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D7.3- KPIs Evolution Report (I to IX) v2

Deliverable No.	D7.3	Due Date	31/08/2022
Description	This deliverable starts the public reporting about the whole project KPIs definition and evolution		
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History

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15/07/2022	0.1	First structure draft
28/07/2022	0.2	Elaborating KPIs refinement from pilots
03/08/2022	0.3	incorporating pilots' contribution
08/08/2022	0.5	Draft ready for review
05/09/2022	1.0	Final version ready for submission

Key data

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Abstract

This is the second issue of the Key Performance Indicators, KPIs Evolution report, which is mainly based on surveying the pilots about the expected outcomes of their experiments.

An updated version of pilots' experiment and associated **Impact Assessment KPIs,** as well as the preliminary work with the monitoring tools, are included in this report. The **Operative KPIs** and related aggregation tool are also introduced in the document an instrument to monitor the pilots experiment execution. IA KPis and Operative KPIs are presented as part of the **overall ODIN KPIs journey** that also includes the **Technical KPIs** (that will be described from the next release of the deliverable).

Every six months, the specified KPIs will be published to illustrate how ODIN is achieving its primary goals.

The Key Performance Indicators (KPIs), which include scales and evaluation techniques, were established as part of the WP7 tasks activities and in a cooperative and collaborative effort with the pilots.

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This deliverable contains original unpublished work except where clearly indicated otherwise.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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List of abbreviations

Abbreviation	Explanation
ODIN	"ODIN - Leveraging AI based technology to transform the future of the health care delivery in Leading Hospitals in Europe" - Grant agreement number 101017331
AI	Artificial Intelligence
API	Application Programming Interface
DoA	Description of Action
Dx.x	Deliverable number x(WP number).x(number of the deliverable)
EIP on AHA	European Innovation Partnership on Active and Healthy Ageing
HCP	Health Care Professional
HCW	Health Care Worker
IA	Impact Assessment
ICT	Information and Communications Technologies
IoT	Internet of Things
IPJ	Innovative Procurement Journey
IPR	Intellectual Property Rights
KET	Key Enabling Technologies
KER	Key Enabling Resources
KPI(s)	Key Performance Indicator(s)
Mx	Project Month x
NHS	National Healthcare System
R&D&I	Research, Development and Innovation
RUC	Reference Use Case
SME	Small and Middle Enterprises
Tx.x	Task x(WP number).x(number of the task)
UC	Use Case
WP	Work Package

1 About this deliverable

This deliverable, in its second edition, examines how IA Key Performance Indicators (KPIs) are effectively used as measurable values, how they will measure the impact of the ODIN experiments pilot per pilot, and how they will evolve from a more general ODIN Project perspective.

This document is linked to the Deliverables 7.1, following the D7.2 and is part of the work done in the different tasks of the Work Package 7 (WP7)

Changes in Pilot settings will inevitably reflect a change and evolution in KPIs, as KPIs correctly evaluate how well the experiments are achieving and fulfilling their goals.

1.1 Deliverable context

Table 1. Deliverable context

PROJECT ITEM IN THE DOA	RELATIONSHIP
Project Objectives	This deliverable is framed in the context of WP7 and contributes directly to the impact evaluation framework the ODIN experiments
Exploitable results	The results of this deliverable will be directly exploited by the technical work packages as well as WP2, WP9 and WP10 related to the open calls.
Workplan	The deliverable will be constantly updated according to the DoA. Our partners will be encouraged to provide constant up-to-date inputs regarding the pilot activities. Pilots' progress in this regard will be monitored and documented.
Milestones	This deliverable is linked to the deployment and running Phases
Deliverables	Related deliverables: D2.2, for the blueprint definition of the pilot needs; D2.3 the catalogue of technology, D7.1 the experiment definition and D7.2 first KPIs report
Risks	Due to the changing nature of hospital contexts, some of the conditions outlined here may change over the course of the ODIN project.

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 D7.3

SECTION	UPDATES/MODIFICATIONS
1	Deliverable context
2	Revised introduction
3	Revised description
4	Revised intro for the RUCs definition
4.2	Introducing the Operative KPIs
5, 6	Revised general IA KPIs
7	Revised conclusions
App. A	Fully revised: Pilots descriptions, (ALL) Pilots' experiments definition, (ALL) defined timelines, (ALL) detailed technology, (ALL) redefined goals (ALL) defined IA KPIs (ALL but MUL) detailed involved staff (ALL)

2 Introduction

Due to the Public dissemination level, this document will report some info already included in D7.1 Experiment definition.

For readability purposes as a standalone document, this deliverable will include the necessary forewords, concepts and descriptions already included in the previous editions.

As stated in the DOA, the hospital becomes the primary infrastructure leading towards the necessary evolutions of the Industry 4.0. One out of three hospitals promoted or planned to adopt particular strategies or policies to implement new technological tools in the last five years. In fact, technology is becoming more prevalent in all parts of the hospital, not just for particular functions like diagnosis and treatment, but also for managing and logistical operations and procedures. Clinical algorithms, patient pathways, decision-assist tools, and optimisation techniques could be created using a combination of clinical skill, patient data, environmental resource availability, and the best available research findings. Evidence-Based Medicine (EBM) changed medicine by relying on the core notion that data-driven processes can significantly improve medicine's effectiveness and safety while keeping costs in check.

This second edition includes the pilots' redefined experiments with the deadlines and their related refined IA KPIs. The main aim is to show how these indicators will effectively show as the evolution of the ODIN experiment framework.

This Report Series will give the measure of the impact of the ODIN experiments pilot per pilot as well as the evolution of their execution. To monitor the execution phase, the next versions will include another class of indicators: the operative KPIs. These indicators will help to report about different stages of the deployment and running phases of the ODIN experiments, pilot per pilot.

In future releases will also include the KPIs defined in the technical work packages, from WP3 to WP6.

