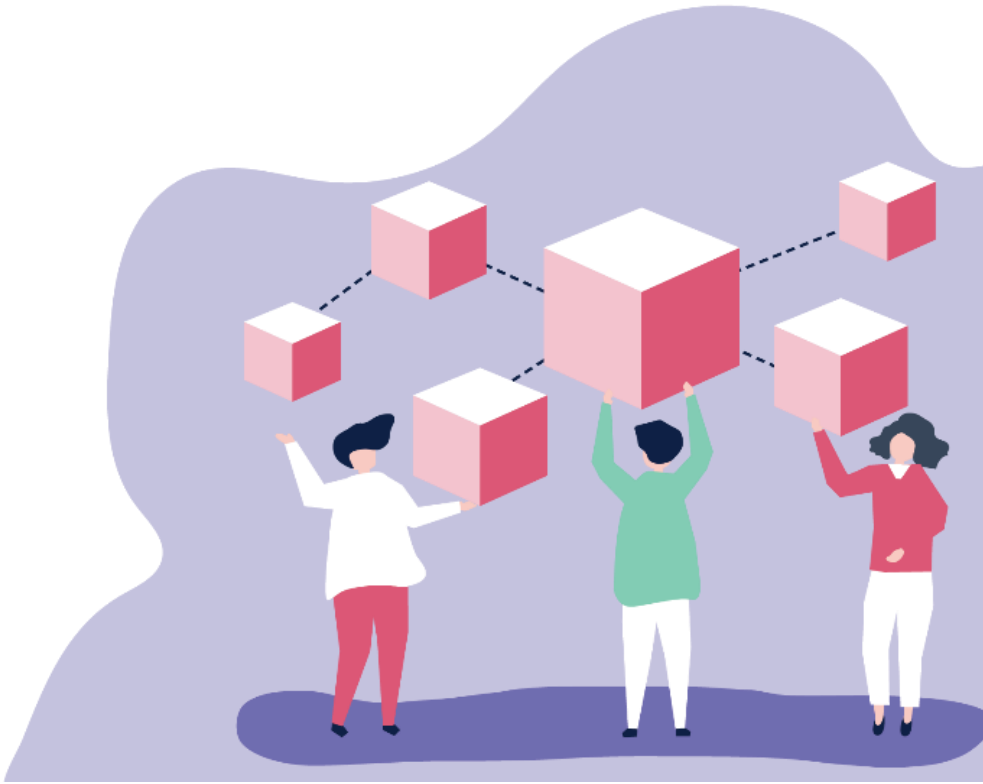
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 857223

D7.2 – KPI Evolution Report (I to VIII) [M12 updated every 6 months]

Deliverable No.	D7.2	**Due Date**	30/September/2020
Description	Report on KPIs periodically to measure the evolution both at Pilots' and LSP Cluster level		
Type	Report	**Dissemination Level**	PU
Work Package No.	WP7	**Work Package Title**	Large Scale Pilot definition and execution
Version	1.0	**Status**	Final Release



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	l.pecchia@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

History

Date	Version	Change
31/08/2020	0.1	Creation of the Structure Content
10/09/2020	0.2	Integrating content
30/09/2020	0.3	Integrating content
20/10/2020	0.4	updating content
30/10/2020	0.5	Internal review
28/11/2020	0.6	Updating content and structure
29/01/2021	0.7	Updating content and structure
08/02/2021	0.8	Quality review
15/02/2021	1.0	Release version

Key data

Keywords	Key Performance Indicators
Lead Editor	Name: Silvio Marcello Pagliara Partner: University of Warwick
Internal Reviewer(s)	Jordi de Batlle (CIBER), Frans Folkvord (OE), Laura López Pérez (UPM)

Abstract

This document represents the first issue of the **KPI Evolution report** based on the results of use cases and comparison with the previously locally observed and measured KPIs.
Its periodicity is every six month and is meant to be available to Public domain and will report on KPIs as measurable values that demonstrate (or refute) how effectively GATEKEEPER is achieving its key (business) objectives.

