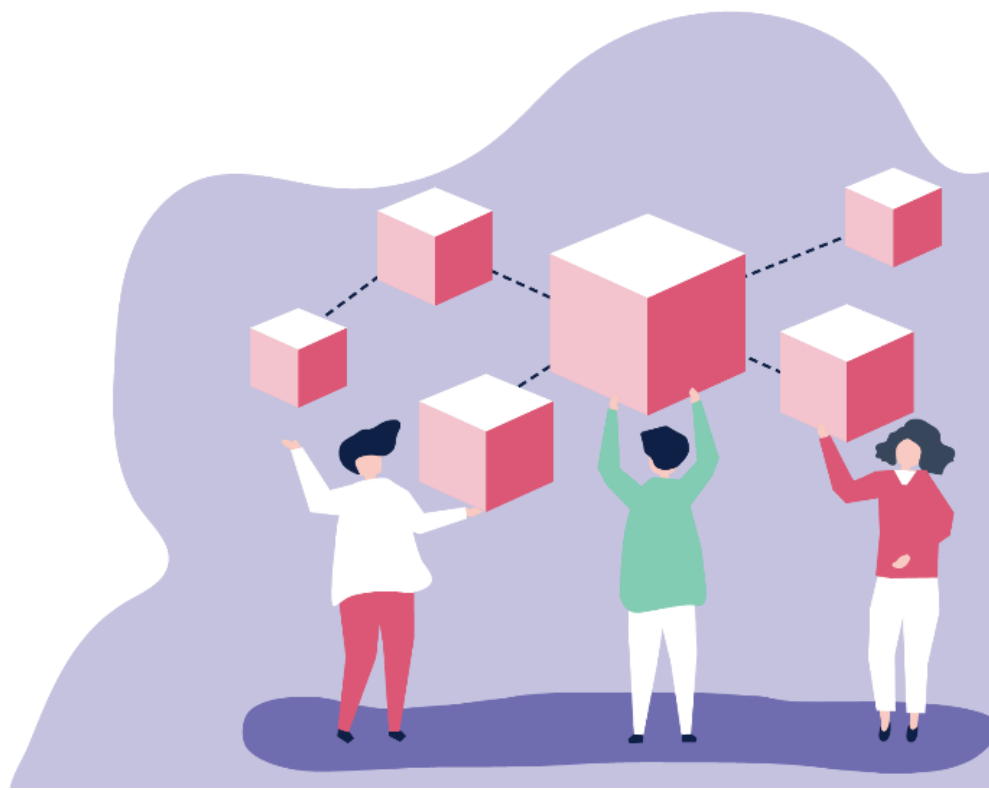




GATE KEEPER

D1.3 Final Report

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1 Final Publishable Summary Report

1.1 Executive Summary

The main objective of the Project is to create a GATEKEEPER, that connects healthcare providers, businesses, entrepreneurs, elderly citizens and the communities they live in, in order to originate an open, trust-based arena for matching ideas, technologies, user needs and processes, aimed at ensuring healthier independent lives for the ageing populations. By 2023, GATEKEEPER will be embodied in an open source, European, standard-based, interoperable and secure framework available to all developers, for creating combined digital solutions for personalised early detection and interventions that (i) harness the next generation of healthcare and wellness innovations; (ii) cover the whole care continuum for elderly citizens, including primary, secondary and tertiary prevention, chronic diseases and co-morbidities; (iii) straightforwardly fit "by design" with European regulations, on data protection, consumer protection and patient protection (iv) are subjected to trustable certification processes; (iv) support value generation through the deployment of advanced business models based on the VBHC paradigm. GATEKEEPER will demonstrate its value by scaling up, during a 51-months work plan, towards the deployment of solutions that will involve ca 40.000 elderly citizens, supply and demand side (authorities, institutions, companies, associations, academies) in 8 regional communities, from 7 EU member states.

1.2 Summary description of project context and Objectives

The main objective of the Project is to create a GATEKEEPER, that connects healthcare providers, businesses, entrepreneurs, elderly citizens and the communities they live in, in order to originate an open, trust-based arena for matching ideas, technologies, user needs and processes, aimed at ensuring healthier independent lives for the ageing populations. By 2023, GATEKEEPER will be embodied in an open source, European, standard-based, interoperable and secure framework available to all developers, for creating combined digital solutions for personalised early detection and interventions that (i) harness the next generation of healthcare and wellness innovations; (ii) cover the whole care continuum for elderly citizens, including primary, secondary and tertiary prevention, chronic diseases and co-morbidities; (iii) straightforwardly fit "by design" with European regulations, on data protection, consumer protection and patient protection (iv) are subjected to trustable certification processes; (iv) support value generation through the deployment of advanced business models based on the VBHC paradigm.

The achievement of the overall objective is supported by the following specific objectives:

O1. To deliver the **GATEKEEPER DIGITAL PLATFORM** implemented through fault tolerant, secure, flexible and scalable micro-services infrastructure, based on open source and data standards with strong developer community, built on top of reference W3C-Web of Things architectural models and including services referred to the health domain through HL7-FHIR and to the home domain through SAREF, for the establishment of a new generation of digitalized multi-domain health services validated within the large scale pilot.

O2. To deliver the **GATEKEEPER HEALTHCARE SPACE**, 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 for design, deployment and validation of innovative personalized treatments and therapies.

O3. To deliver the **GATEKEEPER CONSUMER SPACE**, where certified solutions, services and devices are provided to citizens for the management and prevention of health and social risks in their homes, in connection with their neighbourhoods and communities.

O4. To deliver the **GATEKEEPER BUSINESS SPACE**, where certified companies are able to develop solutions, services and devices alone or in partnership, following a set of standards in order to reach and boost the Digital Single Market. This space will also cover the whole range of companies.

O5. To deliver the **GATEKEEPER ECOSYSTEM TRANSACTION SPACE**, where services for data storage and processing, big data analytics and advanced visualization of business-oriented KPIs are provided for the exchange of solutions among providers and suppliers, based on data sharing and Value-based healthcare paradigms.

O6. To execute a series of **PILOTS** to demonstrate the effect, benefit, value and scalability of the GATEKEEPER solutions around **REFERENCE USE CASES COVERING PRIMARY, SECONDARY and TERTIARY PREVENTION**, initially deployed in 8 regions of 7 European countries.

O7. To provide an **ECOSYSTEM COCREATION** framework, resulting from Responsible and Social Innovation principles, aiming at engaging and generate TRUST from Citizens, Healthcare Professionals, Supply and Demand Side, extended through open calls to SMEs, Start-ups, and new regions in an open innovation fashion.

O8. To implement a **STANDARDIZATION STRATEGY** that allow the GATEKEEPER solution to be aligned with SDOs around legal and privacy aspects, healthcare, ageing, homes, cities and energies, IoT, Big Data and other Key Enabling Technologies, as well as value-based procurement.

O9. To transform and process GATEKEEPER results in a reference and sustainable **IMPACT FRAMEWORK** for decision making about procurement of innovative solutions, integrating elements from Value-based Healthcare, Real World Data, and Health-Technology Assessment, involving relevant actors inside and outside the consortium through communication and dissemination activities, for worldwide outreach of project activities and achievements.

Table 1 - Overview in specific GATEKEEPER project objectives and related measurable results

Objective	Main Result	Verification (success criteria)	WPs
Main	Demonstrated value of the platform in delivering home-based risk stratification and interventions	Project successfully executed, GK platform validated with ca 40.000 citizens involved at least 8 services demonstrated and evaluated by end-users during pilot realisation	WP1, WP2, WP6, WP7 and WP9
O1	GATEKEEPER PLATFORM demonstrated and running	> 8 connected HC infrastructures > 8 smart home systems integrated	WP3-WP4, and WP6
O2	GATEKEEPER HEALTHCARE SPACE delivered and evaluated	> 3 components of the HC space validated per each pilot > 10 included from open calls	WP3-WP5
O3	GATEKEEPER CONSUMER SPACE delivered and evaluated	> 3 components validated per each pilot > 10 included from open calls	WP3-WP5, and WP6
O4	GATEKEEPER BUSINESS SPACE ecosystem of companies	1 Digital Single Market strategies 1 Digital Single Market operators	WP3-WP5

Objective	Main Result	Verification (success criteria)	WPs
O5	ECOSYSTEM TRANSACTION SPACE delivered and evaluated	> 3 services exchanged per pilot according to risk stratification needs	WP5-WP6, WP8
O6	Pilot executed across all sites; KPI collected	Risk stratification and Intervention models validated by Internal and External Sites	WP1, WP7, and WP9
O7	User needs covered by the provided digital solutions	TRUST is shared by end-users and stakeholders (e.g. above a defined threshold)	WP5, and WP8
O8	Standard Governance Framework	Contribution to each identified SDOs	WP2, WP8-9
O9	Impact Framework Available for key decisions	Procurements defined, GATEKEEPER foundation and legal entity created	WP1, WP2, WP7 and wp9

GATEKEEPER project works plan unfolds in 5 different phases with a total duration of 42 months. The path to innovation for GATEKEEPER is summarized in the following figure:

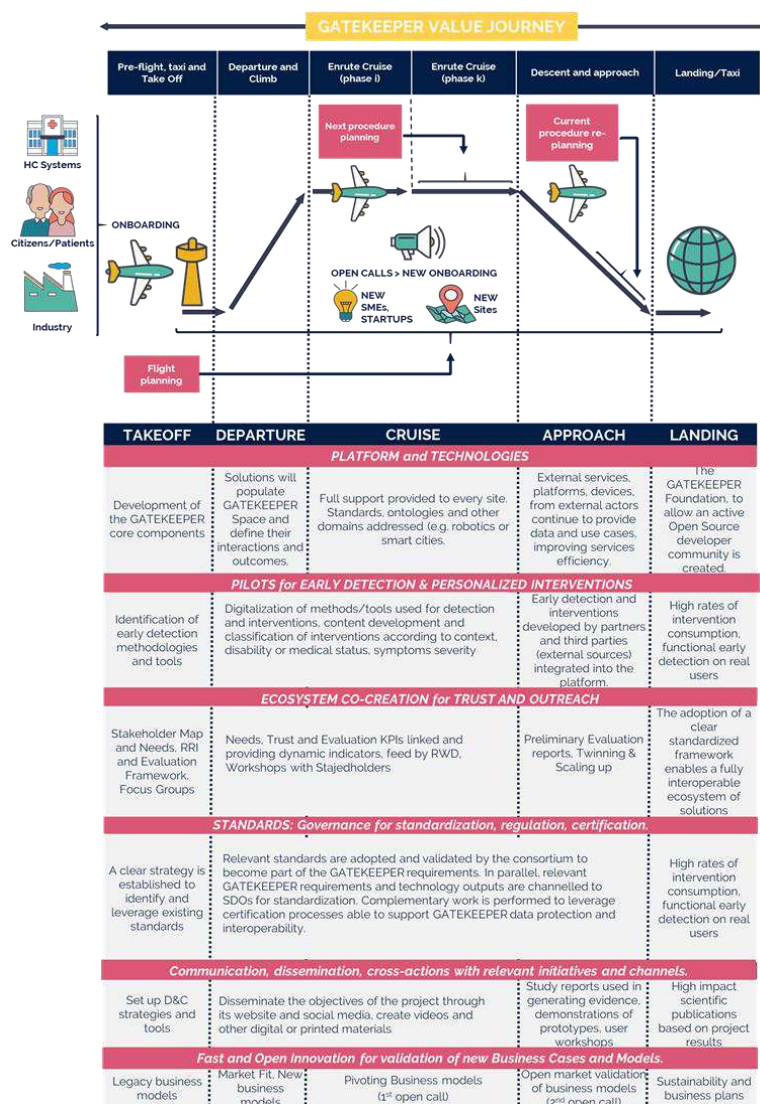


Figure 1. GATEKEEPER Value Journey

Through five phases each one of them designed to deliver a set of strategic and incremental innovations in terms of quality and scaling-up effect.

