



## D5.7 Technical validation report

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## History

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## Abstract

D5.7 aims to provide an intermediate technical validation report, demonstrating the progress of the verification and validation procedure for the GATEKEEPER platform. Starting from the description of the platform integration status, the deliverable proceeds with the verification of system requirements' fulfilment through a first round of unit and integration tests. Furthermore, the evaluation framework of specific aspects of the platform is outlined, so as to cover non-functional aspects of the platform and ensure high quality of services. On the way towards the planned validation by more than 40,000 end-users, the integration with WP7 large-scale pilots and WP2 open call awardees is then presented, as well as a list of critical activities requiring reassignment of responsibilities in the project. The first results show a modular, highly flexible platform with many integration scenarios and a well-guided installation process, with further testing and validation

planned for D5.7.2 to provide more evidence. Test reports, clear architecture figures of the pilot systems after their integration, and training material are provided in appendices.

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This deliverable contains original unpublished work except where clearly indicated otherwise.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

# Table of contents

<b>TABLE OF CONTENTS</b>	<b>7</b>
<b>LIST OF TABLES</b>	<b>9</b>
<b>LIST OF FIGURES</b>	<b>10</b>
<b>1 INTRODUCTION</b>	<b>11</b>
<b>2 GATEKEEPER PLATFORM INTEGRATION STATUS</b>	<b>13</b>
<b>3 REQUIREMENT VERIFICATION</b>	<b>16</b>
3.1 UNIT/INTEGRATION TEST REPORT TEMPLATE	16
<b>4 SOFTWARE QUALITY EVALUATION</b>	<b>18</b>
4.1 OVERVIEW	18
4.2 ACCESSIBILITY	18
4.3 SECURITY	20
4.3.1 Penetration testing	20
4.3.2 Standards' compliance	21
<b>5 AI/ML MODELS' TESTING</b>	<b>23</b>
<b>6 VALIDATION IN REAL ENVIRONMENT</b>	<b>28</b>
6.1 VALIDATION THROUGH LARGE – SCALE PILOTS (T7.5 – T5.7 COLLABORATION)	28
6.1.1 Integration	28
6.1.2 Training material and support	29
6.1.3 Pilot adaptation to project evolution	30
6.1.3.1 Pilot forms	30
6.1.3.2 Pilot forms' analysis	31
6.1.3.3 Corrective actions	33
6.2 VALIDATION BY THIRD PARTIES (T2.4 – T5.7 COLLABORATION)	36
6.2.1 Integration	36
6.2.2 Training material and support	36
<b>7 CONCLUSION</b>	<b>38</b>
<b>8 REFERENCES</b>	<b>39</b>
<b>APPENDIX A UNIT AND INTEGRATION TEST REPORTS</b>	<b>42</b>
AUTHORING TOOL	42
Test Data Processing	42
Test Generic Services	47
DATA FEDERATION	51
IntegrationEngine	51
FHIR server	56
RDFWatcher	57
FHIRProfileValidator	59

ROBOT CONNECTOR	63
INTELLIGENT CONNECTED CARE SERVICE – DATA FEDERATION – PILOT APPLICATION	65
GATEKEEPER TRUST AUTHORITY (GTA)	67
<b>APPENDIX B REPORTING OF AI/ML MODEL-BASED STUDIES</b>	<b>69</b>
TRANSPARENT REPORTING OF A MULTIVARIABLE PREDICTION MODEL FOR INDIVIDUAL PROGNOSIS OR DIAGNOSIS (TRIPOD): THE TRIPOD STATEMENT	69
<b>APPENDIX C ASSESSING THE RISK OF BIAS</b>	<b>72</b>
PROBAST: A TOOL TO ASSESS THE RISK OF BIAS AND APPLICABILITY OF PREDICTION MODEL STUDIES	72
<b>APPENDIX D TRAINING MATERIAL</b>	<b>75</b>
DEPLOYMENT GUIDES	75
OPEN CALLER MANUALS	77
<b>ANNEX T7.5 INTEGRATION ACTIVITIES</b>	<b>79</b>
SUPPORT AND MONITORING	79
PILOT FORMS	80
<i>Pilot form template</i>	80
<i>Aragon</i>	82
<i>Basque Country</i>	93
<i>Cyprus</i>	107
<i>Greece</i>	110
<i>UK</i>	116
<i>Puglia</i>	123
<i>Saxony</i>	131
<i>Poland</i>	136
<i>Covid-19 survey</i>	140



## List of tables

TABLE 1 : TEST REPORT TEMPLATE .....	16
TABLE 2: RELEVANT STANDARDS IN THE ISO 27000 FAMILY .....	21
TABLE 3: ML TESTING COMPONENTS.....	25
TABLE 4 ML TESTING PROPERTIES .....	25
TABLE 5: GK COMPONENT AND CONNECTOR USAGE BY PILOTS.....	28
TABLE 6: SUMMARY OF CRITICAL TECHNICAL ACTIVITIES TO BE ADDRESSED IN WP4, WP5, T7.5.....	33
TABLE 7 : OPEN CALL 1 MENTORS (TABLE ADAPTED FROM D2.6.2) .....	36
TABLE 8: OPEN CALL 2 MENTORS.....	37
TABLE 9: PILOT MENTORS FROM T7.5.....	79

## List of figures

FIGURE 1 – THE GATEKEEPER PLATFORM ARCHITECTURE.....	11
FIGURE 2 – T5.7 VALIDATION IN RELATION TO OTHER TASKS (FLOW ADAPTED FROM IEEE STD 1012™-2016 [2]).....	12
FIGURE 3 – GATEKEEPER PLATFORM V1.....	13
FIGURE 4 – DEPLOYED APPLICATIONS IN THE DEVELOPMENT ENVIRONMENT OF THE GATEKEEPER INFRASTRUCTURE AT THE TIME OF WRITING (INCL. PLATFORM COMPONENTS, PILOT APPS SUCH AS MAHA AND CONNECTOR MODULES SUCH AS FOR MULTI-ROBOT CONNECTORS BY OU).....	14
FIGURE 5 – DEPLOYED APPLICATIONS IN THE TEST ENVIRONMENT OF THE GATEKEEPER INFRASTRUCTURE AT THE TIME OF WRITING.....	15
FIGURE 6 – (A) MARKETPLACE – GTA USER MANAGEMENT MODULE INTEGRATION (B) MARKETPLACE-TMS-GTA INTEGRATION FLOW FOR THING REGISTRATION .....	15
FIGURE 7 – FUNCTIONAL TESTS FOR VERIFICATION .....	16
FIGURE 8 – PENETRATION TESTING PHASES (IMAGE ADAPTED FROM [7]) .....	21
FIGURE 9 – IDEALISED WORKFLOW OF ML TESTING (ADAPTED FROM ZHANG ET AL. [11]) .....	24
FIGURE 10 – AI/ML TESTING (T5.7) IN RELATION TO OTHER TASKS.....	24
FIGURE 11 – SCREENSHOT FROM "GK PLATFORM TICKETING SYSTEM" TRELLO BOARD .....	30
FIGURE 12 – DATA FEDERATION DEPLOYMENT GUIDE ToC [36] .....	75
FIGURE 13 – GTA USER MANAGEMENT MODULE DEPLOYMENT GUIDE ToC [37] .....	76
FIGURE 14 – TMS DEPLOYMENT GUIDE ToC [38].....	77
FIGURE 15 – OPEN CALLERS' MANUAL FOR THING REGISTRATION IN THE MARKETPLACE ToC [39]...	78
FIGURE 16 – SCREENSHOT FROM "GK T7.5 PILOT INTEGRATION" TRELLO BOARD.....	80

# 1 Introduction

Verification and validation are necessary to “build the product right” and to “build the right product” respectively for the GATEKEEPER Platform (Figure 1). Verification ensures that system requirements are satisfied from component to system level, aiming at consistency, completeness, correctness and accuracy. On the other hand, validation refers to user requirement compliance, as it provides evidence that the intended use and user needs are satisfied [1,2].

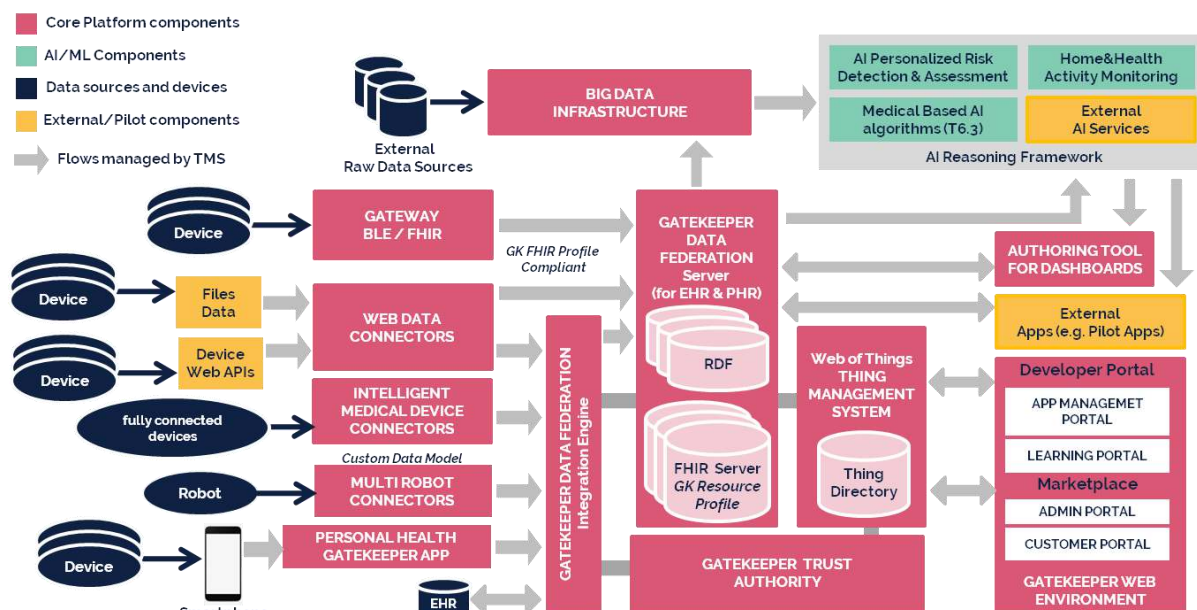


Figure 1 – The GATEKEEPER Platform architecture

Before the final step of validation, T5.7 is conducting a series of unit, integration, and system tests for the software qualification of the platform. Non-functional aspects, such as reliability, accessibility, security and more, will be evaluated afterwards based on metrics, while acceptance tests with end-users will be the final step before the composition of a detailed final validation report.

Figure 2 indicates how T5.7 activities are interrelated with the activities of other tasks, showing the process steps in the realisation of the platform.

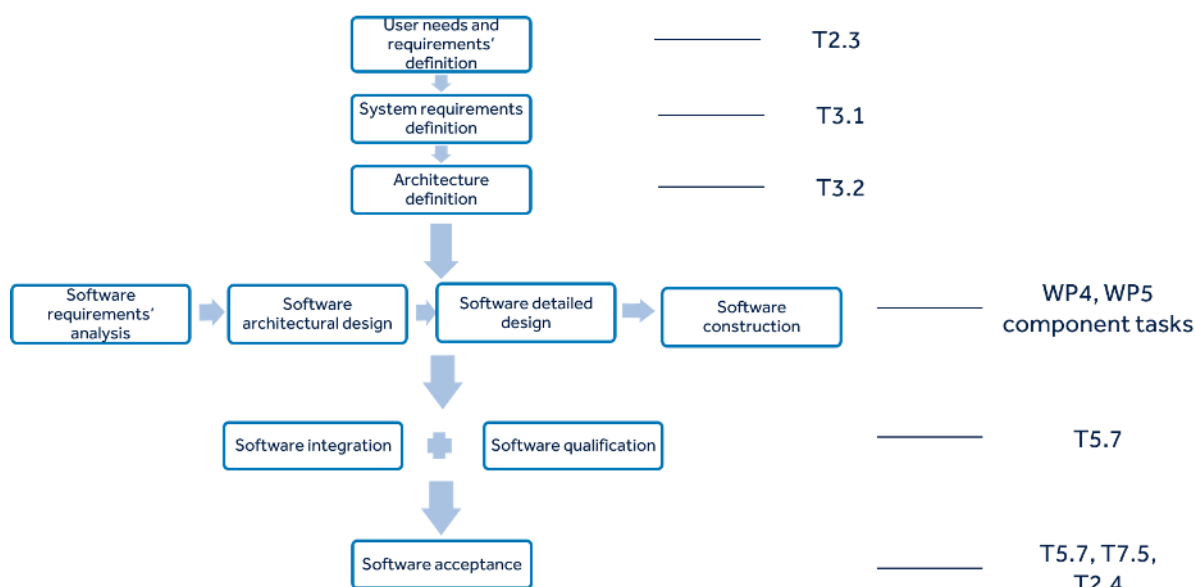


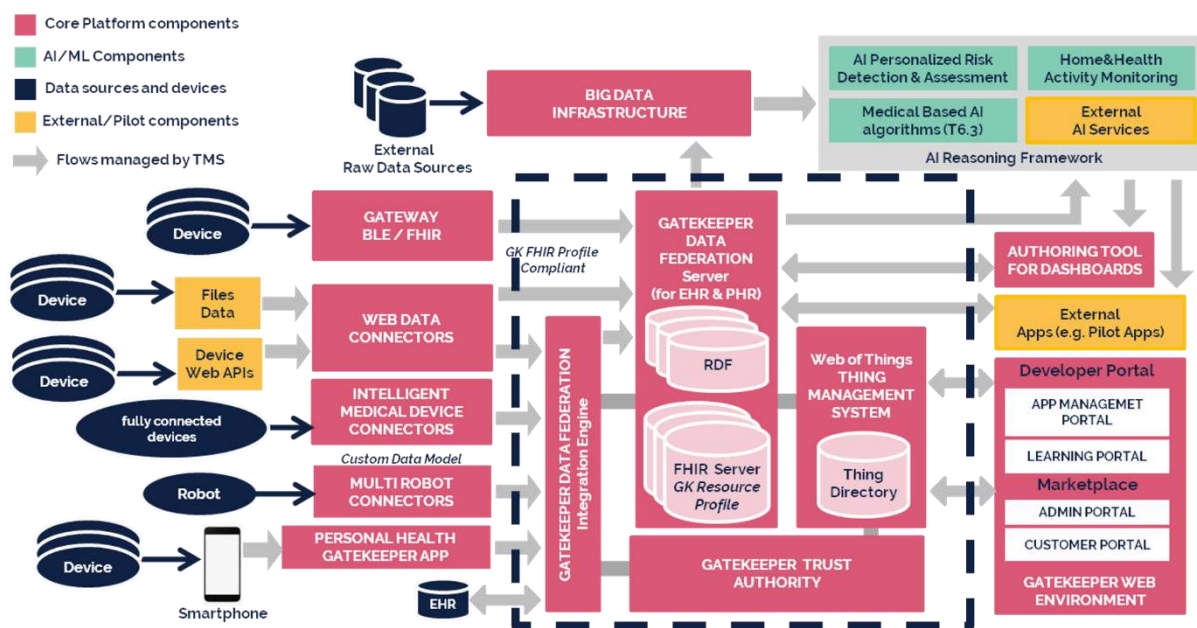
Figure 2 - T5.7 validation in relation to other tasks (flow adapted from IEEE Std 1012™-2016 [2])

This deliverable is **structured** as follows:

- [Section 2](#) refers to the platform integration process and current status, describing the environment for verification and validation.
- [Section 3](#) specifies testing for (functional) requirement verification, providing a pertinent report template.
- [Section 4](#) outlines software quality evaluation factors, which will cover the non-functional aspects of the platform.
- Special focus is given to AI/ML models' testing in [section 5](#), referring to both functional and non-functional requirements additional to those mentioned in D3.1.2.
- [Section 6](#) covers the progress towards validation in real environment and also reports on technical activities identified as critical and leading to responsibilities reallocation.
- [Appendix A](#) includes the implemented tests' reports, in this way complementing section 3.
- [Appendices B and C](#) present the templates for AI/ML reporting and assessing bias risk, complementing section 5.
- [Appendix D](#) includes the deployment guides and manuals delivered to pilots and open callers respectively in the scope of T5.7 to guide their integration with the platform, complementing section 6.
- The [Annex](#) provides depictions of the integration of pilots with the platform, demonstrating how each of them will use and validate it, as well as a summary of T7.5 integration activities, complementing section 6.

## 2 GATEKEEPER Platform integration status

The GATEKEEPER platform release plan foresees two versions. Version 1 (Figure 3), which has already been released, comprises the core components necessary for pilot deployment and running, while version 2, which has not been released yet, will extend it in order to fully support the value-based healthcare ecosystem envisioned, through the Marketplace and the Developer Portal.



With regard to the process followed, the GATEKEEPER infrastructure, provided within the scope of T4.1 and described in detail in D4.7 [3], hosts a development, a testing and a general production environment as independent tenants in OpenShift/OKD Kubernetes. In order to properly install and integrate the platform components developed within T4.2 (Thing Management System), T4.4 (Data Federation Framework) and T4.5 (GATEKEEPER Trust Authority) the following procedure has been established:

- (i) deployment in development tenant (called "gatekeeper-dev")
- (ii) deployment in testing tenant and integration test implementation (called "gatekeeper-test")
- (iii) deployment in production tenant (called "gatekeeper-production").

It should be noted that since the infrastructure does not provide public access, components requiring it, such as the Marketplace, the Authoring Tool and the Developer Portal will be deployed in different servers but will communicate via site-to-site VPN access with the components within the infrastructure.

The components deployed in "gatekeeper-dev" and "gatekeeper-test" at the time of writing are depicted in Figure 4 and in Figure 5 respectively.

Progressing towards version 2 of the platform, the Marketplace, the Gatekeeper Trust Authority (GTA) User Management Module, the GTA Things Validation System and the GTA Things Certification have been integrated in the component provider (CERTH) premises and delivered to open callers.

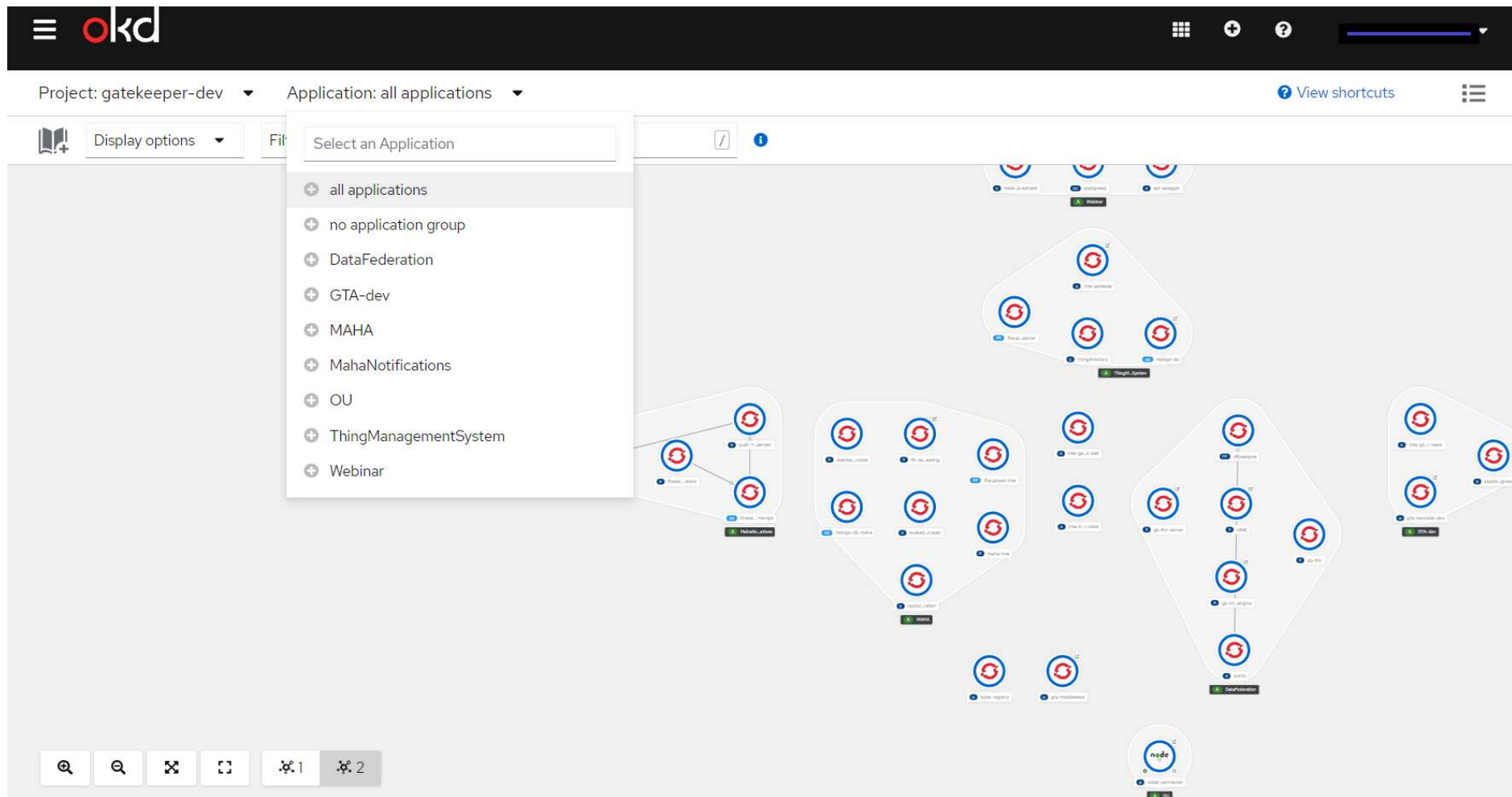


Figure 4 - Deployed applications in the development environment of the GATEKEEPER infrastructure at the time of writing (incl. platform components, pilot apps such as MAHA and connector modules such as for Multi-Robot Connectors by OU)

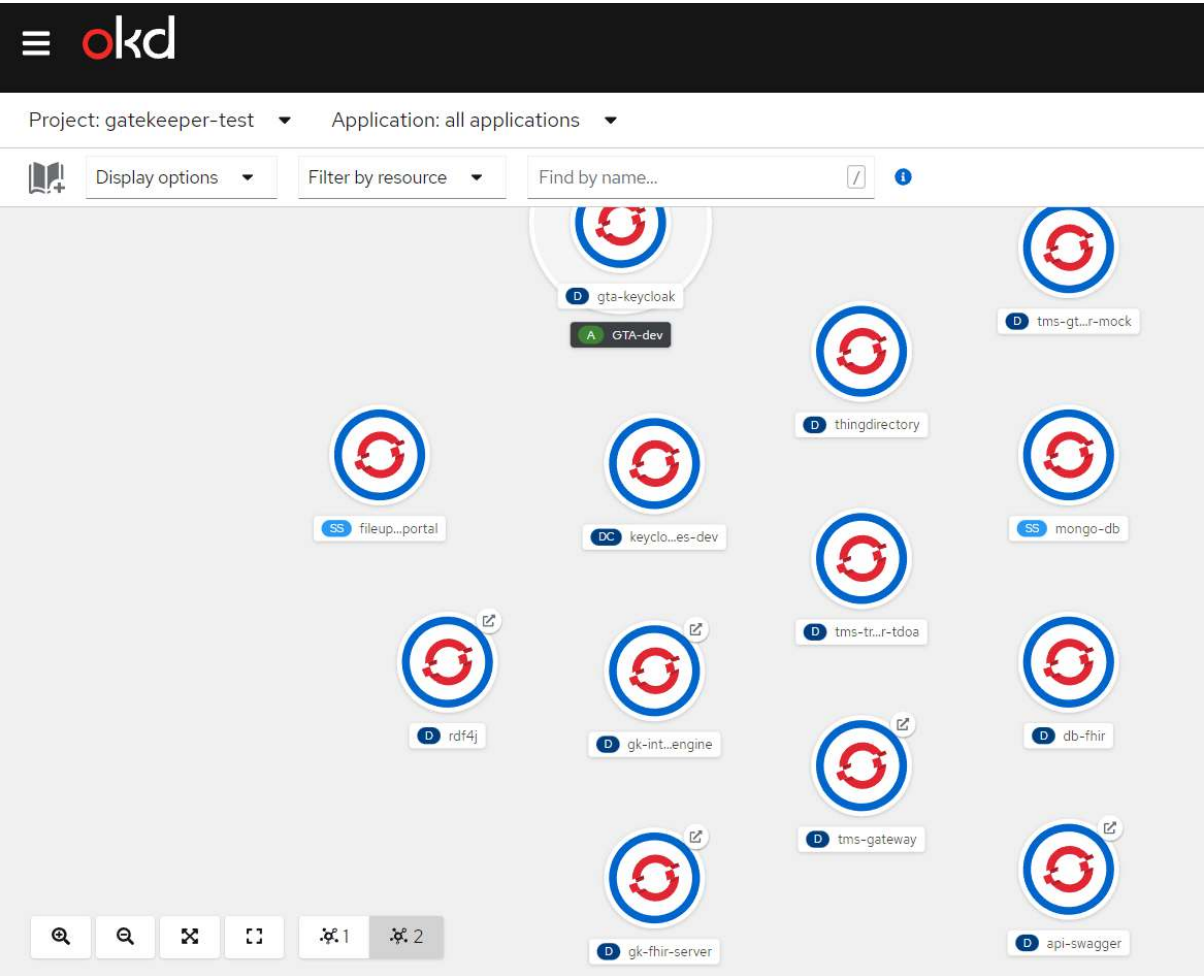


Figure 5 - Deployed applications in the test environment of the GATEKEEPER infrastructure at the time of writing

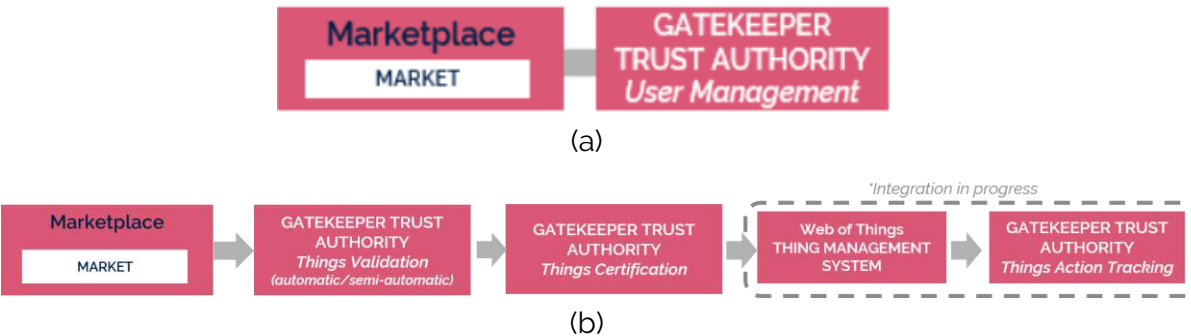


Figure 6 - (a) Marketplace - GTA User Management module integration  
(b) Marketplace-TMS-GTA integration flow for Thing registration

Deployment in OKD and integration with TMS are the next steps, as in Figure 6, and will be presented in the next version of this deliverable.



### 3 Requirement verification

Requirement verification for platform components is a necessary step to ensure their proper functioning and their alignment with the goals of the GATEKEEPER project. In order to prove the fulfilment of the platform requirements through tests, a fit criterion was defined for each of the functional and technical requirements in D3.1.2 [4]. The current outcomes of WP4 and WP5 component development were then tested and any bugs detected were fixed before the components were made available to end users.

The tests performed include both unit tests for the verification of components individually and integration tests to prove that components interact as expected. It is important to note that this is an iterative and ongoing process, as neither all tools nor their integration have been finalized at this stage. In the current version of the deliverable, the tests implemented focus on services that will be used during the pilot studies and especially the Data Federation component, which is consistent with the fact that most pilots' experiments are close to starting.

The process is pictured in Figure 7. The template used for test reporting is presented in the next sub-section, while the test reports provided by component owners are included in Appendix A.

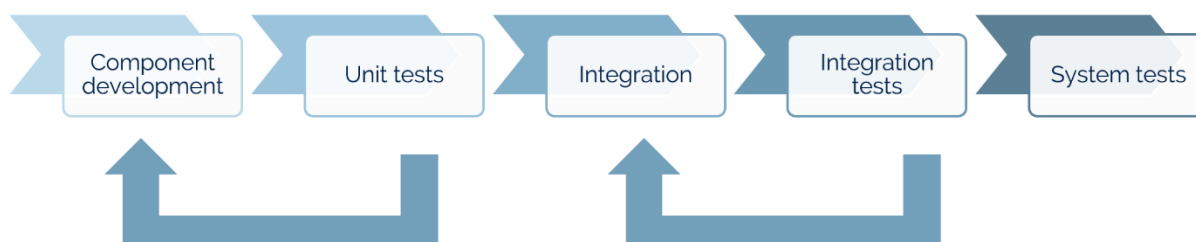


Figure 7 – Functional tests for verification

#### 3.1 Unit/Integration test report template

The following template (Table 1) was used for the reporting of the unit and integration tests.

Table 1 : Test report template

<b>Test ID</b>	(to be added by T5.7 leader)
<b>Component(s)</b>	
<b>Test objective</b>	
<b>Verified requirement(s)</b>	from D3.1.2
<b>Tool</b>	e.g. JUnit/PyUnit/Karma/...
<b>Input</b>	
<b>Expected result</b>	



Output	
Screenshot(s)	screenshot(s) as evidence
Comments	

## 4 Software quality evaluation

### 4.1 Overview

Software quality is an important aspect of the GATEKEEPER platform because of its intended use for eHealth and real-time data acquisition. Therefore, T5.7 will provide an evaluation framework to assess non-functional aspects with specific metrics and ameliorate it based on the assessment outcomes. The quality factors to be taken into account include:

1. Reliability (maturity, availability, fault tolerance, recoverability)
2. Speed (average response time)
3. Interoperability
4. Scalability (e.g. maximum number of concurrent users)
5. Accessibility
6. Security

The work on accessibility and security is presented in the next subsections,

### 4.2 Accessibility

With regard to accessibility, a clear audit process has been defined by Funka.