This document reports in section 3 the co-creation process done with the pilots and the other Partners to lay the structure of the overall ODIN federated experiment. Section 4.1 presents the reference use cases (RUCs) of the ODIN project and section 4.2 introduces the Operative KPIs ad related aggregation tool. Section 5 and 6 report about the RUC A and RUC B description and the related IA KPIs per RUC and per pilot. Appendix A reports the detailed pilots' experiments and their IA KPIs.

3 The ODIN Experiment framework

The ODIN Experiment framework consists of a federation of local case studies aiming to prove the safety, efficacy, and cost-effectiveness of AI, big data, robots, and IoT Key Enabling Technologies (KER). for improving hospital safety, productivity, and quality. The **11 ODIN Challenges** and the **3 areas of intervention**, as outlined in the DOA and presented in the table below, are covered in detail in the pages that follow.

Table 3 – ODIN Challenges

Challenges and ODIN answers
Challenge 1. Financial challenges and hospital productivity Data-driven management will enable pervasive data collection, data analytics, real time in-hospital tracing of devices, workers and patients. This will enable optimisation of clinical and logistic processes while reducing the time required to accomplish common hospital tasks and optimise shared resources. Predictive analytic modelling will reveal ways to break down barriers between departments. eWorkers, eRobots, and eLocation will support this optimisation.
Challenge 2. Increase patient and staff safety Advance process for tracing people and medical tools/instruments will help to prevent exposure to risky areas (e.g., infections, electrocution). In case of infection events, ODIN will contribute to the early detection, monitor and intervention measures. The use of autonomous robots will prevent infections. The use of exoskeletons or lifters together with rehabilitation robots will improve the treatment of the patients, while enhancing working conditions of the professionals.
Challenge 3. Logistics, regulatory standards and energy mandates Tracing the real usage of medical locations and goods (e.g., drugs, furniture, medical devices), as well as the path of objects will help optimising internal/external processes, while ensuring the compliance with regulatory standards, facilitation the data exchange and adaptation to new regulations or digital standards.
Challenge 4. Hospital security ODIN surveillance services will contribute to reducing the risk of violence and theft, with support of small-size robots when personnel are not available (i.e., at night), contributing to avoid Mass Casualty Incidents. The use of robots for drugs/objects transportation will provide for more safety when there is a limited number of staff members. Moreover, the employment of block-chain will help facing emerging security issues, such as cyber-security.
Challenge 5. Patient satisfaction (value-based healthcare). Health literacy and patient empowerment will start during the stay in the hospital with the use of robotic assistants that motivate and coach patients, preparing them for self-care after discharge, giving information, entertaining, making teleconferences with family.
Challenge 6. Too many avoidable patient days (reducing unneeded hospital stay). The ODIN platform will enable data collection from patient home/residence in the days after of the discharge, with the use of IoT support services, companions and rehabilitation robots, and cyber assistants. According to literature, these solutions contribute to better planning the transitional care models, preventing delay discharge and reducing readmissions.

Challenges and ODIN answers
Challenge 7. Desire for physician integration but very few employed physicians Robotic assistants can support healthcare professionals in non-complex tasks (such as food provisioning), internal and external transport of devices and waste and cleaning related tasks. This will free time for staff-patient interactions.
Challenge 8. Unhealthy community The coordination with smart cities (in terms of air quality, transportation habits, etc) will contribute to create awareness and training campaigns. In case of patients performing transitional care pathway at home, the IoT sensors and the robotics support will enhance the self-care training.
Challenge 9. Poor communication between providers (industry 4.0) A mix of advanced analytical data, tracing devices, people and drugs and targeted interpersonal relations will reduce redundancies in communication and provide optimised communication channels and messages.
Challenge 10. Shortages of physician, nurse and well-trained healthcare professionals. The continuous data exchange and processing optimisation contribute the detection of the lack of training of the different types of staff providing mechanisms to apply the needed training mechanisms. The use of ODIN technologies and interactive tools will support staff and process optimisation.
Challenge 11. Disaster preparedness The COVID-19 pandemic demonstrated the vastness of the number of EU hospitals are not prepared to face disasters. In the past 20 years, EU NHSs have reduced the critical beds in their hospitals (average ICU beds per million inhabitants per EU-Nations cut from 10k in 1990 to 3k in 2020[1]) moving the resulting saved budget to investments in non-hospital health services, in response to demographic challenges. While this is a necessity, these changes cannot be left to empirical attempts, but require EBM reasoning, scientific simulations and holistic approaches, supporting systemic responses from different hospital experts (clinical, technical, managerial), who now still work in silos in the majority of EU hospitals.

These challenges are meant to be deployed by the pilots within the following areas of intervention:

- **Enhanced Hospital Workers (eWorkers)**
- **Enhanced Robots (eRobots)**
- **Enhanced Locations (eLocations)**

The areas are defined as follows.

- **Enhanced Hospital Workers (eWorkers):** the aim is to look into how to provide appropriate technology to hospital staff (such as nurses, porters, technicians, and doctors) in order to improve their abilities and support their daily work. Technology will be employed to relieve workers of the weight of their daily tasks, allowing them to focus on the vital jobs that require all of their human abilities. Wearable technologies will be used to improve their 'senses,' increase their 'connectivity,' speed up their reasoning, and improve their physical traits. We'll start with nurses and porters, utilising commercial technologies offered by project partners. Through Open Calls, new healthcare employees and technologies (such as virtual and augmented vision) will be added.
- **Enhanced Robots (eRobots):** the aim is to automate those hospital processes that no longer require humans or can be improved by automatons. These robots will not necessarily be humanoid and will be used in the form of centrally synchronised swarms with some

autonomy. ODIN robots will have advanced perception functions (smell, vision, touch, taste, and hearing), extensive connectivity (with other robots, hospital assets, humans, and medical places), advanced AI reasoning capability (both locally and remotely), and task-performability (wheels, arms, hands, etc.). We will initially focus on the distribution of materials (drugs, food, disposables, consumables, and so on), the management of medical devices (e.g., preparing surgical equipment kits), and the facilitation of hospital processes (human navigation, reception, and patient surveillance) during the project. Other hospital processes will be added through Open Calls.