- Phase 1: TAKEOFF (M1). Sets up all the elements for the next phases, for all the dimensions of the innovation path.
- Phase 2: DEPARTURE (M10). Pilots will start according to the use case defined and refined in phase 1 and deployed with an initial set of solutions for monitoring and intervention
- Phase 3: CRUISE (M12). It facilitates wide interaction of all GATEKEEPER's spaces, allowing multi-lateral cooperation, as well as coherent and complementary replication.
- Phase 4: APPROACH (M24). It allows the enlargement of the ecosystem from demand and supply side, integrating new players/stakeholders and opening to European external actors.
- Phase 5: LANDING (M39). It allows market validation of the complete ecosystem. Reports on evidence and value of the whole process are delivered. It enables the near to the market vision for reaching sustainability on top of the validated business model, exploitation plans, procurement schemas and industrial synergies.

The Goal for this period was to put in place all the needed activities to execute the pilots in all sites.

From an overall perspective we had identified 8 strategic challenges and corresponding achievements:

- The Problem: we have identified the 8 most prevalent chronic diseases + COVID health condition, addressed across primary, secondary and tertiary prevention and treatment. We called them Reference Use Cases. The use of the GATEKEEPER Key Enabling Technologies (Wearable and mobile solutions, smart homes and smart environment IoT technologies, among others) will allow the generation of a federated European Health Data Space of about 50.000 users in 8 European Regional Healthcare Systems, with the addition of 3 strategic pilots from Hong Kong, Singapore and Taiwan.
- The Tool: the GATEKEEPER Platform allows for Trust authority-enabled secured environment for data acquisition, federation and sharing. The platform is disease-agnostic, provides open connectivity to many different types of sensors, and legacy systems upon health and interoperability standards.
- The Service: The Data Federation Space will allow deploying, validating and scaling a set of AI solutions both created in GK for early detection, smart intervention and treatments, in line with new regulations, standards and guidelines.
- The Value: our Large Scale Pilot is a federation of multiple Randomized Control Trials that will allow for Cost-effectiveness evaluation of AI, Big-Data and IoT for chronicity management in elderly population
- The Business: a Marketplace based on open innovation and ecosystem co-creation approach building for the expansion worldwide. GATEKEEPER is expanding already through the new winners of the 1st Open Call to solve technological challenges. The 2nd Open Call, to be published at the beginning of the second period, will be more focused on clinical, business and standard-oriented challenges. In between, a Community of Interest already composed of about 100

stakeholders as already joined our consortium and we will establish synergistic collaboration to align our results to the needs from the market and real practices.

1.3 Work Packages Interaction

Structurally the project is organised in 9 highly interlinked Work Packages (WP), forming three main groups

- Operational WPs: WP3, WP4 and WP5 will provide, driven by WP2, the user-led innovations to build the different GATEKEEPER components and digital solutions of the platform, delivered to the other WPs.
- LSP WPs: WP7 uses the results of the operational work packages to verify and evaluate the benefits of the GATEKEEPER platform in the different pilots, continuously supported by WP6, in charge of delivering the innovative and personalized interventions.
- Supporting WPs: WP1, WP8 and WP9 provide support to all the work packages and project as a whole. WP1 deals with the project management, WP8 addresses standardisation and certification and WP9 on impact maximization activities, resulting in European-led outreach of GATEKEEPER's innovation.

The following figure shows the interactions and main exchanges among the project work packages.

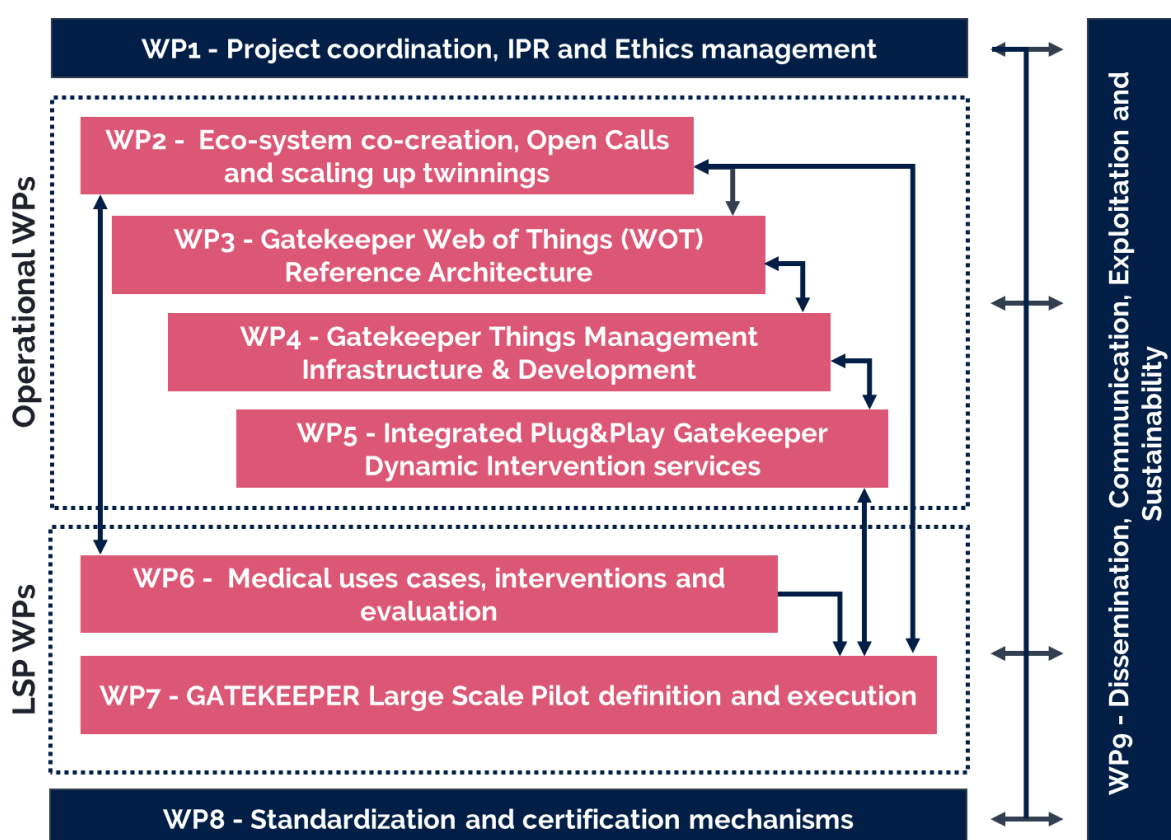


Figure 2. Work Packages Structure

WP1 - Project coordination, IPR and Ethics management. WP1 provides the technical and administrative coordination and the overall management for the project, and addresses innovations and IPR management issues taking into consideration ethical and legal issues.

WP2 - Eco-system value co-creation, Open Calls and scaling up twinning. WP2 creates a viable user-led innovation ecosystem of partnering healthcare professionals, industry players and end-users, cutting across all four project spaces, aligned behind the objective of implementing and scaling GATEKEEPER solutions

WP3 - Gatekeeper Web of Things (WOT) Reference Architecture. This WP aims to expand the Web of Things concept and needs in relation to healthcare and the smart and healthy living at home market domains and to propose the overall architecture of the GATEKEEPER solution with references to its components and general data flows.

WP4 - GATEKEEPER Things Management Infrastructure & Development - this WP supports the implementation, and operational maintenance of the reference implementation of the Gatekeeper core infrastructure, develops the core services of the GATEKEEPER platform in order to build the thing management system, the concept of trustiness within the project platform and the marketplace, provides the implementation, and operational maintenance of Big Data capable services to enable the development and execution of personalized risk detection, Interventions and advanced visualization, delivers a Data Federation Framework and to establish a Semantic Data Lake for the Healthcare space for capturing, formalizing and integrating the Personal Health Background with Environmental Measurements.

WP5 - Integrated Plug&Play Gatekeeper Dynamic Intervention services.- This WP delivers the integrated GATEKEEPER Dynamic Intervention solution ready to support the pilot studies in order to build and populate the consumer, business and healthcare spaces but also the future exposure of these intelligent services within the Ecosystem Transaction space

WP6 - Medical uses cases, early detection and interventions. The objective of this WP is to elicit the design of the early detection and interventions use cases, deployed at each reference site, and to ensure that they (i) consistently address GATEKEEPER's objectives, (ii) are of high clinical and scientific standards, and (iii) define the study protocols to be used for impact evaluation.

WP7 - GATEKEEPER Large Scale Pilot definition and execution - The main objective of this WP is to define, manage and execute the LSP activities in the different pilots' sites. It will establish and consolidate the different Use Cases through Europe enabling the deployment of digital solutions for early detection and intervention and support the risk stratification models.

WP8 - Standardization and certification mechanisms - This WP is identifying and analysing the relevant standardization tracks for GK supporting an effective certification strategy to develop trust in data processing and interoperability of GATEKEEPER solutions. In addition, it is developing a model of procurement process for the outcomes of the GK platform.

WP9 - Dissemination, Communication, Exploitation and Sustainability. This WP aims to maximize the impact of the project in the ICT, cross-cutting enabling technologies and AHA fields and evaluate the actual impact achieved across the innovation tracks and socio-economic environment.

1.4 Main S&T results/foregrounds

We can categorize the main S&T results as follows:

- 1) Clinical and Medical: GATEKEEPER has produced a data driven approach for preventive digital services for the 9 Reference Use Cases, resulting in a set of standardized AI-pipelines for > 25 models
- 2) Technological Infrastructure: the GATEKEEPER platform is a state-of-the-art solution enabling federated data sharing on a secure and protected environment, as well as a platform based on an ML-ops approach for deployment, training and validation of AI models, based HL7-FHIR Implementation Guidelines for Chronic Disease Management.
- 3) Business and Healthcare Level: GATEKEEPER represent a new set of digital services and solutions validated in a multisided market and related multisided platform through the GATEKEEPER marketplace. The services have been analyzed from a cost-effectiveness perspective in all the Reference User Cases in the 8 healthcare systems of the European Pilots.

1.5 The potential impact and the main dissemination activities and exploitation of results

1.5.1 INNOVATION Impact

1.5.1.1 The main KPIs of TECHNOLOGY ECOSYSTEM impact

Following (Table 2) is described a comprehensive overview of the technology ecosystem impact of the Gatekeeper platform across various dimensions.

