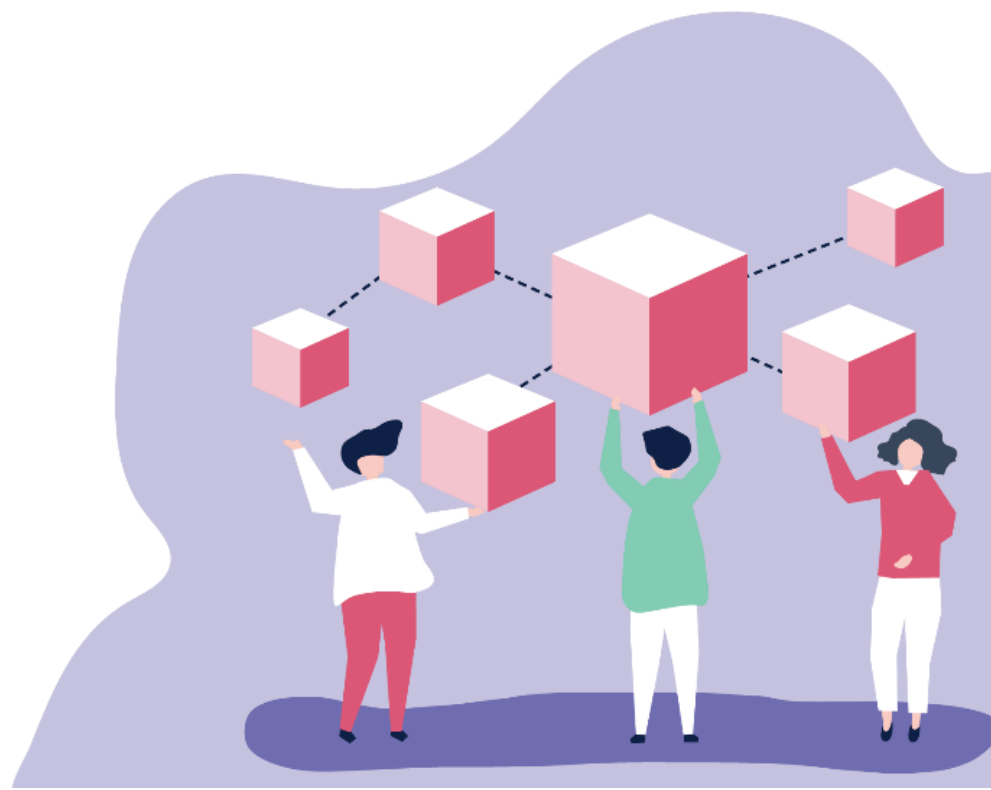




GATE KEEPER

D7.5 – KPI Evolution Report (I to VIII) [M18 updated every 6 months]

| | | | |
|-------------------------|--|----------------------------|--|
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Authors

| Name and surname | Partner name | e-mail |
|-------------------------------|--------------|--|
| Silvio Pagliara | UoW | silvio.pagliara@warwick.ac.uk |
| Alessia Maccaro | UoW | Alessia.maccaro@warwick.ac.uk |
| Salman Haleem | UoW | Salman.haleem@warwick.ac.uk |
| Leandro Pecchia | UoW | Lpecchia@warwick.ac.uk |
| Frans Folkvord | OE | ffolkvord@open-evidence.com |
| Nuria Febrer | OE | nfebrer@open-evidence.com |
| Francisco Lupiáñez-Villanueva | OE | flupianez@open-evidence.com |
| Gloria Cea Sánchez | UPM | gcea@lst.tfo.upm.es |
| Laura López Pérez | UPM | llopez@lst.tfo.upm.es |
| Alba Gallego Montejo | UPM | agallego@lst.tfo.upm.es |
| Giuseppe Fico | UPM | gfico@lst.tfo.upm.es |
| M Teresa Arredondo | UPM | mta@lst.tfo.upm.es |

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Abstract

This deliverable is the first of four issues (i.e., D7.5, D7.6, D7.7 and D7.8), which are aimed at updating and complementing the information provided in the D7.2, **KPI Evolution report** each 6 months.

In fact, while the D7.2 provides the *definition and description of the GATEKEEPER KPIs*, organised in meaningful classes, for each of the European pilot and per each Reference Use Case (RUC), this following series is intended to report on the *values for each KPI* at months 18, 24, 30 and 36. The KPI values will allow the continuous monitoring, control and benchmarking of each RUC, during the project lifespan, triggering corrective actions, if necessary. Moreover, the KPIs values will feed the D7.4 (*Pilot Studies*), which will provide the final economic evaluation and the sustainability assessment of each RUC.

Considering the progress of the pilot definition and execution, **detailed plans for each pilot** are included in this deliverable. These plans cover the deployment and running phases to ensure the pilots are ready for their execution.

We took this opportunity to publish in this deliverable an updated version of the Impact assessment KPIs defined in the D7.2, which overcome the previous deliverable in many ways. Beyond the definition and the description of the KPIs for the new RUC, all the RUC KPIs have been reviewed in light of the pandemic burden. In particular, a revised version of the D7.2, considering the COVID-19 amendments and the new RUCs #8 High Blood Pressure and #9 Covid-19 related.

Moreover, this deliverable defines and describes the **Operative KPIs**, which were not yet defined in D7.2, and reports the target values of these indicators per pilot summarized in tables per pilot-execution phases.

Additionally, the current document describes the harmonised templates and the guidelines for reporting the KPIs. The collection of these KPIs enables to monitor the progress of the LSP execution. **Error! Reference source not found.** gathers the current reports of each pilot with the target values.

Alongside this, the inclusion process of the **Asian Pilots**, Hong Kong, Singapore and Taiwan fully started in M17 after the first amendment approval. The LSP Management Team developed with them the inclusion strategy plan and begun to collect their preliminary experiments definition with the selected Reference Use Cases to be deployed, here reported in the *Section 4.9 Asian Pilots*. The next issue of this report series will include their study design, the impact assessment framework with the preliminary

definition of the KPIs and the related measurement tool and the operative performance indicators.

All the changes from the previous edition are stated in Section 1.2 - Summary of key updates and modifications

Statement of originality

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

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1 About this document

This document aims to consolidate the pilot plans details, the definition and description of the KPIs and the measurement tools redefined at Pilot level after the final definition of their clinical studies, including the necessary changes due to the pandemic and pilots' evolutions.

1.1 Deliverable context

Table 1: Deliverable context

| PROJECT ITEM | RELATIONSHIP |
|---------------------|--|
| Objectives | <p><u>Main objective</u>: define and describe the Impact Assessment and the Operative KPIs for measuring the cost-efficacy of the GATEKEEPER health technologies.</p> <p><u>O1, O6, O9</u>: Define bases for the local and global evaluation of the multicentric longitudinal federate study large scale pilot</p> |
| Exploitable results | Definition and explanation of the KPIs for the impact assessment (T7.8), Active users' involvement, (T7.4) Local evaluation framework T6.4 |
| Workplan | This deliverable is one of the outcomes of the WP7 (i.e., task 7.1, 7.2, 7.3 and 7.4). This document will be a reference for the future work within this task and will guide many other project tasks, especially Tasks T6.4 and 7.8. |
| Milestones | MS3 Cruise |
| Deliverables | D6.1 D6.4, D7.1, D7.2 |
| Risks | Pilots' delays reflect in fewer quantitative data to feed the interim Impact Assessment Framework. the Operative KPIs will measure pilots' progresses to ensure affective monitoring and control |

1.2 Summary of key updates and modifications

In table below are reported the list of changes from D7.2

Table 2: Changes between D7.2 and D7.5

| SECTION | UPDATES/MODIFICATIONS |
|--------------------------------------|--|
| 2 | New section: Pilot plans details |
| 3 | GATEKEEPER Evaluation strategy plan updated |
| 4 | Addition of information about new RUCs #8 and #9 |
| 4.1 AragonUSE CASE 9 - COVID | Study design updated adding RUC#9 and actual status report |
| 4.1.8 UC 9USE CASE 9 - COVID | Added a new study related to RUC#9 and KPIs with measurement tools |
| 4.2 Basque Country | Study design updated splitting RUC#6 in two phases and actual status report |
| 4.2.1 UC 1 | Changed KPIs and measurement tools for all categories |
| 4.2.5 UC 7 | Changed KPIs and measurement tools for all categories |
| 4.3 Cyprus | Study design updated about the subjects in intervention and those in control, actual status report |
| 4.3.1 UC 7 | Changed clinical KPIs and redefined measurement tools addressing the different categories of users |
| 4.4 Central Greece and Attica | Study design updated on numbers and actual status report |
| 4.5 Milton Keynes | Reformulation of RUC1. In RUC#9 for the COVID-19 management, no. of subjects reduced, adding a new site, actual status report. |
| 4.5.1 UC 9 | RUC#9 KPIs and tools defined |
| 4.5.2 UC 7 | KPI QoL tool redefined |
| 4.6 Poland | actual status report |
| 4.6.1 UC 1 | KPI QoL tool redefined |
| 4.6.2 UC 7 | Clinical KPIs and related tools redefined |
| 4.7 Puglia | Added RUC# 8 about High blood pressure, study design redefined alongside the three levels of complexity |
| 4.7 UC 1, 2, 3, 5, 7, 8 | Redefined specific measures per each RUC |

| SECTION | UPDATES/MODIFICATIONS |
|--|---|
| 4.8 Saxony | actual status report |
| 4.8.1 UC 1 | Redefined Clinical KPI about Patient visits and time spent |
| 4.9 Asian Pilots | Added this section with the Asian Pilots descriptions |
| 5.1 Operative KPIs template | Definition of the template for the data collection |
| 5.2 LSP multicentred operative repost | Definition of the operative report data collection with target values |
| 6 Conclusions | Updated conclusions |
| Appendix A | Added the appendix about the Operative KPIs tool sheets |
| Appendix B | Added the individual, pilot per pilot, KPIs evolution reports |

2 Pilot plans details

This section presents an overall view of each pilot definition and planning. For each pilot, the same structure has been provided. Some relevant information is not included at pilot level because it was already considered in previous deliverables. In Table 3, the sections of the pilot plans are presented.

Table 3: Pilot plan details structure

| Section | Subsection | Details |
|---------------------------------|--|--|
| 1 Pilot Context | 1.1 Context & Ecosystem | 'Appendix A Reference use case forms' of D6.1, where each subsection belongs to each pilot site. |
| | 1.2 Clinical Study protocol highlights | section x.1.1 of D6.4, where x refers to each pilot site. |
| 2 Planning | - - | Described in this document |
| 3 Technological solution | 3.1 Conceptual architecture | 'Pilot Figure' element in section 5 of D3.1.2. |
| | 3.2 Pilot infrastructure | 'Pilot components' description in section 5 of D3.1.2 |
| | 3.3 GK platform integration | 'Expected integration with Gatekeeper' details in section 5 of D3.1.2 |
| | 3.4 Data collection flow | 'Pilot Figure' element in section 5 of D3.1.2. |
| | 3.5 Functionalities and components | 'List of needed tasks for development and integration of pilot components', 'Expected partner interactions' and 'Time plan' in section 5 of D3.1.2 |
| 4 Deployment Phase | 4.1 Deployment phases per RUC | Described in this document |
| | 4.2 User recruitment strategy and consent procedures | |
| | 4.3 Ensuring COVID19 prevention | |
| | 4.4 Technology acquisition | |
| | 4.5 Installation procedures | |
| | 4.6 Pre-testing | |
| | 4.7 User training and support | |
| 5 Running Phase | 5.1 Operation procedures (execution and maintenance) | Described in this document |
| | 5.2 Termination procedures | |
| | 5.3 Evaluation procedures | |

Figure 1 shows the different actors involved in the overall process of pilot execution. Green actors represent pilot actors, pink actors represent GATEKEEPER managers, blue actors represent other GATEKEEPER representatives and yellow actor refers to an external technology provider. In future releases, each pilot will define their internal mapping of actors, identifying specific persons for each actor.

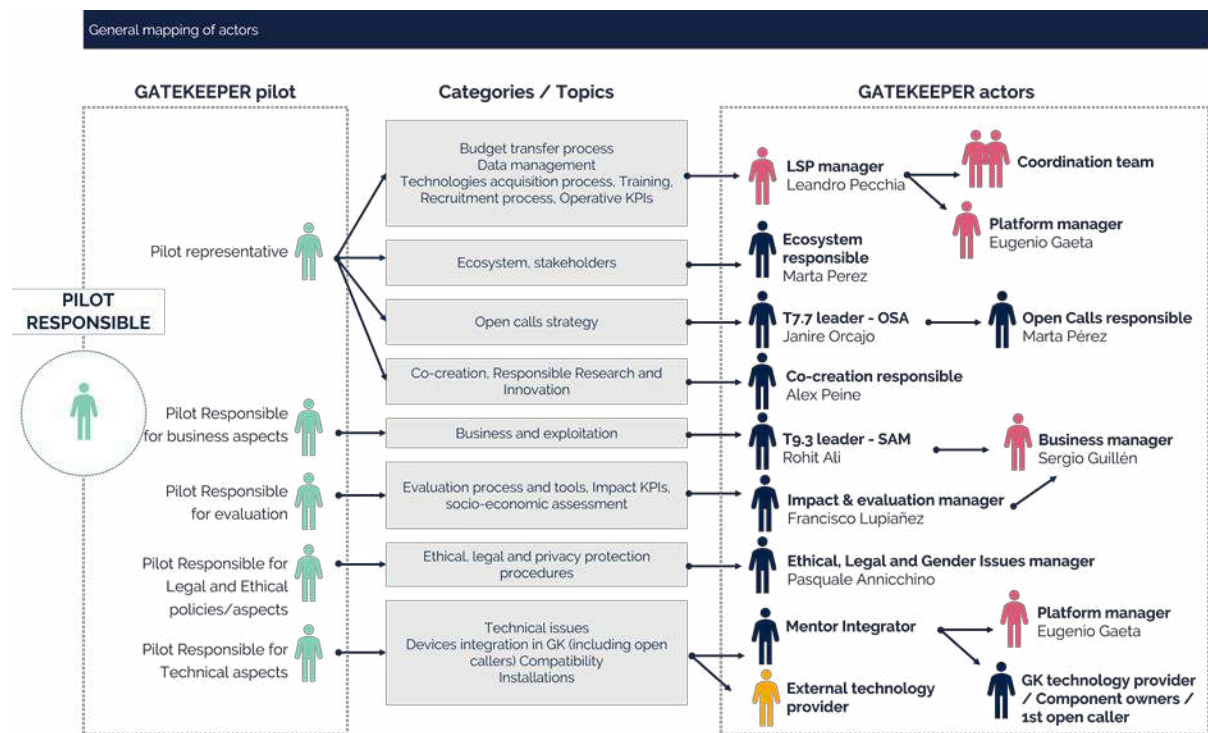


Figure 1 - General mapping of actors during the pilot execution

In the following sub-sections, each pilot plan details are included.

2.1 ARAGON pilot plan

2.1.1 Planning

The following tasks and subtasks apply to all the RUCS. Details are shown in Figure 2.

- Preparation
 - o Protocol and KPI definition
 - o Technology acquisition (some devices may also be purchases during the running phase if the needs change)
 - o Protocol preparation (e.g. ethical committee approval)
- Deployment
 - o Technical adaptations and installation
 - o Pre-testing and validation
 - o Recruitment strategy
 - o User training strategy
 - o User support strategy
- Running
 - o Recruitment
 - o Training
 - o Execution and maintenance
 - o Support
 - o Integration with GK platform
 - o Evaluation
 - o Inclusion of predictive models in service provision

Some of them will run in parallel as for instance, recruitment, training, execution and support that will be held during the whole lifetime of the pilots. This reduces the number of activities, especially in the running phase.

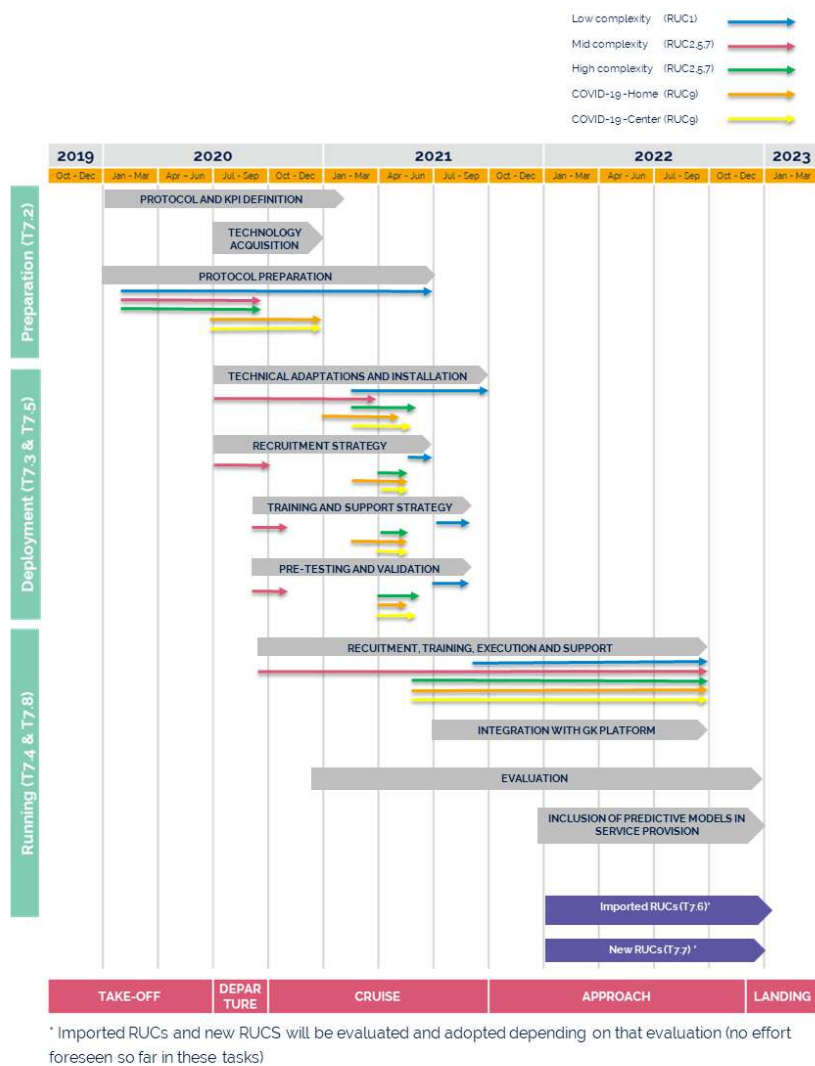


Figure 2 - Aragón piloting phases

2.1.2 Deployment phase

2.1.2.1 Deployment phases per RUC

Low Complexity (RUC1)

| Start Date | End Date | Explanation |
|------------|-------------|--|
| Feb 2021 | Oct 2021 | Technical adaptations and installation |
| May 2021 | June 2021 | Recruitment strategy |
| July 2021 | August 2021 | Training and support strategy |
| July 2021 | August 2021 | Pre-testing and validation |
| Sept 2021 | - | User training (to be done also during the running phase) |

Mid complexity (RUC2,5,7)

| Start Date | End Date | Explanation |
|--------------|------------|--|
| July 2020 | March 2021 | Technical adaptations and installation |
| July 2020 | Oct 2020 | Recruitment strategy |
| Sept 2020 | Oct 2020 | Training and support strategy |
| Sept 2020 | Oct 2020 | Pre-testing and validation |
| October 2021 | - | User training (to be done also during the running phase) |

High Complexity (RUC2,5,7)

| Start Date | End Date | Explanation |
|------------|----------|--|
| Feb 2021 | May 2021 | Technical adaptations and installation |
| Apr 2021 | Apr 2021 | Recruitment strategy |
| Apr 2021 | Apr 2021 | Training and support strategy |
| Apr 2021 | May 2021 | Pre-testing and validation |
| May 2021 | - | User training (to be done also during the running phase) |

COVID 19 home

| Start Date | End Date | Explanation |
|------------|------------|--|
| Jan 2021 | April 2021 | Technical adaptations and installation |
| Feb 2021 | Apr 2021 | Recruitment strategy |
| Feb 2021 | Apr 2021 | Training and support strategy |
| Apr 2021 | Apr 2021 | Pre-testing and validation |
| May 2021 | - | User training (to be done also during the running phase) |

COVID 19 center

| Start Date | End Date | Explanation |
|------------|----------|--|
| Feb 2021 | May 2021 | Technical adaptations and installation |
| Apr 2021 | Apr 2021 | Recruitment strategy |
| Apr 2021 | Apr 2021 | Training and support strategy |
| Apr 2021 | May 2021 | Pre-testing and validation |
| May 2021 | - | User training (to be done also during the running phase) |

2.1.2.2 User recruitment strategy and consent procedures

Table 4: Aragon recruitment process procedures

| | |
|--------------------|---|
| RESPONSIBLE | SALUD |
| PURPOSE | Recruitment strategy and components for all the use cases |
| INPUTS | - |
| OUTPUTS | Recruitment strategy |

| | PROCEDURE DESCRIPTION |
|----------|---|
| 1 | Information campaign with healthcare professionals (primary care, specialized care, emergency units, social workers at salud involved in each specific use case) |
| 2 | Information campaign with social care organisations (for those use cases that require it: mid complexity and high complexity use cases) |
| 3 | Definition and agreements with social care organisations for service provision. This applies to mid complexity and high complexity use cases (those that involve integrated care) |
| 4 | Vertical Information and support inside the organisation. Process to inform management and other internal stakeholders about the project activities |
| 5 | Identification and enrolment of professionals for service provision |

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the recruitment process: Low Complexity Use Case (RUC1) |
| INPUTS | |
| OUTPUTS | Candidate for recruitment |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Two routes for users recruitment: 1.- Identification of potential users at primary care consultations of GPs and nurses belonging to different healthcare centers where previous training of the project has been held. 2.- Promotion campaign through different media (e.g. webpage, regional app) for self-recruitment |
| 2 | Evaluation of the inclusion and exclusion criteria through an (online) questionnaire (under evaluation) |

| | |
|--------------------|---|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the recruitment process: Mid Complexity Use Cases (RUC2, RUC5, RUC7) |
| INPUTS | To be defined |
| OUTPUTS | List of users candidates |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Identification of potential users from different sources - Primary care doctors - Social care organisations - Emergency unit This identification is driven by the health and social care professionals who have been previously informed about the project, know the patient profile and propose participants that could benefit from the project. The identification of patients is done continuously and not in a specific period of time. |
| 2 | Evaluation of the inclusion and exclusion criteria at health and social level |
| 3 | If inclusion criteria and no exclusion criteria are met, patient is considered as a candidate |

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the recruitment process: High Complexity Use Cases (RUC2, RUC5, RUC7) |
| INPUTS | |
| OUTPUTS | Candidate for recruitment |

PROCEDURE DESCRIPTION

| | |
|----------|---|
| 1 | Identification of potential users at three different locations: 1.- Emergency units. Patients who have attended to the emergency unit due to an exacerbation of their chronic condition 2.- Hospital floor of the specialties that have patients suffering from one condition related to the RUCS (pneumology, internal medicine or cardiology) 3.- Chronic care unit. Patients who are under evaluation or admitted to this unit can also be candidates for recruitment |
| 2 | Evaluation of the inclusion and exclusion criteria at health and social level |
| 3 | If inclusion criteria and no exclusion criteria are met, patient is considered as a candidate |

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the recruitment process: COVID-19 Use Cases |
| INPUTS | |
| OUTPUTS | Candidate for recruitment |

PROCEDURE DESCRIPTION

| | |
|----------|--|
| 1 | Identification of potential users under two different scenarios: 1.- COVID-19 Home. Patients who are diagnosed with COVID-19 and attend either the emergency services of the hospital or the ones at the healthcare centers because they are suffering a worsening of their condition. 2.- COVID-19 Center. Patients who are admitted to COVID-19 center that are either diagnosed with COVID-19 or are under a process of recovery from a recent infection. |
| 2 | Evaluation of the inclusion criteria: worsening of their condition that does not require hospital admission but requires follow up to some extent |
| 3 | If inclusion criteria and no exclusion criteria are met, patient is considered as a candidate |

Table 5: Aragon consent form process procedures

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the consent form process Low Complexity (RUC1) |
| INPUTS | Patient considered as candidate once he/she fills the inclusion and exclusion criteria |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | <p>The procedure has not been finished yet, but two options are being taken into account.</p> <p>1.- For those patients recruited at the Primary Care Center, an information sheet and consent form will be available. GP and / or nurse will also provide information on the project and solve any questions related to his/her participation</p> <p>2.- If the recruitment is made through self-referral, the application will include an information sheet about the project implications. Once the patient is invited to read this information sheet, he/she will also be invited to pose questions related to the project through a telephone number and/or an email.</p> |
| 2 | <p>1.- For those patients recruited at primary care, once the participant claims that he/she has understood the project and the consequences that his/her participation implies, he is invited to sign the informed consent form.</p> <p>2.- For self-referral patients, At the end of the information sheet, there will be a consent form that the patient will be invited to accept /decline before continuing the process.</p> |
| 3 | When the patient signs the informed consent, he is considered as a participant of GK project. |

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the consent form process Mid Complexity Use Cases (RUC2, RUC5, RUC7), High Complexity Use Cases (RUC2, RUC5, RUC7) and COVID 19 Use Cases |
| INPUTS | Patient considered as candidate once he/she fills the inclusion and exclusion criteria |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Patients considered as candidates are informed about the project and their participation on it. They are invited to read the informed consent, to pose questions based on it. They can ask for some time to do the decision and also to share this information with their carers and/or relatives (e.g. son/daughter) |
| 2 | Once the participant claims that he/she has understood the project and the consequences that his/her participation implies, he is invited to sign the informed consent form. |
| 3 | When the patient signs the informed consent, he is considered as a participant of GK project. |

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the consent form process High Complexity Use Cases (RUC2, RUC5, RUC7) |
| INPUTS | Patient considered as candidate once he/she fills the inclusion and exclusion criteria |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Patients considered as candidates are informed about the project and their participation on it. They are invited to read the informed consent, to pose questions based on it. They can ask for some time to do the decision and also to share this information with their carers and/or relatives (e.g. son/daughter) |
| 2 | Once the participant claims that he/she has understood the project and the consequences that his/her participation implies, he is invited to sign the informed consent form. |
| 3 | When the patient signs the informed consent, he is considered as a participant of GK project. |

2.1.2.3 Ensuring COVID19 prevention

SALUD is the public provider of healthcare in the Aragón region. The public health department of the regional government of Aragón has developed and updates continuously a [set of guides which purpose is to inform citizens and organisations on how to deal with different situations related to COVID-19, specially on the prevention side.](#)

The mid-complexity use cases for COVID-19 consist on the provision of integrated care with the collaboration of socialcare organisations. The GK training sessions including social care professionals have also included contents of two guides included in the aforementioned directory: the [guide to prevent COVID-19 in the Home Support Service](#) and [the guide to prevent COVID-19 at the elderly homes without COVID-19 cases](#).

Among all the measurements that have been taken in order to prevent COVID19 transmission, two of them are highlighted below:

- All the f2f training sessions have been held adopting the necessary preventive measures (number of people per room, 2m distance, use of hidro-alcoholic solutions for hands, use of masks)
- Training sessions for social care providers Include hygienization procedures for all the devices that are shared among different end-users

2.1.2.4 Technology acquisition

Table 6: Aragon technology acquisition procedures

| | |
|--------------------|---|
| RESPONSIBLE | SALUD |
| PURPOSE | Supply of technologies |
| INPUTS | Description of the need |
| OUTPUTS | Purchase orders and tracking of the equipment |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | <ul style="list-style-type: none"> • Allocation of budget • Description of the need of the equipment to be acquired • Description of the technical and functional requirements of the equipment to be acquired |
| 2 | Selection of the adequate procedure for the purchase of the devices following Spanish Law for public procurement (LCSP Law 9/2017, 8 th November) |
| 3 | Launch of tender for acquisition |
| 4 | Evaluation of proposals |
| 5 | Selection of the winning offer |

2.1.2.4.1 Device purchase details

Details of technology acquisition is provided below per RUC.

RUC 1

- 2000 health promotion apps (€0)
- 2000 smartphones (€0)
- 10 tablets (€1230)

RUC 2

- 6 pulsi-oximeter (€0)
- 6 Blood Pressure Monitor (€594)
- 6 thermometer (€390)
- 6 ECG (€0)
- 20 smart patch (€6050)
- 8 tablets (€1896)
- 30 telemonitorization platform (€1620)

RUC 5

- 6 pulsi-oximeter (€0)
- 6 Blood Pressure Monitor (€594)
- 6 thermometer (€390)
- 5 ECG (€0)
- 4 weight scales (€382.4)
- 20 smart patch (€6050)
- 8 tablets (€1896)
- 30 telemonitorization platform (€1620)

RUC7

- 10 pulsi-oximeter (€0)
- 10 Blood Pressure Monitor (€990)
- 10 thermometers (€650)
- 10 ECG (€0)
- 10 glucometers (€0)
- 20 Smart patch (€6050)
- 4 tablets (€948)
- 40 telemonitorization platform (€2160)

RUC 9 (COVID)

- 45 pulsi-oximeter + respiratory frequency (€17424)
- 115 telemonitorization platform (€25040)
- 40 smartwatch (€10040)
- 2 tablets (€500)
- 4 tablets (€948)

2.1.2.5 Installation procedures

Table 7: Aragon installations procedures

| | |
|--------------------|---|
| RESPONSIBLE | SALUD |
| PURPOSE | Operation of the technical infrastructure |
| INPUTS | To be defined |
| OUTPUTS | Technical infrastructure ready |

| | PROCEDURE DESCRIPTION |
|-----------|---|
| 1 | Identification of key personnel at AST, CGIPC, SALUD |
| 2 | Identification of key personnel from technical companies |
| 3 | Definition of the hardware requirements for the server(s) where the application should be deployed |
| 4 | Virtual creation and setup of the pre-production server based on the requirements |
| 5 | Installation and setup of the software, database environment(s) and services needed for the application operation. Network configuration, |
| 7 | Setup and configuration of the client application(s) to work against the pre-production server(s) |
| 8 | Validation test(s) of the solution in the preproduction environment. Security tests. |
| 9 | Replication of the pre-production server in the production environment. Additional setup, network configuration |
| 10 | Setup and configuration of the client(s) application to work against the production server(s) |
| 11 | Validation tests in the production environment. Security tests |
| 12 | DMP from technological companies |
| 13 | Integration of elements with the EHR |
| 14 | Integration of elements with GK |

2.1.2.6 Pre-testing

NOTE: Pre-testing phase in the Aragón pilot will only include a few tasks because of the characteristics of the project itself:

- The TRL of the technologies in GK should be high (in market or close to market).
- There are strict time constraints in the project that do not allow several iterations for improving products through the direct interaction of patients with the technology providers. The pilot itself can be considered a proof of concept where the satisfaction with the technology will be assessed.
- Tests are being held with end users during the technical adaptations and installations phase

Pre-testing phase will specially be used to check the direct use by the end-users.

Table 8: Aragón pre-testing procedures

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | To be defined |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Validation tests with professionals in pre-production environment |
| 2 | Validation tests with end-users in pre-production environment |
| 3 | To be defined |

2.1.2.7 User training and support

Previous projects held at SALUD have shown that training procedures should be as close as possible to the service provision in order to minimize the need for additional training and to keep a good progress in the work related to the project.

Table 9: Aragón user training procedures

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | User training procedures generic for all the use cases |
| INPUTS | To be defined |
| OUTPUTS | User training procedures to be adapted for each RUC |

| | PROCEDURE DESCRIPTION |
|----------|---|
| 1 | Preparation of training material and recruitment procedures. |
| 2 | Training materials for Social care and Home assistant professionals |
| 3 | Training materials for Healthcare professionals (provision and contact center) |
| 4 | Training materials for patients / end users |
| 5 | Training sessions for Social care and Home assistant professionals (in those RUCs where needed) |
| 6 | Training sessions for Healthcare professionals (provision and contact center) |
| 7 | Training sessions for Technical professionals (support and contact center) |

Table 10: Aragon user support procedures

| | |
|--------------------|---|
| RESPONSIBLE | SALUD |
| PURPOSE | User support procedures for all the use cases |
| INPUTS | To be defined |
| OUTPUTS | Definition of the user support procedures (to be adapted for each RUC and to be also done during the running phase) |

| | PROCEDURE DESCRIPTION |
|----------|--|
| 1 | Identification of the professionals responsible for support in the local coordination team |
| 2 | Identification of professionals for the contact center (technical, social and clinical profiles) |
| 3 | Design of the protocol for the contact center |
| 4 | Design of the protocol for training and solving technical and operational issues |
| 5 | Creation/adoption of an email address and identification of the telephone numbers for the contact center |

2.1.3 Running phase

2.1.3.1 Operation procedures (execution and maintenance)

Table 11: Aragon operation procedures

| | |
|--------------------|--|
| RESPONSIBLE | SALUD |
| PURPOSE | Definition of the operation process |
| INPUTS | To be defined |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Periodic report to the management of the Innovation, Digital Transformation and Users Attention Unit and to the management of the Healthcare Area(s) where the pilot is taking place |
| 2 | Periodic report to the management team of the GK project |
| 3 | Continuous operation of the project coordination team of the next processes that will take place in each RUC |
| 4 | Recruitment process (identification of candidates, assessment of clinical and social status for those RUCS where needed), informed consent signature, technology provision and training) |
| 5 | Service provision |
| 6 | Support (contact center: technical, clinical, operational) |
| 7 | Integration with the GK infrastructure |
| 8 | Data capture for evaluation |
| 9 | Risk assessment and contingency plan |
| 10 | Inclusion of predictive models in service provision |

2.1.3.2 Termination procedures

- **Mid complexity (RUC2,5,7).** Service provision is expected to continue once the evaluation period finishes and also once the project ends.
- **High complexity (RUC2,5,7).** Service provision depends on the use of expensive disposable technology. Patients are expected to be included in the pilot for periods between 5 and 30 days. Once this period ends, they will be offered the opportunity to continue in the mid complexity use cases. The continuation of the service once the project ends will depend very much on the results that are obtained from the evaluation of the project. The cost-benefit evaluation of the service based on the technology will provide specific information on the sustainability of the service outside the project scenario.
- **COVID-19 (RUC9).** Patients may be eligible to be included in the pilot for short periods of 5 to 10 days. The specific COVID-19 use case is expected to finish once the incidence of the virus decreases. The devices, the technologies, the protocols and the evaluation results will be used to give the technology a secondary use, probably in terms of the mid complexity use cases.
- **Low complexity (RUC1).** The technological adaptations that are being held in this RUC1 case have as its main objective to obtain a KET that may serve to the important number of users that should be included in the project and also to last once the project finishes.