The **Impact assessment Key Performance Indicators (KPIs)**, including the scales and assessment tools have been defined within the activities of Tasks 7.1, 7.2, 7.3 and 7.8 along with a cooperative and collaborative work with the Pilots. The last part of the document, section 4, shows the template and the guidelines that will be used for reporting the operational performance of the pilots through the **Operative KPIs**.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise.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

Table of contents

TABLE OF CONTENTS **6**
1 ABOUT THIS DOCUMENT **8**
1.1 DELIVERABLE CONTEXT 8
2 HOW IMPACT ASSESSMENT KPIS WERE DEFINED AT PILOTS' LEVEL **9**
3 IMPACT ASSESSMENT KPIS EVOLUTION REPORTS: PILOT PER PILOT **12**
3.1 ARAGON 13
Study design *13*
3.1.1 USE CASE 1 - Low complexity KPIs *14*
3.1.2 USE CASE 2 - Mid complexity KPIs *14*
3.1.3 USE CASE 2 High complexity KPIs *15*
3.1.4 USE CASE 5 - Mid complexity KPIs *16*
3.1.5 USE CASE 5: High complexity KPIs *17*
3.1.6 USE CASE 7 - Mid complexity KPIs *18*
3.1.7 USE CASE 7: High complexity KPIs *19*
3.2 BASQUE COUNTRY 20
Study Design *20*
3.2.1 USE CASE 1 - Low complexity KPIs *20*
3.2.2 USE CASE 3 – High complexity KPIs *21*
3.2.3 USE CASE 4 – High complexity KPIs *22*
3.2.4 USE CASE 6 – Mid complexity KPIs *23*
3.2.5 USE CASE 7 – Mid Complexity KPIs *24*
3.3 CYPRUS 25
Study Design *25*
3.3.1 USE CASE 7 – High Complexity KPIs *25*
3.4 CENTRAL GREECE AND ATTICA (GREECE) 27
Study Design *27*
3.4.1 USE CASE 1 - Low complexity KPIs *27*
3.4.2 USE CASE 3 – Medium complexity KPIs *28*
3.5 MILTON KEYNES 29
Study design *29*
3.5.1 USE CASE 1 – Low Complexity KPIs *30*
3.5.2 USE CASE 7 – Low Complexity KPIs *31*
3.6 POLAND 32
Study design *32*
3.6.1 USE CASE 1 – Low complexity KPIs *33*
3.6.2 USE CASE 7 – Mid and High Complexity KPIs *33*
3.7 PUGLIA 34
Study design *34*
3.7.1 USE CASE 1 interventional - Low Complexity KPIs *35*
3.7.2 USE CASE 2, 3, 5 interventional - Mid Complexity KPIs *36*

3.7.3 USE CASE 3 observational (CSS) – Mid Complexity KPIs 37
3.7.4 USE CASE 1, 2, 3, 5, 7 observational – Low and Mid Complexity KPIs 38
3.8 SAXONY 39
Study design 39
3.8.1 USE CASE 1 – Low Complexity KPIs 40
3.8.2 USE CASE 7 – Mid and High Complexity KPIs: 41
4 OPERATIVE KPIS REPORT 42
4.1 OPERATIVE KPIS TEMPLATE 42
4.1.1 Deployment phase KPIs 42
4.1.2 Running phase KPIs 44
4.1.3 Ecosystem enlargement phase KPIs 45
4.2 LSP MULTICENTRED OPERATIVE REPORT 45
5 CONCLUSIONS 46
6 REFERENCES 47

1 About this document

This document will determine how Key Performance Indicators (KPIs) are effectively used as measurable values, and how effectively each and every Pilot experiment is achieving its objectives. In a wider and GATEKEEPER (GK) Project perspective, this Report Series will give the impact of the GK Platform along with the GK Multicentric Federated Study and the Pilots' execution evolution. This document is within the work done in the *Task 7.2 Detailed experiment and KPI definition, Task 7.3 Experiment deployment, and it's* linked to the *Deliverables 7.1 Pilot Studies Definition and KPIs*, *D6.4 Clinical Study Definition*.