Table 2: KPIs Gatekeeper technology KPIs across various dimensions

Infrastructure Scalability	User Engagement	AI Resource Allocation	AI Services Deployment	Model Operations Capabilities	Computational Power	Hardware Infrastructure
20+ servers running Linux	175+ users: ~50 data scientists 125 developers	<u>Runtime</u> 400 vCPU 16 vGPU 3 TB RAM 20 TB storage <u>Data Fabric</u> OS: Rocky Linux 8.5 4 servers 128 vCPU 256 GB RAM	Aragon: 2 BasqueC: 3 Cyprus: 2 Greece: 1 Puglia: 3 Lodz: 1	Data preparation Model development Model training and optimization Model deployment Model serving	768 vCPU 6 TB RAM 70 TB DISK 16 vGPU 125 teraFLOPS	14 servers 7 switch 3 storage 70 VMs

Infrastructure Scalability	User Engagement	AI Resource Allocation	AI Services Deployment	Model Operations Capabilities	Computational Power	Hardware Infrastructure
		50 TB storage				

- **Infrastructure Scalability:** With over 20 servers running Linux and a Kubernetes v1.23 setup, the Gatekeeper platform demonstrates scalability to accommodate diverse workloads and tenant requirements. The presence of multiple tenants, including pilots and cross-cutting projects, showcases the platform's ability to cater to a wide range of use cases and stakeholders.
- **User Engagement:** The platform boasts over 175 users, including data scientists and developers, distributed across different regions and projects. This user base indicates active engagement and utilization of the platform's capabilities for AI and big data analytics, contributing to its overall impact and relevance.
- **Resource Allocation:** Detailed specifications of the runtime platform and data fabric highlight substantial computational resources allocated to support AI and big data processing. This includes a significant number of servers, vCPUs, RAM, storage capacity, and vGPUs, indicating the platform's robustness in handling large-scale data analytics and machine learning tasks.
- **AI Services Deployment:** The deployment of 12 AI services across various pilot sites demonstrates the practical application of AI technologies within the Gatekeeper ecosystem. These services cater to specific regional needs and use cases, fostering innovation and driving tangible outcomes in areas such as healthcare, agriculture, and urban mobility.
- **Model Operations Capabilities:** The inclusion of model ops functions such as data preparation, model development, training, deployment, and serving underscores the platform's end-to-end capabilities in managing AI and machine learning workflows. This comprehensive support for model lifecycle management enhances efficiency and accelerates the development and deployment of AI solutions.
- **Computational Power:** The substantial computing power available within the Gatekeeper platform, including vCPUs, RAM, disk space, and GPU acceleration, enables high-performance data processing and modeling tasks. This computational prowess empowers users to tackle complex analytics challenges and derive actionable insights from large datasets.
- **Hardware Infrastructure:** The presence of dedicated hardware components, including servers, switches, and storage units, reflects the platform's robust underlying infrastructure. This hardware backbone ensures reliability, availability, security, privacy and performance optimization for serving a diverse user base and supporting mission-critical AI and big data applications.

Overall, these KPIs collectively demonstrate the technological maturity, scalability, and impact of the Gatekeeper platform in facilitating AI and big data-driven innovation across multiple domains and regions.

1.5.1.2 The main KPIs of USER'ACCEPTANCE and co-creation impact

User acceptance

1. UK Pilot

Overall, the feedback received concerning reception and usability was average:

- A. **MK RUC 7** – The system was found to be challenging to use, not easy to recommend. However, it was positively received in terms of value and frequent use.
- B. **MK RUC 1** – The App was poorly received, with problems with registration and key functionalities, as well as concerns about risks and liability.

2. Saxony Pilot

Overall, the usability feedback collected with a digital version of the SUS questionnaire was poor for both RUCs. The average SUS score being 24.93. The score for RUC7 was slightly higher than for RUC1,

- A. **SAX RUC 1** – low complexity (113 surveys) with a SUS score of 23.88.
- B. **SAX RUC 7** – medium complexity (79 surveys) with a SUS score of 26.01 on average among the three study groups.

The personal feedback by users does not reflect the SUS score and was a lot more positive. It mostly focused on the app-contents rather than the apps usability. The main challenges were technical/digital illiteracy with new devices and apps as well as multiple apps to configure and collect data.

3. Basque Country Pilot

Overall, the feedback collected through the SUS questionnaire, across the different RUCs, proved high scores for usability in most cases:

- A. **RUC 1 – Community based Intervention.** An effective intervention, but with low adherence and high dropout rates. No information regarding the usability due to the non-completion of the questionnaire.
- B. **RUC 3 – Diabetes.** 52 patients involved, with a SUS score of 93.4 (highly usable).
- C. **RUC 4 - Parkinson's Disease.** 43 patients involved, with a SUS score of 88.1 (highly usable).
- D. **RUC 6.1 - Stroke Identification.** 52 volunteers involved, with a SUS score of 85.91 (highly usable).
- E. **RUC 6.2 – Stroke Monitoring.** 42 volunteers involved, with a SUS score of 82.05 (highly usable).
- F. **RUC 7 - Polypharmacy & Treatment Adherence.** 690 patients involved. Pharmacological treatment reviewing platform received high usability reports from pharmacists, while Adherence app received low usability scores from patients.

4. Puglia Pilot

Overall, the feedback received regarding usability was average:

- A. **RUC 1,2,3,5,7,8 - AReSS Study.**

- a. RUC1 - Low Complexity: High usability. Most participants rated the approach as friendly and easy-going and claimed that everything worked perfectly.
- b. RUC2,3,5,7,8 - Moderate Complexity: 8 users interviewed for a qualitative usability analysis. Low usability, mainly due to complexity to use and digital illiteracy.
- B. **RUC 3 - CSS Study.** RUC3 Moderate Complexity: Low usability for the Samsung GATEKEEPER App, which was then changed with the more stable Samsung Health App.

5. Aragon Pilot

Overall, the feedback received demonstrated satisfactory usability, with users generally accepting the technology, although some challenges and variations were observed in specific interventions:

- A. **RUC 1** – Maha App was well received by most users, who voted for a high level of usability, despite some drawbacks including the unnecessarily complex usage, registration process and standalone nature of the App.
- B. **RUC 2,5,7 Mid-intervention** – 8 participants took part in the SUS survey. Average SUS value was 64.63, suggesting good usability.
- C. **RUC 2,5,7 High-intervention** – 7 participants took part in the SUS survey. Average SUS value was 60.50, suggesting good usability.

6. Cyprus Pilot

- A. **Cancer study** – The healthcare professionals (HCPs) rated the platform with a SUS score of mean \pm SD of 58.2 ± 19.74 , suggesting challenges, while the informal caregivers with a 67.45 ± 28.66 , which is close to the SUS average benchmark of 68, Patients rated the device use with 62.41 ± 25.47 and the combined use of devices and platform higher, with 66.8 ± 28.03 , which are both close to the average benchmark. Their difference is not statistically significant ($p = 0.162$). All user categories also rated the system by responding to the Single Ease Question (SEQ). The use of the platform received an average rating of 4.38 by the HCPs, 5.23 by the informal caregivers, and 5.16 by patients on a scale of 1 (very difficult) to 7 (very easy).
- B. **Dementia study** – The healthcare professionals rated the platform with a SUS score of mean \pm SD of 38.61 ± 17.6 , suggesting challenges, while the informal caregivers with a median (IQR) of 67.5 (32.5), which is close to the average benchmark of 68, Patients rated the device use with 57.13 ± 21.52 and the combined use of devices and platform higher, with 61.69 ± 18.47 , which are both close to the average benchmark. Their difference is not statistically significant ($p = 0.188$).

All user categories also rated the system by responding to the SEQ. The use of the platform received an average rating of 3.04 by the HCPs and 4.56 by the informal caregivers. Patients rated the ease of the device use with a mean \pm SD of 5 ± 2.79 and the combined use of devices and platform higher, with 5.19 ± 1.41 , which indicates high ease. The difference is not statistically significant ($p = 0.445$).

7. Greek Pilot

- A. **RUC1** – The Post-Study Usability Questionnaire (PSSUQ) was used for rating the usability of the system, where smaller scores refer to a system of better performance and satisfaction. The rating received from patients showed high usability in both intervention types (intervention 1 – platform, intervention 2 – platform and devices) and at both iterations (baseline, end of study). In comparison, the average end-of-study scores for Intervention 2 are lower than Intervention 1 (Table 2), indicating that Intervention 2 is characterized as more useable by the participants, but the results are not statistically significant. The overall comparison between baseline and follow-up (unpaired *t*-test) also revealed a statistically significant improvement in perceived system usefulness by 0.24 ($p = 0.028$).

Table 3. PSSUQ scores by Intervention 1 and 2 patients at the end of the Greek pilot RUC1 study.

Score type	Mean (Interv. 1)	Mean (Interv. 2)	p-value
Overall	2.64	2.43	0.198
System usefulness	2.57	2.40	0.351
Information quality	2.72	2.55	0.307
Interface quality	2.64	2.31	0.063

HCPs gave the system lower PSSUQ scores than patients. On average, they rated it higher a few days after starting to use it than at the end of the study, which is possibly influenced by the overall higher pressure and workload of the professionals to complete the study.

Table 4. PSSUQ scores by HCPs of the Greek pilot RUC1 study

Score type	Mean (baseline)	Mean (follow-up)	Mean diff.	p-value
Overall	3.44	4.45	1.01	0.027
System usefulness	3.74	4.37	0.63	0.216
Information quality	3.07	4.4	1.33	0.003
Interface quality	3.46	4.68	1.22	0.014

- B. **RUC3** – Patients responded to the PSSUQ and rated the devices an overall score of 5.23 ± 1.61 , with patients reporting difficulties, such as the need for daily device calibration.

8. Poland Pilot

Generally, users spoke positively about the application. The app was user-friendly and designed in a way that even elderly individuals could easily make use of it.

RUC 1 – the application included a question assessing the user's feedback on improving adherence to therapeutic recommendations. It asked the user 'Was this suggestion helpful?' after each recommendation was given with two possible answers: 'Yes' and 'No'. A remarkable 72.6% of opinions about the validity of the received suggestions agreed that they were helpful. Therefore, it can be said that users who answered this question indicated that the advice provided in the application for improving adherence to therapeutic recommendations was effective, valid, and useful.

Cocreation

The co-creation approach followed and embraced in the project, is inspired by the Social Sciences and Humanities, more specifically the field of Responsible Research and innovation (RRI) and Valuation Studies. Rather than measuring and comparing indicators, the approach focused on better understanding specific value positions and constellations embedded in local practices and relations, as comes with the qualitative inductive nature related to the social science-based co-creation approach.

The co-creation approach informed a template design for the workshops focused on the organization of two cycles of co-creation workshops at (all) pilot sites, aiming to map and explore value positions and to develop implementation pathways per pilot. The approach is further described in D2.2. and in Van Hees et al (2023)^[1]. In workshops, among others awareness was raised among pilot stakeholders and project partners about the great variety and dynamics between many values in practice.

Considering the impact of the workshops: in total 17 co-creation workshops took place at 9 different pilot sites (cycle 1 in 2020 with 137 participants, cycle 2 in 2022-23 with 141 participants), and in this period continuous discussions with pilot and platform cluster partners took place, with discussion input also from in-depth ethnographic fieldwork in Use Case 1 at two GK pilot sites in 2022-23 (Milton Keynes and Puglia). This included a wide range of stakeholder engagement during the workshops. For a complete overview of different types of participants (see D2.9 and D2.10, tables with overview of stakeholders). In D2.2. another overview of stakeholders is included, showing the great diversity and international spread of stakeholders engaged in this project via the co-creation work.