2.1.3.3 Evaluation procedures

Evaluation is going to be held

- a. at operational level through the follow up of impact indicators as requested in task D7.2
- b. through the assessment KPIs that will also be included in the evaluation in the context of the MAFEIP tool

2.2 BASQUE COUNTRY pilot plan

2.2.1 Planning

For the 'Imported RUCs' from other pilots and 'New RUCs' activities, please set up the arrows based on your times.

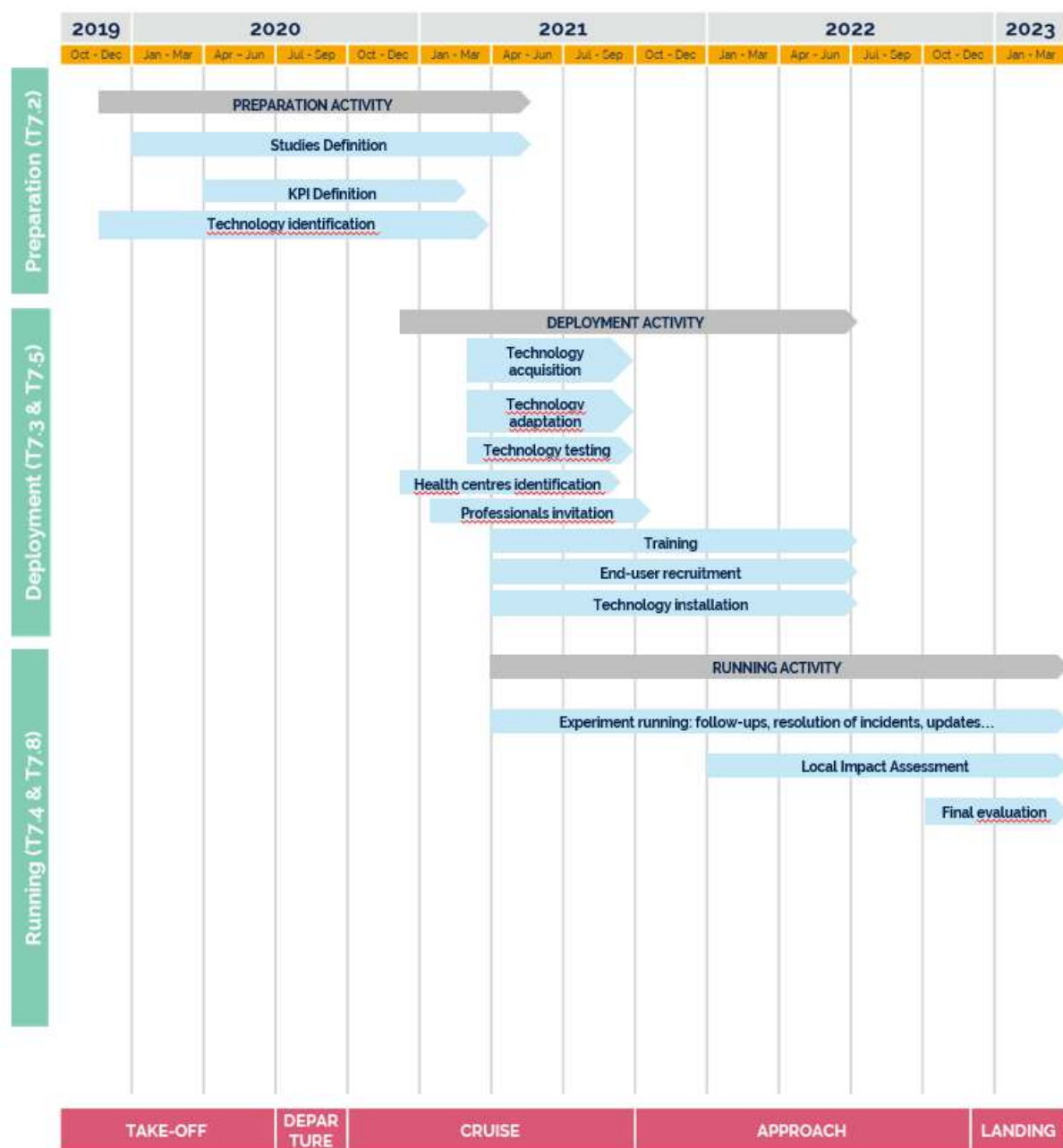


Figure 3 – OSAKIDETZA's piloting phases

2.2.2 Deployment phase

2.2.2.1 Deployment phases per RUC

At organizational level:

1. Acquisition of technologies for UC3, UC4, UC6: Smartwatch (SAMSUNG), Smartphone (SAMSUNG), SmartThings (SAMSUNG), CGM System FreeStyle Libre 2 (ABBOTT), Parkinson's Disease STAT-ON holter (S4C), Blood Pressure Monitor (Beurer). The order is unknown.
2. Internal testing of the technologies by the corresponding investigator teams.
3. The Blood Pressure Monitor from Beurer must be tested previously to verify its integration within the platform.
4. RUC3 - Diabetes deployment: 50 users wearing the Smartwatch, Smartphone and CGM System.
5. RUC4 - Parkinson's Disease deployment: 50 users wearing the Smartwatch, Smartphone and CGM System.
6. RUC6 - Stroke Prevention deployment: 25 users wearing the Smartwatch and Smartphone. The SmartThings and Blood Pressure Monitor will be installed in their homes.
7. RUC6 - Stroke Identification cases creation: Recording of 360° videos with different scenes of stroke events to be reproduced in Virtual Reality Glasses.
8. RUC6 - Stroke Identification deployment: 20 users receiving education in stroke symptoms identification through the 360° videos in one session in-place (in the health care service).
9. RUC1 and RUC7 - Organize meetings with the managers of the IHO (Integrated Health Organization)
10. RUC1 and RUC7 - Approval by the managers of the IHO
11. RUC1 and RUC7 - Prepare a list of participating health centers
12. RUC1 and RUC7 - Organize introductory meetings with the managers and professionals of health centers.
13. Prepare material for recruitment campaign in RUC1 and its deployment
14. Prepare material for the professional's training session (RUC1 MAHA app and RUC7 Checkthemeds):
 - RUC1 - Prepare MAHA app leaflet and MAHA tutorial
 - RUC7 - Prepare My treatment app leaflet and user tutorial, Checkthemeds tutorial, study information, app information and technical information of My treatment app
15. RUC1 and RUC7 - Organize training sessions with professionals
16. RUC1 and RUC7 - Professionals contact candidates and invite them to the study
17. RUC1 and RUC7 - Candidates who agree to participate in the study receive study information and app information.
18. Intervention deployment:
 - RUC1 - 10.000 candidates will use their own devices and download the MAHA app
 - RUC7 - 500 candidates will use their own devices (Smartphones) and download the My treatment app
19. RUC7- 50 professionals will use Checkthemeds on their own computers

At technological level:

RUC1

- Agree on the adaptations for MAHA app
- Agree on a delivery plan for MAHA app adaptation
- Prepare content for MAHA app adaptation
- Adaptation of MAHA app
- Pre-testing MAHA app and MAHA dashboard with end-users and professionals respectively

RUC3 Diabetes

- To integrate Abbott GCM system within the platform
- Pre-test the technology integration by the IT team
- To train the investigator team
- To install the tech in the clinician's consultation
- To train and follow-up the patients intensively during the first week

RUC4 Parkinson's Disease

- To integrate STAT-ON holter (S4C) within the platform
- Pre-test the technology integration by the IT team
- To train the investigator team
- To install the tech in the clinician's consultation
- To train and follow-up the patients intensively during the first week

RUC6 Stroke Identification

- Perform the videos in 360° with actors
- Transfer the videos to the Virtual Reality glasses

RUC 6 Stroke Prevention

- Pre-test the SmartThings by the IT team
- To train the investigator team
- To install the tech in the patients' homes
- To train and follow-up the patients intensively during the first week

RUC7

- For Checkthemedes: to develop of an interoperability module to communicate between web services of Osakidetza and Checkthemedes
- For My treatment: to develop an adaptation to track user data
- Pre-testing Checkthemedes with professionals

2.2.2.2 User recruitment strategy and consent procedures

Table 12: Basque Country recruitment process procedures for professionals and patients (RUC1 and RUC7)

| | |
|--------------------|--|
| RESPONSIBLE | Osakidetza and Kronikgune |
| PURPOSE | Define the recruitment process |
| INPUTS | Inclusion/Exclusion criteria: List of candidates List of professionals |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION for RUC3, RUC4 and RUC6: only patients | |
|--|--|
| 1.1 | The patient attend to the clinician's consultation in a routinary visit and meets the inclusion criteria |
| 1.2 | The clinician makes a phone call to the patients that meet the inclusion criteria |
| 2 | The clinician invites the patient to participate in the study and explain the intervention |

Table 13: Recruitment process procedures for patients (RUC3, RUC4, RUC6)

| PROCEDURE DESCRIPTION for RUC1 and RUC7: professionals and patients | |
|---|---|
| 1 | The research team will invite the health centres of the IHOs and the social services that have agreed to participate in the study. |
| 2 | The research team will draw up a preliminary list of people who meet the inclusion and exclusion criteria and belong to the health centres of the IHOs that have agreed to participate. |
| 3 | Social service workers and PA professionals will contact candidates (by phone or mail) to invite them to participate and to introduce them to the study (objectives, necessary involvement, evaluation, etc.). Candidates will be provided with the information sheet explaining the nature of the study, a sheet with the functionalities of the application on the promotion of healthy lifestyle habits, how to use it, how to download it to their mobile device (mobile phone or Tablet), the URL address to download the application from the Gatekeeper platform and a contact address. Additionally, posters will be distributed in the participating health centres, so that people can auto-administer the application. In this case, the study-related information will be available at the application. |

| PROCEDURE DESCRIPTION for RUC1 and RUC7: professionals and patients | |
|---|--|
| 4 | Candidates who agree to participate in the study will have to download the application and will be asked to sign the informed consent form |
| 5 | The research team will draw up a preliminary list of people who meet the inclusion and exclusion criteria for the study. |
| 6 | This preliminary list will be reviewed and verified by Primary Care professionals (GPs, nurses and pharmacists) from the participating health centres and a definitive list of candidates to participate in the study will be created. |
| 7 | Primary Care professionals will contact study candidates to invite them to participate and to present the study (objectives, necessary involvement, evaluation, etc). In addition, they will be provided with the information sheet explaining the nature of the study and the informed consent. |
| 8 | Candidates who finally agree to participate in the study will be asked to sign the informed consent form. |

Table 14: Basque Country consent form process procedures

| | |
|--------------------|------------------------------------|
| RESPONSIBLE | Osakidetza and Kronikgune |
| PURPOSE | Define the consent form process |
| INPUTS | Instruction Sheet and Consent Form |
| OUTPUTS | Consent Form signed |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1.1 | In the clinician's consultation, candidates receive a verbally explanation of the study, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation, etc.) and will be allowed to ask questions to the person who is explaining the study. |
| 1.2 | The patient agrees to be part of the study by signing the informed consent |
| 1.3 | Candidates may be provided with a study information sheet (written summary) and they will have time to consider whether or not to participate in the research. |
| 1.4 | Once candidates have had all their questions answered and have agreed to participate in the study, candidates should sign the consent form. |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1.5 | The consent document to use in this intervention will be provided to candidates in order to be signed. |
| 1.6 | Candidates will be provided with a copy of the consent form. |
| 2.1 | Telematically, candidates who agree to participate in the study will have to download the application and will be asked to sign the informed consent form. |
| 2.2 | Study information sheet will be available in the MAHA application (written summary) |

2.2.2.3 Ensuring COVID19 prevention

For the studies that implies visits to the clinician's consultation at the hospital, the regulations established by the Government will prevail against the execution of the study in order to prioritize the safety of patients. The procedure to attend the visits to the clinician's consultation during the study will follow the hospital's policy.

For the studies that can be remotely deployed, specifically:

RUC1

- Social service workers and PC professionals will contact candidates by phone or mail to invite them to participate and to present the study. Additionally, posters will be distributed in the participating health centres, so that people can auto-administer the application.
- During the follow-up of the study, professionals will be able to check participants' evolution through MAHA dashboard.
- Baseline evaluation and final evaluation information will be gathered through MAHA app, so no face-to-face care visits will be required.

RUC7

- Professionals will contact candidates by phone or mail to invite them to participate and to present the study.
- During the follow-up of the study, professionals will check participant situation by phone, if deemed necessary by the practitioner, face-to-face care visits will be arranged with the participant.
- Focus groups and semi-structured are envisaged to be developed virtually.

2.2.2.4 Technology acquisition

The acquisition process depends on the technology to be acquired. In the case of Smartwatch, Smartphone, Smarthings, Holter and holter's license, we are awaiting a response from the project coordinator as to whether we can pass on part of our budget for equipment to the technology providers, so that they are the ones who contribute to the project against their budget.

For the rest of the equipment to be purchased, the process is as follows:

Table 15: Basque Country technology acquisition procedures

| | |
|--------------------|--|
| RESPONSIBLE | Biocruces |
| PURPOSE | Supply of technologies |
| INPUTS | The inputs will be defined by the requirements of the GK project, the consortium and Biocruces Bizkaia |
| OUTPUTS | Purchase orders and tracking of the equipment |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | The purchase of goods or contracting of services must be carried out through the Institute's Purchasing Area, through the Purchasing Platform located on the Institute's website, where the researcher enters with his/her passwords. |
| 2 | <p>The purchase request is associated with a flow of authorisations in the Purchasing Platform depending on the project to which the expenditure is attributed and the type of good to be purchased.</p> <p>In this sense, the purchase requires the authorization of the Project Manager, who will verify that there are funds in the project for the purchase that the technology fits in the project and verifies that it is an expense directly related to the project.</p> <p>For its part, the Purchasing Area, in addition to carrying out the procurement process, verifies that the purchase complies with the terms of Law 9/2017, of 8 November, on Public Sector Contracts, which transposes into Spanish law the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014 (https://www.boe.es/eli/es/L/2017/11/08/g)</p> |
| 3 | Once the supplier sends the order, the purchasing area monitors the date of receipt or any incidents that may arise until the reception. |
| 4 | Once the reception is completed and it fulfils the requirements, it must be formalized in order to process the corresponding invoice. |
| 5 | <p>The Institute's Economic Management Area will send the invoice to the supplier.</p> <p>Once verified the invoices accordance with the purchase order, payment will be made within the stipulated deadlines.</p> |

2.2.2.4.1 Device purchase details

Details of technology acquisition is provided below per RUC.

RUC 1

- 5000 ACTIVAGE-MAHA apps (€0)
- 5000 smartphones (€0)

RUC3

- 50 smartwatches (€8930)
- 50 smartphones (€6498)
- 50 blood Pressure Monitor (€-)
- 50 Glucose Monitoring System (€0)

RUC4

- 50 smartwatch (€8930)
- 50 smartphones (€6498)
- 30 SENSE4CARE Holter (€92160)

RUC6

- 25 smartwatch (€4465)
- 25 smartphone (€3249)
- 25 Blood Pressure Monitor (€-)
- 25 SAMSUNG SmartThings Hub (€877)
- 100 SAMSUNG SmartThings Motion sensor (€1247)
- 100 SAMSUNG SmartThings Plug (€1264)
- 75 SAMSUNG SmartThings multipurpose sensor (€771)
- 25 SAMSUNG SmartThings Temperature/Humidity Sensor (€239.75)
- 25 SAMSUNG SmartThings Tracker (€513.1)
- 3 Virtual glasses (€0)

RUC7

- 50 Checkthemeds apps (€15000)
- 500 Smartphones (€0)
- 500 Mi tratamiento app (€0)

2.2.2.5 Installation procedures

Table 16: Basque Country installations procedures

| | |
|--------------------|--|
| RESPONSIBLE | Osakidetza, Biocruces and Kronikgune |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | The pre-testing is OK |
| OUTPUTS | Simple installation instructions |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The technologies of UC3 and UC4 will be installed in the clinician's consultation (Osakidetza) during the Baseline (Visit 0). |
| 2 | The RV Glasses of UC6 Stroke Identification do not need to be installed. |
| 3 | The technologies of UC6 Stroke Prevention will be installed at home by an IT of the Research Institute of Biocruces. |
| 4 | MAHA application for RUC1 will be integrated into Gatekeeper platform. Participants will be able to download MAHA application on their own devices from Google play and App store. In the case of professionals, they will use MAHA dashboard through Gatekeeper platform. UPM will be in charge of integrating it. |
| 5 | <p>In RUC7:</p> <ul style="list-style-type: none"> - Checkthemeds: installation is not required. Checkthemeds will develop a specific interoperability module and API. These developments will be carried out by Checkthemeds technology. Professionals will be able to make enquiries to Checkthemeds web service from the environment of Osakidetza. Checkthemeds technology will be in charge of any integration procedure required. - My treatment: Participants will be able to download My treatment application on their own devices from Google play and App store. This application is linked to the pharmacological treatment prescribed (in Osakidetza) to the patient through an interoperability module already in place. |

2.2.2.6 Pre-testing

Table 17: Basque country pre-testing procedures

| | |
|--------------------|--|
| RESPONSIBLE | Osakidetza, Ibermática and Kronikgune |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | Manufacturer instructions and integration in the GK platform |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Pre-test of 2 days by the technicians and the corresponding research teams |
| 2 | Pre-test with members of the target study population (professionals and end-users). |
| 3 | Installation of technologies as detailed in point 4.5 of this document |
| 4 | Follow-up of the intervention groups to verify a proper use of the technologies |

2.2.2.7 User training and support

Table 18: Basque Country user training and support procedures

| | |
|--------------------|--|
| RESPONSIBLE | Osakidetza, Ibermática, Biocruces and Kronikgune |
| PURPOSE | Develop user's manuals and training procedures |
| INPUTS | Prepare training material |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Day 0, Baseline: Training in technologies characteristics and instructions by the health care professionals, social service workers, or the IT team, depending on the UC |
| 2 | Research team and project management group: responsables for preparing the materials for the training session, where appropriate |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 3 | First week: Phone assistance by health care professionals, social service workers, or the IT team, depending on the UC |
| 4 | Following: If necessary, assistance in-place (hospital, health center or home, depending on the UC) |

2.2.3 Running phase

2.2.3.1 Operation procedures (execution and maintenance)

Table 19: Basque Country operation procedures

| | |
|--------------------|--|
| RESPONSIBLE | Osakidetza and Kronikgune |
| PURPOSE | Definition of the operation process |
| INPUTS | Technology acquisition |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The pilot will start with the RUC that first gathers the necessary technology |
| 2 | Users will receive instructions on site and through regular phone-calls |
| 3.1 | Risk 1. Adaptation to technologies due to age → Permanent support |
| 3.2 | Risk 2. To achieve with statistical significance all the objectives due to sample size → To consider it as an interim analysis that allows the development of a trial with a larger sample and a longer follow-up period |
| 3.3 | Risk 3. Covid-19 → To prioritize the patient safety over the trial |

2.2.3.2 Termination procedures

At the end of the project, the devices provided will be collected to allow the closing and editing of the database, analysis of the data of the patients and main caregivers, and preparation of the final study report. An evaluation will be carried out at the end of the interventions to assess the impact of the intervention. Promising results are expected to gather from the intervention. These results will help to make decisions with policy makers on whether to continue with the implementation of these digital solutions

2.2.3.3 Evaluation procedures

Table 20: Basque Country evaluation procedures

| | |
|--------------------|---|
| RESPONSIBLE | Osakidetza, Biocruces and Kronikgune |
| PURPOSE | Define the evaluation process |
| INPUTS | Data Variables Type of evaluation Timepoints of evaluation |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1.1 | For monitorized interventions (RUC3, RUC4 and RUC6), along the studies, the patients will periodically attend to the clinician's consultation to be evaluated. Results will be reported in the Data Collection Notebook: physical examination, clinical data, questionnaires (quality of life, diet, satisfaction, morbidity, ...) |
| 1.2 | Besides, the intervention groups will be monitorized during the study |
| 1.3.1 | Statistic analysis of the data from the monitorized data (Intervention), and the Data Collection Notebook for Control and Intervention groups |
| 1.3.2 | KPIs analysis |
| 2.1 | RUC1 aims to evaluate the effectiveness (impact of the digital solution on the promotion of healthy habits and well-being), user experience (accessibility, satisfaction, usefulness and appropriateness of the app) and to measure application usage of a mobile health application to promote healthy lifestyle habits over 12 months. |
| 2.2 | The evaluation will be developed at three timepoints: at the beginning of the study (June-October 2021), when participants are recruited and before the intervention starts. The final assessment will be conducted after the end of the study (May-September 2022) for study participants and professionals involved. |
| 2.3 | A mixed methods approach will be employed, which refers to a research methodology that advances the systematic integration of quantitative and qualitative data into a single investigation. |
| 2.4 | Quantitative analysis |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| | <p>The analysis will be carried out on the basis of available data for all persons participating in the study; data from the intervention and control group will be evaluated, including for cases lost to follow-up in the intervention group.</p> <ul style="list-style-type: none"> - Baseline assessment will be conducted before the intervention begins. This evaluation will be based on quantitative data information collected through questionnaires in the app. - Final evaluation will be carried out at the end of the defined monitoring period. This evaluation shall be based on information from quantitative data collected through questionnaires in the app server. |
| 2.5 | <p>Qualitative analysis</p> <p>The use of qualitative methodology is intended to allow participants to detail their experience with the mobile health app. The qualitative analysis will be carried out at the end of the intervention to find out satisfaction, acceptability and usefulness of the app, and adherence to the app.</p> |
| 3.1 | <p>The RUC7 aims to evaluate over 12 months the effectiveness (impact of digital solutions on participants' health), user experience (accessibility, satisfaction, usefulness and appropriateness of the applications) and to measure digital solutions usage of two applications to optimize drug therapy and adherence to treatment.</p> |
| 3.2 | <p>In the case of the intervention group, participants will be assessed at the beginning of the study (June-September 2021), when they are recruited and before the intervention starts, and then followed up for one year (October 2021-September 2022). At mid-term assessment related to the use of the <i>My Treatment</i> mobile app and the <i>CheckTheMeds</i> website will be conducted and the final assessment will be conducted after the end of the study (May-September 2022) for study participants.</p> |
| 3.3 | <p>A mixed methods approach will be employed, which refers to a research methodology that advances the systematic integration of quantitative and qualitative data into a single investigation.</p> |
| 3.4 | <p>Quantitative analysis</p> <ul style="list-style-type: none"> -Baseline assessment will be carried out before the intervention begins. This assessment will be based on information from quantitative data collected through questionnaires and from the Osakidetza administrative database. -Mid-term evaluation will be based on information from quantitative data collected from the applications. -Final evaluation will be carried out at the end of the defined monitoring period. This evaluation will be based on information from quantitative data collected through questionnaires, from the Osakidetza administrative database and from the application servers. |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| | For the control group, data will be collected from the Osakidetza administrative database for a defined period of time. |
| 3.5 | <p>Qualitative analysis</p> <p>Qualitative techniques will deepen the evaluation process, the use of qualitative methodology aims to have participants detail their experience with the <i>CheckTheMeds</i> web application and the <i>My Treatment</i> mobile health application.</p> <p>Qualitative analysis will take place at the end of the intervention and will be conducted through semi-structured interviews or focus groups with participants and professionals to understand: ease of use, satisfaction, acceptability and usefulness of the apps, and adherence to the apps.</p> |

2.3 CYPRUS pilot plan

2.3.1 Planning

Below, the detail plan for this pilot site.

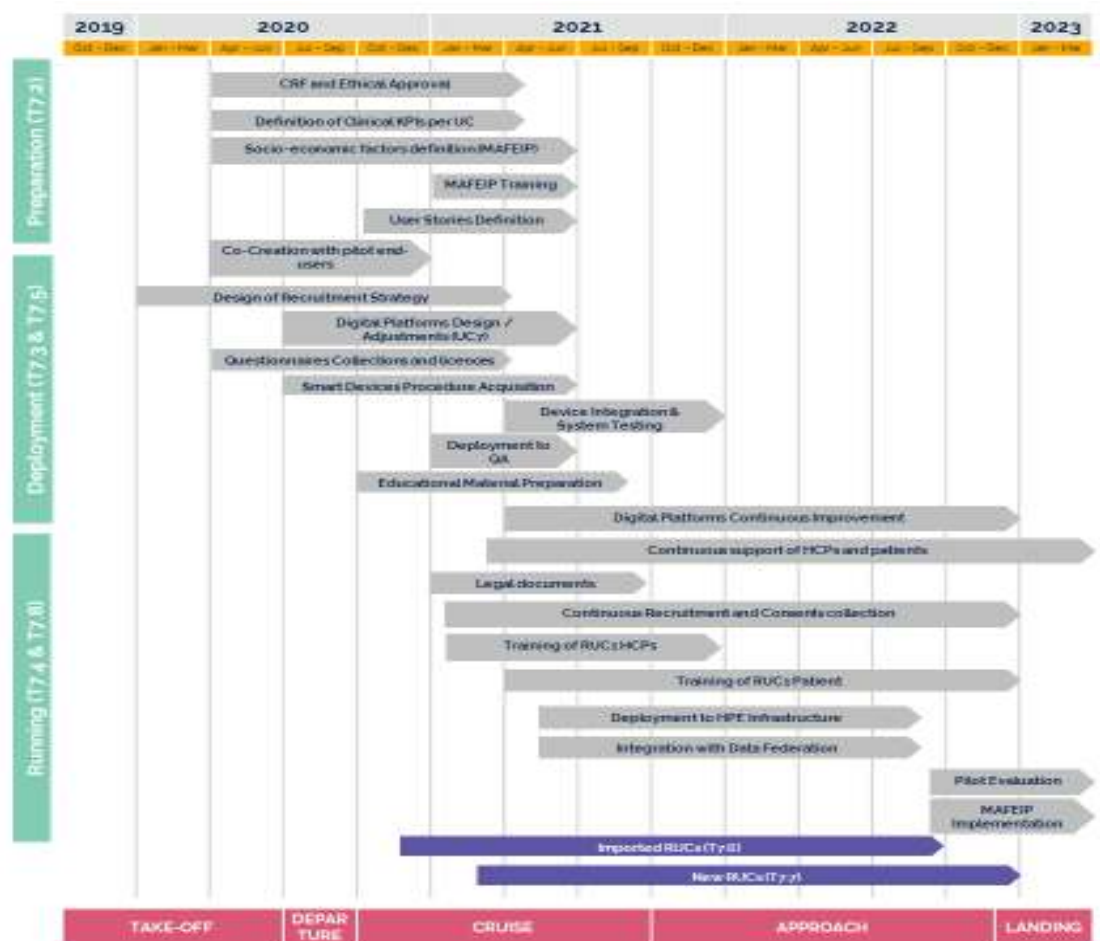


Figure 4 – Cyprus piloting phases

2.3.2 Deployment phase

2.3.2.1 Deployment phases per RUC

This is a pilot randomized controlled trial (RCT) with between and within subject design. The steps needed to deploy the full pilot solution are:

1. Participants Selection: We will use a Stratified Random Sampling method to identify the sample of the study and to create subgroups based on gender, age range, and stage of illness for both organizations.
2. Consent to the study: Once potential participants are identified, patient's capacity to consent to participate will be established with a capacity assessment undertaken by a registered professional. Where participants are considered to lack capacity to consent, a representative will be contacted in the form of a friend, family member or independent advocate that can consider consent as part of a best interest decision.

3. Assigned into groups: Once potential participants consent to participate to the study, the participants will be assigned into groups. The control group will receive standard health care with no technical support, where the intervention groups will receive platform and device services provided to each user. In that respect, Intervention Group 1 will receive no real-time feedback, where Intervention Group 2 will unhand with real data and notifications.
4. Internal testing: Internal testing will be run from both organizations with 5 users assigned to each group (the total participants for the internal testing will be 30 – 15 from each organization).
5. Baseline assessment: All questionnaires will be completed and patients and caregivers in intervention groups will receive the devices.
6. Intervention phase: 136 patients with dementia (AMEN) and 470 cancer patients (PASYKAF) will be given the equipment. For a six-week period self-report, physiological data and physiological parameters will be gathered using the wearable devices and the platform's app.
7. Follow up at 6 weeks phase: All questionnaires will be completed and in addition patients, caregivers and healthcare professionals in intervention groups will complete questionnaires related to usability, feasibility and acceptability of technology.
8. Devices will return at PASYKAF: All devices will be return back at PASYKAF premises.

2.3.2.2 User recruitment strategy and consent procedures

Table 21: Cyprus recruitment process procedures

| | |
|--------------------|---|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Define the recruitment process |
| INPUTS | Gender, age range, and stage of illness |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The patients of both organisations will be screened to fulfil the inclusion criteria (i.e., face difficulties with co-morbidities). |
| 2 | <p>The users involved in the pilot are cancer patients (+50) and dementia patients (+65) that face comorbidities, professional caregivers or relatives that have the role of the informal caregivers and health care professionals of the participating organizations.</p> <p>In more detail:</p> <ol style="list-style-type: none"> i. Two hundred five patients with mild, moderate, and severe dementia (n = 205) aged 65+ and seven hundred high complexity level cancer patients (n = 700), aged 50+, will participate in the study. People with dementia will be recruited by the |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| | <p>"Archangelos Michael" nursing home (AMEN) and people with cancer will be recruited by the Cyprus Association of Cancer Patients and Friends (PASYKAF).</p> <p>ii. One hundred health care professionals (n = 100) from both organisations will participate in the study. This includes professions of psychologists, social workers, speech therapists, nursing staff, physiotherapists, gymnasts and art therapists (e.g., music therapists, paint therapist, theatre therapist).</p> <p>iii. Two hundred and fifty cancer patients' caregivers (n=250) and one hundred and forty-five dementia patients' caregivers (n= 145) will also participate in the study.</p> |

Table 22: Cyprus consent form process procedures

| | |
|--------------------|----------------------------------|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Define the consent form process |
| INPUTS | Information forms and Signatures |
| OUTPUTS | Consent Forms Signed |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Once potential participants are identified, patient's capacity to consent to participate will be established with a capacity assessment undertaken by a registered professional not part of the study. The proposed study faces a high probability that patients will not be able to consent to participate due to the nature of dementia and cancer. |
| 2 | Where participants are considered to lack capacity to consent, a representative will be contacted in the form of a friend, family member or independent advocate that can consider consent as part of a best interest decision. Participants who lack capacity will not be able to participate if their representative withdraws from the study. It is justifiable to pursue the proposed research even if individuals are not able to provide consent themselves as the benefits of potentially improving quality of life outweigh the alternative of not taking part. |

2.3.2.3 Ensuring COVID19 prevention

To ensure appropriate COVID-19 protection for potential users, both organizations are in line with the measurements announced by the ministry of health in the Republic of Cyprus. At this moment, both organizations have restricted their activities. Specifically, AMEN has terminated services due to COVID – 19. Only inpatients are now receiving care, while PASYKAF provides health care only to patients in their end-of-life period who decided to die home. Therefore, mitigation meters developed to face difficulties in the patient's recruitment:

- Social service workers and HCPs will contact potential users by phone or mail to inform them about the pilot deployment. Additionally, a social media campaign will be running.
- During the baseline and post-intervention assessment, HCPs will assess users through the Cyprus Pilot Platform made by CERTH.

2.3.2.4 Technology acquisition

For the acquisition of the devices the internal procedure of the Organisation will be used.

The procurement process sets out the basic principles regarding the supply of materials and services to be followed by the Cypriot Pilot. The process applies to all employees, suppliers, contractors and consultants participating at any point in the procurement process.

For this process the PASYKAF Head of Technology Department is responsible.

The purpose of the process is the purchase of materials and services in an efficient, effective and financially interesting way, as well as the definition of the duties and responsibilities of the PASYKAF (Cypriot Pilot's site) staff members who take part in it.

Below you can see the steps and the outcome of each output generated.

Table 23: Cyprus technology acquisition procedures

| | |
|--------------------|---|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Supply of technologies |
| INPUTS | Internal procedure (purchase of materials and services) |
| OUTPUTS | Purchase orders and tracking of the equipment |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | <p>Completion of Purchase Application form</p> <p>By recognising the need to purchase equipment/services, a staff member completes the form.</p> <p>The completed and signed form is sent to the member of the Management of the Association who is authorized to approve the specific market based on the approval limits of purchases of the Association.</p> |
| 2 | <p>Purchase Application Evaluation</p> <p>Upon receipt of the Purchase Application form, the relevant member of the Association's Management evaluates the application according to the budget, goals and needs of the Association and proceeds to approve or reject it.</p> <p>For any clarifications, the member of the Management communicates with the staff member who submitted the application.</p> |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| | <p>The approval or rejection of the application is noted in the Purchase Application form which is signed and sent to the staff member who submitted the application.</p> <p>The signed form is archived.</p> |
| 3 | <p>Submission of Bids</p> <p>With the approval of the application for the purchase of equipment, the staff member selects a number of suppliers (at least 3) to whom a request will be sent.</p> <p>The selection of suppliers is based on experience from past or existing partnerships between the Organisation after a relevant market research.</p> <p>The staff member then prepares a written communication for the tender request which will be sent to the selected suppliers. The communication presents relevant information regarding the equipment (e.g. technical specifications, contact details, etc.).</p> |
| 4 | <p>Receipt and evaluation of offers</p> <p>Upon receipt of the offers from the suppliers, the staff member proceed to their evaluation.</p> <p>The evaluation criteria (technical specifications, price, etc.) are applied depending on the equipment related to the market.</p> <p>An offer evaluation team is be set up which will include the staff member who requested the purchase, the relevant Provincial Director, the General Manager and the Chief Accountant of the Organisation.</p> <p>Upon completion of the evaluation, it is decided which supplier will be awarded the bid.</p> |
| 5 | <p>Updating bidders</p> <p>Upon completion of the evaluation of tenders, the staff member shall inform all tenderers who have submitted a tender in writing of the results of the evaluation.</p> <p>All Communication is archived.</p> |
| 6 | <p>Purchase of materials / Concluding an agreement</p> <p>Upon informing the bidders, the staff member communicates with the supplier selected for the purchase of equipment for the conclusion of a relevant agreement.</p> <p>With the confirmation of the above data, the agreement is signed by the General Manager of the Organisation and is sent to the Accounting Office for archiving. A copy of the signed agreement is sent to the supplier and the responsible staff member.</p> |
| 7 | <p>Payment of supplier invoice</p> <p>Upon completion of the purchase of equipment, the staff member sends the invoice to the Accounting Office.</p> |

PROCEDURE DESCRIPTION

Upon receipt of the invoice, the Accounting Office confirms that the purchase of equipment has been approved in accordance with the present procedure, the invoice is based on the terms of the signed agreement with the supplier (if any) and proceeds to pay the invoice based on the Organisation's payment policy and the entry of the relevant accounting entries.

