end-user management system, in order to follow up.
3. The selected **EMR** of retrospective data has to be integrated in the GK Data Federation.
4. We expect that **end-user management** will be provided by the GK project, at least to follow up patients through the T5.5 Dashboards.
5. The **STAT-ON Holter** for Parkinson's Disease has also to be integrated within the platform and Samsung's technologies.
6. The **CGM System** for Diabetes has also to be integrated within the platform and Samsung's technologies.
7. **Integration of MAHA app**, is planned to be integrated in Gatekeeper data federation space of Gatekeeper. Option 2 (see figure below)

8. **MY TREATMENT APP** is already integrated in the Basque Country space (third party provider). Option 3 (see figure below)
9. **CHECKTHEMEDS** is planned to be integrated with Osakidetza through web services (third party provider). Option 3 (see figure below)
10. **Monitoring and authoring interface** is planned to be integrated in Gatekeeper data federation space of Gatekeeper. Option 2 (see figure below) for KRONIKGUNE. OSAKIDETZA is still evaluating.



### List of needed tasks for development and integration of pilot components

1. Adaptation of Activage to the needs of the all UCs.
2. Adaptation of T5.5 Dashboard to the HCP's needs and allow them the management and download the data for internal studies.
3. Adaptation of MAHA app to the needs of:
  - a. Brain training: Games oriented not only to maintain cognitive abilities but also to prevent cognitive impairments.
  - b. Leisure activities: Adapt the events available with cultural, social and sporting information of the Basque Country.
  - c. Notifications: Possibility to create personalized reminders.
  - d. Physical activities: Adapt activities according to user typology with corporative videos and informative material. Possibility to register the type of exercise and duration of the activity, to measure the number of steps, to receive daily/weekly/monthly information on the activity performed, to send motivational messages and to receive rewards for achievements.
  - e. Emotional status: Possibility to link to Basque Country resources.
4. Adaptation of CHECTHEMEDS to the needs of:
  - a. Developing a Module of communication between Web services of Checkthemeds and Web services of Osakidetza.
  - b. Developing a Module of communication and visualisation to receive the required data by the professional.

#### Expected partner interactions

1. We have to coordinate a meeting for the integration of OSA's retrospective data within the GK since the OSA database is restricted to any access
2. It is foreseen to coordinate bilateral meetings with MyS, OSA and clinicians of RUC#3 and RUC#4.
3. UPM for the adaptation and customisation of MAHA app
4. Aragon pilot site to work together in the adaptation and customisation process of MAHA app
5. CHECKTHEMEDS for the adaptation and customisation of CHECKTHEMEDS computer-based tool
6. TECNALIA for the development of Monitoring and authoring interfaces

#### Risks and criticisms

1. Lack of strategy (or information) for the pilot technical deployment from the GK platform that may not fit with the Basque Pilot's strategy

## Time plan (GANTT)

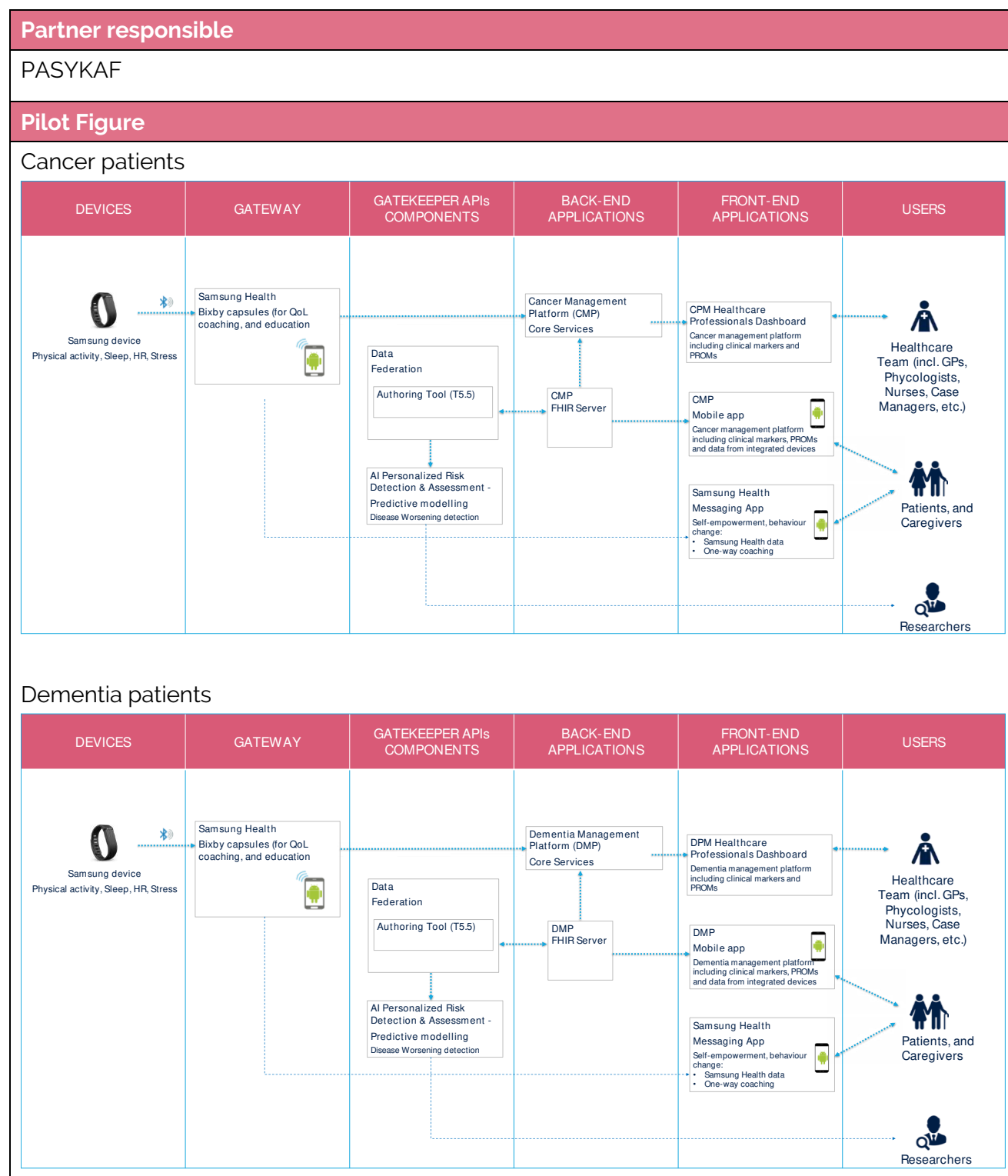
Table 10: Basque Country pilot time plan

#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Technologies acquisition												
2	GK-adapted ACTIVAGE application												
3	T5.5 Dashboards												
4	Technological integration												
5	MAHA app adaptation and customisation												
6	MAHA app integration in GK platform												
7	MAHA app interactions												
8	MY TREATMENT interaction												
9	CHECKTHEMEDS integration												
10	CHECKTHEMEDS interaction												



## 5.2.3 Cyprus

Table 11: Cypriot pilot development and deployment strategy



### Pilot components

To be deployed and/or acquired

- Clinical Platform for chronic diseases management developed by CERTH. The platform is adjusted to requirements collected by PASYKAF and AMEN users to support the needs of cancer and dementia. Interfaces for healthcare professionals, patients and caregivers are developed for data collection.
- Smart Watch (acquired by commercial providers ex. Garmin, Fitbit, etc.)
- Tablets with an interface that will be user friendly in order to support the interaction of the patients with the digital platform that will be used for interventions management in both UCs of the pilot.
- AI analytics: UoI will develop AI services (within the framework of WP6) in order to identify important clinical parameters in patients' profiles.

### Expected integration with Gatekeeper

- Data collection related to CRF will be integrated with the Data Federation Component.
- Data from medical devices and sensors will be integrated with the related Intelligent Connector
- AI Services that will be developed in WP6 are applicable to this pilot objectives will be integrated with the platform.
- Anonymisation service and Identity management service developed by GTA will be integrated with the Pilot platform
- Pilot technologies will be deployed in the HPE infrastructure

### List of needed tasks for development and integration of pilot components

Collection of user requirements

Prioritisation of requirements related to CRF

Adjustment of CERTH's platform based on the new requirements

Internal Testing and Evaluation of the dashboards with a group of pilot users

Integration of sensors

Integration of anonymisation and identity management services

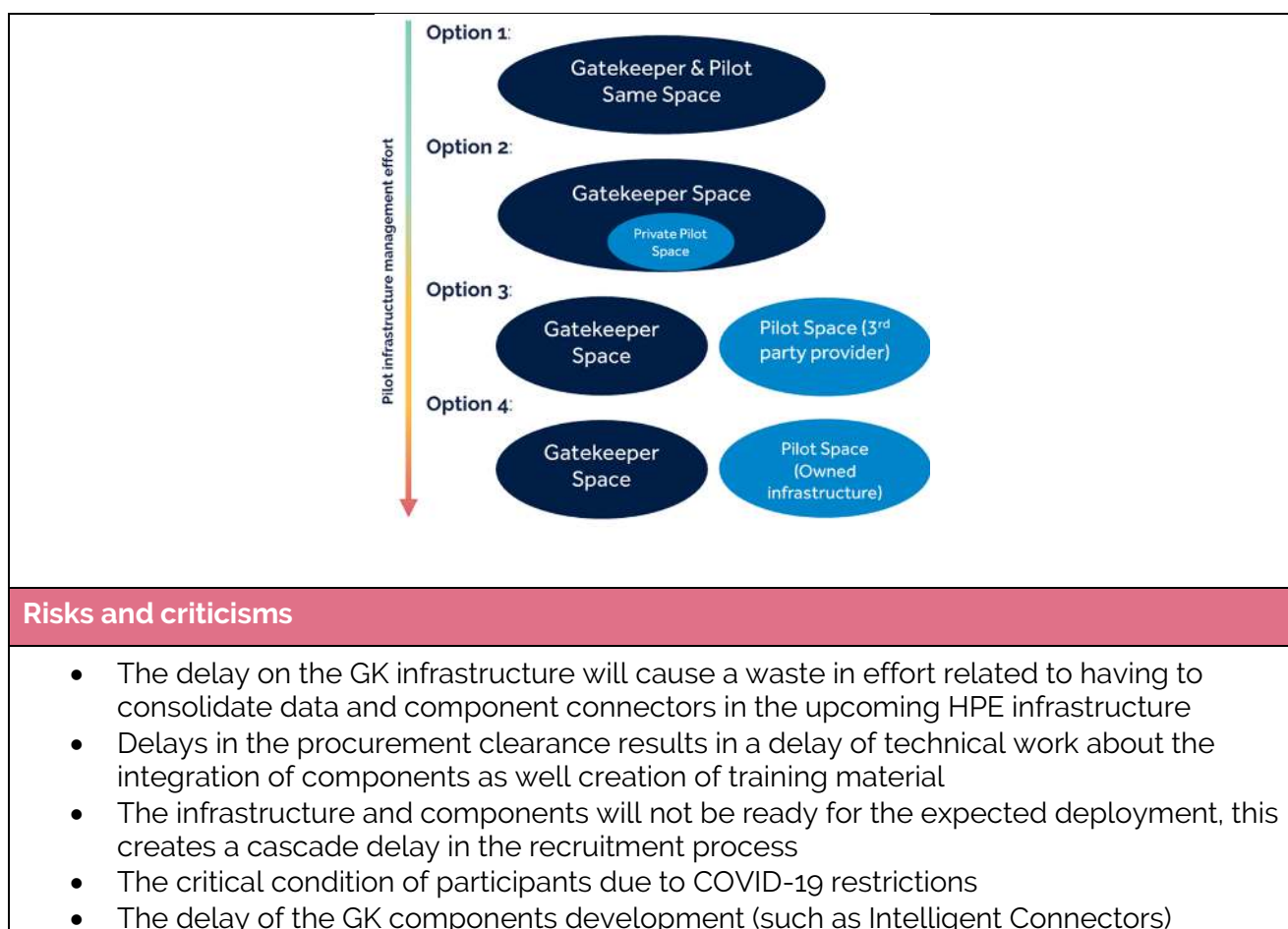
Data Transformation from platform into Data Federation

Integration with Analysis Services

Platform Deployment

### Expected partner interactions

- CERTH as technology provided and in the development of Pilot platforms and the integration of devices and sensors.
- ENG & HL7 for the data model in FHIR and testing
- UoI and UPAT for AI services
- CERTH for data privacy and security services
- CERTH for pilot deployment (Option 2, see figure below)



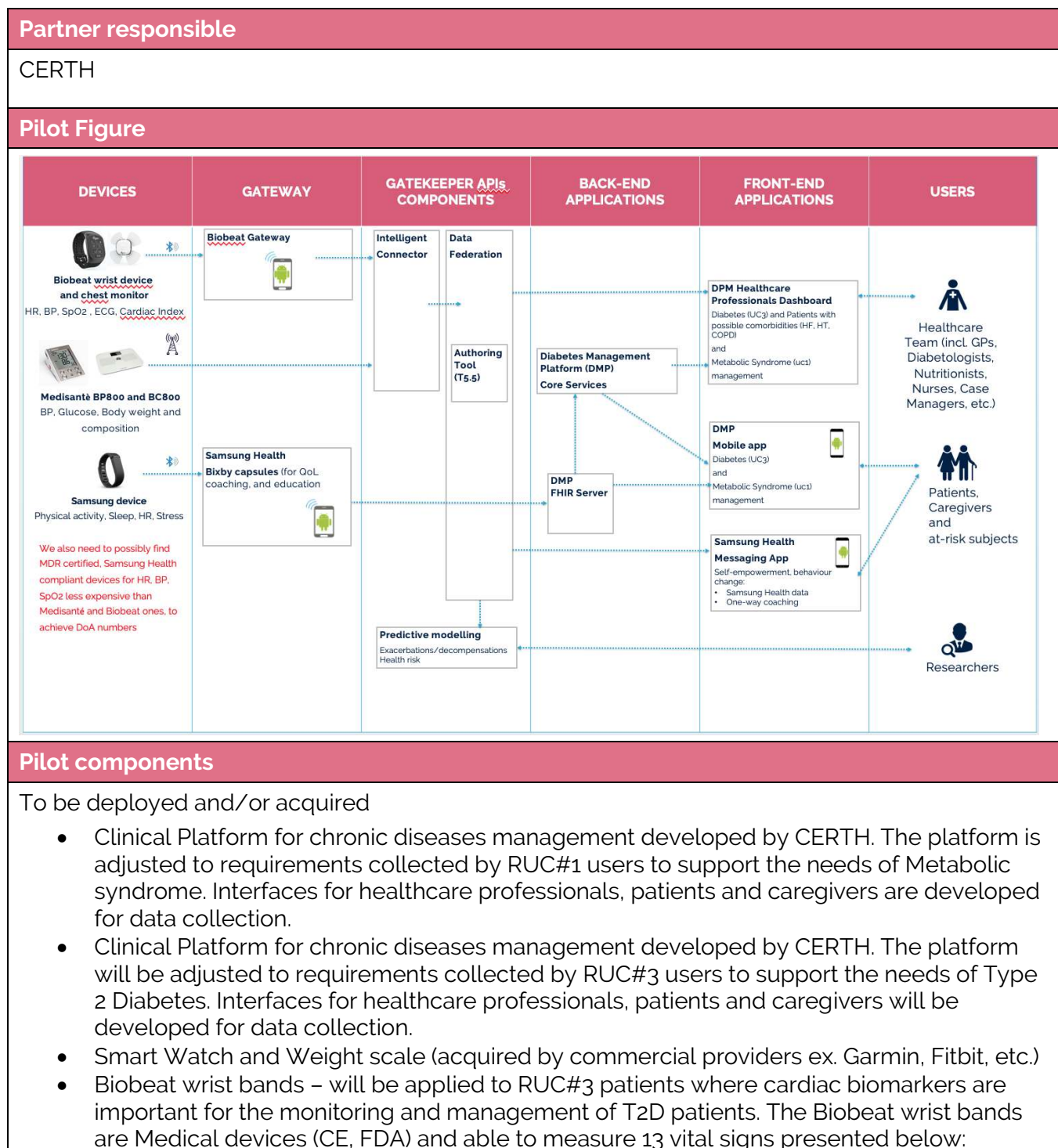
## Time plan (GANTT)

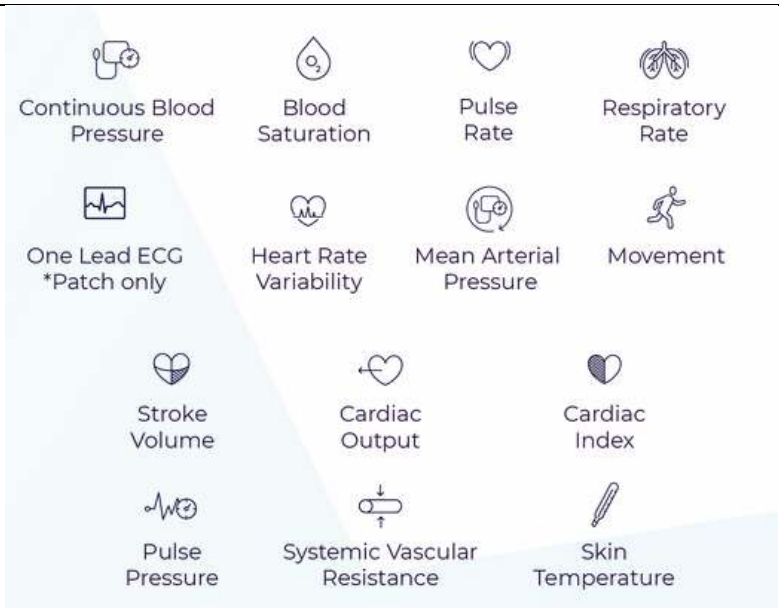
Table 12: Cypriot pilot time plan

#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Internal Co-creation Workshops												
2	Requirements collection for platform design												
3	CRF and Ethical Approval (Documents and Deliverables)												
4	KPIs definition and Deliverable												
5	Platform Adjustments												
6	Internal Testing												
7	Collection and Preparation of the Questionnaires												
8	Devices Integration												
9	Integration with Analytics Services												
10	Platform Deployment												
11	Recruitment Strategy												
12	Collection of Educational and Training Material												
13	Platform Training Material												
14	Users Training												
15	DPP and Terms of Use												

## 5.2.4 Greece

Table 13: Greek pilot development and deployment strategy

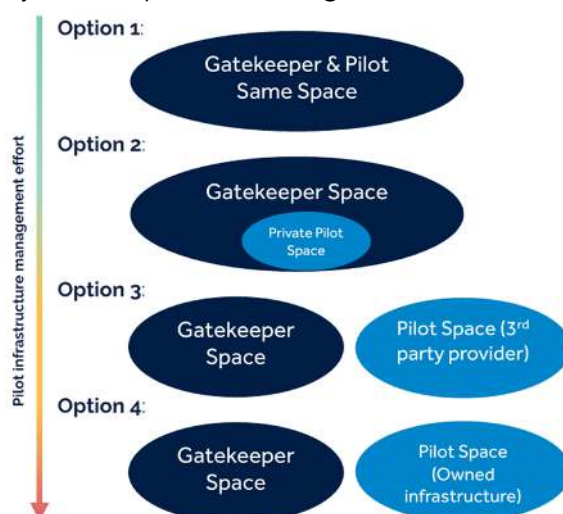


			
<ul style="list-style-type: none"> <li>Continuous glucose monitor systems from commercial medical device provider (ex. Menarini, iHealth) to support the glycaemia management in RUC#3.</li> <li>Tablets with an interface that will be user friendly in order to support the interaction of the patients with the digital platform that will be used for interventions management in both UCs of the Greek pilot.</li> <li>AI analytics: UoI and UPAT (Greek pilot partners) will develop AI services (within the framework of WP6) in order to identify important clinical parameters in patients' profiles.</li> </ul>			
<b>Expected integration with Gatekeeper</b>			
<ul style="list-style-type: none"> <li>Data collection related to CRF will be integrated with the Data Federation Component.</li> <li>Data from medical devices and sensors will be integrated with the related Intelligent Connector</li> <li>AI Services that will be developed in WP6 are applicable to this pilot objectives will be integrated with the platform.</li> <li>Anonymisation service and Identity management service developed by GTA will be integrated with the Pilot platform</li> <li>Pilot technologies will be deployed in the HPE infrastructure</li> </ul>			
<b>List of needed tasks for development and integration of pilot components</b>			

Prioritisation of requirements related to CRF  
 Adjustment of CERTH's platform based on the new requirements  
 Internal Testing and Evaluation of the dashboards with pilot operational managers (HUA, DCCG)  
 Integration of Medical Devices and sensors  
 Integration of anonymisation and identity management services  
 Data Transformation from platform into Data Federation  
 Integration with Analysis Services  
 Platform Deployment

### Expected partner interactions

- CERTH as technology provided and in the development of Pilot platforms and the integration of devices and sensors.
- ENG & HL7 for the data model in FHIR and testing
- UoI and UPAT for AI services
- CERTH for data privacy and security services
- CERTH for pilot deployment (Option 2, see figure below)



### Risks and criticisms

- The delay on the GK infrastructure will cause a waste in effort related to having to consolidate data and component connectors in the upcoming HPE infrastructure (see section 6.5)
- Delays in the procurement clearance results in a delay of technical work about the integration of components as well creation of training material
- The infrastructure and components will not be ready for the expected deployment, this creates a cascade delay in the recruitment process
- The low number of participants due to COVID-19 restrictions and the seasonality that is mostly related to RUC#1

- The delay of the GK components development (such as Intelligent Connectors)



## Time plan (GANTT)




Table 14: Greek pilot time plan

#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Internal Co-creation Workshops												
2	Requirements collection for platform design												
3	CRF and Ethical Approval (Documents and Deliverables)												
4	KPIs definition and Deliverable												
5	Platform Adjustments												
6	Internal Testing												
7	Collection and Preparation of the Questionnaires												
8	Devices Integration												
9	Integration with Analytics Services												
10	Platform Deployment												
11	Recruitment Strategy												
12	HCPs enrolment												
13	Consents preparation												
14	Collection of Educational and Training Material												
15	Platform Training Material												