Co-creation was also adopted among project partners in other internal and external project-related meetings, inspiring further interdisciplinary workshops and sessions (e.g. in the business cluster). A further clear and important impact is the continuation and further refinement of the approach in other projects (e.g. IDEA4RC and QoLEAD project).

^[1] Van Hees, S., Greubel, C., Moors, E., & Peine, A. (2023). Valuation in health and ageing innovation practices. *Ageing and Society*, 43(9), 2022-2040. doi:10.1017/S0144686X21001483

1.5.1.3 The main KPIs of BUSINESS & EXPLOITATION impact

The main innovation KPIs from the business & exploitation for GATEKEEPER was to create new business models and validate them. The main challenge in creating a business model that can cater to multiple stakeholders was addressed using a Newtork-based business model. The business model improves service delivery and provides greater operational efficiency. The business & exploitation impact will be delivered in the final delivery of D9.5, where GATEKEEPER will describe the next 5-year business plan and a non-commercial sustainability plan. As a direct impact, partners from the project are already applying for

new public tenders using GATEKEEPER technology and there is a clearly defined path for integrating GATEKEEPER outputs in many industry partners' products.

1.5.1.4 Main KPI of achievement and impact in the DISSEMINATION & COMMUNICATION innovation

Overall, the expectations for a project of this magnitude have been met, and in many instances, the anticipated impact has been exceeded. The communication team has diligently worked to underscore the significance of this large-scale pilot, both locally and within the broader European context, engaging key stakeholders effectively.

Table 5: KPIs by D&C action

ID	D&C Action	KPI from DoA	Source	Total target	Results
1	WEBSITE	Number of visitors	Google Analytics	20K visitors	76K Sessions 139K Pageviews 40K Users
2	BLOG	Number of articles published	Internal tracking	24 (2 per month)	22 blog posts
3	MATERIALS	<u>Print</u> : number of copies <u>Videos</u> : number of views	<u>Print</u> : internal tracking <u>Videos</u> : number of views from YouTube	<u>Print</u> : 500 copies <u>Videos</u> : 2Kviews	<u>Print</u> : more than 500 copies have been produced and distributed <u>Videos</u> : More than 5_K views
4	MEDIA	Number of press releases launched	Clipping	1 per year	4 global press release launched
5	SOCIAL MEDIA	<u>Twitter</u> : number of followers <u>LinkedIn</u> : number of contacts	Twitter and LinkedIn analytics	<u>Twitter</u> : 1000 <u>LinkedIn</u> : 500	<u>Twitter</u> : 1115 <u>LinkedIn</u> : 293 (*In the previous account we had 1000 contacts).
6	CONFERENCES	Number of conferences attended	Internal tracking	International: 2 National: 5	More than 90 national and international conferences attended
7	PUBLICATIONS	Number of publications generated	Internal tracking	20 articles published	15 publication presented

1.5.2 Socio-economic impact

In WP7, and more specifically in Task 7.2 Detailed experiment and KPI definition and Task 7.8 Local Impact assessment: exploitation, communication, replicability and growth, PredictBy has, together with the WP7 leader UoW and WP6 leader CIB, and all pilot partners established the most important KPIs and assessment methodologies (e.g., MAFEIP-analyses, PESTLE, SWOT) to collect the relevant socio-economic impact factors to analyse the outcomes of the GATEKEEPER project. Subsequently, over the years of the project, the pilots have collected all the relevant data in order to conduct the analyses needed to establish the socio-economic impact of the GATEKEEPER platform and solutions for local and general context. This is reported in more detail in Deliverable 7.4 Pilot Studies Evaluation Results and sustainability plan. Clinical effectiveness of the solutions is reported, and in addition ex-ante or post-hoc cost-effectiveness assessment have been conducted to report the socio-economic impact of the solutions at a local context. As GATEKEEPER aims at continuing with the pilot site operations after the project ends, which can also be seen in this report where some pilots have communicated their plans for the future, the socio-economic impact assessment.

1.5.3 EXPLOITATION

1.5.3.1 Global exploitation

GATEKEEPER has produced several exploitable results; the key ones being listed below. Some of these will be made available free of charge to government organisations and interested partners. Each partner will identify suitable manager for the service, host the service and make it available beyond the project.. Further maintenance of these services will also be agreed among partners along with economic support model for each of the services.

Sustainability of these FERs is a key and we consider the following specific factors that will support the sustainability.

1. External funding for continuation of services
2. Training workshops
3. Joint ventures
4. Adoption of GATEKEEPER products in multiple EU projects

FER 1 – Marketplace

The GATEKEEPER marketplace is the single-entry point for all users to consume the services from GATEKEEPER. The GATEKEEPER Marketplace offers a unique variety of content like applications, services, and datasets. Interconnected with the GATEKEEPER Platform it provides secure authentication, discovery and validated/certified content.

FER 2 - AI Services

GATEKEEPER has designed and developed the entire pipeline required to create AI/ML services that enable AI services that is trustworthy, adheres to all the guidelines and EU medical device regulations. The AI services catalogue include the following;

1. **Advanced and personalised Health & Home Monitoring Services:** ADA
Adherence for intervening on the sedentary behaviours for T2D patients,
Assessment & Interpretation for Depression, PTSD and social interaction, Mobility
Concern for elderly based on WHO Adherence, Mobility Progress for elderly

based on WHO Adherence, Personalized Fitness Activities for cancer survivors, Physical Activity Recommender based on ADA Guidelines, T2D-Risk Estimator & Analysing the impact of Physical Activities and WHO Adherence.

2. AI-powered services for Personalized Early Risk Detection and Risk

Assessment: "Risk of fall assessment" based on interaction of poly-medication, Clustering of patients Frailty Risk, Early prediction of Metabolic Syndrome-related parameters, Predictive modelling of sleep quality and weight management and Risk estimation of non-adherence to medication.

3. Big Data-Enabled Medical AI Services for Proactive Detection and Intervention:

Early detection of a stroke episode or a transient ischemic attack, Early-detection of advanced Parkinson disease (APD), Emerging prognostic and diagnostic patterns connecting cancer symptoms, Explaining depression and anxiety levels in people with dementia, Hypoglycaemia predictive modelling, Long-term prediction of cardiovascular events in people with type 2 diabetes, Prediction of exacerbations for people with COPD, or heart failure, or poly-medicated people (Moderate and High Complexity), Recognition of data patterns associated with PROMs for advanced cancer patients, Risk prediction of cancer symptoms and recurrence and Short-term prediction of hypoglycaemia-related cardiac arrhythmias in people with type 2 diabetes.

4. Synthetic Data Generation Services: Probabilistic-Based Generator and Generative Adversarial Network (GAN)-Based Generator.

FER 3 – Clinical Research Platform a.k.a Multi-sided Platform

The Gatekeeper platform operates as a multi-sided platform connecting multiple stakeholders across different domains and regions. On one side, it serves data scientists, developers, and other users who require access to advanced AI and big data processing capabilities. These users benefit from the platform's robust infrastructure, computational power, and comprehensive support for AI model operations.

On the other side, Gatekeeper provides a marketplace for AI-based healthcare solutions, indicating its role as a platform for solution providers to offer their services. This marketplace likely attracts healthcare organizations, researchers, and other entities seeking innovative AI solutions for early detection and intervention.

Additionally, Gatekeeper accommodates multiple tenants, including pilots and cross-cutting projects, demonstrating its ability to cater to a diverse range of use cases and stakeholders. This suggests that the platform serves as a hub for collaboration and innovation, facilitating interaction and exchange among users and solution providers.

Overall, the Gatekeeper platform embodies a multi-sided platform business model by bringing together users and solution providers, facilitating interactions, and creating value for all stakeholders involved in the healthcare innovation ecosystem.

FER 4 - Data Services

The overall goal of the Action Topic 2 on GK Data Federation Model within the Gatekeeper Working Group has been to align and propose orientation to create a **Gatekeeper Data Marketplace (GDM)** compatible with the EU trends, policy and regulations. Specifically,

the goal has been to define how GDM can enable service for **monetization, digital contracts and brokerage** of a data economy based on secondary use of data. The pathway to reach this goal has been the following:

- 1) the **Data Federation architecture** by positioning GK model within the EU initiatives concerning the data spaces specifically from a point of view of the standards adopted, the compliance with the principles and regulations, etc.,
- 2) the **Data Federation production** to understand the overall framework governing the data exploitation, its sharing and governance; and,
- 3) **GK Data Marketplace implementation** to define the Business Model of the GK Data Market.

Community of Interest

The GATEKEEPER Community of Interest (Col) brings together and structures a network of stakeholders across Europe that work or are interested in the healthcare and technology offering portfolio. It is a network of key stakeholders interested in following the developments of the project and as such, attracted by topics at the crossroads of healthcare, artificial intelligent and big data.

The Col has been initiated in September 2020. It aims to connect the large network of stakeholders to foster learning, encourage collaboration, and offer an opportunity for creative problem-solving and innovation.

One element of Col is eGATEKEEPER Hub. It is a place for organizations already engaged in the community that wants to offer, publish, or communicate their solutions, products, or services (in case of the digital health companies); Or share their interest and needs (in case of health organizations, regulatory entities and/or policy makers).

FER 6 - Training and Education in digital transformation

The University of Warwick Team, as LSP and Pilot Manager with their partners as the table below has developed training course and materials on a variety of topics, including ethical approval in the D6.5, open calls WP2, personnel costing – D7.2.x and Project Periodic reporting, and pilot training. D6.4 and D7.1. It is designed to be used by a variety of stakeholders, including researchers, developers, and entrepreneurs. The materials are available within the different Deliverables as mentioned above.

The ethical approval module covers the different ethical considerations that need to be considered when developing and deploying AI models. The open calls module provides information on how to apply for funding from the GATEKEEPER project. The pilot training module provides training on how developing and deploying piloting experiences and their impact measures in Large Scale Pilots.

FER 7– Interoperability and integration guidelines

This section refers to the opportunity for partners to provide reference customers, i.e. software developers, with education, training and consulting services to facilitate the adoption of the GateKeeper Platform.

These services can be based on the guidelines that have been developed during the GateKeeper project:

- a set of guidelines for the development of connectors for the integration of data; indeed, if it is needed to provide a new converter for a new data source (it doesn't matter if such data source is going to call EHR or IOT interface), it is needed to implement a new converter following Data Federation framework guidelines.
- the guidelines for simplifying the understanding and adoption of GK FHIR.
- the guidelines for integrating new software as a Web of Things standard.

The results offer exploitation opportunities to industry partners, academies and health care organisations through measured observational benefits of the FERs during the life of the project. While industrial partners intend to continue the development work towards marketable products or services and to generate revenues in near future, academic partners aim at gaining benefits from increased visibility, from sales of licence fees on protected intellectual properties and from turning foreground into background in follow-up project activities.

From the societal perspective, the project seeks to ensure continued use of the products of GATEKEEPER for improving quality of life and proactive healthcare.

Target Groups for Exploitation

GATEKEEPER has involved different kinds of players in the use of the developed technologies, including.