The receipt to be delivered by the supplier is archived by the Accounting Office.

2.3.2.4.1 Device purchase details

Details of technology acquisition is provided below.

RUC 7

- 156 activity watches (€24804)
- 110 tablets v1 (€17490)
- 88 tablets v2 (€13992)
- 55 smartphones (€6545)

2.3.2.5 Installation procedures

The acquired technologies which will be used are:

- Activity Tracker – Garmin Venu Sq. 37mm is a wearable watch suitable for Health Monitoring (i.e. wrist-based heart rate, daily resting heart rate, abnormal heart rate alerts, all-day stress, relaxation reminders, relaxation breathing timer, sleep)
- Tablet – LENOVO Tab M10 10.1" 64GB
- Tablet – LENOVO Tab M10 4G LTE 10.1" 32GB
- Mobile XIAOMI Redmi 9C

The technologies will be installed mainly in the two intervention groups as follows:

- Full technology group. Heart rate will be measured as an indicator of stress levels. Heart Rate & sleep patterns will be recorded continuously using Activity Tracker – Garmin Venu Sq. 37mm. Mobility will be measured continuously using the same smartwatch that will record the daily steps and the physical activity of the patient.
- For the limited technology group, patients and caregivers will record this data but will not receive tailored interventions according to the data they provide. For the full technology group, patients and caregivers will also receive tailored interventions according to the data they provide.

The technologies will be installed by the Head of Technology Department and will be placed to patient's private homes and one site's hospice with the help of HCPs. By the end of each interval the devices (smart watches/tablets/mobiles) will be returned by the HCPs and the Head of Technology will prepare them for the next interval

For the HCPs, tablets will be given at the start of the pilot which will be user throughout the timeline of the pilot.

Table 24: Cyprus installations procedures

| | |
|--------------------|--|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | Acquired technologies |
| OUTPUTS | Simple installation instructions |

| | PROCEDURE DESCRIPTION |
|----------|--|
| 1 | Technology Acquisition |
| 2 | Technology Log (Serials, description) |
| 3 | Programming of devices |
| 4 | Installation to HCPs |
| 5 | Installation to patients' private homes & hospice |
| 6 | Returning of devices at the end of interval period |
| 7 | Installation of devices to next cluster |

2.3.2.6 Pre-testing

Table 25: Cyprus pre-testing procedures

| | |
|--------------------|---|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | 156 Activity Tracker - Garmin Venu Sq 37mm 110 Tablet - LENOVO Tab M10 10.1" 64GB 88 Tablet - LENOVO TAB M10 4G LTE 10.1" 32GB 55 Mobile - XIAOMI Redmi 9C |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Running a pilot test recruiting a small sample of our target population, going through every step of the experiment process, checking potential errors and issues. Internal testing will be run from both organizations with 5 users assigned to each group (the total participants for the internal testing will be 30 – 15 from each organization). |
| 2 | All questionnaires will be completed imitating the pilot data collection process. |

2.3.2.7 User training and support

Training workshops will be continually offered to patients, caregivers and healthcare professionals. For this process, the PASYKAF Head of Education Department is responsible.

Table 26: Cyprus user training and support procedures

| | |
|--------------------|--|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Develop user's manuals and training procedures |
| INPUTS | Educational Material, Devices Manuals, Guidelines |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Educational material based on the devices manuals purchased will be developed (PASYKAF-AMEN) |
| 2 | Platform manuals (videos and pdf) will be developed - CERTH |
| 3 | Health care professionals will be trained in the use of digital devices (smartwatches, tablets, mobiles) chosen for the deployment of the pilot. (PASYKAF-AMEN) |
| 4 | Users will be trained in the use of platform developed by CERTH (PASYKAF-AMEN) |
| 5 | Patients randomised to intervention groups will attend at least two training sessions. Sessions were practice-based and will take place one week apart. The training aimed to ensure that patients had a theoretical understanding of the devices and platforms used to ensure they will be able to fill in the questionnaires uploaded to the platform, following also the instructions provided by the smartwatch. (PASYKAF-AMEN). |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 6 | Health care professionals will attend a recruitment training program. The recruitment to randomized controlled trials (RCTs) would be challenging and, health professionals can experience difficulties in conveying positive potential patients to participate (low rates of recruitment). The training program consisted of workshops with a mix of health professionals covering trial-specific issues such as communicating key RCT concepts to patients. The recruitment training goal will be to increase actual recruitment rates and patient understanding, satisfaction, or informed consent levels. (PASYKAF-AMEN). |

2.3.3 Running phase

2.3.3.1 Operation procedures (execution and maintenance)

Table 27: Cyprus operation procedures

| | |
|--------------------|--|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Definition of the operation process |
| INPUTS | Recruitment Strategy Plan |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Patients pre-screening in line with the inclusion criteria (age and health condition) using an excel file. |
| 2 | HCPs enrolment receiving two questionnaires in Google forms/Microsoft Forms |
| 3 | Inform consent and enrol the control group subjects. |
| 4 | Installation of the technologies |
| 5 | Enroll the intervention groups |
| 6 | Participants feedback throughout the process to troubleshoot issues that come up during the pilot program |

2.3.3.2 Termination procedures

Once the project is finished, we will follow the “Dissemination and Exploitation” section of the H2020 Online Manual to communicate the EU-funded scientific excellence. For academics and clinicians, we will seek to publish papers in top-tier conferences (e.g., ACM SIGCHI), and journals (e.g., The Gerontologist). We will strive to make our publications at gold open access level (e.g., via internal funding). Alternatively, we will follow a green open access strategy, making available the pre-prints in existing public repositories (e.g., Research Gate).

Based on the aforementioned results we will evaluate whether the system will continue to run or not. We will also decide if the technology will continue to operate by the pilots or if will be used as alternatives.

No additional support is expected to need since we expect to test the sustainability of the system within the data collection period of GATEKEEPER which is 18 months for our trial.

2.3.3.3 Evaluation procedures

Table 28: Cyprus evaluation procedures

| | |
|--------------------|---|
| RESPONSIBLE | Cyprus Pilot |
| PURPOSE | Define the evaluation process |
| INPUTS | Self-report questionnaires, physiological data and physiological parameters will be gathered using the wearable devices and the platform's app. |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Baseline assessment will be run, all self-report questionnaires will be completed and patients and caregivers in intervention groups will receive the devices. |
| 2 | During the intervention (6-week period), self-report questionnaires, physiological data and physiological parameters will be gathered using the wearable devices and the platform's app. |
| 3 | Follow up at the end of 6 weeks will run with all the self-report questionnaires to be completed. In addition, patients, caregivers and healthcare professionals in intervention groups will complete questionnaires related to usability, feasibility and acceptability of technology. |

2.4 GREECE pilot plan

2.4.1 Planning

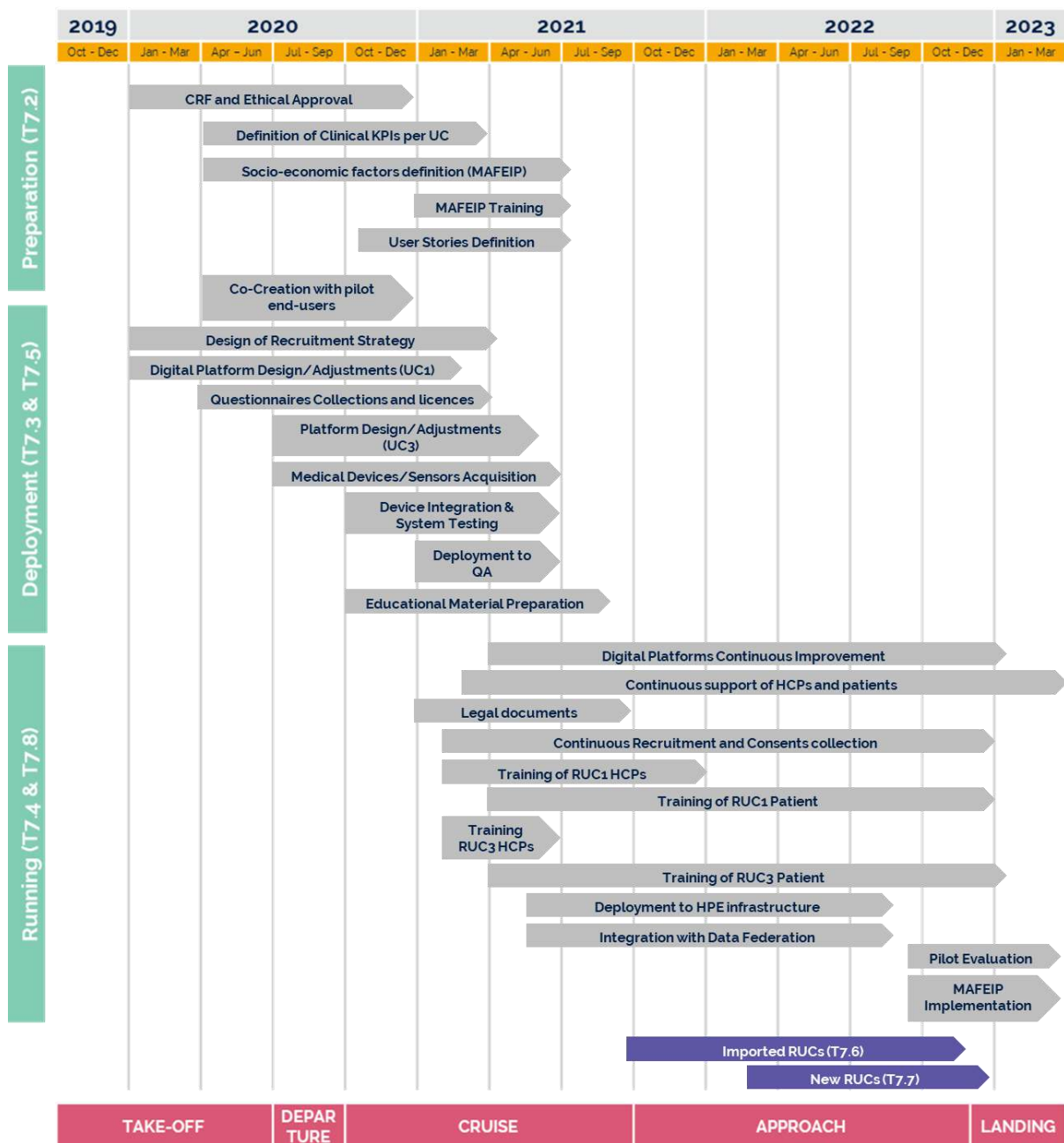


Figure 5 – Attica and Central Greece piloting phases

2.4.2 Deployment phase

2.4.2.1 Deployment phases per RUC

1. Co-creation workshops with a small group of participants (HCPs and patients) for user preferences collection
2. Adjustments in the digital platforms based on the output of the co-creation workshops. Different types of requirements identified for UC1 and UC3.

3. Collection of the necessary questionnaires to support the CRF, the evaluation of the pilots and the user technology acceptance.
4. Medical devices plan and acquisition
 - a. 220 Fitbit Weight scales will be delivered to 320 patients (in groups)
 - b. 200 Fitbit smartwatched will be delivered to 320 patients (in groups)
 - c. 320 Tablet devices will be delivered to 640 patients (in groups)
 - d. CGM devices from Menarini will be delivered to 150 patients (UC3)
 - e. 10 Biobeat wrist bands will be delivered to 150 patients (UC3 – in groups of 10)
5. Internal testing of the integrations
6. Internal testing of the system with a small group of end-users (15HCPs, patients and technology testers)
7. Deployment of the platform to the QA Server (will remain until the deployment to the HPE infrastructure)
8. Preparation of the educational material for the use of the platform (videos and pdfs)
9. Preparation of educational material for the training of the HCPs and the patients on system and devices usage
10. Design recruitment strategy, identify person with existing technologies to be included in the pilot study.

2.4.2.2 User recruitment strategy and consent procedures

Table 29: Greece recruitment process procedures

| | |
|--------------------|--------------------------------------|
| RESPONSIBLE | HUA (Attica) , DCCG (Central Greece) |
| PURPOSE | Define the recruitment process |
| INPUTS | Recruitment strategy plan |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Identification of participants with the inclusion criteria by the individual HCPs |
| 2 | Inform the potential participants about the pilot study, present benefits and impact (use of the related educational material) |
| 3 | Sign the consent form |
| 4 | Include the participant in the Recruitment strategy plan in order to identify their group and start date |
| 5 | Update the central pilot repository with the information |

Table 30: Greece consent form process procedures

| | |
|--------------------|--------------------------------------|
| RESPONSIBLE | HUA (Attica) , DCCG (Central Greece) |
| PURPOSE | Define the consent form process |
| INPUTS | Recruitment strategy plan |
| OUTPUTS | Consent Form |

| | PROCEDURE DESCRIPTION |
|----------|---|
| 1 | Potential participants accept the invitation for participation |
| 2 | Consents (per institute) are signed by the participants |
| 3 | Consents are stored in HCPs repositories in (digital and hardcopy formats) |
| 4 | The participants of the intervention groups provide e-consent through the platform to the HCPs in order to track the progress monitored by the platforms and the data collected from the integrated medical devices and sensors |

2.4.2.3 Ensuring COVID19 prevention

Participants in UC1 will be enrolled through HCPs private offices that comply with COVID-19 protection guidelines.

HCPs will promote remote monitoring through the digital platform in order to reduce the interaction with the patients and their risk to COVID-19.

HCPs beyond Attica and Central Greece will be enrolled into the UC1 pilot in order to include as many participants as possible through a more country regions.

The pilot aims on engaging caregivers into the remote monitoring process in order to minimize the risk in high-risk patients (UC3)

2.4.2.4 Technology acquisition

Table 31: Greece technology acquisition procedures

| | |
|--------------------|---|
| RESPONSIBLE | CERTH |
| PURPOSE | Supply of technologies |
| INPUTS | Procurement Plan |
| OUTPUTS | Purchase orders and tracking of the equipment |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Identify the optimal number of devices to be used by the pilot participants |
| 2 | Identify internal and external technology providers |
| 3 | Prepare the procurement procedures ~ 1Month of administrative preparations |
| 4 | Publish procurements – 1 Month of offer collection |
| 5 | Acquire the devices based on the best offer |
| 6 | Distribute the devices according to the Recruitment strategy plan |

2.4.2.4.1 Device purchase details

Details of technology acquisition is provided below per RUC.

RUC 1

- 310 weight scales (€11000)
- 240 smartwatches (€32000)
- 510 tablets (€34100)

RUC 3

- 10 tablets (€1100)
- 10 wrist bands (€0)
- 166 chest monitor patches (€0)
- 350 CGM sensors (€23100)
- 14 CGM transmitters (€2800)

2.4.2.5 Installation procedures

Table 32: Greece installations procedures

| | |
|--------------------|--|
| RESPONSIBLE | CERTH, HUA, DCCG |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | Recruitment strategy plan |
| OUTPUTS | Simple installation instructions |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Integrate medical devices and sensors APIs to the digital platform |
| 2 | Containerise the system |
| 3 | Deploy the system to the server |
| 4 | Test local devices integration with the system |
| 5 | Deliver devices set to HCPs for assignment to participants |
| 6 | Collect devices by the end of the intervention period |
| 7 | Configure the devices before re-distributing |

2.4.2.6 Pre-testing

Table 33: Greece pre-testing procedures

| | |
|--------------------|--|
| RESPONSIBLE | CERTH, HUA, DCCG |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | Digital System, medical devices, sensors |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Deploy a stable version of the system |
| 2 | Identify a small group of system end-users |
| 3 | Train the users to the system |
| 4 | Deliver credentials for testing |
| 5 | Support the participants and collect the issues |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 6 | Deliver user acceptance questionnaires |
| 7 | Collect and prioritise the feedback for system improvement |

2.4.2.7 User training and support

Table 34: Greece user training and support procedures

| | |
|-------------|--|
| RESPONSIBLE | CERTH, HUA, DCCG |
| PURPOSE | Develop user's manuals and training procedures |
| INPUTS | Educational Material |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Prepare platform manuals (videos and pdf) - CERTH |
| 2 | Prepare material for HCPs and patients training (HUA, DCCG) |
| 3 | Arrange small group HCP training to the platform (HUA, DCCG) |
| 4 | Train the HCPs for enrolling and training the patients to system and device use (HUA, DCCG) |

2.4.3 Running phase

2.4.3.1 Operation procedures (execution and maintenance)

Table 35: Greece operation procedures

| | |
|-------------|--|
| RESPONSIBLE | CERTH, HUA, DCCG |
| PURPOSE | Definition of the operation process |
| INPUTS | Recruitment strategy plan |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Enrol HCPs in RUC1 |
| 2 | HCPs will identify the potential participants, inform them about the study and share the consent if they agree to participate |
| 3 | Participant will be included in the Recruitment strategy plan of the pilot where Start/End dates will be assigned. This is affected by the capacity of the HCPs, the equipment availability and the availability of the participant. |
| 4 | Enrol HCPs in RUC3 |
| 5 | HCPs in RUC3 will enrol participants that are already identified |
| 6 | To ensure that 1000 participants will be enrolled in RUC1, HCPs from other regions will be included in the study. |

2.4.3.2 Termination procedures

The Greek pilot site is willing to exploit the system through the involved participants in order to identify a setting for the application beyond this pilots. Furthermore, we plan to have 6M and 12M follow up to the participants in order to identify whether the evaluation results are affected. The positive system evaluation will create a value based report that will be used by the participants in order to promote the use of the systems to other type of settings, such as day care centers where can be used by many communities in order to improve the quality of life to a significant number of population.

2.4.3.3 Evaluation procedures

Table 36: Greece evaluation procedures

| | |
|--------------------|--|
| RESPONSIBLE | BIO, CERTH, HUA, DCCG |
| PURPOSE | Define the evaluation process |
| INPUTS | Data collected by the pilot implementation |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Clinical, operational and socio-economic KPIs definitio |
| 2 | Clinical evaluation through data collection |
| 3 | Operational evaluation through data collection |
| 4 | Socio-economic evaluation through the MAFEIP tool |
| 5 | Dissemination of the results to national and international level |

2.5 MILTON KEYNES pilot plan

2.5.1 Planning

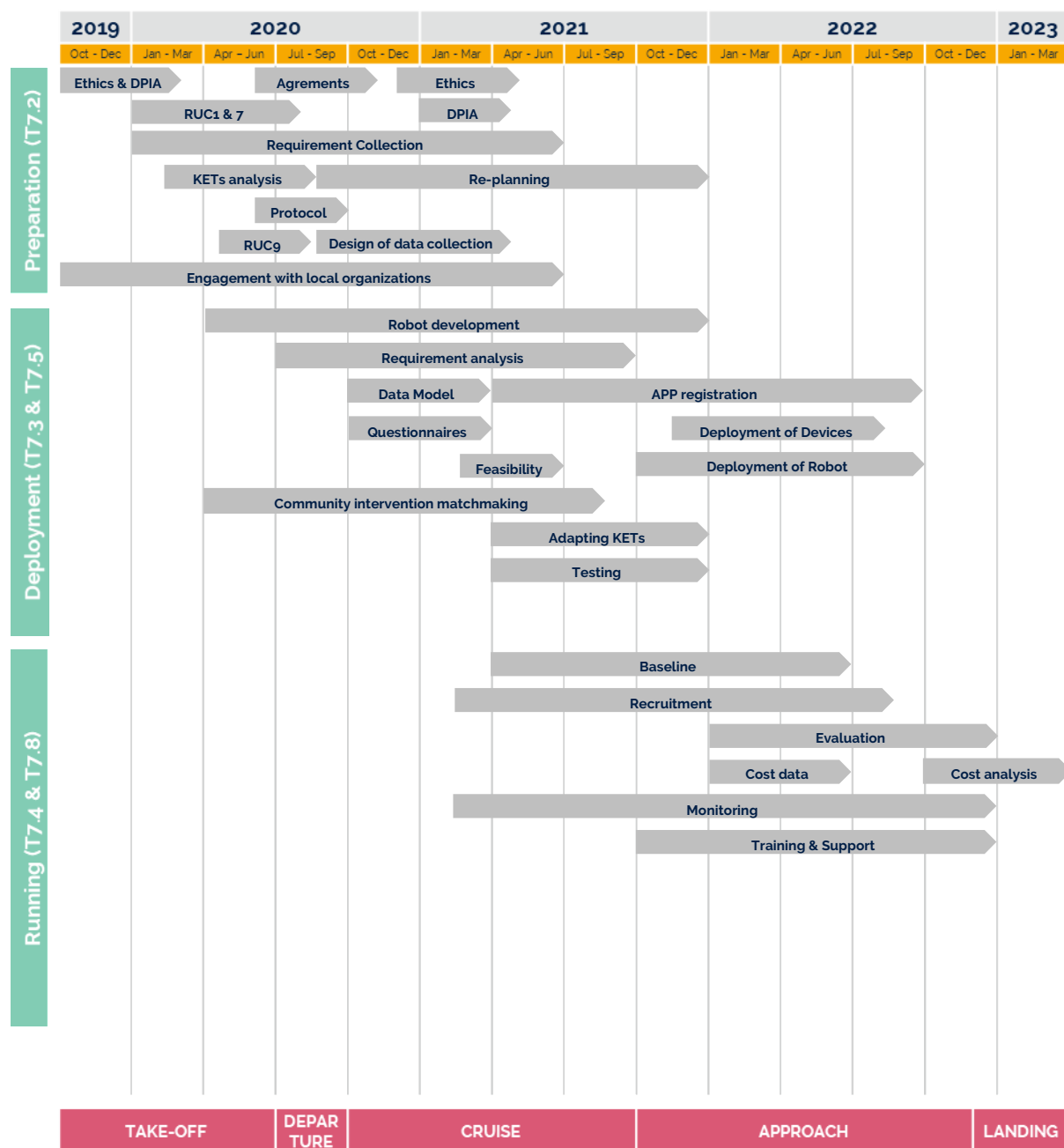


Figure 6 – UK piloting phases

2.5.2 Deployment phase

2.5.2.1 Deployment phases per RUC

RUC 1 & 9 requires adaptation of the pilot app (Samsung's ActiveAge) for supporting:

- 1) Supporting requests from users of community intervention
- 2) Matchmaking of requests with community caregivers & volunteers available
- 3) Monitoring requests in the community

While this work is ongoing, the App is being setup as it is (M18) for a first testing with community caregivers and the teams involved in the development of the functionalities. This testing phase will involve up to 30 caregivers in 2021.

RUC 7 requires the use of wearables (Samsung Smartwatch) and a robotic platform for the risks & hazard monitoring and activity support. In this view, the pilot App requires further adaptation concerning the integration with the robotic platform.

The deployment of the robotic platform is planned for M23. However, the current COVID-19 makes the deployment of robot risky as the robot requires extensive in person setup and monitoring in the participants homes. Thus, we started a pre-study on the robot platform in home environment (M18) aimed to assess the feasibility of a pre-configured robot that can be deployed "out of the box". Secondly, the pre-study is aimed to collect data about different home settings, objects and activities, as well to assess the potential use of robot in shielding elders during the COVID-19, e.g. taking care of door deliveries.

Due to the COVID-19 pandemic, we have to postpone the deployment of physical devices (and therefore the recruitment) involving elders of both RUC 1/9 and RUC 7. The deployment during 2021 will primarily concern the pilot app and involve community caregivers and volunteers, with the aim of supporting the adaptation and testing of KETs and integrations.

2.5.2.2 User recruitment strategy and consent procedures

Table 37: Milton Keynes recruitment process procedures

| | |
|--------------------|---|
| RESPONSIBLE | Open University & Woughton Community Council (WCC) |
| PURPOSE | Define the recruitment process |
| INPUTS | WCC's social services, list of local organizations working and volunteering in community care, lists of households and elders they currently support, social services open line and drop-in |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The first adopters will be the members of WCC social services team and the caregivers operating in collaboration with WCC in the pilot area. Target 15 caregivers Period: M18– M22 |
| 2 | The second pool of users identified are other community and volunteers organizations operating in Milton Keynes (MK) more generally. In this regard, we engaged with a second-level organization Community Action:MK coordinating the volunteer-organizations matchmaking and training in MK. Through the pilot app, we will provide them a channel to collect volunteers to be further engaged and trained. |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| | <p>Target : 15 caregivers</p> <p>Period: M22 – M26</p> |
| 3 | <p>The third pool of users will be the elders and households followed by the WCC social services and community caregivers. The caregivers will identify and propose the participation to the pilot based on their personal experience and understanding of the potential benefits.</p> <p>Target 70 elders</p> <p>Period: M24 – M32</p> |
| 4 | <p>Through the enrolment of elders, we will extend the participation to their families and close friends.</p> <p>Target to be defined in M24 accordingly with the evolution of the Covid-19 pandemic</p> <p>Period: M24 – M32</p> |
| 5 | <p>By exploiting local events (remote and face-to-face), we aim to extend the participation to other organizations and citizen groups, e.g. elders socialization gatherings and community events.</p> <p>Target to be defined in M28 accordingly with the evolution of the Covid-19 pandemic</p> <p>Period: M28 – M32</p> |

Table 38: Milton Keynes consent form process procedures

| | |
|--------------------|---|
| RESPONSIBLE | Open University & Woughton Community Council (WCC) |
| PURPOSE | Define the consent form process |
| INPUTS | Expression of interest collected via social services phone calls, remote meetings and face-to-face events |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Development of the consent form, legal validation and testing with WCC |
| 2 | Development of the information sheet in collaboration with WCC tailored for the communities in the pilot area |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 3 | Phone call to each contact collected as direct or indirect expression of interest. Pre-screening and first contact done by WCC. |
| 4 | Consent collected remotely of caregivers, organizations' community workers and elder's relatives, or in person, specifically for elders and community volunteers. The consent of social and community workers and professional caregivers will be collected by the OU, while the consent of elders and community volunteers will be collected by the OU and WCC. This consent will concern the processing of personal information (contacts) aimed to the setup and monitoring of the pilot. |
| 5 | Consents will be followed by the request of filling baseline anonymous surveys (e.g. quality of life) and the registration to the pilot app for the pilot data collection. The registration on the App will collect the information sharing agreement and terms of use concerning the data collection. |

2.5.2.3 Ensuring COVID19 prevention

Please describe how your site is ensuring appropriate COVID-19 protection measures to ensure that participants (patients and professionals) are safe and participation does not increase their risk of having COVID-19.

The UK Pilot works in collaboration with community social services instead of healthcare services. During the COVID-19 pandemic, social services and community activities are suspended as deemed not essential but a source of risks for both elders and workers. Of similar opinion is the Open University (lead of the UK pilot). In this regard, the OU prevention of COVID-19 included the closing of the campus from March 2020 and for the full duration of the pandemic and, through its ethics committee, a suspension of all ethics approval involving face-to-face activities (from March 2020 to August 2020) and now a guidelines for human research during the COVID-19¹. For instance, the ethics committee states

"Where participants or researchers are shielding due to underlying conditions, or shielding someone in their household, there should not be any face to face contact.

A list of these conditions can be found here:

<https://www.nhs.uk/conditions/coronavirus-covid-19/people-at-higher-risk-from-coronavirus/whos-at-higher-risk-from-coronavirus/>"

In this view, the target population mostly consists of frail subjects or people at risk. Furthermore, the setup and deployment of physical devices, recruitment and training cannot be done purely remotely but must involve a direct or caused face-to-face interaction (i.e., by a OU team member or by a member of the WCC). In this view and as

¹ <http://www.open.ac.uk/research/governance/ethics/human-research/ethics-review-process/conducting-human-research-during-covid-19>

result of an internal assessment of the COVID-19 risks & safety (see Annex X), we opted for postponing the recruitment and deployment involving elder participants to late 2021 and mostly in 2022. Differently, the engagement, recruitment and deployment from M18 to M24 involving caregivers will be carried out exclusively remotely. About the deployment, we will focus on the pilot App, but it will also involve pre-study with the robot platform, and the testing and training with wearable. In this regard, the main risks concern the robotic platform that must be configured and monitored in person. To mitigate this risk, the pre-study will be done in the households of OU researchers able to set up and monitor the robot platforms on their own or with little remote assistance. Differently, wearable devices will be shipped following the NHS guidelines to caregivers, while the setup and training will be done remotely.

2.5.2.4 Technology acquisition

Table 39: Milton Keynes technology acquisition procedures

| | |
|--------------------|---|
| RESPONSIBLE | Open University & Samsung UK |
| PURPOSE | Supply of technologies |
| INPUTS | Requirement analysis and RUCs definitions |
| OUTPUTS | Purchase orders and tracking of the equipment |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Study design with pilot partners (OU, WCC and Samsung UK), identifying 1) the type of data to collect, 2) the interactions with participants in the context of the intervention and 3) constraints for the KETs deployment and use |
| 2 | With the technical partner Samsung UK identify among their catalogue the available KETs to be use as is and to be used readapted to RUCs |
| 3 | Draft of the budget for KETs including intervention and monitoring devices as well as all equipment necessary to the deployment and use of the KETs (e.g., smartphones and tablets for the use of the pilot App by elders not owning a smartphone) |
| 4 | Draft of the scheduling of the deployment plan for each recruitment batch, considering the collected expression of interest Analysis with the recruitment partner (WCC) of the needs of each participant and definition of the devices including a projection for the next batch |
| 5 | Request fro quote by the technical partner Samsung UK. |
| 6 | Acceptance of the quote, payment and shipment of the devices |

2.5.2.4.1 Device purchase details

The following figures concern the devices acquisition under the hypothesis of scaling down the recruitment of elders from 130 to 70. In M24 and M28, the target will be revised up considering the evolution of the COVID-19 pandemic and the acquisition of devices could be consequently extended up to the doubling the number of devices smartphones, tablets and smartwatch.

Lastly, this list represents a reasonable pessimistic scenario in which all elders will require all devices, including either a smartphone or tablet for using the pilot app.

RUC 1 & 9

- 25 smartphone Samsung A51 (€194.25)
- 25 tablets Samsung Tab A 8" wifi (€115)
- 70 accounts to the Pilot App Samsung ActiveAge (€0)
- 50 smartwatch Samsung Galaxy Active 2 (€167)
- 20 smartphones/tablets owned by the caregivers

RUC 7

- 20 tablets Samsung Tab A 8" wifi (€115)
- 70 accounts to the Pilot App Samsung ActiveAge (€0)
- 1 robot platform with arm and gripper PAL Tiago Robot (€48,556)
- 2 robot platforms Turtle Bot 2 provided by the OU

2.5.2.5 Installation procedures

Table 40: Milton Keynes installations procedures

| | |
|--------------------|---|
| RESPONSIBLE | Open University, Samsung and Woughton Community Council |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | List of users enrolled |
| OUTPUTS | Simple installation instructions |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | During the COVID-19 pandemic, devices will be acquired by the OU, controlled, tested, ogged and shipped individually to the participant. The setup will be done remotely. |
| 2 | After the COVID-19 pandemic, devices will be acquired by the OU, logged and then given to WCC for distribution to participants. The setup will be done in person, one to one or in groups. |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 3 | A weekly remote and face-to-face drop-in session for fixing or troubleshooting will be provided to all participants. |

2.5.2.6 Pre-testing

Table 41: Milton Keynes pre-testing procedures

| | |
|--------------------|---|
| RESPONSIBLE | Open University |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | First batch of community and professional caregivers, pilot App, robot platform and scenarios |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The ore-study with the Robot platform will be used to setup and test the FHIR profile and data model by the OU (M18 -M22) |
| 2 | The use of the pilot APP with the first batch of caregivers will provide the opportunity to test the integration between the APP and the GATEKEEPER platform, and to test the data model by Samsung UK (M18 -M22) |
| 3 | The integration between the robot platform and the pilot app (robot connectyor) will be tested in collaboration between the OU and Samsung UK (M20 – M24) |
| 4 | The matchmaking mechanism for community volunteers and intervention will be tested firstly as a design (user scenarios) from M19-M20 and then as a running simulation (M22 – M24) involving the recruited caregivers and a multi-agent simulation of the community |
| 5 | The new version of the pilot APP integrating the robot connector and matchmaking mechanism will be tested with the pilot participants from M24-M26. |

2.5.2.7 User training and support

Table 42: Milton Keynes user training and support procedures

| | |
|--------------------|--|
| RESPONSIBLE | The Open University & Woughton Community Council |
| PURPOSE | Develop user's manuals and training procedures |
| INPUTS | Testing of the pilot app, robot pre-study and testing of the matchmaking mechanism |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The outcomes of testing of the different components will be used as input for the documentation, reporting the protocols defined with the caregivers, the main applicative scenarios and addressing the key issues emerging from the testing |
| 2 | Remote training will be provided to caregivers and community workers (OU) |
| 3 | Elders and volunteer participants will be given a face-to-face group training involving caregivers and participants already involved in the pilot (OU and WCC) |
| 4 | All participants will be provided a weekly slot for remote or face-to-face (when possible) support (OU and WCC) |

2.5.3 Running phase

2.5.3.1 Operation procedures (execution and maintenance)

Table 43: Milton Keynes operation procedures

| | |
|--------------------|--|
| RESPONSIBLE | The Open University, Samsung UK and Woughton Community Council |
| PURPOSE | Definition of the operation process |
| INPUTS | User registered on the Pilot APP, deployed devices, contact point and a weekly drop-in session |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | The monitoring of the technical system, use of the KETs and data collection, will be done by the technology providers (Samsung UK for the Pilot APP and wearables and the OU for the robot) The OU will lease a periodical report from them |
| 2 | The weekly drop-in session and the open line of the Woughton Community Council will measure the engagement of participants (e.g., show up to the sessions and requests for support). The issues and requests will be logged by WCC and analysed by the OU to identify the need for re-planning or corrections of the pilot plan |
| 3 | The recruitment and piloting is organised in batches of users with a delayed start. The evaluation of batches (e.g., the feedback from and interviews) will be used to monitor and identify potential issues in the pilot planning, technology and support to be addressed in the piloting of the following batches. |

2.5.3.2 Termination procedures

Following the conversation with our local partner (Woughton Community Council), they expect the system to be available after the end of the project as well as the devices to be left available for the community and elders. In this view, the aim of the collaboration is to extend the adoption of the solutions we design within the framework of GATEKEEPER to the wider population of the pilot area (~20.000) and in the newer Milton Keynes “estates” that do not benefit of community services and an organised, resilient community.