#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
16	Users Training												
17	DPP and Terms of Use												

## 5.2.5 Milton Keynes

Table 15: Milton Keynes pilot development and deployment strategy

Partner responsible					
Open University (UK Pilot)					
Pilot Figure					
DEVICES	GATEWAY	GATEKEEPER APIs COMPONENTS	BACK-END APPLICATIONS	FRONT-END APPLICATIONS	USERS
 Samsung devices Physical activity, Sleep, Stress   Smartphone Requests for support, socialization and behavioural data   Robotic platform Human activities Environmental data Remote control	Samsung ActiveAge (geriatric scales and intervention requests)  HAR aggregation (Combine data streams from robot, smartphone, and other smart devices)  Robot Event Logger (emergency and hazards events, activity recognition, communication interface)  Robot remote control (Interaction between the robot and external users)	Data Federation Authoring Tool (T5.5)  AI Personalized Risk Detection & Assessment - Predictive modelling Community issues emergence detection (prediction on location-based data aggregation)	Intervention broker • Intervention request • Intervention scheduling • Volunteer registry • Intervention logger  Robot Remote Interface Bidirectional interface with the robot. Supports video streaming and teleoperation	Samsung ActiveAge • Healthy lifestyle support • Self-Monitoring • One-way coaching  Community Dashboard  Messaging App • Intervention Manager • Intervention handling  Robot dashboard Audio-visual interface to remotely control the robot  App-based interface  Web-based interface	Family Members  Elders  Community Volunteers  Community Manager
Pilot components					
<p>To be deployed and/or acquired</p> <ul style="list-style-type: none"> <li>• Samsung ActiveAge (to be deployed)</li> <li>• Samsung SmartWatch (to be acquired)</li> <li>• Robot platform Tiago (to be deployed)</li> </ul> <p>To be developed</p> <ul style="list-style-type: none"> <li>• <b>Community dashboard</b> providing insights about the emerging issues, state of the requests and monitoring of the community interventions of a given area</li> <li>• Extension of <b>ActiveAge app</b>:               <ul style="list-style-type: none"> <li>○ Questionnaires for the pilot data collection</li> <li>○ Resilient to off-line use</li> <li>○ Sharing information with informal carers outside the user network in case intervention is required</li> <li>○ Introduce the concept of intervention as response to triggers such as data collected, milestone, or user request</li> </ul> </li> </ul>					

<ul style="list-style-type: none"> <li>• <b>Robot connector</b> for Long-term autonomy &amp; Integration with ActiveAge/Gatekeeper platform <ul style="list-style-type: none"> <li>◦ Perception: human activity recognition -&gt; routine identification, object classification -&gt; hazard identification</li> <li>◦ Remote monitoring and intervention</li> <li>◦ Support for unreliable internet connection</li> <li>◦ Multi-modal interface with the user (app, web, direct interaction)</li> </ul> </li> </ul>
<b>Expected integration with Gatekeeper</b>
Data-driven integration between robot component, ActiveAge (and Samsung devices) and the Community Dashboard through the GK platform in the GK FHIR profile.
<b>List of needed tasks for development and integration of pilot components</b>
<ul style="list-style-type: none"> <li>• T3.4 Definition of Semantic Models &amp; T3.5 FHIR <ul style="list-style-type: none"> <li>◦ finalizing the UK Pilot data model</li> </ul> </li> <li>• T5.2 Advanced and personalised Health &amp; Home Monitoring Activity Treatments <ul style="list-style-type: none"> <li>◦ integration of IoT, robot home monitoring and community-based monitoring</li> </ul> </li> <li>• T5.5 Dynamic Gatekeeper personalised Authoring Tool and modelling interfaces <ul style="list-style-type: none"> <li>◦ Community Dashboard</li> </ul> </li> <li>• T5.6 Multi-robot-based Connectors in smart community care <ul style="list-style-type: none"> <li>◦ Robot interfaces, integration with ActiveAge, community-based intervention broker for ActiveAge</li> </ul> </li> </ul>
<b>Expected partner interactions</b>
<ul style="list-style-type: none"> <li>• Samsung as technology provided and in the development of ActiveAge extensions</li> <li>• ENG &amp; HL7 for the data model in FHIR and testing</li> <li>• Tecnia for the dashboard</li> </ul>
<b>Risks and criticisms</b>
<p>[Describe any risk related to preparation, implementation and deployment of your pilot]</p> <ul style="list-style-type: none"> <li>• The delay on the GK infrastructure will cause a waste in effort related to having to consolidate data and component connectors in the upcoming HPE infrastructure</li> <li>• Delays in the procurement clearance results in a delay of technical work about the integration of components as well creation of training material</li> <li>• The infrastructure and components will not be ready for the expected deployment, this creates a cascade delay in the recruitment process</li> </ul>

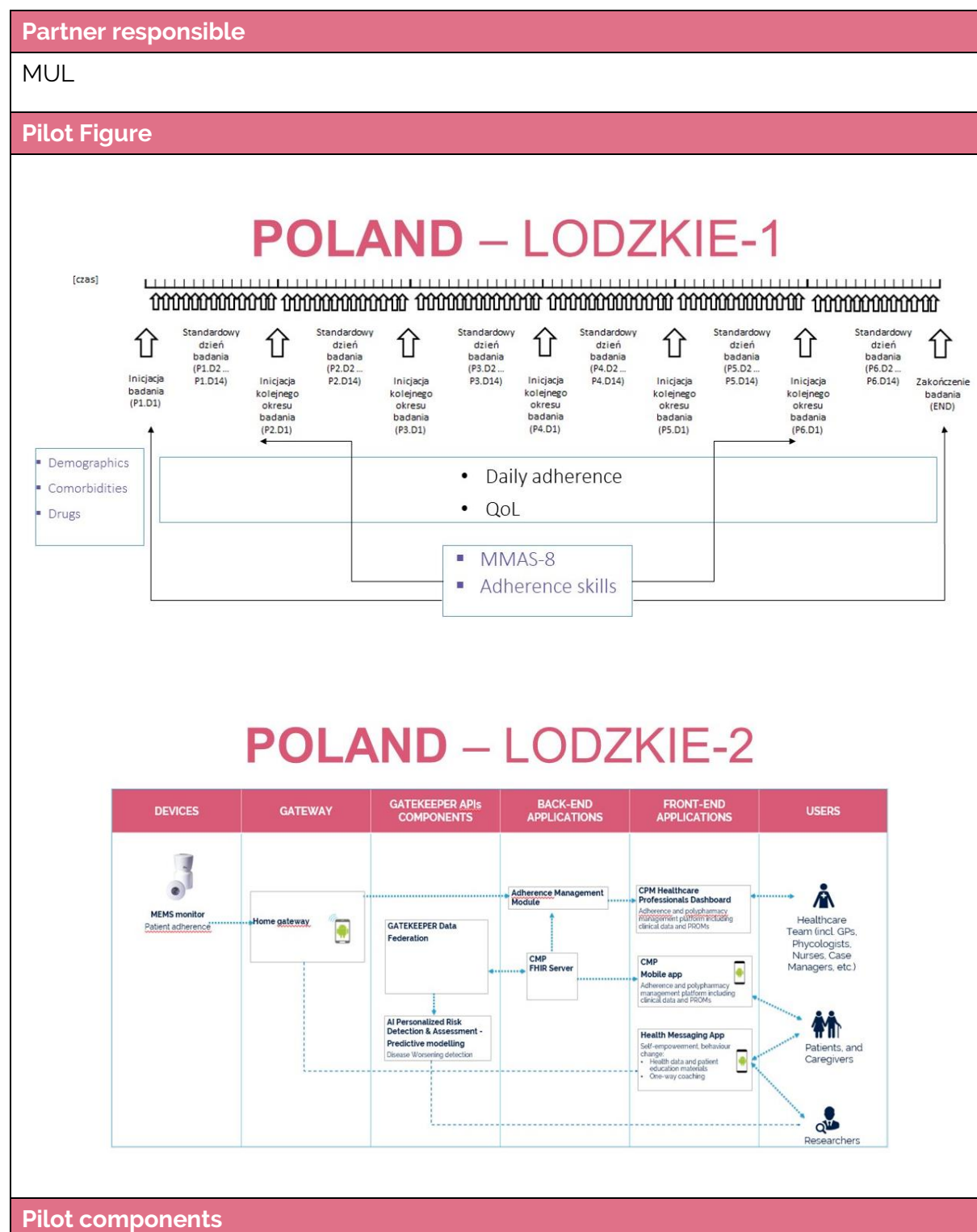
**Time plan (GANTT)**

Table 16: Milton Keynes pilot time plan

		2021												2021			
#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
1	Extending Activage application																
2	Community Dashboard																
3	AI for community-based early detection																
4	Intervention broker for community-based intervention																
5	Integration between robot and ActiveAge																
6	Activity recognition module for the robot																
7	Robot control for remote care																
8	Recruitment																
9	Pre-study on robot intervention at home																
10	Hazard detection module for the robot																
11	Multi-modal interface for the robot																

## 5.2.6 Poland

Table 17: Polish pilot development and deployment strategy



<ul style="list-style-type: none"> <li>• Components available:</li> <li>• Web based battery of questionnaire</li> <li>• Patient application</li> <li>• Reasoning module</li> <li>• Library of patient-oriented information</li> <li>• Medication adherence monitor</li> <li>• Home gateway</li> </ul> <p>Components that need to be developed for the pilot:</p> <ul style="list-style-type: none"> <li>• AI predictive module</li> </ul>
<b>Expected integration with Gatekeeper</b>
<ul style="list-style-type: none"> <li>• Data collected in LODZ-1 and LODZ-2 will be transferred after anonymisation to the GATEKEEPER ecosystem.</li> <li>• AI Module embedded in GATEKEEPER ecosystem will be trained with retrospective data (first tranche of LODZ-1 data) analyzed with machine learning, and then, used for prospective analysis of second tranche of data.</li> <li>• Anonymised data will be made available in GATEKEEPER ecosystem for secondary analyses.</li> </ul>
<b>List of needed tasks for development and integration of pilot components</b>
<ul style="list-style-type: none"> <li>• Internal testing of LODZ-1 technology in healthy volunteers followed by fine-tuning</li> <li>• LODZ-1 'Pilot of the pilot' followed by fine-tuning of technology</li> <li>• Development of AI component for LODZ-1</li> <li>• LODZ-1 Data transfer into Data Federation</li> <li>• Mass scale deployment – 1st tranche; collected data used for retrospective analysis with AI</li> <li>• Mass scale deployment – 2<sup>nd</sup> tranche; collected data used for real-time analysis with AI</li> </ul>
<b>Expected partner interactions</b>
<ul style="list-style-type: none"> <li>• Mysphera will be target of interaction regarding AI Module designed and implementation.</li> <li>• Samsung is expected to be targeted for integration of their solutions in LODZ-2 high complexity group</li> </ul>
<b>Risks and criticisms</b>
-

## Time plan (GANTT)

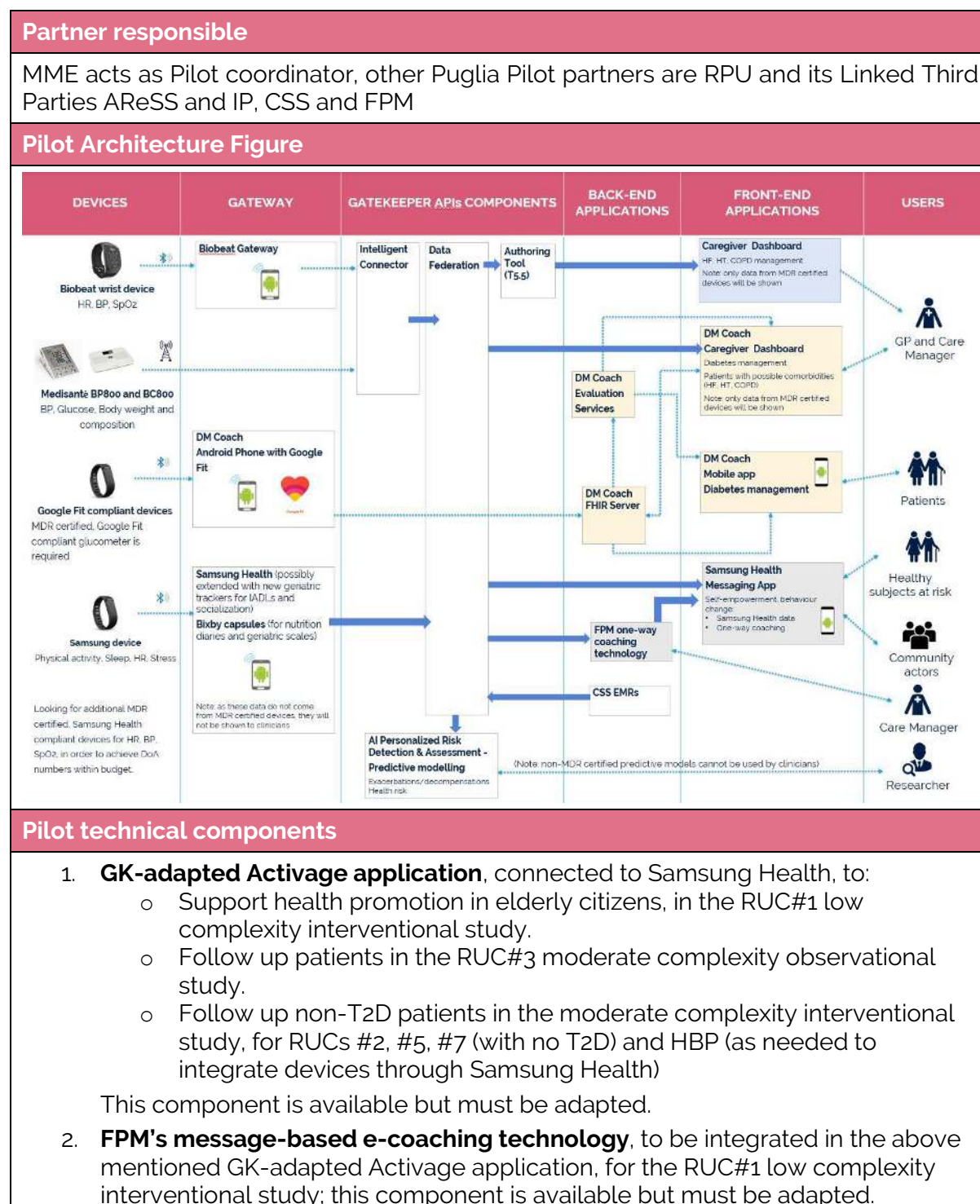
Table 18: Polish pilot time plan

#	Task	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Internal testing of LODZ-1 technology in healthy volunteers followed by fine-tuning												
2	LODZ-1 'Pilot of the pilot' followed by fine-tuning of technology												
3	Development of AI component for LODZ-1												
4	LODZ-1 Data transfer into Data Federation												
5	Mass scale deployment – 1st tranche; collected data used for retrospective analysis with AI												
6	Mass scale deployment – 2nd tranche; collected data used for real-time analysis with AI												
7	LODZ-1 pilot results analysis and design of mid- & high-complexity pilot (LODZ-2)												



## 5.2.7 Puglia

Table 19: Puglia pilot development and deployment strategy



3. **GK-aware version of the DMCoach application**, to follow up T2D patients in the moderate complexity interventional study for RUCs #3 and #7 (with T2D). This component is available but must be adapted.
4. **T5.5 Dashboards** to visualise:
  - Patients' data to GPs in the moderate complexity interventional study, for RUCs #2, #5, #7 (with no T2D) and HBP.
  - Patients' data to clinical researchers in the RUC#3 moderate complexity observational study.

This component is planned for development in T5.5.

5. **Integration of selected data from CSS's EMRs** with the GK Data Federation, to conduct the RUC#3 moderate complexity observational study on prediction of diabetes control. This component needs to be developed.
6. **T5.3 AI-Powered services**, although we do not have yet precise information of what will be made available to Pilots, we are willing to experiment with such services if they are useful to support relevant modelling activities in the frame of the RUC#3 moderate complexity observational study.
7. **Procurement of devices** for all studies, as illustrated here: [https://docs.google.com/spreadsheets/d/1KoSzu\\_v6qWA77ib1FzycVUQzCljA492joMgex4nKPGI/edit#gid=0](https://docs.google.com/spreadsheets/d/1KoSzu_v6qWA77ib1FzycVUQzCljA492joMgex4nKPGI/edit#gid=0); development may be needed to integrate external devices (i.e. devices not provided by GK partners; currently, for the Puglia Pilot, these are: iHealth BG5S-Kit glucometer, iHealth Air SpO<sub>2</sub> meter, and iHealth View BP7S BP monitor) with the GK Data Federation, depending on the available integration options being decided by the Platform Cluster.
8. **Integration of M+ devices** BP800 and BC800 with the GK Data Federation. We understand that development for this is already planned in GK.
9. **Integration of Biobeat wrist PPG device** with the GK Data Federation. We understand that development for this is already planned in GK.
10. **Integration of devices already owned by patients** (e.g., glucometers, BP monitors, etc.) with the GK Data Federation. For example, this integration is needed if a patient owns this BP monitor: <https://www.withings.com/it/en/bpm-connect>, that can be accessed through this API: <https://developer.withings.com/oauth2/>. We understand that development depends on the available integration options being decided by the Platform Cluster.
11. We would need the **implementation of an end-user management system** (for managing patients, healthy elderlies, GPs, clinical researchers, and relationships among these, including authorisation and authentication mechanisms, possibly based on eIDAS compatible digital identity systems, such as SPID in Italy <https://www.spid.gov.it/?lang=en-001>). This component is especially needed for following up patients in the moderate complexity interventional study, for RUCs #2, #5, #7 (with no T2D) and HBP, as for the other studies we can reasonably rely on application-specific end-user management from DMCoach and Activage. This component needs to be developed, although we understand that the already planned GK user management component (for developers) can easily be reused. We will provide preliminary User Stories to specify our needs in more detail.

### Expected integration with Gatekeeper

1. We expect the Activage application to be able to store data in the GK Data Federation, including data collected through Samsung Health.
2. We need to investigate more if the integration of the FPM e-coaching technology within the Activage application will need GK and how; this investigation will be done as part of the specification of such integration.
3. We expect the DMCoach application to be able to access patient data stored in the GK Data Federation
4. We expect the T5.5 Dashboards to be able to visualise data stored in the GK Data Federation to GPs and to clinical researchers, on both a patient-by-patient as well as aggregated form. We also need that such Dashboards are coupled with an end-user management system, in order to follow up patients in the moderate complexity interventional study, for RUCs #2, #5, #7 (with no T2D) and HBP, as previously specified.
5. We expect selected EMR data from the CSS HIS, necessary for the RUC#3 moderate complexity observational study, to be integrated in the GK Data Federation
6. We will consider usage of the T5.3 AI-powered services that will be made available to Pilots, if they are useful to support relevant modelling activities in the frame of the RUC#3 moderate complexity observational study.
7. We expect all devices that we will procure to be able to store data in the GK Data Federation (see also items 8, 9, and 10, below). In particular, we expect that data from external devices (currently: iHealth BG5S-Kit glucometer, iHealth Air SpO<sub>2</sub> meter, and iHealth View BP7S BP monitor) can also be stored in the GK Data Federation.
8. We expect data from M+ BP800 and BC800 devices to be stored in the GK Data Federation
9. We expect data from the Biobeat wrist PPG device to be stored in the GK Data Federation
10. We expect that data from patients' own devices can be stored in the GK Data Federation, if the patient consents to this
11. We expect that end-user management will be provided by the GK project, at least to follow up patients through the T5.5 Dashboards, in the moderate complexity interventional study, for RUCs #2, #5, #7 (with no T2D) and HBP.

### List of needed activities for development and integration of pilot components

1. Adaptation of Activage to the needs of
  - a. RUC#1 low complexity interventional study
  - b. RUC#3 moderate complexity observational study
  - c. Moderate complexity interventional study, for RUCs #2, #5, #7 (with no T2D) and HBP
2. Integration of the FPM technology into the Activage application
3. Adaptation of DMCoach to the needs of the moderate complexity interventional study, for RUCs #3 and #7 (with T2D)
4. Development of T5.5 Dashboards and possible integration with end-user management as per item 11

5. Development of the modules necessary to store selected EMR data from the CSS HIS and unconventional data collected from Samsung devices in the GK Data Federation
6. Development of the T5.3 AI-powered services
7. Possible development to store data from external devices in the GK Data Federation, depending on the available integration options being decided by the Platform Cluster.
8. Development of the modules necessary to store data from M+ BP800 and BC800 devices in the GK Data Federation
9. Development of the modules necessary to store data from Biobeat wrist PPG devices in the GK Data Federation
10. Development of the modules necessary to store data from patients' own devices in the GK Data Federation
11. Development of an end-user management system, possibly based on existing eIDAS-compatible digital identity systems (like SPID in Italy)

#### **Expected partner interactions**

This is the list of partners with which we are discussing support to conduct the development activities mentioned in the previous section of the form:

1. A general agreement with SAM has been reached, specifications are to be drafted asap.
2. A general agreement with FPM and SAM has been reached, specifications are to be drafted asap.
3. A general agreement with ENG has been reached, specifications are currently being worked out.
4. We understand that this component is to be developed by T5.5 partners. We are interacting with Tecnia.
5. Working with ENG in the frame of T4.4 and T7.5; CSS has already provided the necessary specifications in the frame of T4.4
6. We understand that this component is to be developed by T5.3 partners.
7. To be defined in agreement with Platform Cluster Partners.
8. To be defined in agreement with Platform Cluster Partners.
9. To be defined in agreement with Platform Cluster Partners.
10. To be defined in agreement with Platform Cluster Partners.
11. To be defined in agreement with Platform Cluster Partners.