1. End users
2. Healthcare developer community
3. Medical device vendors/producers
4. Individual persons (consumers) and caregivers
5. Data providers, e.g. regional health authority/hospital organising datathon
6. Scientific and professional community
7. End users

1.5.3.2 Individual exploitation plans from project organisations.

Engineering Ingegneria Informatica S.P.A

Since the beginning of the project, ENG has been discussing the progress of the GK results with its Healthcare Business Unit Sales to develop commercial strategies for customers potentially interested in our portfolio. In the meantime, the Company has undergone a profound transformation at every level, from the top leadership positions and strategies down to each specific unit of interest. On the one hand, this transformation is having a positive effect on the knowledge and technology transfer mechanism from the research and innovation areas to the business areas, promoting a systemic exploitation of project results. On the other hand, the transformation is still in progress and strategic commercial decisions are waiting for a more stable moment. All in all, this transformation can have a

positive impact on the GK results, as they are in the hype of the list of R&I exploitable results.

Funka

Funka will exploit the knowledge gathered through the project implementation to support new working groups and work items for European standards. The project results and experiences will be included into Funka's commercial portfolio to provide better interoperability across technologies for customers in public as well as private sector focusing on health. Furthermore, partnerships developed during the project will lead to proposals for new innovative project in AHA.

PredictBy

PredictBy will continue with the exploitation and sustainability of the project via other initiatives that recently have been launched, such as the IHI-projects BEAMER and IMPROVE, that can learn significantly from the GATEKEEPER-project. Furthermore, in several proposals we have proposed to continue with the platform and use the data collected in an efficient and effective way to continue the legacy of GATEKEEPER. In addition, the scientific papers that will come from the GATEKEEPER platform will be published after the project and will feed the impact of cost-effectiveness assessments in future projects as well, and the continuous

Medtronic

Medtronic Ibérica, as an industrial partner providing its expertise and knowledge in the GATEKEEPER project, will use the new knowledge generated during the project execution to increase its solutions portfolio and expand the market access in the chronic disease management and remote patient monitoring area. Thanks to the knowledge generated in the ecosystem and co-creation activities within the project, Medtronic will promote the services among the key stakeholders and clients of the healthcare system, promoting and fostering the growth. Medtronic is actively assessing the capabilities of the GATEKEEPER platform and its components, including interoperability, connectivity, AI, data analytics, security, and privacy, to revolutionize the delivery of integrated health services. Specifically, they are exploring how these technologies can enhance remote monitoring for both chronic and perioperative patients, potentially transforming the way healthcare is provided in hospitals and across healthcare systems. By leveraging these advancements, Medtronic aims to facilitate seamless communication and data analysis, ensuring efficient and effective remote monitoring solutions that improve patient outcomes and streamline healthcare delivery processes. Finally, all the knowledge generated in the Open Call Standard and the systematic process created, best practices and lessons learnt, will enable the future implementation of this knowledge in forthcoming projects and market scouting initiatives.

Samsung

Samsung has chosen two main products for the direct exploitation of GATEKEEPER results, mainly the AI services that are referenced in the FER-2. Samsung Health & Samsung Health monitor are the flagship Samsung applications shipped on every Samsung mobile that enable health and wellness monitoring. Based on the outcomes and TRL levels of the FER-XX services generated during GATEKEEPER, we plan to create

roadmap for product integration. The relevant publications from the project will be also published in Samsung Health developer website to facilitate wider dissemination. Samsung also plans to include the GATEKEEPER platform in Samsung Health Stack to create new self-service solutions for developers for clinical trials and non-interventional studies.

HPE

AGENAS the Italian Agency for Regional Health services has issued a Tender nation-wide to provide "Proximity Network for tele-medicine and health assistance supported by Artificial Intelligence".

The final tender has just been issued as a last step in the process during these days, a process initiated a few months ago.

HPE, leading a proposal to answer the tender, has gathered with others territorial large size companies and an extensive number of other entities from Italy and Europe to set up a competitive ecosystem to cover all branches of competence needed in several fields required, like Legal, Medical, IT, etc.

At the time of writing, Dec 2023, HPE along with all the other partners are to compile the final proposal.

The GATEKEEPER consortium during these years of collaboration has built up the necessary competence and networks to answer the tender.

Partners form GATEKEEPER partnering the tenders up to now are: UPM, UoI, CSS -IRCCS and some derived by the project like Campus Biomedico in Roma.

The HPE led proposal is to exploit the GATEKEEPER platform set up and built by HPE, to propose as a reference architecture to be adopted should the tender be assigned to the team. The architecture, readily available, will constitute the baseline during the first phases of the execution project gaining a significant advantage over the competitors. The architecture to be expanded in a federation of clouds as next steps, cloning the GATEKEEPER design based on Open-Source approach.

Once submitted the proposals, time will be unveiled on the date for results and assignment by the agency.

MYSHERA

The exploitation plans of Mysphera are the following:

1. Two Streams of Exploitation:

- A) Platform and Platform Components: MYSPHERA aims to exploit the platform and its components. The GK platform has been proposed as a central element in a recently issued tender in Catalonia, Spain. The offer for this tender was made in January 2024. The Mysphera's proposal includes an open-source platform featuring the enhanced Smart Connector, FHIRE server, Data Federation, and the GK Big Data platform for data management, analytics, and AI generation. MYSPHERA anticipates that similar approaches can be followed in future tenders.

- B) AI Models: MYSPHERA is also focusing on the exploitation of AI models developed within Task 5.3. They are currently involved in a regional project for implementing AI

solutions for clinical use. The Synthetic Data Generator developed in Task 5.3 is being adapted to meet the specific use cases required by the customer. Additionally, MYSPHERA plans to develop new AI models using the Gatekeeper AI Framework infrastructure.

2. Future Development:

- MYSPHERA is looking forward to developing new AI models, leveraging the Gatekeeper AI Framework infrastructure whenever possible.

In summary, MYSPHERA is strategically positioning itself to exploit both the platform and AI models, with ongoing projects and a proactive approach to participating in tenders that align with their capabilities and offerings.

ECHAlliance

ECHAlliance, gathering more than 1000+ members coming from government, industry, academia and society sectors, as well as 78+ digital health ecosystems and reaching out to 25,000+ professionals, represents a large community of targeted stakeholders that the Gatekeeper projects results will be disseminated to. ECHAlliance will continuously promote Gatekeeper results to this community and the International Network of Ecosystems including organisations from US, Africa and India. This will be done through the newsletter, Thematic Innovation Ecosystems gatherings (eg. On TIE on health data and TIE on healthy ageing), as well as ECHAlliance's data arm, The Digital Health Society Summit at the AI Club. Additionally, the events hosted by ECHAlliance (eg. at HLTH Europe 2024) are willing to present Gatekeeper's results, especially the marketplace as well as AI services, data services and course and materials. At the same time the interoperability and integration guidelines will be exploited through the two projects on the European Electronic Record Exchange Format (EEHRxF), namely XpanDH (<https://xpandh-project.iscte-iul.pt/>) and xShare (<https://xshare-project.eu/>)

MME

MME an innovative SME – will cooperate with FPM, AReSS as well as other regional agencies targeting health promotion for the aging population segments, in order to further improve and deploy the e-coaching services experimented on top of the GATEKEEPER platform, and further replicate the excellent results obtained during the GATEKEEPER RUC1 experiment, particularly in terms of high user acceptability, significant impact on EQ5D Quality of Life measures and economic viability (locating the ICER value at an highly affordable 2,550 €/QALY value, when charging a monthly fee of 5.7 €/month, as computed by MME in the RUC1 HTA, as reported in D7.4). MME will extract value from the specific activities it conducted in such RUC1 experiment, that it coordinated, including expertise in gathering and classifying resources targeting health promotion e-coaching services, establishing messages and mini-plans for the optimal delivery of such resources to participants, assessment of impact through satisfaction questionnaires and validated PROM scales.

1.5.4 Dissemination and Communication

Throughout 4 years, intensive work has been conducted in communicating the project objectives, progress, and the innovation it has generated in the field of chronic disease management by generating innovative services based on digital technologies and artificial intelligence.

The focus of this task has centred, in a first phase, on creating awareness among the identified targets and, in subsequent stages, on engaging these actors with the intention of sharing the project value and involve them in a cocreation process to validate the solutions proposed at different levels.

Overall, the expectations for a project of this magnitude have been met, and in many instances, the anticipated impact has been exceeded. The communication team has diligently worked to underscore the significance of this large-scale pilot, both locally and within the broader European context, engaging key stakeholders effectively.

1.6 Address of the project public website

- Website: <https://www.gatekeeper-project.eu/>
- X: https://twitter.com/GATEKEEPER_EU
- YouTube: <https://www.youtube.com/channel/UCSRkDhGl2FGtfJuYhCsoVzw/videos>
- LinkedIn: <https://www.linkedin.com/company/gatekeeper-project/about/>

1.7 Relevant contact details and list of partners

Table 6. Partners contacts

Name	Role	Partner	Email
Germán Gutierrez	Project Coordinator	MDT	german.gutierrez@medtronic.com
Paula Currás	Project Manager and WP1 Leader	MDT	paula.curras@medtronic.com
Sergio Guillén	Deputy project coordinator and Business Cluster manager	MYS	sguillen@mysphera.com
Giuseppe Fico	Technical Manager	UPM	gfico@lst.tfo.upm.es
Eugenio Gaeta	Platform Cluster Manager	UPM	eugenio.gaeta@lst.tfo.upm.es
Leandro Pecchia	LSP Cluster Manager	UoW	l.pecchia@warwick.ac.uk
Leire Bastida	Risk and Quality Manager	TEC	leire.bastida@tecnalia.com
Lidia Manero	Dissemination and Communication Manager	MDT	lidia.manero.mijangos@medtronic.com
Francisco Lupiáñez	Impact and Evaluation Manager	PBY	flupianez@predictby.com
Konstantinos Votis	Security & Privacy Manager	CERTH	kvotis@iti.gr
Dimitris Fotiadis	Scientific Manager	UoI	dimitris.fotiadis30@gmail.com

Name	Role	Partner	Email
Adrián Quesada	Ethical, Legal and Gender Issues Manager	MI	aquesada@mandint.org
Rohit Ail	Innovation Manager	SAM	rohit.ail@samsung.com
Susan Van Hees	WP2 Leader	UU	s.v.vanhees@uu.nl
Ioanna Drympeta	WP3 Leader	CERTH	idrympeta@iti.gr
Claudio Caimi	WP4 Leader	HPE	claudio.caimi@hpe.com
Carlo Allocca	WP5 Leader	SAM	c.allocca@samsung.com
Jordi de Batlle	WP6 Leader	CIBER	jordidebatlle@gmail.com
Davide Piaggio	WP7 Leader	UoW	davide.piaggio@warwick.ac.uk
Susanna Laurin	WP8 Leader	FUNKA	susanna.laurin@funka.com
Marta Perez	WP9 Leader	MDT	marta.perezalba@medtronic.com