In this view, we expect the pilot app to be maintained and further developed and that the access to WCC and residents of the pilot area to be provided. Furthermore, the physical devices will donate to the WCC after the piloting, to be re-allocated as needed to the members of the community that would benefit from their use.

2.5.3.3 Evaluation procedures

Table 44: Milton Keynes evaluation procedures

| | |
|--------------------|-------------------------------------|
| RESPONSIBLE | The Open University |
| PURPOSE | Define the evaluation process |
| INPUTS | Data collection forms and Pilot APP |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The baseline will be collected from M18 through quality of life questionnaires and through the expression of interest form and the elders recruitment form. These data will be analysed for each recruitment batch and submitted for quality control to the large-scale pilot management |
| 2 | Collecting data about the costs for the community and local authorities of the effects of social isolation. This assessment will involve engaging with local police, fire police and social services to reconstruct these costs that are currently fragmented and spread among multiple actors |
| 3 | The pilot data collection will be collected through the pilot app and the followup questionnaire. The data will be aggregated and analysed at the end of each piloting batch and submitted for quality control to the large-scale pilot management |
| 4 | At the end of the piloting period (M37-M38) data of different batches will be integrated and archived. The final data will be used for the final MAFEIP assessment, following the protocol defined with Open Evidence. |

2.6 PUGLIA pilot plan

2.6.1 Planning

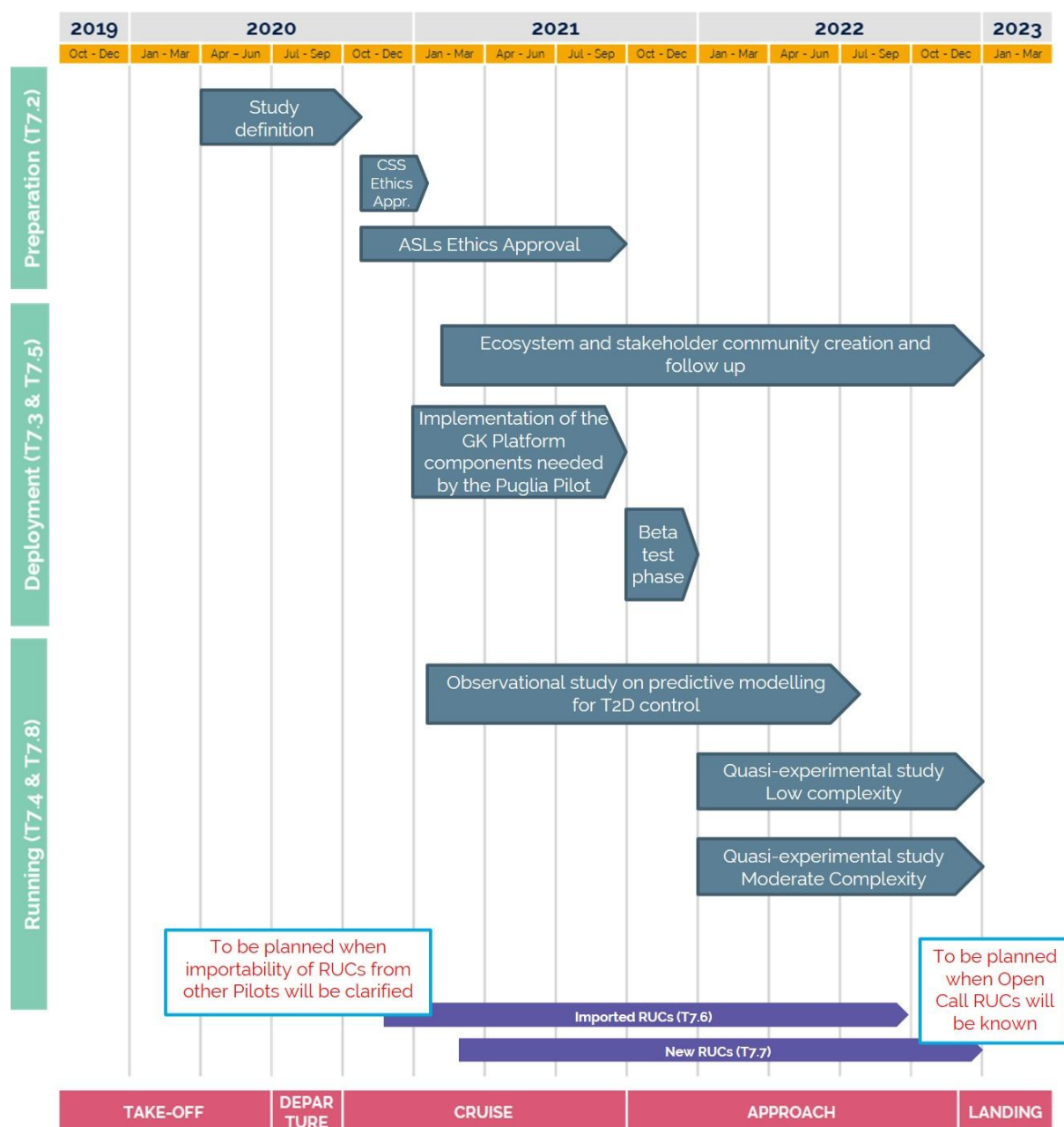


Figure 7 – Puglia piloting phases

2.6.2 Deployment phase

2.6.2.1 Deployment phases per RUC

The Puglia Pilot consists of two studies, that involve three experiments, planned to be executed as follows:

- **Observational study on predictive modelling for T2D control**
 - It addresses RUC#3.
 - It involves a population of T2D patients, cared for by partner CSS.

- It has been started on January 18, 2021, when the Ethics Approval for the study has been obtained and CSS could start recruitment.
- At the time of this writing, it is waiting for the project Platform Cluster to provide the necessary devices to be delivered to patients, in order to proceed with the first recruit.
- The study will last 12 months plus the recruitment accrual time (4 months at most)
- When the patient devices will be available, and before patient recruitment, CSS will perform a test session involving three team members who will test the solution with the following objectives:
 - To test that everything (from the hardware to the application) works smoothly.
 - To identify the most critical passages for the patients in terms of routine use of the technology (how to charge the devices, what services to turn on, e.g., Bluetooth, etc.)
 - To build a visual/video troubleshooting guide to help patients to independently solve common issues related to technology use.
- **Quasi-experimental study, including two types of sampling.**
 - **Low Complexity**
 - It addresses RUC#1.
 - It involves a population of 9,400 healthy elderly citizens (including intervention and control arms) from three Puglia provinces, as well as the stakeholders that form their surrounding community.
 - The recruitment of community stakeholders has been started on February 15, 2021, with the first actions of an ongoing Stakeholder Engagement Plan, to be conducted until December 31, 2021.
 - The recruitment of elderly citizens will start, as part of the above plan, by September 2021
 - By December 31st, 2021 the Ethics Approval, the participants recruitment and the implementation and deployment of the GATEKEEPER Platform Cluster components and other GATEKEEPER applications that are necessary to conduct the experiment intervention will be completed.
 - The intervention will start on January 1st, 2022 and will last for 12 months.
 - **Moderate Complexity**
 - It addresses RUC#2, RUC#3, RUC#5, RUC#7 and RUC#8, according to a quota sampling that reflects the stratification of the chronic patients enrolled in the regional CCM Puglia Care
 - It involves a population of 996 Puglia chronic patients (including intervention and control arms) from three Puglia provinces and the healthcare professionals that follow them up.
 - The recruitment of healthcare professionals and of patients will be conducted jointly with the Low Complexity case, along the same plan as previously described.
 - By December 31st, 2021 the Ethics Approval, the participants recruitment and the implementation and deployment of the GATEKEEPER Platform Cluster components and other GATEKEEPER applications that are necessary to conduct the experiment intervention will be completed.

- The intervention will start on January 1st, 2022 and will last for 12 months

2.6.2.2 User recruitment strategy and consent procedures

Table 45: Puglia recruitment process procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|--|
| RESPONSIBLE | Fondazione Casa Sollievo Della Sofferenza – IRCSS (CSS) |
| PURPOSE | Define the recruitment process |
| INPUTS | The list of patients followed by the Diabetology Unit of CSS that satisfy the inclusion criteria |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Recruitment: the PI selects potential participants to the study that meet the inclusion criteria outlined in the study protocol and invites them to the screening phase. If the patient is eligible, then he/she can be enrolled into the study. |
| 2 | Consent Form: each study participant receives an informed consent to be signed before starting the participation to the study. |
| 3 | Device delivery: at the time of the enrolment, each study participant will undergo a blood exam and will receive a Samsung smartwatch and a Samsung smartphone (the latter only in case the patient is not in possession of a compatible smartphone) which he/she must wear continuously until the end of the study. |
| 4 | Follow up Visits: at 6 and 12 months from enrolment, patient will be invited to undergo a follow up blood exam to collect the same values collected at baseline visit. |
| 5 | Study Close Out: at the end of the 12 months from enrolment, the patient will return the Samsung devices received. |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|--------------------------------|
| RESPONSIBLE | AReSS |
| PURPOSE | Define the recruitment process |
| INPUTS | Stakeholder engagement plan |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | <p>Stakeholder recruitment (February 2021-August 2021): institutional communication actions will be conducted to contact relevant institutional stakeholders on the regional territory (focusing on the engagement of the Local Health Authorities located in the provinces of Barletta-Andria-Trani, Lecce and Taranto) and to recruit them as part of the ecosystem community that will support the development of RUC#1. Such stakeholders include: Patient associations, Auser Puglia, Labour unions, Professional associations, Università della Terza Età ("<i>Third Age Universities</i>"), Non-profit organizations, Healthcare professionals, Social care professionals. Specific material is being prepared to illustrate the Pilot objectives and the role expected from these actors (what, when, where) in order to encourage their decision to enrol in the experiment. In particular, stakeholders' recruitment is being supported with the creation of general communication material –brochure, flyers, posters, roll up – and the setup of communication channels – Facebook page (set up on Feb 15th, achieved the 1,500 followers mark on Mar 22nd), a dedicated website on AReSS's third level domain, promotion on Pilot partners' own online channels.</p> <p>The stakeholder recruitment activities will also synergistically cooperate with valuation ad co-creation actions in Task T2.4, in cooperation with Partner UU.</p> |
| 2 | <p>Elderly citizens recruitment (September 2021-December 2021): leveraging the stakeholder community recruited as per item 1 above, in this step 9,400 Puglia healthy elderly citizens residing in the three provinces targeted by the experiment (Barletta-Andria-Trani, Lecce and Taranto) will be contacted and proposed to enlist as potential participants in the Low Complexity quasi-experimental study, respectively as intervention or control group subjects. Communication material to disseminate such call for participation will be distributed in locations attended by the targeted population, including public offices, health districts, senior centres and other socializing places, primary healthcare facilities. Online communication will also be tuned on the targeted population, with affiliation web pages, affiliation letters and online surveys.</p> <p>As in the case of the previous step, the elderly citizens recruitment activities will also synergistically cooperate with valuation ad co-creation actions in Task T2.4, in cooperation with Partner UU.</p> |
| 3 | <p>Stakeholders recruited in the Puglia Pilot ecosystem will be recorded in a registry manually managed by AReSS.</p> |
| 4 | <p>Given the high numbers involved (9,400 citizens), recruits of elderly citizens will be necessarily collected online. A relevant, GDPR-compliant online system for this need to be designed and setup by the end of August 2021. The Puglia Pilot team will investigate with technical partners involved in T7.5 how this will be best addressed as part of the work in such Task.</p> |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|--------------------------------|
| RESPONSIBLE | AReSS |
| PURPOSE | Define the recruitment process |
| INPUTS | Stakeholder engagement plan |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Stakeholder recruitment (February 2021-August 2021): This step jointly conducted with step #1 for the Low Complexity case, previously described. |
| 2 | <p>Patient recruitment (September 2021-December 2021): leveraging the stakeholder community recruited as per item 1 above, in this step 996 Puglia chronic patients residing in the three provinces targeted by the experiment (Barletta-Andria-Trani, Lecce and Taranto) will be contacted and proposed to enlist as potential participants in the Moderate Complexity quasi-experimental study, respectively as intervention or control group subjects. Such call for participation will be mainly vehiculated through healthcare professionals (HCPs), that care for such patients. This includes the preparation of a specific Info Kit for HCPs and the organization of relevant Webinars for them (including educational content on the new KETs experimented in GATEKEEPER, awarding associated credits for the National Program on Continuing Education in Medicine), so that they agree to participate in the experiment and also act as intermediaries, proposing recruitment to the patients they care for. HCPs will select patients on the basis of their enrolment in the Care Puglia CCM and of a related quota sampling of specific comorbidity profiles reflecting the stratification of the Puglia Care population, as specified in the experiment's protocol.</p> <p>As in the case of the Low Complexity case, the experiment participants recruitment activities will synergistically cooperate with valuation ad co-creation actions in Task T2.4, in cooperation with Partner UU.</p> |
| 3 | HCP recruits for the participation in the experiment will be recorded in a registry manually managed by AReSS, while patient recruits will be recorded in a registry manually managed by the HCPs that will support the recruitment, to be also shared with AReSS. |

Table 46: Puglia consent form process procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|---|
| RESPONSIBLE | Fondazione Casa Sollievo Della Sofferenza – IRCSS (CSS) |
| PURPOSE | Define the consent form process |
| INPUTS | List of recruited patients |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Give the subject information about the research and make sure he/she understands all the information. |
| 2 | Obtain the subject's voluntary informed consent to participate. |
| 3 | Continue to inform the subject throughout the research study in case something changes in the data processing/objective of the research. |
| 4 | Manage the possibility of withdrawal from the study |

Quasi-experimental study Low Complexity (RUC#1) and Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|---|
| RESPONSIBLE | AReSS, in cooperation with Technical Partners developing the apps that will be used by the participants |
| PURPOSE | Define the consent form process |
| INPUTS | List of recruited patients |
| OUTPUTS | Consent Form |

Table 47: Consent form process procedures

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Prepare the project information sheet and the informed consent forms, both for participation in the experiment and for privacy management. |
| 2 | Inform the participant about the project and the experiment for which participation is proposed. This step has to be conducted through online means, due to the number of subjects involved (9,400 citizens plus the stakeholders that form their ecosystem community) |
| 3 | Obtain the explicit consent from the participant. This step has to be conducted through online means, due to the number of subjects involved (9,400 citizens plus the stakeholders that form their ecosystem community). |
| 4 | Allow the participant to review information on the project along the duration of the experiment. |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| | This step has to be conducted through online means, due to the number of subjects involved (9,400 citizens plus the stakeholders that form their ecosystem community). |
| 5 | <p>Allow the participant to withdraw from the experiment and to have their personal data removed from project servers.</p> <p>This step has to be conducted through online means, due to the number of subjects involved (9,400 citizens plus the stakeholders that form their ecosystem community).</p> |

2.6.2.3 Ensuring COVID19 prevention

The Puglia Pilot Partners involved in recruitment and follow up of participants, as well as other entities external to the Consortium involved in such activities (e.g. local healthcare authorities and agencies, involved healthcare professionals), will ensure Covid-19 protection for all participating actors by strictly applying the rules that are mandated, and that will be mandated, on the subject by relevant national and regional health authorities, according to the evolution of the pandemics in the Puglia Region.

Regarding the access to the CSS hospital, safety guidelines are in place to minimize any risk to patients and staff members:

- Phone based screening to determine the need to undergo a rapid COVID-19 test before having the visit.
- Dedicated entrance into the facility through specific pathways
- Temperature screening at entry point
- Mandatory use of masks in the facility for the patient and staff members. All staff members are vaccinated against SARS-CoV-2

2.6.2.4 Technology acquisition

Table 48: Puglia technology acquisition procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|--|
| RESPONSIBLE | Fondazione Casa Sollievo Della Sofferenza – IRCSS (CSS) |
| PURPOSE | Supply of technologies |
| INPUTS | Number of patients to be enrolled in a given time period |
| OUTPUTS | Purchase orders and tracking of the equipment. In the CSS observational study case, the technologies will be provided for free by Samsung UK |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Samsung provides the devices to CSS for use on loan |
| 2 | CSS catalogs the devices that will be delivered to each single patient |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|---|
| RESPONSIBLE | N/A |
| PURPOSE | Supply of technologies |
| INPUTS | N/A |
| OUTPUTS | No technology acquisition will be needed for RUC#1, as it will be based on the participants' own devices (smartphones). |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|--|
| RESPONSIBLE | AReSS with the technical support of IP |
| PURPOSE | Supply of technologies |
| INPUTS | Device procurement planning (spreadsheet referred to in subsection 2.6.2.4.1 below) |
| OUTPUTS | <p>Purchase orders and tracking of the equipment, for equipment to be acquired on the market.</p> <p>Relevant budget transfer for equipment to be procured at production cost from GATEKEEPER partners (SAM, Medisanté).</p> <p>Biobeat PPG wrist devices will be temporarily loaned for free by partner BB.</p> |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Set up, publish and follow up a public tender, according to European, national and regional regulations, for the devices that need to be procured on the market |
| 2 | Agree and formalize, in a relevant GA amendment, the necessary budget transfers to obtain devices that need to be procured, at production cost, from other GATEKEEPER partners (SAM, Medisanté). |
| 3 | Agree on loan conditions for temporary loan of Biobeat PPG wrist devices with partner BB |

2.6.2.4.1 Device purchase details

Details of technology acquisition is provided below per RUC.

RUC1

- 4700 smartphones (€0)

RUC2

- 26 GearFit 2 (€563.68)
- 26 smartphones (€3864.64)
- 26 iHealth Air (€2078.7)

RUC3

- 100 smartwatch (€0)
- 125 smartphones (€3716)
- 100 glucometers (€0)
- 25 iHealth (€4223.75)

RUC5

- 60 Medisantè BC800 (€7200)
- 60 GearFit 2 (€1300.8)
- 60 smartphones (€8918.4)
- 60 iHealth (€4797)

RUC7

- 30 Biobeat wrist devices (0€)
- 62 Medisantè BP800 (€11160)
- 26 Medisantè BC800 (€3120)
- 26 GearFit 2 (€563.68)
- 114 smartphones (€16944.96)
- 26 iHealth BG5S-Kit (€4392.7)
- 26 iHealth Air (€2078.7)
- 26 iHealth View (€2078.7)

RUC8

- 273 smartphones (€40578.72)
- 273 iHealth (€21826.35)

2.6.2.5 Installation procedures

Table 49: Puglia installations procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|---|
| RESPONSIBLE | Fondazione Casa Sollievo Della Sofferenza – IRCSS (CSS) |
| PURPOSE | Prepare the devices to be ready to use and deliver them to the study participants |
| INPUTS | Devices, Installation instructions received from Samsung, device management platform from Samsung |
| OUTPUTS | Device and instructions delivery to the patient |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Configuration of the devices (smartphone, smartwatch) so that the data for the use case can be gathered. This process will be performed by CSS through the Samsung Knox management platform upon guidance by Samsung UK. |
| 2 | Filling the enrolment form with patient data, creation of the e CRF and association to the patient identity of a casual pseudonymization code assigned by Samsung (in the GATEKEEPER CSS platform) |
| 3 | Association of the pseudonymization code with the ACTIVAGE app on the smartphone |
| 4 | Pairing the smartwatch with the smartphone (that could be either the one owned by the patient or the one provided by the hospital) |
| 5 | Verify that all the systems work properly and deliver to the patient together with the operation instructions |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|--|
| RESPONSIBLE | SAM, FPM with support from IP, MME and supervision from AReSS |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | Adapted Activage app interoperated with FPM message-based e-coaching technology |
| OUTPUTS | Adapted Activage app interoperated with FPM message-based e-coaching technology installed on participants' own smartphones |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | SAM and FPM will develop the adapted Activage app interoperated with FPM message-based e-coaching technology and will make it available on Android Google Play Store and iOS Apple Store. |
| 2 | Participants will download and install the Adapted Activage app interoperated with FPM message-based e-coaching technology on their smartphones according to instruction given to them at recruitment phase. |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|--|
| RESPONSIBLE | HCPs supporting patients follow up during the experiment, with supervision from AReSS and technical support from IP, MME |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | Devices acquired as per subsection above |
| OUTPUTS | Devices delivered to the patients |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Devices will be sent by IP/AReSS to the HCPs supporting patients follow up during the experiment |
| 2 | <p>According to instructions received by IP and MME, HCPs supporting patients follow up during the experiment will decide which device kits to prescribe to which of their patients, following a quota sampling approach.</p> <p>In order to minimize management complexity for the HCPs, the Puglia Pilot team will endeavor to distribute devices so that each involved HCP will have to manage a limited number of comorbidity profiles (possibly, a single one) and, consequently, to manage a limited number of device kits (possibly, a single one) to be provide to her/his patients.</p> |
| 3 | Installation of relevant applications on the Samsung smartphones, that will be part of the device kits delivered to the patients, will be completed with the support of Samsung Knox. |
| 4 | HCPs supporting patients follow up during the experiment will deliver the devices to the selected patients |

2.6.2.6 Pre-testing

Table 50: Puglia pre-testing procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|--|
| RESPONSIBLE | Fondazione Casa Sollievo Della Sofferenza – IRCSS (CSS) |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | The observational study technologies |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Identification of the CSS team members who will pre-test the technologies |
| 2 | Create test profiles on Samsung Health |
| 3 | Use of the system for at least 1 week |
| 4 | Reporting of all possible issues to Samsung and to the pilot team |
| 5 | Production of instructional materials that will be used to train users and to let them know how to troubleshoot possible issues |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|--|
| RESPONSIBLE | IP, MME, FPM, SAM |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | GATEKEEPER Platform components and Pilot application |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Setup a beta-test environment in cooperation with relevant technical partners |
| 2 | Conduct beta-testing with volunteers drawn from the Puglia Pilot team in the period September 2021-November 2021 |
| 3 | While conducting the beta-test, adjust the GATEKEEPER Platform components and Pilot application as needed, in cooperation with relevant technical partners |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|--|
| RESPONSIBLE | IP, MME, ENG, SAM, TEC |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | GATEKEEPER Platform components and Pilot applications |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Setup a beta-test environment in cooperation with relevant technical partners |
| 2 | Conduct beta-testing with volunteers drawn from the Puglia Pilot team in the period September 2021-November 2021 |
| 3 | While conducting the beta-test, adjust the GATEKEEPER Platform components and Pilot applications as needed, in cooperation with relevant technical partners |

2.6.2.7 User training and support

Table 51: Puglia user training and support procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|---|
| RESPONSIBLE | Fondazione Casa Sollievo Della Sofferenza – IRCSS (CSS) |
| PURPOSE | Develop user's manuals (printed and video segments) and training procedures |
| INPUTS | Evidence gathered in the pre-test activities |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Each subject will receive a user manual at the enrolment. CSS Staff will be responsible to ensure subject understands how to use the device and to troubleshoot possible technical/practical issues. |
| 2 | Support contacts are outlined in the user manual in case of technical issues during the study |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|---|
| RESPONSIBLE | N/A |
| PURPOSE | Develop user's manuals (printed and video segments) and training procedures |
| INPUTS | N/A |
| OUTPUTS | <p>No training is needed for this experiment, as</p> <ul style="list-style-type: none"> the participants will use a conventional smartphone app UI, which they are expected to be already able to use. the experiment is planned to be conducted in naturalistic settings, reproducing as much as possible what users would do without the influence of experimenters. <p>The participants will be directed to download the adapted Activage app interoperated with FPM message-based e-coaching technology, respectively, from the Google Play Store or Apple Store platforms, and to follow relevant basic instructions, provided to them at recruitment phase.</p> |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|---|
| RESPONSIBLE | IP, MME with the support of ENG, TEC |
| PURPOSE | Develop user's manuals (printed and video segments) and training procedures |
| INPUTS | Evidence gathered in the pre-test activities |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | The Puglia Pilot team will provide to HCPs supporting patients follow up during the experiment with relevant information and training regarding their role in follow up |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| | with GATEKEEPER technologies and applications (e.g., GK User/identity management component, HCP-facing DMCoach UI, GK Authoring Tool Dashboards), in relation with study objectives. |
| 2 | User Manuals available from the manufacturers of the equipment to be procured and delivered to patients and of the applications to be used by them (e.g., Patient-facing DMCoach app, apps for device pairing, etc.) will be gathered. |
| 3 | Basic training will be delivered to patients by HCPs supporting patients follow up during the experiment, as per usual practice when they prescribe similar devices. After training, the relevant User Manuals will be delivered to the patients together with the devices, as per usual practice. |

2.6.3 Running phase

2.6.3.1 Operation procedures (execution and maintenance)

Table 52: Puglia operation procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|--|
| RESPONSIBLE | Fondazione Casa Sollievo della Sofferenza – IRCCS (CSS) |
| PURPOSE | Definition of the operation process |
| INPUTS | Users' support request |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | In the day of the recruitment each user will receive the reference email and phone number to contact in case there will be a need for support |
| 2 | In case the internal staff would not be able to solve the issue, the support request will be forwarded to Samsung |
| 3 | Once a solution is available CSS will contact the single patient and act to solve the issue according to Samsung suggestions |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|--|
| RESPONSIBLE | AReSS, with the support of all Puglia Pilot Partners, SAM and FPM |
| PURPOSE | Definition of the operation process |
| INPUTS | GATEKEEPER Platform components and Pilot application after beta testing |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | The experiment will be conducted according to the approved study protocol and the information sheet delivered to the participants |
| 2 | An online tutorial will be designed by IP and MME, and supervised by AReSS, based on receiving questions and compiling and maintaining a relevant FAQ list. To compile the FAQ list, IP and MME will rely on the cooperation from other Puglia Pilot partners as well as from Platform Cluster partners (in particular, SAM and FPM), as needed to compile accurate, optimal answers. |
| 3 | Risk of non-adherence will be managed as part of the e-coaching intervention |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|--|
| RESPONSIBLE | AReSS, with the support of all Puglia Pilot Partners, ENG, SAM and TEC |
| PURPOSE | Definition of the operation process |
| INPUTS | To be defined |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | The experiment will be conducted according to the approved study protocol and the information sheet delivered to the participants |
| 2 | An online tutorial will be designed by IP and MME, and supervised by AReSS, based on receiving questions and compiling and maintaining a relevant FAQ list. |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| | To compile the FAQ list, IP and MME will rely on the cooperation from other Puglia Pilot partners as well as from Platform Cluster partners (in particular, ENG, SAM and TEC), as needed to compile accurate, optimal answers. |
| 3 | Risk of non-adherence will be managed in cooperation with HCPs supporting patients follow up during the experiment and by checking relevant information on the usage of Samsung smartphones, that will be part of the device kits delivered to the patients, as made available by Samsung Knox |

2.6.3.2 Termination procedures

Observational Study on predictive modelling for T2D control (RUC#3)

The observational study will be complete after a 12-month period, as per protocol. To validate the developed model, we will in the future need to identify a novel cohort to assess it in terms of prediction accuracy, clinical applicability, sensibility, specificity. Then, we plan to publish on the internet a novel risk engine on T2D control that will run the model. The tool will be intended for the General Practitioners' use.

Quasi-experimental study Low Complexity (RUC#1)

The experiment will be completed after a 12-month period, as per protocol.

After the termination of the experiment, data collected during the operations will be linked with data extracted from regional administrative healthcare databases in order to conduct the cost-utility assessment (see subsection 2.6.3.3 below) and to assess other secondary endpoints regarding feasibility and acceptability.

In case of a positive evaluation, the possibility to run the RUC#1 as a permanent service will be considered.

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

The experiment will be completed after a 12-month period, as per protocol.

After the termination of the experiment, data collected during the operations will be linked with data extracted from regional administrative healthcare databases in order to conduct the cost-utility assessment (see subsection 2.6.3.3 below) and to assess other secondary endpoints regarding feasibility and acceptability.

In case of a positive evaluation, the possibility to run the experiment, for one or more of the addressed RUCs (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8), as a permanent service will be considered.

2.6.3.3 Evaluation procedures

Table 53: Puglia evaluation procedures

Observational Study on predictive modelling for T2D control (RUC#3)

| | |
|--------------------|---|
| RESPONSIBLE | Fondazione Casa Sollievo della Sofferenza – IRCCS (CSS) |
| PURPOSE | Define the evaluation process |
| INPUTS | Data and AI models developed in the study |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Identification of the most important variables (conventional, i.e., from blood samples and unconventional, i.e., from the wearable device) that can predict the outcome variable value (Glycosylated Haemoglobin), a proxy for diabetes control |
| 2 | Building of the model that will be based on the result of step 1. |

Quasi-experimental study Low Complexity (RUC#1)

| | |
|--------------------|--|
| RESPONSIBLE | IP, MME |
| PURPOSE | Define the evaluation process |
| INPUTS | Outcome data collected during the experiment |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Outcome data collected during the experiment will be linked with additional data coming from regional administrative healthcare databases in order to complete it with healthcare resource usage information |
| 2 | Data obtained from the previous step will be used to populate a three-state MAFEIP model |
| 3 | The MAFEIP Tool will be run to compute the cost effectiveness of the Low Complexity intervention (primary objective of the experiment), by comparing data for 4,700 participants in the control group with 4,700 participants in the intervention group, in the frame of a 3-state Markov model. |
| 4 | The data will also be used to assess the achievement of the secondary objectives of the experiment |
| 5 | A final evaluation report will be produced, to inform subsequent decision making |

Quasi-experimental study Moderate Complexity (RUC#2, RUC#3, RUC#5, RUC#7, RUC#8)

| | |
|--------------------|--|
| RESPONSIBLE | IP, MME |
| PURPOSE | Define the evaluation process |
| INPUTS | Outcome data collected during the experiment |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Outcome data collected during the experiment will be linked with additional data coming from regional administrative healthcare databases in order to complete it with healthcare resource usage information |
| 2 | Data obtained from the previous step will be used to populate a three-state MAFEIP model |
| 3 | The MAFEIP Tool will be run to compute the cost effectiveness of the Moderate Complexity intervention (primary objective of the experiment), by comparing data for 498 participants in the control group with 498 participants in the intervention group, in the frame of a 3-state Markov model |
| 4 | The data will also be used to assess the achievement of the secondary objectives of the experiment |
| 5 | A final evaluation report will be produced, to inform subsequent decision making |

2.7 POLAND pilot plan

2.7.1 Planning

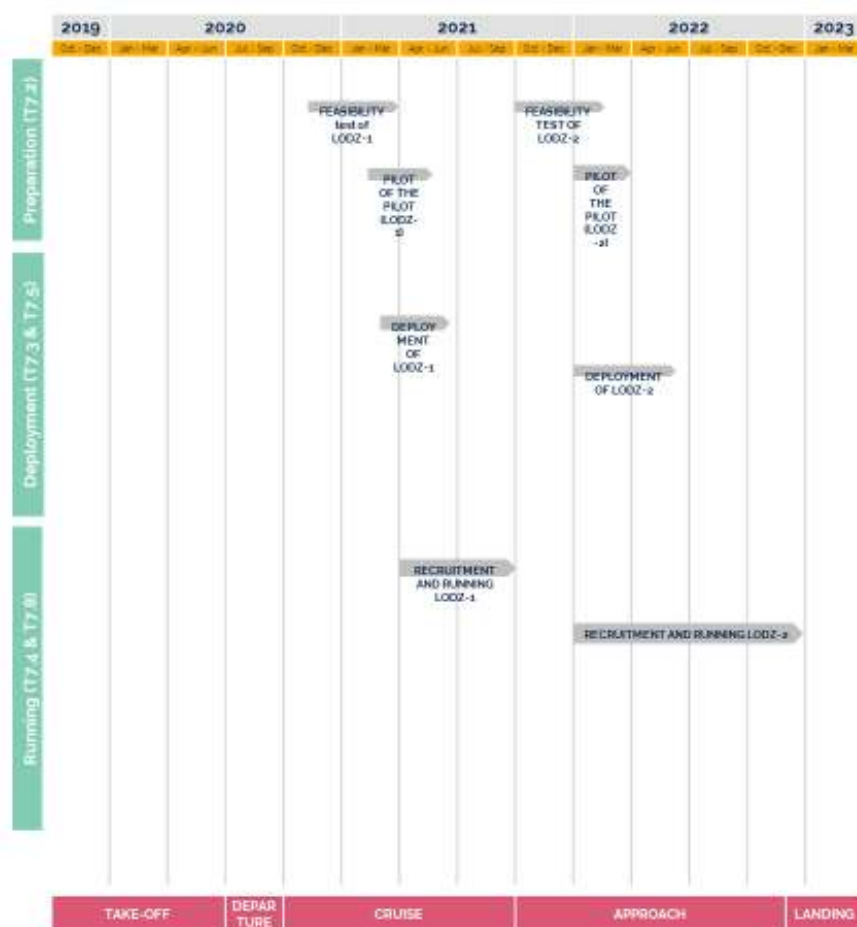


Figure 8 – Lodz piloting phases

2.7.2 Deployment phase

2.7.2.1 Deployment phases per RUC

To be included in the next version

2.7.2.2 User recruitment strategy and consent procedures

Table 54: Lodz recruitment process procedures

| | |
|--------------------|---|
| RESPONSIBLE | LODZ |
| PURPOSE | Define the recruitment process |
| INPUTS | Recruitment to LODZ-1 & LODZ-2 |
| OUTPUTS | Users recruited will be elderly patients with asymptomatic chronic conditions (LODZ-1) or those equipped with multimorbidity (LODZ-2) |

Table 55: Lodz consent form process procedures

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Open invitation posted online at own website |
| 2 | Open invitation posted online at own social media profiles |
| 3 | Invitation circulated via the networks of collaborating patients and HCPs associations |

| | |
|--------------------|---|
| RESPONSIBLE | LODZ |
| PURPOSE | Define the consent form process |
| INPUTS | Consent form being defined according to binding national regulations, and approved by local Ethical Committee |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Review of updated national regulations |
| 2 | Drafting the consent form |
| 3 | Getting approval of local Ethical Committee |

2.7.2.3 Ensuring COVID19 prevention

Entire process of recruitment and running of the LODZ-1 pilot under RUC1 is held in remote way. Thus, Covid-19 does not possess major impact of this study.

LODZ-2 pilot under RUC7 requires direct contact with selected patients. Hopefully, its activities scheduled for 2022 will take place in a scenario of limited impact of Covid-19, due to ongoing process of mass vaccination started in Poland in December 2020.