**Objective:**

The objective of the validation is that the Gatekeeper Marketplace and Authoring tool will comply with the minimum requirements of the Web Accessibility Directive.

The European standard "EN301549 v.2.1.2 Accessibility requirements for ICT products and services" [5] acts as the presumed conformance to the minimum requirements of the Web Accessibility Directive (Req\_S\_15 in D3.1.2). The EN301549 contains functional performance statements and technical specifications for ICT in a broad sense. In addition to the web, the standard covers, among other things, vending machines, telephones and computers.

When it comes to the technical requirements for web accessibility, the EN301549 is referring to the international standard WCAG 2.1 AA .

**Scope:**

The audit will be performed on the Gatekeeper Marketplace, and the Authoring tool.

**Process:**

The audits will be performed in close cooperation with the Gatekeeper partners responsible for the development of the platform, in order to ensure that the developing

partners have the necessary information and understanding of the issues that arise in case any eventual remediation is needed.

The process of audits will follow the conformance evaluation procedure recommended by W3C in the WCAG Evaluation method (WCAG-EM) [6], including five main steps:

1. Defining the scope and objective of the evaluation
2. Exploring the interface to identify for example the key functionalities and designs
3. Selecting a representative sample of pages for the audit
4. Evaluating the selected sample and determining successes and failures in meeting the requirements
5. Reporting on the findings of the evaluation, and making evaluation statements; and calculating overall scores.

### **Methodology:**

The accessibility audits will be performed by a combination of manual and automatic testing in accordance with Funka's well-established methodology, where two experts determine the level of compliance independent from each other to ensure consistency.

When needed, the audit is supplemented with tests on various assistive technologies. Each relevant success criterion in EN301549 v.2.1.2/WCAG 2.1 AA is tested and documented as:

- No errors found. The interface adequately meets the requirement. This may mean that the solution is very good, or acceptable. There may be room for improvement.
- No errors found but can be improved. Either the interface has a few problems in need of fixing (not a consistent error, more a result of carelessness or misunderstandings), or the interface has problems in parts that are beyond the scope of the audit, or problems that for one reason or another needs to be discussed with the client.
- Fail. The interface has consistent, clear accessibility issues that need to be rectified.
- Not applicable. The interface does not contain the kind of solution the requirement applies to, or the requirement has not been scored for one reason or another.

All failed criteria are thoroughly documented with clear examples and page references.

### **KPIs**

The Marketplace and the Authoring Tool will be validated separately.

The auditors will include an overall assessment based on the following criteria:

Green flag:

- The interface supports all of the requirements
- OR
- No non-compliant functionalities are deemed as excluding users from using the interface

Yellow flag:

- The interface has non-compliant functionality with regards to a maximum of two requirements that have serious consequences for users being able to perceive, operate and understand the user interface.
- OR
- The interface has non-compliant functionality with regards to a maximum of 10 requirements that do not have serious consequences for users being able to perceive, operate and understand the user interface

Red flag:

- The interface has non-compliant functionality with regards to more than two requirements that have serious consequences for users being able to perceive, operate and understand the user interface.
- OR
- The offering has non-compliant functionality with regards to more than 10 requirements that do not have serious consequences for users being able to perceive, operate and understand the user interface

In the case of a yellow or red flag, a time-plan for remediating the functionalities must be provided by the developing partners.

It should be noted that since accessibility cannot be considered as something that is static, therefore Funka recommends that a periodic accessibility check is maintained for the Gatekeeper platform.

## 4.3 Security

### 4.3.1 Penetration testing

Special mention should be made of the penetration testing that will be implemented.

#### Objective

Penetration testing, or 'pen test', takes place after the completion of vulnerability assessment (or scanning), which generates a report on risk exposure. It is a manual process where an ethical hacker simulates attacks to the system in order to test it in terms of security.

In particular for application security testing and examination techniques, according to the NIST Special Publication 800-115 [7], they can be categorised into:

- white box, where an application's source code is directly analysed (not applicable in GATEKEEPER),
- black box, where there is no source-code information,
- grey box, which is a combination of the above.

## Scope

Penetration testing will cover both versions of the platform (pilot-related data flow, Marketplace data flow) in special testbeds, in order not to pose a threat to personal data.

## Process

The general process to be followed is represented in Figure 8.

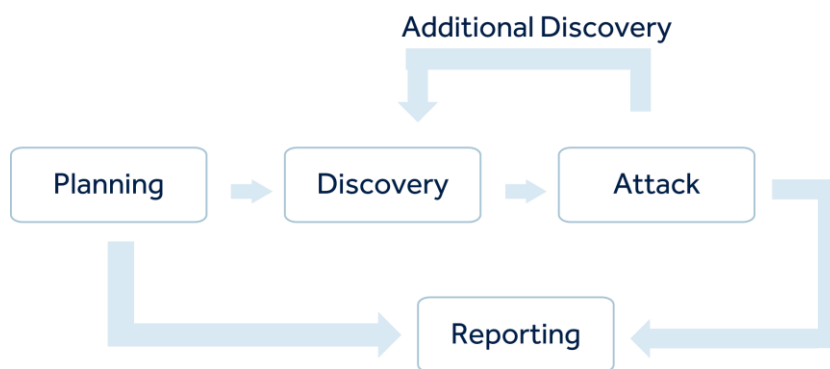


Figure 8 - Penetration testing phases (image adapted from [7])

The exact methodology identification is ongoing.

### 4.3.2 Standards' compliance

In terms of security-related standards that must be examined for applicability to the project, D3.1.2 [4] refers to OAuth 2.0 (Req\_S\_14), OpenID Connect and SAML (Req\_S\_27). These are satisfied by design by the Gatekeeper Trust Authority User Management Module, since it is implemented via Keycloak [8]. Keycloak allows the administrator to select between OpenID Connect (an extension to Auth 2.0) and SAML.

According to Req\_S\_36, ISO 27000 family of standards should also be examined for applicability. Preliminary research on auditability and KPI definition revealed that in the 27000 series of standards, only the first standard (27001:2013) is auditable. The others provide guidance for the implementation, monitoring and audit of the system. The framework is flexible depending on the size of the organisation or the project that should be monitored.

For the GK platform, the most relevant standards to look at in the 27K family have been identified by Funka and are presented in Table 2. Analysis towards KPI definition for an evaluation is ongoing.

Table 2: Relevant standards in the ISO 27000 family

ISO/IEC 27001:13 Information technology — Security Techniques — Information security management systems — Requirements.
ISO/IEC 27002: Code of practice for information security controls
ISO/IEC 27004: Information security management — Monitoring, measurement, analysis and evaluation

ISO/IEC 27701:2019 Information technology — Security Techniques — Information security management systems — Privacy Information Management System

ISO 27799 — Information security management in health using ISO/IEC 27002

## 5 AI/ML models' testing

As it has been specified in D6.3.2, the evaluation of the technical performance of the GATEKEEPER AI/ML models, as part of T5.2, T5.3, and T6.3 activities, is an iterative and continuous process providing evidence on their ability to accurately, reliably and precisely generate the intended technical output from the input data. This is through verification and validation activities, e.g., unit-level, integration, and system testing, or by generating new evidence through the use of previously collected data [9]. In accordance with the EC's "Ethics guidelines for trustworthy AI" [10] (D6.3.2) as well as drawing on structured AI/ML testing frameworks [11, 12, 13, 14], we consider the technical performance of an AI/ML system can be holistically characterised and tested with respect to both functional (i.e., correctness and model relevance) and non-functional (i.e., robustness and security, data privacy, efficiency, fairness, interpretability) quality properties.

In particular, AI/ML testing refers to any activity designed to reveal bugs in an AI/ML system, i.e., any imperfection in an AI/ML item that causes a discordance between the existing and the required conditions [11]. By adopting the terminology introduced by Zhang et al. [11], 'testing activities', 'AI/ML items' and 'required conditions' are, hereinafter, respectively referred to as testing workflow (e.g., test input generation, test oracle identification, test adequacy evaluation, bug triage), testing components (i.e., training/test data, learning program, ML framework), and testing properties (e.g., correctness, efficiency, fairness). Figure 9 (adapted from Zhang et al. [11]) illustrates the AI/ML testing workflow, with (i) offline testing, lying before model deployment, aiming at examining the AI/ML system's behaviour using retrospective test data, whereas (ii) online testing evaluates a deployed AI/ML model, before it is delivered to the target environment, using an A/B or Multi-Armed Bandit testing approach or, evaluates the runtime behaviour of a deployed AI/ML model when used as intended in its target environment (e.g., to trigger a retraining of the model on its predictive performance sudden or slow degradation in the context of CI/CD MLOps).

In the remainder of this section, we (UoI) outline the AI/ML tests to be applied in GATEKEEPER organising them according to: (i) the AI/ML components in which bugs may be located (Table 3), and (ii) the functional and non-functional testing properties of an AI/ML system that shall be guaranteed (Table 4). The specification of the exact tests pertinent to each GK AI/ML model (and the respective AI/ML services) will be described in D5.7.2, whereas the related methods and results will be described in D6.3.3, D5.2.2 and D5.3.2. Figure 10 indicates how AI/ML testing activities in T5.7 are interrelated with the activities of other tasks, showing the process steps in the realisation of the platform. Our objective is to provide a high-quality, rigorous evaluation of the technical performance of the GATEKEEPER AI/ML models by implementing best practices used in the development of AI/ML solutions [12, 15, 16], while avoiding common mistakes made in the evaluation of AI/ML tools [17] (e.g., absent or incorrect quantitative evaluation, or inability to detect dataset shifts [18]) aiming at their safe and effective adoption. In this direction, the adherence to TRIPOD statement [19] in reporting the AI/ML models' methods and results shall support the transparent appraisal of their quality by researchers, clinicians, systematic reviewers and policy makers.

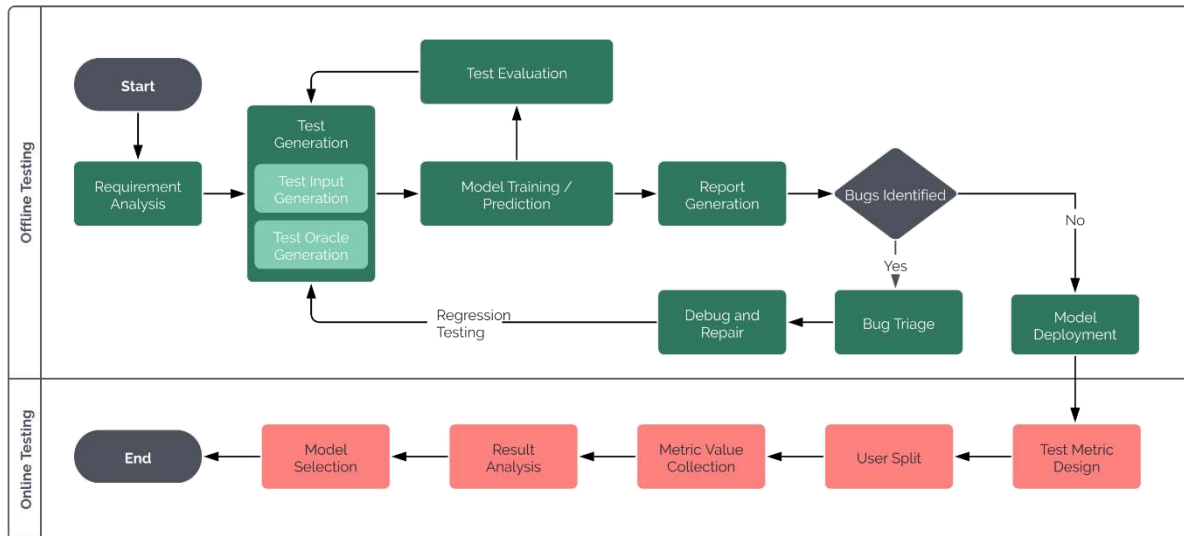


Figure 9 - Idealised workflow of ML testing (adapted from Zhang et al. [11])

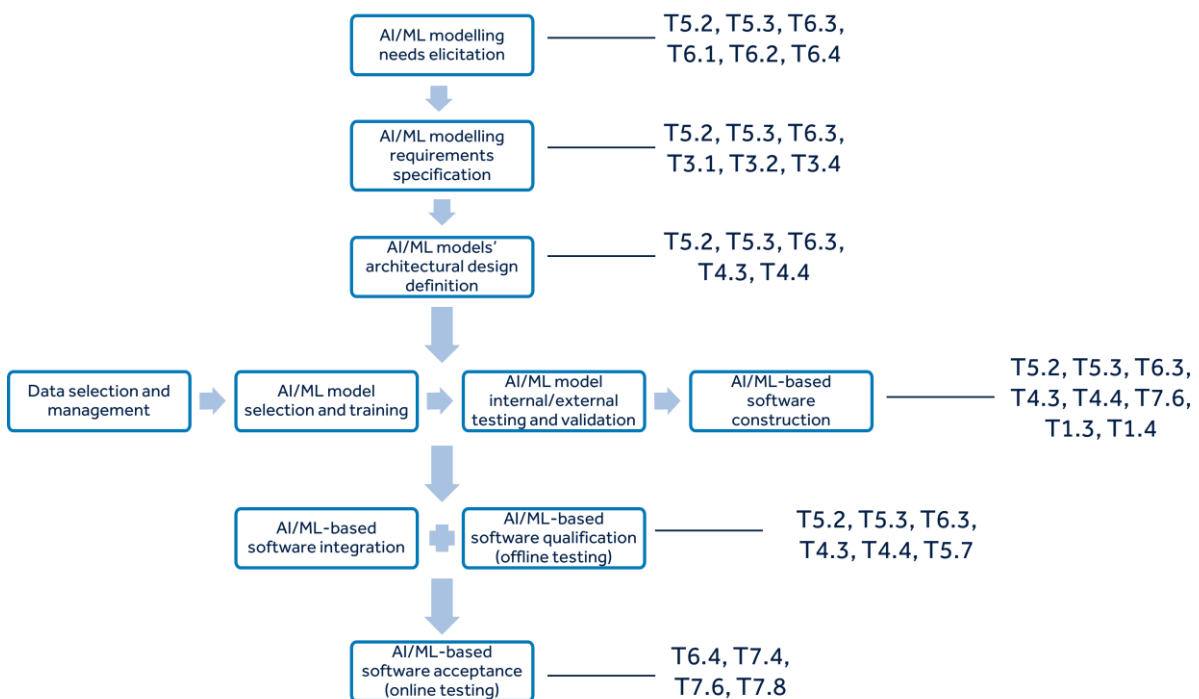


Figure 10 – AI/ML testing (T5.7) in relation to other tasks



Table 3: ML Testing Components

BUG DETECTION IN DATA
<ul style="list-style-type: none"> <li>▪ Test the completeness of the training/test/serving dataset. Semantic information encapsulated into the GATEKEEPER semantic data models (T3.4, D3.8) will be utilised to validate training/test data against type, domain and valency constraints in the data schema (e.g., outliers, scaling).</li> <li>▪ Test the representativeness of training/test data with respect to the intended patient population's characteristics, as they have been specified in the related pilot study protocols.</li> <li>▪ Test the existence of bias in the training/test data (e.g., biased labels). The PROBAST tool [20] will be applied, complementary to the methods used to identify and prevent algorithmic bias (see methods related to 'Fairness'), to assess the presence of systematic errors in a study design, conduct, or analysis originating from the data quality used for their development.</li> <li>▪ Test the existence of skew between training data and test data or between training data and serving data (the data that the ML model predicts after deployment).</li> <li>▪ Test the existence of training/test data poisoning or adversary information that may affect the model's performance (see methods related to 'Robustness &amp; Security').</li> </ul>
BUG DETECTION IN LEARNING PROGRAM
<ul style="list-style-type: none"> <li>▪ Unit testing of each component of the AI/ML pipeline (i.e., feature engineering, data pre-processing, dimensionality reduction, training algorithm, testing algorithm) to ensure that 'code will function as expected'.</li> <li>▪ Integration testing of the entire AI/ML pipeline.</li> <li>▪ Test the model selection procedure.</li> <li>▪ Test the configuration of the AI/ML algorithm by verifying the compatibility of the ML model with the target infrastructure in terms of hardware and software dependencies.</li> </ul>
BUG DETECTION IN ML FRAMEWORK
<ul style="list-style-type: none"> <li>▪ The existence of bugs in the AI/ML framework will not be examined, presuming that the use of a stable version of each AI/ML library alleviates the risk of bugs that may impact the implementation of the AI/ML learning program.</li> </ul>

Table 4 ML Testing Properties

FUNCTIONAL REQUIREMENTS
<b>Empirical Correctness</b>

Test the empirical correctness [11] of the ML model via cross-validation (i.e., hold-out, k-fold, or leave-one-out cross-validation) or bootstrapping. Empirical correctness gives an estimation of the correctness of an ML model on future (unseen) data, i.e., the probability that the predicted label for an input  $x$ , where  $\mathcal{D}$  is the distribution of future data, equals the true label, by pertinent correctness measures (e.g., sensitivity, precision, mean absolute percentage error, R squared) subject to the characteristics of the dataset, and the intended use of the ML model.

### Model Relevance

Test model relevance [11], i.e., the difference between the simplest required capacity of any ML algorithm given the training data distribution and the capacity of the ML model under test. Best practices in model selection and optimisation (e.g., nested cross-validation, constraining model complexity via regularisation, dropout, early stopping, or perturbed model validation) are useful for detecting underfitting (high bias, low variance) or overfitting (low bias, high variance) of the training data.

## NON-FUNCTIONAL REQUIREMENTS

### Robustness & Security

Test the adversarial robustness [21] of the ML model via apt measurement criteria; adversarial robustness is a sub-category of robustness measuring the resilience of the ML model's correctness in the presence of adversarial perturbations on any ML component, i.e., the data, the learning program, or the framework. As it has been specified in D6.3.2, the open-source Adversarial Robustness Toolbox [22] will be utilized in GATEKEEPER to defend and evaluate the developed ML models against the adversarial threats of evasion, poisoning, extraction, and inference, making them more secure and trustworthy at training, test and inference time.

### Data Privacy

- Data privacy is respected and preserved by applying the EU General Data Protection Regulation (GDPR), with related activities falling under GATEKEEPER WP1-related work.
- Test the data pipeline has appropriate privacy controls, e.g., any user-requested data deletion shall propagate to the data in the ML training pipeline, and to any learned models [13].

### Efficiency

Test the efficiency (or computational performance) of the ML model (training time, prediction time, throughput, RAM usage), as it constitutes a proxy of an ML model's complexity that need to be considered during model selection.

### Fairness

Test the fairness of the ML model with respect to characteristics that are sensitive and need to be protected (referred as protected or sensitive attributes). A large number of fairness formulations and measurement metrics have been proposed in the literature [i.e., Fairness Through Unawareness, Group Fairness (Demographic Parity, Equalised Odds, Equal Opportunity), Counter-factual Fairness, Individual Fairness] which form the basis of test generation techniques for fairness testing. The AI Fairness 360 [23] (AIF360), Aequitas [24], DeepLIFT [25], and Fairlearn [26] open-source toolkits will be utilised in

GATEKEEPER providing us with a comprehensive set of methods to examine, report, and mitigate discrimination and algorithmic bias (systematic errors) in ML models throughout their lifecycle (please see D6.3.2).

### **Interpretability**

Test the interpretability of the ML model, i.e., the degree to which an observer can understand the cause of a decision made by an ML model [27,28]. Interpretability contains two aspects: transparency (how the model works) and post hoc explanations (other information) that could be derived from the model [11, 29]. The open-source AI Explainability 360 (AIX360) toolkit [23] has been identified in GATEKEEPER as one of the core tools to add explainability to a complex dataset or an ML model, providing also two quantitative metrics of the "goodness" of feature-based local explanations (i.e., faithfulness and monotonicity) (D6.3.2). In addition to AIX360, the SHAP [30], LIME [31], InterpretML [32], ELI5 [33], Skater [34] and Alibi [35] open-source explainability toolkits will be utilised aiming at embedding their explainability methods into the AI/ML pipelines developed in GATEKEEPER.

## 6 Validation in real environment

### 6.1 Validation through Large – Scale Pilots (T7.5 – T5.7 collaboration)

#### 6.1.1 Integration

The GATEKEEPER Platform aims to be deployed as a digital ecosystem at a large scale and validated through the 9 European pilots of the project (Aragon, Basque Country, Cyprus, Greece, Milton Keynes, Bangor, Puglia, Saxony, Poland), with multiple reference use cases (RUCs) each, the 3 Asian pilots (Hong Kong, Taiwan, Singapore) and the Covid-19 survey, which is also treated as a pilot study. According to pilot plans, the total number of end users is estimated to be at least 40,000, including patients, healthcare professionals and caregivers.

Each pilot has decided which components best serve its needs, leading to pilot developers employing the support material that component owners have prepared (T5.7) to deploy them in the independent tenant of the pilot in the GATEKEEPER infrastructure and integrate them (T7.5) with technologies used in the pilot (adjusted in T7.5 and presented in the D3.8 GK Catalogue). All pilots will use the Data Federation component and the Big Data Infrastructure. An overview of component and connector usage in all pilots is provided in Table 5 and any changes during the course of the project, especially with regard to the Asian pilots that joined later and their integration is at an earlier stage, will be presented in the next version of D5.7. The Annex presents the pilot integration per use case in architecture figures.

Table 5: GK component and connector usage by pilots

Component	No. of pilots using	Pilots
Data Federation (T4.4)	13	All
Things Management System (T4.2)	2	Aragon, Basque Country
Gatekeeper Trust Authority (T4.5)	4	Aragon, Basque Country, Greece, Saxony
Authoring Tool (T5.5)	6	Aragon, Basque Country, Milton Keynes, Bangor, Puglia, Saxony
Intelligent Medical Device Connectors (T5.4)	5	Aragon, Milton Keynes, Bangor, Puglia, Singapore
Multi-Robot Connectors (T5.6)	1	Milton Keynes
Personal Health GK App	6	Basque Country, Milton Keynes, Bangor, Puglia, Saxony, Singapore

Big Data Infrastructure (hosting AI processing activities)	13	All
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By M30, all of the European pilots, as well as the Covid-19 survey pilot, have successfully deployed in their tenants the needed components. Integration of the components with the pilot applications has not been completed for all pilots, owing to the pending signature of data processing agreements between the pilot data controllers and HPE as provider of the infrastructure and, therefore, data processor.

### 6.1.2 Training material and support

The pilots have been efficiently guided towards the deployment and integration with the platform. Apart from the T7.5 efforts summarised in the Annex, T5.7 has provided instructive and comprehensive material in the form of a **deployment guide for each component** of the first version of the platform. The guides were prepared by the respective component provider, tested during a virtual meeting by a developer familiar with Kubernetes or OKD/OpenShift (on which the infrastructure has been built) but not involved in component development and then made available to the pilots on the release date of the platform. The tests concluded that the deployment of all three components is relatively simple with the help of the guides and requires approximately two hours of effort. The Table of Contents (ToC) and a link to the current version of the deployment guides, as updated after changes to the components, is provided in Appendix D.

Support is continuously available through the **Slack channel #deployments**, which was created to facilitate interaction and accelerate problem-solving. The small number of support requests in the channel indicate that deployment of Platform version 1 was of low complexity (for developers familiar with containerisation and having access to the provided guides). More specifically:

- 2 operational issues: pending tenant access rights, update to deployment file needs (solved)
- 1 support request after an error message (solved)
- 1 clarification to deployment guide requested (clarification provided and updated guide uploaded)

Moreover, after delivering the technologies to end-users, a **ticketing system** for the Gatekeeper platform was introduced, in order to create, manage and maintain a list of user issues. After an inspection of available tools, it was decided to use a Trello board due to (i) its free support to unlimited users, (ii) familiarity of pilot representatives with it owing to the pre-existing "T7.5 GK Pilot Integration" board (see Annex), (iii) high customisability and notification feature, and (iv) connection with Slack.

The board is private and platform component owners, pilot representatives and open caller representatives have already joined. It features an overview of component status (labelled as "up", "down" or "not released yet"), and enables pilots, as well as open callers, to issue tickets using a pre-defined template. The tickets progress to "In progress", "Under review" and, finally, "Resolved" by the users and can be labelled as "Urgent". Informative material is also included. It is noted that the ticketing system in question does not involve

the data centre. For data-centre-related issues, there is a dedicated issue tracker available to platform users through VPN that is described in D4.7.

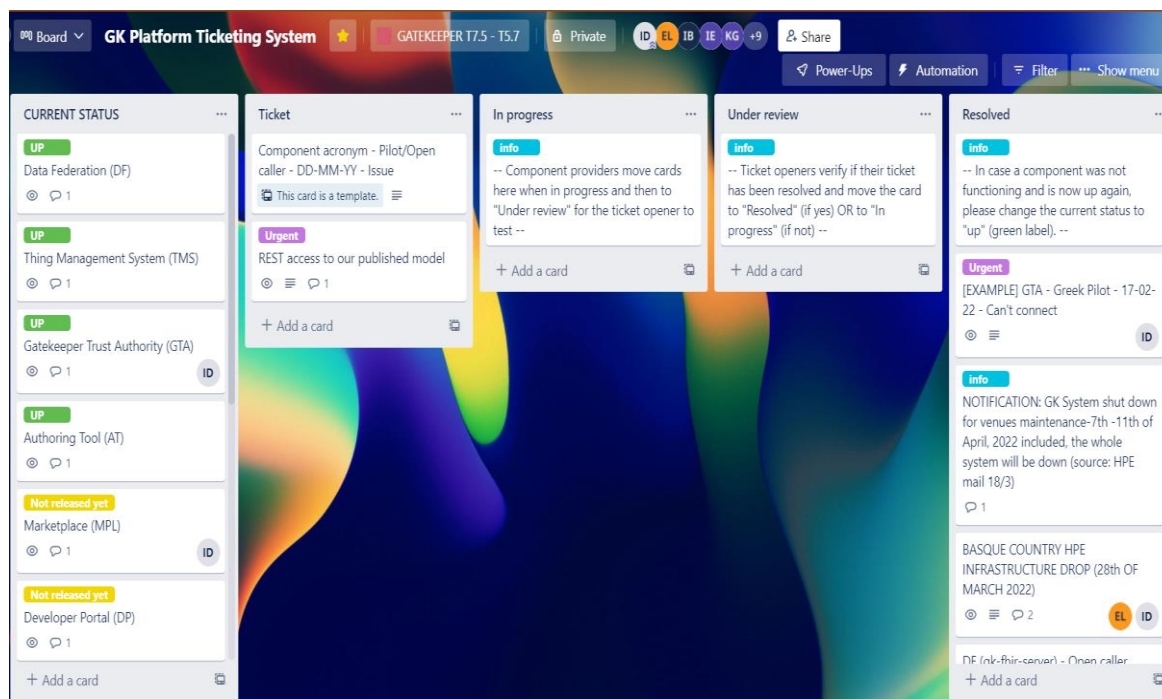


Figure 11 – Screenshot from “GK Platform Ticketing system” Trello board

### 6.1.3 Pilot adaptation to project evolution

Gatekeeper project is evolving fast and novel actions such as the project extension are affecting the current technical work carried out in the pilots and the platform. Unexpected activities such as long-term maintenance, the extension of technical support to include re-adaptation of pilot environments towards asynchronous integration with the GATEKEEPER infrastructure as a decoupling technique for improving platform resilience, and the modification of some pilot architecture for improving local resilience must be considered.

A deep analysis of pilot and platform activities is needed at this point of the project. Due to the COVID-19 pandemic, the Ukrainian war, and the related crisis of electronic components a deep review of interrelations among pilot and platform tasks is necessary to understand the incoming risky situations that could cause deviations from the right path towards the project's successful conclusions. Through this analysis, we expect to understand the influence of external and internal factors that may negatively affect the running of the pilot technical activities and define a set of corrective actions.

#### 6.1.3.1 Pilot forms

Schematic reporting of pilot technical activities was requested from all pilots through a form presented in the Annex. The pilot form was designed to collect information regarding:

- pilot architecture,
- functionalities of the pilot solutions,
- plan of remaining activities and status,
- FHIR resources used in the pilot,
- pilot user management schema,
- Gatekeeper platform connectors used,
- completed activities,
- ongoing activities,
- pending activities,
- critical (unassigned) activities,
- identified risks.

By analysing the pilot form for each reference use case (RUC) of every pilot, we have achieved a clear overview of the technical tasks in 3 dimensions:

- identification of the planned remaining activities of each pilot for each RUC
- identification of unexpected activities not yet planned in each pilot for each RUC
- estimation of the additional needed resources that need to be reorganized for the correct execution of each pilot and each RUC

For completeness, all pilot forms are included in the Annex.

### 6.1.3.2 Pilot forms' analysis

In this section, the results of the analysis of each pilot per RUC are reported. To easily identify where there are problems to be solved, the following colour codes have been used. The partner(s) responsible for the technical implementation of the RUC is (/are) given in parentheses.

Colour legend:

- RUC is under control in terms of resources, no action needed.
- RUC can be controlled in terms of resources, some actions are needed.
- RUC is out of control in terms of resources, resource realignment is expected.

Results of the analysis:

- All pilots
  - COVID-19: no major issue detected (UPAT)
- Basque Country
  - RUC-1, 7, 4: no major issue detected (UPM, Sense4Care)
  - RUC-3, RUC6.2: additional information is needed (Ibermatica, MYS, Samsung)
    - The user management approach and Authoring tool (T5.5) integration need further discussion, as it is not clear how they will be performed.
- Aragon



- RUC-1, 2, 5, 7: no major issue, further work needs to be done (UPM, SALUD)
  - FHIR mapping processes need some improvements.
- Poland
  - RUC-1, 7: few additional information is needed (MUL)
    - Finalize the FHIR profiles to be used. Improve the asynchronous data transfer to data federation from local pilot infrastructure.
- Greece
  - RUC-1: no major issue detected (CERTH)
  - RUC3: no major issue detected (CERTH)
- Cyprus
  - RUC-7: no major issue detected (CERTH)
- UK
  - MK-RUC-1, 7: additional support is needed (OU)
    - We need to discuss how to address pilot-platform decoupling in order to improve pilot resilience.
    - Additional support is needed from HPE in the specific piloting events with users and robots.
  - BANGOR-RUC-7: few additional information needed (OU)
    - It's not clear if it is possible to decouple asynchronously Data Federation and Personalized Recommendations Engine from GK infrastructure. Further discussions are needed.
- Puglia
  - RUC-1: no major issue detected (MME, ENG)
  - RUC-1: no major issue detected (MME, CSS)
  - RUC-3, 7: no major issue detected (MME, AReSS)
  - RUC-2,5,7,8: few additional developments are needed (MME, AReSS)
    - Development of user management related to the initial population of Practitioner and Patient entities has no responsible. In this case the development has no responsible, but it is a common and reusable activity to be shared at least with Puglia and Basque Country.
- Saxony
  - RUC-1: no major issue detected (TUD)
  - RUC-7: needs action on unassigned activities (TUD)
    - Dashboard development is still pending to be defined and has no responsible. Further discussion is needed to understand if the activity can be shared with Puglia and Basque Country.
    - Translation of Samsung GK App to German is blocked. There is no technical partner assigned to this task.