- **Enhanced Locations (eLocations)**: the aim is to instrument medical locations so that they can support hospital activities more proactively. In order to interact with personnel, robots, devices, and other necessary hospital assets securely and effectively, medical places will be improved with sensors (smell, vision, feel, taste, and hearing), technology for communicating with humans (screens, lighting, speakers), and high connection. Furthermore, eLocations will be able to provide real-time data about their underlying technological infrastructures (e.g., power plants, water pipes, air conditioning, medical gases) that are vital for human safety (patients, visitors, and staff), as well as robotics, medical devices, and equipment. Initially, we will concentrate on lower-risk medical settings as part of the study (e.g., reception, diagnostics, laboratories, non-severe patient rooms).Other medical locations will be added through Open Calls.

To understand how the ODIN pilots has to design their experiment to address the challenges we started a co-creation process. In order to achieve a clear Use Cases definition and an experiment description pilot per pilot the co-creation work has been organised in three methodological steps:

1) The Proposition, Thesis, analysis of the UCs
2) The Deconstruction, Antithesis (or growing),
3) Production, Synthesis of UCs and Reference Use Cases definition

The step 1 was conducted from the beginning of the project during the WP7 meetings and bilateral calls with pilots. The main result of this phase is the template, called “Pilot Journey”, to orient/support the pilots in the preliminary experiment definition of the Step 2.

In the Step 2, from M4 to M7 pilots had to rephrase their own vision about the UCs. For this step different tool have been used:

- A template, from step1, the so-called “Pilot Journey”, administered to all the pilots in order to get their reflections and propositions about their specific needs in relation to each UC
- Focus groups were organised with each UC to discuss their answers to the questionnaires

The results were discussed with all the pilots. Below some excerpts are reported, the full pilots’ descriptions are in the Appendix A

The need to harmonise the experiment descriptions, identifying commonality and stressing specificities, resulted from these reports.

This led to the Step 3. There were defined three Reference Use Cases leveraging on the initial UC description as per DOA and based on the pilots’ inputs to the ODIN UC.

The RUCs are the described in the next section and are the following:

- RUC A Health Services Management, including all the clinical use cases from the DOA, UC3, UC4, UC5, UC6;
- RUC B Devices and Facilities Management, including the UC1 and UC2
- RUC C Disaster Preparedness with the UC7

All the subsequent activities were organised following each RUC group to start defining pragmatic constrains, such as: ODIN partner available technology, Open Call challenges, and external factors.

It was chosen to adopt the WHO navigation diagram used in the "WHO list of priority medical devices for management of cardiovascular diseases and diabetes" (2021 – Reference). In this publication, the priority medical devices that are discussed, selected and presented are organised by clinical units in a health service provision. The navigation diagram in the figure below represents the range of health-related interventions, from pre-hospital activities to highly specialised tertiary hospital-based care. The diagram has been adapted where the phases represent the departments/units required to perform the different tasks of the selected RUC