2.7.2.4 Technology acquisition

Table 56: Lodz technology acquisition procedures

| | |
|--------------------|--|
| RESPONSIBLE | LODZ |
| PURPOSE | Supply of technologies |
| INPUTS | Securing digital adherence monitors for LODZ-2 |
| OUTPUTS | Purchase orders and tracking of the equipment |

| | PROCEDURE DESCRIPTION |
|----------|---|
| 1 | Review of best available market solutions providing proven effectiveness, applicability and cost-effectiveness |
| 2 | Critical review of monitors specification in order to verify whether they will work smoothly with the rest of LODZ-2 technologies |
| 3 | Purchase order issued and internally accepted by MUL administration |

2.7.2.4.1 Device purchase details

Details of technology acquisition is provided below per RUC.

RUC 1

- 1000 medication adherence apps (€20000)
- 1000 smartphones (€0)

RUC7

- 100 MEMS monitor (€8000)
- 180 medication adherence apps (€3600)
- 50 smartwatches (€22500)
- 230 smartphones (€0)

2.7.2.5 Installation procedures

Table 57: Lodz installations procedures

| | |
|--------------------|--|
| RESPONSIBLE | LODZ |
| PURPOSE | Define the optimal installation procedures |
| INPUTS | Manufacturer's instructions |
| OUTPUTS | Simple installation instructions |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | Drafting first version of the medication adherence monitors' user guides according to manufacturer's instructions |
| 2 | Internal testing of monitors in feasibility study |
| 3 | Fine-tuning of the user guide and releasing of its final version |

2.7.2.6 Pre-testing

Table 58: Lodz pre-testing procedures

| | |
|--------------------|--|
| RESPONSIBLE | LODZ |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | Feedback from test participants |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Internal testing in volunteers with feedback collected and analysed |
| 2 | "Pilot of the pilot" in limited number of real patients with feedback collected and analysed |
| 3 | Final fine-tuning of the technology |

2.7.2.7 User training and support

Table 59: Lodz user training and support procedures

| | |
|--------------------|--|
| RESPONSIBLE | LODZ |
| PURPOSE | Develop user's manuals and training procedures |
| INPUTS | Participants needs |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | LODZ-1 training will be provided online to the pilot participants |
| 2 | LODZ-2 training will be subject to predefined being a part of study protocol approved by local Ethical Committee, this will be provided to participants by trained member of MUL staff |

2.7.3 Running phase

2.7.3.1 Operation procedures (execution and maintenance)

Table 60: Lodz operation procedures

| | |
|--------------------|--|
| RESPONSIBLE | LODZ |
| PURPOSE | Definition of the operation process |
| INPUTS | Stipulations of LODZ-1 and LODZ-2 pilots |
| OUTPUTS | Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Pilot will be started with LODZ-1 under RUC1 in 2021, in order to test basic components of the technology |
| 2 | At the top of LODZ-1, additional features will be added to create LODZ-1 under RUC7 |
| 3 | LODZ-2 under RUC7 will start in 2022 |
| 4 | Continuous support to LODZ-2 participants will be provided both in remote way (via calls, mail, etc), as well as in F2F mode, if necessary |

2.7.3.2 Termination procedures

After termination of the project, the technology will stay live. We plan to find actively search for interested stakeholders and offer scaling-up of the designed technology. Moreover, according to the feedback collected, and analysis of study results, we want to further fine-tune our technology.

2.7.3.3 Evaluation procedures

Table 61: Lodz evaluation procedures

| | |
|--------------------|---|
| RESPONSIBLE | LODZ |
| PURPOSE | Define the evaluation process |
| INPUTS | Need to critically evaluate study results |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | Analysis of the source data coming from pilots |
| 2 | Statistical analysis with relevant tests |
| 3 | Critical analysis of obtained results against preselected criteria, including accepted KPIs |
| 4 | Peer-based evaluation of results published in scientific publications and presented at professional meetings |

2.8 SAXONY pilot plan

2.8.1 Planning

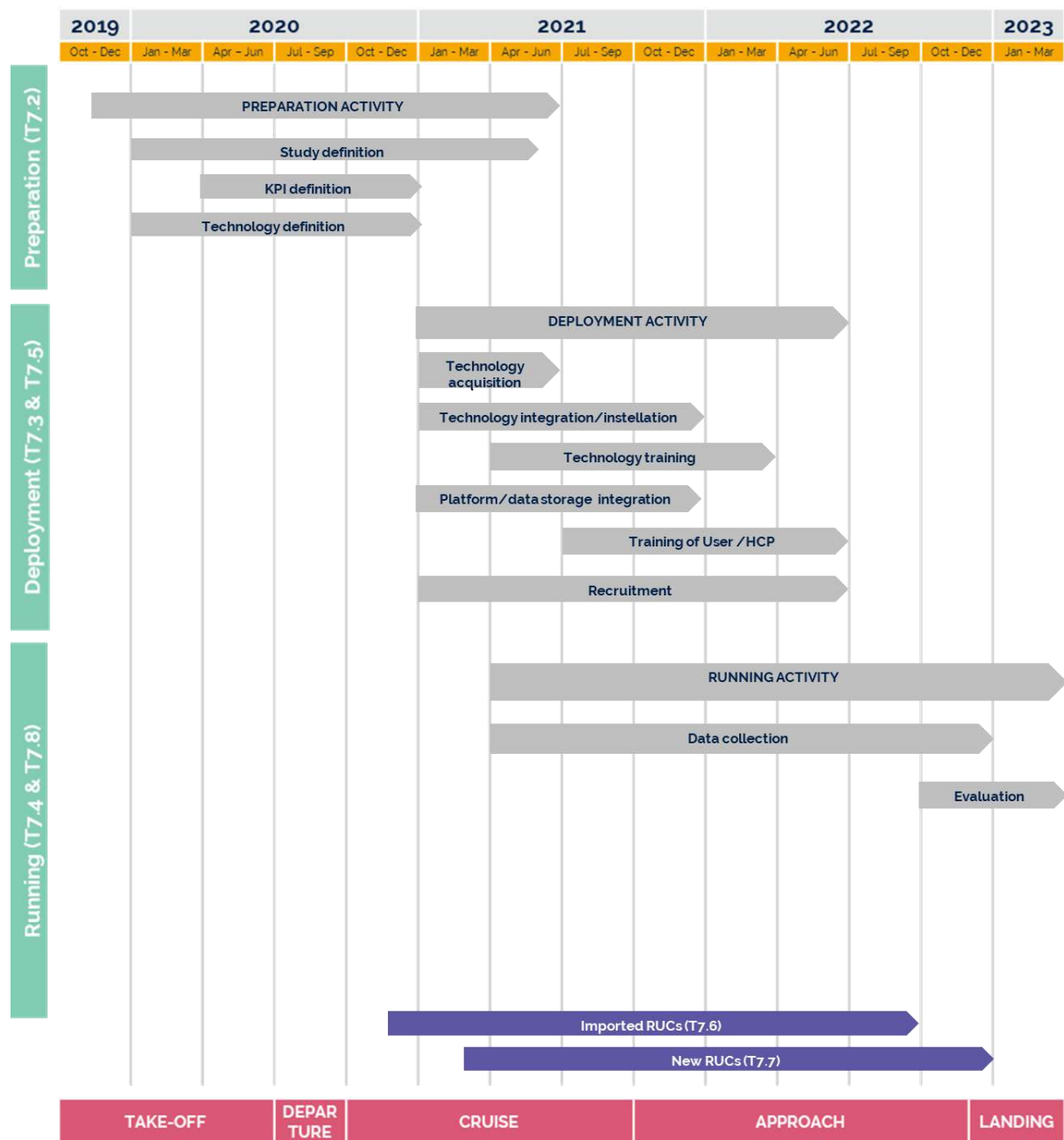


Figure 9 – Saxony piloting phases

2.8.2 Deployment phase

2.8.2.1 Deployment phases per RUC

1. Internal testing of RUC1 technologies with ten users for technical training.
1. RUC1 deployment (as soon as ethics approval is ready): 30 users will bring their own devices and download the app
2. RUC 7 with Samsung for internal Usage/testing (as soon as integration of apps is ready)
3. RUC7 deployment: 20 users wearing Samsung smartwatch will start collecting data
4. MDR-Issue is important for us and needs to be cleared asap

2.8.2.2 User recruitment strategy and consent procedures

Table 62: Saxony recruitment process procedures

| | |
|--------------------|--|
| RESPONSIBLE | CCS, TUD |
| PURPOSE | Participants are actively approached using recruitment materials (Advertising, flyers) during their stay in one of our clinic facilities. Cooperation with different partners and institutions is sought e.g. geriatric clinics and senior citizens center, outpatient clinics and clinics, nursing homes, counseling centers for the elderly. |
| INPUTS | Advertising, Flyer, List of cooperation partner |
| OUTPUTS | List of users recruited |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | RUC 1 especially cooperating with the memory clinic of geriatric psychiatry within our university clinic (participants will be informed about the app and our study. Informed consent will be obtained through the app. No training is necessary as we expect the app to be a standalone tool.) |
| 2 | RUC 7 especially cooperating with an outpatient geriatric clinic and hip surgery within our university clinic (participants will be informed about the study. After being sufficiently informed and written informed consent, they will be trained before starting the study.) |
| ... | To be defined |

Table 63: Saxony consent form process procedures

| | |
|--------------------|--|
| RESPONSIBLE | TUD |
| PURPOSE | Informed consent will be obtained from the user before data collection starts. |
| INPUTS | To be defined |
| OUTPUTS | Consent Form |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | RUC1: Within our mental health app, we ask participants for the collection of their data via an electronic consent form. Afterwards, the app will run free of charge on their smartphone. The study can be ended by the user by withdrawing consent at any time. |
| 2 | RUC7: Informed written consent will be obtained during an information and clarification talk before data collection starts. The study can be ended by the user by withdrawing consent at any time. |
| ... | To be defined |

2.8.2.3 Ensuring COVID19 prevention

UC1: Since we are using an app and data will only be collected via app, no physical meetings or physical contact with participants will be needed. Therefore no further protection measures are necessary.

UC7: Trainings with participants will be physical. We hope most participants will be vaccinated until the start of the data collection (as the elderly and clinical staff have the highest priority given the official vaccination strategy) so that there might not be a high risk of infection. This will be checked for prior to the meetings. Medical personnel will be regularly tested. Further protection measures are dedicated hygiene concept, informing about potentially risky behaviours und masks for all.

2.8.2.4 Technology acquisition

Please describe acquisition process with the steps, responsible, purpose, inputs needed and outputs generated. Outputs should be in all/most cases 'Purchase orders and tracking of the equipment'. Details should be provided by each different type technology acquired if applicable.

Table 64: Saxony technology acquisition procedures

| | |
|--------------------|--|
| RESPONSIBLE | Samsung |
| PURPOSE | Supply of technologies |
| INPUTS | Number of devices, prices; overall approval of the budget transfer procedure both by Samsung and th Project Management |
| OUTPUTS | Purchase orders and tracking of the equipment |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 0 | Preparatory steps: overall procedural confirmation and start of actual acquisition; concept to distrube devices |
| 1 | RUC1 not applicable, participants use their own devices |
| 2 | RUC7: Participants will use a Samsung Smartphones A51 and Samsung Galaxy 3 watches, Health carers will use a Samsung Tab A7 |
| ... | To be defined |

2.8.2.4.1 Device purchase details

Details of technology acquisition is provided below per RUC.

RUC1

- 10000 smartphones/tablets (GBP0)
- 10000 mental health app (GBP0)

RUC7

- 50 tablets (GBP4935.5)
- 250 smartwatches (GBP36772)
- 250 smartphones (GBP38850)
- 250 health app (GBP0)
- 250 Active Age App (GBP0)

2.8.2.5 Installation procedures

Table 65: Saxony installations procedures

| | |
|--------------------|----------------------------------|
| RESPONSIBLE | Samsung, TUD |
| PURPOSE | Apps will either be downloaded |
| INPUTS | - |
| OUTPUTS | Simple installation instructions |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | RUC1 Participants will use SAX app on their own devices. They get an instruction how to download and install the app. |
| 2 | RUC7 Participants will use Samsung Smartphones in combination with Samsung Galaxy watch 3. Participants will use Samsung health and ActiveAge as well as SAX app (Integration of apps , details will be defined between Sam and TUD) Apps will be preinstalled on the Smartphones and participants will get a training how to use it. |
| 3 | RUC1/RUC7: interim data storage solution (server within TUD) needs to be installed. |

2.8.2.6 Pre-testing

Table 66: Saxony pre-testing procedures

| | |
|--------------------|--|
| RESPONSIBLE | TUD |
| PURPOSE | Define the technologies test before installation and usage with real users |
| INPUTS | Pre-test version of the app for internal technical training with test users |
| OUTPUTS | Adapt the installation procedures demonstrated in the pre-testing to the end-users needs |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | RUC1 pre-testing of first version of the app with 10 test persons as soon as data storage will be ready, on different devices (cell phones, tablets) with specific foci (e.g. content, usability, applicability) |
| 2 | RUC7 moderate: pre testing with 10 participants and 5 health carers to test the apps in combination with the smartwatch and its functions |
| 3 | RUC7 high: pre testing with 5 participants and 5 health carers to test the apps in combination with the smartwatch and its extended functions. |

2.8.2.7 User training and support

Table 67: Saxony user training and support procedures

| | |
|--------------------|--|
| RESPONSIBLE | CCS, TUD |
| PURPOSE | Develop user's manuals and training procedures |
| INPUTS | Devices, Samsung apps, Sax app, feedback from tester |
| OUTPUTS | User's training manuals and face-to-face training protocol |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | RUC1 SAX app is a standalone tool that is easy to use. Information will be provided in the flyer and if more are necessary (pre-testing) within an attached explanation. |
| 2 | RUC7: training manuals will be developed in accordance to the pre-testing outcome (e.g. how to use the device efficiently). Face-to-face trainings with participants and health carer will be conducted if possible (e.g. COVID-19 situation). |
| ... | To be defined |

2.8.3 Running phase

2.8.3.1 Operation procedures (execution and maintenance)

Table 68: Saxony operation procedures

| | |
|--------------------|--|
| RESPONSIBLE | CCS, TUD |
| PURPOSE | Data collection in the field |
| INPUTS | Data input by participants |
| OUTPUTS | Raw data, Definition of organization and protocol for operations management and strategies |

| PROCEDURE DESCRIPTION | |
|-----------------------|---|
| 1 | <p>RUC1:</p> <p>As the low complexity use case under RUC1 includes only Saxony pilot owned components at the first, we will start with this. In the following, function range, technical and medical scope will be extended reaching the higher complexity use cases.</p> <p>Starting point will be chosen by user. Communication needs to be started by participants, since only pseudonymized data will be used. Participants can address GK Saxony research team in case of questions, technical problems or if they need help. They can get contact information (e.g. phone number, e-mail address) from the app, flyer and homepage. Possible risks include external circumstances (such as covid-19 that limits recruitment) as well as technical problems (crashing of the app, participants losing phones). Therefore we ensure regularly system check-ups and an option for the participants to save their Token (identification code).</p> |
| | <p>RUC7: Starting point will be defined in batches by the study team. Communication with participants will be conducted via phone, videochat, e-mail, postal way and face-to-face-meetings (if possible and necessary). Communication will be necessary for research information and consent, in case of questions or technical problems. Possible risks include external circumstances (such as covid-19 that limits recruitment) as well as technical problems (crashing of the app, participants losing/crashing devices). Therefore we ensure regularly system check-ups and comprehensive technical introduction and support.</p> |

2.8.3.2 Termination procedures

RUC1: Data collection will end user controlled.(At llast when project ends.)

RUC7: Data collection will end after 3 months.

Open issues: Details on applicability of medical device regulation on the apps and their CE-certified status (SAX mental health app, Samsung apps) need to be provided.

Legal aspects need to be cleared out: e.g., where do devices belong after data collection/end of project? Who owns GK-platform after end of project? Will the GK platform be provided afterwards?

2.8.3.3 Evaluation procedures

Table 6g: Saxony evaluation procedure

| | |
|--------------------|---|
| RESPONSIBLE | TUD |
| PURPOSE | Define the evaluation process |
| INPUTS | Ethics approval documents, collected data |
| OUTPUTS | Evaluation plan |

| PROCEDURE DESCRIPTION | |
|-----------------------|--|
| 1 | RUC1: On basis of the ethics approval document and current state of research a detailed plan will be developed: clinical and operational evaluation: descriptive statistics and changes over time (t0:baseline evaluation, t1:after 4-6 weeks) t3: after 3 month) will be analyzed as well as usability and applicability of the different sections in the app |
| 2 | RUC7: On basis of the ethics approval document and current state of research a detailed plan will be developed |
| 3 | Socio-economic evaluation through MAFEIP tool |
| 4 | Dissemination of the results |

3 KPIs and Impact assessment strategy

As stated in the previous edition of this report, **The University of Warwick (UoW)** and the main GK Partner on Impact evaluation and assessment, **Open Evidence (OE)**, have developed and conducted an analysis on all the parameters to be considered in close collaboration with the Pilots in the Gatekeeper project.

This report reflects the overall impact assessment strategy within GATEKEEPER Project and the ongoing work in WP6 and WP7, with their deliverables plans as per the following table:

Table 70: Gatekeeper Evaluation Strategy

| Deliverable Number | Deliverable Title | WP number | Lead beneficiary | Type | Dissemination level ¹⁶ | Due Date M |
|--------------------|---|------------|------------------|---|--|------------|
| D6.6 | Report about the pilots' outcome: A document that includes clinical and QoL results together with the cost-effectiveness study per pilot. | WP6 | 18 - UoW | Report | Confidential , only for members of the consortium (including the Commission Services) | 24 |
| D6.13 | D6.6.2 Report about the pilots' outcome: A document that includes clinical and QoL results together with the cost-effectiveness study per pilot. | WP6 | 18 - UoW | Report | Confidential , only for members of the consortium (including the Commission Services) | 36 |
| D7.1 | Pilot Studies Use Case Definition and Key Performance Indicators (KPIs): Report on pilots plans, KPIs for measuring and reporting, the training material and dissemination/communication plans. | WP7 | 17 - OE | Report | Confidential , only for members of the consortium (including the Commission Services) | 12 |
| D7.2 | Updated KPI Evolution | WP7 | 18 - UoW | Report/ database of KPI (with numbers) updated | Public | 12 |
| D7.5 | Report (I to IX): | | | | M18+: | 18 |
| D7.6 | KPI periodic report based on the results of use cases and comparison with the previously locally observed KPIs. | | | | - clinical (self-reported) | 24 |
| D7.7 | | | | | - impact (self-reported) | 30 |
| D7.8 | Updates every six months D7.2 and D7.5 provided definitions and descriptions of each KPI and described the tools for KPI collection. D7.6 to D7.8 are expected to report on KPIs values. | | | | - operative KPI & target values M18+ & statistical analysis | 36 |
| D7.4 | Pilot Studies Evaluation Results and sustainability plan: Report on the overall progress made in pilot studies and the commitments of each stakeholders in the sustainability of the pilot site. | WP7 | 22 - OE | Report | Confidential , only for members of the consortium (including the Commission Services) | 42 |

The ambition of D7.2 and D7.5 is to define and describe KPIs and the harmonised tools for their collection. D7.6-8 will report on the numerical values of KPIs from the running experiments that will feed the D6.6 Report about the pilots' clinical outcomes at M24 and its update D6.13 at M36 and D7.4 Pilot Studies Evaluation Results and sustainability plan at M42. Therefore, the evolution of this document will collect KPIs measurable values, which will allow disclosing how cost-effectively each and every Pilot experiment (i.e., GATEKEEPER health technology) is achieving its objectives.

The section 4 and 5 of this Deliverable includes the **Impact assessment** and **Operative KPIs** and the tools used pilot per pilot and starting from the first measures, in the next issues from M24 and on the annex will include the measures.

By M24 with the D6.4.2 defining the overall multicentric federated study of GATEKEEPER Project this report will show the GK overall evolution tools.

As a KPI accurately measure how effectively the experiments are achieving their goals, changes in Pilots' contexts will necessarily reflect a change and evolution in KPIs.

Many studies were redesigned due to COVID-19 Pandemic and it was added a specific RUC #9 to address specifically this peculiarity as described further.

Alongside the Impact assessment framework, in section 5 Operative KPIs are defined and reported. These KPIs aim to collect the status of pilots' deployment, running, and ecosystem enlargement to monitor the progress of each pilot execution. The assessment of these KPIs will be used to ensure a correct and synchronised execution of all pilot sites, and therefore, of the LSP multicentre pilot.

The indicators described in 5.1 will be formalised in an excel file template here described in the Appendix A. These KPIs will be filled in by each pilot site every 6 months and individual reports will be included as appendixes (Appendix B. Individual KPI Evolution Reports) in the forthcoming releases of this deliverable. Consolidated information of the indicators will be reported in 5.2 as a report of the entire LSP multicentre pilot progress.

4 Impact KPIs Evolution Reports per Pilot

This section reports all the 'Impact assessment KPIs per categories and per RUCs in each Pilot' as redefined after a series of bilateral meetings previously described.

Updated clinical studies including the new RUCs #8 about High Blood Pressure and #9 about COVID-19 related experiments and their consequent KPIs and measurement tools along with the already defined ones are reported below.

The RUC #8: eHealth solutions for the management of High Blood Pressure, proposes novel integrated care management for patients with High Blood Pressure, aiming to enable blood pressure monitoring for early detection of health problems, e.g., linked to heart problems and stroke.

RUC #9: eHealth solutions for the management of COVID-19 proposes multiple solutions aiming to improve the management and control of COVID-19 patients.

The next editions will continue to assess the KPIs and their effectiveness to monitor the evolutions in each experiment site.

The work done so far built a framework of investigational designs in which each and every pilot defined its experiment definition and the KPIs to correctly measure its own experiment effectiveness and impact under all the aspects: clinical, societal and adoption potential. This approach will be used in all the evolutions reports, which are going to be published in the remaining project months.

Here is reported the Impact Assessment KPIs defined per classification in D7.2:

Table 71: Impact assessment KPIs

| Pilot site | | PILOT N. XXXX |
|------------|--------------------|--|
| | | RC1 – RC7 |
| KPIs | clinical | Hospital admissions / health deteriorations |
| | | Patient visits and time spent |
| | | Patient adherence to treatment |
| | | Quality of life |
| | | Adverse events |
| | | Physical activity increase |
| | | Waist circumference reduction |
| | | Reduction of BMI, % body fat |
| | | Sleep quality |
| | | Vital signs' values improvement |
| | | Risk assessment of diabetes |
| | | Minimisation of hypoglycaemic events / Glycaemic control |
| | | Social activity increase |
| | | Avoid/prevent appearance of chronic diseases |
| | | Promote healthy habits |
| | societal | Technology acceptance |
| | | Patient/Citizen empowerment / health literacy |
| | | Cultural/Social discomfort/isolation alleviation |
| | | Return on investment |
| | | User satisfaction |
| | | Informal Caregivers empowerment |
| | adoption potential | Health Professionals quality of life in relation to technology adopted |
| | | Cost-effectiveness / Monthly-Annual health care costs |
| | | Integrability with current infrastructure |
| | | Compatibility with clinical workflows/protocols |
| | | Usability issues |
| | | Specificity, sensitivity and AUC of models / Effectiveness |
| | | Privacy / data issues |
| | | Sustainability (Measured with an analysis of service(s)) |

4.1 Aragon

Study design

The study is organized around three levels of complexity of patients management (prevention, medium complexity - stable chronic patients, and high complexity- chronic patients in acute phases) and it is composed of six use cases (1-prevention, 2-COPD, 5-Heart Failure, 7-Polymedication and Multimorbidity, 9-Covid-19 Home and Center monitoring).

The experiment started with the Mid complexity RUCs targeting 170 citizens + 160 with the Covid-19 related experiments reaching 330 in total. The overall experiment will include 2360 citizens. Next steps are the tests and validation of the technical solution for the other RUCs. From M19-20, will start the recruitment for the High Complexity RUCs and later with the Low complexity. The users' enrolment and the training strategy are planned with the social care organizations

The actual status is:

- Ethical procedures approved
 - Low complexity: Expected to submit it by 1T 2021. Protocol already defined. Waiting for submission until final decision on the appropriate KET to be used.
 - Mid complexity: Ethical approved (Oct 2020).
 - High-complexity: Ethical approved (Oct 2020).
 - COVID-19 Ethical approved (March 2021)
- Study protocol defined (with KPIs)
 - KPIs and tools/questionnaires defined
- Technologies identification completed and acquisition in progress

The main objectives for each level of complexity are shown in Table 72.

Table 72: Aragon Study Design

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|---------------------|---------------|-------------------------------------|--|--------------------------|---------------------|
| Low | 2000 | 1 – Prevention | Descriptive | NA* | NA |
| Medium | 170 | 2 – COPD | Between subject design with randomized intervention and control groups | 25 | 25 |
| | | 5 – Heart Failures | Between subject design with randomized intervention and control groups | 25 | 25 |
| | | 7 – Polymedication / Multimorbidity | Between subject design with randomized | 35 | 35 |

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|-----------------------|---------------|-------------------------------------|--|--------------------------|---------------------|
| | | | intervention and control groups | | |
| Medium – COVID | 80 | 9 - COVID-19 Home Monitoring | Between subject design with randomized intervention and control groups | 40 | 40 |
| | 80 | 9 - COVID-19 center | Between subject design with randomized intervention and control groups | 40 | 40 |
| High | | 2 – COPD | Between subject design with randomized intervention and control groups | 5 | 5 |
| | 30 | 5 – Hearth Failures | Between subject design with randomized intervention and control groups | 5 | 5 |
| | | 7 – Polymedication / Multimorbidity | Between subject design with randomized intervention and control groups | 5 | 5 |

*NA: Not applicable

The 'Impact assessment KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.1.1 USE CASE 1 - Low complexity KPIs

Table 73: USE CASE 1 - Low complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|--|--|---|
| Clinical | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI ¹), ZARIT |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off Costs Recurrent costs Healthcare costs self-report time horizon | Qualitative / self-report |
| | Sustainability costs and benefits | Time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology: ² | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.2 USE CASE 2 - Mid complexity KPIs

Table 74: USE CASE 2 - Mid complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|---|---|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT |
| | N/A | Adverse events | Qualitative / self-report |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.3 USE CASE 2 - High complexity KPIs

Table 75: USE CASE 2 High complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|---|---|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT |
| | N/A | Adverse events | Qualitative / self-report |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.4 USE CASE 5 - Mid complexity KPIs

Table 76: USE CASE 5 - Mid complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|---|---|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT |
| | N/A | Adverse events | qualitative/self-report |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.5 USE CASE 5 - High complexity KPIs

Table 77: USE CASE 5: High complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|---|---|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT |
| | N/A | Adverse events | Qualitative / self-report |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.6 USE CASE 7 - Mid complexity KPIs

Table 78: USE CASE 7 - Mid complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|---|---|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT |
| | N/A | Adverse events | Qualitative / self-report |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use user satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.7 USE CASE 7 - High complexity KPIs

Table 79: USE CASE 7: High complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|---|---|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT |
| | N/A | Adverse events | qualitative/self-report |
| | N/A | Self-management disease | Patient Activation Measure (PAM) |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance |
| Societal | N/A | Healthy habits | PROMS, use of the APP |
| | N/A | Cultural discomfort alleviation | Qualitative |

4.1.8 USE CASE 9 - COVID

SALUD has designed a new use case for COVID patients during their recovery from their illness in two different scenarios: at home and at a COVID-center. The KPIs have already been defined but they may still be subject to changes.

Table 80: USE CASE 2 - COVID Mid complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-----------------------------------|---|---|----------------------------|
| Clinical | N/A | Patient adherence to treatment | Brief Medication Questionnaire (BMQ) | NEWLY ADDED |
| | N/A | Quality of life of patients and caregivers | Short Form Health Survey (SF-12v2) and Caregiver Strain Index (CSI), ZARIT | NEWLY ADDED |
| | N/A | Adverse events | Qualitative / self-report | NEWLY ADDED |
| | N/A | Self-management disease | Patient Activation Measure (PAM) | NEWLY ADDED |
| Impact Assessment | Sustainability costs and benefits | Quality of life | EQ-5D | NEWLY ADDED |
| | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline Planned patients visits Unplanned patients visits Unplanned hospitalizations Length of visits | Qualitative / self-report | NEWLY ADDED |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature | NEWLY ADDED |
| Technology | N/A | Integrability with current infrastructure | Qualitative / self-report | NEWLY ADDED |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative / self-report | NEWLY ADDED |
| | Usability issues Technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Questionnaire on technology acceptance | NEWLY ADDED |
| Societal | N/A | Healthy habits | PROMS, use of the APP | NEWLY ADDED |
| | N/A | Cultural discomfort alleviation | Qualitative | NEWLY ADDED |

4.2 Basque Country

Study Design

The pilot in the Basque Country is managed by two organizations, Osakidetza and Kronikgune and it is organized around the three levels of complexity of patients management (low level, medium, and high complexity) and it is composed by five Reference Use Cases (RUC1- prevention, RUC3 – diabetes, RUC4 – Parkinson's disease, RUC6 – Stroke and RUC7 Polymedication and Multimorbidity).

The Pilot will include a total of 11300 citizens along the three levels of complexity: Low 10000, Mid 1100, High 200.

The experiment was delayed by the pandemic and started with the acquisition, the deployment and the adaptation of the technology to be used in the different experiments. Recently started the training of the HCP – health care professionals. The recruitment for the most mature experiments is waiting for the last ethical approval procedures expected by the M18-M20 for all the RUCs. The managing organizations created a list of the potential participants and planned their recruitment strategy.

--The study is summarized in Table 81.

Table 81: Basque Country Study Design

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|---------------------|---------------|---------------------------|---|--------------------------|---------------------|
| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control |
| Low | 10000 | 1 – Prevention | Randomized clinical trial: intervention group (prospective analysis) and control group (retrospective analysis) | 10000 | 0 |
| Medium | 1100 | 6 - stroke prevention | Between subject design with randomized intervention and control groups | 25 | 25 |
| | | 6 – stroke identification | Between subject design with randomized intervention and control groups | 20 | 30 |

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|---------------------|---------------|-------------------------------------|--|--------------------------|---------------------|
| High | 200 | 7 - polymedication / multimorbidity | Between subject design with randomized intervention and control groups | 500 | 500 |
| | | 3 - diabetes | Between subject design with randomized intervention and control groups | 50 | 50 |
| | | 4 - Parkinson's disease | Between subject design with randomized intervention and control groups | 50 | 50 |

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.2.1 USE CASE 1 - Low complexity KPIs

Table 82: USE CASE 1 - Low complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-------------|---|--|------------------------------------|
| Clinical | N/A | Quality of life Functionality | Barthel | Changed KPIs and measurement tools |
| Societal | N/A | Technology usability | Questionnaire on technology usability MAUQ | Changed KPIs and measurement tools |
| | N/A | Technology accessibility Technology satisfaction Technology usability Technology utility | Focus groups or semi-structured interviews | Changed KPIs and measurement tools |
| Metric usage | | number of app downloaded number of active users how much time users spend in the app/ how often users visit the app how much time users spend in each module how often users visit each module | App server | Changed KPIs and measurement tools |

4.2.2 USE CASE 3 – High complexity KPIs

Table 83: USE CASE 3 – High complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-------------|---|--|
| Clinical | N/A | Hospital admissions Health deteriorations | Functionality of the technical solutions Utilities Resources use of Primary Care Resources use of Hospital Care |
| | N/A | Patient visits and time spent | number of on-site visits and length of visits |
| | N/A | Patient adherence to treatment | Qualitative/self-report |
| | N/A | Quality of life | EQ5D |
| | N/A | Adverse events | Qualitative/self-report |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance |
| | N/A | Patient empowerment health literacy | Qualitative/self-report |
| | N/A | Cultural discomfort alleviation | Qualitative/self-report |
| | N/A | Return on investment | Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome |
| Adoption Potential | N/A | Integrability with current infrastructure | Qualitative/self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative/self-report |
| | N/A | Usability issues | Qualitative/self-report |

4.2.3 USE CASE 4 – High complexity KPIs

Table 84: USE CASE 4 – High complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|------------------------------------|-------------|---|--|
| Clinical | N/A | Hospital admissions Health deteriorations | Functionality of the technical solutions Utilities Resources use of Primary Care Resources use of Hospital Care |
| | N/A | Patient visits and time spent | number of on-site visits and length of visits |
| | N/A | Patient adherence to treatment | Qualitative/self-report |
| | N/A | Quality of life | EQ5D |
| | N/A | Adverse events | Qualitative/self-report |
| | N/A | Physical activity increase | Qualitative/self-report |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance |
| | N/A | Patient empowerment health literacy | Qualitative/self-report |
| | N/A | Cultural discomfort alleviation | Qualitative/self-report |
| | N/A | Return on investment | Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome |
| Adoption Potential | N/A | Integrability with current infrastructure | Qualitative/self-report |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative/self-report |
| | N/A | Usability issues | Qualitative/self-report |

4.2.4 USE CASE 6 – Mid complexity KPIs

Table 85: USE CASE 6 – Mid complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-------------|---|--|
| Clinical | N/A | Hospital admissions Health deteriorations | Functionality of the technical solutions Utilities Resources use of Primary Care Resources use of Hospital Care |
| | N/A | Patient visits and time spent | number of on-site visits and length of visits |
| | N/A | Patient adherence to treatment | qualitative/self-report |
| | N/A | Quality of life | EQ5D |
| | N/A | Adverse events | qualitative/self-report |
| | N/A | Physical activity increase | qualitative/self-report |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance |
| | N/A | Patient empowerment health literacy | qualitative/self-report |
| | N/A | Cultural discomfort alleviation | qualitative/self-report |
| | N/A | Return on investment | Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome |
| Adoption Potential | N/A | Integrability with current infrastructure | qualitative/self-report |
| | N/A | Compatibility with clinical workflows/protocols | qualitative/self-report |
| | N/A | Usability issues | qualitative/self-report |

4.2.5 USE CASE 7 – Mid Complexity KPIs

Table 86: USE CASE 7 – Mid Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-------------|--|---|----------------------------|
| Clinical | N/A | Number of drug-related adverse events | Osakidetza administrative database | Changed KPI and tool |
| | | Number of hospitalizations | Osakidetza administrative database | Changed KPI and tool |
| | N/A | Number of hospital readmissions | Osakidetza administrative database | Changed KPI and tool |
| | | Number of drugs prescribed | Osakidetza administrative database | Changed KPI and tool |
| | N/A | Quality of life | Barthel | Changed tool |
| Societal | N/A | Technology usability | Questionnaire on technology usability :- SUS and MAUQ | (N/C) |
| | N/A | Technology accessibility Technology satisfaction Technology usability Technology utility | Focus groups or semi-structured interviews | (N/C) |
| | | number of app downloaded number of active users how much time users spend in the app/ how often users visit the app/WS how much time users spend in each module how often users visit each module | App server and Web service | (N/C) |

4.3 Cyprus

Study Design

The Cyprus pilot mainly focuses on the early detection of the condition worsening of cancer and dementia patients by monitoring whether the use of technology can trigger appropriate management, thereby reducing the need for higher acuity care, and even, at times, improving survival by supporting demand-driven solutions through high-quality health mobile systems.