### 6.1.3.3 Corrective actions

After the pilot analysis we have the overall picture of the technical needs of pilots per RUC to accomplish necessary project changes:

- A common additional effort is needed at each pilot site to improve platform-pilot infrastructure asynchronous decoupling. Apart from Basque Country and UK pilots, that need more specific corrective actions, all associated activities are relatively easy to implement and can be covered by the current distribution of resources.
- User management has still not been addressed clearly in several pilots. A strict link with task T5.5 has been identified. Therefore, a specific taskforce will be set up among Tecnia, Basque Country, Puglia and Saxony to define a common approach to user management and finalise shared requirements, so that user management can be included in the Authoring Tool developed in T5.5. This task force will be in charge of identifying the expected resources and the responsible partner that will carry out this work based on the unspent resources available at this point of the project.
- There are several tasks with no technical responsible that are fundamental for some pilots (connectors towards Data Federation, additional measures for privacy protection, local user management etc.). In this case a taskforce including WP4, WP5 and T7.5 partners will be set up in order to assign technical responsibilities based on the unspent resources available at this point of the project.
- A review and continuous work of FHIR mapping of all pilots is needed. Partners that have been working on those activities need to further support pilots. Rearrangement of resources among pilots and other technical partners will be evaluated where necessary.

As discussed in the Project Steering Committee (PSC) on Friday 13th of May, the technical activities of both pilots and the platform need to be realigned for the proper execution of the project. In this regard, in addition to the technical analysis provided by the pilots also WP4 and WP5 have provided their input. After the end of this process and by merging the input coming from pilots the following activities have been identified and need to be addressed in WP4, WP5 and T7.5 (Table 6)..

Table 6: Summary of critical technical activities to be addressed in WP4, WP5, T7.5

#	Task	Activity description
1.	T7.5, T5.4	Within these tasks, the pilot infrastructure will be further decoupled, by providing asynchronous communication with the connectors and alternative deployment outside Gatekeeper platform for redundancy.
2.	T7.5	In the case of Basque Country, Aragon and the UK, where the platform and pilot-specific applications are highly coupled, additional effort is needed for support and maintenance.

3.	T5.5, T5.4	The Authoring Tool (T5.5) is not fully usable for a pilot. It lacks patient management on top of the Gatekeeper FHIR services, so additional effort is needed to align the tools completely with the pilots' needs.
4.	T7.5	In Saxony a connector that gathers the data from the Personal Health GK Samsung app to Data Federation needs to be developed.
5.	T7.5	The FHIR data model in Aragon is still missing some parts and needs to be updated.
6.	T7.5	An overall review of the FHIR data mapped in all pilot sites is needed.
7.	T5.2, T5.3, T6.3	Within this task a mapping of AI input and output features associated with the predictive models will be provided.
8.	T7.5	Some pilots are using the same tenant for different RUCs. In some cases, a separation of data in different physical spaces is needed.
9.	T7.5	It is still not clear how local pilot patient data will be linked within the Data Federation. This work needs to be done as soon as possible.
10.	T7.5	In agreement with the idea of the separation of RUCs in the same pilot space, Puglia is demanding additional effort for the separation of their RUC into different physical spaces.
11.	T5.2	Synthetic data Generator Framework is the set of algorithms for generating artificial data that mirror the statistical properties of the original data but with the purpose of preserving privacy and creating training data for machine/deep learning algorithms in the context of GATEKEEPER project.
12.	T5.2	Extending HeLiFit Ontology and HeLiFit Engine for formalizing structured workouts and fitness quantities and implementing a personalized and dynamically re-adopted algorithm in order to coach, train and educate patients to achieve WHO goals.
13.	T5.2	Develop the data aggregation to fit the needs of running AI models, including ML and semantic AI models.
14.	T5.2	Algorithm for condition worsening of T2D risk based on EMR + PHR.
15.	T5.2	(As above) Extending HeLiFit Ontology and HeLiFit Engine for formalizing structured workouts and fitness quantities and implementing a personalized and dynamically re-adopted algorithm in order to coach, train and educate patients to achieve WHO goals; w.r.t Bangor's Requirements.
16.	T5.3	Extending HeLiFit Ontology and HeLiFit Engine for formalizing structured workouts and fitness quantities and implementing a

		personalized and dynamically re-adopted algorithm in order to coach, train and educate patients to achieve guidelines goals;
17.	T5.3	AI-based algorithm for classifying the patient behaviour w.r.t. WHO guidelines and BC's requirements.
18.	T5.3	AI-based algorithm for classifying the patient behaviour w.r.t. WHO guidelines and Saxony's requirements.
19.	T5.3	As above. Algorithm for condition worsening of T2D risk based on EMR + PHR.
20.	T5.3	Data wrangling, Data Quality (noisy, unbalanced), Data Missingness, Data outliers,
21.	T5.3	Training and model implementation for Basque Country, Aragon, Lodz RUCS 1-7, Greece RUC 1, Early prediction of Metabolic Syndrome.
22.	T4.5	Anonymisation has been requested from pilots for data donation and secondary usage of data.

In order to reorganize the work among the partners, the platform, pilot cluster managers, WP4, WP5 and relevant task leaders will estimate the resources needed and the assignment of new responsibilities in agreement with the following rationale:

- In the analysis of WP5, we will assume as critical the activities where there is no responsible partner.
- We will not consider the reassignment of resources, the transfer of person-month (PM) from one task to another to compensate for work.
- We will consider as reassignable the PMs where the task leaders have reported not receiving contributions from the PM partner owner.
- We will consider as reassignable the PMs where the task leader has stated that task work can continue smoothly without these PMs.
- We will reassign work taking into account the knowledge that each partner has, in order to minimize the probability of rejection of work.
- We have evaluated the technical difficulty and knowledge necessary to develop the FHIR - AI data transformers.
- The pilots have to readjust first the PMs with the saved resources related to the acquisition of the devices.
- We will first reduce the actual work of partners who asked for new resources rather than give them new ones coming from other partners.

Following these rules, the project set up a series of meetings with technical partners involved in WP4, WP5, and WP7 in order to find a consensus on the redistribution of the resources. Some of the work assignments have still to be completed and they will be included in a further version of the deliverable and/or the PMR.

## 6.2 Validation by third parties (T2.4 – T5.7 collaboration)

### 6.2.1 Integration

Apart from the large-scale pilots that consist of project partners, the Gatekeeper ecosystem aims at being enlarged through open calls to SMEs, start-ups and new sites in an open innovative fashion. Two open calls have been organised in the scope of T2.4, their detailed description included in D2.6 and D2.6.2:

- Open Call 1, 11 awardees (ongoing)
- Open Call 2, 7 awardees (ongoing)

Open callers have been invited to test and integrate with the Data Federation, the Big Data Infrastructure and the Marketplace.

The final open call reports have not been issued yet. However, successful integrations have already been presented, namely of Open Call 1 awardee Envira with the Data Federation and GTA as described in D4.12.

### 6.2.2 Training material and support

Thorough instructions and adequate support have been provided to open callers so that they are guided to integrate with the GATEKEEPER platform. In terms of training material, open callers have been offered detailed **manuals** for the GATEKEEPER infrastructure and the components. The latest editions are listed in Appendix D but cannot be included as a whole due to their confidential nature.

As far as support is concerned, WP5 partners have been assigned **mentorship** to the open callers as in Table 7. In addition, a series of **webinars** have been organised, while continuous support is available through **Slack**.

Table 7 : Open Call 1 mentors (table adapted from D2.6.2)

Open Call 1 Project	Mentor assigned	Partner
Envira	Paolo Zampognaro	ENG
Spirocco Ltd.	Alessio Antonini	OU
Braingaze	Leire Bastida	TEC
Ab.Acus	Catherine Chronaki	HL7
Nissatech	Salman Haleem	UOW
Gripwise	Eleni Georga	UOI
Promptly	Sergio Copelli	MME
University of Vigo	David Martin Barrios	IBER
CognitEye	David Ragget	W3C
Quadible Ltd	Bangfu Tao	SAM

NIM Center	Competence	Claudio Caimi	HPE
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Table 8: Open Call 2 mentors

Open Call 2 Project	Mentor assigned	Partner
DTX@GK	Silvio Pagliara	UOW
iwelli4ageing	Silvio Pagliara	UOW
GastricAITool	Silvio Pagliara	UOW
ParkinsonAID	Silvio Pagliara	UOW
CONCERTO	Marta Perez	MDT
Abruzzo That Cares	Robin Kleiner	M+
FHIRING DATA	SHARE Albert Pages	S4C

## 7 Conclusion

As an innovative, large and complex system, the GATEKEEPER platform requires rich verification and validation. The current version of D5.7 follows up on requirement elicitation, architecture design, and system construction by presenting the current platform integration status and software qualification test results.

After overcoming the delay caused by the Covid-19 outbreak, a first version of the platform has now been tested and is ready to be used by the project pilots in a wide variety of integration scenarios and component combinations. The test results demonstrate the successful implementation of the components that pilots will use for data acquisition, adaptation to FHIR and visualisation, as well as for user management. A small number of tests with connectors are still pending, but will be provided before pilots start. The open call awardees will also provide evidence of different employments of the GATEKEEPER platform according to the needs and wishes of every stakeholder. The flexibility of the platform is, therefore, already apparent, while the first impressions on the ease of deployment are also promising.

The next steps planned for the coming months, whose report will be the second version of the deliverable, include not only the continuation of requirement verification for the components, but also the definition and execution of specific test cases for the validation of the platform across different aspects, starting from security, and in real-world environments. Their outcome will give valuable insights into the adoption and evolution of the architecture as well. Finally, they will ensure that at the end of the project the GATEKEEPER Platform has accomplished in practice its conceptual goal to be fault-tolerant, secure, flexible, accessible and scalable, building on standards and enabling early detection, personalised interventions and value-based care overall as an asset.

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## Appendix A Unit and integration test reports

### Authoring Tool

The Authoring Tool test reports have been provided by Tecnalía.

#### Test Data Processing

Test ID	AT1
Component	ProcessRemoteDataUtils
Test objective	<p>Check that all incoming Use Cases with their patients list, from the JSON file (Input field), which simulates the output of the following RESTful service, are the same as retrieved practitioners, with their corresponding user names, and "active" fields.</p> <p><a href="http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/CareTeam?_include=CareTeam:patient&amp;_pretty=true&amp;participant=###PRACTITIONER_ID###&amp;_elements=subject,reasonCode">http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/CareTeam?_include=CareTeam:patient&amp;_pretty=true&amp;participant=###PRACTITIONER_ID###&amp;_elements=subject,reasonCode</a></p>
Verified requirement(s)	Req_AP_25, Req_AP_31
Tool	Django unittest
Input	.../tests/raw_data/get_usecases_and_patients_list-remote_response.json
Expected result	Retrieve the same Use Cases, with their patients IDs.
Output	Retrieved the same Use Cases, with their patients IDs.
Repository link	<p>.../test/test_data_processing.py-&gt;</p> <p>Method "test_use_cases_and_patients_extraction"</p>
Comments	

Test ID	AT2
Component	ProcessRemoteDataUtils
Test objective	<p>Check that all incoming variables of a patient, from the JSON file (Input field), which simulates the output of the following RESTful service, are the same as retrieved variables with their IDs, descriptions and units.</p> <p><a href="http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/CareTeam?_include=CareTeam:patient&amp;_pretty=true&amp;participant=###PRACTITIONER_ID###&amp;_elements=subject,reasonCode">http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/CareTeam?_include=CareTeam:patient&amp;_pretty=true&amp;participant=###PRACTITIONER_ID###&amp;_elements=subject,reasonCode</a></p>

	server/fhir/Observation?subject=###PATIENT_ID###&_format=json&_elements=code,valueQuantity
Verified requirement(s)	from D3.1.2
Tool	Django unittest
Input	<ul style="list-style-type: none"> <li>.../tests/raw_data/get_observations-remote_response.json</li> <li>Patient ID</li> </ul>
Expected result	Retrieve all the patient variables with their IDs, descriptions and units.
Output	Retrieved all the patient variables with their IDs, descriptions and units.
Repository link	.../test/test_data_processing.py-> Method "test_vars_extraction"
Comments	

Test ID	AT3
Component	ProcessRemoteDataUtils
Test objective	<p>Check that all incoming practitioners, from the JSON file (Input field), which simulates the output of the following RESTful service, are the same as retrieved practitioners, with their corresponding user names, and "active" fields.</p> <p><a href="http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Practitioner?_elements=id,active,name,qualification">http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Practitioner?_elements=id,active,name,qualification</a></p>
Verified requirement(s)	from D3.1.2
Tool	Django unittest
Input	.../tests/raw_data/get_practitioners_list-remote_response.json
Expected result	Retrieve the same practitioners, with their IDs, user names, and active fields.
Output	Retrieved the same practitioners, with their IDs, user names, and active fields.
Repository link	.../test/test_data_processing.py->

	Method "test_practitiones_extraction"
Comments	

Test ID	AT4
Component	ProcessRemoteDataUtils
Test objective	Check that all incoming variable values of a patient, from the JSON file (Input field), which simulates the output of the following RESTful service, are returned and grouped correctly by selected frequency.  http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?subject=###PATIENT_ID###&_format=json&_elements=code,valueQuantity,valueBoolean,effectiveDateTime
Verified requirement(s)	Req_AP_04, Req_AP_08
Tool	Django unittest
Input	<ul style="list-style-type: none"> <li>• .../tests/raw_data/get_observations-remote_response.json</li> <li>• Patient ID</li> <li>• Frequency = "DAILY"</li> </ul>
Expected result	Retrieve all the patient variable values grouped correctly by selected frequency.
Output	Retrieved all the patient variable values grouped correctly by selected frequency.
Repository link	.../test/test_data_processing.py-> Method "test_observations_extraction_freq_daily"
Comments	

Test ID	AT5
Component	ProcessRemoteDataUtils
Test objective	Check that all incoming variable values of a patient, from the JSON file (Input field), which simulates the output of the following RESTful service, are returned and grouped correctly by selected frequency.  http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-

	server/fhir/Observation?subject=###PATIENT_ID###&_format=json&_elements=code,valueQuantity,valueBoolean,effectiveDateTime
Verified requirement(s)	Req_AP_04, Req_AP_08
Tool	Django unittest
Input	<ul style="list-style-type: none"> <li>.../tests/raw_data/get_observations-remote_response.json</li> <li>Patient ID</li> <li>Frequency = "WEEKLY"</li> </ul>
Expected result	Retrieve all the patient variable values grouped correctly by selected frequency.
Output	Retrieved all the patient variable values grouped correctly by selected frequency.
Repository link	.../test/test_data_processing.py-> Method "test_observations_extraction_freq_weekly"
Comments	

Test ID	AT6
Component	ProcessRemoteDataUtils
Test objective	<p>Check that all incoming variable values of a patient, from the JSON file (Input field), which simulates the output of the following RESTful service, are returned and grouped correctly by selected frequency.</p> <p><a href="http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?subject=###PATIENT_ID###&amp;_format=json&amp;_elements=code,valueQuantity,valueBoolean,effectiveDateTime">http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?subject=###PATIENT_ID###&amp;_format=json&amp;_elements=code,valueQuantity,valueBoolean,effectiveDateTime</a></p>
Verified requirement(s)	Req_AP_04, Req_AP_08
Tool	Django unittest
Input	<ul style="list-style-type: none"> <li>.../tests/raw_data/get_observations-remote_response.json</li> <li>Patient ID</li> <li>Frequency = "MONTHLY"</li> </ul>

<b>Expected result</b>	Retrieve all the patient variable values grouped correctly by selected frequency.
<b>Output</b>	Retrieved all the patient variable values grouped correctly by selected frequency.
<b>Repository link</b>	.../test/test_data_processing.py-> Method "test_observations_extraction_freq_monthly"
<b>Comments</b>	

<b>Test ID</b>	AT7
<b>Component</b>	ProcessRemoteDataUtils
<b>Test objective</b>	Check that all incoming variable values of a patient, from the JSON file (Input field), which simulates the output of the following RESTful service, are returned and grouped correctly by selected frequency.  http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?subject=###PATIENT_ID###&_format=json&_elements=code,valueQuantity,valueBoolean,effectiveDateTime
<b>Verified requirement(s)</b>	Req_AP_04, Req_AP_08
<b>Tool</b>	Django unittest
<b>Input</b>	<ul style="list-style-type: none"> <li>.../tests/raw_data/get_observations-remote_response.json</li> <li>Patient ID</li> <li>Frequency = "YEARLY"</li> </ul>
<b>Expected result</b>	Retrieve all the patient variable values grouped correctly by selected frequency.
<b>Output</b>	Retrieved all the patient variable values grouped correctly by selected frequency.
<b>Repository link</b>	.../test/test_data_processing.py-> Method "test_observations_extraction_freq_yearly"
<b>Comments</b>	

<b>Test ID</b>	AT8
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<b>Component</b>	ProcessRemoteDataUtils
<b>Test objective</b>	Check that it is not allowed an incorrect frequency value, for the extraction and grouping variable values of a patient.
<b>Verified requirement(s)</b>	Req_UI_21, Req_UI_24
<b>Tool</b>	Django unittest
<b>Input</b>	<ul style="list-style-type: none"> <li>.../tests/raw_data/get_observations-remote_response.json</li> <li>Patient ID</li> <li>Frequency = "aaaaa"</li> </ul>
<b>Expected result</b>	Retrieve an error, indicating only allowed frequencies.
<b>Output</b>	Retrieved an error, indicating only allowed frequencies.
<b>Repository link</b>	.../test/test_data_processing.py-> Method "test_observations_extraction_freq_aaaaa"
<b>Comments</b>	

### Test Generic Services

<b>Test ID</b>	AT9
<b>Component</b>	Django view: GetCurrentUserSettings
<b>Test objective</b>	Test preferences retrieve
<b>Verified requirement(s)</b>	Req_UI_20
<b>Tool</b>	Django unittest
<b>Input</b>	None
<b>Expected result</b>	User preferences (external_user_id, aggregated_users, username, language)
<b>Output</b>	User preferences (external_user_id, aggregated_users, username, language)
<b>Repository link</b>	.../test/test_generic_services.py-> Method "test_preferences_retrieve"
<b>Comments</b>	

<b>Test ID</b>	AT10
<b>Component</b>	Django view: SetCurrentUserSettings
<b>Test objective</b>	Test language change
<b>Verified requirement(s)</b>	Req_AP_56
<b>Tool</b>	Django unittest
<b>Input</b>	A valid language code
<b>Expected result</b>	Same base user preferences with language replacement
<b>Output</b>	Same base user preferences with language replacement
<b>Repository link</b>	.../test/test_generic_services.py-> Method " test_language_change"
<b>Comments</b>	

<b>Test ID</b>	AT11
<b>Component</b>	Django view: SetCurrentUserSettings
<b>Test objective</b>	Test invalid language change
<b>Verified requirement(s)</b>	Req_AP_56
<b>Tool</b>	Django unittest
<b>Input</b>	An invalid language code
<b>Expected result</b>	User preferences (external_user_id, aggregated_users, username, language)
<b>Output</b>	User preferences (external_user_id, aggregated_users, username, language)
<b>Repository link</b>	.../test/test_generic_services.py-> Method "test_invalid_language_change "
<b>Comments</b>	

<b>Test ID</b>	AT12
<b>Component</b>	Django view: GetLanguagesList



<b>Test objective</b>	Test coverage of main languages (German, English and Spanish)
<b>Verified requirement(s)</b>	Req_AP_56
<b>Tool</b>	Django unittest
<b>Input</b>	None
<b>Expected result</b>	List containing id and names for each language. List includes 'de', 'en' and 'de'
<b>Output</b>	List containing id and names for each language. List includes 'de', 'en' and 'de'
<b>Repository link</b>	.../test/test_generic_services.py-> Method "test_available_languages"
<b>Comments</b>	

<b>Test ID</b>	AT13
<b>Component</b>	Django view: DashboardCrud
<b>Test objective</b>	Test dashboard details retrieve
<b>Verified requirement(s)</b>	Req_UI_04, Req_UI_07, Req_UI_17, Req_UI_19, Req_UI_20, Req_AP_02, Req_AP_54, Req_AP_55
<b>Tool</b>	Django unittest
<b>Input</b>	<ul style="list-style-type: none"> <li>Dashboard id</li> </ul>
<b>Expected result</b>	An object describing the dashboard including all required data to edit and render dashboards and the nested panels
<b>Output</b>	JSON object without no substantial difference from the dashboard stored in database
<b>Repository link</b>	.../test/test_model_views.py-> Method "test_dashboard_details_retrieve "
<b>Comments</b>	

<b>Test ID</b>	AT14
<b>Component</b>	Django view: DashboardCrud

<b>Test objective</b>	Test dashboard list retrieve
<b>Verified requirement(s)</b>	Req_UI_04, Req_UI_07, Req_UI_17, Req_UI_19, Req_UI_20, Req_AP_02, Req_AP_54, Req_AP_55
<b>Tool</b>	Django unittest
<b>Input</b>	None
<b>Expected result</b>	A list containing the id and some general info about the existing dashboard
<b>Output</b>	JSON object list containing the only dashboard stored in database
<b>Repository link</b>	.../test/test_model_views.py-> Method "test_dashboard_retrieve_list "
<b>Comments</b>	

<b>Test ID</b>	AT15
<b>Component</b>	Django view: DashboardCrud
<b>Test objective</b>	Test dashboard update
<b>Verified requirement(s)</b>	Req_UI_04, Req_UI_07, Req_UI_17, Req_UI_19, Req_UI_20, Req_AP_02, Req_AP_54, Req_AP_55
<b>Tool</b>	Django unittest
<b>Input</b>	Modified dashboard object to replace the existing one <ul style="list-style-type: none"> <li>• A modified object</li> </ul>
<b>Expected result</b>	No output, state change of the dashboard. New object should be equal to the input
<b>Output</b>	No output, state change of the dashboard. New object equal to the input
<b>Repository link</b>	.../test/test_model_views.py-> Method "test_dashboard_update"
<b>Comments</b>	

<b>Test ID</b>	AT16
<b>Component</b>	Django view: DashboardCrud

Test objective	Test dashboard create
Verified requirement(s)	Req_UI_04, Req_UI_07, Req_UI_17, Req_UI_19, Req_UI_20, Req_AP_02, Req_AP_54, Req_AP_55
Tool	Django unittest
Input	<ul style="list-style-type: none"> <li>A dashboard object</li> </ul>
Expected result	A new dashboard object with the same fields posted
Output	A new dashboard object with the same fields posted
Repository link	.../test/test_model_views.py-> Method "test_dashboard_create"
Comments	

## Data Federation

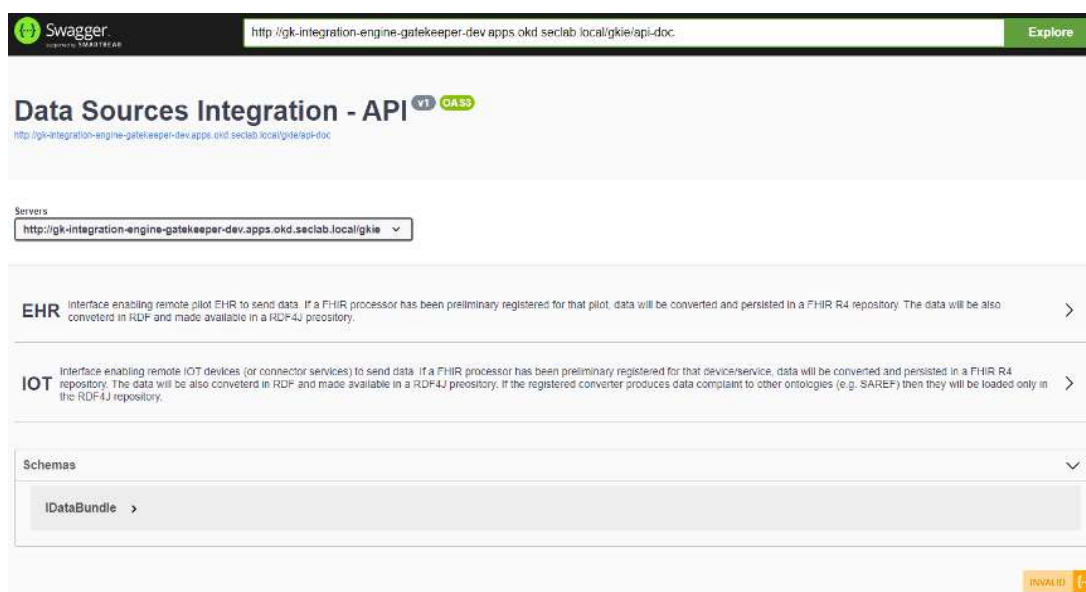
The Engineering components that have been "unit" tested are those related to the DF module. The requirements gathered in T3.1 highlight the need for (i) heterogeneous data acquisition and adaptation (to a GK-FHIR profile) and (ii) retrieval of FHIR-compliant adapted data and have been gathered at the end of the section.

Such components are respectively, the IntegrationEngine, the FHIRServer, the FHIRProfileValidator and the RDFWatcher.

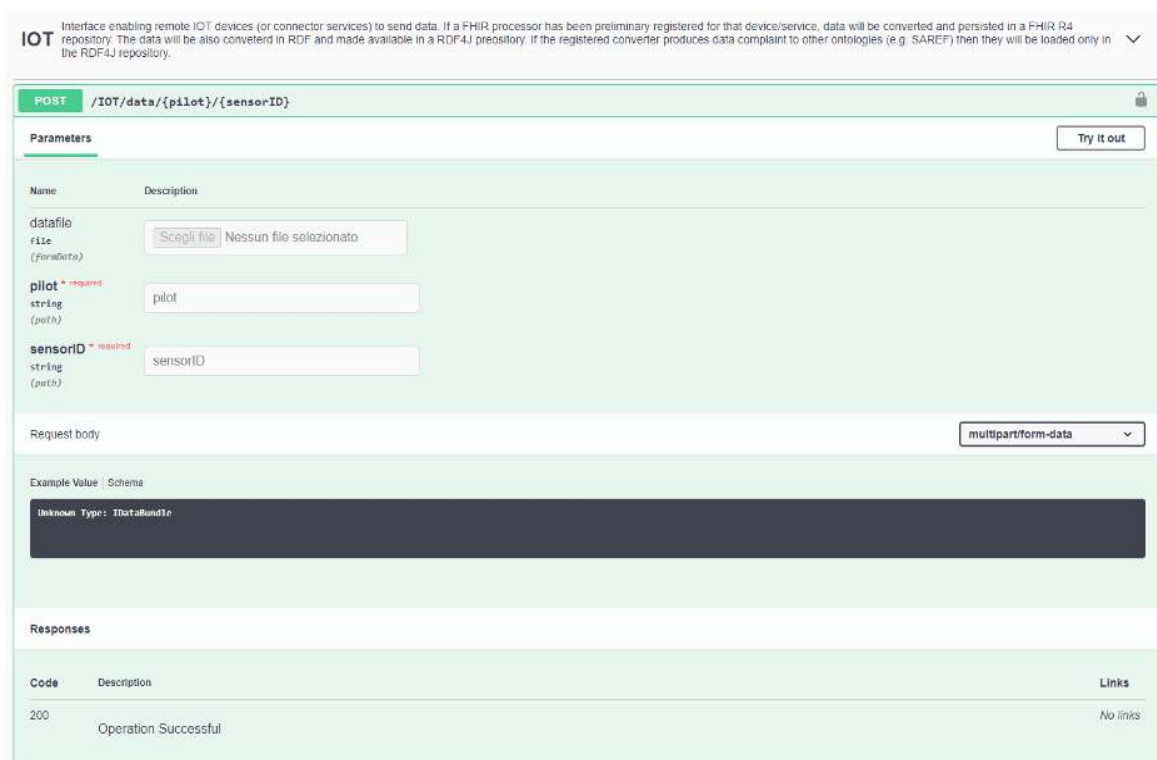
The Data Federation test reports have been provided by Engineering.

### IntegrationEngine

This component is a REST Service exposing two APIs (i.e. Southbound API) in order to support the **heterogeneous data acquisition and adaptation**. Here below the Swagger Interface documentation. The two entries are related to the acquisition of the data from IoT devices (or IoT gateway) and from health organisation legacy electronic health record (EHR).



Here below some unit tests executed for one of these entries.