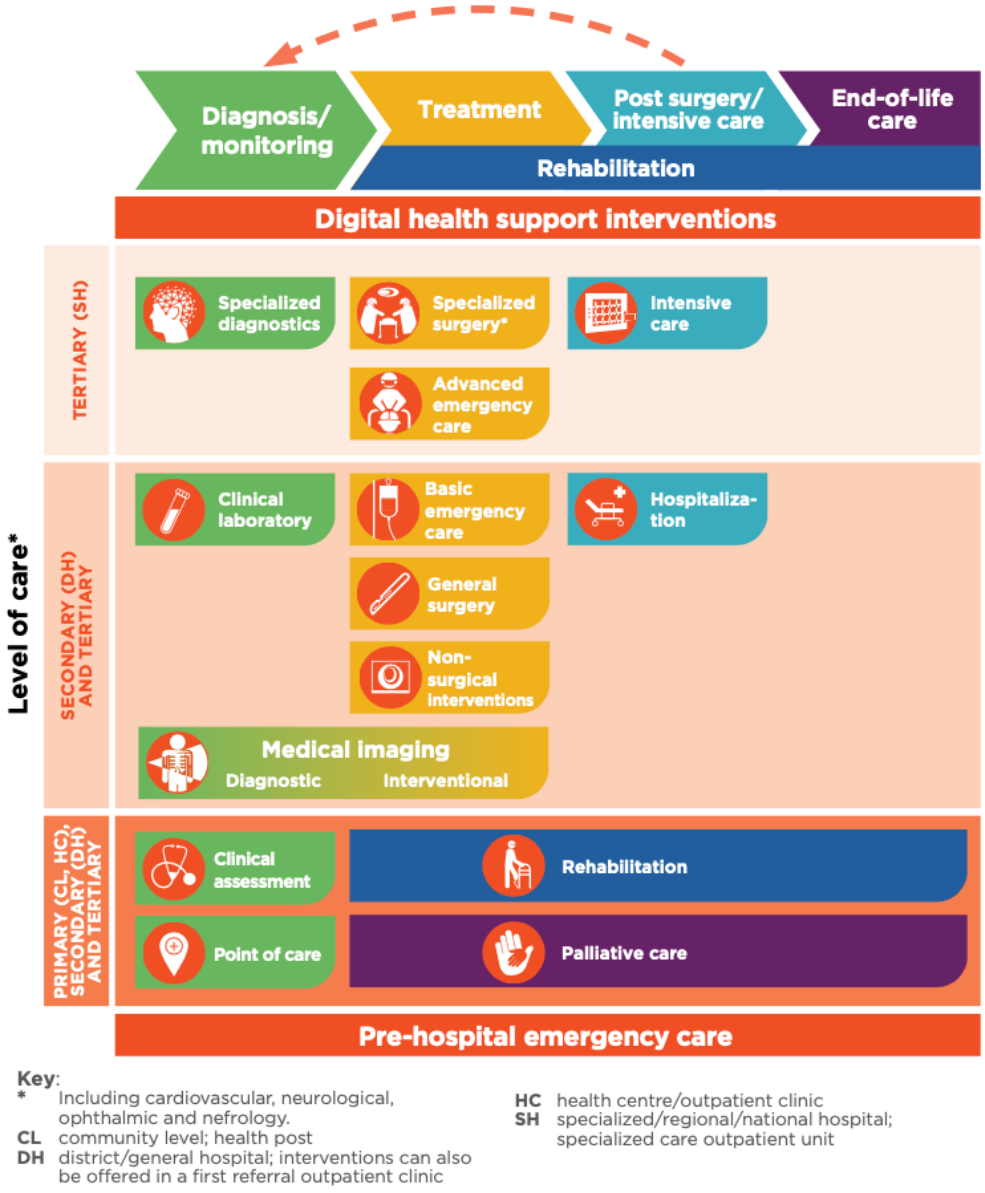

Figure 1 - WHO Navigation Diagram

The phases for each RUC were developed and revised during the workshops, and for each step, the pilots required to specify the Description, Goals / Outcomes, IA KPIs, Technology, and ODIN Contribution, as shown in the pictures below.

The process of KPIs further re-definition is undergoing in the impact assessment framework and involves not only the pilots but all the ODIN Partners.

The final goal of this phase is to achieve a *complete framework of indicators* (ODIN KPIs journey) from different perspectives: *experiment evolution (operative KPIs), technology deployment (Technical KPIs), impact assessment (IA KPIs)*.

3.1 ODIN Pilots

So far in the ODIN Experiment framework at M18 includes the pilots described below.

This list will be updated as the ODIN Open innovation framework will also include new pilots belonging to the running Open Call, from M17 to M19 and starting in M23-M24

3.1.1 Charité - Universitätsmedizin Berlin, Germany (CUB)

Charité University Hospital has 3,000 beds and 14,000 employees. It is distributed over 4 campuses in the city of Berlin. It is one of the largest hospitals in Europe with a strong focus on excellent patient care and research. The aim is to combine patient care, medical research, education to provide best practice for the future of medical services in Europe.

The sleep medicine centre is part of Charité, linked to the department of pneumology. The sleep medicine centre has 10 beds for patient care and 2 beds for research studies. We have about 3,000 sleep studies in the hospital with polysomnography (sleep recording) per year and about 5,000 home sleep studies (with fewer signals recorded) per year. The staff includes pneumologists, neurologists, ENT physicians, cardiologists, engineers, specialised medical technologists, and nurses.

3.1.2 Medical University of Lodz, Poland (MUL)

Medical University of Lodz (MUL) is a higher state school having over 70 years-long history. With its 5 faculties, 3 teaching hospitals and 80 clinics, 9,500 students, 1,000 foreign students and approximately 1,600 academics, Medical University of Lodz belongs to the leading Polish medical universities. The University is strongly committed to scientific research in a number of health-related disciplines as well as national and international scientific cooperation. The University is considered a leader in the number of scientific publications and citations among medical schools in Poland. In 2022, MUL ranked 9th among Polish Universities, according to national 'High Schools Ranking Perspectives'. MUL's scientists conduct extensive basic and translational research. The Medical University of Lodz has reached the leading position in various research areas, and particularly in patient adherence and healthy ageing. In acknowledgment of these achievements, the Medication Adherence Research Centre (MARC) was founded in 2020 in MUL, headed by Prof. Przemyslaw Kardas.

MUL makes a substantial contribution to the development of the health care system by promoting modern standards of prophylaxis and treatment, and by building long-lasting cooperation with institutions realizing objectives of public health at regional, national and international levels. Last but not least, MUL is strongly committed to Silver Economy. Being formally recognised as the EIP on AHA Reference Site, MUL plays the key role in facilitation of collaboration between academia and industry, in order to transform the demographic challenge into opportunity. Initiating creation of dedicated businesses clusters, MUL is pioneering and helps boosting the local economy.

With its own complete ecosystem of healthcare services, covering full range of healthcare system levels, from primary health centres to tertiary teaching hospitals, MUL is perfectly well-placed for the purpose of testing and implementation of novel health technologies. Serving over 86,000 patients yearly, MUL is also one of the major local healthcare providers, active in each and every area of modern medicine. This potential will be of particular use within the framework of ODIN project.

3.1.3 Hospital Clínico San Carlos, Madrid, Spain (SERMAS)

This pilot is going to take place in Hospital Clínico San Carlos. Three main departments are going to be involved: the Procurement Department, the Cardiovascular Institute and the Innovation Unit.

The Procurement Department is in charge of the supply and logistics distribution of the medical equipment and consumable materials inside the hospital, being a key player in the smooth development of all clinical processes and procedures. This department has transversal action, so the problems we want to tackle affect the performance of the entire hospital.

The Cardiovascular Institute (ICV) represents around 48% of the total hospital's expenditure in medical equipment and consumables. Inside the ICV, the therapeutic areas dedicated to hemodynamic and electrophysiology have high-impact equipment and some of the best-described pathways for consumables provision.

Finally, the Innovation Unit is the hospital team that is part of the ODIN Consortium. It will act as bridge between the ODIN partners and the hospital staff.

3.1.4 Università Campus Bio-Medico di Roma, Italy (UCBM)

Università Campus Bio-Medico di Roma (UCBM) is a young, yet rapidly developing, private academic institution, devoted to undergraduate and postgraduate education and to advanced research also linked with the high-quality healthcare services provided by the Research Hospital of Fondazione Policlinico Campus Bio-Medico (FPCBM). Established in 1992, today the University runs the School of Medicine and Surgery, the School of Engineering, the School of Science and Technology for Humans and the Environment, as well as a PhD programme in "Integrated Biomedical Sciences and Bioethics" and "Science and Engineering for Humans and the Environment". In Italy, UCBM has been systematically top ranked for the quality of the education provided to a selected group of students. The institution has increasing:

i) scientific production per year;

ii) funding raised from competitive sources in Italy, Europe and worldwide (40+ research projects ongoing);

iii) technology transfer activities (16 patents families owned/co-owned and 7 spin-off companies from 2015).