#### **Risks and criticisms**

The main risks stem from the fact that, although a relevant strategy for the Puglia Pilot technical deployment is established at this time, we still need to agree in details the specifications for the expected development results, which in turn depend on details of the GK Platform which have not yet been fully provided to Pilots. To move towards and break this chicken-and-egg issue, we are formulating relevant User Stories to be discussed with partners.

A specific risk is linked to device procurement (see remarks on the Time plan).

In addition, the development and procurement of technologies for the RUC #3 moderate complexity observational study is time critical, due to potential issues with insufficient recruitment accrual times (see Time plan below).

## Time plan (GANTT)

Table 20: Puglia pilot time plan

		2021												2022		
#	Activity list	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
1	GK-adapted Activage application															
2	FPM's message-based e-coaching technology															
3	GK-aware version of the DMCoach application															
4	T5.5 Dashboards															
5	Integration of selected data from CSS's EMRs															
6	T5.3 AI-Powered services															
7	Procurement of devices															
8	Integration of M+ devices															
9	Integration of Biobeat wrist PPG device															
10	Integration of devices already owned by patients															
11	Implementation of a user management system															
	Beta-testing of low complexity interventional study technology															

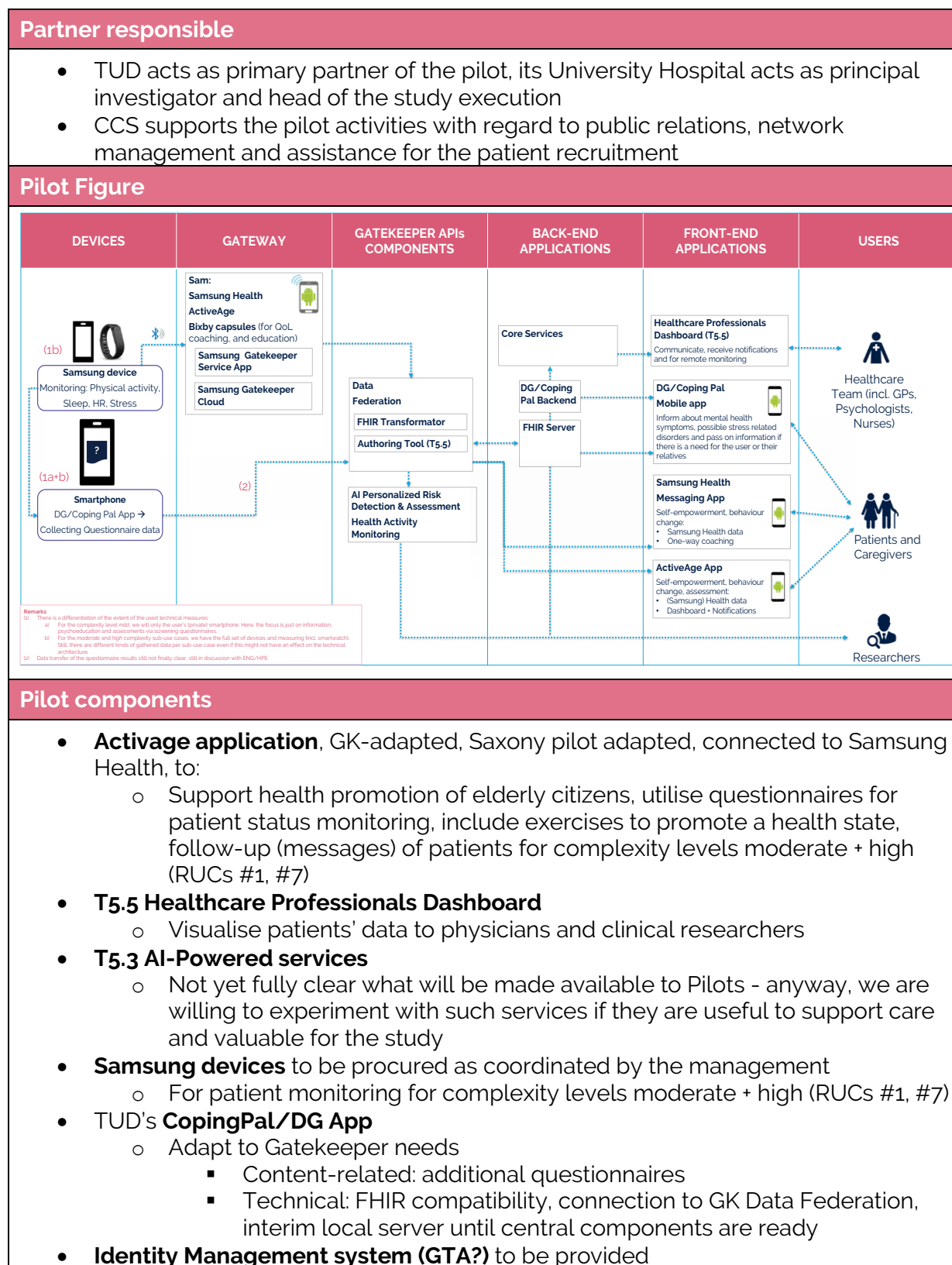
		2021												2022		
#	Activity list	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	Beta-testing of moderate complexity interventional study technology															
	Recruitment of observational study starts				◆											
	Recruitment of "before" arm of interventional studies starts			◆												
	Recruitment of "before" arm of interventional studies stops and "after" arm starts															◆

#### Important remarks on the time plan:

- Technology for the interventional studies will be provided to patients recruited for such studies starting from March 2022 – after the end of the "before" period and at the start of the "after" period – as established by the relevant study designs reported in D7.1 and D6.4. For this reason, technology for interventional studies must be fully deployed and both alfa- and beta-tested at this time.
- Procurement of devices and implementation of CSS's EMRs integration technology for the RUC #3 moderate complexity observational study is time critical: it should be completed by March 31<sup>st</sup>, 2021, if we are to start patient recruitment in April 2021. Delays in this activity will correspondingly delay the study, resulting in risks related to insufficient recruitment accrual time.
- Device procurement may depend on a GA Amendment (to shift budget from RPU to device providing partners, SAM and Medisanté).

## 5.2.8 Saxony

Table 21: Saxony pilot development and deployment strategy





<ul style="list-style-type: none"> <li>○ Manage multiple identities through different systems (or pilots) as well as general issues regarding authentication and access, allow clear logical identification of single users</li> <li>○ IDM to support or provide central services for coding data for pseudonymisation?</li> </ul>
<b>Expected integration with Gatekeeper</b>
<ul style="list-style-type: none"> <li>• Samsung components (Activage application, Samsung Health or their GK Service App/GK Cloud): able to store data in the GK Data Federation, including data collected through Samsung Health (as measured by smartwatch, smartphone)</li> <li>• TUD's CopingPal/DG App: to be connected to GK Data Federation to store and access data; physicians and clinical researchers to retrieve that data</li> <li>• T5.5 Dashboards: able to visualise data stored in the GK Data Federation to GPs and to clinical researchers (single data and in aggregated form), connection to IDM needed to be able to make statements on a particular patient/data set</li> <li>• T5.3 AI-powered services: be made available to Pilots, if useful to support care/study, to be tested and compared with own experiences/actual observations</li> </ul>
<b>List of needed tasks for development and integration of pilot components</b>
<ul style="list-style-type: none"> <li>• Adaptation of Activage <ul style="list-style-type: none"> <li>○ Additional questionnaires</li> <li>○ German translations</li> <li>○ Feasibility and usefulness of connection/integration to TUD's App (e.g., in relation to the training exercises within that) still to be clarified</li> </ul> </li> <li>• Further integration and alignment tasks with Samsung, dependent on clear alignments and on their developments and provision of several access points by them (GK Service App itself, GK Cloud, connections between the systems, connectivity bridges, FHIR transformation, Activage/health data to Data Federation, accessibility by pilot user and dashboard) <ul style="list-style-type: none"> <li>○ Ongoing deep discussions</li> </ul> </li> <li>• Further clarifications on common data model and needed data types, (FHIR) transformation with ENG needed</li> <li>• Provision of the central Data Federation components by HPE needed to really progress; quite effortful interim solution (local server for some time; shift of data storage mode and data sharing when possible) needed to try to cope with its absence</li> <li>• Development of T5.5 Dashboards and possible integration with IDM</li> <li>• Adaptions and connections of TUD's App to be able to share data with GK Data Federation</li> </ul>
<b>Expected partner interactions</b>
<p>Partners with which we are discussing support to conduct the development activities:</p> <ul style="list-style-type: none"> <li>• Samsung: <ul style="list-style-type: none"> <li>○ General agreement reached (utilisation of their devices/services for health monitoring)</li> <li>○ Data sharing agreement to be prepared</li> <li>○ Further technical architectural alignments needed</li> </ul> </li> </ul>



- Further work on T5.3 AI-powered services to be expected, more details on their utilisation and actual usability needed
- Operational procedures of the procurement/provision of the devices to be sorted out, when management's "go" is there
- Start operational work (adapting and connecting things when all is specified)
- Tecnalia
  - Requirements for dashboards discussed and provided
  - Dashboard/authoring tool to be further specified and to be provided
  - Available for further clarifications if needed
- ITI/CERTH:
  - Expect clarifications on possibly upcoming T7.5 tasks (if any)
  - GTA/IDM to be further specified and to be provided
- ENG:
  - Further discussions on connectivity, retrievability of data to be expected
  - Further alignments on common data model to be expected
  - Further alignments on FHIR transformation to be expected
- HPE:
  - Awaiting provision of Data Federation
  - Awaiting seminar/general explanations on the actual usage and linkage of the data spaces

### Risks and criticisms

- Some detailed clarifications on the technical components, connections, data flows and data types pending
  - Needed for our data protection concept
  - Internally approved data protection concept as precondition for approval of the Ethic's approval
  - Ethic's approval needed to start real patient inclusion
- We hope that we now have a good understanding of all the expectations with regard to the study conduction (technical + clinical) so that we can finally clarify the last open points soon (SAM, HPE, ENG) and will then be, hopefully, fully prepared to conduct the study
- Unavailability of central services, delays on local Ethical approval process (at least partly related to technical issues):
  - Risk to further delay patient inclusion and start of study
  - Risk to disappoint the expectations of patients and physicians
  - Need to plan interim solution with local data storage to be least able to start data collection for complexity level mild in some time
    - Possible need to amend ethical approval
- Further COVID-related restrictions could further inhibit patient recruitment/conduction of the study at all (unforeseeable risk)
- Quite lengthy device procurement process, still not clear when decided and approved on the central level
  - Not possible to schedule any preparatory tasks (test with devices, tutorials, operational handling of the devices)
  - For us, this is linked to a request to shift budget (devices -> staff)
    - Not possible without finalized procurement process (as clear budget overview is a first precondition)
    - Additional staff budget would be much appreciated in order to better work on the study operation (technical and clinical)

## Time plan (GANTT)

Table 22: Saxony pilot time plan

#	Task	2021											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Adaption of Activage application												
2	Connections Samsung infrastructure												
3	Work on data models, FHIR integration												
4	T5.5 Dashboards												
5	Procurement of devices												
6	T5.3 AI-Powered services												
7	TUD's CopingPal/DG App: connectivity, FHIR compatibility, data storage/sharing (first locally, later centrally), function range extension (content)												
8	Identity management												

**Remark:** Due to the aforementioned imponderables, the schedule is only provisional. Partly, assumptions were made without the exact plan being clear yet.

## 5.2.9 Hong-Kong

The content of the plan for the Hong-Kong pilot site is undergoing adjustments, so no development or deployment can be reported yet.

## 5.2.10 Singapore

The content of the plan for the Singapore pilot site is undergoing adjustments, so no development or deployment can be reported yet. Based on D3.1.1, the pilot figure is the following:

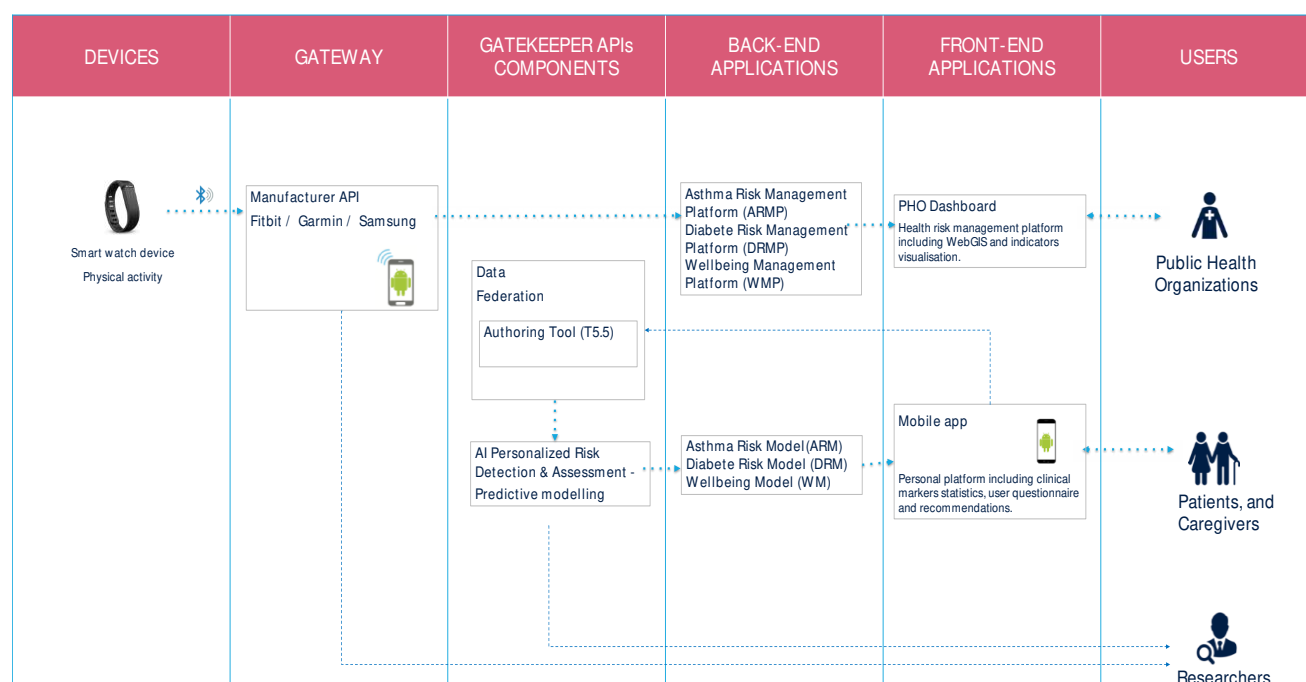


Figure 7 - Singapore pilot architecture figure

## 5.2.11 Taiwan

The content of the plan for the Taiwan pilot site is undergoing adjustments, so no development or deployment can be reported yet.

## 5.3 COVID-19 survey implementation

Table 23: COVID-19 survey implementation strategy

<b>Partner responsible</b>					
COVID-19 Taskforce led by CIBER					
<b>Figure</b>					
<b>Components</b>					
<ul style="list-style-type: none"> <li>a) COVID-19 questionnaire content</li> <li>b) Stand-alone application and interfaces</li> <li>c) Dedicated Data Federation server</li> </ul>					
<b>Expected integration with Gatekeeper</b>					
<ul style="list-style-type: none"> <li>• The integration of the application with Data Federation module</li> <li>• The integration with the Authoring tool for visualisation of the collected data</li> <li>• The unique ID integration with patients' IDs in pilot KETs</li> <li>• The deployment in HPE infrastructure</li> </ul>					
<b>List of needed tasks for development and integration of pilot components</b>					
<ul style="list-style-type: none"> <li>▪ The finalisation of the COVID-19 questionnaire content and translations to local languages</li> <li>▪ The development of the stand-alone application</li> <li>▪ The integration of the application with Data Federation</li> <li>▪ The deployment of the application to the HPE infrastructure</li> </ul>					
<b>Expected partner interactions</b>					
All involved partners are interacting through the COVID-19 Taskforce channel					
<b>Risks and criticisms</b>					
<p>To deliver the questionnaire during COVID-19 outbreak</p> <p>To create a user-friendly questionnaire in terms of content and interfaces</p> <p>To identify the proper markers that affect patients' quality of life during COVID-19 outbreak</p>					

## Time plan (GANTT)

Table 24: COVID-19 survey implementation time plan

#	Task	2021											
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Finalisation of the COVID-19 questionnaire content												
2	Implementation of the COVID-19 questionnaire dashboards												
3	Testing of the interfaces with the COVID-19 Taskforce												
4	Integration with Data Federation												
5	Integration with Authoring Tool												
6	Deployment to HPE												
7	Dissemination of the Questionnaire												

## 6 Level-based analysis and requirements capturing

The platform is analysed using the level-based approach introduced in the first version of this deliverable. Each level includes:

- The level analysis as it was defined by the architecture (T3.2) and the GK reference components, vocabulary and semantics that are delivered or will be developed by the GK partners to support the scope and the functionalities of the level
- The requirements related to the level in question.

Header	Explanation
<b>ID</b>	<i>Req_XX_##</i> where <i>Req</i> = Requirement, <i>XX</i> = layer acronym, <i>##</i> =progressive number
<b>Description</b>	Short description of the current system requirement
<b>Requirement Type</b>	<i>functional</i> : describing what the product has to do or what processing actions it is to take <i>non-functional</i> : describing properties that the functions must have, such as performance and usability
<b>Priority</b>	Level of priority of the fulfilment of this requirement. The priority is a result of different contributing factors, arriving from different contexts (Industrial context, business context, etc.). Prioritisation was performed using MoSCoW analysis <sup>1</sup> . Possible levels: <i>must</i> (Mandatory) <i>should</i> (Of high priority) <i>could</i> (Desirable but not necessary) <i>won't</i> (Will not be implemented in the given release but suggested for future execution)
<b>Fit Criterion</b>	A statement such that can be systematically proven to be true as a test if the solution matches the original requirement
<b>Related GK Component</b>	The Gatekeeper (GK) component that the requirement refers to. In some levels, such as the User and the Application levels, there are more than one options. Thus, this column highlights the component(s) that are related with the requirement. The option "General" applies to all the system design. This column is optional.
<b>Difficulty</b>	Level of difficulty of the fulfilment of this requirement. Possible levels: <i>high</i> <i>medium</i> <i>low</i>

The User level includes requirements for the Authoring Tool and the GATEKEEPER Web Environment, but also desirable features of Pilot KETs:

- GK-enabled applications/platforms (e.g. pilot applications) of **Pilot KETs** registered in the system, are described in D6.1, D6.2 and in section 5.2.
- The **Authoring Tool** is a web-based component offering a visual service allowing pilot sites to configure specific dashboards targeting healthcare professionals/health service providers in order to show a graphical representation of the patient data and observations collected (current status and historical data), on which more information can be found in the context of T5.5.
- The **GATEKEEPER Web Environment**, composed of:
  - the **Marketplace**, the business hub of the GATEKEEPER project, on which more information can be found in D4.6.
  - the **Developer Portal**, a front-end where technology developers can building novel software solution by using components of the Gatekeeper platform developed in T4.1.

**Legend:**

- Core Platform components (Pink)
- AI/ML Components (Green)
- Data sources and devices (Dark Blue)
- External/Pilot components (Yellow)
- Flows managed by TMS (Grey arrow)

**Architecture Components and Flow:**

- Data Sources:** Device, Device, Device, fully connected devices, Robot, Device (Smartphone), EHR.
- Gatekeepers:** GATEWAY BLE / FHIR, WEB DATA CONNECTORS, INTELLIGENT MEDICAL DEVICE CONNECTORS, MULTI ROBOT CONNECTORS, PERSONAL HEALTH GATEKEEPER APP.
- Integration Engine:** GATEKEEPER DATA FEDERATION Integration Engine.
- Federation Server:** GATEKEEPER DATA FEDERATION Server (for EHR & PHR).
- Storage:** RDF, FHIR Server GK Resource Profile.
- Trust & Management:** GATEKEEPER TRUST AUTHORITY, Web of THING MANAGEMENT SYSTEM, Thing Directory.
- AI Reasoning Framework:** AI Personalized Risk Detection & Assessment, Medical Based AI algorithms (T6.3), Home&Health Activity Monitoring, External AI Services.
- External Tools & Portals:** AUTHORIZING TOOL FOR DASHBOARDS, External Apps (e.g. Pilot Apps), Developer Portal (APP MANAGEMENT PORTAL, LEARNING PORTAL, Marketplace, ADMIN PORTAL, CUSTOMER PORTAL), GATEKEEPER WEB ENVIRONMENT.

Figure 8 – Components related to the User level in the architecture

The requirements of this level are organised in the following order:

1. UI/UX (Req\_UI\_1-Req\_UI\_8)
2. Help services/documentation/training/integrating guidelines (Req\_UI\_9- Req\_UI\_14, Req\_UI\_23)
3. UI configuration (Req\_UI\_17-Req\_UI\_20)
4. Other requirements (Req\_UI\_20-Req\_UI\_25).

Table 25: User level requirements

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_UI_01	End-users with disabilities are able to access the interfaces and all the included information. (see also Req_49 in D2.13)	non-functional	must	The solution and information are accessible to people with disabilities	Authoring Tool Pilot KETs	low
Req_UI_02	User Interfaces have easy interaction for elderly end-users (to write, to read, hand tremor handling, etc.) (see also Req_09 in D2.13)	non-functional	must	Web Content Accessibility Guidelines (WCAG), User Agent Accessibility Guidelines (UAAG) and Authoring Tool Accessibility Guidelines (ATAG) <sup>6</sup> by W3C are followed to achieve easy interaction with Pilot KETs for the elderly	Pilot KETs	high
Req_UI_03	User Interfaces are intuitive and easy to understand and use for all stakeholders, especially those with low digital literacy. (see also Req_13 in D2.13)	non-functional	must	Design principles for easy interactions are followed, such as easy interaction with visual cues,	Pilot KETs	high

<sup>6</sup> W. (WAI), "Older Users and Web Accessibility: Meeting the Needs of Ageing Web Users", Web Accessibility Initiative (WAI). [Online]. Available: <https://www.w3.org/WAI/older-users/>. [Accessed: 15- Mar- 2021].