1.8 Project figures



Figure 3. GATEKEEPER in numbers

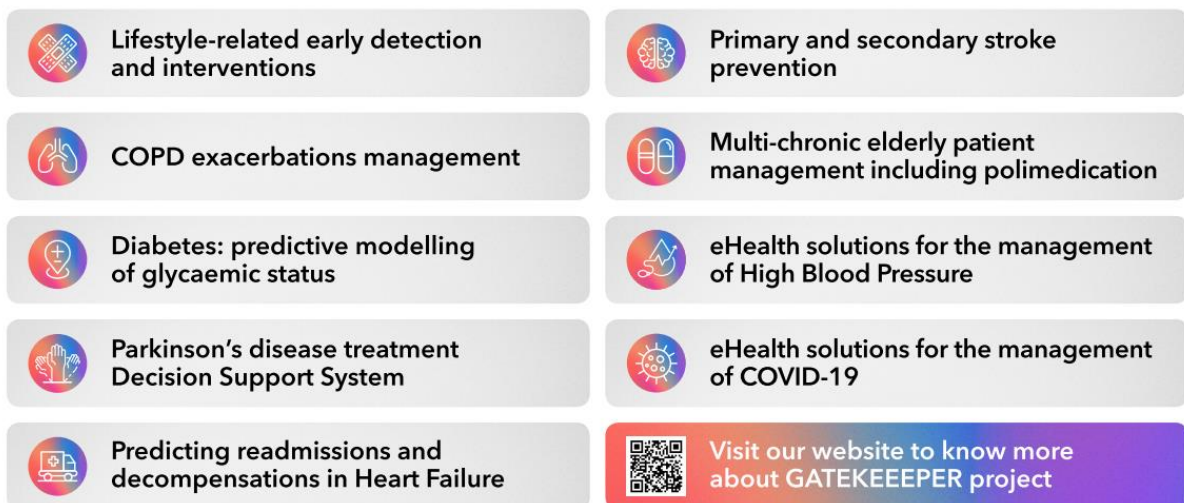


Figure 4. GATEKEEPER Use Cases

1.9 Project Logo

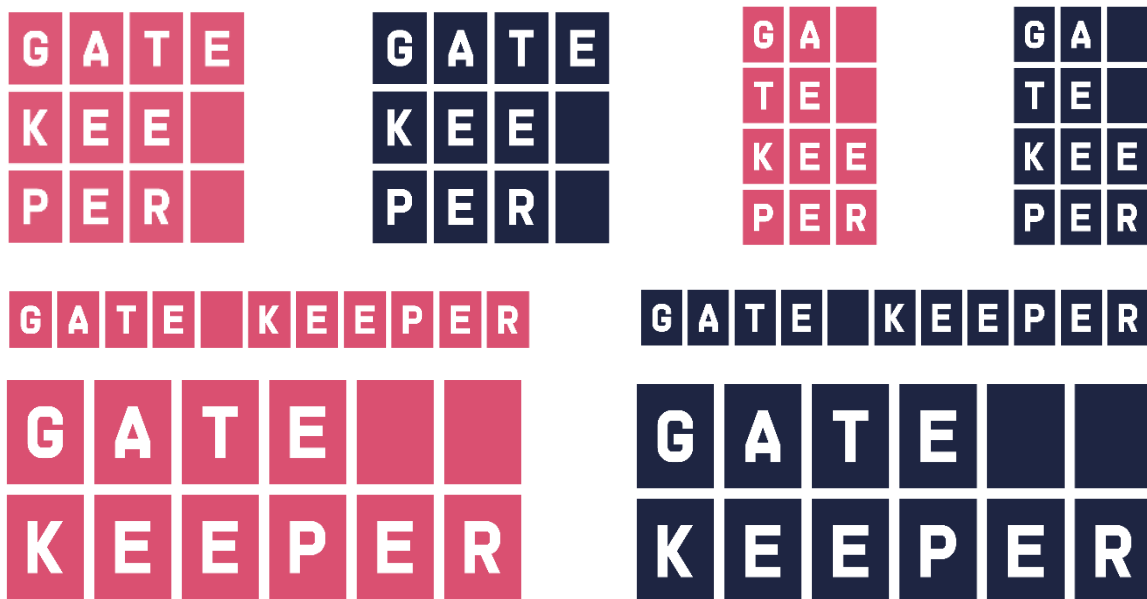
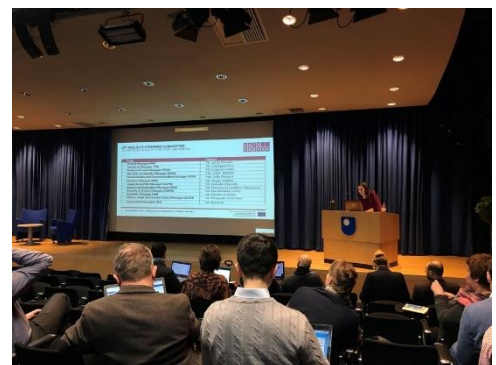
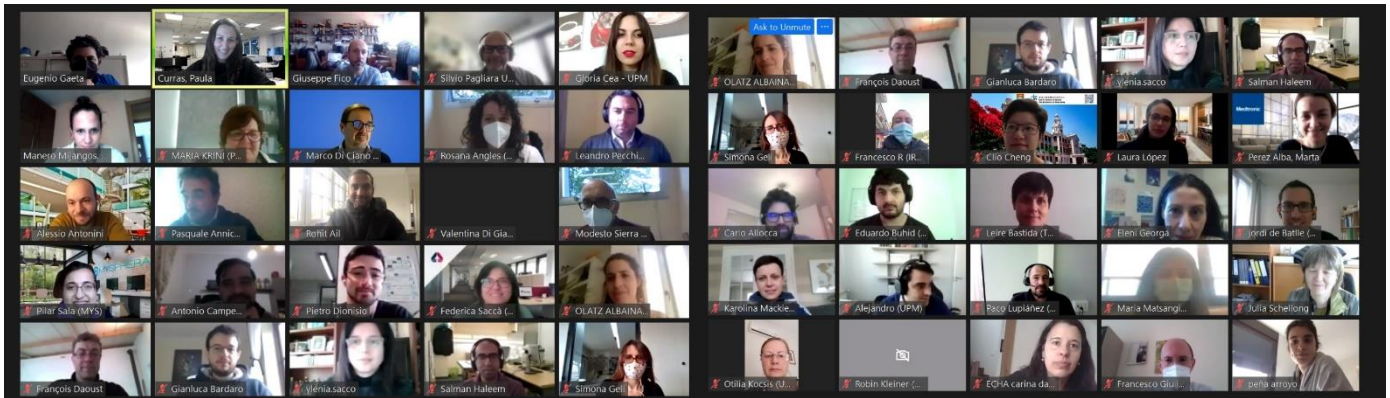


Figure 5. Project Logo

1.10 Project photos









1.11 Promotional Videos

All the project promotional videos can be found at:

<https://www.youtube.com/channel/UCSRkDhGl2FGtfJuYhCsoVzw/videos>

1.12 Graphic Materials

Throughout the entire lifespan of the GATEKEEPER project, a significant focus has been on the creation and distribution of comprehensive dissemination materials. These materials were meticulously crafted to effectively communicate the project's objectives, challenges, and impact. The strategy was to provide a clear and engaging overview of the project, ensuring that the core message resonated with a diverse range of stakeholders.

The development of these materials involved producing a variety of resources, such as brochures, presentations, infographics, flyers, and audiovisuals. Each piece was designed to be informative yet accessible, catering to both professional profiles and the general public. These materials were widely distributed among the project consortium members, ensuring that team members had access to consistent and cohesive resources that they could utilize during various interactions, such as meetings, conferences, and workshops.

Recognizing the importance of digital accessibility, a repository of these dissemination materials was created and added to the download section of the GATEKEEPER project's website. This online presence allowed for broader reach, enabling interested parties from around the globe to easily access and learn about the project.

Some examples of the pieces generated are shown below:

1.12.1 General communication materials



Figure 6 – GATEKEEPER brochure of the Reference Uses Case

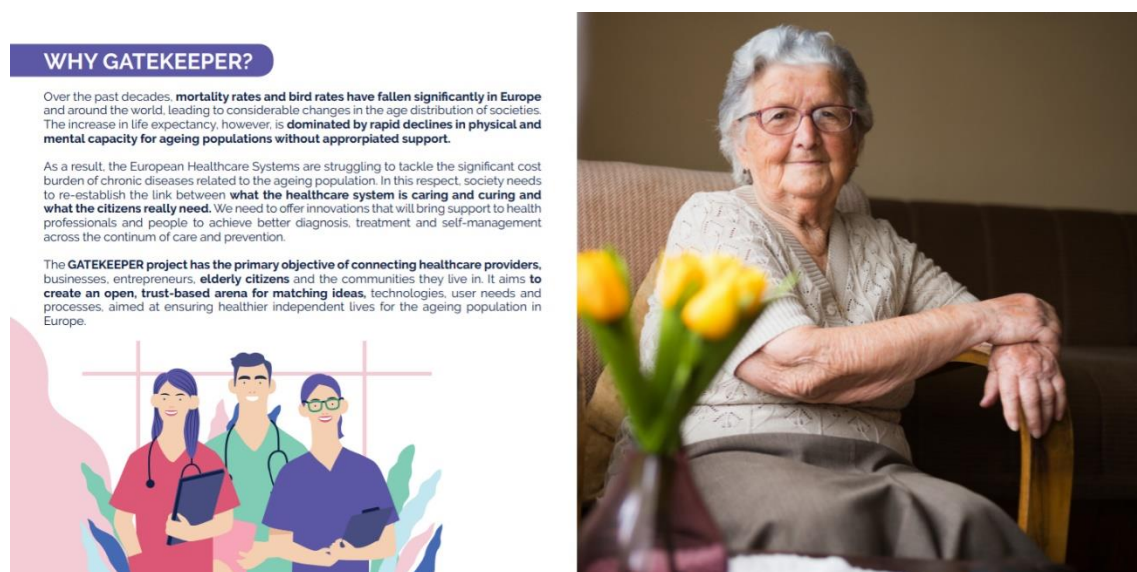


Figure 7 – GATEKEEPER brochure oriented to professionals' targets.



Figure 8 – GATEKEEPER overview presentation

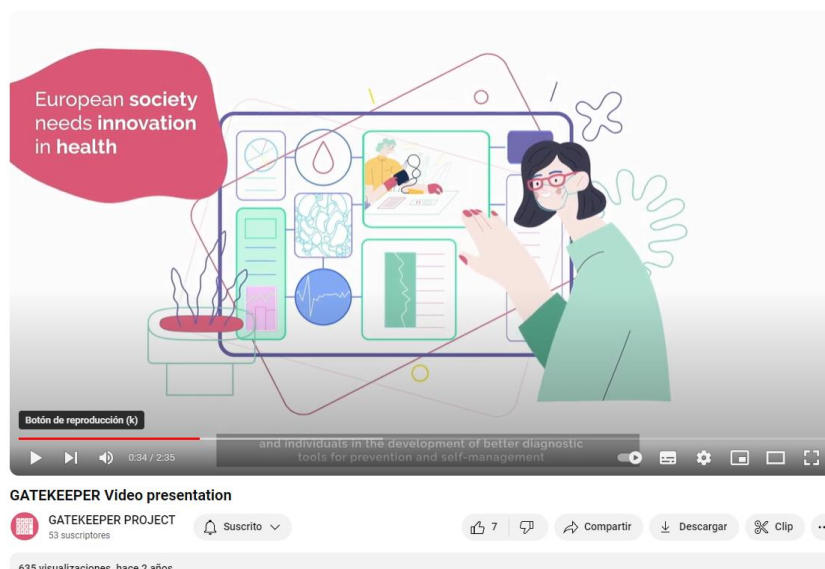


Figure 9 – Informative video

1.12.2 Ad-hoc materials generated to support pilot activities.



Figure 10 – Example of Puglia pilot materials



Figure 11 – Example of Basque country pilot materials

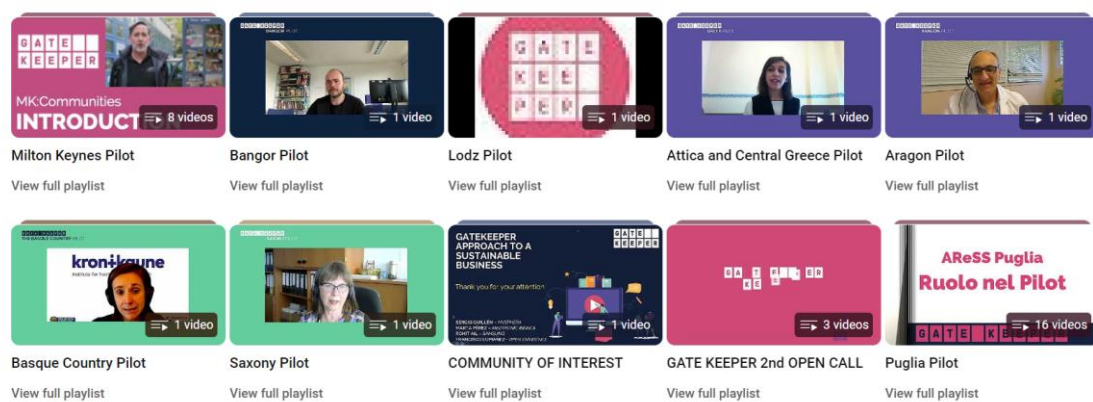


Figure 12 – Pilot testimonials

1.12.3 Community enlargement materials



Figure 13 – Col offer brochure.