Two organizations are managing the studies PASYKAF and AMEN, respectively with 1000 and 400 patients implementing the RUC 7.

The aim, for both organizations, is placed in improving the quality of life for people living with Dementia (AMEN) or Cancer (PASYKAF) via early detection of the illness. A focus will be placed on symptom control methods and palliative care via pain management interventions.

To date, due to the pandemic, all ethical approvals not covid related are stopped. Nonetheless the two Organizations arranged all the necessary steps to start as they'll get the ethics response:

The study is summarized in the Table 87.

Table 87: Cyprus Study Design

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|---------------------|---------------|--|--|--------------------------|---------------------|
| High | 1000 | 7 - polymedication / multimorbidity PASYKAF | Between subject design with randomized intervention and control groups | 334 + 335 | 331 |
| | 400 | 7 - polymedication / multimorbidity AMEN | Between subject design with randomized intervention and control groups | 132 + 132 | 136 |

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.3.1 USE CASE 7 – High Complexity KPIs

Table 88: USE CASE 7 – High Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-------------|--|--|--|
| Clinical | N/A | quality of life | 1. To all: 2. EORTC Quality of Life – Core Questionnaire 3. 4. To cancer patients: 5. IPOS 6. QLQ-C30 7. The Hospital Anxiety and Depression Scale (HADS) 8. 9. To dementia patients: 10. Mini-Mental State Examination (MMSE) questionnaire | Defined the target group for each tool |
| | N/A | Sleep Quality | qualitative/self-report | (N/C) |
| | N/A | Anxiety and Depression | 11. To cancer patients: Hospital Anxiety and Depression Scale (HADS) 12. To caregivers: BECK (Depression Inventory) STAI (state trait anxiety inventory) 13. To dementia patients: Geriatric Depression Scale (GDS) 5. Geriatric Anxiety Scale (GAS) | Defined the target group for each tool |
| | N/A | Physical activity increase | qualitative/self-report | (N/C) |
| Societal | N/A | Technology acceptance | System Usability Scale (SUS) The Single Ease Question (SEQ) Unified Theory of Acceptance and use of Technology (UTAUT) Questionnaire (Adapted version) | Tool redefined |
| | N/A | Patient empowerment health literacy | qualitative/self-report | (N/C) |
| | N/A | Informal Caregivers empowerment | Zarit Burden Interview (caregiver burden) 2. BECK 3. STAI | 4. Tool redefined |
| | N/A | Health Professionals quality of life in relation to technology adopted | System Usability Scale (SUS) The Single Ease Question (SEQ) 3. STAI | 4. Tool redefined |
| Adoption Potential | N/A | Specificity, sensitivity and AUC of models / Effectiveness | Cost analysis | (N/C) |
| | N/A | Usability issues | System Usability Scale (SUS) The Single Ease Question (SEQ) | (N/C) |

4.4 Central Greece and Attica (Greece)

Study Design

Attica and Central Greece will focus their studies on the Lifestyle-related early detection and intervention for older adults & elderly at risk for Metabolic Syndrome and Short term predictive modeling of glycemic status for elderly patients with Type 2 Diabetes Mellitus. Early prevention measures especially for elderly at high risk of chronic conditions, such as prediabetics or obese, include structured lifestyle-change programmes that help people achieve and sustain changes in dietary and physical activity habits.

The Greek pilot will include 1150 citizens in their studies, 1000 on RUC1 about prevention and 150 on RUC3 about predictive modelling of glycaemic status.

The experiment started with UC1 in Attica enrolling and training HCPs on the software of Metabolic syndrome management. There is close collaboration among pilot site partners and CERTH so that any questions on platform use are answered fast.

The pilot sites have prepared a care pathway so that dietitians and patients are better presented with what they can gain from the study. To start enrolling participants for Intervention Group B (software + sensors) and for UC3 is necessary for the pilot to acquire all the equipment in the next weeks. Preparing tendering process documents is in progress. The relevant legislation was modified in Greece this month and we need to make sure no adjustments are needed.

A brief overview can be seen in Table 89.

Table 89: Greece Study Design

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|---------------------|---------------|---------------------|--|--------------------------|---------------------|
| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control |
| Low | 1000 | 1 – Prevention | Between subject design with randomized intervention and control groups | 640 | 320 |
| Medium | 195 | 3 – Diabetes | Between subject design with randomized intervention and control groups | 155 | 40 |

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.4.1 USE CASE 1 - Low complexity KPIs

Table 90: USE CASE 1 – Low Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|--|---|
| Clinical | N/A | Waist circumference | Qualitative/self-report / HCP report |
| | N/A | BMI | Qualitative/self-report / HCP report |
| | N/A | Body fat | Qualitative/self-report / HCP report |
| | N/A | Sleep quality | Qualitative/self-report / HCP report |
| | N/A | Patient adherence to treatment | Qualitative/self-report |
| | N/A | Sedentary time | Qualitative/self-report |
| | N/A | Physical activity | Qualitative/self-report |
| | N/A | Diet quality | Qualitative/self-report |
| | N/A | Quality of life | ED5Q and MQLI-gr |
| Impact Assessment | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline | Qualitative/self-report |
| | Sustainability costs and benefits | Time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Adoption Potential | N/A | Integrability with current infrastructure | Qualitative assessment |
| | N/A | Compatibility with clinical workflows/protocols | Qualitative/self-report |
| | Usability issues technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Qualitative/self-report |
| | N/A | Training time of healthcare professionals and patients | Self-report hours/days |

4.4.2 USE CASE 3 – Medium complexity KPIs

Table g1: USE CASE 3 – Medium complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------------------|--|---|
| Clinical | N/A | Hypoglycaemic events | Qualitative/self-report / HCP report |
| | N/A | Glycaemic control | % (Time in Range, Time below range) ³ |
| | N/A | Problem Areas in Diabetes scale | self-report PAID (Disease specific HRQL) |
| | N/A | HSF-II (Hypoglycaemia Fear Survey-II) | Survey – self-report |
| | N/A | GMSS Glucose Monitoring System Satisfaction | Survey – self-report |
| | N/A | Quality of life | ED5Q and MQLI-gr |
| Impact Assessment | Sustainability costs and benefits | One-off costs Recurrent costs Healthcare costs Societal costs baseline | Qualitative/self-report |
| | Sustainability costs and benefits | Quality of life | EQ-5D |
| | Sustainability costs and benefits | time horizon | Expected length of effectiveness assessed by historical data and based on scientific literature |
| Adoption Potential | N/A | Integrability with current infrastructure | Qualitative assessment |
| | N/A | Compatibility with clinical workflows/protocols | qualitative/self-report |
| | Usability issues technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | qualitative/self-report |
| | N/A | Training time of healthcare professionals and patients | self-report hours/days |

4.5 Milton Keynes

Study design

This study aims to build a community-based care system through the collection of real-life scenarios that could be used as guidelines to (re)design and to develop of technologies to foster socialization among elders in such contexts. The specific requirement about the participants is to be representative of the composition of the local community. This study cannot be strictly defined "clinical" like the others and will include at least 100 citizens,

Due to the COVID-19 SARS COV2, the RUC1 is associated with a new RUC9 addressing social isolation and quality of life in a pandemic scenario of social isolation. Furthermore, due to the prolonged pandemic, we had to scale down the targets for the RUCs 1, 7 & 9 to be compatible with the current changes and modalities of work of the community services in the Pilot area, and to consider the impossibility to safely engage with elders (e.g., training and deployment) during the pandemic. Lastly, to compensate the reduction of the participant target in the Milton Keynes pilot area, we are currently working with the LSP management and our technical partner Samsung UK in identifying a secondary site and a local partner in the UK and therefore to extend the following described RUCs 1, 7 & 9 with one or two new RUCs.

The main objectives for each level of complexity are described in Table g2.

Table g2: Milton Keynes Study Design

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|---------------------|---------------|-------------------------------------|--|--------------------------|---------------------|
| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control |
| Low | 130 | 1/9 - Prevention | Between subject design with randomized intervention and control groups | 50 + 30 | 50* |
| Low | 70 | 7 - polymedication / multimorbidity | Between subject design with randomized intervention and control groups | 20 | 20* |

* Participants will be join the control group before the KETs deployment for collecting baseline data

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.5.1 USE CASE 9 – Low Complexity KPIs

Table 93: USE CASE 1 – Low Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-----------------------------|---|--|----------------------------------|
| Clinical | N/A | Quality of life | EQ-5D-3L | New RUC, KPIs and tool redefined |
| | N/A | Promote healthy habits | Qualitative/self-report | New RUC, KPIs and tool redefined |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance | New RUC, KPIs and tool redefined |
| | N/A | Patient empowerment health literacy | Qualitative/self-report | New RUC, KPIs and tool redefined |
| | N/A | Cultural/Social discomfort/isolation alleviation | Qualitative/self-report | New RUC, KPIs and tool redefined |
| | N/A | Return on investment | Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome | New RUC, KPIs and tool redefined |
| | N/A | Privacy / data issues | Qualitative assessment | New RUC, KPIs and tool redefined |
| Adoption Potential | | Perceived of usefulness | | |
| | Usability issues technology | Perceived ease of use User satisfaction Attributes of usability | Qualitative/self-report | New RUC, KPIs and tool redefined |

4.5.2 USE CASE 7 – Low Complexity KPIs

Table g4: USE CASE 7 – Mid Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-----------------------------|--|--|----------------------------|
| Clinical | N/A | Quality of life | EQ-5D-3L | Tool redefined |
| | N/A | Patient visits and time spent | Number of on-site visits and length of visits | N/C |
| | N/A | Adverse events | Qualitative/self-report | N/C |
| | N/A | Physical activity increase | Qualitative/self-report | N/C |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance | N/C |
| | N/A | Patient empowerment health literacy | Qualitative/self-report | N/C |
| | N/A | Cultural/Social discomfort/isolation alleviation | Qualitative/self-report | N/C |
| | N/A | Return on investment | Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome | N/C |
| Adoption Potential | N/A | Privacy / data issues | Qualitative assessment | N/C |
| | Usability issues technology | Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability | Qualitative/self-report | N/C |

4.6 Poland

Study design

The studies to be conducted in this Pilot Site are on Prevention of non-adherence to medication in community-dwelling older adults at different level of complexity. One Low Complexity involves 1000 patients and health care professionals; one Medium Complexity will recruit 130 patients and health care professionals and the last on High Complexity will work with 100 patients and health care professionals.

The experiment started with the low complexity use case, LODZ-1, with a limited number of patients in early March, 2021, providing the prove of practical implementation of technology in real-life conditions. Two activities are in place:

- internal test of the technology with staff members - at the moment, ongoing, the next phase to conclude by M18
- "pilot of the pilot" with limited number of external user has already started

After each round, fine-tuning of the system is envisaged and the deployment will continue with deployment: 1,000 users use the download app and offered coaching. The main objectives for each level of complexity are described in Table 95.

Table 95: Poland Study Design

| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control |
|---------------------|------|-------------------------------------|---|--------------|---------|
| Low | 1000 | 1 - Prevention | retrospective data to estimate-simulate a control group in the impact assessment analyses | 1000 | - |
| Medium | 130 | 7 - polymedication / multimorbidity | retrospective data to estimate-simulate a control group in the impact assessment analyses | 130 | - |
| High | 50 | 7 - polymedication / multimorbidity | retrospective data to estimate-simulate a control group in the impact assessment analyses | 50 | 50 |

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.6.1 USE CASE 1 – Low complexity KPIs

Table g6: USE CASE 1 – Low complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-------------|--|-------------------------------|----------------------------|
| Clinical | N/A | Quality of life | Self-reported on visual scale | Tool redefined |
| | N/A | Patient adherence to treatment | Qualitative/self-report | N/C |
| | N/A | Adverse events | Qualitative/self-report | N/C |
| Societal | N/A | Patient / Citizen empowerment Health literacy | Qualitative/self-report | N/C |

4.6.2 USE CASE 7 – Mid and High Complexity KPIs

Table g7: USE CASE 7 – Mid and High Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-------------|--|------------------------------------|--|
| Clinical | N/A | Quality of life | Self-reported on visual scale | Redefined Clinical KPIs / Tool redefined |
| | N/A | Patient adherence to treatment | Quantitative (digital measurement) | Redefined Clinical KPIs / Tool redefined |
| | N/A | Adverse events | Qualitative/self-report | Redefined Clinical KPIs / Tool redefined |
| Societal | N/A | Patient / Citizen empowerment Health literacy | Qualitative/self-report | N/C |

4.7 Puglia

Study design

The study in this pilot includes 10,000 subjects in the Low Complexity Use Case, and 500 subjects in the Moderate Complexity Use Case. The lower number of participants in the second Case is due to the higher costs of equipping them with appropriate KETs.

The two different study designs are planned for the Puglia Pilot, as follows:

- Quasi-experimental study design including two types of sampling:
 - o for the cost effectiveness assessment of the Moderate Complexity Medical Use Case 2 – COPD, 3 – Diabetes, 5 – Heart failure prevention and early intervention, 7 – polymedication / multimorbidity, 8 – High Blood Pressure
 - o for the cost effectiveness assessment of the Low Complexity Medical Use Case 1-Prevention
- Observational study design for developing a model for predicting the control of type 2 diabetes mellitus (DMT2) based on the use of "conventional" clinical parameters and of "unconventional" data from wearable devices. More specifically we will also assess the effect of physical activity and sleep on health risk trajectories in T2D patients. This study is aimed at covering an example of management of hospitalized chronic patients and related follow up, in the frame of the Moderate Complexity Use Case 3 – Diabetes

The last one is the first experiment started with the HCPs training, technology has been acquired and will be on place by the end of M19, recruitment is running with 5 persons per week.

About the interventional studies (RUCs #2, #3, #5, #7, #8) the

The matter with Ethics Approvals is still complex, as problems related to Covid-19 compounded with recent regulatory modifications in Italy on the organization of local Ethics Committees. On the other side, the improvement of the Covid-19 situation is now allowing a more intense cooperation with relevant roles. The main objectives for each level of complexity are described in Table 98.

Table 98: Puglia Study Design

| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control | Partner |
|---------------------|-------|---|--|--------------|---------|-------------------|
| Low | 9,400 | 1 – Prevention | Quasi-experimental design with intervention and control groups | 4,700 | 4,700 | RPU, AReSS, IP |
| Medium | 996 | 2 – COPD 3 – Diabetes 5 – Heart failure prevention and early intervention 7 – Polymedication / multimorbidity | Quasi-experimental design with intervention and control groups | 498 | 498 | RPU, AReSS, IP |

| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control | Partner |
|---------------------|-----|------------------------|------------------------|--------------|---------|---------|
| | | 8– High Blood Pressure | | | | |
| | 100 | 3 – Diabetes | - Observational design | 100 | - | CSS |

Puglia Pilot plans to execute both quasi-experimental and observational studies within RUCs 2, 3, 5, 7 and 8 and this led to different evolution KPIs definitions as follows.

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.7.1 USE CASE 1 interventional - Low Complexity KPIs

Table gg: USE CASE 1 interventional - Low Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|---------------------|---|--|
| Clinical | Primary objective | Health Related Quality of life | EQ-5D - HRQL (ICER denominator) |
| | Primary objective | Healthcare expenditure disbursed for drugs, specialist visits, hospitalizations | ICER numerator |
| Societal | Secondary objective | User engagement | mHealth apps scales (PAM scale items) |
| | Secondary objective | Usage of GK technology | App / software logs |
| | Secondary objective | Technology acceptance | Questionnaire on technology acceptance (TAM scale) |
| | Secondary objective | Patient empowerment | Qualitative/self-report (PAM scale items) |
| | Secondary objective | Health literacy | Qualitative/self-report (PAM scale items) |
| | Secondary objective | Usability | SUS scale |
| | Secondary objective | Trust | PATAT scale |

4.7.2 USE CASE 2, 3, 5 quasi-experimental - Mid Complexity KPIs

Table 100: USE CASE 2, 3, 5, 7 and 8 quasi-experimental - Mid Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-----------------------|--|--|
| Clinical | Primary objective | Health Related Quality of life | EQ-5D - HRQL (ICER denominator) |
| | Primary objective | Healthcare expenditure disbursed for drugs, specialist visits, hospitalizations | ICER numerator |
| | Secondary objective | Patient and HCP Usage of GK technology | App / software logs |
| | Secondary objective | Patient and HCP Technology acceptance | Questionnaire on technology acceptance (TAM scale) |
| | Secondary objective | Patient and HCP Usability | SUS scale |
| | Secondary objective | Patient and HCP Trust | PATAT scale |
| | Exploratory objective | Variation of HRQoL per disease and comorbidity profiles | HRQoL level |
| | Exploratory objective | Variation of Healthcare expenditure disbursed for drugs, specialist visits, hospitalizations per disease and comorbidity profile | Expense over 12 months |
| | Exploratory objective | Number of unplanned hospitalizations | Number over 12 months |
| | Exploratory objective | Duration of unplanned hospitalizations | Time over 12 months |
| | Exploratory objective | DDCI at enrolment | |
| Societal | Secondary objective | Specialist visits | Cost over 12 months |
| | | Drug usage | Costs of drugs |
| | | Usage of GK technology | App / software logs |

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-------------|--|--|
| | | Technology acceptance | Questionnaire on technology acceptance (TAM scale) |
| | | Patient empowerment health literacy | qualitative/self-report (PAM scale items) |
| | | Usability | SUS scale |

4.7.3 USE CASE 3 observational (CSS) – Mid Complexity KPIs

Table 101: USE CASE 3 observational (CSS) – Mid Complexity KPIs*

*(not changed from the previous version)

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|---|--|----------------------------------|
| Clinical | N/A | Specificity, sensitivity and AUC of models | |
| | N/A | Estimated ICER resulting from the integration of the models in the clinical practice | ICER |
| | N/A | ENFORCE score at enrolment and after 12 months of follow up | ENFORCE with clinical parameters |
| | Unconventional data from GATEKEEPER Consumer Space technologies | Step count Walk distance Walk time Walk speed Walk calories HR/HRV Sleep quality Stress level | Clinical parameters data |

4.7.4 USE CASE 1, 2, 3, 5, 7, 8 observational – Low and Mid Complexity KPIs

Table 102: USE CASE 1, 2, 3, 5, 7 observational – Low and Mid Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-----------------|---|--------------------------|--|
| Clinical | | Specificity, sensitivity and AUC of models | | N/C |
| | | Estimated ICER resulting from the integration of the models in the clinical practice | ICER | N/C |
| | | Healthcare expenditure disbursed for drugs, specialist visits, hospitalizations | ICER numerator | N/C |
| | For RUC5 (HF) | Blood pressure Respiratory rate Blood oxygen saturation Pulse rate Heart rate variability Stroke volume Cardiac output Cardiac index Pulse pressure Systemic vascular resistance Mean arterial pressure Sweat level Temperature Body composition | Clinical parameters data | Redefined Clinical KPIs / Tool redefined |
| | | Physical activity Sleep quality | Activity parameters data | N/C |
| | For RUC8 (HBP) | Blood pressure | Clinical parameters data | NEW RUC Redefined Clinical KPIs / Tool redefined |
| | | Physical activity Sleep quality | Activity parameters data | N/C |
| | For RUC2 (COPD) | SpO2 Blood Pressure | Clinical parameters data | Redefined Clinical KPIs / Tool redefined |
| | | Physical activity Sleep quality | Activity parameters data | N/C |
| | For RUC1 | Step count Walk distance Walk time Walk speed Walk calories | Activity parameters data | Redefined Clinical KPIs / Tool redefined |

In addition to the above variables, that come from KETs deployed for Moderate and Low Complexity quasi-experimental studies, other conventional clinical data may become available from the EHRs of the Puglia Region's healthcare. This availability is still under discussion at the time of this writing, in the frame of technology deployment.

4.8 Saxony

Study design

The SAX use cases aim to maintain mental well-being. Changes in daily habits and activities as well as worsening in psychological (e.g. anxiety, depressive, somatoform and dissociative) and physical symptoms lead to an early detection of mental health symptoms. Moreover, EME could be helpful in Multi-chronic elderly patient management including polymedication especially in case of comorbidity with mental health symptoms. The experiment will include 10300 citizens on three levels of complexity: Low Complexity – Sax 1 – Self Care 10000 citizens, Moderate Complexity – Sax 2 – Disease management 200 citizens, High complexity – Sax 3 – Case management 100 citizens.

For low complexity RUC#1 as soon as ethics approval is granted (an amendment due to changed data storage solution was requested and submitted) participants will be actively approached using the prepared recruitment material and with the support of local partners. The participants are actively approached using recruitment materials (Advertising, flyer) during their stay in the university clinic facilities or by other health care services, health care providers and health insurance companies. A cooperation with different partners and institutions is initialized, e.g., geriatric clinics and senior citizens centre, outpatient clinics, nursing homes, counselling centres for elderly.

Advertisement and promotion will be coordinated by the local partner CCS through flyers, advertisements in clinic and prints, social media, and reinforcing contact with the local partners: Psychiatric Gerontology, Department of Endocrinology / diabetes / metabolic bone diseases, Outpatient clinic of geriatric medicine, Radeburg, Outpatient hip department.

The deployment strategy so far:

- Internal testing of RUC1 technologies with 10 test users for technical training.
- RUC1 deployment (as soon as ethics approval is ready): 30 users will bring their own devices and download the app
- RUC 7 with Samsung for internal Usage/testing (as soon as integration of apps is ready) and 20 users wearing Samsung smartwatch will start collecting data. The main objectives for each level of complexity are described in Table 103.

Table 103: Saxony Study Design

| Level of complexity | N of subjects | Reference Use Cases | Study Type | Subjects in Intervention | Subjects in Control |
|--------------------------------|---------------|---------------------|--|--------------------------|---------------------|
| Low (SAX – mild) | 10000 | 1 (SAX-1) | Experimental Design: Between, Within, Mixed | Up to 10000 | - |
| Mid (SAX – moderate) | 200 | 7 (SAX-2) | Between subject design with randomized intervention and control groups | 100 | 100 |
| High (SAX – High) | 100 | 7 (SAX-3) | Between subject design with randomized intervention and control groups | 50 | 50 |

The Evolution KPIs defined with the Pilot are described in the below tables per RUCs, Complexity, Categories along with the related measurement tools.

4.8.1 USE CASE 1 – Low Complexity KPIs

Table 104: USE CASE 1 – Low Complexity KPIs

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool | Changes from D7.2 (if any) |
|---------------------------------|-------------------------------|--|--|----------------------------|
| Clinical | N/A | Hospital admissions Health deteriorations | Qualitative/self-report | N/C |
| | Patient visits and time spent | PROMs in the beginning/end of the pilot (for users) Advances in clinical practice/effectiveness and user satisfaction | Qualitative/self-report | KPI s Redefined |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance | N/C |
| | N/A | Patient/Citizen empowerment Mental health literacy | qualitative/self-report | N/C |
| | N/A | Cultural/Social discomfort /isolation alleviation | qualitative/self-report | N/C |
| Adoption Potential | N/A | Usability issues | qualitative/self-report | N/C |

4.8.2 USE CASE 7 – Mid and High Complexity KPIs:

Table 105: USE CASE 7 – Mid and High Complexity KPIs*

**(not changed from the previous version)*

| Impact assessment KPIs Category | Subcategory | KPI | Measurement tool |
|---------------------------------|-------------------------------|--|--|
| Clinical | N/A | Hospital admissions Health deteriorations | Qualitative/self-report |
| | Patient visits and time spent | The Multidimensional of Perceived Social Support PROMs in the beginning/end of the pilot (for users) RCT – intervention (practitioner supervised group) compared to intervention non supervised group Certification as medical devices for prevention and detection, and accompanying treatments Prescriptions | Qualitative/self-report |
| | | N/A | EQ-5D |
| | | N/A | Quality of life |
| Societal | N/A | Technology acceptance | Questionnaire on technology acceptance |
| | N/A | Patient/Citizen empowerment Mental health literacy | qualitative/self-report |
| | N/A | Cultural/Social discomfort /isolation alleviation | qualitative/self-report |
| | N/A | User satisfaction | qualitative/self-report |
| | N/A | Cost-effectiveness | Monthly-Annual health care costs |
| Adoption Potential | N/A | Usability issues | Qualitative/self-report |
| | N/A | Compatibility with clinical workflows/protocols | qualitative/self-report |

4.9 Asian Pilots

The ongoing inclusion activities are being implemented through a collaborative process to define the experiments under all the aspects: clinical, ethical and socio economical.

In this section the three Asian Pilots are described with their preliminary experiment definitions and their chosen RUCs.

The next issues of these report series will align the Asian Pilots accordingly.

4.9.1 Hong Kong

4.9.1.1 Preliminary Study design

This pilot site is focusing the experiments in the following RUCs / levels of complexity as the following table:

Table 106: Hong Kong preliminary study design

| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control |
|---------------------|-----|---|---|--------------|---------|
| Low | TBD | 1 – Lifestyle-related 6 – stroke management / prevention 8– High Blood Pressure | Observational Between subject design with randomized intervention and control groups | TBD | - |
| Medium | 50 | 6 – Primary and secondary stroke prevention | Mixed method design | 50 | no |

The experiments are going to be implemented as the following experiments:

- Register-based Big Data Platform, an online big data platform to construct risk measured based on established indices and track the trajectories by linking personal characteristics, neighbourhood characteristics, service utilisation and critical outcomes. This will include Moderate complexity chronic patients (Disease management) and Risk factors/Low complexity patients (Self-care) recruiting all elderly aged 60 or above who are members of a local NGO, The Aberdeen Kai-fond Welfare Association Social Service (AKA). The expected results are to provide clear trajectories of AKA members; meet elderly's care needs via data pooling; improve predictive accuracy by utilising machine learning and deep learning
- Digital coach via HealthCap, is One-stop health management platform to predict and prevent health and cardiovascular disease to address Risk factors/Low complexity patients (Self-care) in RUC#8. This use case serves as a one-stop health management platform for user to monitor blood pressure regularly, personalized reports showing blood pressure variation and trend are provided. It also prevents heart and cardiovascular disease by embedded health AI for prediction of elevated health risk

WeRISE App: One-stop family-based stroke management platform to empower family caregivers and stroke patients and address Low intensity (i.e.: a health-promotion app), Moderate Intensity (i.e.: a program involving medical personnel; or some degree of monitoring) and High intensity (i.e.: a program with intensive monitoring or complex clinical or social interventions/interactions). This use case serves as a one-stop stroke prevention and management platform for user to monitor blood pressure and blood glucose regularly, personalized reports showing blood pressure variation and trend are provided. It also provides family-oriented features for caregivers to manage the stroke patients' health conditions. The main expected results are: raise public awareness on stroke prevention and management and enhance quality of life of family caregivers and stroke patients.

The actual status is the organisation and management of the overall experiment defining the deployment of the technology.

4.9.2 Singapore

4.9.2.1 Preliminary Study design

Singapore pilot will work on RUC# 1 (Lifestyle-related early detection and interventions), RUC#2 (COPD exacerbations management), RUC#3 (Diabetes: predictive modelling of glycaemic status). Within the RUC1, the aim is to develop personal risk models about COPD and type 2 diabetes which should be useful for RUC2 and RUC3.

Hereby the table with the preliminary study design:

Table 107: Singapore preliminary study design

| Level of complexity | Number of patients | Use cases | Description | Objectives |
|---------------------|--------------------|--------------------------|--|---|
| Low | 200 | 1 - Prevention | Health promotion | <ul style="list-style-type: none"> - User satisfaction - Empowerment |
| Medium | 80 | 2 – COPD, 3- Diabetes | Integrated care for early detection of exacerbations | <ul style="list-style-type: none"> - To decrease the programmed activity (consultations) and not programmed (emergencies), reduction of admissions and length of stays. - Exacerbations prevention - Users satisfaction - Quality of life improvement |
| High | 20 | 2 – COPD, 3- Diabetes | Integrated care during exacerbations | <ul style="list-style-type: none"> - Reduction of the number of admissions and length of stays. - Users satisfaction - Improvement of the quality of life |

The main experiment called Chronic diseases prevention and early diagnosis for urban citizens. Smoking is the major risk factor for COPD and also has an impact on T2D. However, they won't focus the intervention only on preventing people from smoking. Nevertheless, prevention of exposure to toxic fumes is another major way to prevent COPD. For instance, air pollution including biomass fuel used for cooking, or pollutants in the workplace such as dusts and chemicals, may lead to the progression of COPD. In any

event, keeping a healthy lifestyle is crucial for vulnerable and elder people subject to T2D and COPD.

In details, the intervention consists in building:

- Personal spatio-temporal exposure models to enable COPD exacerbation risk assessment and early diagnostic according to the profile of the patient gathering different parameters as:
 - environmental variables
 - multiple personal data thanks to wearable devices
- Personal risk model on TD2 based on personal background, daily habits and general lifestyle.
- Early diagnostic methods.

For the clinical part: they already have developed few risk models for chronic diseases and the associated tools for patients and public health authorities (mobile apps and web dashboards). Thus, they are currently working on analysing state of the art about COPD and T2D (and COVID-19) personal risk models in order to update theirs for Gatekeeper use cases. The deployment and validation phases are being coordinated with the UoW and the other GK partners.

Currently they're testing some new IoT devices (smartwatch and air quality sensors) they want to use for the project.

Participant recruitment is in pause for Singapore site until a more precise planning is build. Additional random delays will come due to COVID-19.

4.9.3 Taiwan

4.9.3.1 Preliminary Study design

This pilot site will work on RUC# 1 (Lifestyle-related early detection and interventions) through the Health Management System for the people with Osteoporosis in Greater Hsinchu (Taiwan) as described in the following table and below:

| Level of complexity | N | Reference Use Cases | Study Type | Intervention | Control |
|---------------------|-----|-----------------------|--|--------------|---------|
| Low | TBD | 1 – Lifestyle-related | Observational Between subject design with randomized intervention and control groups | TBD | - |

The aim of this study is to address the following main objectives:

- To establish the concept of self-health management.
- To improve self-health management and health literacy.
- To improve the knowledge and skills of self-health management.
- To establish long-term self-health management behaviour.
- To be capable to do self-assessment on own health.

They are at the stage of designing the intervention strategy including: pre-test, post-test, the location (day care/elderly care centre), experiment period (12 months or longer). The recruitment strategy involves HCPs like orthopaedics doctors for participants enrolment.

On the technological part they're going to work with the Open data infrastructure from the government, Hospital medical records. The participants will use an App they will provide questionnaires and gather data from wearable sensors as dietary habits, exercise habits and mental health status. As to the mental health status, we consider to use established measurement/tool and also ask the user to record their mood verbally. We could have quantitative and qualitative data to analyse the users' mental status. It's planned to have a wide experience exchange with the SAXONY Pilot.

Currently working on the recruitment and on devices selection

5 Operative KPIs report

5.1 Operative KPIs template

This section introduces the elements that is being collected in an Excel form that was created and shared among pilot sites. The purpose of this template is to gather the main parameters that are related to the pilots' execution. This template has been released to collect target values and the progress of the different KPIs at report time (to be updated every 6 months).

Reporting per pilot

Reporting status at: dd/mm/yyyy

| | Started | Start date | End date |
|------------------------|--|------------|------------|
| Deployment preparation | <input type="checkbox"/> YES <input type="checkbox"/> NO | dd/mm/yyyy | dd/mm/yyyy |
| Experiment running | <input type="checkbox"/> YES <input type="checkbox"/> NO | dd/mm/yyyy | dd/mm/yyyy |
| Ecosystem enlargement | <input type="checkbox"/> YES <input type="checkbox"/> NO | dd/mm/yyyy | dd/mm/yyyy |

5.1.1 Deployment phase KPIs

In this section, the operative KPIs associated to the deployment phase are included. These KPIs allow the evaluation of the correct execution of user recruitment according to the target users defined in each pilot protocol, the deployment of all the technologies needed in each site, the conduction of the required training to end-users, and the installation of the entire solution.

5.1.1.1 Technological solution preparation

- Nr of devices to be installed/ used (Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc.) Please provide data separately per type of device indicating, which is already available, which should be acquired).
- Nr of procurements envisaged (one or more call for tenders/ procurement procedures may be planned).
- Stage of procurement (for each case): Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered.
- GATEKEEPER integration (for each component and platform version): progress state (%).
- GATEKEEPER Platform deployment: Yes (GK platform version)/No (expected date).
- Nr of user per type involved in the technical pre-testing.
- Average cost of technological solution per end-user (intervention group; not including possible control groups).

5.1.1.2 Recruitment

- Nr of contacted persons (per RUC and complexity level).
- Nr of expressions of interest received (per RUC and complexity level).
- Nr of confirmed users (that meet the selection criteria and have signed consent forms).
- Nr of excluded users (i.e. users that have signed the consent forms but do not meet the inclusion criteria).
- Nr of confirmed facilities to participate in the pilot (e.g. primary health centre, hospitals, houses, apartments, etc.).

5.1.1.3 Training

- Nr of training sessions completed (train the trainers; train users).
- Nr of trainees received training (overall and per type of stakeholder and/or user group).
- Assistance to training sessions (per stakeholder, gender, age).
- Number of end users trained by type of stakeholder.

5.1.1.4 Installations

- Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities to be named per RUC and level of complexity (installations should be completed, successfully tested, and be ready for operation).
- Nr of devices installed (please mention type of device and the respective number e.g. 10 glucometers, 15 wearables, 10 gateways, 50 tablets, etc.).
- Percentage of installations completed over total targeted, (also distinguish among RUC and level of complexity when possible).
- Person-effort spent per installation.
- Nr of RUC/services/applications actually deployed.

5.1.1.5 Further analysis

A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication.

5.1.2 Running phase KPIs

This section includes the KPIs for ensuring proper execution of the GATEKEEPER running phase. These KPIs cover the value associated with users' commitment during the experiment and operational effectiveness which guarantees the continuous evaluation and maintenance of the deployment site in a real environment.

5.1.2.1 Users commitment

- Nr of users in operation, i.e. actually participating in the study (per RUC and complexity level).
- Nr of users finalised, i.e. that have completed the experiment (per RUC and complexity level).
- Nr of drop-outs compared to the number of confirmed users and the number of signed informed consents (per RUC and complexity level).
- Average usage level of the GK solution: usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.).