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.

COVID-19 Pandemic affected all Pilots' experiments and they had to review, adapt, redefine or redesign their studies, at least in terms of the users' management: recruitment, surveying, etc. This led to an iterative work with all the Pilots to the date of its first publication, in order to report the defined Impact assessment KPIs per Pilot and RUCs with their measurement tools and their actual studies. The last part focuses on the Operational KPIs to keep track each and every Pilots' progress. The next versions of this deliverable, to be issued from M18 every six months, will describe the evolution and refinement of all the KPIs and their measures per Pilot and per Reference Use case, reflecting changes in their studies.

1.1 Deliverable context

Table 1-1: Deliverable context

PROJECT ITEM	RELATIONSHIP
Objectives	Main objective: measure how effectively the experiments are achieving their goals, O1, O6, O9: Define bases for the local and global evaluation of the multicentric longitudinal federate study
Exploitable results	Input for the impact assessment (T7.8), Active users' involvement, (T7.4)
Workplan	This deliverable is one of the outcomes of 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 7.8.
Milestones	MS3 Cruise
Deliverables	D6.4, D7.1
Risks	None for this first edition.

2 How Impact assessment KPIs were defined at Pilots' level

Here is described which 'Impact assessment KPIs will be taken as measurements to assess effectiveness and impact of each Pilots' experiment.

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 led to a framework of investigational designs in which each and every pilot defined its experiment definition and the Key Performance Indicators (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.

During the General Meeting in Milton Keynes, February 2020, Open Evidence and The University of Warwick have conducted a workshop outlining the importance of using experimental designs to conduct impact assessment and cost-effectiveness evaluation. The main focus was the use of impact assessment models, such as the Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing (MAFEIP)[1]. As Prof. Dr. Guenther Jonitz, president of the Berlin Chamber of Physicians stated: "*"Medicine today resembles the church in the sixteenth century. What we need is a reformation. Few doctors are trained to judge and evaluate a scientific study. I myself chose to be trained as a surgeon to avoid two things: statistics and psychology. Now I realize that both are indispensable"*[2].

To improve the validity and reliability of the data that will be collected by the Pilots to conduct a valid impact assessment with MAFEIP to show the effectiveness of the digital solution, a clear and straightforward experimental design is a key element of the studies that will be conducted, with validates scales to assess the outcomes. In addition, the assessment of quality of life with a validated scale (e.g., ED5Q) is essential to analyse the cost-effectiveness and take into account the importance of valuable years, therefore this presentation was mostly focused on these elements,

Following this workshop and within the above-mentioned framework were conducted several bilateral meetings with the Pilots' representatives to point out all the aspects of the impact assessment. This led to the Deliverables 7.1 and 6.4 and the basis of this document, where KPIs were defined.

To support a better definition of the experimental design at Pilot level, OE developed a White Paper where these are clearly described with their advantages and limitations. All of the methodologies and tools used in this work were shared, discussed and modified with the Pilots' representatives in a continuous and cooperative construction work made by several steps and iterations back and forth.

In addition, in close collaboration with OE and UPM has have developed plans to conduct a meta-analysis on all the outcomes summarized in an extensive excel-file were all the different factors have been established, see Table 2-1 - Meta-analysis of Pilots' outcomes. This has been done in order to feed the general evaluation framework of the federated multicentric study to examine to what extent the GATEKEEPER is effective in improving the KPIs and to conduct the impact assessment for the socio-economic reports in D9.4. The work done in Tasks 6.4 and 7.2 first led to an analytic description of all the information for all pilot sites and a definition of the measurements for the use cases separately.

Second, the work defined pilot details (e.g., technology adopted, intervention details, recruitment period), defined the differences in clinical variables at final follow-up (e.g., patients per group, proportion patients in baseline state, proportion patients in disease/impairment state), healthcare costs baseline (e.g., Markov model States, one-off costs, recurrent costs), and societal aspects (e.g., utility baseline, utility disease/impairment, technology acceptance).