Figure 14 – Col engagement emailings

1.12.4 Newsletters

Throughout the lifespan of the Gatekeeper project, a concerted effort was made to keep our community informed and engaged through regular newsletters. Over the course of the project, a total of four general newsletters were sent out, each thoughtfully curated to share updates, achievements, and insights related to the project's progress.

These newsletters were strategically spaced to provide timely updates without overwhelming our subscribers. Each edition was carefully crafted to include a variety of content, such as: project progress and updates, event announcements, Open Calls and Community of Interest opportunities and insightful articles on the domain.

The Gatekeeper project's newsletters achieved significant success in terms of subscriber engagement. Over the duration of the project, we managed to build a robust subscriber base, with more than **300 individuals** signing up to receive our updates. This enthusiastic response represents a substantial level of interest and active engagement with the project, indicating a wide-reaching impact and a strong community connection.



Figure 15 – Examples of GK newsletter

2 Use and dissemination foreground.

2.1 Section A

Table 7: List of scientific publications

DOI	Type of pub.	Repositoring Link	Link to publication	Titile	Authors	Title of the Journal/Proceedings/B ooks series/Book (for book chapters)	ISBN	Publisher	Year of publication	Is this publication available in Open-Access, or will it be made available?	Is this a peer - reviewe d pub?	Is this a joint publ ic/p rivat e pub?
https://doi.org/10.1007/s12369-021-00816-3	Article in Journal		https://doi.org/10.1007/s12369-021-00816-3	Robots for Elderly Care in the Home: A Landscape Analysis and Co-Design Toolkit	Gianluca Bardaro, Alessio Antonini & Enrico Motta	International Journal of Social Robotics		Springer	2021	Yes - available in Gold Open Access	Yes	No
https://doi.org/10.3390/app12041776	Article in Journal		https://www.mdpi.com/2076-3417/12/4/1776	Toward a Symbolic AI Approach to the WHO/ACSM Physical Activity & Sedentary Behavior Guidelines	Carlo Allocca, Samia Jilali, Rohit Ail, Jaehun Lee, Byungho Kim, Alessio Antonini, Enrico Motta, Julia Schellong, Lisa Stieler, Muhammad Salman Haleem, Eleni Georga, Leandro Pecchia, Eugenio Gaeta, and Giuseppe Fico	Applied sciences		MDPI	2022	Yes - available in Gold Open Access	Yes	No
	Article in Journal		http://www.rosenbergesellie.it/ita/scheda-libro?aaref=1470	Modellare il "funnel della comunicazione" di un progetto di ricerca: l'esempio del Pilota Puglia GATEKEEPER	Serena Mingolla, Ylenia Sacco, Francesco Fera, Giovanni Gorgoni	QUADERNI DI COMUNICAZIONE SCIENTIFICA	ISBN pdf 9791259930699	Rosenberg & Sellier	2021	Yes – available	Yes	No

	Dissemination/education material	N/A	https://papier.gazetalekarska.pl/pdf/Gazeta_Lekarska_07-08_2022.pdf	Lekarzu, nie zapominaj o swoim leczeniu!	Przemyslaw Kardas	Gazeta Lekarska	NA	Naczelna Rada Lekarska	2022	Yes - available in Gold Open Access	No	No
	Publication in Conference proceedings/Workshop	https://www.researchgate.net/profile/Elias-Dritsas/publication/363347665_Efficient_Data-driven_Machine_Learning_Models_for_Hypertension_Risk_Prediction/links/6318bf8b0a70852150d6c221/Efficient-Data-driven-Machine-Learning-Models-for-Hypertension-Risk-Prediction.pdf	https://ieeexplore.ieee.org/abstract/document/9894186	Efficient Data-driven Machine Learning Models for Hypertension Risk Prediction	Elias Dritsas; Sotiris Alexiou; Konstantinos Moustakas	2022 International Conference on INnovations in Intelligent SysTems and Applications (INISTA)	NA	IEEE SMC	2022	No	Yes	No
	Publication in Conference proceedings/Workshop	https://www.researchgate.net/profile/Elias-Dritsas/publication/363347840_Sleep_Quality_Evaluation_in_Rich_Information_Data/links/6341117aff870c55ce0c7d4b/Sleep-Quality-Evaluation-in-Rich-Information-Data.pdf	https://ieeexplore.ieee.org/abstract/document/9904403/	Sleep Quality Evaluation in Rich Information Data	Ioannis Konstantoulas, Elias Dritsas, Konstantinos Moustakas	2022 13th International Conference on Information, Intelligence, Systems & Applications (IISA)	NA	IEEE	2022	No	Yes	No
	Publication in Conference proceedings/Workshop	https://www.researchgate.net/profile/Elias-Dritsas/publication/363347814_Metabolic_Syndrome_Risk_Forecasting_on_Elderly_with_ML_Techniques/links/6318bf0c70cc936cd3ed484f/Metabolic-Syndrome-Risk-Forecasting-on-Elderly-with-ML-Techniques.pdf	https://link.springer.com/chapter/10.1007/978-3-031-24866-5_33	Metabolic Syndrome Risk Forecasting on Elderly with ML Techniques	Elias Dritsas, Sotiris Alexiou, Konstantinos Moustakas	The 16th Learning and Intelligent Optimization Conference	NA	Springer-Verlag	2022	No	Yes	No

	Publication in Conference proceedings/Workshop	https://drive.google.com/file/d/1iZ675pv1-6SJekPp4kiDyodgJaxTH4i/view	https://dl.acm.org/doi/abs/10.1145/3529190.3534748	COPD Severity Prediction in Elderly with ML Techniques	Elias Dritsas, Sotirios Alexiou, Konstantinos Moustakas	Proceedings of the 15th International Conference on Pervasive Technologies Related to Assistive Environments	978-1-4503-9631-8	ACM	2022	No	Yes	No
10.3390/ijerph18147596	Article in Journal		https://doi.org/10.3390/ijerph18147596	From Matter to Matter: 'Goods' and 'Bads' in Ageing and Innovation Policy Discourses	Carla Greubel, Ellen H.M. Moors, Alexander Peine	Int. J. Environ. Res. Public Health	NA	MDPI	2021	Yes - available in Gold Open Access	Yes	No
10.26314/GARR-Conf22-proceedings	Publication in Conference proceedings/Workshop	N/A	https://www.garr.it/en/garr-en/documents/selected-papers/selected-papers-conferenza-2022/6097-conferenza-2022-selected-papers-16-ricciardi	The hospital research network for the GATEKEEPER project: a case study	Francesco Ricciardi, Sergio Russo, Stella Grazia Pastore, Francesco Giuliani	CONDIVISIONI. La rete come strumento per costruire il futuro. Selected papers	978-88-946629-1-7	Associazione Consortium GARR	2022	Yes - available in Green Open Access	Yes	No
10.1017/S0144686X21001483	Article in Journal	N/A	https://doi.org/10.1017/S0144686X21001483	Valuation in health and ageing innovation practices	Van Hees, S., Greubel, C., Moors, E., & Peine, A.	Ageing and Society		Cambridge University Press	2021	Yes - available in Gold Open Access	Yes	No
10.3233/SHTI230435	Publication in Conference proceedings/Workshop		https://ebooks.iospress.nl/doi/10.3233/SHTI230435	Experience from the Development of HL7 FHIR IG for Gatekeeper Project	Roberta Gazzarata, Catherine Chronaki, Alba Gallego, Eugenio Gaeta, Giuseppe Fico, Paolo Zampognaro, Franco Mercalli, Francesco Giuliani, Carlo Allocca, Giorgio Cangiali	Studies in Health Technology and Informatics	978-1-64368-401-7	IOS Press	2023	Yes - available in Green Open Access	Yes	No

IN PRESS	Publication in Conference proceedings/Workshop		https://pubmed.ncbi.nlm.nih.gov/38270032/#:~:text=In%20this%20platform%20the%20role,was%20created%20for%20this%20purpose	The role of HL7 FHIR in the European Project GATEKEEPER	Roberta GAZZARATA, Catherine CHRONAKI, Alba GALLEGRO, Eugenio GAETA, Giuseppe FICO, Paolo ZAMPOGNARO, Franco MERCALLI, Francesco GIULIANI, Carlo ALLOCCA and Giorgio CANGIOLI	Studies in Health Technology and Informatics	IN PRESS	IOS Press	2023	Yes - available in Green Open Access	Yes	No
IN PRESS	Publication in Conference proceedings/Workshop		https://pubmed.ncbi.nlm.nih.gov/37869817/	Design and adoption of a FHIR IG to support a telemonitoring environment in Gatekeeper Project	Roberta GAZZARATA, Catherine CHRONAKI, Francesco RICCIARDI, Francesco GIULIANI, Paolo ZAMPOGNARO, Franco MERCALLI, Carlo ALLOCCA, Eugenio GAETA, Giuseppe FICO and Giorgio CANGIOLI	Studies in Health Technology and Informatics	IN PRESS	IOS Press	2023	Yes - available in Green Open Access	Yes	No
https://doi.org/10.3390/electronics12091989	Article in Journal		https://doi.org/10.3390/electronics12091989	Deep-Learning-Driven Techniques for Real-Time Multimodal Health and Physical Data Synthesis	Haleem, M.S.; Ekuban, A.; Antonini, A.; Pagliara, S.; Pecchia, L.; Allocca, C.	Electronics		MDPI	2023	Yes - available in Gold Open Access	Yes	No

2.2 Section B: Exploitable foreground results

Table 8. List of exploitable foreground

IP Name	Type of IP (SW/HW/P roduct/Serv ice)	Partners	BFMULO analysis	Protection (patents, copyrights, trademarks, and trade secrets)	Description/Licence/Copyrigh t information
SW module for eCRF clinical data collection	SW	CSS	BFMUL	Copyright	Licence
Dataset on patients with T2D@CSS	Product	CSS	BFMULO	Copyright	Description
Leaflet on traditional recipes/educational for patients with T2D	Product	CSS	BFMULO	Copyright	Description
OSCE questionnaire for RUC6.1 - Stroke identification	Product	OSA-Biobizkaia	F, U, O	Copyright	Copyright with permission to use
360° stroke videos	Product	OSA-Biobizkaia Tecnalia	F, U, O	Copyright	Copyright with permission to use
Stroke Scenes	Product	OSA-Biobizkaia Tecnalia	F, U, O	Copyright	Copyright with permission to use
Android application to connect with Samsung wearables	SW	Samsung	BFMUL	Copyright	Copyright with permission to use

3 Report on societal implications

A General Information *(completed automatically when Grant Agreement number is entered.)*

Grant Agreement Number:	857223
Title of Project:	GATEKEEPER
Name and Title of Coordinator:	Germán Gutiérrez – IHS Iberia Director

B Ethics

1. Did your project undergo an Ethics Review (and/or Screening)?

- If Yes: have you described the progress of compliance with the relevant Ethics Review/Screening Requirements in the frame of the periodic/final project reports?