An outstanding network of national and international key scientific and educational partners, including 200+ national and international partners, has been continuously developed and consolidated with specific collaboration agreements over the years.

Within FPCBM, the Geriatrics Unit conducts research activities in the following areas:

i) evaluation of the elderly patient health condition, with particular focus on multidimensional evaluation techniques in various disorders or multimorbidity pattern;

ii) evaluation of respiratory functions, with particular focus on the interpretation of spirometry results in elderly patients; study of diagnosis/prognosis properties of breath volatile organic compounds in the following disorders: heart failure, chronic obstructive bronchitis, obstructive sleep apnoea syndrome, diabetes mellitus, liver diseases;

iii) development and application of remote telemonitoring systems for patients with chronic diseases;

iv) pharmacoepidemiologic and epidemiologic geriatric research.

The Unit research activity can make use of a wide range of equipment for functional evaluations. It also has epidemiologic and statistical competences for the designing, planning, execution and analysis of interventional and observational epidemiological studies.

3.1.5 The University Medical Center Utrecht, the Netherlands (UMCU)

The University Medical Center Utrecht (UMCU) is one of the leading and largest medical centres in the Netherlands and ranks among the best European academic hospitals in international rankings. The core activity of UMCU is to provide healthcare for which special knowledge is required, provide leading research and offer excellent education to students, medical doctors, researchers and other healthcare providers. UMCU has a strong track record in both pre- and clinical research and forges strong links with companies and scientific institutions across the world.

UMC Utrecht's research focusses on six strategic themes, the ODIN projects fall into the Circulatory Health theme. Healthcare is divided over ten divisions, ODIN falls into the Division Laboratories, Pharmacy and Biomedical Genetics division, where the Central Diagnostic Laboratory is located. CDL's translational subunit ARCADIA (Academic Research for Clinical Applications of DIAgnositcs) hosts the Utrecht Patient Oriented Database (UPOD).

Established in 2003, UPOD provides access to the comprehensive and complete electronic health record information of all patients that visited the UMC Utrecht since the 1990's. Overall, 650k individual patients that have been hospitalised were included. UPOD comprises more than 2.4 million individuals, including out-patients. The UPOD group in brief aims to improve clinical diagnostics using routine care data and is involved in efforts to turn the UMC Utrecht into a learning healthcare system.

The UMCU ODIN project members will work in close collaboration with the recently established (2020) UMCU department of Digital Health, which is located in the corporate (permanent) staff.

All projects within the UMCU use case will take place in the strategic theme Circulatory Health. Within this area, UMCU has established a Center for Circulatory Health where a multidisciplinary team sees every patient with a cardiovascular disease. The Circulatory health strategic area includes a long-standing research cohort (Utrecht Cardiovascular Cohort) that already encompasses 13,000+ patients. Combining the Center for Circulatory Health and Utrecht Cardiovascular Cohort efforts has led to the first steps towards transitioning patient care for cardiovascular disease patients into a learning healthcare system. Within this system we are currently developing (clinical decision) support systems. This is where ODIN has its home.

4 Introducing the Reference Use Cases (RUCs)

The above mentioned hospitals will deploy and run the ODIN experiment framework according to the different case studies that we're going to describe in this paragraph.

Seven use cases in total, which have been thoroughly discussed in the DoA, were defined for the proper execution of the ODIN project, while taking the demands of the pilots who were taking part in it into consideration. In order to best organise the project given these factors and the aims as well as categories each of them addresses, it has been decided to develop Reference Use Cases (RUCs) that span all of the case studies to be included in ODIN. The three major key elements of a hospital are covered by the three RUCs that were chosen, supporting the partners and acting as a high-level guide:

- RUC A, on the health services management:
- RUC B, including goods and devices management
- RUC C, on disaster preparedness, comprehensive of all the previous ones in a disaster management.

The figure below shows the RUCs and Use Cases (UCs) distribution per pilot.