Table 2-1 - Meta-analysis of Pilots' outcomes

	Pilot site		PILOT N. XXXX		
	Use case		RC1	...	RC7
Pilot details	Technology adopted				
	Intervention details				
	Recruitment period				
	Follow-up period				
	Pilot country / region				
	Time Horizon for Analysis				
Differences in Clinical Variables at Final Follow-up	Number of Patients in the DOA				
	Number of Patients estimated NOW				
	if the number(s) in I is different than the number(s) in J explain why				
	Minimum age participants				
	Maximum age participants				
	Patients per group	Intervention			
		Control			
	Proportion patients in baseline state	Intervention			
		Control			
	Proportion patients in disease/impairment state	Intervention			
		Control			
	Transition probabilities - Incidence rate	Intervention			
		Control			
	Transition probabilities - Recovery rate	Intervention			
		Control			
	Patient Information and Frequency of Monitoring	Daily			
		Weekly			
		Monthly			
	Gender	General			
		Intervention			
		Control			
	Comorbidities/Conditions/ Risk Factors (BASELINE)	Type [units]			
		Intervention [units]			
		Control [units]			
	Dementia (BASELINE)	Intervention [units]			
		Control [units]			
	IT literacy (BASELINE)	Intervention [units]			

		Control [units]			
	other_characteristics_to_be_added (BASELINE)	Intervention [units]			
		Control [units]			
	Planned patients visits	Intervention [units]			
		Control [units]			

Since March 2020 bilateral intra and inter cluster meetings have been conducted to discuss the ongoing work with Pilots and other partners of the Consortium.

The next chapter will describe Pilot per Pilot which 'Impact assessment KPIs has been defined and will be measured to assess the impact. Further editions of this document issued every 6 months from M18 will include the measurements conducted.

3 Impact assessment KPIs Evolution Reports: Pilot per Pilot

This Chapter will report all the 'Impact assessment KPIs per categories and per RUCs in each Pilot after bilateral meetings as described above. The 'Impact assessment KPIs were literally tailored to the experiments and they will be reported and refined all project long.

In general, the KPIs should represent a measurable feature representative of the specific problem. KPIs do not integrate attributes such as better or increase. They should represent features and they could be integrated with the method that the research group intend to use to measure that feature. Where already available have been reported the sources and the tools to be used.

The following represents one of the tool used to build the Impact assessment KPIs hierarchy table per Pilot and per RUC:

Table 3-1 - Impact assessment KPIs

Pilot site			PILOT N. XXXX		
Use case			RC1	...	RC7
KPIs	clinical	Hospital admissions / health deteriorations			
		Patient visits and time spent			
		Patient adherence to treatment			
		Better 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			
		Health Professionals quality of life in relation to technology adopted			
		Cost-effectiveness / Monthly-Annual health care costs			
	adoption potential	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))			

3.1 Aragon

Study design

The study is organized around three levels of complexity of patients (prevention, medium complexity - stable chronic patients, and high complexity- chronic patients in acute phases) and it is composed of four use cases (1- prevention, 2-COPD, 5-Heart Failure, and 7 Polymedication and Multimorbidity). The main objectives for each level of complexity are shown in the table below Table 3-2

Table 3-2 – Aragon Study Design

Level of complexity	N	Reference Use Cases	Study Type	Intervention	Control
Low	2000	1 – Prevention	Descriptive	NO	NO
Medium	170	2 – COPD	Between subject design with randomized intervention and control groups	25	25
		5 – Hearth Failures	Between subject design with randomized intervention and control groups	25	25
		7 – Polymedication / Multimorbidity	Between subject design with randomized intervention and control groups	35	35
High	30	2 – COPD	Between subject design with randomized intervention and control groups	5	5
		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

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

3.1.1 USE CASE 1 - Low complexity KPIs

Table 3-3 - 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[3]), 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:[4]	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