Test ID

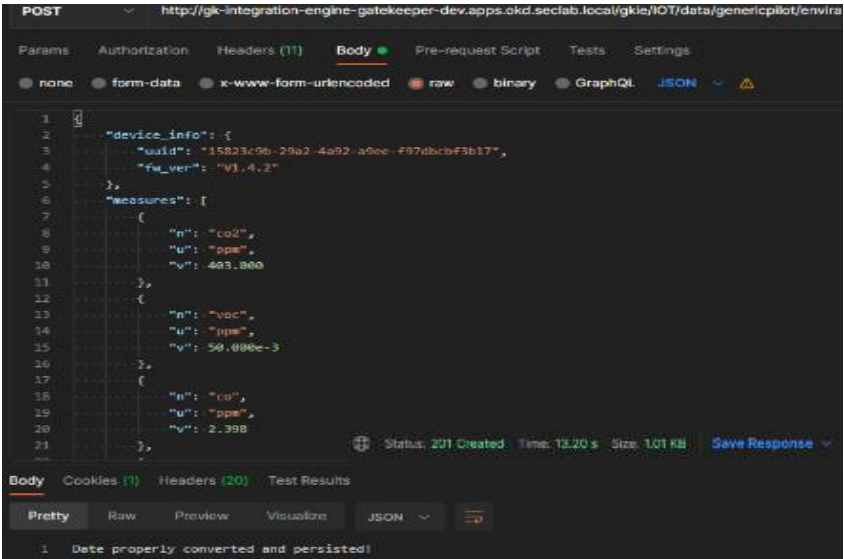
DF1

Component

IntegrationEngine

<b>Test objective</b>	<p>The objective of the test is to demonstrate the capability of the component to accept data from an IoT data source and to adapt it against a FHIR profile.</p> <p>PRECONDITIONS</p> <ul style="list-style-type: none"> <li>a converter, associated to the specific data source, has been already integrated within the IntegrationEngine</li> </ul> <p>NOTE</p> <ul style="list-style-type: none"> <li>Being a unit test, we used mock IoT data (i.e. not associated to any real device)</li> </ul>
<b>Verified requirement(s)</b>	from D3.1.2
<b>Tool</b>	Postman
<b>Input</b>	<pre>[   {     "device_info": {       "uuid": "30afdf79-b363-40d4-ac99-70db778c744b",       "fw_ver": "V1.4.2"     },     "measures": [       {         "n": "co2",         "u": "ppm",         "v": 673.000       },       {         "n": "voc",         "u": "ppm",         "v": 275.000e-3       },       {         "n": "co",         "u": "ppm",         "v": 0.206       },       {         "n": "pm10",         "u": "ug/m3",         "v": 0.000       },       {         "n": "pm2.5",</pre>

	<pre>"u": "ug/m3", "v": 0.162 }, {   "n": "temp",   "u": "Cel",   "v": 32.966 }, {tci   "n": "hum",   "u": "%RH",   "v": 44.355 }, {   "n": "prb",   "u": "hPa",   "v": 1002.427 }, {   "n": "pm1",   "u": "ug/m3",   "v": 2.813 }, {   "n": "pm4",   "u": "ug/m3",   "v": 0.162 }, {   "n": "iaqi",   "u": "count",   "v": 65 }, {   "n": "tci",   "u": "count",   "v": 37 }, {   "n": "eiaqi",   "u": "count",</pre>
--	--

	<pre>"v": 3 } } }</pre>
Expected result	<ol style="list-style-type: none"><li>1. HTTP response: code response 201</li><li>2. The server FHIR holds the converted data</li></ol>
Output	Same as Expected result
Screenshot(s)	<p>screenshot related to Expected result 1</p>  <p>screenshot related to Expected result 2</p>

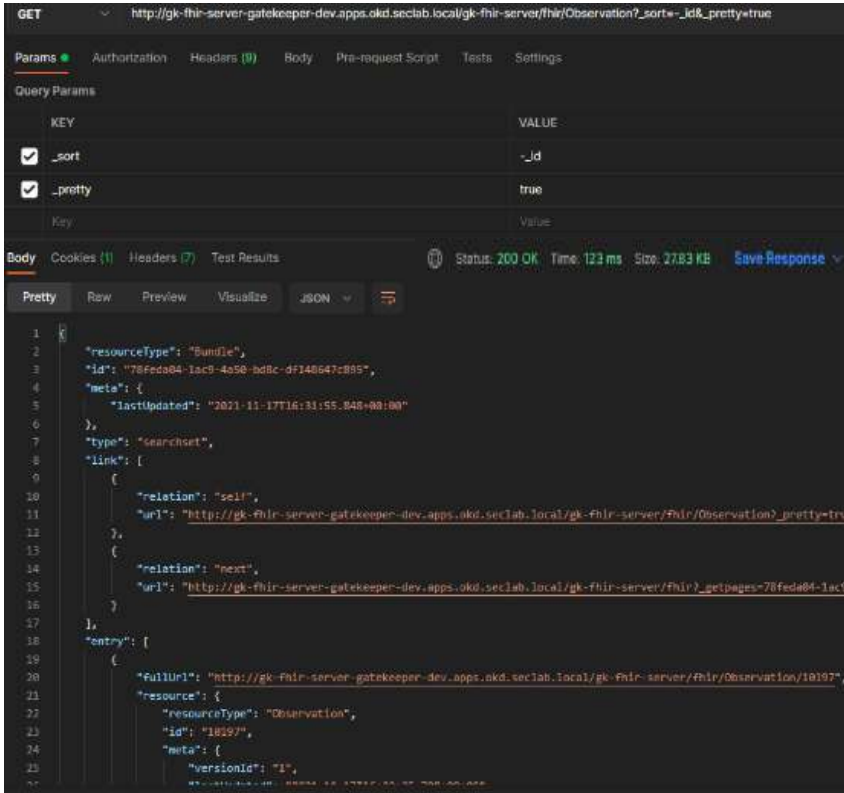
	<b>Request</b> GET http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?_sort=-_id&_pretty=true																														
	<b>Request Headers</b> Accept-Charset: utf-8 Accept: application/fhir+xml;q=1.0, application/fhir+json;q=1.0, application/xml+fhir;q=0.9, application/json+fhir;q=0.9 User-Agent: HAPI-FHIR/4.1.0 (FHIR Client; FHIR 4.0.0/R4; apache) Accept-Encoding: gzip																														
	<b>Response</b> ✓ HTTP 200																														
	<b>Response Headers</b> date: Wed, 17 Nov 2021 16:23:22 GMT x-request-id: XdevQ2G01r33mmpm set-cookie: b0e53e24fef6f5e1b3edae5d513f1f5-ba4503625595cf53cccebf8e3d8743e; path=/; HttpOnly last-modified: Wed, 17 Nov 2021 16:23:22 GMT transfer-encoding: chunked x-powered-by: HAPI FHIR 4.1.0 REST Server (FHIR Server; FHIR 4.0.0/R4) content-type: application/fhir+json; charset=utf-8 cache-control: private																														
	<b>Result Body</b> JSON bundle (28186 bytes)																														
	Bundle contains 20 entries <a href="#">Prev Page</a> <a href="#">Next Page</a> <table> <thead> <tr> <th>ID</th><th>Updated</th></tr> </thead> <tbody> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10197/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10196/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10195/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10194/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10193/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10192/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10191/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10190/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10189/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10188/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10187/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10186/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10185/_history/1</td><td>16:22:25</td></tr> <tr><td><a href="#">Read</a> <a href="#">Update</a> Observation/10184/_history/1</td><td>16:22:25</td></tr> </tbody> </table>	ID	Updated	<a href="#">Read</a> <a href="#">Update</a> Observation/10197/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10196/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10195/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10194/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10193/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10192/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10191/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10190/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10189/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10188/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10187/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10186/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10185/_history/1	16:22:25	<a href="#">Read</a> <a href="#">Update</a> Observation/10184/_history/1	16:22:25
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<b>Comments</b>																															

## FHIR server

This component is an implementation of the HL7-FHIR specification in Java based on a REST Service exposing all the FHIR APIs.

<b>Test ID</b>	DF2
<b>Component</b>	FHIR server
<b>Test objective</b>	<p>The objective of the test is to demonstrate the availability of the FHIR server and its compliance with FHIR standard.</p> <p>PRECONDITIONS</p> <ul style="list-style-type: none"> <li>Some Observations must be stored in the server</li> </ul>
<b>Verified requirement(s)</b>	from D3.1.2
<b>Tool</b>	Postman
<b>Input</b>	Request parameters



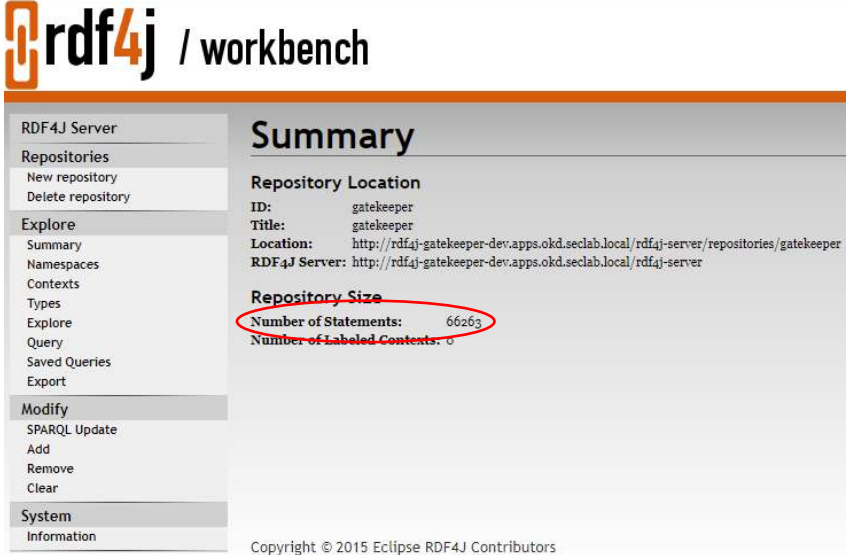
	<ul style="list-style-type: none"> <li>• <code>_sort=-_id</code>, orders the Observations in descending way by its stored time;</li> <li>• <code>_pretty=true</code>, the response is printed in a human-readable form</li> </ul>
Expected result	<ol style="list-style-type: none"> <li>1. HTTP response: code response 200</li> <li>2. The server FHIR returns the requested Observations</li> </ol>
Output	Same as Expected result
Screenshot(s)	 <pre> 1 GET http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?_sort=-_id&amp;_pretty=true 2 3 Params Authorization Headers (9) Body Pre-request Script Tests Settings 4 5 Query Params 6 KEY VALUE 7 _sort -_id 8 _pretty true 9 10 Body Cookies (1) Headers (7) Test Results 11 Status: 200 OK Time: 123 ms Size: 27.83 KB Save Response 12 13 Pretty Raw Preview Visualize JSON 14 15 { 16   "resourceType": "Bundle", 17   "id": "78Feds84-1ac9-4a58-bd8c-df148647c895", 18   "meta": { 19     "lastUpdated": "2021-11-17T16:31:55.848+00:00" 20   }, 21   "type": "searchset", 22   "link": [ 23     { 24       "relation": "self", 25       "url": "http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation?_pretty=true" 26     }, 27     { 28       "relation": "next", 29       "url": "http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/_getpages-78Feds84-1ac9-4a58-bd8c-df148647c895" 30     } 31   ], 32   "entry": [ 33     { 34       "fullUrl": "http://gk-fhir-server-gatekeeper-dev.apps.okd.seclab.local/gk-fhir-server/fhir/Observation/10197", 35       "resource": { 36         "resourceType": "Observation", 37         "id": "10197", 38         "meta": { 39           "versionId": "1", 40           "lastUpdated": "2021-11-17T16:31:55.848+00:00" 41         } 42       } 43     } 44   ] 45 } </pre>
Comments	

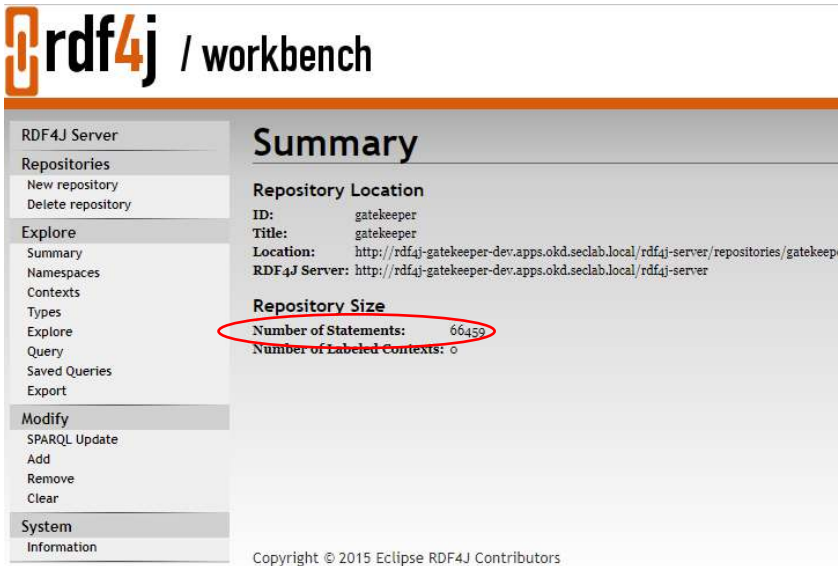
## RDFWatcher

This component is a series Linux scripts that executes the RDF conversion. In fact, it shares a folder with the FHIR Server and it listens for all new files that wrote in it; when a new file has been written the watching process launch an RDF conversion procedure. After that, the new RDF content is sent to the RDF Server.

Test ID

DF3

Component	RDFWatcher
Test objective	<p>The objective of the test is to demonstrate that the system observes the FHIR Resources creation and for each of them it executes a transformation process in RDF.</p> <p>PRECONDITIONS</p> <ul style="list-style-type: none"> <li>Observe the number of Resources within the FHIR server;</li> <li>the GK Integration Engine test should have been already executed.</li> </ul>
Verified requirement(s)	from D3.1.2
Tool	RDF4JWorkbench
Input	JSON is the same used for GK Integration Engine test
Expected result	It confirms that exists an increase of the Resources within the RDF server.
Output	The Resources were increased, confirming new RDF statements are available in the triple store.
Screenshot(s)	 <p>The screenshot displays the RDF4J Workbench interface. The main panel shows the 'Summary' page for a repository named 'gatekeeper'. Key information includes the Repository Location (ID: gatekeeper, Title: gatekeeper, Location: http://rdf4j-gatekeeper-dev.apps.okd.seclab.local/rdf4j-server/repositories/gatekeeper) and the Repository Size (Number of Statements: 66263, Number of Labeled Contents: 0). The 'Number of Statements' value is circled in red. The sidebar on the left contains navigation options such as 'Repositories', 'Explore', 'Modify', and 'System'.</p>

	
Comments	

## FHIRProfileValidator

This component is a java library (released in a jar container) to invoke when needed.

Test ID	DF4
Component	FHIRProfileValidator
Test objective	<p>The objective of the test is to demonstrate the capability of the FHIRProfileValidator to validate a GK resource.</p> <p>PRECONDITIONS</p> <p>In order to provide an invalid resource, the 'code' and 'effectiveDateTime' parameters have been deleted from the valid resource.</p>
Verified requirement(s)	from D3.1.2
Tool	ad hoc java main

Input	<ol style="list-style-type: none"> <li>1. a JSON string representation about a valid GK Observation resource</li> <li>2. a JSON string representation about a not valid GK Observation resource</li> </ol>
Expected result	<ol style="list-style-type: none"> <li>1. Resource successfully validated</li> <li>2. Resource not validated</li> </ol>
Output	<p>In case of Input 1 (a valid resource):</p> <p>Validating resources...</p> <p>Validated successfully!</p> <p>as Expected result 1</p> <p>In case of Input 2 (a not valid resource):</p> <p>Validating resources...</p> <p>Next issue ERROR - Observation - Observation.code: minimum required = 1, but only found 0 (from http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk)</p> <p>Next issue ERROR - Observation - Observation.subject: minimum required = 1, but only found 0 (from http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk)</p> <p>Next issue ERROR - Observation - Observation.effective[x]: minimum required = 1, but only found 0 (from http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk)</p> <p>Next issue ERROR - Observation.component[0].value.ofType(Quantity) - Observation.component:SystolicBP.value[x].unit: minimum required = 1, but only found 0 (from http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk)</p> <p>Next issue ERROR - Observation.component[1].value.ofType(Quantity) - Observation.component:DiastolicBP.value[x].unit: minimum required = 1, but only found 0 (from http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk)</p> <p>NOT Validated!</p> <p>as Expected result 2</p>
Screenshot(s)	-
Comments	-

Here below the two JSON string representation samples related to the FHIRProfileValidator test.

### 1. Blood pressure valid JSON

```
{
  "resourceType": "Observation",
  "meta": {
    "profile": [
      "http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk"
    ]
  },
  ...
}
```

```

    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "http://terminology.hl7.org/CodeSystem/observation-category",
            "code": "vital-signs",
            "display": "Vital Signs"
          }
        ]
      }
    ],
    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "85354-9",
          "display": "Blood pressure panel with all children optional"
        }
      ]
    },
    "text": "Blood pressure systolic and diastolic",
    "effectiveDateTime": "2021-01-12T11:17:48.887807025Z",

    "component": [
      {
        "code": {
          "coding": [
            {
              "system": "http://loinc.org",
              "code": "8480-6",
              "display": "Systolic blood pressure"
            }
          ]
        },
        "valueQuantity": {
          "value": 103,
          "system": "http://unitsofmeasure.org",
          "code": "mm[Hg]"
        }
      }
    ]
  }

```

```

    "code": {
      "coding": [
        {
          "system": "http://loinc.org",
          "code": "8462-4",
          "display": "Diastolic blood pressure"
        }
      ]
    },
    "valueQuantity": {
      "value": 74,
      "system": "http://unitsofmeasure.org",
      "code": "mm[Hg]"
    }
  ]
}

```

## 2. Blood pressure not valid JSON (missing 'code' and 'effectiveDateTime' parameters)

```

{
  "resourceType": "Observation",
  "meta": {
    "profile": [
      "http://hl7.eu/fhir/ig/gk/StructureDefinition/observation-bp-gk"
    ]
  },
  "status": "final",
  "category": [
    {
      "coding": [
        {
          "system": "http://terminology.hl7.org/CodeSystem/observation-category",
          "code": "vital-signs",
          "display": "Vital Signs"
        }
      ]
    }
  ],
  "component": [
    {
      "code": {

```

```

    "coding": [
      {
        "system": "http://loinc.org",
        "code": "8480-6",
        "display": "Systolic blood pressure"
      }
    ],
    "valueQuantity": {
      "value": 103,
      "system": "http://unitsofmeasure.org",
      "code": "mm[Hg]"
    },
    {
      "code": {
        "coding": [
          {
            "system": "http://loinc.org",
            "code": "8462-4",
            "display": "Diastolic blood pressure"
          }
        ]
      },
      "valueQuantity": {
        "value": 74,
        "system": "http://unitsofmeasure.org",
        "code": "mm[Hg]"
      }
    }
  ]
}

```

Here below the related D3.1.2 requirements for the next integration test:

Req\_AP\_24, Req\_AP\_63, Req\_AP\_64, Req\_AP\_65, Req\_DA\_07, Req\_DA\_12, Req\_DA\_20, Req\_DA\_21, Req\_DA\_23, Req\_DA\_24, Req\_DSP\_18, Req\_DSP\_19, Req\_DSP\_20.

## Robot connector

The Robot connector test reports have been provided by Open University.

Test ID	RC1
Component(s)	Robot connector backend
Test objective	The created FHIR Observation matches the data provided by the robot
Verified requirement(s)	Req_DA_06, Req_DA_11, Req_NT_08
Tool	PyUnit
Input	Identified hazard extracted from the semantic map
Expected result	FHIR Observation containing the correct location of the hazard
Output	The FHIR Observation can be reconverted in the semantic map format without loss of information

Test ID	RC2
Component(s)	Robot connector backend
Test objective	An invalid/incomplete FHIR Observation cannot be sent to the Robot Connector
Verified requirement(s)	Req_DA_06, Req_DA_11, Req_NT_08
Tool	PyUnit
Input	A FHIR Observation missing required fields
Expected result	An error is raised and the FHIR Observation is not created
Output	The system should not allow the creation of invalid/incomplete FHIR Observation

Test ID	RC3
Component(s)	Robot connector
Test objective	The Robot connector receives and store the FHIR Observation
Verified requirement(s)	Req_DSP_01, Req_DSP_06
Tool	PyUnit
Input	A correct FHIR Observation



<b>Expected result</b>	The Robot Connector receives the FHIR Observation and stores it
<b>Output</b>	The FHIR Observation can be retrieved from the FHIR Server and matches the one originally sent by the Robot Connector backend

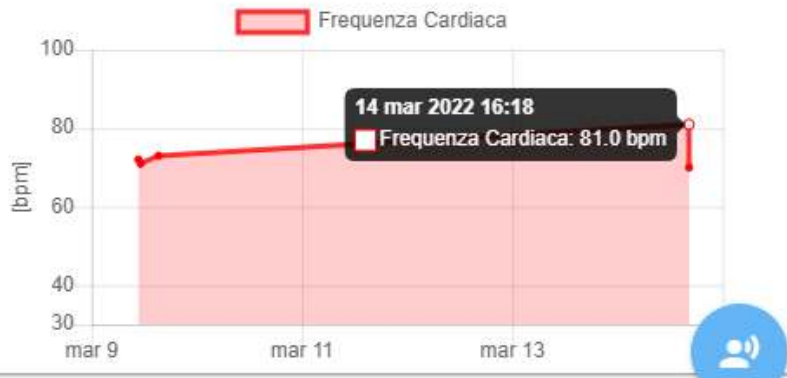

<b>Test ID</b>	RC4
<b>Component(s)</b>	Robot connector
<b>Test objective</b>	The Robot connector can support multiple robotic platforms
<b>Verified requirement(s)</b>	Req_DA_11, Req_DSP_06
<b>Tool</b>	Custom testing framework
<b>Input</b>	Sensor's data regarding the same event coming from different robotic platforms
<b>Expected result</b>	A FHIR Observation is created using the sensor data produced by each platform
<b>Output</b>	Multiple FHIR Observation relative to the same event are comparable even if they are created by using different robotic platforms

## Intelligent Connected Care Service – Data Federation – Pilot application

The Intelligent Connected Care Service – Data Federation – DMCoach test report has been provided by Medisante.

<b>Test ID</b>	FUN1
<b>Component(s)</b>	Data Federation - DM coach (Puglia pilot) – Intelligent Connected Care Service
<b>Test objective</b>	Ensure that data device data can pass through the intelligent care service to Data Federation to DM coach application
<b>Verified requirement(s)</b>	Req_UI_07 & 08; Req- NT_02 & 03 & 04 & 07 & 08 & 09; Req_DSP-06 & 11 & 15 & 24 & 27 ;
<b>Tool</b>	D40g (blood pressure monitor device) connected to the Intelligent Connected Care Service (ICCS) with embedded SIM-card
<b>Input</b>	Blood pressure data from D40g taken on user

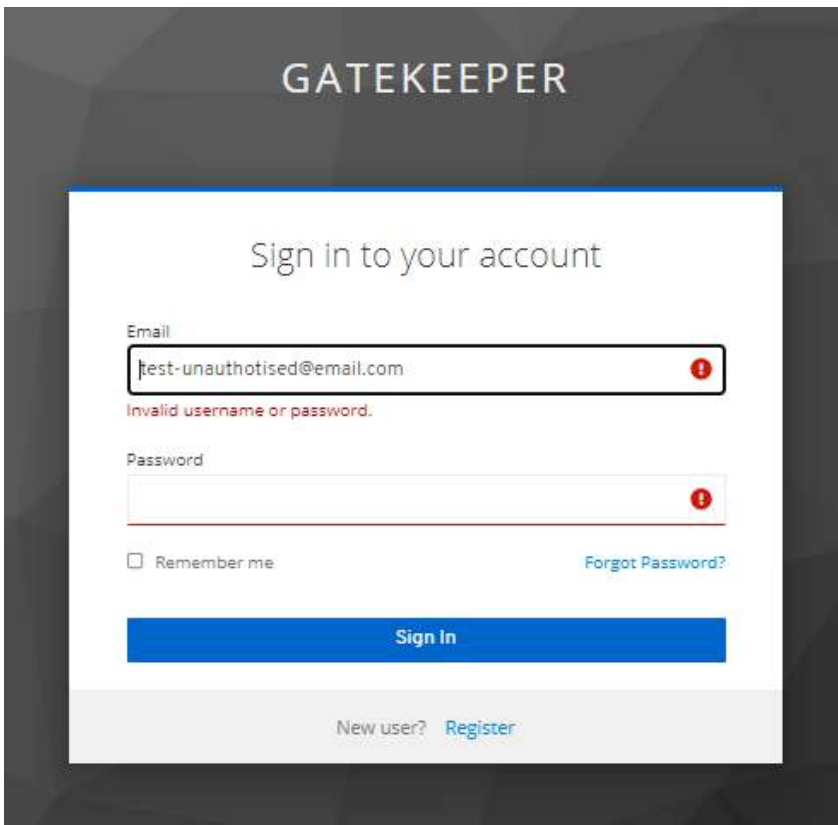
<b>Expected result</b>	Blood pressure data available in DM coach after transition by data federation																						
<b>Output</b>	Data available in DM coach (see screen shot below)																						
<b>Screenshot(s)</b>	<table> <tr> <td>IMEI</td><td>354033090705180</td></tr> <tr> <td>IMSI</td><td>901280023541167</td></tr> <tr> <td>Organisation ID</td><td>56250a52-1619-4784-b26c-41700c968968</td></tr> <tr> <td>Manufactured (UTC)</td><td>1/5/2021, 8:00:00 AM</td></tr> <tr> <td>Time zone</td><td>Europe/Rome</td></tr> <tr> <td>Blood glucose unit</td><td>mg/dL</td></tr> <tr> <td>Number of measurements</td><td>7</td></tr> <tr> <td>Last measurement (UTC)</td><td>3/14/2022, 3:18:00 PM</td></tr> <tr> <td>Last communication (UTC)</td><td>3/14/2022, 3:19:00 PM</td></tr> <tr> <td>Token issued (UTC)</td><td>3/9/2022, 9:42:18 AM</td></tr> <tr> <td>Webhooks</td><td>Data Federation Gatekeeper</td></tr> </table>	IMEI	354033090705180	IMSI	901280023541167	Organisation ID	56250a52-1619-4784-b26c-41700c968968	Manufactured (UTC)	1/5/2021, 8:00:00 AM	Time zone	Europe/Rome	Blood glucose unit	mg/dL	Number of measurements	7	Last measurement (UTC)	3/14/2022, 3:18:00 PM	Last communication (UTC)	3/14/2022, 3:19:00 PM	Token issued (UTC)	3/9/2022, 9:42:18 AM	Webhooks	Data Federation Gatekeeper
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Token issued (UTC)	3/9/2022, 9:42:18 AM																						
Webhooks	Data Federation Gatekeeper																						

	<p><b>Frequenza Cardiaca</b></p>  <p><b>Pressione sanguigna</b></p> 
<b>Comments</b>	Device Data was correctly transmitted into target system DMcoach through the Data Federation: execution successfully operated

## Gatekeeper Trust Authority (GTA)

The GTA test report has been provided by CERTH.

<b>Test ID</b>	GTA1
<b>Component</b>	Gatekeeper Trust Authority User Management Module
<b>Test objective</b>	User with invalid credentials cannot log in
<b>Verified requirement(s)</b>	Req_PS_01

Tool	(manual)
Input	login credentials of unregistered user
Expected result	unauthorised response
Output	did not allow user with invalid credentials to login and provided an error message in the interface
Screenshot(s)	 <p>The screenshot shows the GATEKEEPER login page. The title is 'Sign in to your account'. There are two input fields: 'Email' and 'Password'. The 'Email' field contains the text 'test-unauthorised@email.com' and has a red error icon. Below the 'Email' field, the text 'Invalid username or password.' is displayed in red. The 'Password' field is empty and also has a red error icon. Below the password field, there is a checkbox labeled 'Remember me' and a link 'Forgot Password?'. A blue 'Sign In' button is at the bottom of the form. At the very bottom, there is a link 'New user? Register'.</p>
Comments	Test implemented with OpenID Connect

## Appendix B Reporting of AI/ML Model-based Studies

### Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD): The TRIPOD Statement

Section/Topic	Item		Checklist Item
<b>TITLE AND ABSTRACT</b>			
<i>Title</i>	1	D; V	Identify the study as developing and/or validating a multivariable prediction model, the target population, and the outcome to be predicted.
<i>Abstract</i>	2	D; V	Provide a summary of objectives, study design, setting, participants, sample size, predictors, outcome, statistical analysis, results, and conclusions.
<b>INTRODUCTION</b>			
<i>Background and objectives</i>	3a	D; V	Explain the medical context (including whether diagnostic or prognostic) and rationale for developing or validating the multivariable prediction model, including references to existing models.
	3b	D; V	Specify the objectives, including whether the study describes the development or validation of the model or both.
<b>METHODS</b>			
<i>Source of data</i>	4a	D; V	Describe the study design or source of data (e.g., randomized trial, cohort, or registry data), separately for the development and validation data sets, if applicable.
	4b	D; V	Specify the key study dates, including start of accrual; end of accrual; and, if applicable, end of follow-up.
<i>Participants</i>	5a	D; V	Specify key elements of the study setting (e.g., primary care, secondary care, general population) including number and location of centres.
	5b	D; V	Describe eligibility criteria for participants.
	5c	D; V	Give details of treatments received, if relevant.
<i>Outcome</i>	6a	D; V	Clearly define the outcome that is predicted by the prediction model, including how and when assessed.
	6b	D; V	Report any actions to blind assessment of the outcome to be predicted.

<i>Predictors</i>	7a	D; V	Clearly define all predictors used in developing or validating the multivariable prediction model, including how and when they were measured.
	7b	D; V	Report any actions to blind assessment of predictors for the outcome and other predictors.
<i>Sample size</i>	8	D; V	Explain how the study size was arrived at.
<i>Missing data</i>	9	D; V	Describe how missing data were handled (e.g., complete-case analysis, single imputation, multiple imputation) with details of any imputation method.
<i>Statistical analysis methods</i>	10a	D	Describe how predictors were handled in the analyses.
	10b	D	Specify type of model, all model-building procedures (including any predictor selection), and method for internal validation.
	10c	V	For validation, describe how the predictions were calculated.
	10d	D; V	Specify all measures used to assess model performance and, if relevant, to compare multiple models.
	10e	V	Describe any model updating (e.g., recalibration) arising from the validation, if done.
<i>Risk groups</i>	11	D; V	Provide details on how risk groups were created, if done.
<i>Development vs. validation</i>	12	V	For validation, identify any differences from the development data in setting, eligibility criteria, outcome, and predictors.
<b>RESULTS</b>			
<i>Participants</i>	13a	D; V	Describe the flow of participants through the study, including the number of participants with and without the outcome and, if applicable, a summary of the follow-up time. A diagram may be helpful.
	13b	D; V	Describe the characteristics of the participants (basic demographics, clinical features, available predictors), including the number of participants with missing data for predictors and outcome.
	13c	V	For validation, show a comparison with the development data of the distribution of important variables (demographics, predictors and outcome).
<i>Model development</i>	14a	D	Specify the number of participants and outcome events in each analysis.
	14b	D	If done, report the unadjusted association between each candidate predictor and outcome.
<i>Model specification</i>	15a	D	Present the full prediction model to allow predictions for individuals (i.e., all regression coefficients, and model intercept or baseline survival at a given time point).