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				minimalist design and progressive disclosure of content		
Req_UI_04	The content of the user interface is easy to use for all actors, especially those with low digital literacy. (see also Req_13 in D2.13)	non-functional	must	The user interface is intuitive and easy to use for all actors without the support of a technical person	Authoring Tool Pilot KETs	medium
Req_UI_05	The content of the user interface shall be provided in different formats for varying abilities. (see also Req_09 in D2.13)	non-functional	must	Different content formats, such as visual, text, audio according to user needs	Authoring Tool Pilot KETs Marketplace	medium
Req_UI_06	User Interfaces provide the actors with information (data, elaboration, warning, state, ...) in an appropriate manner (by type of content and by style of representation) with the skills associated with that particular GK actor. (see also Req_13 in D2.13)	non-functional	must	The system provides clear and concise information in an appropriate manner adapted to general public.	Authoring Tool Pilot KETs	medium
Req_UI_07	User Interfaces provide information to Social Services and primary healthcare for better intervention. (see also Req_48 in D2.13)	functional	should	The system provides information about patients/pilot	Authoring Tool Pilot KETs	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				participants to Social Services and primary healthcare in the pilot sites through a dashboard.		
Req_UI_08	User Interfaces provide information to healthcare professionals.	functional	must	The system provides information about end-users to healthcare professionals through a dashboard.	Authoring Tool Pilot KETs	low
Req_UI_09	End-users have available help services to support/inform end-users through email on the use of the platform. (see also Req_12 in D2.13)	functional	must	Help services are available through phone and email for questions related to platform usage.	Authoring Tool Pilot KETs	medium
Req_UI_10	End-users have a help centre where they can turn to for support on the use of devices. (see also Req_12 in D2.13)	functional	should	A help centre is available for support on use of devices.	Pilot KETs	medium
Req_UI_11	End-users to be given full training on all hardware and software on delivery. (see also Req_05 in D2.13)	non-functional	should	Full training material available and provided to participants.	Authoring Tool Pilot KETs	low

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_UI_12	Users will be provided with understandable documentation that explains the use of the system and its assets. (see also Req_21 in D2.13)	non-functional	must	Documentation is available and understandable.	Authoring Tool Pilot KETs Marketplace	low
Req_UI_13	Users and referral services to be offered training material on digital literacy and privacy. (see also Req_05 in D2.13)	non-functional	must	Full training material available and provided to participants.	Authoring Tool Pilot KETs Marketplace	medium
Req_UI_14	The system shall provide integration guidelines for the end-users to integrate own devices. (source: Puglia pilot).	non-functional	must	Integration guidelines for external device integration are available to all end-users.	Pilot KETs	medium
Req_UI_15	Pilot KETs will provide guidance for the use of the connected devices.	functional	must	Guidance for the use of the connected devices is available through Pilot KETs.	Pilot KETs	medium
Req_UI_16	Users must be able to choose the services, service components and applications they will use.	functional	must	Services, service components and applications are available and selectable to users.	Pilot KETs Marketplace	medium
Req_UI_17	Enabled users must be able to delete a measurement (see also	functional	must	A measurement can be deleted by a	Authoring Tool Pilot KETs	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	Req_PS_18).			user with granted permissions.		
Req_UI_18	Users will configure the notification method (audio, vibration, visual and text). (see also Req_14 in D2.13)	functional	should	Notification methods can be configured by the user.	Pilot KETs Marketplace	low
Req_UI_19	Users must be able to choose the data, data periodicity, aggregation values and visualisations they will use. (see also Req_41, Req_44 in D2.13)	functional	must	Selection of data and type of visualisation is available for configuration.	Authoring Tool	high
Req_UI_20	Users will be able to change overall layout, changing font style, colours and logos. (see also Req_39 in D2.13)	functional	should	Configuration of general look & feel aspects is available.	Authoring Tool	medium
Req_UI_21	User input can determine opt-outs and data correction	functional	must	User is able to define opt-outs and data correction.	Authoring Tool Pilot KETs	medium
Req_UI_22	The developers will make sure that the automated alerts and reports of the system will be in compliance with specialists' advice.	non-functional	must	Specialists configuration for reliable alerts and reports which are in compliance with their advice	Pilot KETs	medium
Req_UI_23	The patient's profile includes income support information.	non-functional	should	The patient profile includes income	Pilot KETs	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	(see also Req_48 in D2.13)			support information.		
Req_UI_24	The user interfaces include measures of error tolerance. (see also Req_13 in D2.13)	functional	should	The solutions manage errors and exceptions while supporting users in reducing/avoiding mistakes.	Authoring Tool Pilot KETs Marketplace	low

## 6.2 Applications level

As was stated in D3.1.1, the Applications level provides solutions and services to be used by end users (e.g. Reference Health professional) for health or life-style monitoring in order to compose and "prescribe" early detection/intervention solutions for patient (e.g. an alert is raised and sent to clinicians). Examples of such solutions are:

- wearable sensors to continuously or periodically measure motor symptoms (depending on disease severity)
- digital applications to detect non-motor symptoms could be used to record data into the patient's Electronic Health Record (EHR), accessible in the GK Healthcare Space.

This level represents the added value that the Things registered to the platform bring in enhancing the capabilities of the GATEKEEPER platform:

- They can enable the collection of new health-related data directly (devices exposed as Things).
- They can collect data from devices and make them available on the platform, acting as Connectors.
- They can enrich the reasoning capabilities of the platform by providing ad hoc solutions to elaborate data available on the platform.
- They can offer solutions to the actors to fulfil their goals (front ends or complete applications that exploit services offered by the system).

In the reference architecture, the components related to this level are referenced as:

- GK-enabled applications/platforms (e.g. pilot applications) of **Pilot KETs** registered in the system, on which more information can be found in D6.1, D6.2 and section 5.2.
- the **Authoring Tool**, a web-based component offering a visual service allowing pilot sites to configure specific dashboards targeting healthcare professionals/health service providers in order to show a graphical representation of the patient data and observations collected (current status and historical data), on which more information can be found in the context of T5.5.
- The **GATEKEEPER Web Environment**, composed of:
  - the **Marketplace**, the business hub of the GATEKEEPER project, on which more information can be found in D4.6.
  - the **Developer Portal**, a front-end where technology developers can building novel software solution by using components of the Gatekeeper platform, developed in T5.1.

Many of the requirements in this level stem from user requirements reported in D2.13. In such cases, the user requirement is analysed into many technical ones (e.g. monetisation, deployment automation) to clarify the implementation and/ a pertinent fit criterion is added.

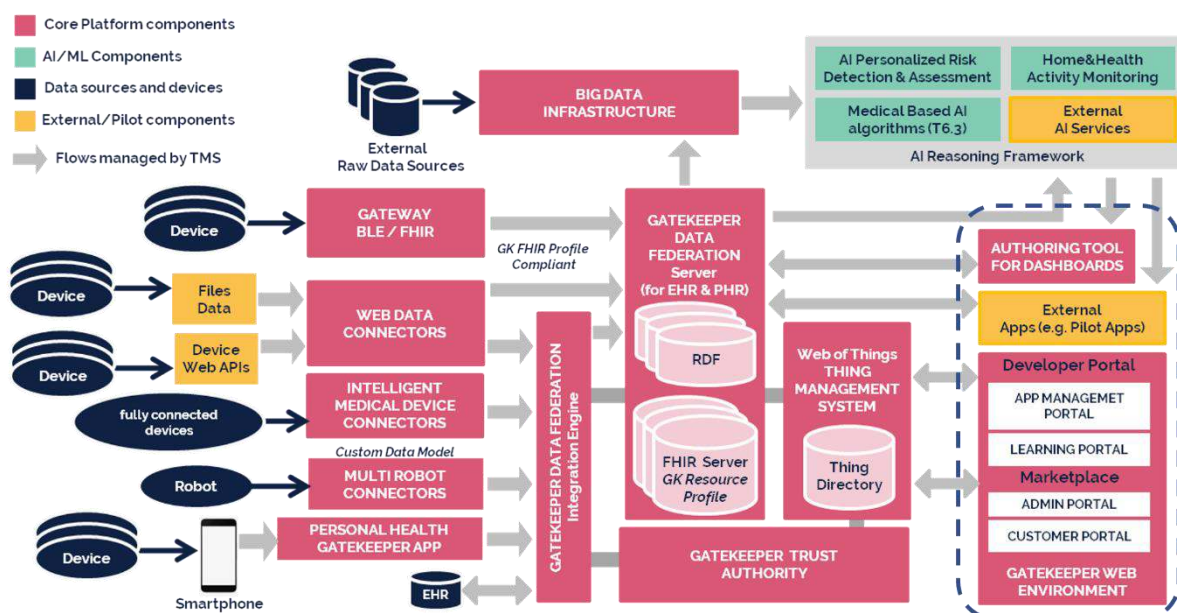


Figure 9 - Applications in the architecture

The requirements of this level are organised in the following order:

1. Visual analytics/Dashboards (Req\_AP\_1- Req\_AP\_8)
2. Virtual assistant functionalities (Req\_AP\_9, Req\_AP\_10)
3. Alerts/notifications/reminders (Req\_AP\_11-Req\_AP\_23)
4. Other features offered (Req\_AP\_24- Req\_AP\_53)
5. Configuration/Customisation possibilities for applications (Req\_AP\_54- Req\_AP\_56)
6. Deployment automation (Req\_AP\_57- Req\_AP\_62)
7. Application integration (Req\_AP\_63-end)

Table 26: Applications level requirements

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AP_01	GK-enabled platforms that are Pilot KETs provide a <b>dashboard</b> displaying the patient's personal data.	functional	should	GK-enabled platforms provide a dashboard displaying the patient's personal data.	Pilot KETs	low
Req_AP_02	Consumers shall be able to have an overview of the data gathered and trends, changes etc. through a web portal.	functional	must	Consumers get an overview of the data gathered, including trends. through a web portal/web dashboard.	Pilot KETs Authoring Tool Marketplace	low
Req_AP_03	Data coming from predictions can be visualised. (see also Req_42 in D2.13)	functional	must	Data coming from predictions is visualised.	Authoring Tool	high
Req_AP_04	Dashboard providing insights about the emerging issues related to thresholds and monitoring of the community interventions of a given pilot site or RUC (source: UK pilot). (see also Req_38 in D2.13)	functional	must	Dashboard provides warnings when a threshold is passed and the status of the patients' evolution through data collected.	Authoring Tool	high



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AP_05	The dashboard shall provide overview for companies clustering data by location (area) and user profile.	functional	must	Companies have an overview of clustered data by location (area) and user profile.	Marketplace	high
Req_AP_06	GK-enabled platforms that are Pilot KETs should include a dashboard with all the uncompleted daily to-dos.	functional	should	The uncompleted daily to-dos are displayed in a dashboard.	Pilot KETs	medium
Req_AP_07	The output of the predictive models, such as the probability of an event to occur in a specific period of days, shall be visualised in dashboards (source: Aragon pilot)	functional	must	The output of the predictive models is visualised.	Pilot KETs Authoring Tool	medium
Req_AP_08	Analysis, comparison and stratification of collective patient data shall be possible through dashboards (source: Aragon pilot)	functional	must	Collective patient data can be analysed, compared and stratified	Pilot KETs Authoring Tool	medium
Req_AP_09	Useful help for end-users on how to do the tasks is provided through <b>a virtual assistant</b>	functional	should	There is a virtual assistant supporting task implementation when asked	Pilot KETs Marketplace	high
Req_AP_10	Virtual assistants generate reminders and feedback on the condition of the patients. (see also Req_10 in D2.13)	functional	should	Virtual assistants that generate reminders and feedback on the	Pilot KETs Marketplace	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				condition of the patients are offered		
Req_AP_11	Alert notifications on medical appointments should be sent to the assisted patients and caregivers.	functional	should	Patients and caregivers receive alert notifications before the medical appointments	Pilot KETs	low
Req_AP_12	Alert notifications to take medication should be sent to the assisted patients and caregivers.	functional	should	Patients and their caregivers are notified for medication taking	Pilot KETs	low
Req_AP_13	Reminders to take medication could be configurable remotely.	functional	could	Patients, caregivers and healthcare professionals can configure medication reminders remotely.	Pilot KETs	low
Req_AP_14	Contingency abnormal alert information should be formatted in a not alarming manner because they only represent suspicions of anomalies.	non-functional	should	Contingency abnormal alert information is formatted in a not alarming manner	Pilot KETs	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AP_15	When an emergency trigger alert is raised, the Pilot KET should alert either a named contact or a statutory service.	functional	should	Pre-decided name contacts or statutory services are alerted in case of an emergency	Pilot KETs	low
Req_AP_16	The notifications about an event should include brief information about the appropriate intervention for informal caregivers	functional	should	Caregivers receive brief information about intervention for an event in a notification	Pilot KETs	medium
Req_AP_17	GK-enabled applications should alert if there are pending support requests from patients	functional	should	Alerts on pending support requests from users	Pilot KETs	high
Req_AP_18	A GK-enabled application notifies a volunteer caregiver in case of events, if a family member or nominated reference is not available / does not respond in a given timeframe (related to the event)	functional	could	System notification for a volunteer caregiver in case of a family member or nominated reference absence	Pilot KETs	medium
Req_AP_19	GK-enabled applications alerts/notifies when a connected device needs battery charging/ changing	functional	should	Battery alarm alert/notification reaches the patient and the caregiver when a device battery is below a certain threshold.	Intelligent Connectors Pilot KETs	low

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AP_20	GK-enabled applications provide ways of promoting physical exercising and mental training. (see also Req_06 in D2.13)	functional	should	Reminders and educational material for physical exercising are provided	Pilot KETs	low
Req_AP_21	Pilot KETs should be able to notify the patient and their caregiver(s) in case of risky or unhealthy habits e.g. overeating, forget to take medication, hasn't gone out for some time	functional	should	Patients and caregivers receive notification when risky or unhealthy habits are detected	Pilot KETs	medium
Req_AP_22	Alerts should be interactive so as to ask questions alongside to gather more information	non-functional	should	Alerts ask questions and have input fields	Pilot KETs Marketplace	high
Req_AP_23	All Marketplace users shall receive notification of updates in software offerings from the Marketplace. (see also Req_29 in D2.13)	functional	must	Marketplace sends notification of updates in software offerings to all Marketplace users	Marketplace	medium
Req_AP_24	<b>OTHER</b> GK-enabled applications should provide user-friendly manual data entry capabilities to the patient/caregiver to allow usage of non-integrated devices to be able to insert raw data and FHIR data. (source: Puglia pilot)	functional	should	A patient/caregiver can provide data input manually easily	Pilot KETs Data Federation	high
Req_AP_25	An end-user management system is provided and connected with the Authoring Tool. (source: Puglia pilot, Basque Country pilot)	functional	must	Simple and/or Advanced users of the Authoring Tool	Authoring Tool Pilot KETs	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				can see end-user management information in the Authoring Tool.		
Req_AP_26	The system should provide users nutrition-related services.	function	should	Support Behavioural Change	Pilot KETs Marketplace	high
Req_AP_27	GK-enabled applications and the system ask the users about any issues/trouble they may have.	functional	must	Interactive tools to ask users about any issues they may have	Pilot KETs Authoring Tool Marketplace	low
Req_AP_28	Temporary notes can be kept to support the handing-over between caregivers and health professionals. (see also Req_52 in D2.13)	functional	must	Contextual and situation-specific information for patient handover is deleted after being used in the specific situation of an intervention	Pilot KETs	medium
Req_AP_29	System provides interfaces where companies share their Things	functional	should	Companies can share their Things	Marketplace	medium
Req_AP_30	System allows Users to share their Things in a dynamic way	non-functional	should	Companies can share their Things in a dynamic way	Marketplace	medium
Req_AP_31	The system GK Authoring Tool's Dashboards shall manage different kinds of user roles and	functional	must	Different roles have different	Authoring tool GTA	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	permissions for access and usage. For example, it should manage HCPs following up patients, allowing each HCP to visualise data for all and only those patients whom she follows up (see also Req_36 in D2.13)			permissions for accessing		
Req_AP_32	The system should not require credit card details to create a free account (see also Req_33 in D2.13)	functional	should	Creation of a free account without a credit card is possible	General	low
Req_AP_33	The system should offer deep reporting with dashboards across key metrics, such as impressions, revenue and fill rate, so that the marketplace product owners can manage monetisation (see also Req_31 in D2.13)	functional	should	The system offers deep reporting with dashboards across key metrics, such as impressions, revenue, CPMs (Cost Per Mille) and fill rate	Marketplace	high
Req_AP_34	The reporting of performance should include filtering options across countries, platforms and custom data ranges to manage monetisation (see also Req_31 in D2.13)	functional	should	Filtering options across countries, platforms and custom data ranges	Marketplace	high
Req_AP_35	Management and performance reporting for all products of the same product owner should be separate but in one place	functional	should	Management and performance reporting for all products of the same product owner is separate	Marketplace	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				but in one place		
Req_AP_36	Consumers should be able to provide reviews of applications. (see also Req_28 in D2.13)	functional	must	Application review process by product consumers	Marketplace	low
Req_AP_37	Buying or downloading offerings must be possible, including the ability to automatically deploy offering to device or infrastructure (see also Req_35 in D2.13)	functional	must	A consumer can buy or download offerings, including automatically deploy offering to device or infrastructure	Marketplace	high
Req_AP_38	The Marketplace shall offer information about its users, their profile and the devices downloaded to estimate the potential for exploitation (see also Req_17 in D2.13)	functional	must	Offer information about Marketplace users, their profile and the devices downloaded are available through the Marketplace	Marketplace	medium
Req_AP_39	Services and products available in the Marketplace shall be categorised per product category (services and APIs, end-user apps, hardware solutions, consultation services) (see also Req_18 in D2.13)	functional	must	Services and products available in the marketplace can appear in categories if requested	Marketplace	low
Req_AP_40	The services and APIs available in the application shall be categorised according to integration capability with existing software	functional	must	The services and APIs available in the marketplace are	Marketplace	low

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	systems (see also Req_18 in D2.13)			categorised according to integration capability with existing software systems		
Req_AP_41	Hardware solutions available in the Marketplace should indicate if they can be installed by end-users (see also Req_18 in D2.13)	functional	should	Indication about installation possibilities visible to consumers in the Marketplace	Marketplace	low
Req_AP_42	Consultation services that can install an offering tailored to consumer needs shall be available (see also Req_18 in D2.13)	functional	must	Available consultation services for offering installing	Marketplace	low
Req_AP_43	Technology developers shall be able to manage their applications (uploading, editing, updates, removal) in the Marketplace (see also Req_23 in D2.13)	functional	must	Application management is possible for technology developers in the Marketplace	Marketplace	medium
Req_AP_44	The application shall provide search capabilities among assets (see also Req_22 in D2.13)	functional	must	Search capabilities by filtering among assets available	Marketplace	medium
Req_AP_45	GK-enabled applications should enable and manage a list of local professional and volunteer informal caregivers with time,	functional	should	Lists of local professional and volunteer informal	Pilot KETs	high



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	location and skills relevant for providing care support. (see also Req_53 in D2.13)			caregivers with information on time, location and skills are available and manageable through GK-enabled applications		
Req_AP_46	GK-enabled applications shall enable end-users to request support (self-referral) concerning their physical limitations, temporary limitations related to self-isolation or other limitations related to condition management	functional	should	End-users can request support concerning their physical limitations, temporary limitations related to self-isolation or other limitations related to condition management	Pilot KETs	high
Req_AP_47	GK-enabled applications shall support communication aimed to specify the nature, time, details of requested support between patient and caregiver	functional	should	Patients and caregivers can exchange information on the nature, time and details of request support	Pilot KETs	high
Req_AP_48	GK-enabled applications should monitor patients through periodical questions concerning their wellbeing	non-functional	should	Patients are monitored through periodical questions	Pilot KETs	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				concerning their wellbeing		
Req_AP_49	GK-enabled applications should collect baseline information for each end-user at registration	functional	should	Collection of baseline information for each end-user is done at registration	Pilot KETs	high
Req_AP_50	GK-enabled applications should be able to adapt to different degrees of vulnerability	non-functional	should	End-users with different degrees of vulnerability can use the GK-enabled application easily	Pilot KETs	medium
Req_AP_51	Pilot KETs should support older patients independently taking correct medication	functional	should	Pilot KET monitors users' medication intake	Pilot KETs	medium
Req_AP_522	Optional free text addition for end-users and healthcare professionals (decided by the pilot) to accompany a measurement from a device/manual input	functional	should	End-users / healthcare professionals (decided by the pilot) can accompany a measurement from a device/manual input with free text	Pilot KETs	low
Req_AP_53	Enabled users must be able to invalidate a measurement (for future processing)	functional	should	Measurements can be invalidated by	Pilot KETs	low

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				healthcare professionals (or whoever pilot chooses)		
Req_AP_54	Authoring Tool users must be able to configure not only the data they want to visualise but also the graphics/charts in their dashboards. (see also Req_39 in D2.13)	functional	must	Data is available using the GK common data model. Data can be configured to be visualised at least in 2-3 different ways.	Authoring Tool	high
Req_AP_55	Authoring Tool users can configure thresholds for data in order to visualise a warning. (see also Req_45 in D2.13)	functional	must	At least one threshold (as minimum or maximum) can be defined related to a data and a RUC	Authoring Tool	high
Req_AP_56	Authoring Tool users can change language of the tools and dashboards (see also Req_40 in D2.13)	functional	must	English supported as main language. At least 1-2 additional languages supported based on pilot sites' countries.	Authoring Tool	high
Req_AP_57	The individual steps of the deployment process shall be idempotent to the greatest extent	functional	could	Any Individual step of the deployment	General	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	possible in the aim of <b>deployment automation</b> (see also Req_35 in D2.13)			process has no additional effect if called twice		
Req_AP_58	The individual steps of the deployment process shall be order-dependent in the aim of deployment automation (see also Req_35 in D2.13)	functional	could	Components and services do not crash in an uncontrolled way if some other component or service they are expecting is absent	General	high
Req_AP_59	An API that deployment scripts can use in the aim of deployment automation is offered. (see also Req_35 in D2.13)	functional	could	Deployment scripts can use the API offered	General	high
Req_AP_60	Use the same deployment process for every environment in the aim of deployment automation (see also Req_35 in D2.13)	functional	could	The same deployment process is used for every environment	General	high
Req_AP_61	Make it possible to recreate the state of any environment from information stored in version control in the aim of deployment automation (see also Req_35 in D2.13)	functional	could	Use retrieved stored information in version control to recreate the state of any environment	General	high
Req_AP_62	Use the same packages for every environment in the aim of deployment automation (see also Req_35 in D2.13)	functional	could	The same packages are used for every environment	General	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AP_63	Once the patient is logged, there should be the possibility to link <b>external accounts</b> (Withings, iHealth, Fitbit, etc) to Gatekeeper to authorise the retrieval of health data on their behalf.	functional	should	Access to possible external accounts to retrieve health data is feasible after logging.	Marketplace GTA Data Federation	medium
Req_AP_64	The Samsung Activage application must be able to send data stored the Samsung Health PHR into the GK Data Federation component. [source: Puglia Pilot]	functional	must	Data from Samsung Health PHR are correctly stored in the GK Data Federation component	Data Federation	high
Req_AP_65	The Samsung Activage application must be able to associate data sent into the GK Data Federation component to relevant patients without requiring the patient to open an account on Activage itself (similarly to Medisanté ELIOT Hub). [source: Puglia Pilot]		should	Data from Samsung Health PHR are stored in the GK Data Federation component correctly associated to the relevant patient even if the patient has no account on Activage	Data Federation	high

## 6.3 Privacy and security level

Copying from D3.1.1, the privacy and security level uses existing standards, technologies and governance models to ensure secure data exchange and the linking of such data to reliable ecosystems. To guarantee privacy, all data entering the platform should already be anonymised at pilot sites, while the platform will enforce and guarantee all GDPR constraints.