3.1.2 USE CASE 2 - Mid complexity KPIs

Table 3-4 - 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

3.1.3 USE CASE 2 High complexity KPIs

Table 3-5 - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.1.4 USE CASE 5 - Mid complexity KPIs

Table 3-6 - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.1.5 USE CASE 5: High complexity KPIs

Table 3-7 - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
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

3.1.6 USE CASE 7 - Mid complexity KPIs

Table 3-8 - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.1.7 USE CASE 7: High complexity KPIs

Table 3-9 - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	N/A	Cultural discomfort alleviation	Qualitative

3.2 Basque Country

Study Design

The pilot in the Basque Country is organized around the three levels of complexity of patients (low level of complexity - prevention, medium complexity - stable chronic patients, and high complexity- chronic patients in acute phases) and it is composed by five Reference Use Cases (RUC1- prevention, RUC3 – diabetes, RUC4 – Parkinson's disease, RUC6 – Stroke and RUC7 Polymedication and Multimorbidity) summarized in Table 3-10.

Table 3-10 - Basque Country Study Design

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)	5000	5000
Medium	1100	6 - stroke prevention	Between subject design with randomized intervention and control groups	50	50
		7 - polymedication / multimorbidity	Between subject design with randomized intervention and control groups	500	500
High	200	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.

3.2.1 USE CASE 1 - Low complexity KPIs

Table 3-11 - USE CASE 1 - Low 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	Better quality of life	EQ5D
Societal	N/A	Technology acceptance	Questionnaire on technology acceptance

3.2.2 USE CASE 3 – High complexity KPIs

Table 3-12 - 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	Better 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.2.3 USE CASE 4 – High complexity KPIs

Table 3-13 - 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	Better 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.2.4 USE CASE 6 – Mid complexity KPIs

Table 3-14 - 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	Better 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.2.5 USE CASE 7 – Mid Complexity KPIs

Table 3-15 - USE CASE 7 – 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 adherence to treatment	Qualitative/self-report
	N/A	Better quality of life	EQ5D
	N/A	Adverse events	Qualitative/self-report
Societal	N/A	Technology acceptance	Questionnaire on technology acceptance

3.3 Cyprus

Study Design

Two organizations are managing the studies PASYKAF and AMEN, respectively with 1000 and 400 patients. Both will implement the RUC 7 aiming at the improvement of the quality of life and the early detection of condition worsening as main outcomes.

The aim, for both organizations, is placed in improving the quality of life for people living with Dementia (AMEN) or Cancer (PASYKAF). This will be done via early detection of the illness. A special focus will be placed on symptoms control methods and palliative care via pain management interventions. The study is summarized in the Table 3-16.

Table 3-16 - Cyprus Study Design

Level of complexity	N	Reference Use Cases	Study Type	Intervention	Control
High	1000	7 - polymedication / multimorbidity PASYKAF	Between subject design with randomized intervention and control groups	350 + 300	350
	400	7 - polymedication / multimorbidity AMEN	Between subject design with randomized intervention and control groups	175 + 50	175

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

3.3.1 USE CASE 7 – High Complexity KPIs

Table 3-17 - USE CASE 7 – High Complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical	N/A	Better quality of life	IPOS Pain Diary QLQ-C30 EORTC Quality of Life – Core Questionnaire The Hospital Anxiety and Depression Scale (HADS) Behavioural activation (BA)

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
			Standardized questionnaires[1]
	N/A	Sleep Quality	qualitative/self-report
	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	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	Informal Caregivers empowerment	qualitative/self-report
	N/A	Health Professionals quality of life in relation to technology adopted	Caregiver Strain Index (CSI),
Adoption Potential	N/A	Specificity, sensitivity and AUC of models / Effectiveness	Cost analysis
	N/A	Compatibility with clinical workflows/protocols	qualitative/self-report
	N/A	Usability issues	qualitative/self-report

[1] https://www.ichom.org/portfolio

3.4 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 modelling of glycaemic status for elderly patients with Type 2 Diabetes Mellitus*** involving almost 1500 persons. 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. A brief overview can be seen in Table 3-18.