	15b	D	Explain how to use the prediction model.
<i>Model performance</i>	16	D; V	Report performance measures (with CIs) for the prediction model.
<i>Model-updating</i>	17	V	If done, report the results from any model updating (i.e., model specification, model performance).
<b>DISCUSSION</b>			
<i>Limitations</i>	18	D; V	Discuss any limitations of the study (such as nonrepresentative sample, few events per predictor, missing data).
<i>Interpretation</i>	19a	V	For validation, discuss the results with reference to performance in the development data, and any other validation data.
	19b	D; V	Give an overall interpretation of the results, considering objectives, limitations, results from similar studies, and other relevant evidence.
<i>Implications</i>	20	D; V	Discuss the potential clinical use of the model and implications for future research.
<b>OTHER INFORMATION</b>			
<i>Supplementary information</i>	21	D; V	Provide information about the availability of supplementary resources, such as study protocol, Web calculator, and data sets.
<i>Funding</i>	22	D; V	Give the source of funding and the role of the funders for the present study.

\*Items relevant only to the development of a prediction model are denoted by D, items relating solely to a validation of a prediction model are denoted by V, and items relating to both are denoted D;V. We recommend using the TRIPOD Checklist in conjunction with the TRIPOD Explanation and Elaboration document.

## Appendix C Assessing the Risk of Bias

### PROBAST: A Tool to Assess the Risk of Bias and Applicability of Prediction Model Studies

#### DOMAIN 1: Participants

##### A. Risk of Bias

*Describe the sources of data and criteria for participant selection:*

	Dev	Val
1.1 Were appropriate data sources used, e.g. cohort, RCT or nested case-control study data?		
1.2 Were all inclusions and exclusions of participants appropriate?		
<b>Risk of bias introduced by selection of participants</b>	<b>RISK:</b> (low/ high/ unclear)	
<i>Rationale of bias rating:</i>		

\*Dev: Development, Val: Validation

#### DOMAIN 2: Predictors

##### A. Risk of Bias

*List and describe predictors included in the final model, e.g. definition and timing of assessment:*

	Dev	Val
2.1 Were predictors defined and assessed in a similar way for all participants?		
2.2 Were predictor assessments made without knowledge of outcome data?		
2.3 Are all predictors available at the time the model is intended to be used?		
<b>Risk of bias introduced by predictors or their assessment</b>	<b>RISK:</b> (low/ high/ unclear)	
<i>Rationale of bias rating:</i>		

\*Dev: Development, Val: Validation

#### DOMAIN 3: Outcome

##### A. Risk of Bias



*Describe the outcome, how it was defined and determined, and the time interval between predictor assessment and outcome determination:*

	Dev	Val
3.1 Was the outcome determined appropriately?		
3.2 Was a pre-specified or standard outcome definition used?		
3.3 Were predictors excluded from the outcome definition?		
3.4 Was the outcome defined and determined in a similar way for all participants?		
3.5 Was the outcome determined without knowledge of predictor information?		
3.6 Was the time interval between predictor assessment and outcome determination appropriate?		
<b>Risk of bias introduced by the outcome or its determination</b>	<b>RISK:</b> (low/ high/ unclear)	

*Rationale of bias rating:*

\*Dev: Development, Val: Validation

## DOMAIN 4: Analysis

### Risk of Bias

*Describe numbers of participants, number of candidate predictors, outcome events and events per candidate predictor:*

*Describe how the model was developed (for example in regards to modelling technique (e.g. survival or logistic modelling), predictor selection, and risk group definition):*

*Describe whether and how the model was validated, either internally (e.g. bootstrapping, cross validation, random split sample) or externally (e.g. temporal validation, geographical validation, different setting, different type of participants):*

*Describe the performance measures of the model, e.g. (re)calibration, discrimination, (re)classification, net benefit, and whether they were adjusted for optimism:*

*Describe any participants who were excluded from the analysis:*

*Describe missing data on predictors and outcomes as well as methods used for missing data:*

	Dev	Val
4.1 Were there a reasonable number of participants with the outcome?		
4.2 Were continuous and categorical predictors handled appropriately?		

4.3 Were all enrolled participants included in the analysis?		
4.4 Were participants with missing data handled appropriately?		
4.5 Was selection of predictors based on univariable analysis avoided?		
4.6 Were complexities in the data (e.g. censoring, competing risks, sampling of controls) accounted for appropriately?		
4.7 Were relevant model performance measures evaluated appropriately?		
4.8 Were model overfitting and optimism in model performance accounted for?		
4.9 Do predictors and their assigned weights in the final model correspond to the results from multivariable analysis?		
<b>Risk of bias introduced by the analysis</b>	<b>RISK:</b> (low/ high/ unclear)	
<i>Rationale of bias rating:</i>		

\*Dev: Development, Val: Validation

### Reaching an overall judgement about risk of bias of the prediction model evaluation

<b>Low risk of bias</b>	If all domains were rated low risk of bias. If a <u>prediction model was developed without any external validation</u> , and it was rated as <u>low risk of bias for all domains</u> , consider downgrading to <b>high risk of bias</b> . Such a model can only be considered as low risk of bias, if the development was based on a very large data set <u>and</u> included some form of internal validation.
<b>High risk of bias</b>	If at least one domain is judged to be at <b>high risk of bias</b> .
<b>Unclear risk of bias</b>	If an unclear risk of bias was noted in at least one domain and it was low risk for all other domains.

## Appendix D Training material

### Deployment guides

The deployment guides are available to registered users in the project repository:

<http://91.121.72.19:8080/share/page/site/gatekeeper/folder-details?nodeRef=workspace://SpacesStore/e2fc4670-e270-471e-9019-a3a379e678ab>

### Table of contents

<b>TABLE OF CONTENTS.....</b>	<b>4</b>
<b>LIST OF TABLES.....</b>	<b>5</b>
<b>LIST OF FIGURES.....</b>	<b>6</b>
<b>1 OPENSIFT ARTIFACT.....</b>	<b>7</b>
11 CONFIG MAP.....	7
12 PERSISTENT VOLUME CLAIM .....	7
13 SERVICE.....	7
14 DEPLOYMENT .....	7
15 ROUTE.....	7
<b>2 DATA FEDERATION COMPONENTS.....</b>	<b>8</b>
2.1 DB-FHIR.....	8
2.2 GK-INTEGRATION-ENGINE.....	8
2.3 GK-FHIR-SERVER.....	8
2.3.1 <i>gk-fhir-server</i> .....	8
2.3.2 <i>gk-rdf-watcher</i> .....	8
2.4 RDF4J.....	9
<b>3 COMPONENT ARTIFACTS.....</b>	<b>10</b>
<b>4 OKD INSTALLATION PROCEDURE.....</b>	<b>12</b>
<b>5 TESTS.....</b>	<b>14</b>

Figure 12 - Data Federation deployment guide ToC [36]

Table of contents

TABLE OF CONTENTS.....4

LIST OF TABLES.....5

LIST OF FIGURES.....6

1 OPENSIFT ARTEFACT .....7

11 PERSISTENT VOLUME CLAIM .....7

12 SERVICE.....7

13 DEPLOYMENT CONFIGURATION.....7

14 DEPLOYMENT.....7

15 ROUTE.....7

2 GTA USER MANAGEMENT COMPONENTS.....8

2.1 POSTGRESQL.....8

2.2 KEYCLOAK.....8

3 COMPONENT ARTEFACTS.....9

4 OKD INSTALLATION PROCEDURE.....10

5 TESTS.....14

6 KEYCLOAK CONFIGURATION.....17

|

Figure 13 - GTA User Management Module deployment guide ToC [37]

## Table of contents

<b>TABLE OF CONTENTS</b>	<b>4</b>
<b>LIST OF TABLES</b>	<b>5</b>
<b>LIST OF FIGURES</b>	<b>6</b>
<b>1 OPENSIFT ARTIFACT</b>	<b>7</b>
11 SERVICE	7
12 DEPLOYMENT	7
13 STATEFULSET	7
14 ROUTE	7
15 ROLE	7
16 ROLEBINDING	7
<b>2 THING MANAGEMENT SYSTEM COMPONENTS</b>	<b>8</b>
2.1 THING DIRECTORY	8
2.2 THING DIRECTORY DATABASE	8
2.3 API GATEWAY	8
<b>3 PREREQUISITES</b>	<b>9</b>
3.1 GTA THING'S VALIDATOR AND CERTIFICATION SERVICE	9
3.2 GTA KEYCLOAK	9
<b>4 COMPONENT ARTIFACTS</b>	<b>10</b>
<b>5 OKD INSTALLATION PROCEDURE</b>	<b>11</b>
<b>6 TESTS</b>	<b>15</b>

Figure 14 - TMS deployment guide ToC [38]

## Open caller manuals

Data Federation (ENG)	Developer Portal (UPM)	HPE Infrastructure (HPE)	Marketplace/GTA (CERTH)
Instructions to add a new conversion in the Data Federation	D5.1	GATEKEEPER_Webinar_Ezmeral	D4.6
Instructions to share data with Data Federation & Integration		GATEKEEPER-WP4-GK_CI-CD_Webinar_HPE	Open callers' manual: Register Thing in the Marketplace (Figure 15)

D4.4		HPE infrastructure access for developer: OKD webinar	
DF Operative Guide		Site-to-Site VPN to HPE GK Data Centre	
		GATEKEEPER ML/OPS Tutorial with HPE: Ezmeral Container Platform	

Open Callers' manual: Register Thing in the Marketplace

G A T E K E E P E R

## Table of contents

<b>TABLE OF CONTENTS</b>	<b>4</b>
<b>LIST OF FIGURES</b>	<b>5</b>
<b>1 INTRODUCTION</b>	<b>6</b>
<b>2 USER REGISTRATION THROUGH GTA USER MANAGEMENT MODULE</b>	<b>7</b>
<b>3 THING REGISTRATION</b>	<b>8</b>
3.1 OVERVIEW OF GK COMPONENT INTERACTION	8
3.2 THING SUBMISSION THROUGH THE MARKETPLACE	8
3.3 STANDARDS' VALIDATION THROUGH GTA THINGS VALIDATION	9
3.3.1 <i>Web of Things validation</i>	10
3.3.2 <i>FHIR validation</i>	11
3.4 CERTIFICATION THROUGH GTA THINGS CERTIFICATION	11
<b>4 CONCLUSION</b>	<b>13</b>

Figure 15 - Open callers' manual for Thing Registration in the Marketplace ToC [39]

## Annex T7.5 integration activities

### Support and monitoring

As T7.5 focuses on the integration of pilot technical solutions with the GATEKEEPER platform, its activities include the mentorship of each pilot by a partner that is active in both T7.5 and WP5. The mentor interacts with the pilot, identifies the proper person for resolution of its issues and oversees the status of technology developments necessary to the pilot. The mentors are presented in Table 9.

In addition, the Trello board "GK T7.5 Pilot integration" is used as a monitoring tool (Figure 16). In this tool, each topic is written separately in a "card" and cards are categorised vertically in columns called "lists". The "GK T7.5 Pilot integration" board includes a list of reference material on platform components (responsible partner, user manuals), as well as a list for each pilot to report their progress, raise technical issues, and answer requests and clarification questions from the task leader. The main advantage of this tool is that it provides a coherent overview of pilot integration status, combined with a tech-related summary of their activities. It now counts 36 members among pilot tech representatives, LSP management representatives, component providers.

Table 9: Pilot mentors from T7.5

Pilot(s)	Mentor
Aragon, Basque Country	UPM
Cyprus, Greece, Covid-19 survey	CERTH
Milton Keynes, Bangor	SAM
Puglia	ENG
Saxony, Poland	MYS
Hong Kong, Taiwan, Singapore	CERTH (may be delegated to other partner when more details on Asian pilot needs are determined)



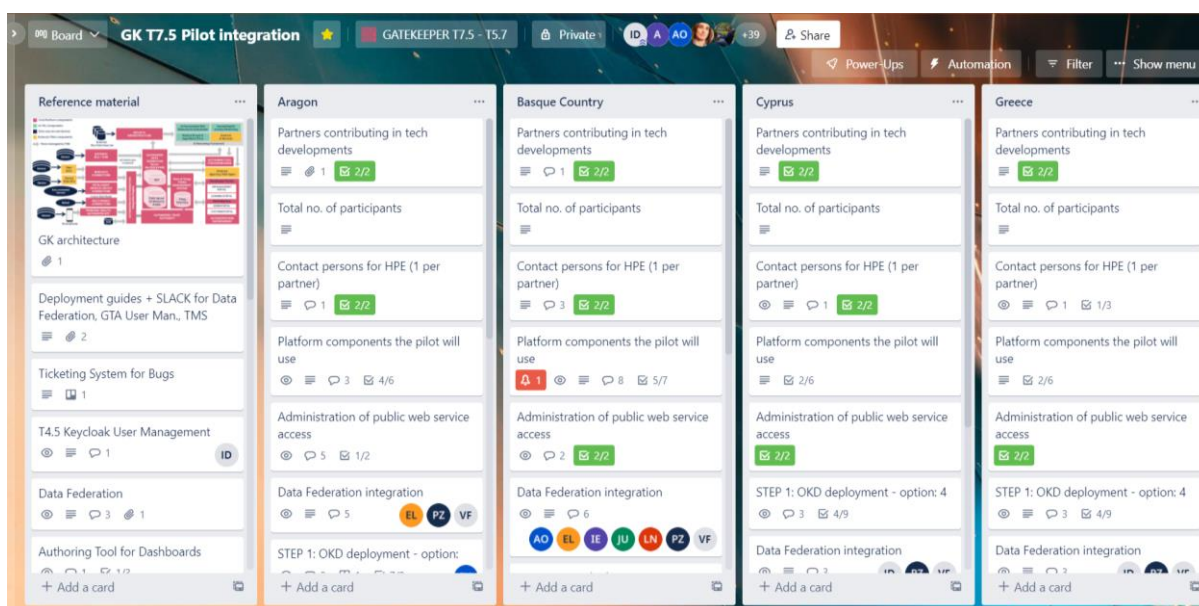


Figure 16 – Screenshot from "GK T7.5 Pilot integration" Trello board

## Pilot forms

### Pilot form template

- RUC: Pilot: Solution:

#### Architecture figure for RUC solution

[Please provide here the RUC architecture figure]

#### Functionalities of the solution

*Please describe the objective of the RUC in no more than 5 lines!*

#### Planned activities and resources, current status of the project

*Please describe the timing of the project in no more than 5 lines, you can use a Gantt chart in alternative!*

#### FHIR resources and profiles used

*Please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC!*

#### User management

*Please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner!*



### Connectors

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

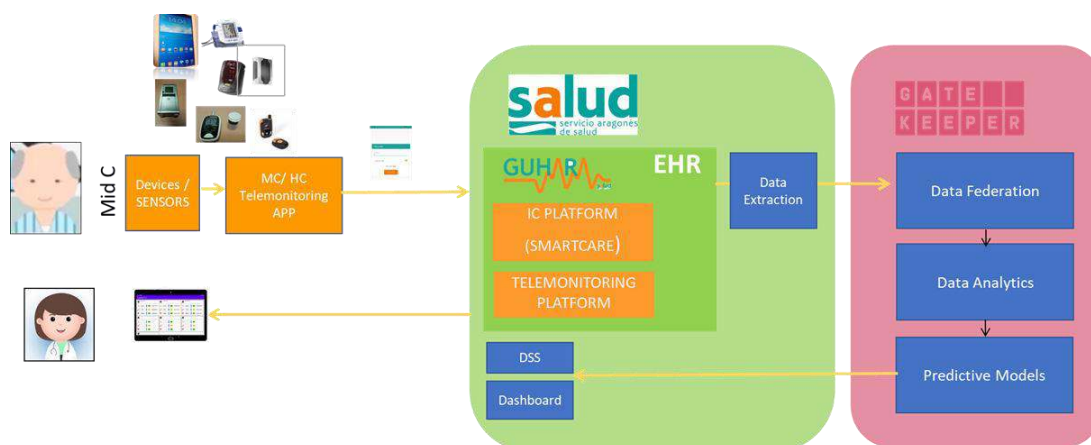
### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

## Aragon

**RUC: 2, 5, 7 Pilot: Aragon Solution: Mid-Intervention COPD, Heart Failures, Polymedication / multimorbidity**

### Architecture figure for RUC solution



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

Prevention of exacerbation episodes in patients with COPD, or heart failure or polymedicated/multimorbidity over 65 years old

### Planned activities and resources, current status of the project

The provision of services is ongoing with patients since 2020. The platforms are installed and working properly and data is being collected on the SALUD telemonitoring databases. The telemonitoring platform is integrated with the SALUD Integrated Care platform and the EHR. Ongoing activities:

- Although target group has been achieved, recruitment of patients will continue along with the provision of integrated care services (Planned till end of GK project)
- Extraction of the data from the SALUD databases
- Anonymization of the data and parsing according to the GK data model
- Send of information to the Data Federation Engine.
- Feeding the AI model
- Analysis of the results of the AI predictive models.
- Multidimensional assessment of the intervention -GK services

### FHIR resources and profiles used

*[please add here the link to the FHIR resources, profiles and examples you are using in the RUC]*

Info collected:

- Questionnaires on the quality of life, lifestyle social assessment (e.g. Barthel)
- medication intake
- Clinical variables: heart rate, blood pressure, oxygen saturation, weight, temperature, dyspnoea degree, ECG.
- Historic data from patient EHR (previous pathologies,)
- Demographic personal data (e.g. age, gender, health area,)
- Some additional measurements such as, breath rate, vascular resistance, sweating level, expiratory volume (volume and peak) will be evaluated.

#### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines]*

Users are managed by SALUD

#### Connectors

*[please describe here how the data flows in your tenant]*

Data is collected on the SALUD servers and after anonymization, will be uploaded to tenant's FHIR server using an ad-hoc local application. A Site to Site connection to the VPN is used to upload the data to the FHIR server.

#### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent]*

Mid intervention platform. Setup, developments for the integration with the EHR, test and deploy the telemonitoring platform.

- Service development - 100% (SALUD)
- data extraction from the local databases, anonymization and parsing according to GK data model- 50% (SALUD)
- FHIR mapping - 10%

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent]*

Service is deployed.

Baseline, mid, final intervention patient data collected.

Although all patients for project have been recruited, service will not stop and continue recruiting more patients

Current activities ongoing are the continuous provision of services and the data extraction and sent to the GK platform

#### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines]*

Extract information from the local databases. Ongoing the parse and sending of information with the DataFederation.

#### Critical activities

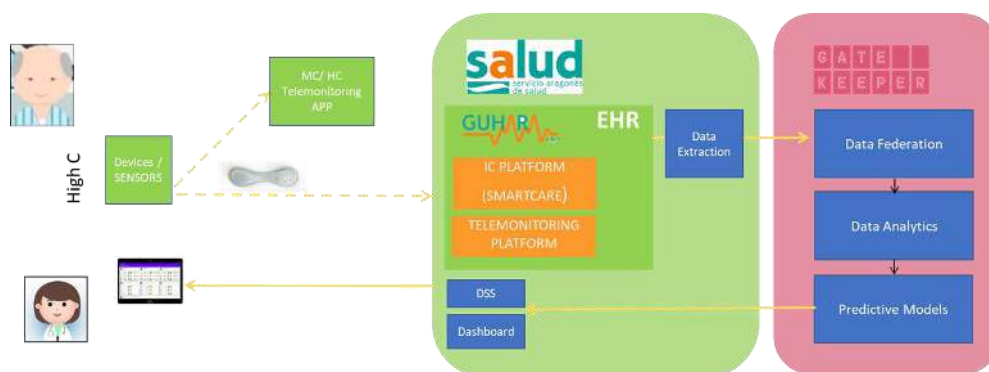
*[please describe here the activities that are pending and not assigned in no more than 5 lines]*  
Sign HPE data processing agreement

#### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

## RUC: 2, 5, 7 Pilot: Aragon Solution: High-Intervention COPD, Heart Failures, Polymedication / multimorbidity

### Architecture figure for RUC solution



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

Management of exacerbation episodes in patients with COPD, or heart failure or polymedicated/multimorbidity over 65 years old.

The final goal of this intervention is to evaluate the treatment of chronic patients during their exacerbations in their own residence (elderly house, home)

### Planned activities and resources, current status of the project

The telemonitoring platform is integrated with the SALUD Integrated Care platform and the EHR.

Ongoing activities:

- Start the recruitment of patients
- Extraction of the data from the SALUD databases
- Anonymization of the data and parsing according to the GK data model
- Send of information to the Data Federation Engine.
- Feeding the AI model
- Analysis of the results of the AI predictive models.
- Multidimensional assessment of the intervention -GK services

### FHIR resources and profiles used

*[please add here the link to the FHIR resources, profiles and examples you are using in the RUC]*

Info collected:

- Questionnaires on the quality of life, lifestyle social assessment (e.g. Barthel)

- medication intake
- Clinical variables: heart rate, blood pressure, oxygen saturation, weight, temperature, dyspnoea degree, ECG.
- Historic data from patient EHR (previous pathologies,)
- Demographic personal data (e.g. age, gender, health area,)
- Some additional measurements such as, breath rate, *vascular resistance*, *sweating level*, *expiratory volume (volume and peak)* will be evaluated.

#### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines]*

Users are managed by SALUD

#### Connectors

*[please describe here how the data flows in your tenant]*

Data is collected on the SALUD servers and after anonymization, will be uploaded to tenant's FHIR server using an ad-hoc local application. A Site to Site connection to the VPN is used to upload the data to the FHIR server.

#### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent]*

Mid intervention platform. Setup, developments for the integration with the EHR, test and deploy the telemonitoring platform.

- Service development - 100% (SALUD)
- data extraction from the local databases, anonymization and parsing according to GK data model- 50% (SALUD)
- FHIR mapping - 10%

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent]*

Awaiting final clinical public contest transfer within region - job position taking. Once final clinicians have taken up their positions, service will be rolled out and recruitment will start.

#### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines]*

Developments to extract the data acquired from the devices from the local databases. Ongoing the parse and sending of information to the DataFederation.)

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines]*

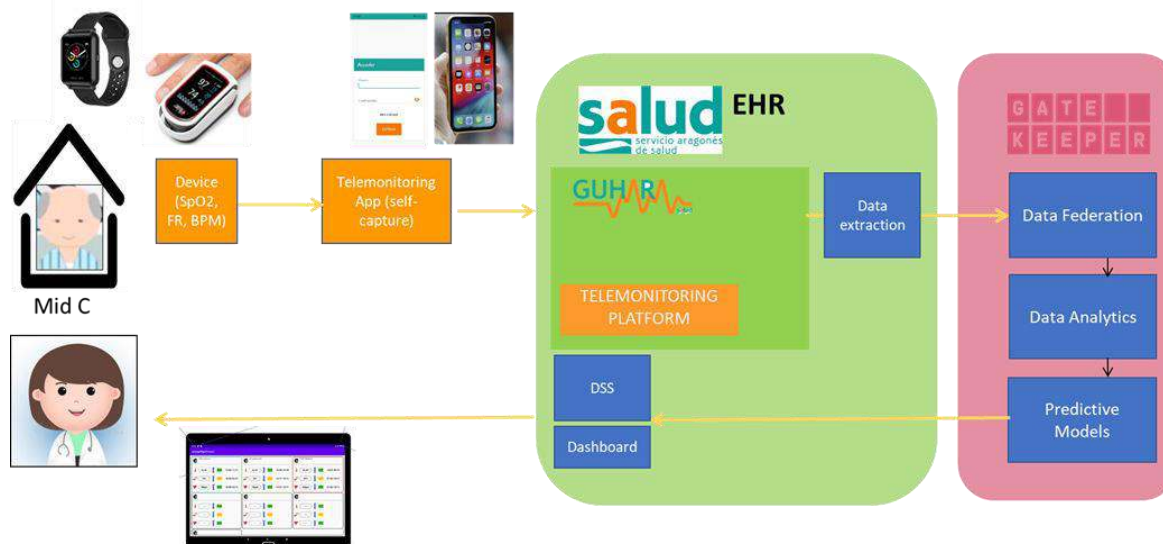
Sign HPE data processing agreement

## Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

## - RUC: 9 Pilot: Aragon Solution: COVID-19 Home Monitoring

## Architecture figure for RUC solution



## Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

Home follow-up of COVID-19 patients through telemonitoring of vital signs to improve their quality of life, reduce the risk of infection and optimize care activity

## Planned activities and resources, current status of the project

The provision of services is ongoing with the target number of patients reached. Recruitment will continue according to the pandemic evolution.

The platforms are installed and working properly and data is being collected on the SALUD telemonitoring databases. The telemonitoring platform is integrated with the SALUD Integrated Care platform and the EHR.

Ongoing activities:

- Although target group has been achieved, recruitment of patients may continue along with the provision of integrated care services (Planned till end of GK project)
- Extraction of the data from the SALUD databases
- Anonymization of the data and parsing according to the GK data model
- Send of information to the Data Federation Engine.
- Feeding the AI model
- Analysis of the results of the AI predictive models.
- Multidimensional assessment of the intervention -GK services

## FHIR resources and profiles used



*[please add here the link to the FHIR resources, profiles and examples you are using in the RUC Info collected is:*

- QoL questionnaire
- Symptom questionnaire
- Clinical variables: heart rate, respiratory rate, oxygen saturation
- Information on the patient's medical history (previous pathologies, medication)
- demographic personal data
- Clinical activity: number of hospitalizations and reason, consultations in primary care, emergency access)

#### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines]*

SALUD performs user management

#### Connectors

*[please describe here how the data flows in your tenant]*

Data is collected on the SALUD servers and after anonymization, will be uploaded to tenant's FHIR server using an ad-hoc local application. A Site to Site connection to the VPN is used to upload the data to the FHIR server.

#### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent]*

- Service development - 100% (SALUD)
- data extraction from the local databases, anonymization and parsing according to GK data model- 50% (SALUD)
- FHIR mapping - 10%

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent]*

RUC completed, pending sending of data to GateKeeper platform, once HPE Data Processing Agreement is signed

#### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines]*  
Extract information from the local databases. Ongoing the parse and sending of information with the DataFederation.

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines]*

Sign HPE data processing agreement

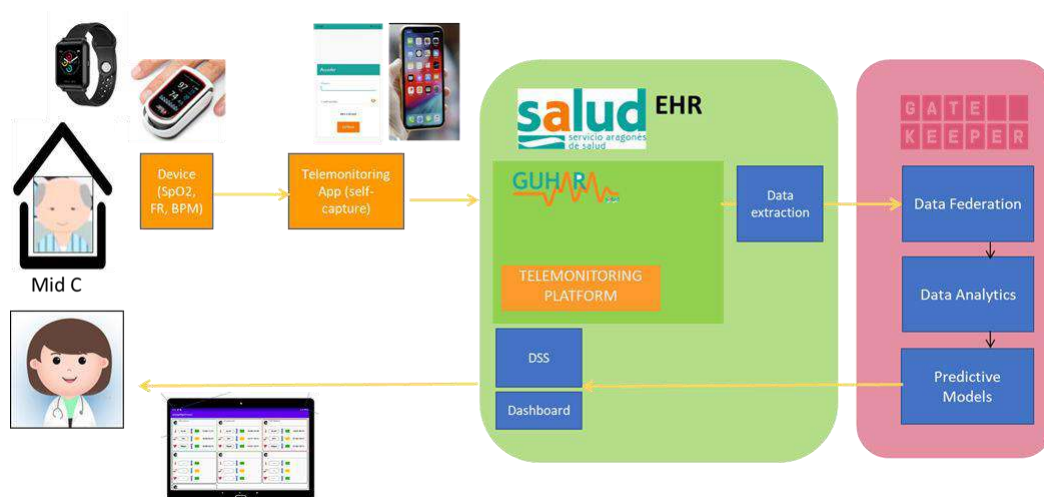
#### Risks

---

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

## - RUC: 9 Pilot: Aragon Solution: COVID-19 Centre

## Architecture figure for RUC solution



## Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

Real-time, passive monitoring of vital parameters (body temperature, oxygen saturation and pulse), movement (monitoring of steps) and monitoring of sleep patterns at night. The Night Protect watch ensures non-invasive monitoring and undisturbed sleep.

Generation of notifications and alerts for night staff.

## Planned activities and resources, current status of the project

The platform is under testing phase

## FHIR resources and profiles used

*[please add here the link to the FHIR resources, profiles and examples you are using in the RUC]*

Info collected is:

- QoL questionnaire
- Symptom questionnaire
- Clinical variables: , pulse, oxygen saturation
- Information on the patient's medical history (previous pathologies, medication)
- demographic personal data
- Clinical activity: number of hospitalizations and reason, consultations in primary care, emergency access)

## User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines]*

SALUD performs user management

### Connectors

*[please describe here how the data flows in your tenant]*

Data will be collected on the SALUD servers and after anonymization, will be uploaded to tenant's FHIR server using an ad-hoc local application. A Site to Site connection to the VPN will be used to upload the data to the FHIR server.

### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent]*

- Development - 90% (HIM)
- Service development - 100% (SALUD)
- FHIR mapping - 0% (SALUD)

### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent]*

The platform for capturing the vital signs is under testing phase to ensure its performance and efficiency according to the SALUD requirements

### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines]*

Undergoing fine-tuning of app

Need to reorient where it will be deployed as it originally was intended to be implemented in a COVID-19 hospital set-up during highest peak of pandemic. More than likely to be implemented within hospital setting for COVID-19 patients or other patient profile.

### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines]*

need to ensure the efficacy of the solution to better choose the deployment place.

### Risks

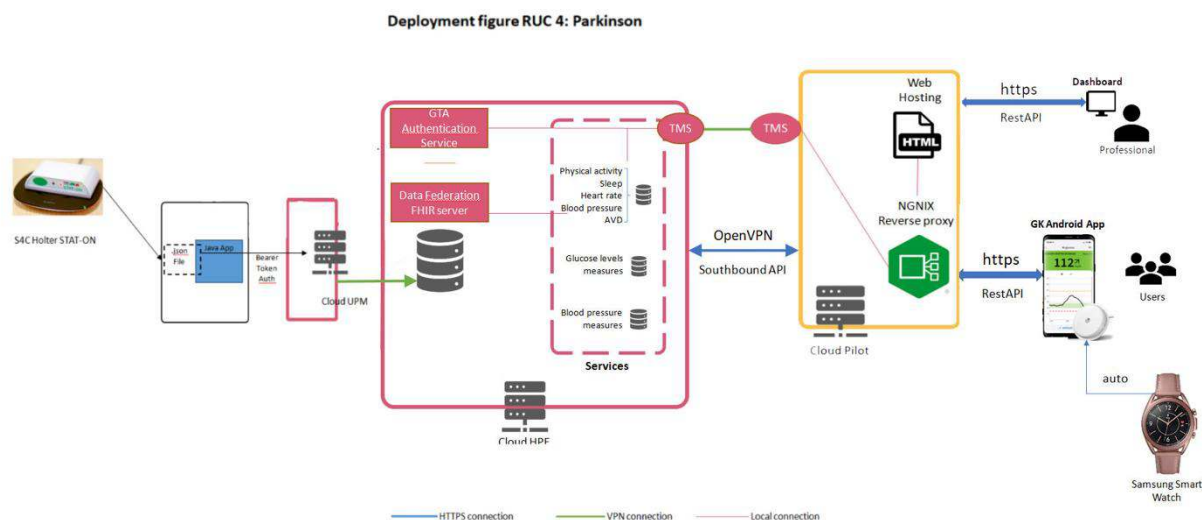
*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

Pandemic situation varies and may result in a lack of patients or casuistic.

## Basque Country

RUC: RUC4 Pilot: Basque Country Solution: Parkinson

### Architecture figure for RUC solution



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

#### - Sense4Care:

STAT-ON is the Parkinson's disease (PD) Holter that permanently registers ON / OFF fluctuations making possible a complete disease management.

According to the necessities by Basque Country Pilot, the parameters defined such as Bradykinesia, Dyskinesia, Freezing of Gait, On and Off states, Gait Parameters and Number of falls will be sent through UPM servers.

### Planned activities and resources, current status of the project

*[please describe the timing of the project in no more than 5 lines, you can use a Gantt chart in alternative]*

#### - Sense4Care:

App design - July 2021

FHIR Models and connectors - September 2021 App development and adaptation - September 2021 Connect Integration through server- January 2021

Technical Support and maintenance - April 2022 till end of task

### FHIR resources and profiles used

*[please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC]*

#### - Sense4Care:

The app will collect FHIR observations:

Hours dysk (<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/StructureDefinition-Observation-hoursDysk-s4c-gk.html>),

HoursINT, hoursMonitorized, hoursOFF, hoursON (<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/StructureDefinition-Observation-OnOff-s4c-gk.html>),

nEvent, nFog, nFalls (<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/StructureDefinition-Observation-nEvent-s4c-gk.html>)

#### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

##### - Sense4Care:

The ID assigned to the patient inside the app is anonymous and does not contain any identification data. Osakidetza performs its own patient relationship. User management isn't performed, the management of users is done by osakidetza, providing the necessary identifiers to the partners in charge of data analysis. Ibermática only uploads the information captured from the devices and previously uploaded to the Libreview and Vitadock repositories via RPA process.

#### Connectors

*[please describe here how the data flows in your tenant]*

##### - Sense4Care:

The data collected via Stat-On Holter are synchronized with Android app and upload to the FHIR server using a service performed in JAVA. For this upload the library developed uses the UPM server as a workaround to the VPN.

#### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

##### - Sense4Care:

- App development
- FHIR mapping

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

##### - Sense4Care:

- Maintenance for the pilot and sensor-related technical support.

#### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

##### - Sense4Care:

- App updates (for pilot issues or connection problems)

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

#### - **Sense4Care:**

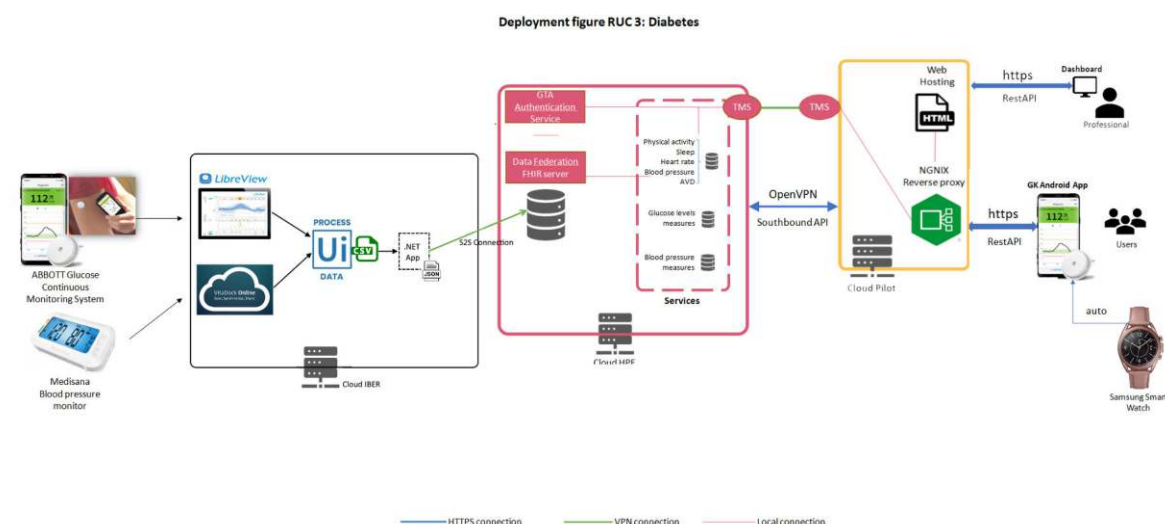
Data synchronization between Android application and server.

#### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

## - RUC: RUC3 Pilot: Basque Country Solution: Diabetes

### Architecture figure for RUC solution



### Functionalities of the solution

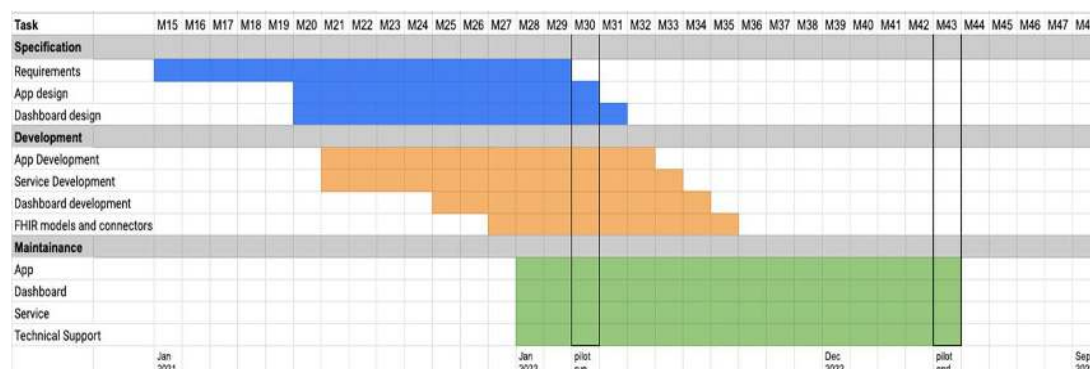
#### Ibermática:

Capture of diabetes-related biometric data from different devices:

- 1: ABBOTT
- 2: Medisana
- 3: Samsung Smartwatch

Transformation of the data to FHIR protocol and uploading of the information to the Gatekeeper platform.

### Planned activities and resources, current status of the project



### FHIR resources and profiles used

#### - Ibermática



The app will collect FHIR observations:

- Observations: **ABBOTT**: Average glucose, coefficient of variation, Glucose standard deviation calculated, Low glucose events average duration, User status, Total hypoglycemia episodes, Percentage in target, Percentage above target, Percentage below target, Percentage of hypoglycemia episodes below target, Percentage of hypoglycemia episodes above target, Likelihood of hypoglycemia, Average scans views per day, Sensor active time percentage

**Medisana**: Blood pressure device Cuff pressure, Systolic blood pressure, Diastolic blood pressure, Heart rate, Cardiac arrhythmia, Cardiovascular finding, Maximum Systolic blood pressure, Minimum Systolic blood pressure, Average Systolic blood pressure, Maximum Diastolic blood pressure, Minimum Diastolic blood pressure, Average Diastolic blood pressure, Maximum heart rate, Minimum heart rate, Average Heart rate

#### User management

User management isn't performed, the management of users is done by osakidetza, providing the necessary identifiers to the partners in charge of data analysis. Ibermática only uploads the information captured from the devices and previously uploaded to the Libreview and Vitadock repositories via RPA

#### Connectors

Data is collected from the LibreView (ABBOTT) and Vitadoc (Medisana) repositories using an RPA process, this data is collected daily and automatically uploaded to the tenant's FHIR server using an application developed in .NET. A Site to Site connection to the VPN is used to upload the data to the FHIR server. (**Ibermática**)

#### Completed activities

- App development - 80% (**Ibermática**)
- FHIR mapping - 90% (**Ibermática**)

#### Ongoing activities

- App development (adapt for all pilot users) - 20% (**Ibermática**)
- FHIR mapping - 10% - Verify that the FHIR format uploaded to FHIR Server is valid for analysis (**Ibermática**)
- Maintenance - Adapt the RPA process for all pilot user, this will be done at the same time as Osakidetza recruits users. (**Ibermática**)

#### Pending activities

Adapting the application for all pilot users and run app unattended once a day (**Ibermática**)

#### Critical activities

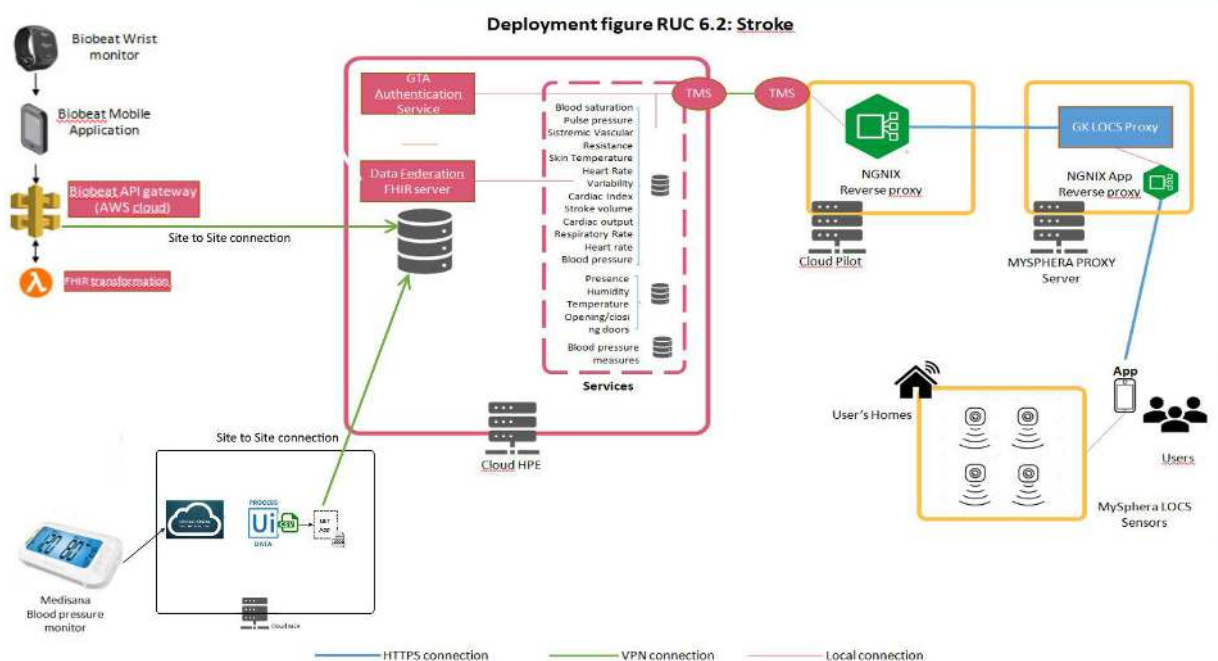
- Maintenance and platform support (**Ibermática**)

#### Risks

- Running the entire service unattended, maintaining the connection and capturing information in case of changes in ABBOTT's libreview and medisana's Vitadock applications. (**Ibermática**)

- RUC: RUC6.2      Pilot: Basque Country      Solution: Stroke

### Architecture figure for RUC solution



## Functionalities of the solution

**Ibermática:**

### Capture of stroke-related biometric data from different devices:

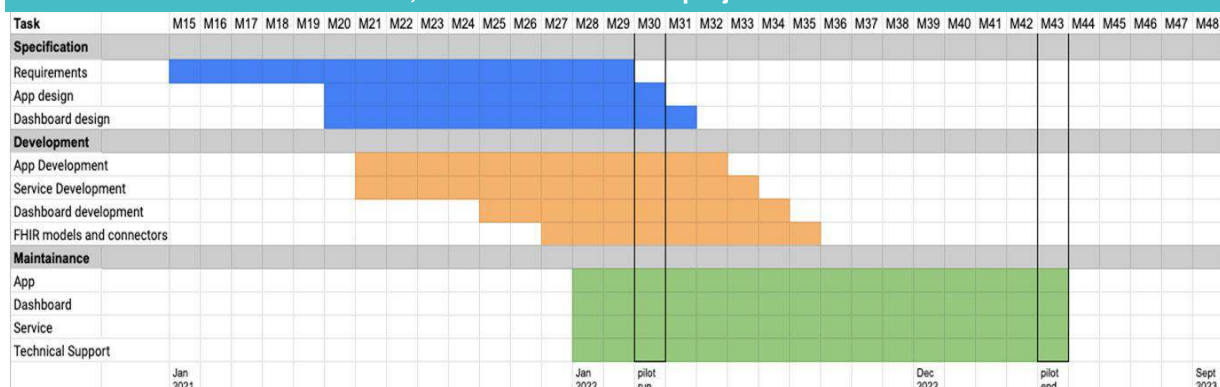
- 1: Medisana
- 2: Biobeat Wrist monitor
- 3: MySphera LOCS sensors

Transformation of the data to FHIR protocol and uploading of the information to the Gatekeeper platform.

- Mysphera:

Monitor daily activities of patient at home from LOCS sensors. Data is transformed into FHIR profiles and uploaded to the pilot tenant FHIR server

## Planned activities and resources, current status of the project



## FHIR resources and profiles used

- **Ibermática:**

The app will collect FHIR observations:

- Observations: **Medisana:** Blood pressure device Cuff pressure, Systolic blood pressure, Diastolic blood pressure, Heart rate, Cardiac arrhythmia, Cardiovascular finding, Maximum Systolic blood pressure, Minimum Systolic blood pressure, Average Systolic blood pressure, Maximum Diastolic blood pressure, Minimum Diastolic blood pressure, Average Diastolic blood pressure, Maximum heart rate, Minimum heart rate, Average Heart rate; **Biobeat:** Automatically measures cuffless systolic and diastolic blood pressure, pulse pressure, mean arterial pressure, pulse rate, blood oxygen saturation, respiratory rate, heart rate variability, stroke volume, cardiac output, cardiac index, systemic vascular resistance.

- **Mysphera:**

The sensors will send FHIR observations:

- Observations: room presence, time in, time out, number of activations, temperature, humidity, battery

## User Management

User management isn't performed, the management of users is done by osakidetza, providing the necessary identifiers to the partners in charge of data analysis. Ibermática only uploads the information captured from the devices and previously uploaded to the Libreview and Vitadock repositories via RPA process.

**Mysphera:** it doesn't perform user management, but a "patient id" is needed to correctly link all observations from the different sensors pertaining to each patient. **Biobeat:** The user is using the Biobeat web management platform to handle all patients recruited and enrolled to the study.

## Connectors

Data is collected from the Vitadoc (Medisana) repository using an RPA process, this data is collected daily and automatically uploaded to the tenant's FHIR server using an application

developed in .NET. A Site to Site connection to the VPN is used to upload the data to the FHIR server. Ibermática doesn't use a public cloud infrastructure. **(Ibermática)**

**Mysphera:** Data is sent in real-time from a gateway deployed at the patient mobile phone that connects to a reverse proxy that will directly send the data to the FHIR server in the pilot cloud.

**Biobeat:** Data is sent in real-time using a VPN connection from Biobeat AWS cloud to the Data-Federation using FHIR protocol.

#### Completed activities

- App development - 80% **(Ibermática)**
- FHIR mapping - 90% **(Ibermática)**
- FHIR mapping - 90% **(Mysphera)** - FHIR mapping - 80%; VPN connection - 90% **(Biobeat)**

#### Ongoing activities

- App development (adapt for all pilot users) - 20% **(Ibermática)**
- FHIR mapping - 10% - Verify that the FHIR format uploaded to FHIR Server is valid for analysis **(Ibermática)**
- Maintenance - Adapt the RPA process for all pilot user, this will be done at the same time as Osakidetza recruits users. **(Ibermática)**
- Adapt LOCS gateway to translate to FHIR profiles - 10% **(Mysphera)**
- Set-up reverse proxy - 10% **(Mysphera)** - Completion of FHIR mapping - 20%; verifying VPN connection

#### Pending activities

Adapting the application for all pilot users and run app unattended once a day **(Ibermática)**  
Test upload of data to FHIR server **(Mysphera)**

Install gateway in mobile phones **(Mysphera)**

Train pilot site to install sensors **(Mysphera)**

#### Critical activities

- Maintenance and platform support **(Ibermática)**
- Define a common approach to user management, to enable sharing patient id between the different applications to link all the observations to the same id and allow for the data analysis **(Mysphera)**

#### Risks

- Running the entire service unattended, maintaining the connection and capturing information in case of changes in Medisana's Vitadock applications. **(Ibermática)**

### Architecture figure for RUC solution

The diagram illustrates the MAHA system architecture, showing the flow of data and services between various components. The system is divided into several main sections:

- Left Section (Data Sources and Services):**
  - Exporters:** Includes the **GTA Authentication Service** and the **Data Federation FHIR server** (which connects to a database icon).
  - adapters:** Connects the Data Federation FHIR server to the MAHA Services.
  - MAHA Services:** A dashed box containing:
    - Optimization functions:** Represented by a vertical stack of database icons.
    - Usuarios:** A database icon.
    - Conocete:** A database icon.
    - Diviertete:** A database icon.
    - ....**: Represented by a database icon.
  - Cloud HPE -Pilot:** Represented by a server rack icon at the bottom left.
- Center Section (TMS):**
  - Two **TMS** (Traffic Management System) nodes, represented by red circles, connected by a green line.
- Right Section (Web Hosting and End Users):**
  - Web Hosting:** Contains an **HTML** document icon and an **NGNIX Reverse proxy** (green hexagon icon).
  - Cloud Pilot:** Represented by a server rack icon below the NGNIX Reverse proxy.
  - MAHA Dashboard:** Represented by a computer monitor icon, connected to the NGNIX Reverse proxy by a blue line.
  - MAHA App:** Represented by a smartphone icon, connected to the NGNIX Reverse proxy by a blue line.
  - Professionals:** Represented by a person icon, connected to the MAHA Dashboard.
  - Users:** Represented by a group of people icon, connected to the MAHA App.

**Legend:**

- Blue line:** HTTPS connection
- Green line:** VPN connection
- Purple line:** Data Centre local connection

*[please describe the objective of the RUC in no more than 5 lines]*

- 1: Learn Healthy Habits, this is a collection of resources that allow the user to learn about healthy habits
- 2: Local Events, this is a collection of local events that users can join
- 3: Wellness, this is an activity tracker that connects with wearable devices through healthkit and google fit
- 4: Know yourself, this is a section where the user reports about his/her status.

Task	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36	M37	M38	M39	M40	M41	M42	M43	M44	M45	M46	M47	M48	
<b>Specification</b>																																			
Requirements																																			
App design																																			
Dashboard design																																			
<b>Development</b>																																			
App Development																																			
Service Development																																			
Dashboard development																																			
FHIR models and connectors																																			
<b>Maintenance</b>																																			
App																																			
Dashboard																																			
Service																																			
Technical Support																																			
	Jan 2024														Jan 2024	pilot											Dec 2024					pilot			Se 2024

### FHIR resources and profiles used

*[please add here the link to the FHIR resources, profiles and examples you are using in the RUC]*

The app will collect FHIR observations, Questionnaire and QuestionnaireResponse:

- Observations:

burned calories (<https://drive.upm.es/s/kHZ2RFxpS81SEY>), walking distance (<https://drive.upm.es/s/1RXgHjMcCpMgla3>),

steps (<https://drive.upm.es/s/1QqZbQ3w03UUWxg>), sleep (<https://drive.upm.es/s/LflxR5BZUaVyBBG>)

- Questionnaires:

falls (<https://drive.upm.es/s/Fls4DjGGVdzHVQ6>), ComoEstas (<https://drive.upm.es/s/vG02NomAZ1UHVeB>), EQ-5D-3L (<https://drive.upm.es/s/jDMFt4RKq5WUMm4>)

EQ-5D-5L (<https://drive.upm.es/s/ny6fCYAL22ROONF>) - is it already into the GK-FHIR-IG??, MAUQ (), SUS (), Test Chair (), Lifestyle (), Home Risks ()

### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines]*

Users are managed with specific services into TMS and connected in a realm of the GTA, some services of GTA such as user registration or password recovery are exposed from the GTA Keycloak. They are not linked neither managed through FHIR patient resource. The connectors schema is presented in the architecture figure and it is replicated in 3 tenants: Gatekeeper dev, Basque Country pilot, Aragon pilot. (UPM)

### Connectors

*[please describe here how the data flows in your tenant]*

The entry point of the MAHA solution is a reverse proxy that is connected with a VPN site-to-site with the GK infrastructure.

The site-to-site connection create a private connection with the TMS inside the GK platform where are hosted the services for the app and dashboard of the MAHA solution.

These service are designed and optimized for low high demanding connections with the App and dashboard. Also an intermediate layer of function for optimizing queries that cress several services are implemented.

Pull services that periodically updated data from MAHA services within the Data Federation are expected for the propagation of the data until the big data infrastructure in agreement with the Gatekeeper FHIR implementation guide.

All connectors are developed by UPM.

### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent]*

- App development - 100% (UPM)
- Service development - 90% (UPM)
- Dashboard development - 50% (UPM)
- FHIR mapping - 80% (UPM)

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent]*

- Service development - 10% (UPM)
- Dashboard development - 50% (UPM)
- FHIR mapping (Questionnaires MAUQ, SUS, Test Chair, Lifestyle, Home Risks ) - 20% (UPM)
- Maintenance (UPM/HPE)

#### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines]*

- FHIR connectors (UPM)
- Dashboard cloud function optimizers (UPM)
- Minor services (UPM)
- FHIR exporters for GK Healthcare data space (UPM)

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines]*

- Maintenance, platform support and denial of service (UPM/HPE)

#### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

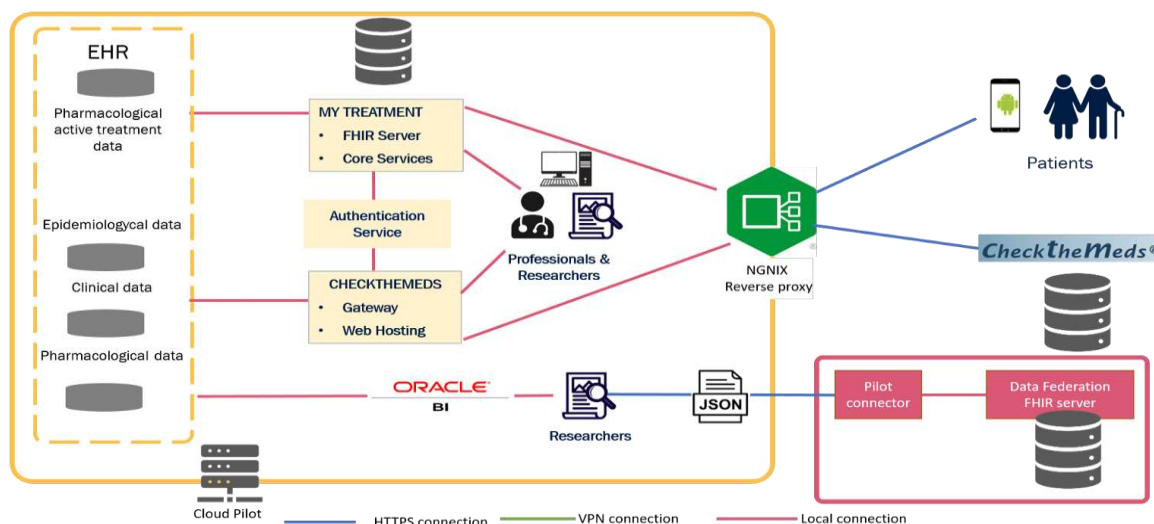
- Migration of services outside HPE infrastructure (UPM)



## - RUC: RUC7 Pilot: Basque Country Solution: Multi-chronic elderly patient management including polimedication

### Architecture figure for RUC solution

Deployment figure RUC7 : CheckTheMeds and My Treatment App



### Functionalities of the solution

CheckTheMeds online platform: Globally processes the information (demographic, clinical and pharmacological treatment data) of each patient to help the professional optimize pharmacotherapy. CheckTheMeds offer to healthcare professional, the following reports and information:

- Personalized report
- Personalized pharmacovigilance
- Non-pharmacological advice
- Drug recommendations
- Coding suggestions
- under and over dosage, contraindications, incompatibilities or interactions, risk drugs and potentially inappropriate drugs.

My Treatment Application: Personal application, tool, that helps to comply with and correctly follow the pharmacological treatment prescribed by the healthcare professional from Osakidetza Basque Health Services. Information about:

- The treatment, inform of the pills, alarms and messages from the healthcare professional



### Planned activities and resources, current status of the project

[illegible]

## FHIR resources and profiles used

The intervention will collect the following data directly in Bussiness Intelligence System which will be export and adapted into .json file and transform to FHIR.

Data that will be export:

- Year of birth
- Morbidities: Chronic obstructive pulmonary disease (COPD), Diabetes, Health Failure
- Polipharmacy: active prescriptions, Barthel test, Morisky Green test
- Effectivity: emergency room visits, hospital admissions

## User management

Kronikgune and Osakidetza perform user management

## Connectors

The data will be export from Osakidetza Oracle Business Intelligence and converted into .json format.

json files are expected for the propagation of the data until the big data infrastructure in agreement with the Gatekeeper FHIR implementation guide.

All connectors are developed by Sence4Care.

## Completed activities

- Tools development - 100% (CheckTheMeds and App My Treatment)
- Service development - 100% (KG)
- Dashboard development - 100% (CheckTheMedsApp Muy Treatment)
- FHIR mapping - 90% (Sence4care, KG)

## Ongoing activities

- Maintenance (CheckThemeds and App My Treatment)

#### Pending activities

- Finalize with the FHIR mapping and send some examples exported from Osakidetza Oracle Business Intelligence
- FHIR connectors (Sence4Care)

#### Critical activities

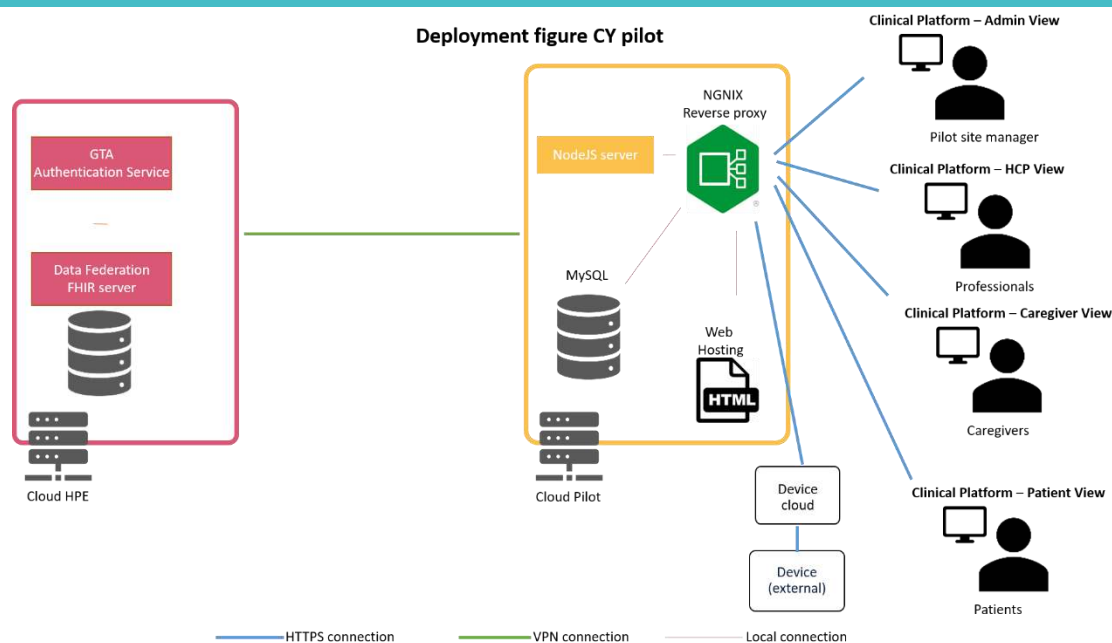
- Testing of FHIR connectors and pull services

#### Risks

## Cyprus

**RUC: 7 Pilot: Cyprus Solution: Cancer Management Platform, Dementia Management Platform (CERTH)**

### Architecture figure for RUC solution



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

AMEN and PASYKAF use the dementia and the cancer management platform respectively (so two web apps in the same RUC due to two different conditions)

Assignment of care plan activities to the patient, HCP and caregiver (e.g. physical exercise, questionnaire completion), clinical monitoring (adherence to care plan, integrated device measurements),

medical record, alerts, HCP-patient appointment setting, chat, questionnaire configuration, completion and scoring, decision-support system, educational material, digital consent mechanism.