In the platform, security and privacy are managed centrally by the GATEKEEPER Trust Authority (GTA), providing, among other functionalities:

- authentication and authorisation within the platform based on specific rules in order to control and the access
- trustworthiness of the transactions within the data exchange, related to Things.

At infrastructure level, the GATEKEEPER Data Centre infrastructure provided by HPE will adopt a number of technologies, products and services that will address security and privacy issues, like the use of VPNs, firewalls and security services for encryption, and intrusion detection.

Privacy and security are therefore handled by:

- **GTA**, which has the task of certifying the Things of the GK platform. In addition, it is responsible for issuing digital certificates and using a distributed ledger so as to keep an audit trail of all transactions related to Things. The data flow up to the GTA is visualised in Figure 10. More details are available in D4.5.
- **GATEKEEPER Cloud Infrastructure**, the infrastructure hosting all GATEKEEPER components deployed in HPE Data Centre. More details are available in the context of T4.1.

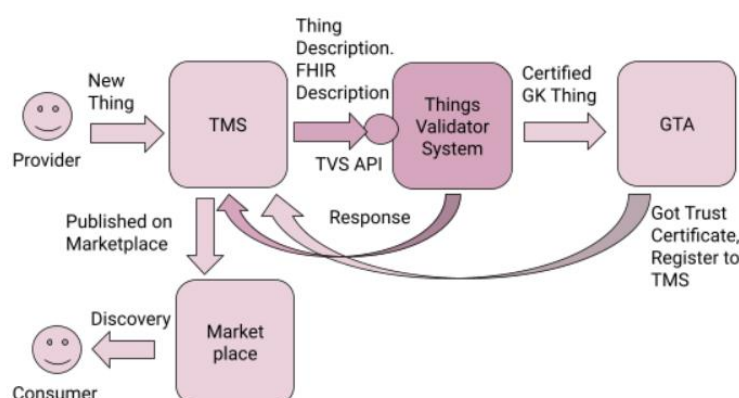


Figure 10 - Visualisation of the flow to and from the GTA (for automatic validations only)

Table 27: Privacy and security level requirements

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_PS_01	Authorisation of data and information generated (prevention from unauthorised access) should be managed by standards such as OAuth.	non-functional	must	Unauthorised access is prevented by the GK User Management module	medium
Req_PS_02	The use of information will be closely linked to identification mode – enabled users will only have access to the information they have been enabled for.	non-functional	must	User Management roles will describe the permissions to permit unauthorised access ensuring confidentiality	medium
Req_PS_03	The system must ensure adequate integrity of the acquired “Things” in terms of protection against possible damage	non-functional	must	GK Certification ensures that integrity of “Things” included in the Things Management System	medium
Req_PS_04	Ensure the confidentiality of the solution	non-functional	must	The User Management module will ensure the confidentiality of the GK platform	medium
Req_PS_05	The solution shall preserve anonymous data and respect data privacy	non-functional	must	GK Data Anonymisation services should be integrated to data collection points	high
Req_PS_06	The system should be managed by a User Management module to control access in UIs and services	functional	must	The Users of the system will be authenticated by the User Management module	medium
Req_PS_07	The system should respect the privacy and data protection of the users	non-functional	must	The system is compliant to privacy standards described in Section 6.9	medium

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_PS_08	Thing Descriptions should be validated in accordance with a set of compliance rules to avoid sharing Things with known vulnerabilities	non-functional	must	The Things Validator System will assess the content and scope of Things submitted to the system	high
Req_PS_09	Things should be certified by a Trusted Certificate Authority ensuring trust among Thing suppliers and Thing consumers	non-functional	must	Things receive certification if compliant with the specification framework of the Things Validator System.	high
Req_PS_10	All actions related to Things should be logged in an immutable way ensuring accountability (non-repudiation of actions from the part of the stakeholders)	non-functional	must	Blockchain mechanism of GTA tracks any action related to the certified Things in order to ensure that they remain immutable. System logs actions related to Thing lifecycle (register, access, share, delete).	high
Req_PS_11	Each certified Thing will have a conformance score in their basic specifications set	functional	must	The Things Validator System will assess the conformance of each Thing to the Interoperability guidelines of the GK platform. The ones above threshold will receive certification from the GTA.	medium
Req_PS_12	System certifies Things according to their conformance to the interoperability guidelines.	functional	must	Appropriate certificates are issued for Things encapsulating the validation scores	high



ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_PS_13	The Authoring tool will identify the link of the users registered in Data Federation	functional	must	Identity Management service will register a unique identification number for each user in data federation	high
Req_PS_14	The user has the right to be informed, so long terms and conditions, of the user's consent should be provided in a human-readable information, GDPR articles 6 and 7.	non-functional	must	As a user, the information is easily accessible through the pilot interfaces.	low
Req_PS_15	The information to the user must be concise, transparent, intelligible, and easily accessible form, using clear and plain language, GDPR article 12.	non-functional	must	As a user, the information is preserved by Data privacy policy in data collection systems	medium
Req_PS_16	The user should be able to see all the data that each of his providers have about him, GDPR article 15.	functional	must	As a user, personal data must be shared based on consent mechanism	medium
Req_PS_17	The user can get his personal data fixed, GDPR article 16.	functional	must	As a user, personal data can be modified	high
Req_PS_18	The user has the right to erasure that is to be deleted from the system, GDPR article 17. (see also Req_UI_15)	non-functional	must	As a user, their data can be deleted	medium
Req_PS_19	The user has the right to restriction of processing, that means the provider will keep the user's data, but cannot use it for other purposes as stated in the consent without further consent of him, GDPR article 18.	non-functional	must	As a user, the use of personal information can be restricted	medium

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_PS_20	The user must be able to export her/his data in a machine-readable format, GDPR article 20.	functional	must	As a user, data can be exported	high
Req_PS_21	Breach notification the supervisory authority within 72 hours after becoming aware of the data breach to make the report to the supervisory authority, GDPR article 33, and in some cases the user, GDPR article 34.	non-functional	must	A notification is sent to all affected users within 72 hours of data breach detection	low
Req_PS_22	The data must have ensured validity. Stored data must not have duplicates and invalid data is not able to damage the system nor its function.	functional	must	Invalid Data sent is always discarded, only valid data (correct and useful) is stored in the system	medium
Req_PS_23	The system must display resilience property. System resilience is an ability of the system to withstand a major disruption within acceptable degradation parameters and to recover within an acceptable time.	functional	should	When the system is overloaded or under attack it should always provide the minimal set of functionalities and recover within an acceptable time.	high
Req_PS_24	The system must support anonymisation of Datasets produced by Pilot experiments and stored in the GK Data Federation component, so that they can be shared with the scientific community according to both GDPR requirements and FAIR principles, for conducting further research on AI models.	functional	should	Anonymised Pilot experiment datasets shared in the GK Data Federation component according to FAIR principles, to conduct AI models' investigations	high

## 6.4 Data abstraction and semantic interoperability level

As described in D3.1.1, Data abstraction level is the first of three tasks linked to the **data federation process**: responsible to integrate and federate data coming from the different sources. In GATEKEEPER health data entering the platform will be translated in a common GATEKEEPER FHIR Profile, so they will be interoperable.

The approach of GATEKEEPER is to address interoperability in a flexible way by using Web of Things standard, JSON-LD contexts and FHIR services and profiles.

Semantics is the study of meaning, and semantic interoperability is about ensuring that the producers and consumers of data have a common understanding of the data they exchange. Traditionally, the meaning is implicit in the documentation and the software used by producers and consumers. This is no longer adequate in dynamic systems with large numbers of changing producers and consumers. Moreover, producers and consumers will not *a priori* know each other, and data may be used for completely new purposes.

The solution to this challenge is to make the semantics explicit by annotating the data with its intended meaning. The terms used for this must be agreed upon, and the concepts, properties and relationships can be formalised as ontologies. Semantic interoperability is thus about exchanging information on the basis of agreed, formalised and explicit semantics. This is also valuable for directories of services, enabling new services to be designed safely in the knowledge that the underlying services will work as described.

Modular ontologies are key to the ability to update the semantics as needs continue to evolve. In larger ecosystems, it may become necessary to integrate services developed using different ontologies. In such cases, it may be practical to relate the definitions via reference to a shared “upper ontology” defining the underlying concepts. In other cases, peer to peer mappings may be needed, and can be context dependent, for instance, dependent on the values of data and metadata.

Robust operation of information systems that exchange data depends on the data and associated metadata conforming to the agreed data models and ontologies. Ideally, this can be dynamically checked at run-time. In addition, agreements should be non-repudiable. This points to opportunities for exploiting W3C’s standards for ontologies (OWL), graph constraints (SHACL) and XML schema and JSON schema for data validation.

The GATEKEEPER semantic interoperability layer will be based on:

- **The Web of Things – Thing Description (TD):** the TD will promote a standard and interoperable way for describing the interfaces of a service, a device, a dataset (in general a GATEKEEPER Thing). The TD can be seen as the entry point for accessing a thing like the index.html page on the Web. A Thing Description describes the metadata and interfaces of Things, where a Thing is an abstraction of a physical or virtual entity that provides interactions to and participates in the Web of Things. Thing Descriptions provide a set of interactions based on a small vocabulary that makes it possible both to integrate diverse devices and to allow diverse applications to interoperate. Thing Descriptions, by default, are encoded in a JSON format that also allows JSON-LD processing. The latter provides a powerful foundation to represent knowledge about Things in a machine-understandable way. A Thing Description instance can be hosted by the Thing itself or hosted externally when a Thing has resource restrictions (e.g.,

limited memory space) or when a Web of Things-compatible legacy device is retrofitted with a Thing Description<sup>7</sup>.

- **JSON-LD contexts:** JSON-LD will be used in GATEKEEPER in order to add semantic to the data that are used in the interfaces described in the Thing Description of a GATEKEEPER thing. JSON-LD is a standard that describes a JSON-based format to serialize Linked Data (LD). The syntax is designed to easily integrate into deployed systems that already use JSON, and provides a smooth upgrade path from JSON to JSON-LD. It is primarily intended to be a way to use Linked Data in Web-based programming environments, to build interoperable Web services, and to store Linked Data in JSON-based storage engines<sup>8</sup>. In JSON-LD it is possible to link data with common vocabularies that can refer to ontologies.

Simply speaking, a context is used to map terms to Internationalized Resource Identifiers (IRIs). IRIs are used for the identification of metadata and for enabling the semantic web<sup>9</sup>. The Semantic Web is an extension of the World Wide Web through standards set by the World Wide Web Consortium (W3C). The goal of the Semantic Web is to make Internet data machine-readable. To enable the encoding of semantics with the data, technologies such as Resource Description Framework (RDF) and Web Ontology Language (OWL) are used.<sup>10</sup>

- **FHIR services and profiles:** FHIR will be the standards that will be used in GATEKEEPER to model the healthcare domain common to every pilot site. Fast Healthcare Interoperability Resources (FHIR) is a standard for exchanging healthcare information electronically. FHIR also defines a set of REST-APIs that are used for exchanging the resources.<sup>11</sup> FHIR also supports RDF format<sup>12</sup> that means FHIR resources can be linked in JSON-LD contexts that can be referenced in Thing Description also with other additional contexts.

Within GATEKEEPER we will certify through a Certification Authority different level of interoperability. In this way we will allow to every provider to join the GATEKEEPER ecosystem certifying the asset that he is bringing into the platform. For instance, if the provider is only providing a Thing Description without any JSON-LD context information, he will have a lower level of certification than another provider that is also providing semantic information with LD contexts.

From a more functional perspective, through the use of mapping processes, health data are all represented in a common **GATEKEEPER FHIR Profile**. Such a profile is being defined in the project to be capable to represent all the concepts that pilots need in order to fulfil their goals.

Following the information flow that leads the data into the platform, entry points for data are smart Devices or services registered as Things, Connectors that mediate the connection of Devices that cannot be registered directly to the platform (for example because they support different connection protocols like Bluetooth) or retrieval from configured EHRs.

Such a variety of data are transformed by the GK-IntegrationEngine in the GATEKEEPER FHIR Data Profile through the application of **semantic models** and are made available to the rest of the GATEKEEPER Platform and all Things authorised to access them. Correlation of such data with external sources is also offered by the **Big Data Infrastructure** services.

<sup>7</sup> Web of Things – Thing Description, <https://www.w3.org/TR/wot-thing-description/> , Last access September 2020.

<sup>8</sup> JSON-LD, <https://www.w3.org/TR/json-ld11/> , Last access September 2020.

<sup>9</sup> JSON-LD context, <https://www.w3.org/TR/json-ld11/#the-context> , Last access September 2020.

<sup>10</sup> Semantic Web, [https://en.wikipedia.org/wiki/Semantic\\_Web](https://en.wikipedia.org/wiki/Semantic_Web) , Last access September 2020.

<sup>11</sup> FHIR, <https://www.hl7.org/fhir/overview.html> , Last access September 2020.

<sup>12</sup> FHIR RDF, <https://www.hl7.org/fhir/rdf.html> , Last access September 2020.

Regarding the related reference components of the GATEKEEPER platform, as they are presented in D3.2.2:

- All connectors registered to GATEKEEPER Platform send health data to the **GATEKEEPER Data Federation** component in the original producer format. It is the responsibility of this component to translate it to the common GATEKEEPER data format, that is the GATEKEEPER FHIR Profile, and store it in the Platform's FHIR Server, so to ensure semantic interoperability.
- Data are also forwarded to the **Big Data Infrastructure**, that offers Big Data analysis services, and can combine data from the Data Federation to external data sources. Among other functionalities, it offers:
  - *data connectors*, responsible to gather data from multiple sources
  - *data lake* integrates the storage systems where multiple data sets are stored, in different data formats.

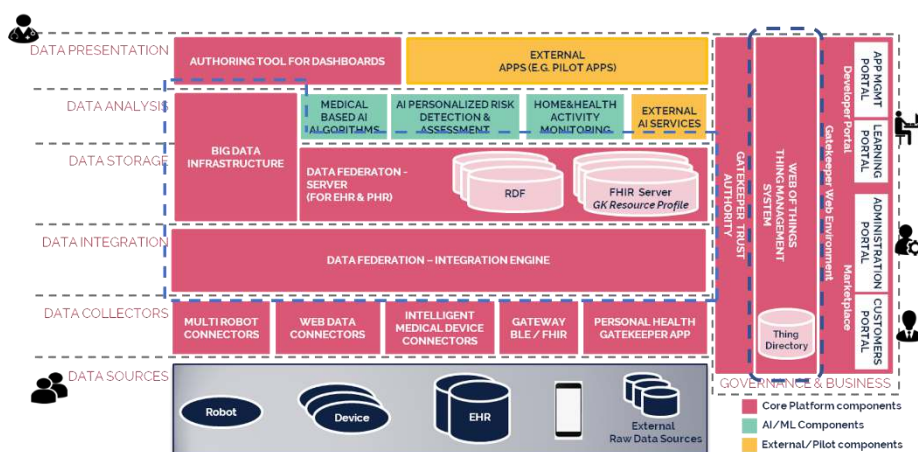


Figure 11 - Data abstraction in the architecture

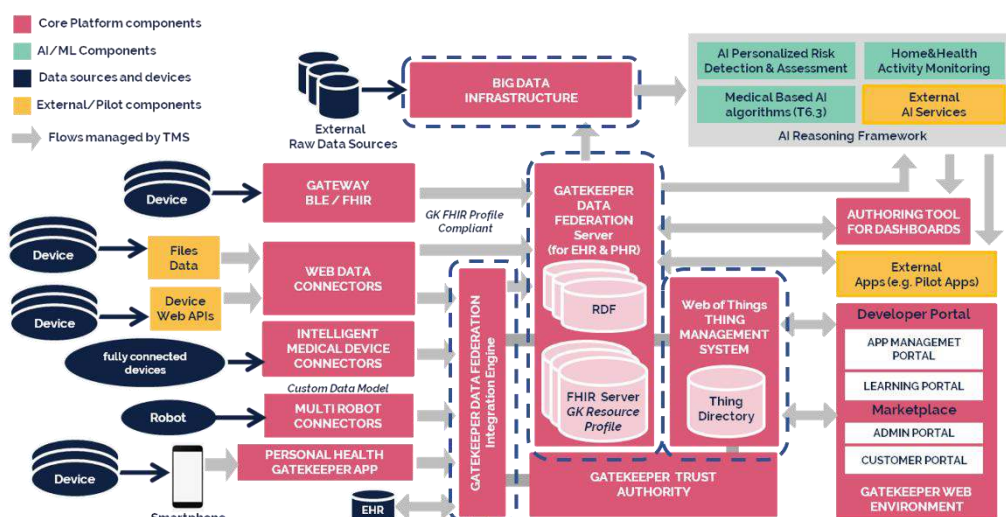


Figure 12 - Data abstraction in the architecture focusing on interactions among the components

Table 28: Data abstraction and semantic interoperability level requirements

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_DA_01	Data gathered must be able to be fed into the legacy health and care records (integrated health & social care) of the pilot sites.	functional	must	Legacy health and care records can receive data gathered from the pilot sites.	Pilot KETs	medium
Req_DA_02	Data should link to EHR/EMR record	functional	should	Data links to EHR/EMR record so that healthcare professionals can view activity, plus gather info on hospital admissions etc.	Pilot KETs	high
Req_DA_03	Every Gatekeeper Thing and component needs to provide a Web of Things - Thing Description TD.	non-functional	must	All Gatekeeper Things and components provide WoT - TD.	General	medium
Req_DA_04	A Thing Description can link the semantics of data using JSON-LD WoT context.	non-functional	must	Thing Descriptions link the semantics of data using JSON-LD WoT context.	General	medium
Req_DA_05	Additional JSON-LD context is optional in the Thing Description.	non-functional	should	Thing Descriptors can optionally contain JSON-LD contexts other than WoT context.	General	medium
Req_DA_06	In order for FHIR resources to be compliant with GATEKEEPER, they must be based on GATEKEEPER FHIR profiles.	non-functional	must	FHIR resources compliant with GATEKEEPER must be based on GATEKEEPER FHIR profiles.	General	medium
Req_DA_07	Use RDF, SPARQL (including	functional	should	Accessing the data in RDF by	General	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	query API) (see also Req_32 in D2.13)			means of SPARQL query is possible		
Req_DA_08	Agreements on data models and semantics must be non-repudiable	non-functional	must	Examine if agreements on data models and semantics are non-repudiable	General	medium
Req_DA_09	Thing Descriptions must be validated, giving feedback for warnings and errors.	functional	must	Thing Descriptions are validated	Things Validator System	high
Req_DA_10	Data and associated metadata must be validated in terms of data type to ensure robust operation of information systems	non-functional	must	Data and associated metadata are validated against the data types	Things Validator System	medium
Req_DA_11	Data from heterogeneous (pilot) data sources (e.g. EHR data and/or IoT data) must be converted to be compliant with the GATEKEEPER FHIR profile	functional	must	Data from heterogeneous (pilot) data sources are compliant with the GATEKEEPER FHIR profile when stored in the Platform's FHIR server	Pilot KETs	low
Req_DA_12	GK FHIR profile is capable of converting between several different syntaxes (e.g. JSON-LD, RDF/XML, RDF-Turtle) to support the possibility to associate converters to new data sources	functional	must	GK FHIR-compliant data is available in several syntaxes (e.g. JSON, RDF)	General	medium
Req_DA_13	The system shall unify the data that may be used for predictive	functional	must	The data to be used for predictive models is unified	Data Federation	high



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	models (source: Aragon pilot)					
Req_DA_14	Questions answered across pilots must be supported by appropriate semantic maps	functional	must	Semantic maps across FHIR resources support questions answered across pilots	General	medium
Req_DA_15	FHIR resources where appropriate should be aligned across pilots	non-functional	must	Interoperability of FHIR resources implemented in different pilots	Pilot KETs	high
Req_DA_16	Semantic Lists (drop downs) when necessary should be mapped across pilots and relate well-known terminology standards	non-functional	should	Semantic lists are mapped across pilots and related with appropriate well-known lists and terminologies	Pilot KETs	high
Req_DA_17	A catalogue of Gatekeeper Things should be available along with semantic tags and supported FHIR resources	non-functional	should	Find the Things implemented and the FHIR resources	Pilot KETs	medium
Req_DA_18	Health Data sets collected in Gatekeeper pilots should be FAIR with respect to metadata	functional	should	FAIR compliant metadata should be associated with data collected in GK pilots	Pilot KETs	medium
Req_DA_19	The model will be continuously enriched with new entities when the interfaces of the components will be further defined. Preferable use of FHIR+SAREF standards.	non-functional	should	The system, and message, data model can be expanded with new entities. Preferably using FHIR+SAREF standards.	General	medium



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_DA_20	Contexts must be validated, to be resilient (syntactically), and to have sense (semantically)	functional	must	Syntactically invalid data (e.g.: wrong JSON format) is discarded. Semantically invalid data (e.g.: defining an instance of an inexistent class) is discarded.	General	medium
Req_DA_21	Vocabularies are versioned while evolving in response to changing needs.	non-functional	must	Both legacy and new services continue to work across different versions of vocabulary.	Data Federation	medium
Req_DA_22	Incremental extensions to vocabularies are possible.	non-functional	should	Incremental extensions do not break legacy service or, if they do, data and metadata are mapped between different versions.	Data Federation	high
Req_DA_23	Performing queries on time intervals (start date – end date) based on the creation date of each entry type compliant to FHIR format	functional	should	The result of the query contains only entries included in the specified time interval compliant to FHIR format.	Data Federation	medium
Req_DA_24	The GK Data Federation component must be able to receive data pushed by the CSS EMRs and eCRFs. [source: Puglia Pilot]	functional	must	Data from CSS EMRs and eCRFs are correctly stored in the GK Data Federation component	Data Federation	high
Req_DA_25	COVID-19 survey results should be integrated to the GK data	non-functional	should	The GK data model includes the COVID-19 survey results.	Data Federation	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	model.					