Table 3-18 - Greece Study Design

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.

3.4.1 USE CASE 1 - Low complexity KPIs

Table 3-19 - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.4.2 USE CASE 3 – Medium complexity KPIs

Table 3-20 - 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)[5]

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	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

3.5 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.

Please note: Due to the COVID-19 SARS COV2, the RUC1 is going to be redesigned in the next amendment, here the actual one will be described.

The main objectives for each level of complexity are described in Table 3-21.

Table 3-21 - Milton Keynes Study Design

Level of complexity	N	Reference Use Cases	Study Type	Intervention	Control
Low	400	1 - Prevention	Between subject design with randomized intervention and control groups	70 + 260	70
Low	100	7 - polymedication / multimorbidity	Between subject design with randomized intervention and control groups	30 + 40	30

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

3.5.1 USE CASE 1 – Low Complexity KPIs

Table 3-22 - USE CASE 1 – Low Complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical	N/A	Quality of life	ED5Q
	N/A	Promote healthy habits	Qualitative/self-report
Societal	N/A	Technology acceptance	Questionnaire on technology acceptance
	N/A	Patient empowerment health literacy	Qualitative/self-report
	N/A	Cultural/Social discomfort/isolation alleviation	Qualitative/self-report
	N/A	Return on investment	Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Adoption Potential	N/A	Privacy / data issues	Qualitative assessment
	Usability issues technology	Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability	Qualitative/self-report

3.5.2 USE CASE 7 – Low Complexity KPIs

Table 3-23 - USE CASE 7 – Mid Complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical	N/A	Quality of life	ED5Q
	N/A	Patient visits and time spent	Number of on-site visits and length of visits
	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/Social discomfort/isolation alleviation	Qualitative/self-report
	N/A	Return on investment	Incremental cost-effectiveness ratio (ICER) MAFEIP Tool Outcome
Adoption Potential	N/A	Privacy / data issues	Qualitative assessment

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	Usability issues technology	Perceived of usefulness Perceived ease of use User satisfaction Attributes of usability	Qualitative/self-report

3.6 Poland

Study design

The studies to be conducted in this Pilot Site have one Low Complexity involving 1000 patients and health care professionals; one Medium Complexity will recruit 130 patients and health care professionals and the last will work with 50 patients and health care professionals.

The main objectives for each level of complexity are described in Table 3-24.

Table 3-24 - 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.

3.6.1 USE CASE 1 – Low complexity KPIs

Table 3-25 - USE CASE 1 – Low complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical	N/A	Quality of life	ED5Q
	N/A	Patient adherence to treatment	Qualitative/self-report
	N/A	Adverse events	Qualitative/self-report
Societal	N/A	Patient / Citizen empowerment Health literacy	Qualitative/self-report

3.6.2 USE CASE 7 – Mid and High Complexity KPIs

Table 3-26 - USE CASE 7 – Mid and High Complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical	N/A	Quality of life	ED5Q
	N/A	Patient adherence to treatment	Qualitative/self-report
Societal	N/A	Patient / Citizen empowerment Health literacy	Qualitative/self-report

3.7 Puglia

Study design

Four different study designs are planned by the Puglia Pilot, as follows:

- Experimental study design for the cost effectiveness assessment of the Moderate Complexity Medical Use Case
- Experimental study design for the cost effectiveness assessment of the Low Complexity Medical Use Case
- Observational study design for assessing the effectiveness of models predicting the influence of physical activity 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 after discharge, in the frame of the Moderate Complexity Use Case
- A design template for observational studies aimed at assessing the effectiveness of models for the prediction of adverse events related to conditions addressed in Low Complexity (e.g. onset of pre-frailty, frailty, or MCI) and Moderate Complexity (exacerbations, decompensations, hypoglycaemic events, etc.) Use Cases. Since at the time of this writing the exact KETs that could be deployed to study participants - and, consequently, the variables that can be fed as input into the models - are not known and the models themselves are still under investigation in T6.3, only a template is provided for this case, which will be consequently instantiated when relevant information will become available.