Roles: 1 per each HCP, caregiver, admin, patient. Admin view for questionnaires and Excel export

### Planned activities and resources, current status of the project

*[please describe the timing of the project in no more than 5 lines, you can use a Gantt chart in alternative]*

Web app delivered and running - June 2021

Garmin device integration - August 2021

Admin view - January 2022

OKD integration - (blocked) Excel report export - May 2022

Improvements and maintenance - June 2021 till end of task

### FHIR resources and profiles used

*[please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC]*

see D3.8

### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

User management is handled by the Cancer Management Platform and the Dementia Management Platform.

### Connectors

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

All data is collected in the web app from manual input / Garmin API. The web app will be connected through s2s VPN with the OKD tenant and data will be transferred to the Data Federation FHIR server via API

### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Cancer Management Platform for HCPs, patients, caregivers as minimum viable product. - 100%  
Dementia Management Platform for HCPs, patients, caregivers as minimum viable product. - 100%  
FHIR mapping - 100%

Garmin device integration - 100%

Admin view - 100 %

Provision of training material (videos) - 100% (all by CERTH)

### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Excel report export for questionnaires (CERTH)

Tech support (CERTH)

Transformation of questionnaires answered before mapping, and therefore saved in MySQL, to FHIR (CERTH)

Maintenance (CERTH)

### Pending activities

*[please describe here the activities that are pending but **already assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

Integration with components in OKD (CERTH, blocked due to lack of data sharing agreement with HPE)

Presentation of AI results in the platform per user and, if needed, aggregated (CERTH)

Backup reconfiguration as suggested by HPE, DPIA update (CERTH)

App improvements (CERTH), e.g. panic button

#### Critical activities

*[please describe here the activities that are pending and **not assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

-

#### Risks

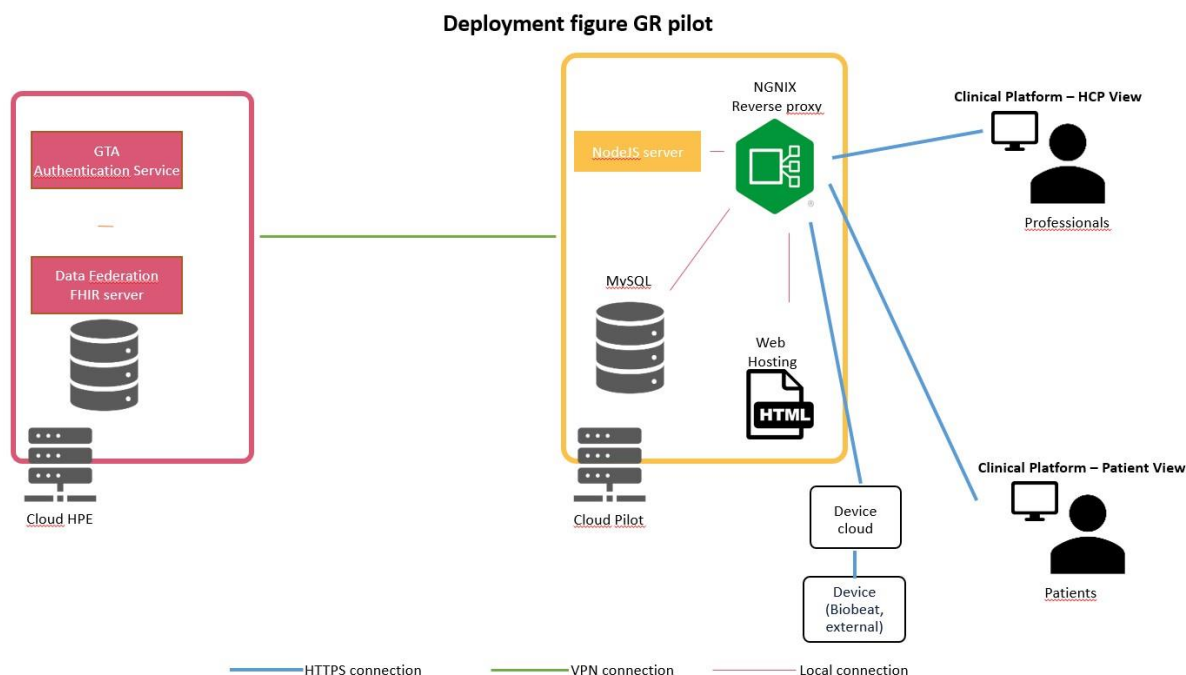
*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

-

## Greece

- RUC: 1 Pilot: Greece Solution: Metabolic Syndrome Management Platform (CERTH)

### Architecture figure for RUC solution



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

Assignment of care plan activities to the patient (e.g. physical exercise, nutrition plan, questionnaire completion), clinical monitoring (adherence to care plan, integrated device measurements), medical record, design of personalised nutrition plan based on editable database, dietary habits list, daily food diary, alerts, HCP-patient appointment setting, chat, questionnaire configuration, completion and scoring, decision-support system, educational material, digital consent mechanism

### Planned activities and resources, current status of the project

*[please describe the timing of the project in no more than 5 lines, you can use a Gantt chart in alternative]*

Web app delivered and running - March 2021

Fitbit device integration - March 2021, November 2021 OKD integration - (blocked)

AI results view - June 2022

Improvements and maintenance - March 2021 till end of task

### FHIR resources and profiles used

*[please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC]*

see D3.8

### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

User management is handled by the Metabolic Syndrome Management Platform.

### Connectors

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

All data is collected in the web app from manual input / Fitbit API. The web app will be connected through s2s VPN with the OKD tenant and data will be transferred to the Data Federation FHIR server via API

### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Metabolic Syndrome Management Platform for HCPs and patients as minimum viable product. - 100% FHIR mapping - 100%

Fitbit device integration - 100%

Provision of training material (videos, pdf guide) and webinar execution - 100% (all by CERTH)

### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Tech support (BIO, CERTH)

Healthy Diet Score calculation for FFQ questionnaire (CERTH)

Transformation of questionnaires answered before mapping, and therefore saved in MySQL, to FHIR (CERTH)

Maintenance (CERTH)

### Pending activities

*[please describe here the activities that are pending but **already assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

Integration with components in OKD (CERTH, blocked due to lack of data sharing agreement with HPE) Presentation of AI results in the platform per user and, if needed, aggregated (CERTH)

Backup reconfiguration as suggested by HPE DPIA update (CERTH)

Link to Covid-19 survey (CERTH) App improvements (CERTH)

### Critical activities

*[please describe here the activities that are pending and **not assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

## Risks

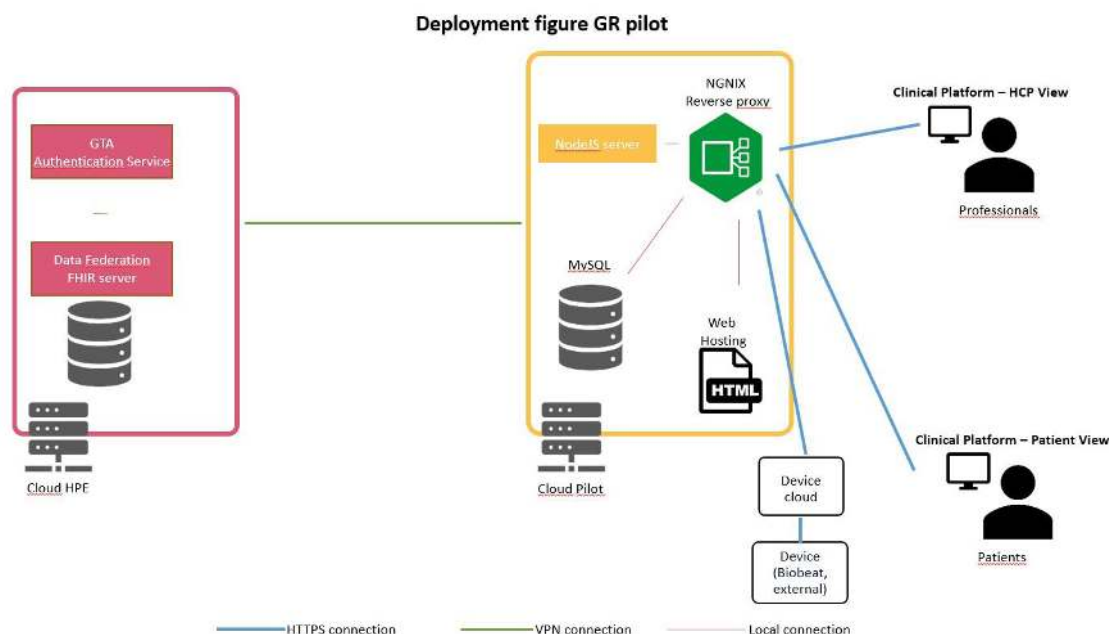
*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

-



- RUC: 3      Pilot: Greece      Solution: Type 2 Diabetes Management Platform (CERTH)

### Architecture figure for RUC solution



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

Assignment of care plan activities to the patient (e.g. physical exercise, questionnaire completion), clinical monitoring (adherence to care plan, integrated device measurements),

medical record, alerts, HCP-patient appointment setting, questionnaire configuration-completion-scoring, decision-support system, educational material, digital consent mechanism.

Roles: doctor, nurse, patient. Categorisation of patient in groups and indication of recommended reasonable glucose range and HbA1c targets according to conceptual framework

developed by the European Society of Endocrinology, the Gerontological Society of America, and the Obesity Society. Monitoring of food and insulin doses

### Planned activities and resources, current status of the project

*[please describe the timing of the project in no more than 5 lines, you can use a Gantt chart in alternative]*

Web app delivered and running - July 2021 Biobeat device integration - May 2021 CGM integration - March-April 2022

OKD integration - (blocked) AI results view - June 2022

Improvements and maintenance - July 2021 till end of task

### FHIR resources and profiles used

*[please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC]*

see D3.8

### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

User management is handled by the Type 2 Diabetes Management Platform.

### Connectors

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

All data is collected in the web app from manual input / Biobeat / GlucologWeb API.

The web app will be connected through s2s VPN with the OKD tenant and data will be transferred to the Data Federation FHIR server via API

### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Type 2 Diabetes Management Platform for HCPs and patients as minimum viable product. - 100%  
FHIR mapping - 100%

Biobeat device integration - 100% Menarini CGM device integration - 100%

Provision of training material (videos, pdf guide) and webinar execution - 100% (all by CERTH)

### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Tech support (CERTH)

Transformation of questionnaires answered before mapping, and therefore saved in MySQL, to FHIR (CERTH) Maintenance (CERTH)

### Pending activities

*[please describe here the activities that are pending but **already assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

Integration with components in OKD (CERTH, blocked due to lack of data sharing agreement with HPE)

Presentation of AI results in the platform per user and, if needed, aggregated (CERTH)

Backup reconfiguration as suggested by HPE DPIA update (CERTH)

App improvements (CERTH)

### Critical activities

*[please describe here the activities that are pending and **not assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

### Risks

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*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

-

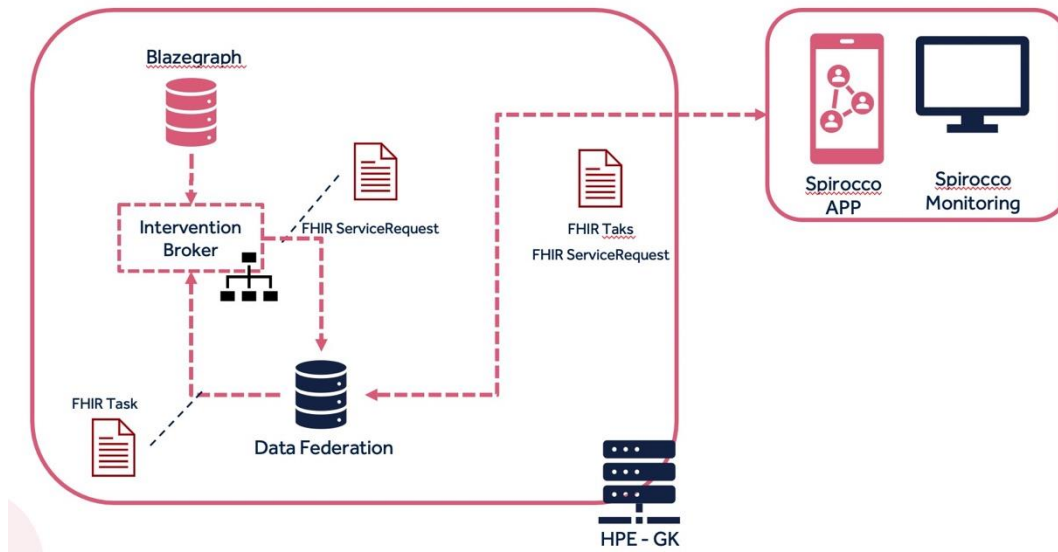
UK

RUC: 9

Pilot: UK

Solution: SPIROCCO

### Architecture figure for RUC solution



### Functionalities of the solution

Mitigation of risks related to loneliness through support community self-provided interventions on activities of daily living

### Planned activities and resources, current status of the project

Ongoing testing of the App on SPIROCCO servers

Piloting of the App from the 14th of June 2022 using SPIROCCO servers Integration of the App with the GK data federation in July-August 2022 (data push)

Development of an AI component, intervention broker, able to generate new requests from other sources from August to October

Deployment of the Intervention Broker in the GK platform in October 2022 (computation + push notification/polling to Spirocco servers)

### FHIR resources and profiles used

Service request (MK) <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-serviceRequest-mk-gk.html> Task (MK) <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-task-mk-gk.html>

Questionnaire response <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-questionnaireResponse-gk.html> Observation <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-gk.html>

Care Team <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-careTeam-gk.html>

Patient <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-Patient-eu-gk.html>

### User management

Users will be managed through SPIROCCO web dashboard for the community-care services

### Connectors

SPIROCCO system will send data in FHIR GK profile to the data federation.

The entry point of SPIROCCO is a reverse proxy that is connected with a VPN site-to-site with the GK infrastructure.

The site-to-site connection create a private connection with the TMS inside the GK platform where data about activities and daily surveys are stored in pseudonymised format

### Completed activities

Testing of the App User guide

Data model

### Ongoing activities

Development of the "intervention broker", a shared component connecting the community activities, robots and other sources of observations. This component should implement a reasoner translating observations and tasks into ServiceRequests for different connected devices

### Pending activities

Integration (data push) with the data federation

### Critical activities

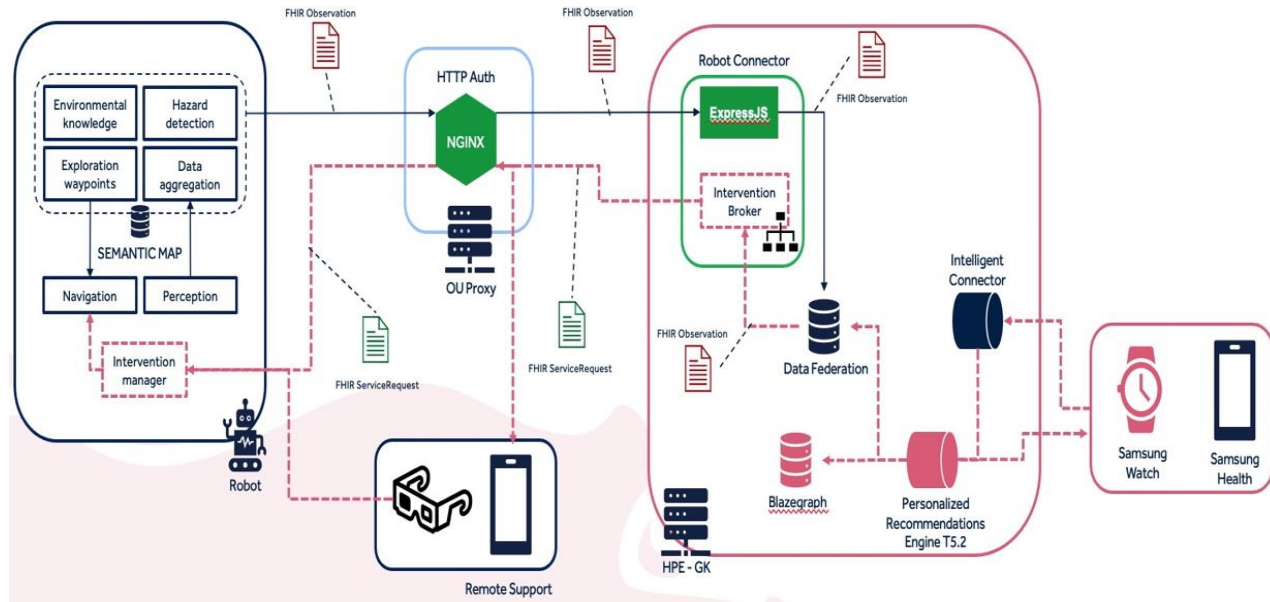
*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

- RUC: 7      Pilot: UK      Solution: Robotic Intervention & Samsung Health

#### Architecture figure for RUC solution



#### Functionalities of the solution

Support to activities of daily living at home and adherence to healthy lifestyle for co-morbidity older adults

Samsung Health system collects behavioural data about sleep, physical activity and biometrics (heart rate)

The Robotic Intervention monitors the home environment, identifying and mapping objects and hazards for the user, generating alarms (FHIR Observations) and performing autonomous tasks prompted by the user, or by FHIR ServiceRequests, as finding and fetching objects or removing obstacles

The Remote Support is a Meta Oculus software for remote controlling the robot in the capacity of elected caregivers. The system uses common messaging system to notify the request for support, generated by FHIR ServiceRequests prompted by the user, the robot or Samsung Health system

#### Planned activities and resources, current status of the project

Development of Samsung APP and Personalized Recommendations Engine Development of the Intervention Broker

#### FHIR resources and profiles used

Service request (MK) <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-serviceRequest-mk-gk.html> Task (MK)

<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-task-mk-gk.html>

Questionnaire response <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-questionnaireResponse-gk.html> Observation

<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-gk.html>

Care Team <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-careTeam-gk.html> Patient

<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-Patient-eu-gk.html>

Risk Assessment <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-riskAssessment-gk.html> Sleep Duration

<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-sleepDuration-gk.html> Steps Number

<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-stepsNumber-gk.html> Condition

<https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-condition-gk.html>

### User management

Users will be managed through Samsung Health app

### Connectors

The entry point of the Robot Connector and of Samsung Health is a reverse proxy that is connected with a VPN site-to-site with the GK infrastructure.

The site-to-site connection create a private connection with the TMS inside the GK platform where data about activities and daily surveys are stored in pseudonymised format Samsung Health system collects data from the App and Wearable into Samsung system Samsung Health system will send data to the intelligent connector for conversion in FHIR format

The Personalized Recommendation Engine converts FHIR data into Samsung HeliFit Ontology used to generate recommendations

Facts generated through the Personalized Recommendation Engine will be stored and queried via a Blazegraph pod

The robot connector enriches the Robot FHIR Observations and stores then into the data federation and Blazegraph pods

Intervention broker sends a push-notification FHIR ServiceRequest to caregiver with access to remote control to the robot (ER system)

### Completed activities

Data model Tenant services

Robotic connector (V1) Blazegraph pod

OU reverse proxy and site-to-site VPN Robotic intervention modules

Robotic remote control via Virtual Reality (Oculus)

#### Ongoing activities

Development of the "intervention broker", a shared component connecting the community activities, robots and other sources of observations. This component should implement a reasoner translating observations and tasks into ServiceRequests for different connected devices, e.g., request remote presence via Robot.

Development of the Robot "Intervention Manager", an onboard module working with the intervention broker for identifying FHIR ServiceRequests that should be fulfilled by the Robot  
Development of the Personalized Recommendations Engine

#### Pending activities

Testing Samsung site-to-site connection and integration with the smart connector

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

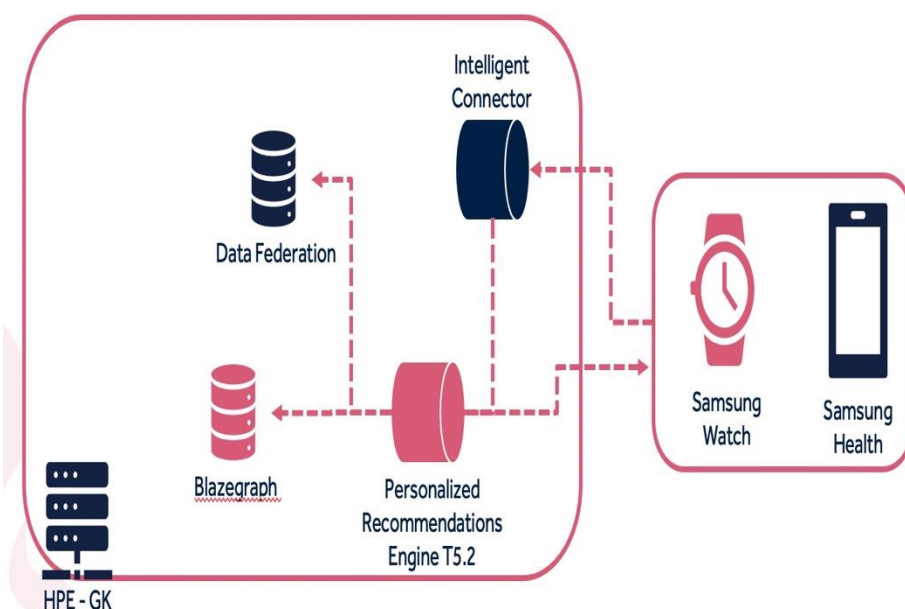
#### Risks

Intervention Broker and Personalized Recommendation Engines are real-time services



- RUC: 9      Pilot: UK      Solution: Samsung Health

#### Architecture figure for RUC solution



#### Functionalities of the solution

Mitigation of risks related to loneliness through support community self-provided interventions on activities of daily living

The system collects behavioural data about physical activity, biometrics (heart rate), nutrition and sleep, and daily self-assessments about cancer related symptoms (ESASS scale)

The solution provides timely recommendations supporting adherence to clinically validated guidelines and the regime of nutrition and physical activity provided by the care team

#### Planned activities and resources, current status of the project

Development of Samsung APP Development of the Intervention Broker

#### FHIR resources and profiles used

Questionnaire response <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-questionnaireResponse-gk.html> Observation <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-gk.html>

Care Team <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-careTeam-gk.html> Patient <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-Patient-eu-gk.html>

Risk Assessment <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-riskAssessment-gk.html> Sleep <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-sleepDuration-gk.html> Steps <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-stepsNumber-gk.html> Nutrition <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-nutritionOrder-gk.html> Order

Heart Rate <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-observation-hr-gk.html> Care Plan <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-carePlan-gk.html> Condition <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/branches/master/StructureDefinition-condition-gk.html>

#### User management

Users will be managed through Samsung Health web dashboard for the care team

#### Connectors

The site-to-site connection create a private connection with the TMS inside the GK platform where data about activities and daily surveys are stored in pseudonymised format

Samsung Health system collects data from the App and Wearable into Samsung system

Samsung Health system will send data to the intelligent connector for conversion in FHIR format

The Personalized Recommendation Engine converts FHIR data into Samsung HeliFit Ontology used to generate recommendations

Facts generated through the Personalized Recommendation Engine will be stored and queried via a Blazegraph pod

#### Completed activities

Tenant and core services Data model

Blazegraph pod

#### Ongoing activities

Development of the Personalized Recommendations Engine and the input system the personalized recommendations from the care team

#### Pending activities

Testing Samsung Health site-to-site connection and integration with smart connector

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

#### Risks

Personalized Recommendations Engine is a real-time service

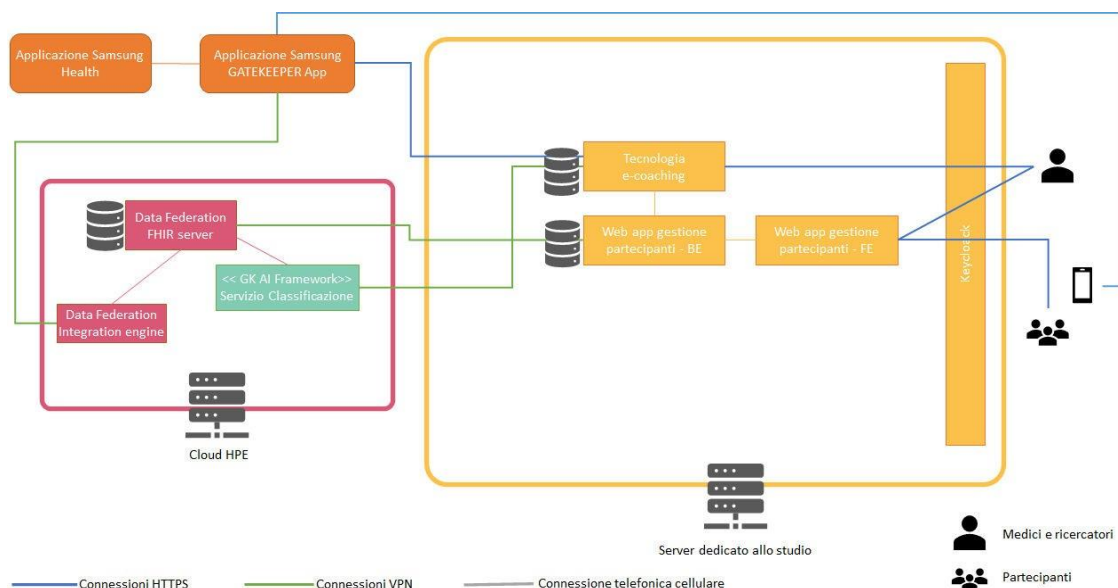
## Puglia

- RUC: 1

Pilot: Puglia

Solution: n/a

### Architecture figure for RUC solution



### Functionalities of the solution

- ENGTeapp for registering participants and storing their personal identifiable details
- FPM message based eCoaching platform for health promotion
- SAM GK App for the delivery of eCoaching messages to participants' smartphones
- GK Data Federation for storing pseudonymized participants data, as necessary to drive the SAM AI Service (see below)
- SAM AI Service for the quasi real-time classification of participants into stereotypes, to which specific coaching plans are associated

### Planned activities and resources, current status of the project

- All technical components are in place
- DSA with FPM and SAM are signed
- DSA with HPE is missing [date of signature is not under full control of the Pilot]
- Recruitment started on M29
- Delivery of eCoaching started on M32
- The experiment is expected to end by M42

#### **FHIR resources and profiles used**

The FHIR profile has been setup with the help of ENG Everything needed is in place

#### **User management**

User management is provided by the ENGTeapp recruitment webapp, the FPM eCoaching platform, and the SAM GK App

Everything needed is in place

#### **Connectors**

No connectors needed for this RUC

#### **Completed activities**

All technical development completed DSA with FPM and SAM signed

#### **Ongoing activities**

Recruitment and delivery of eCoaching

#### **Pending activities**

Signature of DSA with HPE

#### **Critical activities**

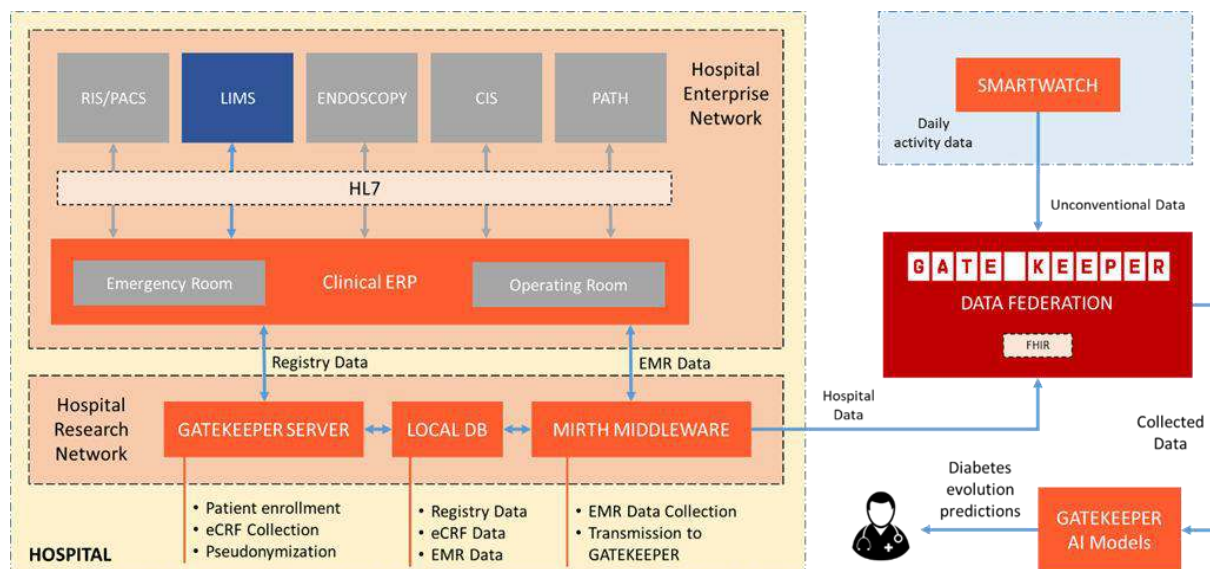
Signature of DSA with HPE

#### **Risks**

Signature of DSA with HPE available too late (beyond M32)

- RUC: 1      Pilot: Puglia      Solution: n/a

### Architecture figure for RUC solution



### Functionalities of the solution

- SAM GK App for the collection of non-conventional data from smartphones and smartwatches
- GK Data Federation for storing pseudonymised participants data, as necessary to drive AI modelling
- Middleware to connect EMR to GK Data Federation

### Planned activities and resources, current status of the project

- All technical components are in place
- DSA with SAM is signed
- DSA with UoW and UoI for AI modelling is ongoing
- DSA with HPE is missing [date of signature is not under full control of the Pilot]
- Recruitment and data collection started on M21
- The experiment is expected to end by M42