## 6.5 Data storage level

As was explained in D3.1.1, data in GATEKEEPER are stored in different components based on their nature.

The main type of data handled by the platform is health-related data. In GATEKEEPER Platform they will be stored mainly through the **Data Federation** where data, after being transformed in the common GK FHIR format, are retained to be processed by the analytics services or visualised by authorised users. To ease the reasoning service's needs, data will be also made available in RDF syntax. When big data analysis is needed, data will also reside in the **Big Data Infrastructure**, that will use stored data for mapping and advanced analytics, possibly combining them with external sources.

Other types of data that will be stored in the GATEKEEPER Platform, and in the Thing Directory in particular, are the **Thing Descriptions** of all Things registered, that are used by the Thing Management System to manage access to the devices and services exposed as Things, as well as the **certificates** guaranteeing the Trustability of Things.

All data concerning users, authentication and authorisation are stored in the GTA.

From a physical point of view, in GATEKEEPER, the Platform will be hosted in a dedicated cloud environment provided in HPE Data Centre and located in Europe. Nevertheless, to fulfil the different pilot requirements and as a mitigation plan for the delay in the Gatekeeper infrastructure developments, some alternative deployments have been identified and will be supported. The different deployment options are also depicted in Figure 13.

Details on such alternatives can be found in D3.2.2, but they can be summarised in the following list, where we give some information on the impact on storage of data.

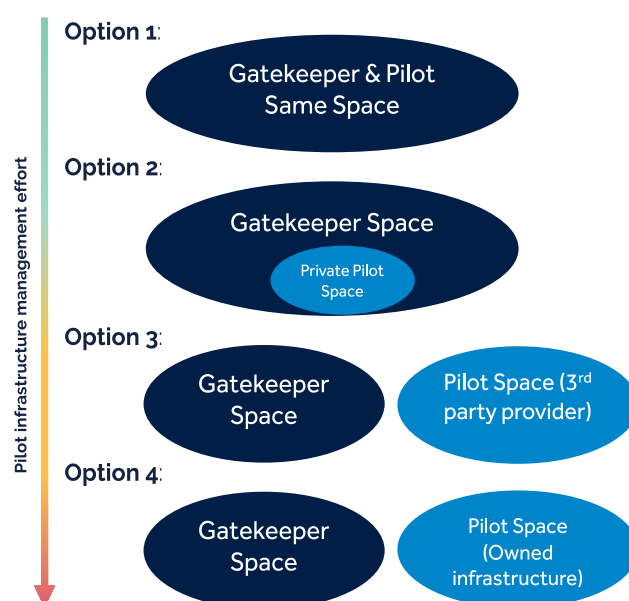


Figure 13 - Pilot deployment options

1. GK Platform is deployed on GK Cloud

All main components of the platform are hosted in GK cloud at HPE data centre in a single reference tenant and connect to pilot sites to fetch data and provide results.

Security, updates, maintenance, separation of data and multitenancy can be managed centrally.

2. Pilots own a private space on GK Cloud and share some data with GK Platform

Private storage spaces are provided in dedicated private “*pilot cloud tenants*”, while the GK Platform remains centralised. The interaction of the pilot systems with the GK Platform for services happens within GK Cloud.

3. Pilots manage a private copy of the GK platform within GK Cloud Infrastructure

This option implies the creation of separated “*pilot cloud tenants*” where the whole platform (storage and computing services) is replicated.

4. Pilots install an instance of GK Platform on their own premises

For those pilots who need that their data do not leave the pilot premises, the GATEKEEPER Platform can be deployed locally.

As already mentioned in D3.1.1, components offering storage capabilities in the GATEKEEPER Platform are the following:

- **Data Federation:** after a preliminary conversion step to the GK FHIR profile, data are routed to a FHIR server (distinct FHIR server will be made available to each pilot). A representation of data in RDF is also made available exploiting a graph database.
- **BigDataInfrastructureService**, which is based on several components:
  - *data connectors*, responsible to gather data from multiple sources
  - *data lake*, that integrates the storage systems where multiple data sets are stored, in different data formats.
  - *execution engine*, responsible for accessing, searching and analysing large amount of data in parallel
  - *advanced analytics*, concerning functionality provided by data science
  - *frameworks, tools etc.*
  - *visualisation and RT search block*, that has the task of providing quick access, show data or insights.
  - *administration, orchestration, and data governance*, horizontal specific functionalities for the data platform in order to manage, perform, monitor data or resources.
  - *data security*, which concerns all the security aspects through the data platform
  - *auditing*
- **Thing Directory:** responsible for storing all Things Descriptions registered in the platform
- **GATEKEEPER Trust Authority:** holding the user-related data

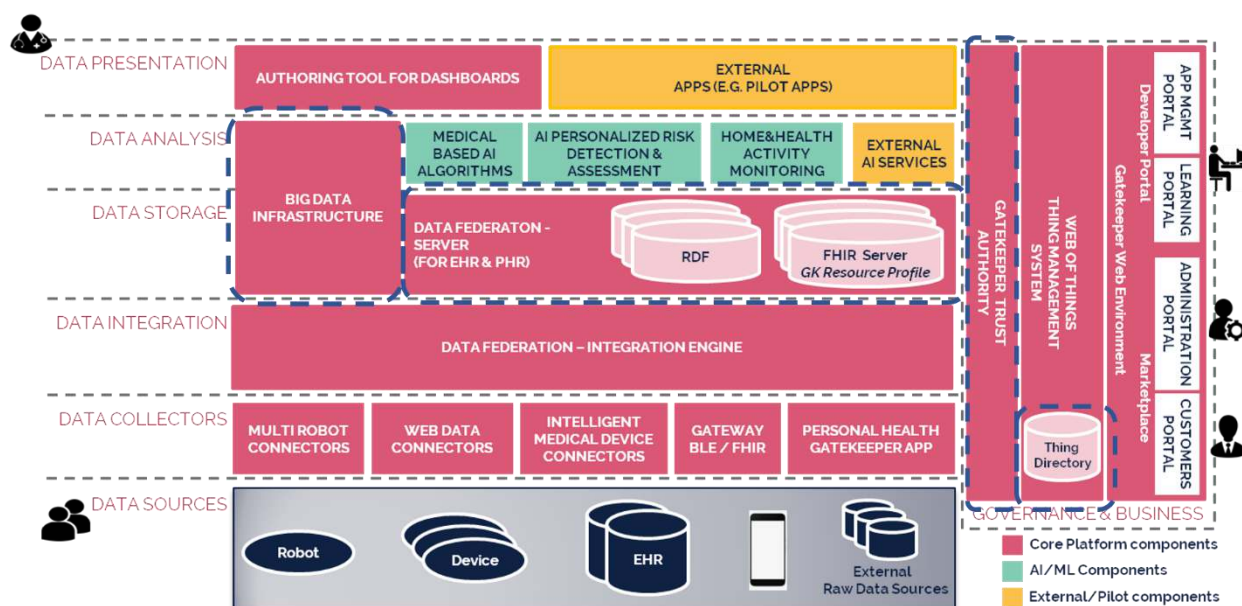


Figure 14 – Components offering storage capabilities

Table 29: Data storage level requirements

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_DS_01	The data produced by IoT sensors must be stored in local premises or in the HPE data centre. However, IoT sensors will not directly connect to HPE data centre, but instead Pilots will collect them, sanitise then send to HPE data centre (see Req_DS_02 and Req_DS_03 below).	functional	must	The data produced by IoT sensors is stored in local premises or in the HPE data centre	medium
Req_DS_02	GATEKEEPER Pilots data must be properly sanitised before being hosted on the Cloud platform provided by HPE	non-functional	must	Only sanitised data is transferred	medium
Req_DS_03	Data must be transferred to GATEKEEPER Cloud platform provided by HPE from pilot applications/services/infrastructures mediating end-user data collection. Data transfer will not be accepted on a by user basis directly on the GK Cloud platform, but only via Pilots collection and aggregation points.	non-functional	must	Access control and data flows to HPE data centre are restricted to appropriate actors.	low
Req_DS_04	Data stored at rest on GATEKEEPER Cloud platform provided by HPE must be stored on encrypted disks	non-functional	must	Check cloud storage encryption of received data at disk-level	low
Req_DS_05	The pilot data produced by IoT sensors, once converted to GK FHIR profile, must be stored in the FHIR server (of that pilot)	non-functional	must	Data produced by IoT sensors are stored in the FHIR server (of that pilot)	medium
Req_DS_06	The pilot data produced by local health information systems (e.g. EHR), once converted to GK FHIR profile, must be stored in the FHIR server (of that pilot)	non-functional	must	Pilot data produced by local health information systems are stored in the FHIR server (of that pilot)	medium

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_DS_07	Each (pilot-specific) FHIR server can be deployed in different ways: e.g. locally in the default GK platform tenant (HPE premise), in a different tenant of the same GK platform (HPE premise) or even in a pilot remote node (pilot premise)	non-functional	should	A platform should be able to handle at least these three types of FHIR server deployment	medium
Req_DS_08	The access to data held in the FHIR server(s) will be under authorisation control of GTA	non-functional	must	Access to data held in the FHIR server(s) is under authorisation control of GTA	medium
Req_DS_09	The HPE Cloud infrastructure will provide encryption capability so that data held in FHIR server(s) are automatically encrypted	functional	must	Data held in FHIR server(s) are automatically encrypted	medium
Req_DS_10	The Gatekeeper Data Centre infrastructure supports high resilience.	non-functional	should	All devices and services have scheduled backup and physical devices are monitored for hardware fault.	medium
Req_DS_11	The COVID-19 survey application should be deployed in GK Cloud.	non-functional	should	HPE infrastructure is the deployment option for the COVID-19 survey standalone application.	medium

## 6.6 Network level

As explained in D3.2.2, data sources produce data that enter the platform through connectors, including the reference component Intelligent Connectors and IoT Connectors (T5.5), that differentiate themselves on the type of devices and protocols they can interact with:

- **IoT Connectors, Gateway** for Standard BLE Health profiles for Bluetooth devices to Gatekeeper FHIR profiles (Figure 15);
- **IoT Connectors, Web Data Collector** for accessing online data files (Figure 16) or Web based APIs (Figure 17) from device vendors;
- **Intelligent medical device connectors** to manage fully connected devices in event-based mode (Figure 18);
- **Multi Robot Connectors** (T5.6) to access data from robot sensors, involving a custom data model;
- **Personal Health GATEKEEPER App**, an extension of Samsung Health App that allows the GATEKEEPER Platform to interact with the devices integrated within Samsung Health ecosystem, and more.

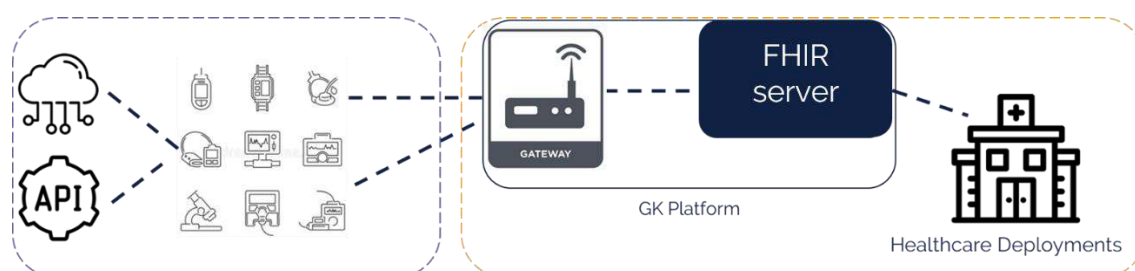


Figure 15 - IoT connectors, Gateway

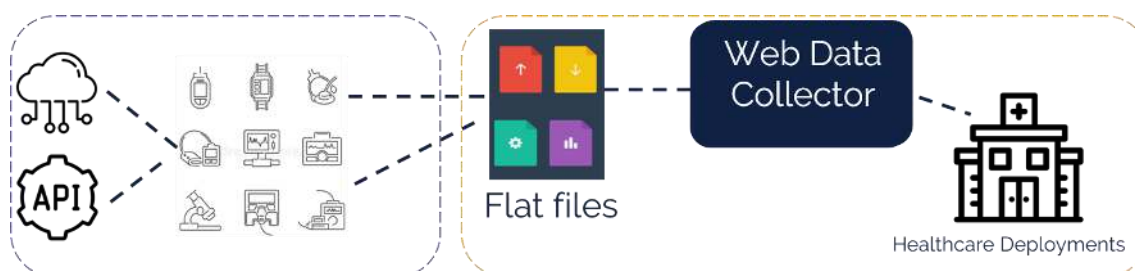


Figure 16 – IoT Connectors, Web Data Collector – Flat Files

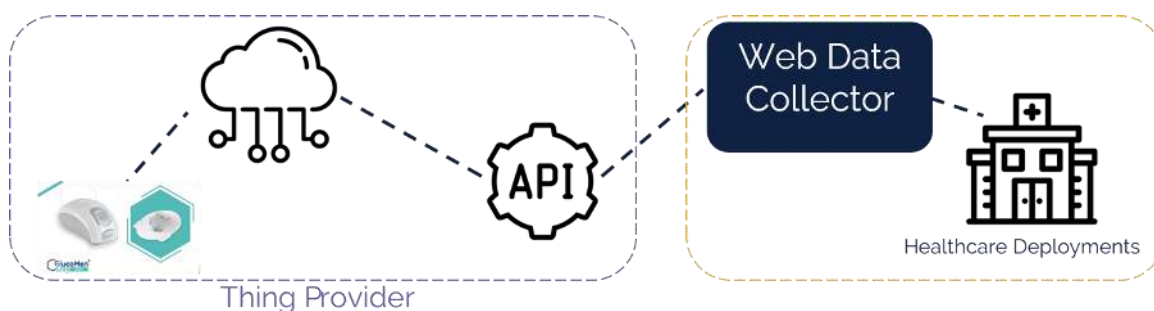


Figure 17 - IoT Connectors, Web Data Collector – Third party APIs



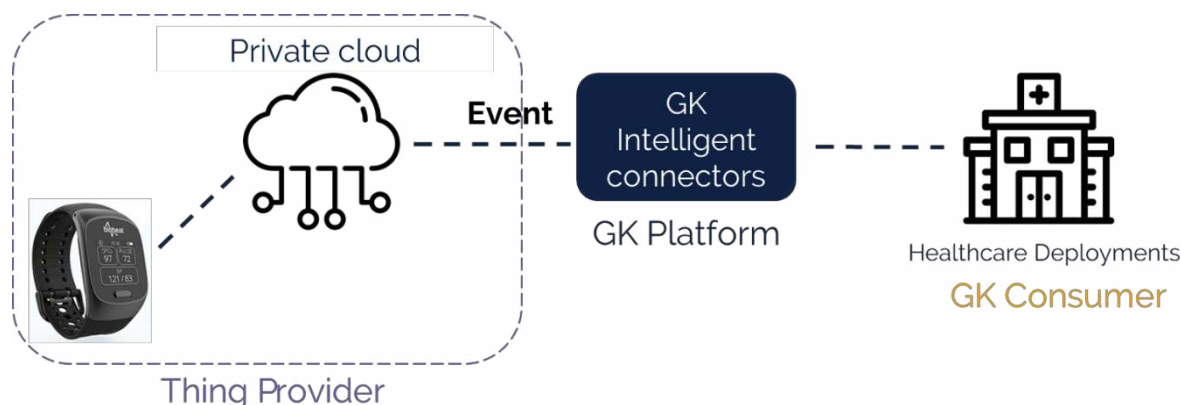


Figure 18 - Intelligent medical device connectors

The nature of GATEKEEPER Platform, following the Web of Things approach, allows to easily extend this set of connectors, yet guaranteeing a high level of assurance in the quality and security of the plugged components, to be able to process virtually all devices a customer might need.

Meanwhile, the Things Management System (T4.2) acts as a central gateway that coordinates all incoming and outgoing communications.

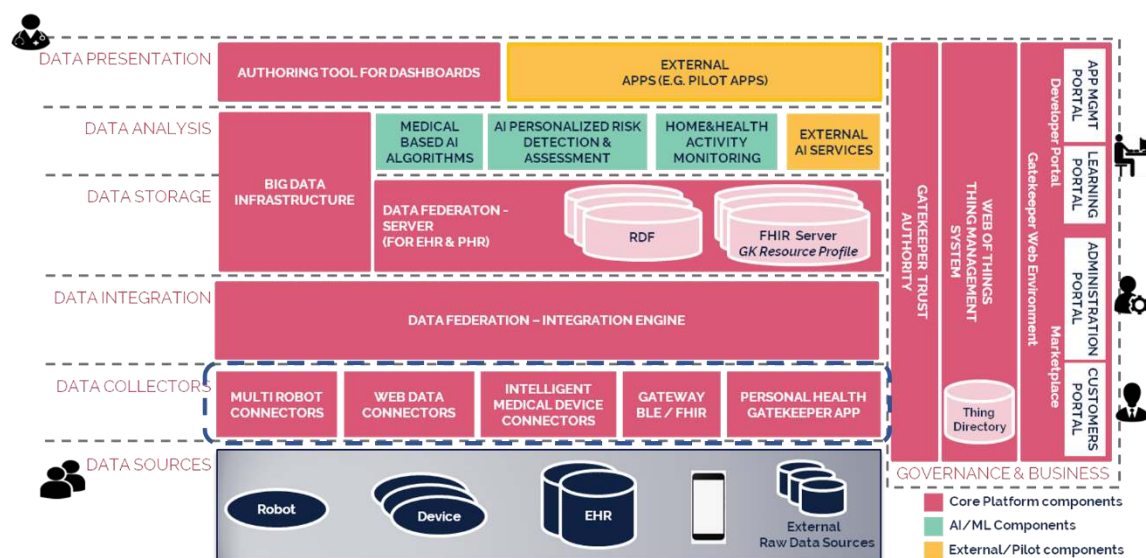


Figure 19 - Connectors in the architecture

Table 30: Network level requirements

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_NT_01	Pilot participants will need mobile data/WiFi access on devices to link, to watch, and also externally to log into GK-enabled platforms.	functional	must	Pilot participants successfully use GK-enabled platforms through mobile data/WiFi.	low
Req_NT_02	Pilot infrastructures must connect on behalf of end-users to HPE data centre to transfer data. Connections happen via point-to-point secure virtual private networks (VPNs)	functional	must	Access control and data flows to HPE data centre.	low
Req_NT_03	Connections to HPE data centre must use an encrypted protocol (e.g. HTTPS) to secure data transfer in transit	non-functional	must	Data flows to HPE data centre uses encrypted channels only.	medium
Req_NT_04	Access to HPE data centre must be strictly controlled by using VPNs, secure channels and user authentication and authorisation.	non-functional	must	Access to HPE data centre is not public and happens via secure mechanisms.	low
Req_NT_05	Devices and solutions registered as Things in the platform must support HTTP Protocol communications	functional	must	All devices and solutions in the platform support HTTP.	low
Req_NT_06	In the aim of pseudo-anonymisation of the system bounds, the device data payload shall not contain patient-identifiable data, such as: geolocation, name, address, patient ID,	non-functional	must	The device data payload does not contain patient-identifiable data	medium

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
	hospital number, ward details, contact details, user details				
Req_NT_07	Intelligent Connectors provide an API for external connectivity	functional	could	Intelligent Connectors provide a public pull-based and a push-based API	medium
Req_NT_08	Intelligent Connectors should translate device data schemas to HL7/FHIR format	functional	should	Intelligent Connectors reformat raw device data containing measurements	medium
Req_NT_09	Devices can be integrated with the platform directly through Intelligent Connectors if the cloud components to push data are provided by the device manufacturer.	functional	must	Open specifications with which a device manufacturer can push data within the platform are provided.	low
Req_NT_10	Devices based on Continua Design guidelines <sup>13</sup> can be integrated into the system.	functional	must	A configurable hardware gateway that connects devices based on Continua Design	high

<sup>13</sup> "CONTINUA DESIGN GUIDELINES", Personal Connected Health Alliance, 2021. [Online]. Available: <https://www.pchalliance.org/continua-design-guidelines>. [Accessed: 9- Mar- 2021].