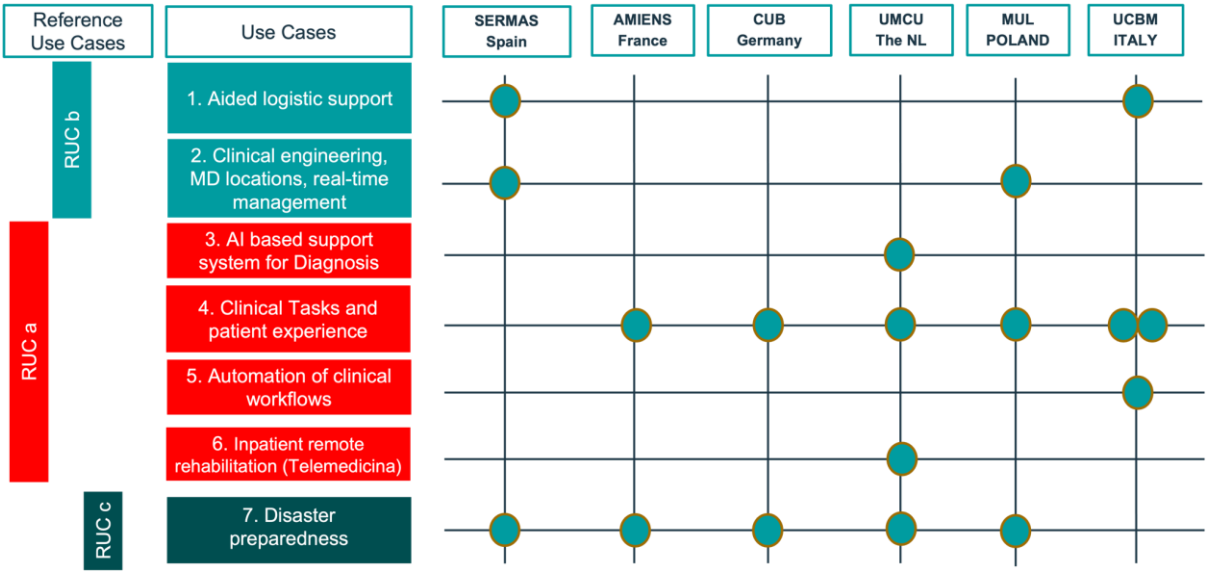

Figure 2 - RUCs - UCs pilots distribution

4.1.1 RUC A

This reference use case encompasses the use cases focused on the clinical (and diagnostic) oriented activities that this ODIN project will address. Under this approach UC4 is considered to be the most relevant use case, due to the number of pilots that chose it, as opposed to the rest of the use cases (UC3, UC5, UC6), which have been chosen by only one pilot.

On the one hand, the UC3 "AI-based support system for diagnosis", focuses on the use of AI technologies to optimise the personalised search for the diagnosis considered most effective in each case, serving as a support to healthcare professionals in decision-making, considering probabilities as well as the capacity of available diagnostic modalities.

On the other hand, UC4 "Clinical Tasks and Patient Experience" is the use case with more pilots involved within the RUC a. It aims to reduce the effort that clinical personnel must exert in therapeutic and diagnostic activities based on ODIN technology. This is intended not only to improve the quality and workflow of clinicians, but also to optimise the comfort perceived by patients during their journey and improve their health conditions.

Likewise, UC5 "Automation of Clinical Workflows" aims to respond/act against the emerging difficulty within workflows, which often follow processes that are not efficient enough. Therefore, this project, taking advantage of workflows and the collection of data and sources, aims to offer a solution by automating clinical research execution processes in order to reduce possible errors.

Finally, UC6 "Inpatient Remote Rehabilitation" focuses on remote patient monitoring covering both patient follow-up and simple and secure communication between patients and the relevant hospital sector. To this end, the ODIN project will deploy an AI system to automatically support patients and help healthcare staff to provide optimised lifestyle monitoring.

4.1.2 RUC B

This reference use case, related to the managerial area, covers the first two defined use cases (UC1, UC2). It is focused on the improvement, based on ODIN technologies, of the design, programming and execution of hospital logistics, clinical engineering and the management of medical devices.

The first of these, UC1, defined in the DoA as "Aided Logistic Support", has been conceived as the entire process of procurement, storage and distribution of different materials in the hospital environment focusing on activities within the hospital environment that are considered redundant (e.g., transport of consumables). UC1 aims to leverage ODIN technology to optimise all these logistic activities, thus improving working conditions, optimising the working time required by healthcare personnel for certain types of repetitive or risky tasks that do not require their attention, and the efficiency and workflow within the hospital.

In addition, RUC B also includes UC2 "Clinical Engineering, MD Locations, Real-Time Management", which focuses on the management of medical devices with ODIN technologies. This is particularly important as the current lack of real-time information exchange is one of the main causes of adverse events in the hospital environment. The correct functioning and adaptation to this use case will allow not only the optimisation of routine activities but also in supporting RUC C - Disaster Preparedness, which will be discussed in more detail in RUC C - UC7.

4.1.3 RUC C

This reference use case is exclusively focused on the action against possible catastrophes that may occur in the future, covering UC7 "Disaster Preparedness", due to the multitude of difficulties that hospitals had to face because of COVID-19. For this purpose, using ODIN technology, different simulations will be carried out to contribute to hospital resilient management (e.g., crowd management, security, IPC support) and prepare hospitals for possible future catastrophes, always with the main objective of ensuring safety.

RUC C description will follow the same co-creation process used to define RUC A and RUC B and will include protocols to manage all their phases during a disaster.

4.2 Introducing the Operative KPIs framework

Beside the evaluation of the impact there's the need to monitor all the project status during the different operative phases. This is to analyse and actively support the project execution,

In light of the significance of tracking the development of the ODIN Experiment architecture we made the decision to begin using various analysis methods. One of these is Microsoft PowerBI, which offers an efficient displaying of the experiments evolution. In order to illustrate the operational perspective, a dashboard has been created. A fresh set of operational KPIs is being validated for this purpose together with each and every RUC/UC.

We chose PowerBI because of its simplicity to use compared to competing products and its versatility in terms of data preparation and design management. The most pertinent data, such as the status of the RUCs/UCs and the pilots participating, is going to be collected in excel files and fed into the dashboard that has been created.

Any user can explore this dashboard starting with the descriptions of the pilots, the RUCs/UCs that have been implemented, the operational state for each phase, the resources that have been spent, and the defined KPIs. With this method, the most pertinent data is obtained uniformly, making it simpler to manage and monitor the project's status and advancement.

Future editions of these Deliverables series will present the progress of the operative KPIs measures.

5 RUC A: Health Services Management

5.1 ODIN Framework for industry 4.0

The RUC A can be represented as the following process with continuous interactions and feedback from each phase.

The National Health Services strategic planning (https://www.who.int/activities/supporting-national-health-policies-strategies-plans), which identifies needs and gaps, along with requests from the territory where the hospital is located, will be used to create the proper ***admission screening***, an evaluation of the hospital entry points. This phase feeds the ***diagnosis & case study*** where patients enter the path of the identification of a disease by examination of the symptoms. The previous phase is necessary to identify the right ***treatment*** and the subsequent ***monitoring and follow-up***.

This reference use case covers aspects related to the exploitation of ODIN technologies for improving execution of clinical tasks and patient overall experience within the hospital ecosystem. Specifically, it consists of the following phases covering all the clinical workflow, as represented in the picture below, from the patient's admission to the follow-up.