### FHIR resources and profiles used

The FHIR profile has been setup with the help of ENG. Everything needed is in place

### User management

User management is provided by the SAM GK App

Everything needed is in place

#### Connectors

No connectors needed for this RUC

#### Completed activities

All technical development completed DSA with SAM signed

Recruitment completed

#### Ongoing activities

Data collection

#### Pending activities

Signature of DSA with HPE, UoW, UoI

#### Critical activities

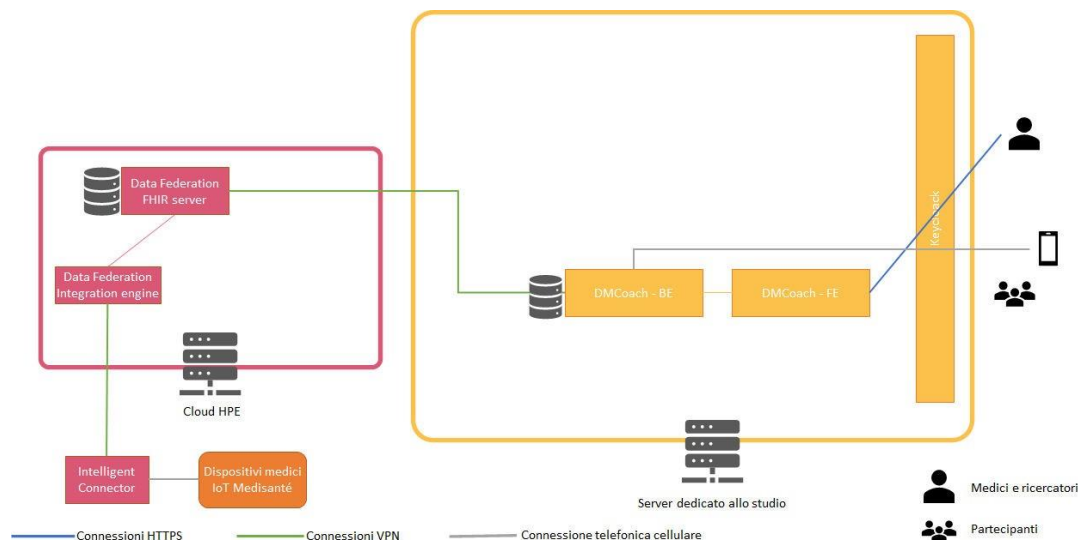
Signature of DSA with HPE, UoW, UoI

#### Risks

Signature of DSA with HPE, UoW, UoI available too late (beyond M32)

- RUC: AReSS 3, 7 for T2D Pilot: Puglia Solution: n/a

#### Architecture figure for RUC solution



#### Functionalities of the solution

- ENG DMCoach: app for T2D management
- GK Intelligent connector to connect KET providers internal to the GK Consortium
- GK Data Federation for storing pseudonymized participants data

#### Planned activities and resources, current status of the project

- All technical components are in place
- DSA with HPE, ENG, BB, M+, are missing [date of signature is not under full control of the Pilot]
- Recruitment of HCPs started on M27
- Experiment to be started as soon as the missing DSA are signed
- The experiment is expected to end by M42

#### FHIR resources and profiles used

The FHIR profile has been setup with the help of ENG Everything needed is in place

#### User management

User management is provided by the ENG DMCoach application

Everything needed is in place

#### Connectors

- GK Intelligent Connector

#### Completed activities

All technical development completed

#### Ongoing activities

DSA negotiation and signature

#### Pending activities

Signature of DSA with HPE, ENG, BB, M+

#### Critical activities

Signature of DSA with HPE, ENG, BB, M+

#### Risks

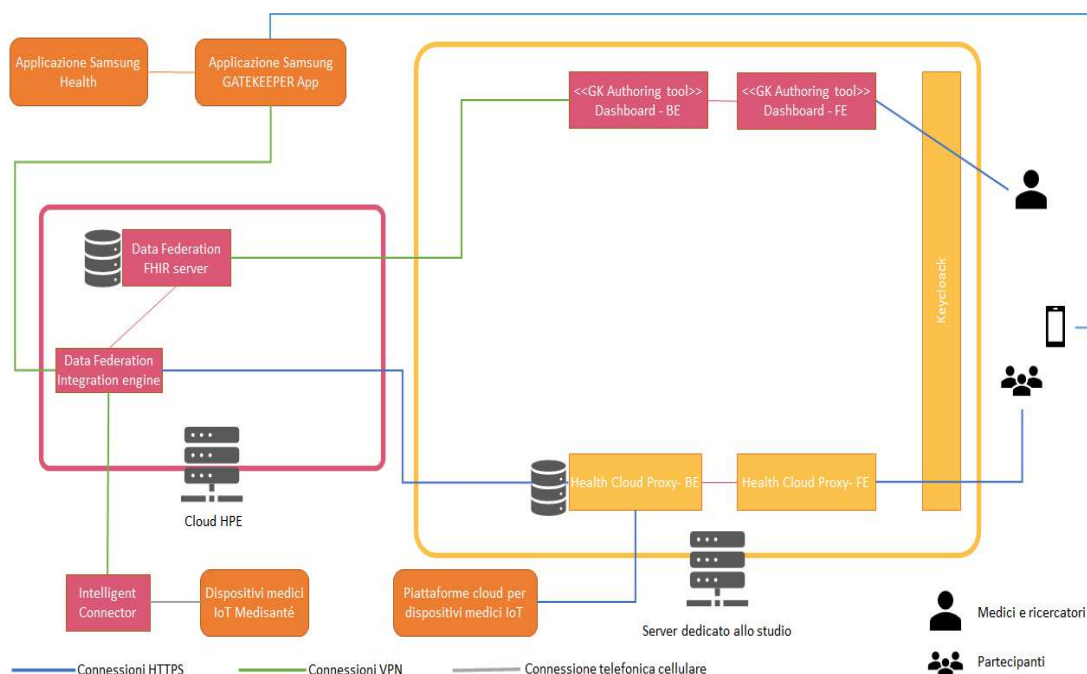
Signature of DSA with HPE, ENG, BB, M+ available too late (M32)



- RUC: 2,5,8 and 7 for non-T2D Pilot: Puglia

Solution: n/a

## Architecture and figure



- All technical components are in place
- DSA with HPE, ENG, BB, M+, are missing [date of signature is not under full control of the Pilot]
- Recruitment of HCPs started on M27
- Experiment to be started as soon as the missing DSA are signed
- The experiment is expected to end by M42

## Planned activities and resources, current status of the project

- TEC T5.5 Dashboard for data visualization
- ENG Health Cloud Proxy to connect KET providers external to the GK Consortium
- GK Intelligent connector to connect KET providers internal to the GK Consortium
- GK Data Federation for storing pseudonymised participants data

## Planned activities and resources, current status of the project

- GK Data Federation, GK Intelligent Connector and ENG Health Cloud Proxy are in place
- DSA with SAM is signed
- DSA with HPE, ENG, M+, TEC are missing [date of signature is not under full control of the Pilot]
- Recruitment of HCPs started on M27

- Experiment to be started as soon as the missing DSA are signed
- The experiment is expected to end by M42

#### **FHIR resources and profiles used**

The FHIR profile has been setup with the help of ENG Everything needed is in place

#### **User management**

User management for data access is provided by TEC T5.5 Dashboard

User management related to initial population of Practitioner and Patient entities is missing

#### **Connectors**

- ENG Health Cloud Proxy
- GK Intelligent Connector

#### **Completed activities**

Technical development of GK Data Federation, GK Intelligent Connector and ENG Health Cloud Proxy completed

DSA with SAM signed

#### **Ongoing activities**

Integration of TEC T5.5 Dashboard DSA negotiation and signature

#### **Pending activities**

Development of user management related to initial population of Practitioner and Patient entities  
Integration of TEC T5.5 Dashboard

Signature of DSA with HPE, ENG, M+, TEC

#### **Critical activities**

Development of user management related to initial population of Practitioner and Patient entities is missing  
Integration of TEC T5.5 Dashboard

Signature of DSA with HPE, ENG, M+, TEC

#### **Risks**

Development of user management related to initial population of Practitioner and Patient entities available too late (beyond M32)

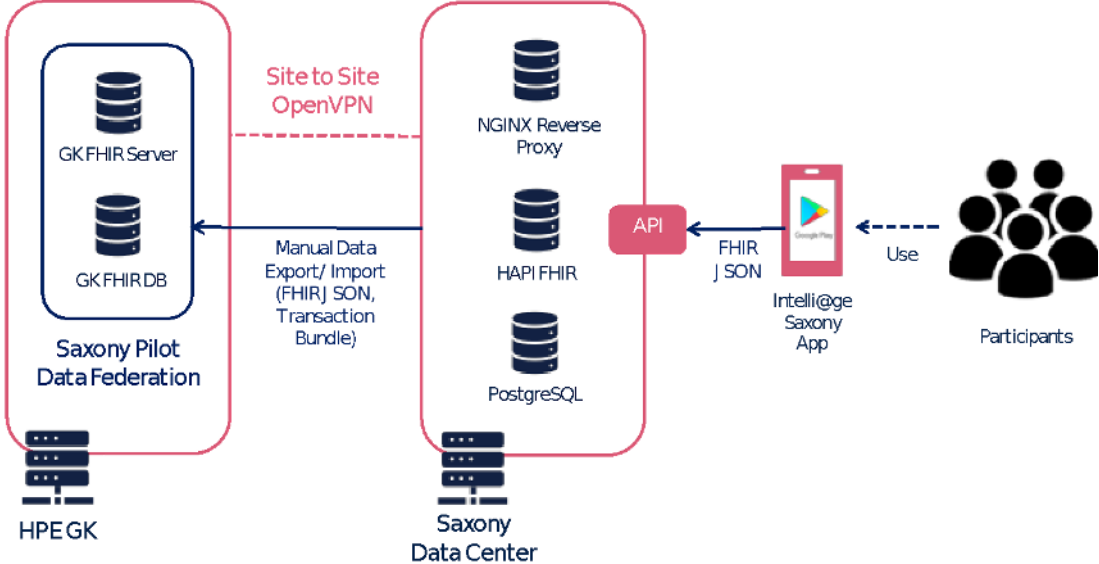
Integration of TEC T5.5 Dashboard too late (beyond M32)

Signature of DSA with HPE, ENG, M+, TEC available too late (beyond M32)

Saxony

RUC: 1      Pilot: Saxony Solution: intelli@ge

Architecture figure for RUC solution

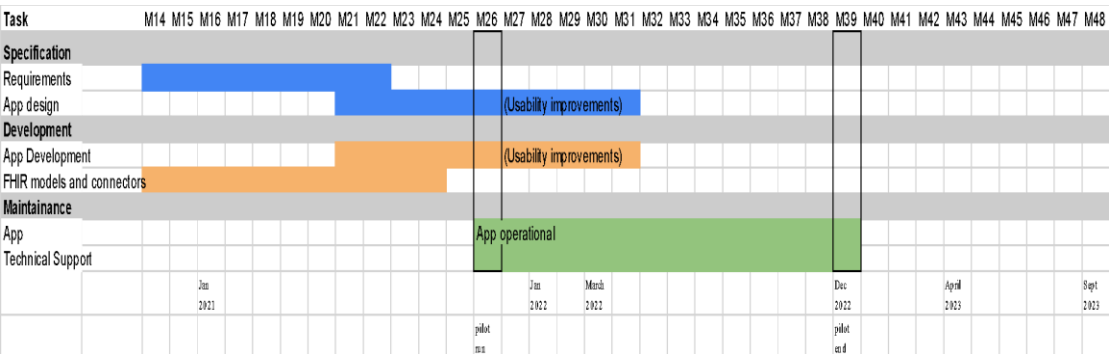


Functionalities of the solution

The app intelli@ge wants to inform elderly citizens about mental and physical health aspects. It is preceded by questions about the citizens' state of health. This information is anonymously included in the research project to improve the quality of life in the second half of life. In the app, users will also find numerous exercises for relaxation and suggestions for dealing with stressful situations, as well as information about support services.

Planned activities and resources, current status of the project

(App is already operational, sub-study running since 26 Nov 2021)



### FHIR resources and profiles used

The app will collect FHIR Questionnaire and QuestionnaireResponse referring to: <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/profiles.html>

- Questionnaires: (all is in/follows the GK-FHIR-IG) EQ5D

Socio-demographics PHQ-4

PC-PTSD-5 WHO-5 ESSI

SUS

Covid19-related burden

### User management

No particular user management is foreseen. The app can be used by any citizen without login or authentication. Therefore, the app usage is anonymous. Only consent approval is required. A token could be created when withdrawing the consent to allow re-starting the study participation.

### Connectors

### Completed activities

- App development - 100% (TUD)
- Service development - 100% (TUD)
- FHIR mapping - 100% (TUD)

### Ongoing activities

- Creation and refinement of the coding list - 75% (TUD)
- Maintenance (TUD): interim server in TUD premises
- Preparation for data transfer to the data federation

### Pending activities

### Critical activities

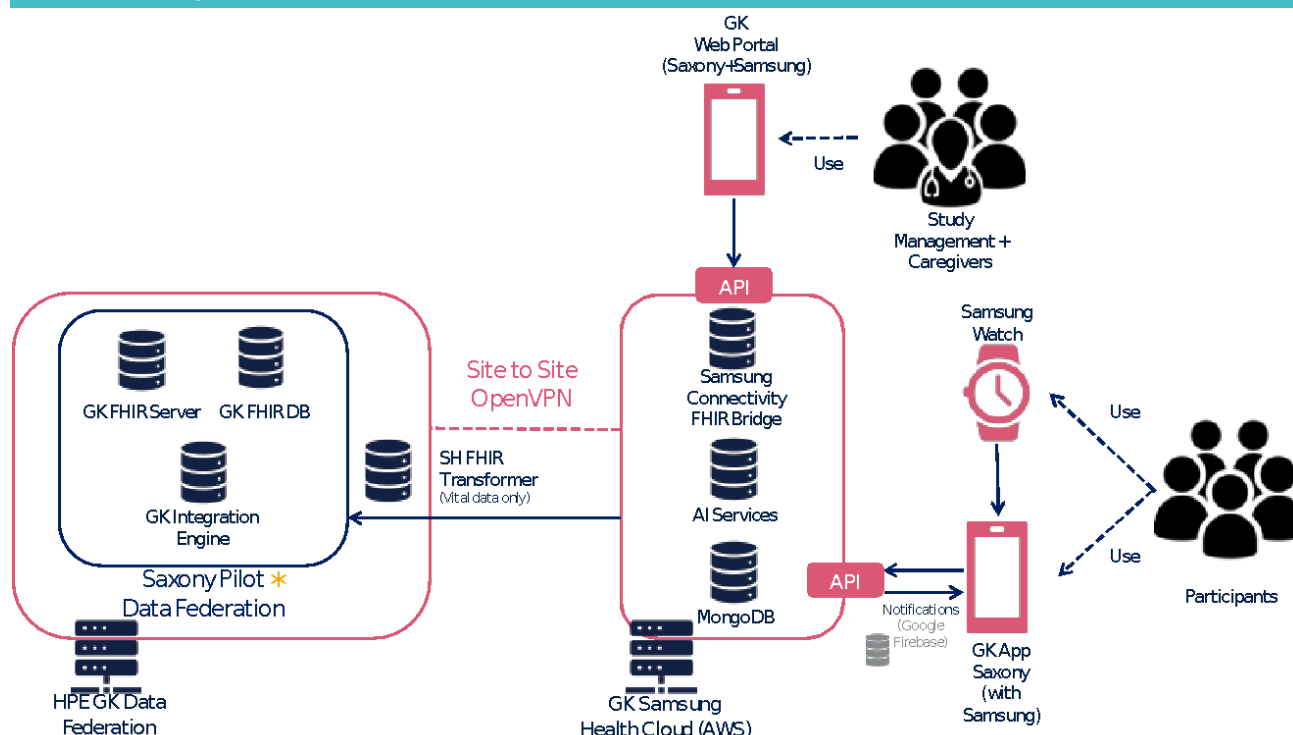
- Maintenance, platform support and denial of service (TUD/HPE)

### Risks

- Migration of data outside HPE infrastructure (TUD)
- promotion of app/project to acquire the desired number of users

**RUC: 7      Pilot: Saxony Solution:**

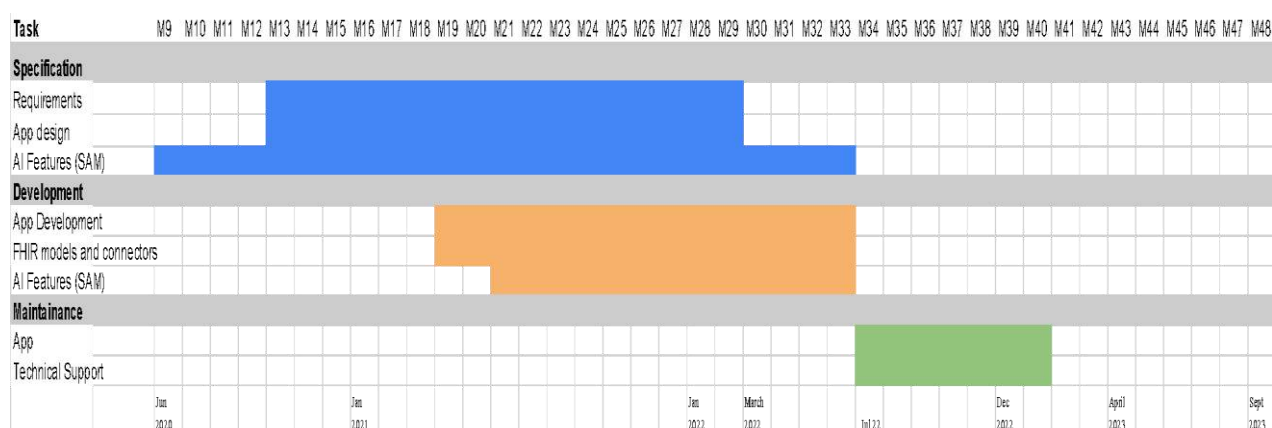
## Architecture figure for RUC solution



## Functionalities of the solution

The app wants to inform elderly patients about mental and physical health aspects. It is preceded by questions about the citizens "state of health". The smartwatch's health data is further feeding the assessment of the patients' state in order to derive appropriate recommendations to improve their well-being. This information is anonymously included in the research project to improve the quality of life in the second half of life.

### Planned activities and resources, current status of the project



## FHIR resources and profiles used

The app will collect FHIR observations, Questionnaire and Questionnaire response: referring to: <https://build.fhir.org/ig/gatekeeper-project/gk-fhir-ig/profiles.html>

- Observations (health data gathered from the Smartwatch device):

- a) Daily activity: steps, active time, activity cal
- b) Exercise: automatic exercise recognition
- c) Sleep: sleep analyse, heart rate measuring and movement
- d) Heart rate: measure and record heart rate
- e) Stress: measuring stress level by using changes in heart rate
- f) Blood oxygen: measurement of blood's oxygen level
- g) Body composition: measurement of body composition, such as skeletal muscle mass or fat mass
- h) Food: record calories eaten in a day and compare with target calories
- i) Water: record and track water consumption
- j) Women's health: cycle tracking

- Questionnaires:

implemented: EQ5D, WHO-5, ESSI

to be implemented: PHQ-4, Socio-demographics, PC-PTSD-5, SUS, Covid 19-related burden

#### User management

It is planned to use pseudo mail addresses (like userxyz@samsung.com) to register users in the SAM platform (GK App). The link of mail address and real person is only known to the clinical principal investigator and is

kept under lock and key to ensure data pseudonymisation.

Furthermore we will use a role system within Samsung Gatekeeper Platform: e.g. Administrator, Supercarer, Carer, User

#### Connectors

See architecture figure of RUC solution.

Data is connected through Samsung Health App (Phone/smartwatch synchronization), Samsung GK app interaction on smartphone, then stored and processed by the Samsung GK Health Cloud, finally transformed to FHIR format and persisted to HP Data federation

#### Completed activities

- App development - minimum requirements: 66% (TUD + SAM), desired functionality: 25%
- Dashboard development - 75% TUD, ??% Tecnia
- FHIR profile definition 100% (TUD)

#### Ongoing activities

- Data Processing Agreement with HP ??%

- FHIR mapping implementation (8x Questionnaires) - 30% (TUD)
- Translation of Samsung GK App to German - 10%, blocked
- Definition and integration of recommendations, 50% (TUD, SAM)
- Migration of further questionnaires - 25% TUD

#### Pending activities

- FHIR data persistence to HP (SAM)
- integration/use of observational data for recommendation (SAM)
- AI based recommendations (SAM+TUD)
- Data processing functions on HP platform for scientific use
- Maintenance of App and platform (TUD/SAM/HPE)

#### Critical activities

- Maintenance, platform support and denial of service (TUD/HPE)

#### Risks

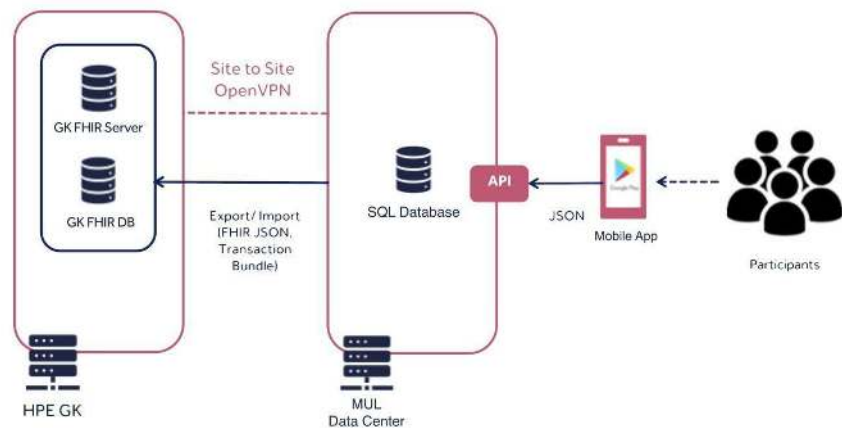
- insufficient support while integrating functions to Samsung GK platform, potential deviation from initial approach, dependency towards Samsung
- additional efforts from aligning with other pilots using the same Samsung GK platform
- legal requirements - additional activities or restrictions (as happened with using the EQ-5D questionnaire, an 8 weeks process)
- insufficient resources for pending development, human and/or financial
- promotion of app/project to acquire the desired number of users

Poland

- RUC: 1      Pilot: Poland Solution: Adherence management app

Architecture figure for RUC solution

DEPLOYMENT [MUL]



Functionalities of the solution

The medication adherence app is a mobile application which helps the patient adhere to one's daily medication regime. The app asks about the level of adherence and if it is poor it provides the patient with one of many solutions to the specific problem which patient has declared. It also assess the level of medication adherence on the basis of validated Morisky's questionnaire.

Planned activities and resources, current status of the project



FHIR resources and profiles used

*please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC*



**User management**

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

**Connectors**

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

**Completed activities**

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

- App development - 100% (MUL)
- FHIR mapping - 100% (MUL)
- App deployment to Google Play and AppStore - 100% (MUL)

**Ongoing activities**

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

recruitment of all 1000 patients – ongoing

**Pending activities**

*[please describe here the activities that are pending but already assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

**Critical activities**

*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

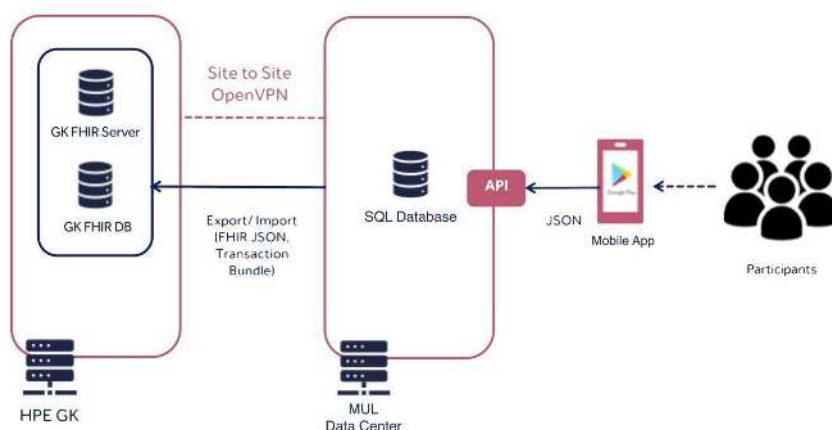
**Risks**

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

**- RUC: 7      Pilot: Poland Solution: Adherence management app**

## Architecture figure for RUC solution

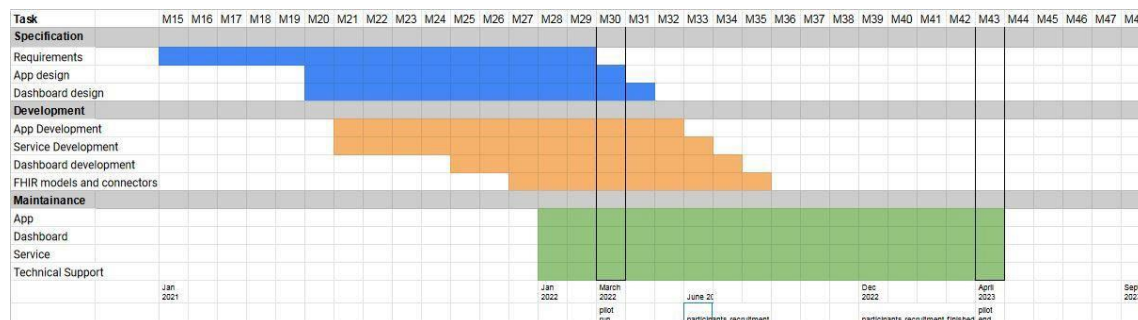
## DEPLOYMENT [MUL]



## Functionalities of the solution

The medication adherence app is a mobile application which helps the patient adhere to one's daily medication regime. The app asks about the level of adherence and if it is poor it provides the patient with one of many solutions to the specific problem which patient has declared. It also assess the level of medication adherence on the basis of validated Morisky's questionnaire. In RUC7 additionally patients will receive AI based feedback.

### Planned activities and resources, current status of the project



## FHIR resources and profiles used

*[please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC]*

## User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

#### Connectors

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

#### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

- App development - 100% (MUL)
- FHIR mapping - 100% (MUL)
- App deployment to Google Play and AppStore - 100% (MUL)

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

#### Pending activities

*[please describe here the activities that are pending but already assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

app connection with Gatekeeper AI

#### Critical activities

*[please describe here the activities that are pending and not assigned in no more than 5 lines, for each activity please indicate the responsible partner]*

#### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*

## Covid-19 survey

RUC: N/A

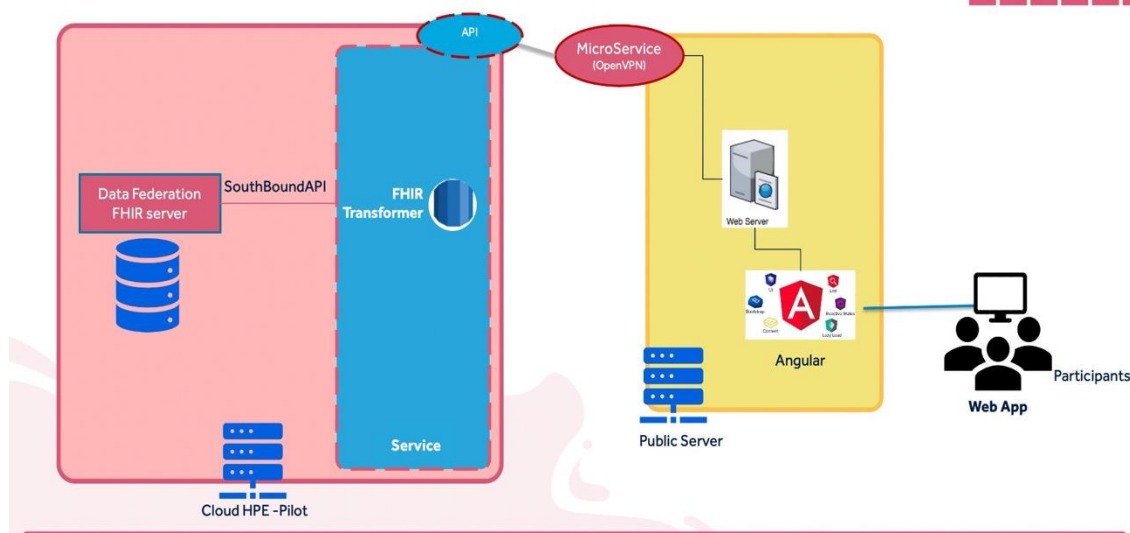
Pilot: PILOTg

Solution: Gatekeeper COVID-19 Survey (UPAT)

### Architecture figure for RUC solution

#### DEPLOYMENT

##### Pilot 9 – COVID19 Survey



### Functionalities of the solution

*[please describe the objective of the RUC in no more than 5 lines]*

### Planned activities and resources, current status of the project

*[please describe the timing of the project in no more than 5 lines, you can use a Gantt chart in alternative]*

### FHIR resources and profiles used

*[please add here the link or any other reference to the FHIR resources, profiles and examples you are using in the RUC]*

### User management

*[please describe here how you will manage the users associated to your RUC in no more than 5 lines, please indicate the responsible partner]*

Users filling the COVID19 survey do not need authorization.

### Connectors

*[please describe here how the data flows in your tenant, please indicate the responsible partner]*

All data is collected in the web app from manual input. The web app is connected through s2s VPN with the OKD tenant and data are transferred to the Data Federation FHIR server via API

#### Completed activities

*[please describe here the activities already carried out in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Service fully deployed and functional in production environment. (all by UPAT)

#### Ongoing activities

*[please describe here the activities that are ongoing in no more than 5 lines in percent, for each activity please indicate the responsible partner]*

Currently under Pilot phase data collection.

#### Pending activities

*[please describe here the activities that are pending but **already assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

#### Critical activities

*[please describe here the activities that are pending and **not assigned** in no more than 5 lines, for each activity please indicate the responsible partner]*

#### Risks

*[please describe here the risks of your RUC in terms of unplanned activities that you have identified could appear if any]*