☐

2. Please indicate whether your project involved any of the following issues:

☐

RESEARCH ON HUMANS

- Did the project involve children?
- Did the project involve patients?
- Did the project involve persons not able to give consent?
- Did the project involve adult healthy volunteers?
- Did the project involve Human genetic material?
- Did the project involve Human biological samples?
- Did the project involve Human data collection?

☐
☐
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RESEARCH ON HUMAN EMBRYO/FOETUS

- Did the project involve Human Embryos?
- Did the project involve Human Foetal Tissue / Cells?
- Did the project involve Human Embryonic Stem Cells (hESCs)?
- Did the project on human Embryonic Stem Cells involve cells in culture?
- Did the project on human Embryonic Stem Cells involve the derivation of cells from Embryos?

☐
☐
☐
☐
☐

PRIVACY

- Did the project involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
- Did the project involve tracking the location or observation of people?

☒
☒

RESEARCH ON ANIMALS

• Did the project involve research on animals?	<input type="checkbox"/>	
• Were those animals transgenic small laboratory animals?	<input type="checkbox"/>	
• Were those animals transgenic farm animals?	<input type="checkbox"/>	
• Were those animals cloned farm animals?	<input type="checkbox"/>	
• Were those animals non-human primates?	<input type="checkbox"/>	
RESEARCH INVOLVING DEVELOPING COUNTRIES		
• Did the project involve the use of local resources (genetic, animal, plant etc)?	<input type="checkbox"/>	
• Was the project of benefit to local community (capacity building, access to healthcare, education etc)?	<input type="checkbox"/>	
DUAL USE		
• Research having direct military use	<input type="checkbox"/>	
• Research having the potential for terrorist abuse	<input type="checkbox"/>	
C Workforce Statistics		
3. Workforce statistics for the project: Please indicate in the table below the number of people who worked on the project (on a headcount basis).		
Type of Position	Number of Women	Number of Men
Researchers	94	115
Workforces other than researchers	137	127
Total	231	242

D Gender Aspects

5. Did you carry out specific Gender Equality Actions under the project?	<input checked="" type="checkbox"/>
6. Which of the following actions did you carry out and how effective were they?	
	<div>Not at all effective</div> <div>Very effective</div>
<input type="checkbox"/> Design and implement an equal opportunity policy	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/> Set targets to achieve a gender balance in the workforce	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/> Organise conferences and workshops on gender	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<input type="checkbox"/> Actions to improve work-life balance	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<input type="radio"/> Other:	<input type="text"/>
7. Was there a gender dimension associated with the research content – i.e. wherever people were the focus of the research as, for example, consumers, users, patients or in trials, was the issue of gender considered and addressed?	
<input checked="" type="checkbox"/> Yes- please specify	<input type="text" value="Patients, elderly"/>
<input type="checkbox"/> No	

E Synergies with Science Education

8. Did your project involve working with students and/or school pupils (e.g. open days, participation in science festivals and events, prizes/competitions or joint projects)?
<input type="checkbox"/> Yes- please specify <input type="text"/>
<input checked="" type="checkbox"/> No
9. Did the project generate any science education material (e.g. kits, websites, explanatory booklets, DVDs)?
<input type="checkbox"/> Yes- please specify <input type="text"/>
<input checked="" type="checkbox"/> No

F Interdisciplinarity

10. Which disciplines (see list below) are involved in your project?
<input checked="" type="checkbox"/> Main discipline ¹ : 1. Natural Sciences 2. Engineering and technology 3. Medical Sciences
<input type="checkbox"/> Associated discipline ¹ : 1.1, 2.2, 3.3

G Engaging with Civil society and policy makers

11a Did your project engage with societal actors beyond the research community? (if 'No', go to Question 14)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
---	--

11b If yes, did you engage with citizens (citizens' panels / juries) or organised civil society (NGOs, patients' groups etc.)?				
<input type="checkbox"/> No <input type="checkbox"/> Yes- in determining what research should be performed <input checked="" type="checkbox"/> Yes - in implementing the research <input checked="" type="checkbox"/> Yes, in communicating /disseminating / using the results of the project				
11c In doing so, did your project involve actors whose role is mainly to organise the dialogue with citizens and organised civil society (e.g. professional mediator; communication company, science museums)?			<input type="checkbox"/> <input checked="" type="checkbox"/>	Yes No
12. Did you engage with government / public bodies or policy makers (including international organisations)				
<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes- in framing the research agenda <input checked="" type="checkbox"/> Yes - in implementing the research agenda <input checked="" type="checkbox"/> Yes, in communicating /disseminating / using the results of the project				
13a Will the project generate outputs (expertise or scientific advice) which could be used by policy makers?				
<input type="checkbox"/> Yes – as a primary objective (please indicate areas below- multiple answers possible) <input checked="" type="checkbox"/> Yes – as a secondary objective (please indicate areas below - multiple answer possible) <input type="checkbox"/> No				
13b If Yes, in which fields?				
Agriculture Audiovisual and Media Budget Competition Consumers Culture Customs Development Economic and Monetary Affairs Education, Training, Youth Employment and Social Affairs		Energy Enlargement Enterprise Environment External Relations External Trade Fisheries and Maritime Affairs Food Safety Foreign and Security Policy Fraud Humanitarian aid		Human rights Information Society Institutional affairs Internal Market Justice, freedom and security Public Health Regional Policy Research and Innovation Space Taxation Transport

13c If Yes, at which level?

- ☒ Local / regional levels
- ☒ National level
- ☒ European level
- ☐ International level

H Use and dissemination

14. How many Articles were published/accepted for publication in peer-reviewed journals?

19

To how many of these is open access² provided?

19

To how many of these is open access not provided?

0

Please check all applicable reasons for not providing open access:

- ☐ publisher's licensing agreement would not permit publishing in a repository
- ☐ no suitable repository available
- ☐ no suitable open access journal available
- ☐ no funds available to publish in an open access journal
- ☐ lack of time and resources
- ☐ lack of information on open access
- ☐ other³:

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15. How many new patent applications ('priority filings') have been made? (*"Technologically unique": multiple applications for the same invention in different jurisdictions should be counted as just one application of grant*).

0

16. Indicate how many of the following Intellectual Property Rights were applied for (give number in each box).

Trademark

Registered design

Other

17. How many spin-off companies were created / are planned as a direct result of the project?

0

Indicate the approximate number of additional jobs in these companies:

18. Please indicate whether your project has a potential impact on employment, in comparison with the situation before your project:

- ☐ Increase in employment, or
- ☐ Safeguard employment, or
- ☐ Decrease in employment,
- ☒ Difficult to estimate / not possible to quantify

- ☐ In small & medium-sized enterprises
- ☐ In large companies
- ☒ None of the above / not relevant to the project

<p>19. For your project partnership please estimate the employment effect resulting directly from your participation in Full Time Equivalent (FTE = one person working fulltime for a year) jobs:</p> <p>Difficult to estimate / not possible to quantify</p>	<p>Indicate figure:</p> <p><input checked="" type="checkbox"/></p>												
<p>I Media and Communication to the general public</p>													
<p>20. As part of the project, were any of the beneficiary's professionals in communication or media relations?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>													
<p>21. As part of the project, have any beneficiaries received professional media / communication training / advice to improve communication with the general public?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>													
<p>22 Which of the following have been used to communicate information about your project to the general public, or have resulted from your project?</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Press Release</td> <td><input checked="" type="checkbox"/> Coverage in specialist press</td> </tr> <tr> <td><input checked="" type="checkbox"/> Media briefing</td> <td><input checked="" type="checkbox"/> Coverage in general (non-specialist) press</td> </tr> <tr> <td><input type="checkbox"/> TV coverage / report</td> <td><input checked="" type="checkbox"/> Coverage in national press</td> </tr> <tr> <td><input type="checkbox"/> Radio coverage / report</td> <td><input checked="" type="checkbox"/> Coverage in international press</td> </tr> <tr> <td><input checked="" type="checkbox"/> Brochures /posters / flyers</td> <td><input checked="" type="checkbox"/> Website for the general public / internet</td> </tr> <tr> <td><input checked="" type="checkbox"/> DVD /Film /Multimedia</td> <td><input checked="" type="checkbox"/> Event targeting general public (festival, conference, exhibition, science café)</td> </tr> </table>		<input checked="" type="checkbox"/> Press Release	<input checked="" type="checkbox"/> Coverage in specialist press	<input checked="" type="checkbox"/> Media briefing	<input checked="" type="checkbox"/> Coverage in general (non-specialist) press	<input type="checkbox"/> TV coverage / report	<input checked="" type="checkbox"/> Coverage in national press	<input type="checkbox"/> Radio coverage / report	<input checked="" type="checkbox"/> Coverage in international press	<input checked="" type="checkbox"/> Brochures /posters / flyers	<input checked="" type="checkbox"/> Website for the general public / internet	<input checked="" type="checkbox"/> DVD /Film /Multimedia	<input checked="" type="checkbox"/> Event targeting general public (festival, conference, exhibition, science café)
<input checked="" type="checkbox"/> Press Release	<input checked="" type="checkbox"/> Coverage in specialist press												
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<input type="checkbox"/> TV coverage / report	<input checked="" type="checkbox"/> Coverage in national press												
<input type="checkbox"/> Radio coverage / report	<input checked="" type="checkbox"/> Coverage in international press												
<input checked="" type="checkbox"/> Brochures /posters / flyers	<input checked="" type="checkbox"/> Website for the general public / internet												
<input checked="" type="checkbox"/> DVD /Film /Multimedia	<input checked="" type="checkbox"/> Event targeting general public (festival, conference, exhibition, science café)												
<p>23 In which languages are the information products for the general public produced?</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Language of the coordinator</td> <td><input checked="" type="checkbox"/> English</td> </tr> <tr> <td><input checked="" type="checkbox"/> Other language(s)</td> <td></td> </tr> </table>		<input checked="" type="checkbox"/> Language of the coordinator	<input checked="" type="checkbox"/> English	<input checked="" type="checkbox"/> Other language(s)									
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<input checked="" type="checkbox"/> Other language(s)													

² Open Access is defined as free of charge access for anyone via Internet.

³ For instance: classification for security project.