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
				guidelines is available.	
Req_NT_11	BLE devices compliant with IEEE 11073 family standards <sup>14</sup> can be integrated into the system.	functional	must	An Android Gateway and SDK in order to connect with BLE devices compliant with IEEE 11073 family standards are available.	high
Req_NT_12	Google Fit <sup>15</sup> -compliant devices and can be integrated into the system.	functional	must	An Android Gateway and SDK in order to connect with Google Fit-compliant devices are available.	high
Req_NT_13	HealthKit <sup>16</sup> -compliant devices can be integrated into the system.	functional	must	An iOS Gateway and SDK in order to connect with HealthKit-compliant devices are available.	high
Req_NT_14	Devices by device manufacturers outside the	functional	must	Integration of	high

<sup>14</sup> "ISO/IEEE 11073-10418:2014", ISO, 2021. [Online]. Available: <https://www.iso.org/standard/61897.html>. [Accessed: 12- Mar- 2021].

<sup>15</sup> Google Fit. Google, 2014.

<sup>16</sup> HealthKit, Apple Inc., 2014.

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
	Gatekeeper consortium can be integrated with the platform through third-party APIs, a gateway or flat files and then the Intelligent Connectors.			devices by device manufacturers outside the Gatekeeper consortium is possible through either of the three options presented (see fit criteria for Req_NT_10, Req_NT_11, Req_NT_12, Req_NT_13 as examples).	

## 6.7 Devices, sensors and physical level

As presented in D3.1.1, in GATEKEEPER, each pilot site will decide on the devices to be used for its users for every reference use case (RUC) studied. The consortium partners have included their own technologies in a catalogue and those developed by non-members will be acquired through open calls. The envisioned devices and sensors based on D6.1, taking into account also section 5.2 of this deliverable, are:

- Wearables/medical devices, intended to monitor and track key variables such as physical activity, blood pressure, weight or real-time adherence to treatment (RUC#1 - Basque country, Greece, Poland).
- Home sensors/robots, to explore the citizen's home for risks while collecting information on daily activities and potentially providing some direct support (RUC#1 - Milton Keynes)
- Wearables/medical devices, intended to monitor and track key variables such as physical activity, oxygen saturation, blood pressure, heart rate or SpO2 (RUC#2)
- Wearables/medical devices, intended to monitor and track key variables including: glucose levels; physical activity; sleep pattern; blood pressure; weight and body composition; and adherence to treatment with electronic pillboxes (RUC#3)
- Continuous Glucose Monitoring system (RUC#3 - Greece)
- Devices/wearables to measure blood pressure and sleep patterns (RUC#4)
- Wearables/medical devices, intended to monitor and track key variables such as physical activity, weight, blood pressure, heart rate or SpO2 (RUC#5)
- Physical activity monitor devices/wearables (RUC#6)
- Wearables/medical devices, intended to monitor and track key variables such as drug adherence, physical activity, falls, sleep patterns, pain, oxygen saturation, blood pressure, heart rate or SpO2 (all sites) (RUC#7)
- Home sensors/robots permanently assessing the house for risks, learning the position of objects of daily use and monitoring the activities of the patient, suggesting activities, and, when needed, requesting telepresence support (Milton Keynes) (RUC#7)

As far as connectivity is concerned, the devices selected will be connected mostly via Bluetooth. Z-Wave, WiFi, 3G/4G cellular networks and USB cables are alternative connectivity options.

Special reference should be made to medical-grade devices. Devices of medical grade are certified to provide clinically actionable data. As described in D3.3, there are four broad classes ranging from low to high risk (Class I, Class IIa, Class IIb and Class III). The classification of medical devices is 'risk-based'. It takes into account the vulnerability of the human body and considers the potential risks associated with the devices. Further background is available in the Guidance document – classification of medical devices (MEDDEV)<sup>17</sup>. The pilots in GATEKEEPER will use either consumer or medical grade devices.

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<sup>17</sup> EUROPEAN COMMISSION DG HEALTH AND CONSUMER Directorate B, Unit B2 "Cosmetics and medical devices", 2007. *MEDICAL DEVICES: Guidance Document - Classification Of Medical Devices*.

As yet, the pilots foresee little need for actuators. It should be noted that actuator use for medical purposes has regulatory implications both for the design and conduct of pilots, leading to higher costs, longer audits and extra documentation requirements.

This section includes requirements for devices and sensors in the following order:

1. general requirements from a technical standpoint (integrability, extensibility) (Req\_DSP\_01- Req\_DSP\_05)
2. ease of use and accessibility (Req\_DSP\_06-Req\_DSP\_13)
3. medical device specification for high-risk patients (should) (Req\_DSP\_14)
4. device-specific requirements (Req\_DSP\_15-Req\_DSP\_20)

Table 31: Devices, sensors and physical level requirements

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_DSP_01	The device can send data to a central cloud space through standardised protocols or directly to an app through HL7/FHIR models (such as lightweight FHIR of T3.5)	functional	must	The device can successfully save its measurements on the cloud following the protocols and synchronise with a connected application through HL7/FHIR.	high
Req_DSP_02	Devices by device manufacturers inside the Gatekeeper consortium can be integrated with the platform directly through the Intelligent Connectors or IoT Connectors. (see Req_NT_09)	functional	must	Device manufacturers inside the Gatekeeper consortium follow the Req_NT_09 approach.	high
Req_DSP_03	An open API and/or SDK is available for the devices so that connection with Intelligent Connectors is possible. (see Req_NT_14)	functional	should	Devices can connect with Intelligent Connectors through API/SDK.	high
Req_DSP_04	Devices and their data flows can be integrated into the current regional systems e.g. the HL7 Electronic Health Record in Aragon	functional	could	Integration of the devices and their data flows into current regional systems according to regional systems' specifications	high
Req_DSP_05	Devices and integrated platforms should allow their own extension with other components (new sensors, new connectors etc) without a need for adaptation	non-functional	should	New hardware and/or software components can be added to devices and integrated platforms without a need for adaptation	medium
Req_DSP_06	Data collection from a device is as	non-functional	could	No change to the daily	medium



ID	Description	Requirement type	Priority	Fit criterion	Difficulty
	"transparent" and unobtrusive to the patient as possible (i.e. no need for user intervention).			living habits of the user required for the device to function properly.	
Req_DSP_07	Instructions to Pilot KETs, provided by the Pilot KET manufacturer or by the pilot partners, should be in the native language of the patient/caregiver/healthcare professional.	non-functional	should	Usage instructions to Pilot KETs are in the native language of the patient/caregiver/healthcare professional	low
Req_DSP_08	The devices should be easy to use by users with low digital literacy. (see also Req_UI_03 and Req_13 in D2.13)	non-functional	should	Devices with interfaces as in Req_UI_03 and/or physical buttons.	medium
Req_DSP_09	It could be possible for patients with reduced mobility to use the devices (see also Req_50 in D2.13)	non-functional	could	Pertinent usability test performed by the corresponding company/interested pilot	high
Req_DSP_10	The device measurements should be available to the patient through visual and/or audio output for varying abilities	functional	should	Visual and/or audio measurement reporting by the devices	medium
Req_DSP_11	Audio notification of alerts and/or reminders by the devices should be available and prioritised (see also Req_14 in D2.13)	functional	should	Audio notification of alerts and/or reminders is available and prioritised	low
Req_DSP_12	Vibration, visual, text should be used as alternative notification methods by the devices (see also Req_14 in D2.13)	functional	should	Vibration, visual, text are offered as alternative notification methods	low
Req_DSP_13	The devices must be accessible to patients with inclusion criteria designed in the pilot.	non-functional	must	Selection of devices according to patient needs.	medium

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_DSP_14	Devices with medical device classification should be available for high-risk patients	non-functional	should	Measurement data is acquired by devices with medical device classification in the case of high-risk patients.	high
Req_DSP_15	Samsung device users must login to Samsung Account in order to collect Samsung Health data for GK Data Federation.	non-functional	must	User must sign in Samsung account to be able to use Samsung Health App	high
Req_DSP_16	Smartphone and smartwatch should always be paired and any connected app should be open in the background for data collection.	non-functional	should	Make sure data collection be more continuous	medium
Req_DSP_17	The devices shall collect data about the users at registration time and periodically accordingly with the definition of the local KPIs	non-functional	must	The system collects data about the users when defined	high
Req_DSP_18	The GK Data Federation component must be able to receive data pushed by the Medisanté BP800 and BC800 devices. [source: Puglia Pilot]	functional	must	Data from Medisanté BP800 and BC800 devices are correctly stored in the GK Data Federation component	high
Req_DSP_19	The GK Data Federation component must be able to receive data pushed by the Biobeat wrist PPG device. [source: Puglia Pilot]	functional	must	Data from Biobeat wrist PPG device are correctly stored in the GK Data Federation component	high
Req_DSP_20	The Biobeat wrist PPG device should be able to send data to the GK Data Federation component without requiring the patient to open an account on the Biobeat cloud. [source: Puglia Pilot]	functional	should	Data from Biobeat wrist PPG device are stored in the GK Data Federation component correctly associated to the relevant patient even if the	high

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
				patient has no account on Biobeat cloud.	

## 6.8 Artificial intelligence and data analytics level

As stated in D3.1.1, Artificial Intelligence and Data Analytics have the objective of providing services for early prevention and intervention in order to improve the accessibility, effectiveness and sustainability of the healthcare systems. In GATEKEEPER, the Platform provides a set of Integrated Dynamic Intervention Things. These Things are the core of added value services for Healthcare Professionals and Patients. Additional Things can also be registered to extend the reasoning capabilities. Such Things will also be able to use the reasoning functionalities provided by the Big Data Infrastructure.

The relevant Gatekeeper components involved at this level are the ones in the **AI Reasoning Framework**. This framework is composed by different services: Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3) and Medical-Based AI Algorithms (T6.3). These services rely on the **Big Data Infrastructure** (T4.3). More information on each of those components can be found in the corresponding deliverables.

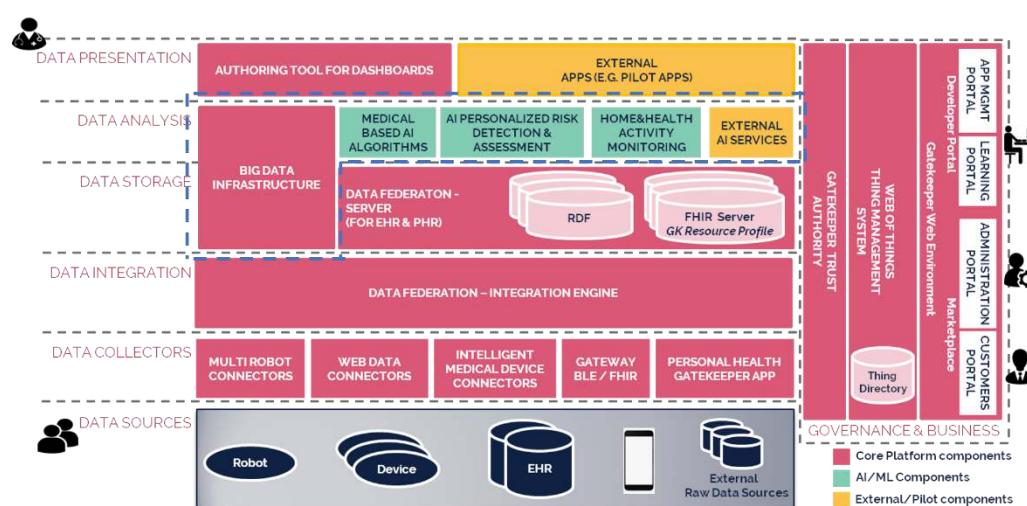


Figure 20 - The AI Reasoning Framework in the architecture

The requirements of this level are organised in the following order:

1. Prediction of short-term (critical events) or long-term disease-related complications
2. Long-term prediction of changes in health status and frailty in healthy elderly subjects, and early-detection of frailty in the context of multi-morbidity and polypharmacy to avoid self-isolation
3. Identification of predictive data patterns related to health promotion, disease management and case management, including (non)adherence to poly-medication
4. Provision of recommendations related to health promotion
5. Information on the inputs/output(s) of the AI algorithms, and their adaptive characteristics
6. KPIs
7. Non-functional requirements

Table 32: Artificial intelligence and data analytics level requirements

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AI_01	The system incorporates AI services on the detection or short-term prediction of critical events (e.g. an upcoming COPD or HF exacerbation, or a hypoglycaemic event), which may require immediate therapeutic intervention in the context of both moderate and high complexity RUCs (i.e. RUC#2, RUC#3, RUC#5, RUC#7).	functional	must	Respective AI services have been developed which embed AI-models of high trustworthiness.	Medical Based AI Algorithms (T6.3)	high
Req_AI_02	The system incorporates AI services on the prediction of long-term type 2 diabetes control and other outcomes related to type 2 diabetes complications in the context of RUC#3.	functional	must	Respective AI services have been developed which embed AI-models of high trustworthiness.	Health Activity Monitoring (T5.2), Medical Based AI Algorithms (T6.3)	high
Req_AI_03	The system incorporates AI services on the on the assessment of the risk associated to group of factors for the evolution of a health condition (i.e. frailty, development of chronic diseases associated to metabolic syndrome) in the context of RUC#1.	functional	must	Respective AI services have been developed which embed AI-models of high trustworthiness.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3)	high
Req_AI_04	The system incorporates AI	functional	must	Respective AI services have	AI	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	services on the prediction of frailty in the self-management of multi-morbidity and poly-medication (RUC#7) by considering the reduction of physical and social activities aiming at avoiding self-isolation.			been developed which embed AI-models of high trustworthiness.	Personalised Risk Detection and Assessment (T5.3)	
Req_AI_05	The system incorporates AI services on the identification of predictive data patterns related to health promotion (i.e. prevention of metabolic syndrome or chronic conditions related to metabolic syndrome (type 2 diabetes, high cholesterol, hypertension, COPD), recognition of data patterns associated with sleep quality and weight management) in the context of RUC#1.	functional	must	Respective AI services have been developed which embed AI-models of high trustworthiness.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3)	high
Req_AI_06	The system incorporates AI services on the identification of predictive data patterns related to case management (i.e. RUC#3 - risk of arrhythmias during hypoglycaemia; RUC#7 - recognition data patterns/associations leading to/associated with adverse events for advanced cancer patients or people with dementia).	functional	must	Respective AI services have been developed which embed AI-models of high trustworthiness.	Medical Based AI Algorithms (T6.3)	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_AI_07	The system incorporates AI services on the identification of predictive data patterns related to (non)adherence to medication (RUC#1 and RUC#7).	functional	must	Respective AI services have been developed which embed AI-models of high trustworthiness.	AI Personalised Risk Detection and Assessment (T5.3)	high
Req_AI_08	The system incorporates AI services on the provision of recommendations in the context of RUC#1 aiming at health promotion and mitigation of frailty, MCI, and mental health risks. In particular, the algorithms should include AI Health Planner covering the RUC#1, including computing measures based on Samsung Health PHR that are to be shared with elderlies and possibly their community actors, especially to mitigate frailty, Mental Health and MCI risks [Puglia Pilot Site].	functional	must	1) Respective AI services have been developed which provide recommendations of high trustworthiness. 2) Monitoring the elderly for the adherence with respect to health recommendations and motivation towards healthy behaviours	Health Activity Monitoring (T5.2)	high
Req_AI_09	The system incorporates AI services on the provision of recommendations in the context of RUC#3 (type 2 diabetes) aiming at tertiary prevention in type 2 diabetes.	functional	must	Respective AI services have been developed which provide recommendations of high trustworthiness.	AI Personalised Risk Detection and Assessment (T5.3)	high
Req_AI_10	The system incorporates AI services on the provision of	functional	must	Respective AI services have been developed which provide	Health Activity Monitoring	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	recommendations in the context of RUC#1 and RUC#7 (mental health disorders), aiming at the prevention and management of mental health disorders.			recommendations of high trustworthiness.	(T5.2)	
Req_AI_11	The AI algorithms, across all RUCs, should include a strong synergy approach between personal health data (PHD), generated by both medical devices and no medical devices, and electronic health data (EHD).	functional	must	1) Respective AI services are built on top of PHD and EHD.  2) The predictive capacity of the AI models' input space is demonstrated with respect to the improvement in prevention of health status decaying or disease worsening.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3)	high
Req_AI_12	The AI algorithms, across all RUCs, shall integrate psychological and emotional aspects of the patients (see also Req_15 in D2.13)	functional	could	Respective AI services integrate psychological and emotional aspects of the patients	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3)	high
Req_AI_13	The services offered should be selected and adapted in relation to	functional	should	Examine if the services offered are selected and adapted in	Health Activity Monitoring	low



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
	the current situation of the user.			relation to the current situation of the user	(T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3)	
Req_AI_14	AI services on critical events detection or prognosis decide where to send alerts based on risk and information given on sign up - informal carers, services etc.	functional	must	Examine if the algorithm on critical events detection or prognosis decides correctly where to send alerts based on risk and information given on sign up	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3)	medium
Req_AI_15	AI services products (data, analysis, messages, highlights) must be purely informative.	functional	must	AI services products convey the required information.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
					(T6.3)	
Req_AI_16	Underlying AI models output (e.g. trend information) may require graphic representations.	functional	must	Respective AI models' output is visualised graphically.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3)	medium
Req_AI_17	System generates information for KPIs to be included into the dedicated platform for monitoring of the AI services and evaluation of AI services benefits (i.e. its positive impact on the health of an individual expresses in terms of measurable, patient-relevant clinical outcomes, or its positive impact on patient management or public health).	functional	must	Information for KPIs is included into the dedicated platform for monitoring of the service and evaluation of service benefits.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3)	high
Req_AI_18	The AI models' learning architecture shall be specified based on the physical location of datasets.	non-functional	must	Both centralised and federated-based learning architectures have been developed considering the adopted in each pilot site GK data sharing options.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
					Assessment (T5.3), Medical Based AI Algorithms (T6.3), GK Data Federation, GK Big Data Infrastructure	
Req_AI_19	Access to the GATEKEEPER Big Data Infrastructure and implementation of the needed mechanisms for transferring pilots' data to it through the Data Federation Layer.	non-functional	must	AI models have been trained/validated/tested on real data stored in GK Big Data Infrastructure, coded according to the FHIR data model.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3), GK Data Federation, GK Big Data Infrastructure	high
Req_AI_20	AI services embed AI/ML algorithms of high trustworthiness based on the European Commission Ethics Guidelines for Trustworthy AI.	non-functional	must	Transparent reporting of the embedded AI/ML algorithms trustworthiness testing results.	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
					Assessment (T5.3), Medical Based AI Algorithms (T6.3)	
Req_AI_21	The data flows associated with the devices and sensors used comply with the regulatory standards and are reliable, safe and robust	non-functional	must	Check if the data flows associated with the devices and sensors used comply with the regulatory standards and are reliable, safe and robust	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms (T6.3), GK Data Federation, GK Big Data Infrastructure	high
Req_AI_22	The AI services provide an API for invoking the AI models	functional	must	Set of APIs available	Health Activity Monitoring (T5.2), AI Personalised Risk Detection and Assessment (T5.3), Medical Based AI Algorithms	high

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
					(T6.3), GK Data Federation, GK Big Data Infrastructure	
Req_AI_23	The system will detect and recognize home activities, and providing info regarding "Did a user perform a specific activity today?" and modelling user behaviour, providing analysis on "What is the trend of a user in performing the daily routines in the last period."	functional	must	The system detects and recognises home activities and provides related information and models about user behaviour, providing analysis	Health Activity Monitoring (T5.2)	medium
Req_AI_24	The solution shall detect if the patient is in bed or chair and estimate the time spent in bed or chair.	functional	must	Being in bed or chair is detected and time spent in bed or chair is estimated.	Health Activity Monitoring (T5.2)	medium
Req_AI_25	System provides periodic reports and historical data about patient activity	functional	must	Periodic reports and historical data about patient activity are provided	Health Activity Monitoring (T5.2)	medium
Req_AI_26	Alarm to alert informal caregivers or emergence services of a risky situation stemming from a period of inactivity	functional	must	Examine if an alarm is triggered to alert informal caregivers or emergence services of a risky situation stemming from a period of inactivity	AI Personalised Risk Detection and Assessment (T5.3), Health Activity	medium

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
					Monitoring (T5.2)	
Req_AI_27	Solution provides information on activities that assisted elderly people like or are keen on	functional	must	Examine if the solution provides information on activities that assisted elderly people like or are keen on	AI Personalised Risk Detection and Assessment (T5.3), Health Activity Monitoring (T5.2)	low

## 6.9 Standardisation level

As described in D3.1, according to D8.1, the existing standards and certifications relevant to GATEKEEPER can be divided into the following main categories:

- Health; monitoring of related technology, measurement of bio-signals, person-facing, wearable medical devices
- Home; location systems, smart-living environment, IoT- and WoT-based solutions, sensors at home, home appliance services, environment control
- Personal autonomy-assistive technology; for instance, general requirements and test methods, robots and robotic devices, sound transmission
- Information and communication technology and data; Web and smartphone applications, HTTPs, security mechanisms, data collection, data storage, IoT, anonymisation, user interface standards, accessibility.

Innovations developed as part of the GATEKEEPER project will be considered for the creation of new standards. Based on the current working version of D8.2, such assets are the GATEKEEPER reference architecture, interoperability enablers, FHIR implementation guides and WoT-related assets.

Standardisation and certification are the scope of WP8, whose outcome will influence nearly all aspects and, therefore, work packages of the project, namely WP2, WP3, WP4, WP5, WP6 and WP7.

Automatic and semi-automatic validation according to the standards decided will be offered by the Things Validator System (more in Figure 10).