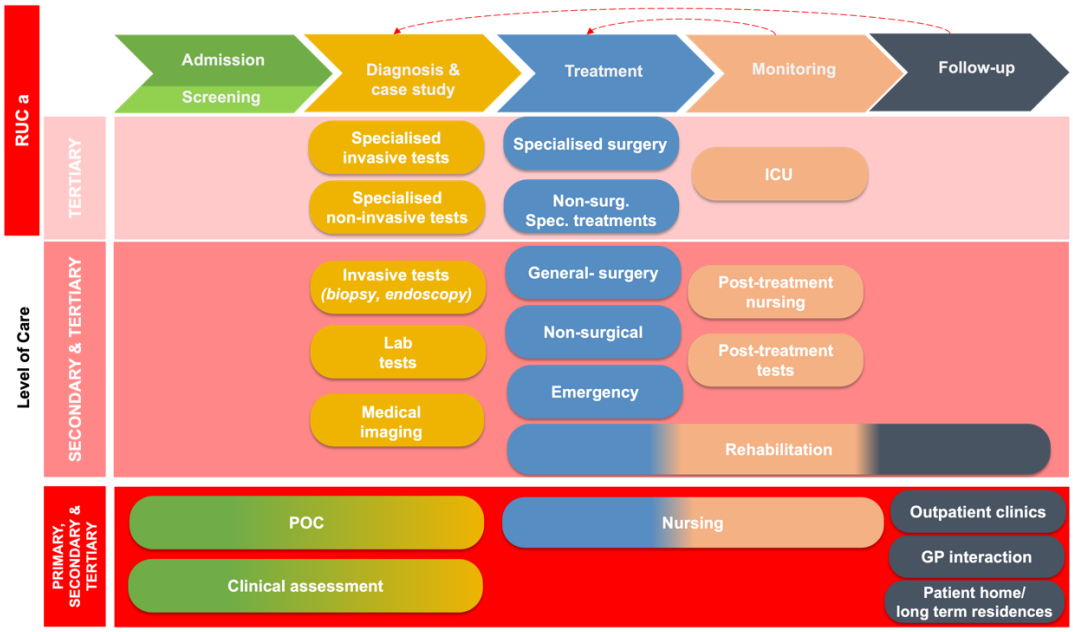

Figure 3 - RUC A Navigation Diagram

5.2 RUC A Phases

As reported in Section 4.1.1 this RUC includes all of the use cases related to clinical (and diagnostic) activities that will be addressed by the ODIN project. Due to the large number of pilots that believe RUC A2 - UC4 to be relevant, it is regarded as the first use case, in contrast to the remainder of the use cases (RUC A1 - UC3, RUC A3 - UC5, and RUC A4 - UC6), which have only been recognised by one pilot.

On the one hand, the RUC A1 - UC3 "AI-based support system for diagnosis" focuses on using AI technologies to optimise the personalised search for the most effective diagnosis in each case,

assisting healthcare professionals in decision-making by taking into account probabilities as well as the capacity of available diagnostic modalities.

RUC A2 - UC4 "Clinical Tasks and Patient Experience," on the other hand, is the use case with the most pilots within the RUC A. Based on ODIN technology, it promises to lessen the effort that healthcare workers must exert in therapeutic and diagnostic activities. This is meant not just to improve clinician quality and workflow, but also to maximise patient comfort and improve their health conditions during their travel.

Similarly, RUC A3 - UC5 "Automation of Healthcare Workflows" strives to respond to/address developing challenges within workflows, which frequently follow inefficient processes. As a result, this project intends to provide a solution by automating clinical research execution processes in order to eliminate possible errors by using workflows and data and source collecting.

Finally, RUC A4 - UC6 "Inpatient Remote Rehabilitation" focuses on remote patient monitoring, including patient follow-up as well as simple and secure communication between patients and the appropriate hospital sector. To this purpose, the ODIN project will implement a robotic component that will automatically support patients and assist healthcare professionals in providing optimal lifestyle monitoring.

Below are presented the phases included in this RUC

Admission & Screening

This phase refers to all the activities aiming to properly manage the admission of a patient following preliminary assessment of the clinical status.

Diagnosis & Case Study

Delivery of the diagnosis as a confirmation/refusal of the preliminary assessment, after patients undergo specialised exams and assessment. This phase ends with the identification and prescription of the treatment.

Treatment

Execution of the prescribed treatment

Monitoring

Monitoring of the compliance to the prescribed treatment, correctness and risks According to the output of this phase, adjustment to the treatment can be introduced.

Follow Up

This phase refers to the assessment of the short – terms effectiveness of the treatment. This might also stop the treatment or modify it to reach the clinical goal.

5.3 RUC A Goals (overall and for each phase)

This reference use case aims at maximising data-driven decisions and supporting execution of clinical tasks through the adoption of ODIN robotic and IoT platforms.

Admission & Screening

Improving preliminary assessment of the patient's clinical status and optimising the admission process management

Diagnosis & Case Study

Optimising Personalised diagnostic pathway

Treatment

Supporting execution of treatment with a reduction of workers' stress and workload

Monitoring

Implementing a cost-effective monitoring of treatment and generating proper data-driven feedback. . During this phase it is necessary to optimise the involvement of the HCW.

Follow Up

Optimising assessment of the short –terms effectiveness of the treatment.

5.4 RUC A IA KPIs (for each phase)

Here below are reported the high level IA KPIs summarised per each phase

The full experiment descriptions and the related, locally defined, KPIs are reported in the Appendix A.