The main objectives for each level of complexity are described in Table 3-27.

Table 3-27 - Puglia Study Design

Level of complexity	N	Reference Use Cases	Study Type	Intervention	Control	Partner
Low	10000	1 – Prevention	- Experimental study design - observational	5000	5000	Regione Puglia
Medium	400	2 – COPD 3 – Diabetes 5 – Hearth failure prevention and early intervention 7 - polymedication / multimorbidity / HBP	- Between subject design with randomized intervention and control groups - observational	200	200	Regione Puglia
	100	3 – Diabetes	observational	100	-	CSS

Puglia Pilot planned to execute both interventional and observational experiments within RUCs 2, 3, 5, and 7 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.

3.7.1 USE CASE 1 interventional - Low Complexity KPIs

Table 3-28 - 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
	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
	Secondary objective	Health literacy	Qualitative/self-report
	Secondary objective	Usability	SUS scale
	Secondary objective	Trust	PATAT scale

3.7.2 USE CASE 2, 3, 5 interventional - Mid Complexity KPIs

Table 3-29 - USE CASE 2, 3, 5 interventional - 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

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
		Usage of GK technology	App / software logs
		Technology acceptance	Questionnaire on technology acceptance
		Patient empowerment health literacy	qualitative/self-report
		Usability	SUS scale

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

Table 3-30 - USE CASE 3 observational (CSS) – Mid Complexity KPIs

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

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

Table 3-31 - USE CASE 1, 2, 3, 5, 7 observational – Low and Mid Complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical		Specificity, sensitivity and AUC of models	
		Estimated ICER resulting from the integration of the models in the clinical practice	ICER
		Healthcare expenditure disbursed for drugs, specialist visits, hospitalizations	ICER numerator
	For RUC3 (T2D)	Blood pressure Glycaemia	Clinical parameters data
		Physical activity Sleep quality	Activity parameters data
	For RUC (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
		Physical activity Sleep quality	Activity parameters data
	For RUC HBP	Blood pressure	Clinical parameters data
		Physical activity Sleep quality	Activity parameters data
	For RUC COPD	SpO2 Blood Pressure	Clinical parameters data
		Physical activity Sleep quality	Activity parameters data

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
	For RUC 1	Step count Walk distance Walk time Walk speed Walk calories	Activity parameters data

In addition to the above variables, that come from KETs deployed for Moderate and Low Complexity interventional experiments, other conventional clinical data may become available from the EHRs of the Puglia Region's healthcare system and, for patients that needed hospitalization, from the EMRs of the CSS hospital. This availability is still under discussion at the time of this writing, in the frame of technology deployment.

3.8 Saxony

Study design

E-health procedures (= electronic health procedures) include both innovative methods of data collection, which provide researchers with new insights into fluctuating clinical pictures such as trauma-related disorders (so-called Ecological Momentary Assessment), and approaches to lower the threshold for seeking help in the case of psychological trauma-related disorders or to bridge waiting times until therapy begins (so-called Ecological Momentary Intervention). This has interesting implications for research into the aetiology and pathogenesis of mental health disorders, but also provides important insights for individual therapy design.

The existing resources being applied to the target population (50 Years+) are of diagnostic natures, rather than technological. However, during the current situation regarding COVID-19 Pandemic, health management is becoming increasingly open to new digitalized technologies that could help detect and monitor symptoms and treat them. Furthermore, our use cases could be deployed in settings where older people could feel autonomous and still stay connected to their family and friends, as well as learn more about their rights and the professional services for support where available.

The SAX use cases aim to maintain mental well-being. Indications for early detection of mental health symptoms would be changes in daily habits and activities as well as worsening in psychological (e.g. anxiety, depressive, somatoform and dissociative) and physical symptoms.

The main objectives for each level of complexity are described in Table 3-32.

Table 3-32 - Saxony Study Design

Level of complexity	N	Reference Use Cases	Study Type	Intervention	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.