5.1.2.2 Operational effectiveness

- Nr of technical/operational issues reported (per RUC). The aim is to measure how the solution works.
- Average response time to end-user requests/inquiries (in hours).
- Effectiveness in incidents management (% of issues solved, % partly addressed, % not solved).
- Nr of solution updates/upgrades (per RUC).

5.1.2.3 Further analysis

A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication.

5.1.3 Ecosystem enlargement phase KPIs

This section shows quantitative indicators reflecting the incorporation of new elements into each pilot contributing to the enlargement and scalability of the GATEKEEPER ecosystem and demonstrating interoperability of the platform.

5.1.3.1 RUCs exchange results

- Nr of pilots interacted with (as a result of the RUC exchange).
- Nr of new users (as a result of the RUC exchange) per RUC and complexity level.
- Nr of new services (as a result of the RUC exchange) per RUC and complexity level.

5.1.3.2 Open call results

- Nr of new users (as a result of the open calls) per RUC and complexity level.
- Nr of new services (as a result of the open calls) per RUC and complexity level.

5.2 LSP multicentred operative report

Considering the individual pilots' reports and following the contents in the template above described a complete report of the entire LSP multicentre pilot is included in this section and it will be updated every six months. It aims to provide the reader with an overview of the pilot progress at project level based on the data reported. The individual reports (per pilot) are included in the Appendix B. Individual KPI Evolution Reports for further details description. This version includes the target values expected for each operative KPI identified in each LSP execution phase, i.e. deployment, running or ecosystem enlargement. Future versions of the deliverable will include an aggregation emphasizing the most relevant points of the pilot execution by collecting every six months the current KPI values.

5.2.1 Deployment phase · target values

Technological solution preparation

Table 108: Operative KPIs · Technological solution preparation target values

| Operative KPI | ARA | BC | CYP | GRE | MK | PUG | POL | SAX | TOTAL |
|--|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|----------------------------|
| Nr of devices to be installed/used | 2.144 | 21.845 | 409 | 920 | 720 | 598 | 1.230 | 550 | 28.416 |
| Nr of procurements envisaged | 5 | 3 | 1 | 1 | 1 | 6 | - | 1 | 18 |
| Stage of procurement (for each case) | Equipment delivered | Equipment delivered | Equipment delivered | Equipment delivered | Equipment delivered | Equipment delivered | Equipment delivered | Equipment delivered | Equipment delivered |
| GATEKEEPER integration | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| GATEKEEPER Platform deployment | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Nr of user per type involved in the technical pre-testing | 20 | 35 | - | 35 | 18 | 20 | 40 | 10 | 178 |
| Average cost of technological solution per end-user | 39€ | 14€ | 58€ | 134€ | 361€ | <500€ | - | 9€ | - |

Recruitment

Table 109: Operative KPIs · Recruitment target values

| Operative KPI | ARA | BC | CYP | GRE | MK | PUG | POL | SAX | TOTAL |
|---|-------|--------|-----|-----|-----|--------|-------|--------|---------------|
| Nr of contacted persons | 2.404 | 11.378 | - | 845 | 30 | 10.626 | 2.360 | 10.350 | 37.993 |
| Nr of expressions of interest received | 2.404 | 11.378 | - | 845 | 30 | 10.626 | 1.436 | 30 | 26.749 |
| Nr of confirmed users | 2.404 | 11.300 | - | 30 | 100 | 10.626 | 1.180 | 10.350 | 35.990 |
| Nr of excluded users | 0 | 0 | - | 0 | 0 | 0 | - | 0 | 0 |
| Nr of confirmed facilities to participate in the pilot | 45 | 13 | - | 41 | 10 | 4 | 5 | 3 | 121 |

Training

Table 110: Operative KPIs · Training target values

| Operative KPI | ARA | BC | CYP | GRE | MK | PUG | POL | SAX | TOTAL |
|--|-----|-----|------|-----|-----|-----|------|-----|--------------|
| Nr of training sessions completed | 55 | 7 | 10 | 3 | 6 | 600 | - | 150 | 831 |
| Nr of trainees received training | 2 | 3 | 5 | 830 | 100 | 628 | - | 10 | 1.578 |
| Nr of end users trained by type of stakeholder | 169 | 295 | 1400 | 810 | 100 | 628 | 1180 | 200 | 4.782 |

Installation

Table 111: Operative KPIs · Installations target values

| Operative KPI | ARA | BC | CYP | GRE | MK | PUG | POL | SAX | TOTAL |
|--|-------|--------|------|------|------|------|------|--------------------------------|---------------|
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | 5 | 125 | 611 | - | - | 4 | - | 10.250 | 11.015 |
| Nr of devices installed | 2.144 | 21.825 | - | 920 | 2 | 598 | 50 | 550 | 26.089 |
| Percentage of installations completed over total targeted | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Person-effort spent per installation | - | - | - | 1PM | - | - | - | Citizen 0h; patient 2h; HCP 1h | - |
| Nr of RUCs actually deployed | 6 | 6 | 1 | 3 | 3 | 6 | 2 | 2 | 8 |
| Nr of services actually deployed | 5 | - | - | 1 | 1 | 3 | - | - | 10 |
| Nr of applications actually deployed | 5 | - | - | 1 | 1 | 3 | - | 2 to 3 | 12 |

5.2.2 Running phase · target values

Users commitment

Table 112: Operative KPIs · Users commitment target values

| Operative KPI | ARA | BC | CYP | GRE | MK | PUG | POL | SAX | TOTAL |
|--|-------|--------|-----|-------------|--|--------|-------|--------|---------------|
| Nr of users in operation | 2.280 | 11.300 | TBD | 810 | 130 | 10.496 | 1.180 | 10.300 | 36.496 |
| Nr of users finalised | 2.280 | 11.300 | TBD | 810 | 130 | 10.496 | 1.180 | 10.300 | 36.496 |
| Nr of drop-outs | 0 | 0 | TBD | 228 | 0 | 0 | 0 | 0 | 228 |
| Average usage level of the GK solution | TBD | - | TBD | 30' per day | RUC1 2 per week RUC7 30'/day RUC9 1 per week | TBD | TBD | TBD | - |

Operational effectiveness

Table 113: Operative KPIs · Operational effectiveness target values

| Operative KPI | ARA | BC | CYP | GRE | MK | PUG | POL | SAX | TOTAL |
|--|-----|-----|-----|-----|-----|-----|-----|-----|-------|
| Nr of technical/operational issues reported | TBD | TBD | TBD | TBD | TBD | TBD | TBD | TBD | - |
| Average response time to end-user requests/inquiries | TBD | TBD | TBD | TBD | TBD | TBD | TBD | TBD | - |
| Effectiveness in incidents management | TBD | TBD | TBD | TBD | TBD | TBD | TBD | TBD | - |
| Nr of solution updates/upgrades | TBD | TBD | TBD | TBD | TBD | TBD | TBD | TBD | - |

5.2.3 Ecosystem enlargement phase · target values

Target values for this phase have not been collected in this version due to the early stage of the pilot execution.

6 Conclusions

Succeeding the D7.2 and the information published in this deliverable, we can state that the ongoing activities with all the Pilots are continuing the co-created path of the experimental designs.

The Section 4 about Operative KPIs gives a picture of the Pilot situation and let to identify issues that pilots encountered during the report of the target values, achieving a refined version of the KPIs and their explanations. The report of the target values of each pilot also helps to understand the dimensionality of the study design and to confirm that it is aligned with GATEKEEPER expected goals.

7 References

¹ Peters, M., Fitzpatrick, R., Doll, H., Playford, D., & Jenkinson, C. (2011). Does self-reported well-being of patients with Parkinson's disease influence caregiver strain and quality of life?. *Parkinsonism & Related Disorders*, 17(5), 348-352.

¹ Abu-Dalbouh, H. M. (2013). A questionnaire approach based on the technology acceptance model for mobile tracking on patient progress applications. *J. Comput. Sci.*, 9(6), 763-770.

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7076978/>

Appendix A Operative KPIs Tool

TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs

Pilot name:

XXX

Reporting period:

From:

DD/MM/Y
YYY

To:

DD/MM/Y
YYY

Name of the responsible person for the report:

XXX

| Initial timetable | Explanatory notes | Start date | End date | Remarks | | Status |
|------------------------------------|--|------------------|------------------------------|--------------|----------------|---------|
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | DD/MM/Y YYY | DD/MM/Y YYY | | | |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | DD/MM/Y YYY | DD/MM/Y YYY | | | |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | DD/MM/Y YYY | DD/MM/Y YYY | | | |
| Deployment phase | | | | | | |
| | | | | | | |
| Reporting status at: | | | | | DD/MM/Y YYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Type of device X | | | |
| | | | Type of device Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |

| | | | | | | |
|---|--|------------------|------------------------------|--|--|--|
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | | | |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | | | |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | | | |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | | | |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | Type of user X | | | |
| | | | Type of user Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | | | |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | Type of user X | | | |
| | | | Type of user Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | Type of user X | | | |
| | | | Type of user Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | Type of user X | | | |
| | | | Type of user Y | | | |
| | | | Add as many rows as you need | | | |

| | | | | | | |
|--|--|-------------------------------|------------------------------|--|--|--|
| | | | | | | |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | Type of user X | | | |
| | | | Type of user Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | Type of facility X | | | |
| | | | Type of facility Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | | | |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | | | |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | Type of end user X | | | |
| | | | Type of end user Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | Type of facility X | | | |
| | | | Type of facility Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | Type of device X | | | |
| | | | Type of device Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | | | |

| | | | | | | |
|--|---|---------------------------|------------------------------|---------------------|-----------------------|----------------|
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | GATEKEEPER solution X | | | |
| | | | GATEKEEPER solution Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of RUCs actually deployed | | Number (integer) | N/A | | | |
| Nr of services actually deployed | | Number (integer) | N/A | | | |
| Nr of applications actually deployed | | Number (integer) | N/A | | | |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | | | | |
| Running phase | | | | | | |
| | | | | | | |
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC X Complexity Y | | | |
| | | | RUC X Complexity Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC X Complexity Y | | | |
| | | | RUC X Complexity Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC X Complexity Y | | | |

| | | | | | | |
|--|--|-------------------------|------------------------------|---------------------|-----------------------|----------------|
| | | | RUC X Complexity Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC X Complexity Y | | | |
| | | | RUC X Complexity Y | | | |
| | | | Add as many rows as you need | | | |
| | | | | | | |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | | |
| Average response time to end-user requests/inquiries | | Hours | N/A | | | |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | | |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | | |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | | | | |
| Ecosystem enlargement phase | | | | | | |
| | | | | | | |
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

| | | | | | | |
|---|---|------------------|-----|-----|-----|-----|
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

Appendix B Individual KPI Evolution Reports

B.1 ARAGON pilot KPI Evolution Report

TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs

Pilot name: **ARAGON**

Reporting period:

From:

2020-10-01

To:

2021-03-31

Name of the responsible person for the report:

Innovation Unit Aragón

| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
|-----------------------------|---|---|--|---|--|
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | RUC1: 1/2/2021 RUC2,5,7(Mid Complexity): 1/06/2020 RUC2,5,7(High Complexity): 1/2/2021 RUC COVID Home: 1/2/2021 RUC COVID Center: 1/2/2021 | RUC2,5,7(Mid Complexity): 1/10/2021 | <ul style="list-style-type: none"> - Each RUC in the Aragón site runs independently. This means that each RUC can be in a different phase. - Some of the actions stated in the "Explanatory notes" for the deployment phase are also held during the Running phase. For instance, as recruitment of pend-users is done continuously, also the training and the installation and setup of devices for these users takes place during the running phase - We consider the end of the deployment phase the date in which the first patient is recruited | RUC1: Not started RUC2,5,7(Mid Complexity): Finished RUC2,5,7(High Complexity): Ongoing RUC COVID Home: Ongoing RUC COVID Center: Ongoing |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made | RUC2,5,7(Mid Complexity): 1/10/2021 | - | - | RUC2,5,7(Mid Complexity): ongoing |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | - | - | - | - |

| Deployment phase | | | | | | |
|--------------------------------------|--|------------------|---|---------------------------------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Health promotion app (BYOD) (low complexity) | 2000 | N/A | - |
| | | | Telemonitoring kit (mid complexity) 1 kit for 5 users | 34 | N/A | - |
| | | | Patch and telemonitoring kit (high complexity) | 30 | N/A | - |
| | | | Telemonitoring kit (COVID-home) | 40 | N/A | - |
| | | | Smartwatch (COVID-center) | 40 | N/A | - |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 5 | N/A | The target value is not an end in itself, the target would be the acquisition of all the equipment needed |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | Equipment delivered | N/A | The target should be the % of equipment delivered vs the equipment planned |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | 100% of data integration routes ready | N/A | Integration will be made at data level, no integration is foreseen at device level. |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | 2021-06-30 | N/A | Integration will be made at data level, no integration is foreseen at device level. |

| Deployment phase | | | | | | |
|---|---|------------------|----------------------|---|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | HCP | 5 | N/A | There is not a target value for this. The goal is to have the full technical pre-testing ready |
| | | | Technical personnel | 5 | N/A | Target value has ben fixed as one per group and level of complexity |
| | | | Social Care Provider | 5 | N/A | |
| | | | Citizen | 5 | N/A | |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | - | RUC2.5.7(Mid Complexity): 130 RUC2.5.7(High Complexity): 1000 RUC COVID Home: 587euros RUC COVID Center: 407 euros | N/A | There is no target value for this without a deeper analysis. The real cost will be estimated at the end of the project as there are many factors involved (e.g. time that each element can be used, devices that the site already had) |

| Deployment phase | | | | | | |
|--|--|------------------|--------------------------------------|--|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | End-users (patients) | RUC1: 2000 RUC2,5,7(Mid Complexity): 170 RUC2,5,7(High Complexity): 30 RUC COVID Home: 40 RUC COVID Center: 40 | N/A | The real target is to have the number of expected patients recruited. There is no target number for the number of contacted persons, neither for the excluded users |
| | | | End-users (healthcare professionals) | RUC1: 50 RUC2,5,7(Mid Complexity): 22 RUC2,5,7(High Complexity): 14 RUC COVID Home: 4 RUC COVID Center: 14 | N/A | The concept of target here has no sense as the number of people involved in the degree in which they are involved depends very much on the different profiles for HCP and how the service is organized. For RUC1 we have included 2 HCP (nurse and doctor) for 25 HC Centers, each of them having 40 patients. For MC , 22 PC Doctors and 2 Doctors Contact Center For HC : 6 : Emergency (2), Cardiology(2) and Internal Medicine (2) and 8 nurses For COVID Home : 4 (ER Doctors) For COVID Center : 10 nurses and 4 Internal Medicine Doctors |
| | | | End-users (socialcare professionals) | RUC2,5,7(Mid Complexity): 20 | N/A | Mid Complexity involves integrated care with social agents (we have included 5 association and 4 SCPs per association) |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | End-users (patients) | RUC1: 2000 RUC2,5,7(Mid Complexity): 170 RUC2,5,7(High Complexity): 30 RUC COVID Home: 40 | N/A | The target would be to have as many people recruited from the contacted people as possible |

| Deployment phase | | | | | | |
|-----------------------|---|------------------|--------------------------------------|--|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | | | RUC COVID Center: 40 | | |
| | | | End-users (healthcare professionals) | RUC1: 50 RUC2,5,7(Mid Complexity): 22 RUC2,5,7(High Complexity): 14 RUC COVID Home: 4 RUC COVID Center: 14 | N/A | - |
| | | | End-users (socialcare professionals) | RUC2,5,7(Mid Complexity): 20 | N/A | - |
| | | Number (integer) | End-users (patients) | RUC1: 2000 RUC2,5,7(Mid Complexity): 170 RUC2,5,7(High Complexity): 30 RUC COVID Home: 40 RUC COVID Center: 40 | N/A | The target would be to have as many people recruited from the contacted people as possible |
| | | | End-users (healthcare professionals) | RUC1: 50 RUC2,5,7(Mid Complexity): 22 RUC2,5,7(High Complexity): 14 RUC COVID Home: 4 RUC COVID Center: 14 | N/A | - |
| | | | End-users (socialcare professionals) | RUC2,5,7(Mid Complexity): 20 | N/A | - |

| Deployment phase | | | | | | |
|--|---|------------------|--------------------------------------|--|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | End-users (patients) | RUC1: 0 RUC2,5,7(Mid Complexity): 0 RUC2,5,7(High Complexity): 0 RUC COVID Home: 0 RUC COVID Center: 0 | N/A | The target would be not to exclude any contacted user |
| | | | End-users (healthcare professionals) | RUC1: 0 RUC2,5,7(Mid Complexity): 0 RUC2,5,7(High Complexity): 0 RUC COVID Home: 0 RUC COVID Center: 0 | N/A | - |
| | | | End-users (socialcare professionals) | RUC2,5,7(Mid Complexity): 0 | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | Primary Care Center | RUC1: 25 RUC2,5,7(Mid Complexity): 10 | N/A | 25 HC Centers for RUC1, 22 PC doctors in 10 HCC |
| | | | Specialized Care Units | RUC2,5,7(Mid Complexity): Contact Center RUC2,5,7(High Complexity): 3 RUC COVID Home: 1 RUC COVID Center: 1 | N/A | See row for healthcare professionals |
| | | | Social Care Center | RUC2,5,7(Mid Complexity):5 | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|---------------------------------------|--|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | 55 | N/A | 5 (MC) + 40 (RUC COVID Home) End Users 5 Social Care Organisations 5 Healthcare Centers and Specialized Care Units |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | 2 | N/A | - |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | End-users | RUC2,5,7(Mid Complexity): 5 RUC COVID Home: 40 | N/A | End-users are only trained in case of mid complexity use cases for those end-users that do not receive help from social care organisations. For those end-users who do not have technical skills, the informal carer is the one to be trained |
| | | | End-users (healthcare professionals) | RUC1: 50 RUC2,5,7(Mid Complexity): 22 RUC2,5,7(High Complexity): 14 RUC COVID Home: 4 RUC COVID Center: 14 | N/A | - |
| | | | End-users (social care professionals) | RUC2,5,7(Mid Complexity): 20 | N/A | - |

| Deployment phase | | | | | | |
|--|--|-------------------------------|--|---|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | - | RUC1:1 RUC2,5,7(Mid Complexity): 1 RUC2,5,7(High Complexity): 1 RUC COVID Home: 1 RUC COVID Center: 1 | N/A | Installations are centralized and there is no need to do individual installations at each facility |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | Health promotion app (BYOD) (low complexity) | 2000 | N/A | - |
| | | | Telemonitoring kit (mid complexity) | 34 | N/A | - |
| | | | Patch and telemonitoring kit (high complexity) | 30 | N/A | - |
| | | | Telemonitoring kit (COVID-home) | 40 | N/A | - |
| | | | Smartwatch (COVID-center) | 40 | N/A | - |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | RUC1: 100% RUC2,5,7(Mid Complexity): 100% RUC2,5,7(High Complexity): 100% RUC COVID Home: 100% RUC COVID Center: 100% | N/A | - |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood | Person-hours per solution | Health promotion app (BYOD) (low complexity) | 0 | N/A | The target would be to invest 0 time in this. |
| | | | Telemonitoring kit (mid complexity) | 0 | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|--|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| | pressure, glucometer - total time spent in the whole installation) | | Patch and telemonitoring kit (high complexity) | 0 | N/A | - |
| | | | Telemonitoring kit (COVID-home) | 0 | N/A | - |
| | | | Smartwatch (COVID-center) | 0 | N/A | - |
| Nr of RUCs actually deployed | | Number (integer) | N/A | 6 | N/A | RUC1,RUC2, RUC5, RUC7, COVID Home and COVID Center |
| Nr of services actually deployed | | Number (integer) | N/A | 5 | N/A | Low Complexity, Mid Complexity, High Complexity, COVID Home and COVID Center |
| Nr of applications actually deployed | | Number (integer) | N/A | 5 | N/A | Low Complexity, Mid Complexity, High Complexity, COVID Home and COVID Center |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Running phase | | | | | | |
|-------------------------|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| | | | RUC1 | 2000 | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC2,5,7 (Mid Complexity) | 170 | N/A | - |
| | | | RUC2,5,7 (High Complexity) | 30 | N/A | - |
| | | | RUC COVID Home | 40 | N/A | - |
| | | | RUC COVID Center | 40 | N/A | - |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC1 | 2000 | N/A | - |
| | | | RUC2,5,7 (Mid Complexity) | 170 | N/A | - |
| | | | RUC2,5,7 (High Complexity) | 30 | N/A | - |
| | | | RUC COVID Home | 40 | N/A | - |
| | | | RUC COVID Center | 40 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC1 | 0 | N/A | - |
| | | | RUC2,5,7 (Mid Complexity) | 0 | N/A | - |
| | | | RUC2,5,7 (High Complexity) | 0 | N/A | - |
| | | | RUC COVID Home | 0 | N/A | - |
| | | | RUC COVID Center | 0 | N/A | - |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC1 | tbd | N/A | - |

| Running phase | | | | | | |
|----------------------|-------------------|------------------|----------------------------|--|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| | | | RUC2,5,7 (Mid Complexity) | depending on pathology, at least once a week | N/A | - |
| | | | RUC2,5,7 (High Complexity) | tbd | N/A | Passive sensor, it may take measurements continuously |
| | | | RUC COVID Home | depending on profile, normally three times a day | N/A | - |
| | | | RUC COVID Center | tbd | N/A | Passive sensor, it may take measurements continuously |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | N/A | N/A | - |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |

| Running phase | | | | | | |
|---|-----------------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication.. | | | - | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.2 BASQUE COUNTRY pilot KPI Evolution Report

TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs

Pilot name: **BASQUE COUNTRY**

Reporting period: **From:** 2020-10-01 **To:** 2021-03-31

Name of the responsible person for the report: **Olatz Albaina and Janire Orcajo**

| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
|-----------------------------|---|------------|------------|--|----------------------|
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | 2021-02-01 | 2021-09-30 | The running strategy is already defined and some pre-testing has been carried out. To end with the Deployment phase the acquisition of KETs is required. | on-going |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | 2021-04-26 | 2023-03-31 | The Running phase will start once the KETs are acquired (still unknow) and tested. | Acquisition on-going |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | DD/MM/YYYY | DD/MM/YYYY | - | - |

| Deployment phase | | | | | | |
|--------------------------------------|--|------------------|----------------------------------|--------------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Smartphone | 10.625 | N/A | UC1: 10.000; UC3: 50; UC4: 50; UC6: 25; UC7: 500 |
| | | | Smartwatch | 125 | N/A | - |
| | | | Smart things | 350 | N/A | - |
| | | | Parkinson's disease Holter | 50 | N/A | - |
| | | | CGM system | 50 | N/A | - |
| | | | Blood Pressure monitor | 75 | N/A | - |
| | | | Virtual Reality Glasses | 20 | N/A | - |
| | | | MAHA app | 10.000 | N/A | - |
| | | | My treatment app | 500 | N/A | - |
| | | | Checkthemeds computer-based tool | 50 | N/A | - |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 3 | N/A | . Public Tender: transfer the budget for the purchase of the devices from our budget to the budget of the suppliers (1) . Purchase outside the consortium (2) |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | Suppliers selected | N/A | - |

| Deployment phase | | | | | | |
|---|--|------------------|----------|--------------|----------------|---------------------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | 100 | N/A | No technical acquisition so far |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | YES | N/A | - |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | ITs | 2 per UC | N/A | - |
| | | | Patient | 2 per UC | N/A | - |
| | | | HCP | 3 per UC | N/A | - |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | 14 € | N/A | - |

| Deployment phase | | | | | | |
|-------------------------|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | | Number (integer) | ITs | 6 | N/A | - |

| Deployment phase | | | | | | |
|--|---|------------------|--------------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | Per type of user. E.g. patient, citizen, HCP, etc. | | Patient | 11300 | N/A | - |
| | | | HCP | 72 | N/A | - |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | ITs | 6 | N/A | - |
| | | | Patient | 11300 | N/A | - |
| | | | HCP | 72 | N/A | - |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | Patient | 11300 | N/A | - |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | Patient | 0 | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | Primary health centre | 7 | N/A | - |
| | | | Hospitals | 2 | N/A | Cruces University Hospital: - Service of Endocrinology - Service of Neurology |
| | | | Integrated health organization | 4 | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|---------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | 7 | N/A | - |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | 3 | N/A | ITs: 1 Ibermatica 1 Biocruces 1 Kronikgune |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | Patients > 50 | 45 | N/A | UC 6 No gender identified |
| | | | Patients > 65 | 100 | N/A | UC 3 and UC 4 No gender identified |
| | | | Professionals | 150 | N/A | UC1: 100 professionals UC7: 50 professionals |

| Deployment phase | | | | | | |
|--|--|-------------------------------|---------------|--------------|----------------|-------------------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | Hospitals | 100 | N/A | (50 UC3 + 50 UC4) (25 UC6) |
| | | | Private homes | 25 | N/A | - |

| Deployment phase | | | | | | |
|---|---|---------------------------|-----------------------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | Smartphone | 10.625 | N/A | - |
| | | | Smartwatch | 125 | N/A | - |
| | | | Smart things | 350 | N/A | 350 devices to 25 patients (14 dev per user) |
| | | | Parkinson's disease Holter | 50 | N/A | - |
| | | | CGM system | 50 | N/A | - |
| | | | Blood Pressure monitor | 75 | N/A | - |
| | | | MAHA app | 10.000 | N/A | - |
| | | | Checkthemeds | 50 | N/A | - |
| | | | My treatment | 500 | N/A | - |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | 100 | N/A | - |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | UC 3 Diabetes solution | - | N/A | - |
| | | | UC 4 Parkinson's Disease solution | - | N/A | - |
| | | | UC 6 Stroke prevention | - | N/A | - |
| | | | UC 1 Healthy ageing | - | N/A | - |
| | | | UC7 Polypharmacy management | - | N/A | - |

| Deployment phase | | | | | | |
|--------------------------------------|-------------------|------------------|----------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of RUCs actually deployed | | Number (integer) | N/A | 6 | N/A | The 5 UCs will be deployed in 6 interventions: - UC1 Healthy ageing - UC3 Diabetes - UC4 Parkinson's Disease - UC6 Stroke identification - UC6 Stroke prevention - UC7 Polypharmacy management |
| Nr of services actually deployed | | Number (integer) | N/A | - | N/A | - |
| Nr of applications actually deployed | | Number (integer) | N/A | - | N/A | - |

| Deployment phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | | | | |

| Running phase | | | | | | |
|--------------------------|--|------------------|--------------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC 1 Complexity Low | 10000 | N/A | - |
| | | | RUC 3 Complexity High | 100 | N/A | - |
| | | | RUC 4 Complexity High | 100 | N/A | - |
| | | | RUC 6 Complexity Mid | 100 | N/A | - |
| | | | RUC 7 Complexity Low | 1000 | N/A | - |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC 1 Complexity Low | 10000 | N/A | - |
| | | | RUC 3 Complexity High | 100 | N/A | - |
| | | | RUC 4 Complexity High | 100 | N/A | - |
| | | | RUC 6 Complexity Mid | 100 | N/A | - |
| | | | RUC 7 Complexity Low | 1000 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC 1 Complexity Low | - | N/A | - |
| | | | RUC 3 Complexity High | - | N/A | - |
| | | | RUC 4 Complexity High | - | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|--------------------------|--|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| | | | RUC 6 Complexity Mid | - | N/A | - |
| | | | RUC 7 Complexity Low | - | N/A | - |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC 1 Complexity Low | 24 h a day | N/A | - |
| | | | RUC 3 Complexity High | 24 h a day | N/A | - |
| | | | RUC 4 Complexity High | 1 week per 6 months | N/A | - |
| | | | RUC 6 Complexity Mid | 24 h a day | N/A | - |
| | | | RUC 7 Complexity Low | 24 h a day (My treatment) and 4-5 times in 12 months (Checkthmeds) | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Average response time to end-user requests/inquiries | | Hours | N/A | N/A | N/A | - |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |

| Running phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.3 CYPRUS pilot KPI Evolution Report

TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs

Pilot name: CYPRUS

Reporting period:

From:

2020-10-01

To:

2021-03-31

Name of the responsible person for the report:

MARIA KRINI &
ANDREAS
CHRISTODOULOU

| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
|-----------------------------|---|------------|------------|---------|--------|
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | DD/MM/YYYY | DD/MM/YYYY | - | - |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | DD/MM/YYYY | DD/MM/YYYY | - | - |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | DD/MM/YYYY | DD/MM/YYYY | - | - |

| Deployment phase | | | | | | |
|---|--|------------------|------------|--------------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Smartwatch | 156 | N/A | UC7:1400 users |
| | | | Tablet | 198 | N/A | - |
| | | | Mobile | 55 | N/A | - |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 1 | N/A | Purchase outside the Consortium |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | Suppliers selected | N/A | - |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | 95% | N/A | 95% will be installed in all groups and another 5 % will be for spare equipment. No technical acquisition so far. |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | Yes | N/A | Initially, CERTH will provide a custom made platform for use which will be connected to the Gatekeeper Platform |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | - | - | N/A | The pre-testing phase will begin as soon as the Cypriot platform |
| | | | - | - | N/A | |

| Deployment phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| | | | - | - | N/A | will be ready and the devices acquisition will be done. |
| | | | - | - | N/A | |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | 58 € | N/A | Total devices acquisition cost: 65000/ 1105 users |

| Deployment phase | | | | | | |
|--|---|------------------|----------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | Patients | 0 | N/A | Still waiting for the ethical approval |
| | | | Garegivers | 0 | N/A | |
| | | | Health Professionals | 0 | N/A | |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | | | - | - | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|----------------------|--------------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | 10 | N/A | - |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | 5 | N/A | IT:2 (PASYKAF &AMEN, PHYCHOLOGISTS:1 NURSE:1 R&D MANAGER:1 |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | Patients | 905 > 50years old | N/A | UC 7 No gender identified |
| | | | Garegivers | 395 > 18 years old | N/A | UC 7 No gender identified |
| | | | Health Professionals | 100 | N/A | UC 7 No gender identified |

| Deployment phase | | | | | | |
|--|---|-------------------------------|----------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | Hospice | 1 | N/A | - |
| | | | Patients Homes | 610 | N/A | - |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | - | N/A | - |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of RUCs actually deployed | | Number (integer) | - | - | N/A | - |
| Nr of services actually deployed | | Number (integer) | - | - | N/A | - |
| Nr of applications actually deployed | | Number (integer) | - | - | N/A | - |

| Deployment phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Running phase | | | | | | |
|--------------------------|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | N/A | N/A | - |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |

| Running phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.4 GREECE pilot KPI Evolution Report

TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs

Pilot name: GREECE - Attica pilot

Reporting period: **From:** 2020-10-01

To: 2021-03-31

Name of the responsible person for the report: Eva Karaglani

| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
|-----------------------------|---|------------|------------|---------|-------------|
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | 2021-02-01 | 2023-02-28 | - | on-going |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | 2021-03-15 | 2022-08-31 | - | on-going |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | 2021-09-01 | 2022-12-20 | - | not-started |

| Deployment phase | | | | | | |
|--------------------------------------|--|------------------|--------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | TABLETS | 320 | N/A | currently under procurement procedures |
| | | | SCALES | 220 | N/A | currently under procurement procedures |
| | | | SMARTWATCHES | 230 | N/A | 10 Biobeat Smartwatches received currently under procurement procedures |
| | | | CGM Kits | 150 | N/A | - |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 1 | N/A | 1 |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | - | N/A | Technical specification ready - on-going |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | 50 | N/A | - |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | No | N/A | Waiting for HPE to train the developers |

| Deployment phase | | | | | | |
|---|---|------------------|-------------------|--|----------------|---|
| Reporting status at: | | | | DD/MM/YYYY | | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | HCPs (dietitians) | 25 | N/A | - |
| | | | Patients | 10 | N/A | - |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | RUC1: 270E/3months of intervention, RUC3: ~500/patient | N/A | The devices are re-used for intervention groups |

| Deployment phase | | | | | | |
|--|---|------------------|-------------------------------|--------------|----------------|-----------------------------------|
| Reporting status at: | | | | DD/MM/YYYY | | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | HCPs (dietitians) | 35 | N/A | recruitment of HCPs still ongoing |
| | | | Patients | 810 | N/A | recruitment to begin week 11 |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | HCPs (dietitians) | 35 | N/A | recruitment of HCPs still ongoing |
| | | | Patients | 810 | N/A | recruitment to begin week 11 |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | HCPs (dietitians) | 30 | N/A | recruitment of HCPs still ongoing |
| | | | Patients | 0 | N/A | recruitment to begin week 11 |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | HCPs (dietitians) | 0 | N/A | - |
| | | | Patients | 0 | N/A | - |
| Nr of confirmed facilities to | For example primary health centre, | Number (integer) | Dietitians' private practices | 30 | N/A | - |

| Deployment phase | | | | | | |
|--------------------------|-------------------------------------|------------------|--|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| participate in the pilot | hospitals, houses, apartments, etc. | | Community facilities ("Open day centers for the elderly"), Diabetes Center, Regional University Hospital of Larisa, Greece | 11 | N/A | Day care centers are closed due to COVID-19 |

| Deployment phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | 3 | N/A | - |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | 830 | N/A | - |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | Patients | 810 | N/A | - |

| Deployment phase | | | | | | |
|--|---|-------------------------------|--|--|----------------|--------------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | Digital Platform - Web Based | Will be deployed in HPE infrastructure | N/A | - |
| | | | Installation of Devices software in Tablets | Will be installed in Users Tablets | N/A | - |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | TABLETS | 320 | N/A | - |
| | | | SCALES | 220 | N/A | - |
| | | | SMARTWATCHES | 230 | N/A | - |
| | | | CGM Kits | 150 | N/A | - |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | 0 | N/A | - |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | Metabolic Syndrome Management platform and devices | 1PM | N/A | - |
| | | | T2Diabetes Management platform and devices | 1PM | N/A | - |
| Nr of RUCs actually deployed | | Number (integer) | N/A | 0 | N/A | RUC1 partially completed |

| Deployment phase | | | | | | |
|--------------------------------------|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of services actually deployed | | Number (integer) | N/A | 1 | N/A | - |
| Nr of applications actually deployed | | Number (integer) | N/A | 1 | N/A | - |

| Deployment phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Running phase | | | | | | |
|--------------------------|--|------------------|-----------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC 1 Complexity 1 | 660 | N/A | - |
| | | | RUC 3 Complexity 3 | 150 | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|--------------------|--------------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC 1 Complexity 1 | 660 | N/A | - |
| | | | RUC 3 Complexity 3 | 150 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC 1 Complexity 1 | 198 | N/A | estimated drop-out rate to be expected: 30% |
| | | | RUC 3 Complexity 3 | 30 | N/A | - |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC 1 Complexity 1 | 30 minutes per day | N/A | - |
| | | | RUC 3 Complexity 3 | 30 minutes per day | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|---|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | Bugs : 1-5hrs. The rest will be prioritised based on how critical they are | N/A | Four types of issues (Bug, Task, Story, Future Development) |
| Effectiveness in incidents management | The percentage of issues solved, partly | % | N/A | N/A | N/A | Based on Trello tabs resolved |

| Running phase | | | | | | |
|---------------------------------|-----------------------------|------------------|----------|--------------|----------------|-------------------------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| | addressed, not solved. | | | | | |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | Based on Versions/Sprints and Epics |

| Running phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.5 MILTON KEYNES pilot KPI Evolution Report

| TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs | | | | | |
|---|---|------------------|------------|--|------------|
| Pilot name: | | MILTON KEYNES | | | |
| Reporting period: | | From: | 2020-10-01 | To: | 2021-03-31 |
| Name of the responsible person for the report: | | Alessio Antonini | | | |
| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | 2021-03-01 | 2022-06-01 | Pre-testing of robot platform aimed to collect preliminary data on home environment and to study the feasibility of deployment during COVID-19 (pre-setting of robotic platform) Deployment of Samsung's ActiveAge as Pilot APP | Yes |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | 01/03/YYYY | 2022-12-31 | Setting up setting ActiveAge accounts for local caregivers and pilot partners Setting up the baseline data collection with the local partner WCC | Yes |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | 2022-01-01 | 2022-06-01 | We have no effort on this task | No |

| Deployment phase | | | | | | |
|--------------------------------------|--|------------------|-----------------------------|-----------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Type of device Turtle Bot 2 | 10 | N/A | Pre-study in home environment |
| | | | Type of device Tiago Robot | 10 | N/A | Deployment expected to start by September 2021. We have still no access to the lab for working on the platform |
| | | | ActiveAge | 500 | N/A | Setting up |
| | | | Samsung's Smartphone | 50 | N/A | Waiting for the finalising of the amendment including new targets and timeline |
| | | | Samsung's Tablet | 50 | N/A | - |
| | | | Wearable (Samsung's Active) | 100 | N/A | - |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 1 | N/A | Waiting for the finalising of the amendment including new targets and timeline |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | Contract signed | N/A | - |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | 30% | N/A | Waiting for the development of the FHIR profile for running integration tests |

| Deployment phase | | | | | | |
|---|--|------------------|--------------------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | Yes | N/A | Waiting for the internal assessment on the new UK GDPR for international data sharing |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | Community Workers | 5 | N/A | Waiting for the set up of the pilot APP |
| | | | Professional Caregiver | 5 | N/A | - |
| | | | Researchers | 3 | N/A | - |
| | | | Informal caregiver / volunteer | 5 | N/A | - |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | 361 € | N/A | This is the worse case scenario with elders to be provided with a smartphone as well as the wearable TO BE NOTED: including the €50k robot makes this calculation €874.25 |

| Deployment phase | | | | | | |
|-------------------------|--|------------------|-------------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | Community Workers | 10 | N/A | - |
| | | | Professional Caregivers | 10 | N/A | - |

| Deployment phase | | | | | | |
|--|---|------------------|---------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | | | Elders | | N/A | - |
| | | | Volunteers | 10 | N/A | - |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | Community Workers | 20 | N/A | Starting now the collection of expression of interest |
| | | | Professional Caregivers | 10 | N/A | - |
| | | | Elders | | N/A | - |
| | | | Volunteers | | N/A | - |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | Community Workers | 15 | N/A | - |
| | | | Professional Caregivers | 10 | N/A | - |
| | | | Elders | 70 | N/A | - |
| | | | Volunteers | 5 | N/A | - |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | Community Workers | 0 | N/A | - |
| | | | Professional Caregivers | 0 | N/A | - |
| | | | Elders | 0 | N/A | - |
| | | | Volunteers | 0 | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | Community Services | 1 | N/A | - |
| | | | Care Organizations | 5 | N/A | - |
| | | | Volunteering organization | 2 | N/A | - |
| | | | Community Groups | 2 | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | 6 | N/A | Waiting for the setup of the pilot APP |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | 100 | N/A | - |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | Caregivers | 30 | N/A | - |
| | | | Elders | 70 | N/A | - |
| | | | Volunteers | | N/A | - |

| Deployment phase | | | | | | |
|--|--|-------------------------------|----------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of devices installed | | | Tiago / Turtle Robot | 1 | N/A | - |

| Deployment phase | | | | | | |
|---|---|---------------------------|-------------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | Smartphone / Tablet | | N/A | - |
| | | | App | 1 | N/A | Finalising |
| | | | Wearable | | N/A | - |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | 70% | N/A | Most of the users will use the APP |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | GATEKEEPER solution ActiveAge | 250 | N/A | Hard to quantify, each account will require some effort |
| | | | GATEKEEPER solution Robot | 20 | N/A | - |
| | | | GATEKEEPER wearable | 0,2 | N/A | - |
| Nr of RUCs actually deployed | | Number (integer) | N/A | 3 | N/A | - |
| Nr of services actually deployed | | Number (integer) | N/A | 1 | N/A | - |
| Nr of applications actually deployed | | Number (integer) | N/A | 1 | N/A | - |

| Deployment phase | | | | | | |
|--|-------------------|------------------|---|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | The setup of ActiveAge is almost ready, this is a major milestone as all users will have to register and use the app. Furthermore, the app is also the main tool for the data collection. The data collection forms are ready to be deployed for building the baseline and enrollment of caregivers, we will wait for the enrollment of elders that all systems are ready and tested and for the safe deployment of devices face-to-face. The robot pre-study in home environment is ongoing and should be extended in April to more users. Furthermore, this pre-study is necessary to understand if possible to pre-configure the robot for the deployment during the covid (i.e., shipped in a parcel and ready to go) | | | |

| Running phase | | | | | | |
|--------------------------|--|------------------|----------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC 1 Complexity Low | 70 | N/A | - |
| | | | RUC 7 Complexity Low | 30 | N/A | - |
| | | | RUC 9 Complexity Low | 30 | N/A | waiting for the account to be set up in the next days |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC 1 Complexity Low | 70 | N/A | - |
| | | | RUC 7 Complexity Low | 30 | N/A | - |
| | | | RUC 9 Complexity Low | 30 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC 1 Complexity Low | 0 | N/A | - |
| | | | RUC 7 Complexity Low | 0 | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|-------------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| | | | RUC 9 Complexity Low | 0 | N/A | - |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC 1 Complexity Low | 2 per week | N/A | - |
| | | | RUC 7 Complexity Low | 30" a day | N/A | - |
| | | | RUC 9 Complexity Low | 1 per week | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | N/A | N/A | - |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |

| Running phase | | | | | | |
|--|-------------------|------------------|--|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | We are ready to recruit caregivers and waiting for the first accounts on the pilot app to be created | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.6 PUGLIA pilot KPI Evolution Report

| TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs | | | | | |
|---|---|-----------------------|------------|--|--|
| Pilot name: | | PUGLIA | | | |
| Reporting period: | | From: | 2020-10-01 | To: | 2021-03-31 |
| Name of the responsible person for the report: | | Franco Mercalli (MME) | | | |
| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | 2020-06-01 | 2022-12-31 | Task T7.3 is originally planned to end at M36, however the Puglia Pilot will end it at M39 with a 3 months delay. | The running strategy has been defined for all Puglia Pilot studies in the respective protocols. Stakeholder recruitment has been started and will continue along the accrual process as planned. Technology deployment has been started and will continue along T7.3. |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | 2021-01-18 | 2022-12-31 | Task T7.4 is originally planned to end at M36, however the Puglia Pilot will end it with a 3 months delay at M39. | <ul style="list-style-type: none"> - The observational study on predictive modelling for T2D control is ready to run since 18/01/2021 (ethics approval) and is waiting for deployment of GK technology to recruit the first patient - The quasi-experimental study on Low and Moderate Complexity is planned to start on 01/01/2022, when ethics approval, participants recruitment and implementation and deployment of GK Platform components and GK Pilot applications will be completed. |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | 2020-09-01 | 2023-03-31 | More information is needed on both other Pilots' (T7.6) and Open Calls' (T7.7) Use Cases to plan their application in the Puglia Pilot enlargement process | N/A |

| Deployment phase | | | | | | |
|------------------------------------|--|------------------|--------------------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | COPD devices kit | 26 | N/A | - |
| | | | T2D devices kit for obs. study | 100 | N/A | - |
| | | | T2D devices kit for exp. study | 25 | N/A | - |
| | | | HF devices kit | 60 | N/A | - |
| | | | HBP+T2D devices kit | 62 | N/A | - |
| | | | HBP+T2D+HF devices kit | 26 | N/A | - |
| | | | HBP+COPD devices kit | 26 | N/A | - |
| | | | HBP devices kit | 273 | N/A | - |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 6 | N/A | (1) Market procurement of glucometer, oxymeter, BP monitor (2) Market procurement of smartphone connectivity (3) Budget transfer to Medisanté for acquisition of BP800 and BC800 devices (4) Budget transfer to SAM for acquisition of A41 smartphones and Gear Fit2 wristbands. (5) Free loan of PPG wrist device by BB (6) Free loan of A41 smartphones and Active 2 smartwatches for the T2D observational study by SAM (provisional, depending on what will eventually be purchased on the market vs provided by GK partners) |

| Deployment phase | | | | | | |
|---|--|------------------|--|---|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | Equipment delivered | N/A | Tender specs will include an extra "backup buffer" on required number of devices, to efficiently tackle e.g. malfunctions, damage, losses, etc. |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | 100% | N/A | - |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | GK components needed by the Pilot: - GK Data Connectors - GK Data Federation - GK Dashboards Authoring Tool - GK User Management - GK-adapted Activage app with FPM technology - GK-adapted DMCoach app | N/A | For the T2D obs. study a temporary GDPR-compliant data storage solution could be used in place of the GK Data Federation component, in order to start the experiment asap. |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | Testers drawn from CSS team members for T2D obs. study | 3 | N/A | - |
| | | | Testers drawn from Puglia Pilot team members for Low Complexity exp. study | 10 | N/A | - |

| Deployment phase | | | | | | |
|---|---|------------------|---|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| | | | Testers drawn from Puglia Pilot team members for Moderate Complexity exp. study | 7 | N/A | - |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | Below 500 | N/A | The number refers to the Moderate Complexity use cases only, as Low Complexity use case involves no costs for users. The reported value is based on estimation of costs related to devices provided for free by Platform Cluster partners and of expected costs for devices to be procured on the market. |

| Deployment phase | | | | | | |
|-------------------------|---|------------------|-----------------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | Healthy elderly citizens | 9400 | N/A | Likes on the Facebook Puglia Pilot page |
| | | | COPD patients | 52 | N/A | Contacts are planned to start in September 2021 |
| | | | T2D patients for obs. study | 100 | N/A | Recruitment will start as soon as devices will be available (very likely by the end of April 2021) |

| Deployment phase | | | | | | |
|--|--|------------------|------------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | | | T2D patients for exp. study | 50 | N/A | Contacts are planned to start in September 2021 |
| | | | HF patients | 120 | N/A | Contacts are planned to start in September 2021 |
| | | | HBP+T2D patients | 124 | N/A | Contacts are planned to start in September 2021 |
| | | | HBP+T2D+HF patients | 52 | N/A | Contacts are planned to start in September 2021 |
| | | | HBP+COPD patients | 52 | N/A | Contacts are planned to start in September 2021 |
| | | | HBP patients | 546 | N/A | Contacts are planned to start in September 2021 |
| | | | HCPs | 30 | N/A | - |
| | | | Other ecosystem stakeholders | 100 | N/A | (8 businesses representatives, 2 NGOs representatives, 4 healthcare organizations representatives, 2 public administration representatives, 15 researchers) |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | Healthy elderly citizens | 9400 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | COPD patients | 52 | N/A | Expression of interests are planned to be asked from September 2021 |

| Deployment phase | | | | | | |
|----------------------|-------------------|------------------|-----------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | | | T2D patients for obs. study | 100 | N/A | Recruitment will start as soon as devices will be available |
| | | | T2D patients for exp. study | 50 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | HF patients | 120 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | HBP+T2D patients | 124 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | HBP+T2D+HF patients | 52 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | HBP+COPD patients | 52 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | HBP patients | 546 | N/A | Expression of interests are planned to be asked from September 2021 |
| | | | HCPs | 30 | N/A | - |

| Deployment phase | | | | | | |
|-----------------------|---|------------------|------------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | | | Other ecosystem stakeholders | 100 | N/A | (8 businesses representatives, 2 NGOs representatives, 4 healthcare organizations representatives, 2 public administration representatives, 15 researchers) |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | Healthy elderly citizens | 9400 | N/A | Recruitment is planned to start in September 2021 |
| | | | COPD patients | 52 | N/A | Recruitment is planned to start in September 2021 |
| | | | T2D patients for obs. study | 100 | N/A | Recruitment will start as soon as devices will be available |
| | | | T2D patients for exp. study | 50 | N/A | Recruitment is planned to start in September 2021 |
| | | | HF patients | 120 | N/A | Recruitment is planned to start in September 2021 |
| | | | HBP+T2D patients | 124 | N/A | Recruitment is planned to start in September 2021 |
| | | | HBP+T2D+HF patients | 52 | N/A | Recruitment is planned to start in September 2021 |
| | | | HBP+COPD patients | 52 | N/A | Recruitment is planned to start in September 2021 |
| | | | HBP patients | 546 | N/A | Recruitment is planned to start in September 2021 |
| | | | HCPs | 30 | N/A | - |

| Deployment phase | | | | | | |
|--|---|------------------|------------------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| | | | Other ecosystem stakeholders | 100 | N/A | - |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | Healthy elderly citizens | 0 | N/A | - |
| | | | COPD patients | 0 | N/A | - |
| | | | T2D patients for obs. study | 0 | N/A | - |
| | | | T2D patients for exp. study | 0 | N/A | - |
| | | | HF patients | 0 | N/A | - |
| | | | HBP+T2D patients | 0 | N/A | - |
| | | | HBP+T2D+HF patients | 0 | N/A | - |
| | | | HBP+COPD patients | 0 | N/A | - |
| | | | HBP patients | 0 | N/A | - |
| | | | HCPs | 0 | N/A | - |
| | | | Other ecosystem stakeholders | 0 | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | CSS Hospital | 1 | N/A | - |
| | | | Aziende Sanitarie Locali | 3 | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|-----------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | 600 | N/A | Two for involved HCPs (for observation and Moderate Complexity exp. studies) and one for each Moderate Complexity patient recruited |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | 628 | N/A | HCPs and patients involved in Moderate Complexity RUCs |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | COPD patients | 26 | N/A | - |
| | | | T2D patients for obs. study | 100 | N/A | - |
| | | | T2D patients for exp. study | 25 | N/A | - |
| | | | HF patients | 60 | N/A | - |
| | | | HBP+T2D patients | 62 | N/A | - |
| | | | HBP+T2D+HF patients | 26 | N/A | - |
| | | | HBP+COPD patients | 26 | N/A | - |
| | | | HBP patients | 273 | N/A | - |
| | | | HCPs | 30 | N/A | - |

| Deployment phase | | | | | | |
|--|--|-------------------------------|--------------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | CSS Hospital | 1 | N/A | - |
| | | | Aziende Sanitarie Locali | 3 | N/A | - |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | COPD devices kit | 26 | N/A | Includes: smartphone, fitness band, oxymeter |
| | | | T2D devices kit for obs. study | 100 | N/A | Includes: smartphone, smartwatch |
| | | | T2D devices kit for exp. study | 25 | N/A | Includes: smartphone, glucometer |
| | | | HF devices kit | 60 | N/A | Includes: smartphone, fitness band, oxymeter, body composition scale |
| | | | HBP+T2D devices kit | 62 | N/A | Includes: smartphone, combined BP monitor+glucometer |
| | | | HBP+T2D+HF devices kit | 26 | N/A | Includes: smartphone, glucometer, body composition scale, multiple vitals wrist monitor |
| | | | HBP+COPD devices kit | 26 | N/A | Includes: smartphone, fitness band, oxymeter, BP monitor |
| | | | HBP devices kit | 273 | N/A | Includes: smartphone, BP monitor |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | 100% | N/A | - |

| Deployment phase | | | | | | |
|--------------------------------------|---|---------------------------|--------------------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | RUC#3 obs. study | N/A | N/A | This KPI is currently not planned for the Pilot. A relevant measurement process will be established to add it. |
| | | | Low Complexity exp. study | N/A | N/A | This KPI is currently not planned for the Pilot. A relevant measurement process will be established to add it. |
| | | | Moderate Complexity exp. study | N/A | N/A | This KPI is currently not planned for the Pilot. A relevant measurement process will be established to add it. |
| Nr of RUCs actually deployed | | Number (integer) | N/A | 6 | N/A | RUC#1, RUC#2, RUC#3, RUC#5, RUC#7, RUC#8 |
| Nr of services actually deployed | | Number (integer) | N/A | 3 | N/A | RUC#3 obs. study, Low Complexity exp. study, Moderate Complexity exp. study |
| Nr of applications actually deployed | | Number (integer) | N/A | 3 | N/A | RUC#3 obs. study, Low Complexity exp. study, Moderate Complexity exp. study |

| Deployment phase | | | | | | |
|--|-------------------|------------------|--|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | Currently, the major risk is to delay the RUC#3 observational study on predictive modeling for T2D control, which is ready to start since 18/01/2021 but cannot recruit the first patient until devices are delivered to the CSS hospital and at least a temporary GDPR-compliant storage solution is provided by the Platform Cluster (while waiting the availability of the GK Data Federation component). The Low and Moderate Complexity quasi-experimental studies' protocol is seeking ethical approval, it is conducting the relevant stakeholder engagement plan and, in cooperation with Platform Cluster partners, it is furthering the implementation and deployment of the needed GK Platform components and GK Pilot applications | | | |

| Running phase | | | | | | |
|--------------------------|--|------------------|---|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC#1 Low Complexity | 9400 | N/A | - |
| | | | RUC#2 Moderate Complexity | 52 | N/A | - |
| | | | RUC#3 obs. study Moderate Complexity | 100 | N/A | - |
| | | | RUC#3 exp. study Moderate Complexity | 50 | N/A | - |
| | | | RUC#5 Moderate Complexity | 120 | N/A | - |
| | | | RUC#7 Moderate Complexity | 228 | N/A | Addressed comorbidity profiles: HBP+T2D, HBP+T2D+HF, HBP+COPD |

| Running phase | | | | | | |
|-----------------------|---|------------------|--|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| | | | RUC#8 Moderate Complexity | 546 | N/A | - |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC#1 Low Complexity | 9400 | N/A | - |
| | | | RUC#2 Moderate Complexity | 52 | N/A | - |
| | | | RUC#3 obs. study Moderate Complexity | 100 | N/A | - |
| | | | RUC#3 exp. study Moderate Complexity | 50 | N/A | - |
| | | | RUC#5 Moderate Complexity | 120 | N/A | - |
| | | | RUC#7 Moderate Complexity | 228 | N/A | Addressed comorbidity profiles: HBP+T2D, HBP+T2D+HF, HBP+COPD |
| | | | RUC#8 Moderate Complexity | 546 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC#1 Low Complexity | 0 | N/A | - |
| | | | RUC#2 Moderate Complexity | 0 | N/A | - |
| | | | RUC#3 obs. study Moderate Complexity | 0 | N/A | - |
| | | | RUC#3 exp. study Moderate Complexity | 0 | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|---|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC#5 Moderate Complexity | 0 | N/A | - |
| | | | RUC#7 Moderate Complexity | 0 | N/A | Addressed comorbidity profiles: HBP+T2D, HBP+T2D+HF, HBP+COPD |
| | | | RUC#8 Moderate Complexity | 0 | N/A | - |
| | | | RUC#1 Low Complexity | - | N/A | To be defined. |
| | | | RUC#2 Moderate Complexity | - | N/A | To be defined. |
| | | | RUC#3 obs. study Moderate Complexity | - | N/A | To be defined. |
| | | | RUC#3 exp. study Moderate Complexity | - | N/A | To be defined. |
| | | | RUC#5 Moderate Complexity | - | N/A | To be defined. |
| | | | RUC#7 Moderate Complexity | - | N/A | To be defined. |
| | | | RUC#8 Moderate Complexity | - | N/A | To be defined. |

| Running phase | | | | | | |
|--|--|------------------|----------------------------------|--------------|----------------|--------------------------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | N/A | N/A | Not significant for the Puglia Pilot |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | Running phase is not yet started | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.7 POLAND pilot KPI Evolution Report

TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs

Pilot name: **POLAND**

Reporting period: **From:** 2020-10-01

To: 2021-03-31

Name of the responsible person for the report: **Przemyslaw Kardas**

| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
|-----------------------------|---|------------|-----------------------|--|---------------------|
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | 2021-03-22 | 30.06.2021 (expected) | First deployment phase initiated with 'pilot of the pilot' on the limited number of patients | - |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | 2021-04-12 | 2021-12-31 | Dates applicable to LODZ-1 | start date expected |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | DD/MM/YYYY | DD/MM/YYYY | - | - |

| Deployment phase | | | | | | |
|---|--|------------------|-----------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Adherence application | 1180 | N/A | to be used in LODZ-1 and LODZ-2 |
| | | | Adherence monitor | 50 | N/A | to be used in LODZ-2 |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | - | N/A | - |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | - | N/A | - |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | - | N/A | - |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | - | N/A | - |
| Nr of user per type involved in the technical pre-testing | E.g. patient, citizen, HCP, etc. | Number (integer) | Volunteers | 20 | N/A | applicable to internal testing of LODZ-1 and LODZ-2 |

| Deployment phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| | | | Patients | 20 | N/A | applicable to 'pilots of the pilots' in LODZ-1 and LODZ-2 |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | - | N/A | - |

| Deployment phase | | | | | | |
|--|---|------------------|---------------------|--------------|----------------|----------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | Patients | 2000 | N/A | applicable to LODZ-1 |
| | | | Patients | 360 | N/A | applicable to LODZ-2 |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | Number (integer) | Patients | 1200 | N/A | applicable to LODZ-1 |
| | | | Patients | 236 | N/A | applicable to LODZ-2 |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | Patients | 1000 | N/A | applicable to LODZ-1 |
| | | | Patients | 180 | N/A | applicable to LODZ-2 |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | Primary care center | 5 | N/A | applicable to LODZ-2 |

| Deployment phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|----------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | - | N/A | - |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | - | N/A | - |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | Patients | 1000 | N/A | applicable to LODZ-1 |
| | | | Patients | 180 | N/A | applicable to LODZ-2 |

| Deployment phase | | | | | | |
|--|--|-------------------------------|-------------------|--------------|----------------|----------------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | - | 5 | N/A | applicable to LODZ-2 |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | Adherence monitor | 50 | N/A | applicable to LODZ-2 |

| Deployment phase | | | | | | |
|---|---|---------------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | - | N/A | - |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | Person-hours per solution | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Nr of RUCs actually deployed | | Number (integer) | N/A | - | N/A | - |
| Nr of services actually deployed | | Number (integer) | N/A | - | N/A | - |
| Nr of applications actually deployed | | Number (integer) | N/A | - | N/A | - |

| Deployment phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Running phase | | | | | | |
|--|--|------------------|-------------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC1 Complexity Low | 1000 | N/A | - |
| | | | RUC 7 Complexity Middle | 130 | N/A | - |
| | | | RUC 7 Complexity High | 50 | N/A | - |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC1 Complexity Low | 1000 | N/A | - |
| | | | RUC 7 Complexity Middle | 130 | N/A | - |
| | | | RUC 7 Complexity High | 50 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC1 Complexity Low | 0 | N/A | - |
| | | | RUC 7 Complexity Middle | 0 | N/A | - |
| | | | RUC 7 Complexity High | 0 | N/A | - |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | - | - | N/A | - |
| | | | - | - | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | | N/A | - |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

B.8 SAXONY pilot KPI Evolution Report

| TARGETS AND REPORT for the GATEKEEPER monitoring and control KPIs | | | | | |
|---|---|-----------------|----------------------|---|----------------|
| Pilot name: | | SAXONY | | | |
| Reporting period: | | From: | 2020-10-01 | To: | 2021-03-31 |
| Name of the responsible person for the report: | | Julia Schellong | | | |
| Initial timetable | Explanatory notes | Start date | End date | Remarks | Status |
| Deployment phase | The deployment phase ends when: running strategy is defined, end-users are recruited, the technologies deployment completed, pre-testing has been carried out, users are trained and installations have been made | 2021-02-01 | 30/06/2022 (ongoing) | Data security concept has been submitted and granted by DPO. Interim local data storage solution has been amended in ethics approval and is being installed and prepared for data collection. Test users will start with testing. | on-going |
| Running phase | The running phase ends when: the pilot execution is finalised. It means that number of drop-outs and users finalised are known and evaluations (baseline, intermediate and final) are made. | 2021-05-01 | 2022-12-31 | waiting for final ethics approval | in preparation |
| Ecosystem enlargement phase | The ecosystem enlargement phase ends when: the interchange of solutions between pilots (T7.6) are made and new RUCs resulting from open calls (T7.7) are implemented. | DD/MM/YYYY | DD/MM/YYYY | - | not started |

| Deployment phase | | | | | | |
|--------------------------------------|--|------------------|------------------------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| Nr of devices to be installed/used | Devices may include: sensors, gateways, smartphones/ tablets, wearables, medical equipment, etc. Please provide data separately per type of device indicating which is already available, which should be acquired | Number (integer) | Samsung Smartphone A51 | 250 | N/A | No devices received so far due to pending budgeting processes |
| | | | Samsung Galaxy Watch 3 | 250 | N/A | No devices received so far due to pending budgeting processes |
| | | | Samsung Tablet A7 | 50 | N/A | No devices received so far due to pending budgeting processes |
| Nr of procurements envisaged | One or more call for tenders/ procurement procedures may be planned | Number (integer) | N/A | 1 | N/A | No actual procurement planned, but a respective transfer of buget (TUD/Saxony pilot -> Samsung); Procedure still not finally set, overall instructions and confirmation both from Samsung and Project Management pending |
| Stage of procurement (for each case) | Technical specification ready; Tender published; Suppliers selected; Contract(s) signed; Equipment delivered. | Type | N/A | 1 | N/A | Technical specification is ready; ; Suppliers selected (SAM); Contract (data sharing agreement with SAM) in preperation Equipment delivered. |
| GATEKEEPER integration | Indicate the percentage of components integrated vs. total components planned to be installed. For pending integrations please, indicate the reason in the remarks cell. | % | N/A | - | N/A | no Gatekeeper component ready for now to be used; HPE server in preperation; interim local server |

| Deployment phase | | | | | | |
|---|--|------------------|---------------------|--|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Technological solution preparation | | | | | | |
| GATEKEEPER Platform deployment | If the pilot solution is deployed in the GATEKEEPER platform, indicate the platform version. If not, indicate the expected date. | Yes/No | N/A | - | N/A | no Gatekeeper component ready for now to be used; waiting for deployment of HPE platform especially Saxony private space |
| Nr of user per type involved in the technical pre-testing | internal test users (TUD) will test the app (technical training) to ensure technical procedures and data storage installation | Number (integer) | Internal test users | 10 | N/A | Installation of the interim local server for data storage, internal pre-testing in march/april |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| | | | - | - | N/A | - |
| Average cost of technological solution per end-user | Consider end user as users in intervention group; not including possible control groups | Number (integer) | N/A | Citizen: 0 €, patients: 350€, HCP: 50€ | N/A | - |

| Deployment phase | | | | | | |
|-------------------------|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of contacted persons | Per type of user. E.g. patient, citizen, HCP, etc. | Number (integer) | citizens | up to 10.000 | N/A | - |
| | | | patients | 300 | N/A | - |
| | | | HCP | up to 50 | N/A | - |
| | | Number (integer) | citizens | 30 | N/A | - |

| Deployment phase | | | | | | |
|--|---|------------------|--------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Recruitment | | | | | | |
| Nr of expressions of interest received | Number of users willing to participate per type of user. | | patients | 0 | N/A | - |
| | | | HCP | 0 | N/A | - |
| Nr of confirmed users | These users should meet the selection criteria and have signed consent forms. | Number (integer) | citizens | up to 10.000 | N/A | - |
| | | | patients | 300 | N/A | - |
| | | | HCP | up to 50 | N/A | - |
| Nr of excluded users | For example users that have been contacted but do not meet the inclusion criteria | Number (integer) | citizens | 0 | N/A | - |
| | | | patients | 0 | N/A | - |
| | | | HCP | 0 | N/A | - |
| Nr of confirmed facilities to participate in the pilot | For example primary health centre, hospitals, houses, apartments, etc. | Number (integer) | hospital clinics | 2 | N/A | - |
| | | | outpatient clinics | 1 | N/A | - |

| Deployment phase | | | | | | |
|-----------------------------------|--|------------------|----------|--------------|----------------|----------------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of training sessions completed | Used to train the trainers and users | Number (integer) | N/A | up to 150 | N/A | in preparation |
| Nr of trainees received training | Indicate the number of trainees that will train the final users. This trainee will be instructed by the technological providers. Indicate the number per type of stakeholder and/or user group | Number (integer) | N/A | up to 10 | N/A | - |

| Deployment phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Training | | | | | | |
| Nr of end users trained by type of stakeholder | Separating by stakeholder, gender, age | Number (integer) | citizens | 0 | N/A | - |
| | | | patients | 150 | N/A | - |
| | | | HCP | up to 50 | N/A | - |

| Deployment phase | | | | | | |
|--|--|-------------------------------|---------------------------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| Nr of total installations completed at facilities such as primary care centres, hospitals, private homes or other facilities | These installations should be named separately (installations should be completed, successfully tested, and be ready for operation). For example 4 primary care centers. | Number (integer) and facility | app for citizens | up to 10.000 | N/A | - |
| | | | app/wearable for patients | 200 | N/A | - |
| | | | app/gadget HCP | 50 | N/A | - |
| Nr of devices installed | Indicate the type of device and the respective number. For example 10 glucometers. | Number (integer) and type | Samsung Smartphone A51 | 250 | N/A | No devices received so far due to pending budgeting processes |
| | | | Samsung Galaxy Watch 3 | 250 | N/A | No devices received so far due to pending budgeting processes |
| | | | Samsung Tablet A7 | 50 | N/A | No devices received so far due to pending budgeting processes |
| Percentage of installations completed over total targeted | Distinguish among RUC and level of complexity when possible. | % | N/A | 100 | N/A | No devices received so far due to pending budgeting processes |
| Person-effort spent per installation | Average type spent for installing a complete GATEKEEPER solution. | Person-hours per solution | citizens | 0 | N/A | - |

| Deployment phase | | | | | | |
|--------------------------------------|---|------------------|----------|--------------|----------------|---|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Installations | | | | | | |
| | (E.g. If RUC3 diabetes solution includes smartwatch, smartphone, blood pressure, glucometer - total time spent in the whole installation) | | patients | approx. 2h | N/A | No devices received so far due to pending budgeting processes, needed time for installation cannot be estimated yet |
| | | | HCP | approx 1 h | N/A | No devices received so far due to pending budgeting processes, needed time for installation cannot be estimated yet |
| Nr of RUCs actually deployed | | Number (integer) | N/A | 2 | N/A | - |
| Nr of services actually deployed | | Number (integer) | N/A | ? | N/A | - |
| Nr of applications actually deployed | | Number (integer) | N/A | 2 to 3 | N/A | - |

| Deployment phase | | | | | | |
|--|-------------------|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | | | | |

| Running phase | | | | | | |
|--|--|------------------|-----------------------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Users commitment | | | | | | |
| Nr of users in operation | Users that actually are participating in the study (Indicating RUC and complexity level) | Number (integer) | RUC 1 Complexity Low | up to 10.000 | N/A | - |
| | | | RUC 7 Complexity Mid | 200 | N/A | - |
| | | | RUC 7 Complexity High | 100 | N/A | - |
| Nr of users finalised | Users that have completed the experiment (Indicating RUC and complexity level). | Number (integer) | RUC 1 Complexity Low | up to 10.000 | N/A | - |
| | | | RUC 7 Complexity Mid | 200 | N/A | - |
| | | | RUC 7 Complexity High | 100 | N/A | - |
| Nr of drop-outs | Indicate RUC and complexity level | Number (integer) | RUC 1 Complexity Low | up to 10.000 | N/A | - |
| | | | RUC 7 Complexity Mid | 200 | N/A | - |
| | | | RUC 7 Complexity High | 100 | N/A | - |
| Average usage level of the GK solution | Usage level may refer to the use of GK solutions (per RUC and complexity level) by the end-users (e.g. 2 times per week, 45' per day, etc.). | Time frequency | RUC 1 Complexity Low | up to 10.000 | N/A | - |
| | | | RUC 7 Complexity Mid | 200 | N/A | - |
| | | | RUC 7 Complexity High | 100 | N/A | - |

| Running phase | | | | | | |
|--|--|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Operational effectiveness | | | | | | |
| Nr of technical/operational issues reported. | Indicate this value per RUC. It is used to measure how the solution works. | Number (integer) | N/A | N/A | N/A | - |
| Average response time to end-user requests/inquiries | | Hours | N/A | N/A | N/A | - |
| Effectiveness in incidents management | The percentage of issues solved, partly addressed, not solved. | % | N/A | N/A | N/A | - |
| Nr of solution updates/upgrades | Indicate this value per RUC | Number (integer) | N/A | N/A | N/A | - |
| Further analysis | | | | | | |
| A short description of the overall progress on deployment preparation with a selective reference on the most important challenges being experienced, solutions given and lessons learned, as well as knowledge that may facilitate further scale-up and replication. | | | - | | | |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|--|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| RUCs exchange results | | | | | | |
| Nr of pilots interacted with, as a result of the RUC exchange | | Number (integer) | N/A | N/A | N/A | highest interest to interact with Puglia |
| Nr of new users, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the RUC exchange | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

| Ecosystem enlargement phase | | | | | | |
|---|---|------------------|----------|--------------|----------------|---------|
| Reporting status at: | | | | | DD/MM/YYYY | |
| Operative KPI | Explanatory notes | Measurement unit | Category | Target value | Reported value | Remarks |
| Open calls results | | | | | | |
| Nr of new users, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |
| Nr of new services, as a result of the open calls | Indicate these numbers per RUC and complexity level | Number (integer) | N/A | N/A | N/A | N/A |