Table 33: Standardisation level requirements

ID	Description	Requirement type	Priority	Fit criterion	Difficulty
Req_S_01	Compliance with HL7 Fast Healthcare Interoperability Resources (FHIR) standard (see also Req_30 in D2.13)	functional	must	Validation against Gatekeeper FHIR Implementation Guide and HL7 FHIR standard v4.0 in the Things Validator System	medium
Req_S_02	General Data Protection Regulation (GDPR)	legal	must	Examine if this standard is applicable to the UCs of the project. The Things Validator System provides semi-automatic validation of services (Things), apps and devices offered in the project marketplace with compliance information to a selection of various standards selected by the project and validated per offering by an	medium
Req_S_03	ISO/IEC 19944:2017 Information technology — Cloud computing — Cloud services and devices: Data flow, data categories and data use	functional	should		medium
Req_S_04	ISO/IEC 22624:2020 Information technology — Cloud computing — Taxonomy based data handling for cloud services	functional	should		medium
Req_S_05	Web of Things architecture with JSON-LD contexts and including SAREF	functional	must		medium
Req_S_06	IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices	functional	should		medium
Req_S_07	EN ISO 12967-1:2011 Health informatics - Service architecture	functional	should		medium
Req_S_08	IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and	functional	should		medium



	essential performance - Collateral standard: Usability			expert committee	
Req_S_09	ISO TR 12300:2014 Health informatics — Principles of mapping between terminological systems	guideline, not standard. functional	should		medium
Req_S_10	ISO/IEC 20547-3:2020 Information technology — Big data reference architecture — Part 3: Reference architecture	functional	should		medium
Req_S_11	ISO/IEC TR 23186:2018 Information technology — Cloud computing — Framework of trust for processing of multi-sourced data	guideline, not standard. functional	should		medium
Req_S_12	ISO/IEC TR 10032:2003 Information technology — Reference Model of Data Management	guideline, not standard. functional	should		medium
Req_S_13	TLS Transport Layer Security	standard	could		medium
Req_S_14	OAuth 2.0	standard	must		medium
Req_S_15	EN 301 549 Accessibility requirements for ICT products and services	functional (semi-legal as EU Web directive refers to it)	must		medium
Req_S_16	CEN ISO/TR 22411:2008 Ergonomics data and guidelines for the application of ISO/IEC Guide 71 to products and services to address the needs of older persons and persons with disabilities	functional	should		medium

Req_S_17	"Ethics guidelines for trustworthy AI" of the High-Level Experts Group on Artificial Intelligence	guideline	should		medium
Req_S_18	Standards for Reporting of Diagnostic Accuracy Studies (STARD 2015, in anticipation of STARD-A)	standard	could		medium
Req_S_19	EU Medical Device Regulation (Regulation (EU) 2017/745)	legal document	must		medium
Req_S_20	Transparent Reporting of a Multivariate Prediction Model for Individual Prognosis or Diagnosis (TRIPOD, in anticipation of TRIPOD-ML)	standard	should		medium
Req_S_21	IEEE 802.11 WiFi standard	standard	must		medium
Req_S_22	Bluetooth standards	standard	could		medium
Req_S_23	Organisational - IHE	standard	should		medium
Req_S_24	Semantic - CIE, LOINC, ICD-10, SNOMED	standard	must		medium
Req_S_25	Syntactic - DICOM	standard	could		medium
Req_S_26	Technical – REST, EDI	standard	could		medium
Req_S_27	OpenID Connect, SAML	standard	must		medium
Req_S_28	EN ISO 13485:2012, Medical devices — Quality management systems — Requirements for regulatory purposes (for high-risk patients) (Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as	functional	must		medium

	applying to medical devices, the requirements apply equally to associated services as supplied by the organisation)				
Req_S_29	IEC 62366-1:2015, Medical devices — Part 1: Application of usability engineering to medical devices (Process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. – Revised 2020)	functional	should		medium
Req_S_30	EN ISO 14971:2012, Medical devices — Application of risk management to medical devices (terminology, principles and a process for risk management of medical devices)	functional	should		medium
Req_S_31	ISO/IEC JTC 1/SC 27: Information security, cybersecurity and privacy protection	non-functional	should		medium
Req_S_32	ISO/PC 317 Consumer protection: privacy by design for consumer goods and services	non-functional	should		medium
Req_S_33	ISO /IECJTC 1/SC 27 IT Security techniques	non-functional	should		medium
Req_S_34	CEN/CLC/ETSI/TC 13 Cybersecurity and data protection	non-functional	should		medium
Req_S_35	ISO/IEEE 11073 Personal Health Device Standards	standard, functional	should		medium
Req_S_36	ISO 27000 series of information security standards	non-functional	should	The Things Validator System provides automatic and semi-automatic approval and	medium

				review of standards for each provided service/Thing on TMS	
Req_S_37	Ability to upload files and code on the Things Validation System, which in turn provides automatic (using internal and external validator modulers) and semi-automatic (using advice from experts) approval and certification of Things/Services according to all of the above standards.	functional	must	The Things Validator System provides automatic and semi-automatic approval and review of standards for each provided service/Thing on TMS	high

## 6.10 Business level

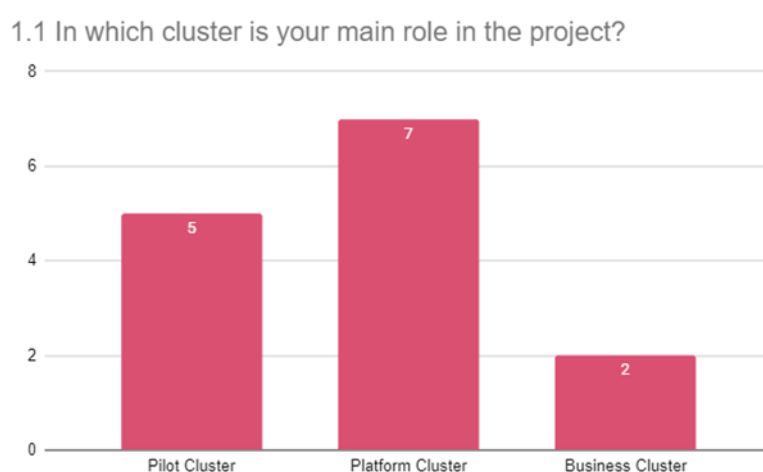
### 6.10.1 Marketplace requirements

The **Marketplace** is the business hub of the GATEKEEPER project, on which more information can be found in D4.6.

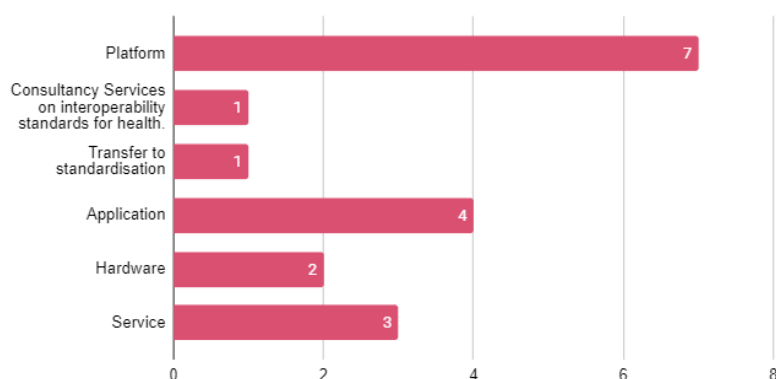
To elicit Marketplace requirements, a synergy between T4.6 (led by CERTH), T2.3 (led by TECNALIA) and the Business Cluster carried out an online survey within the project. This is reported in D2.3 and summarised below:

- 32 answers collected, of which 20 from the Pilot Cluster, 8 from the Platform Cluster, 2 from the Business Cluster, 1 from both Pilot and Business, 1 from a multi-stakeholder network
- Equally distributed between Providers/Vendors and Consumers
- Most providers/vendors do not yet offer packaged solutions on a marketplace yet, but intend to do so using Docker, OSGi, Android and SaaS servers
- Providers/Vendors expect the Marketplace to increase audience, promote discovery and monetization.
- Consumers expect to find:
  - Services and APIs to integrate with existing software
  - End-user Apps to deploy and use directly
  - Hardware to install themselves
  - Consultation services to install a system tailored to their needs
- 70% expects improvement in health outcomes and patient self-management
- 56% expects improvement in usability and caregiver performance

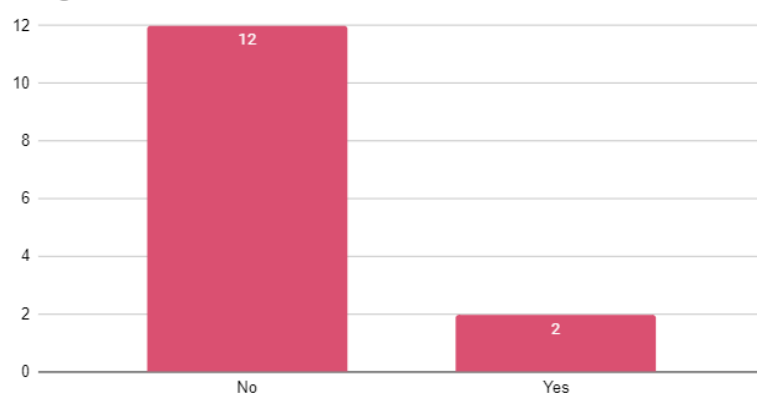
Some responses are visualised in Figure 21.



## 2.1 How would you characterize your solution



## 2.3 Is your solution uploaded in any other marketplace or listing?



## 3.1 What do you expect to find in the marketplace?

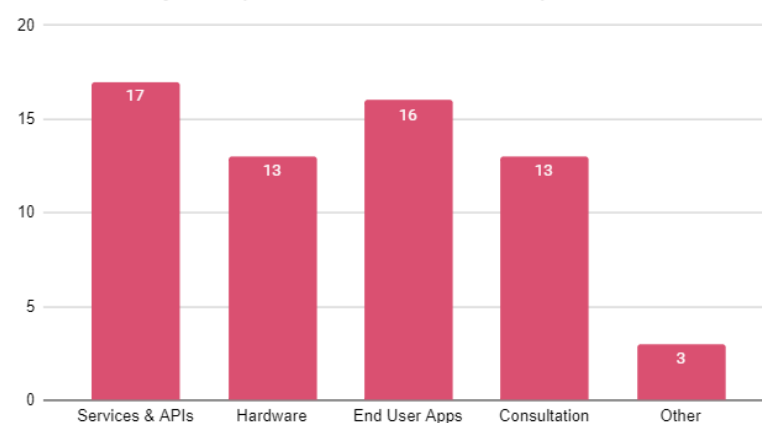


Figure 21 - Some responses from the Marketplace Requirements User Survey

These requirements, together from platform development and the GK architecture, are translated into functional requirements on the table below. Requirements related to the Marketplace can also be found in section 6.2 (Applications level), yet from a less business-oriented approach.

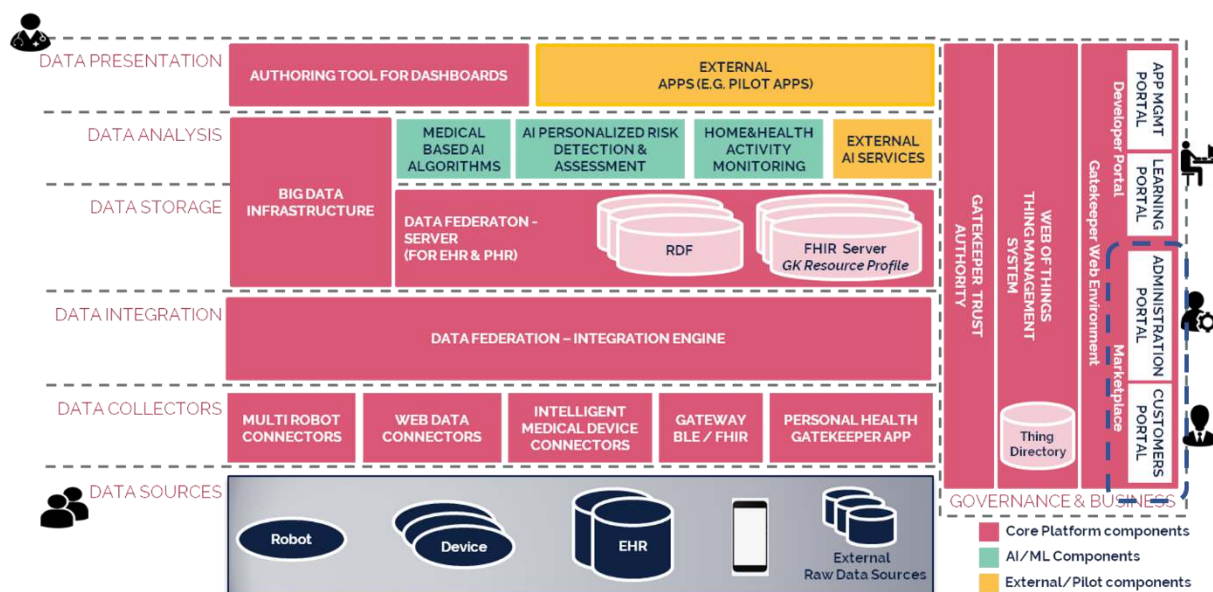


Figure 22 - The Marketplace in the architecture

Table 34: Marketplace requirements focusing on business

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_BM_01	Transparent and simple workflow for completing transactions on the platform	non-functional	must	The users experience a transparent and simple workflow of transactions on the platform	Marketplace	low
Req_BM_02	Efficient and intuitive onboarding and support for new vendors	non-functional	must	New vendors are on-boarded efficiently and intuitively	Marketplace	low
Req_BM_03	Provide options for vendors to improve engagement with the customers	functional	could	Vendors can optimize customer engagement e.g. by replying to comments and reviews	Marketplace	medium
Req_BM_04	Providers must be able to view and monetise their services registered within Gatekeeper	functional	must	Things/Services in TMS are available on the Marketplace	TMS/GTA	medium
Req_BM_05	Providers can also upload or link files and descriptions to monetize their standalone Apps (e.g. Android/iOS) and IoT Device hardware	functional	must	Apps and Devices are available on the Marketplace	-	low
Req_BM_06	Consumers must be able to easily search and discover Things/Services, Apps and Devices	functional	must	Things/Services in TMS, Apps and Devices are on the Marketplace	TMS/GTA	medium



ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_BM_07	Users are able to view and filter offerings based on WoT metadata and certification/compliance to standards on the Marketplace	functional	must	Offerings on the Marketplace show their WoT and Certification/Compliance information	TMS/GTA, Things Validation System	medium
Req_BM_08	Administrators can moderate contents and view analytics, Providers also see analytics and monetisation information	functional	should	Content is moderated by Administrators. Various users view respective analytics	-	low
Req_BM_09	Users view respective offerings and related content depending on the GK Space they belong to (Consumers, Business, Healthcare)	functional	must	Different views filter offerings depending on the Consumer, Business or Healthcare space	-	medium
Req_BM_10	Developers/Companies sign up & accept terms of usage of GK platform for the Market place before publishing services	functional	must	The Marketplace requires acceptance of Terms of Usage	-	low
Req_BM_11	Publication rules are clear & acceptable by Healthcare Space / Consumer Space / Business Space depending on the type of service to be published	non-functional	must	The Marketplace terms are clear and understandable	-	low
Req_BM_12	Links to the conventional marketplaces for applications (e.g., Google Play, Apple Store etc.) if published	functional	must	The Marketplace offers links to external marketplaces for respective Apps	-	low

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_BM_13	Provides payment method for subscription services	functional	must	The Marketplace offers subscription payment methods	-	medium
Req_BM_14	Must be hosted and accessible through all internet browsers & have categories defined for easy search	non-functional	must	The Marketplace is compatible with established browsers	-	low
Req_BM_15	Pre-defined categories facilitate search	functional	must	The Marketplace offers pre-defined categories for search	-	low
Req_BM_16	Must provide methods of certification for services/applications	functional	must	The Marketplace provides certified offerings	Things Validator System	medium
Req_BM_17	Every service must clearly specify the cost of service	non-functional	must	Prices are defined and visible for each service	-	low
Req_BM_18	Sharing capabilities for anonymised collected data as data donations from the pilots shall be provided in the Marketplace.	functional	could	General, merged statistics and/or individual anonymised patient data can be shared in the Marketplace after the end of the project in compliance with GDPR	Marketplace	low
Req_BM_19	Legal and ethical approach to manage data should be clearly described	non-functional	should	Clear description of legal and ethical	Marketplace	low

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
				approach to manage data is offered.		
Req_BM_20	GK platform shall guarantee secure and private transactions	functional	must	Transactions in the Marketplace are secure and private.	Marketplace	high

### 6.10.2 Pricing requirements

It is still early for the business cluster to provide a clear overview of the pricing requirements. However, an initial approach is provided below by WP9 about product pricing and registration pricing.

Table 35: Pricing requirements

ID	Description	Requirement type	Priority	Fit criterion	Related GK Component	Difficulty
Req_BPR_01	Subscription services are available.	non-functional	must	-.	Marketplace	medium
Req_BPR_02	The product should not cost more than £100 per customer.	non-functional	should	-	Marketplace	medium
Req_BPR_03	Marketplace registration fees should not exceed a set limit.	non-functional	should	-	Marketplace	medium

## 7 Conclusions

D3.1.2 is the result of diligent work and continuous communication among Platform Cluster partners, but also of their response to the technical needs of the Business Cluster and the LSP Cluster as presented here. As an outcome, an extensive list of functional and technical requirements was compiled and each of these was analysed in terms of difficulty and priority with the aim of determining the next steps.

The Platform Cluster itself has progressed in the development of the GK Platform components. Consequently, the updated requirements are more detailed than in D3.1.1, cover a wider range of features and proper ways to test the implementation of each of them have been decided.

The Business Cluster efforts, albeit being at an early stage, have been helpful for the collection of requirements related to the Marketplace component and have also provided a first approach to pricing, regarding both registration and product pricing. Moreover, the first steps towards compliance with established standards have been made. Further interaction between the Platform Cluster and the Business Cluster is expected as the work of the latter progresses.

The LSP Cluster requirements mostly concern Artificial Intelligence, dashboard requirements and integration of Pilot KETs into the GK Platform. The COVID-19 survey can be implemented with a few additions to the functions already provided by the GK components. Any new requirements from the side of the Asian pilots, which are still early in development and could not offer detailed insights in this deliverable, are expected to run smoothly given the wide range of options offered to serve the needs of the European pilots and the guidance that can be offered to them.

In conclusion, the comprehensive list of requirements in this deliverable, in combination with the GK architecture principles described in D3.2.2, builds on the concrete basis for platform development presented in the previous version and expands it to serve the needs of all stakeholders involved.

## Appendix A – Component interactions

The following table reports the mapping between component interactions identified in D3.2.2 and the requirements associated with them as an update to Appendix A in D3.1.1. For more details on the component interactions reported, see section 7 of D3.2.2.

Table 36: Component interactions and associated requirements

Interaction ID	Description	Associated requirements
HD_01	Data enter the platform from KETs behind collectors	Req_NT_09, Req_DSP_02
HD_02	Data enter the platform from EHRs	Req_DA_02, Req_DA_11
HD_03	Data enter the platform from BT devices	Req_DA_11, Req_NT_11, Req_S_22
HD_04	Data enter the platform from Cloud APIs	Req_DS_02, Req_DS_03, Req_DS_04, Req_DSP_01, Req_DSP_01, Req_S_03, Req_S_04, Req_S_11
HD_05	Data enter the platform from services compliant to GK FHIR standard	Req_DA_06, Req_DA_11, Req_DA_19, Req_DS_05, Req_DS_06, Req_S_01, Req_NT_08
HD_06	Historical data enter the platform (only for training purposes)	Req_DA_02, Req_DA_11, Req_DA_13, Req_DS_02, Req_DS_06, Req_AI_25
<b>HEALTH DATA PRESENTATION</b>		
HD_07	Data are visualised in the Authoring Tool	Req_AP_03, Req_AP_54, Req_UI_20, Req_AP_31
HD_08	Data are visualised in External services	Req_NT_01, Req_NT_07
HD_09	Healthcare providers can receive notifications in their dashboards	Req_UI_07, Req_UI_08
<b>HEALTHCARE USERS MANAGEMENT</b>		
HCU_01	The user registers to the platform through external services	Req_NT_01, Req_NT_07
HCU_02	The user registers to the platform through the Authoring Tool	Req_UI_01, Req_PS_13
HCU_03	The user links external accounts to the platform	Req_AP_63
HCU_04	A patient is assigned to a healthcare professional	Req_UI_07, Req_UI_08
<b>DEVICE MANAGEMENT</b>		
DM_01	A device is registered in the platform from a connector	Req_NT_14, Req_NT_07, Req_NT_09, Req_DSP_02, Req_DSP_03
DM_02	A device is manually registered in the platform	Req_NT_14

Interaction ID	Description	Associated requirements
DM_03	A device is associated to a patient	Req_DSP_13
<b>GDPR RIGHTS</b>		
GDPR_01	The user asks for a copy of the data	Req_PS_20, Req_PS_16
GDPR_02	The user revokes the permission to access the data	Req_PS_19, Req_AP_31
GDPR_03	The user asks for deletion of their data	Req_PS_18, Req_PS_19, Req_UI_17
GDPR_04	The user modifies own data	Req_PS_17
<b>DEVELOPER PORTAL</b>		
DV_01	The developer registers to the platform	Req_AP_43
DV_02	The developer asks for an authorisation token for a service	Req_BM_10, Req_DS_09
DV_03	A developer certifies a service in the platform	Req_BM_16, Req_DS_09, Req_AP_43
DV_04	A registered service performs a call to a Thing of the platform	Req_DSP_3, Req_NT_05
<b>MARKETPLACE</b>		
BS_01	A customer browses available services	Req_BM_06, Req_UI_16, Req_AP_42
BS_03	Data is donated to the platform through the MarketService	Req_BM_18
<b>AI FRAMEWORK</b>		
AI_01	An alert is generated by the framework and pushed to the appropriate users	Req_AP_11, Req_AP_13, Req_AP_16, Req_AP_18, Req_AP_19, Req_AP_21, , Req_AI_14,, Req_AI_26
AI_02	Results of AI / ML algorithms are shown in a dashboard	Req_AP_03, Req_AP_07, Req_AP_08
AI_03	Data are forwarded to the Big Data infrastructure and processed by AI algorithms	Req_AI_18, Req_AI_19

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