3.8.1 USE CASE 1 – Low Complexity KPIs

Table 3-33 - USE CASE 1 – Low Complexity KPIs

Impact assessment KPIs Category	Subcategory	KPI	Measurement tool
Clinical	N/A	Hospital admissions Health deteriorations	Qualitative/self-report
	Patient visits and time spent	PROMs in the beginning/end of the pilot (for users) Advances in clinical practice/effectiveness and user satisfaction Certification as medical devices for prevention and detection, and accompanying treatments Prescriptions	Qualitative/self-report
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
Adoption Potential	N/A	Usability issues	qualitative/self-report

3.8.2 USE CASE 7 – Mid and High Complexity KPIs:

Table 3-34 - USE CASE 7 – Mid and High Complexity KPIs

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	Better quality of life	EQ-5D
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 Operative KPIs report

Operative 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 4.1 will be formalised in an excel file template that will be provided in the next deliverable version (M18). These KPIs will be filled in by each pilot site every 6 months and individual reports will be included as annexes in the new releases of this deliverable. Consolidated information of the indicators will be reported in 4.2 as a report of the entire LSP multicentre pilot progress.

4.1 Operative KPIs template

This section introduces the elements that will be collected in an Excel form that will be 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 that will be released in the next version of this document, will 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	☐ YES ☐ NO	dd/mm/yyyy	dd/mm/yyyy
Experiment running	☐ YES ☐ NO	dd/mm/yyyy	dd/mm/yyyy
Ecosystem enlargement	☐ YES ☐ NO	dd/mm/yyyy	dd/mm/yyyy

4.1.1 Deployment phase KPIs

In this section, the operative KPIs associated to the deployment phase are included. These KPIs will 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.

4.1.1.1 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).

4.1.1.2 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.).

4.1.1.3 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.

4.1.1.4 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.

4.1.1.5 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.

4.1.2 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.

4.1.2.1 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.).

4.1.2.2 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).

4.1.2.3 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.

4.1.3 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.

4.1.3.1 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.

4.1.3.2 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.

4.2 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 will be included in this section. 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) will be included in the Annexes for further details description. Future versions of the deliverable will include an aggregation emphasizing the most relevant points of the pilot execution according to the LSP execution phase, i.e. deployment, running or ecosystem enlargement.

5 Conclusions

Following the information in this deliverable, we can conclude that the training we have provided to the Pilots has resulted in a better understanding of experimental designs and the definition of the KPIs. Considering the work that has been done in task 7.1, 7.2, 7.3, 7.4 and 7.8, summarized in this deliverable, to plan the exact pilot use cases definition and the experimental design that will be conducted. Together with partners working in Work Package 6 and 9 we have developed a large excel file to collect all the information that will lead to a meta-analysis assessing the overall outcome. In the next versions of D7.2 due every six months from M18 we will continue the work presented here to describe the exact measurements of the KPIs evolution and operative reports and which scales will be used, to align as much as possible between the pilots across GATEKEEPER.

The innovative element of GATEKEEPER is that we are able to actively involve different stakeholders in the co-creation of the evaluation framework, whereby all partners, together with the pilot-sites (from Basque country, Aragon, Saxony, Puglia, Poland, Milton Keynes, Greece and Cyprus), have worked on establishing the evaluation framework and therefore can deliver higher qualities of research.

Designing a methodological sound evaluation framework with valid and reliable key performance indicators is necessary to effectively test the outcomes of digital solutions in the healthcare sector, taking into account methodological aspects such as validity and reliability for the results. Subsequently, it provides the opportunity to conduct cost-effectiveness analyses to support evidence-based decision-making processes for stakeholders with the MAFEIP tool, part of WP9.

6 References

[1] The "Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing" (MAFEIP) intends to support evidence-based decision-making processes for all institutions and users in the health and care sector: http://mafeip.eu

[2] In Gigerenzer, Gerd. Risk savvy: How to make good decisions. Penguin, 2015.

[3] 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.

[4] 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.

[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7076978/