Table 4 - RUC A KPIs

Phase	KPIs	Measure unit
Admission & Screening	Waiting time before admission	[hours]
	Patients enrolled	[n]
	Early detection of patients at risk	[%]
Diagnosis & Case Study	Time to diagnosis	[days]
	Number of exams for diagnosis	[n]
	Personalisation level	[scores TBD]
Treatment	Adherence to guidelines	[%]
Monitoring	Adherence to prescribed treatment: correct execution, specific KPIs, number of errors	[…]
	Users' acceptance	[%]
Time that each HCW spends with each patient	HCW Stress	[%]

Phase	KPIs	Measure unit
Follow up	Effectiveness of the treatment	[specific KPIs TBD]
	Length of stay in hospital	[days]
	Hospitals visits and re-hospitalisation	[%]

5.4.1 RUC A Sub Cases

5.4.1.1 RUC A1 - UC3: AI for diagnosis

Diagnostic trajectories in hospitals and medical centres can become difficult, long, expensive and cumbersome for patients. The objective of this use case is to verify if AI and IoT-driven approach is able to improve the diagnostic pathway by (A) Personalising the diagnostic trajectory of patients based on a priori and post priori probabilities and (B) provide integrated capacity management of the full diagnostic supply chain.

RUC A1 is focused on the second phase of RUCA: Diagnosis.

5.4.1.2 RUC A2 UC4: Clinical tasks and patient experience

This reference use case includes experiments linked to the exploitation of ODIN technologies for enhancing clinical task execution and patient experience across the range within the hospital ecosystem.

5.4.1.3 RUC A3 UC5: Clinical workflow

This reference UC aims to implement and validate a workflow-driven solution supporting the automation of the clinical research execution processes. It usually covers all the RUC A phases.

5.4.1.4 RUC A4 UC6: Telemedicine

Many patients spend unnecessary time in hospitals for monitoring, resulting in higher costs and a higher burden for the them. COVID-19 reinforced the value of home telemonitoring services.

According to these needs, this use case aims to implement a home telemonitoring service of clinical parameters integrated with the EHR system to promote the patient's continuity of care.

RUC A4 is focused on the following phases of RUC A: Monitoring and Follow-Up.

5.4.2 Pilots implementing RUC A

Once the reference structure of the RUC A were defined and foreseeable services (RUC A1- A4) were focused on, ODIN pilots described their experiments as a specialisation of these models.

This resulted in the following ODIN RUC A table:

Table 5 - RUC A Pilots implementation

Use Case	Name	Pilot(s)
RUC A1 - UC3	AI for Diagnosis	UMCU
RUC A2 – UC4	Clinical Tasks and Patient Experience	CUB, MUL, UCBM, UMCU
RUC A3 - UC5	Clinical Workflow	UCBM,
RUC A4 - UC6	Telemedicine	UMCU

Tables below summarises for each pilot the different implementation of RUC A. Appendix A reports the details per pilot.

5.4.3 CUB

Table 6 - RUC A - CUB

Use Case	Name / Description	RUC A Phase (s)
RUC A2 – UC4	Sleep disorders	Diagnosis, Treatment, Follow-Up

5.4.4 MUL

Table 7 - RUC A - MUL

Use Case	Name / Description	RUC A Phase (s)
RUC A2 – UC4	Blood transport Robotic transportation of blood samples from the Emergency Department to the Central Lab	All the phases

5.4.5 UCBM

Table 8 - RUC A - UCBM

Use Case	Name / Description	RUC A Phase (s)
RUC A2 – UC4	Monitoring of food assumption to prevent malnutrition	All the phases

RUC A2 – UC4	Rehabilitation to prevent loss of mobility	Treatment, Monitoring, Follow-up
RUC A3 – UC5	Monitoring of oxygen therapy to prevent hypoxia complications	Monitoring Follow-up

5.4.6 UMCU

Table 9 - RUC A - UMCU

Use Case	Name / Description	RUC A Phase (s)
RUC A1 – UC3	AI for Diagnosis AI tools to improve Personalisation and efficiency of CVD diagnostic pathways outpatient clinic setting	Diagnosis
RUC A2 – UC4	Identification of eligible patients Automatically identify new patients eligible for CVD learning healthcare system	Admission & Screening
RUC A4 – UC6	Telemonitoring Post-operative home-tele monitoring of vascular surgery patients	Monitoring, Follow-up

6 RUC B Devices, Goods, Facilities Management

This RUC was created to enable ODIN technologies to contribute to improving the design, scheduling, and execution of Hospital Logistic, Clinical Engineering, and Medical Device management, starting with the description of UC1 in the DOA.

It includes the phases of material procurement, storage, and distribution (medicines, medical and hotel supplies, meals, linens, waste, etc) part of the logistic management and those phases related to the clinical engineering and medical devices management.

All this processes, e.g., order consumables after using them, transport of objects, refill of ward magazines etc; most of the time need duplication of efforts generating additional, and unnecessary load to the hospital workflows, and extra burden to both administrative and healthcare staff.

This reference use case will employ various combinations of eRobots, eWorkers, and eLocations to optimise procedures, improve healthcare operators' working conditions, and improve hospital efficiency and workflow. This is projected to improve the work of personnel who are primarily responsible for hospital logistic processes (e.g., porters, managers), as well as free up time for healthcare workers (e.g., nurses) by removing them from repetitive, time-consuming, and potentially dangerous jobs.

6.1 ODIN Framework for industry 4.0 hospital logistic management

By approaching RUC B in a similar manner as RUC A, we can build a workflow, which describes the interactions among the different phases and inputs. As per RUC A, all the phases are interconnected and interdependent on each other. The starting points come from the Strategic Management Plan and the gap analysis from the different hospital units. These steps feed the Planning phase where the hospital management is in charge to design and develop what is needed by the next phase the Procurement Stockage. This last phase is dealing with all the necessary activities to acquire good in the hospital context. The next phase is related to the Preparation and Delivery of the acquire good to the final destination / department. Completing this process is the Real Use Monitoring and Management in charge of the follow up steps after the acquisition

The similar navigation schema of the RUC B can be described as the picture below, where instead of having the levels of care there are the different objects managed by the logistics for the RUC sub case B1 or type of the equipment for the RUC sub case B2 as shown in the figures below:

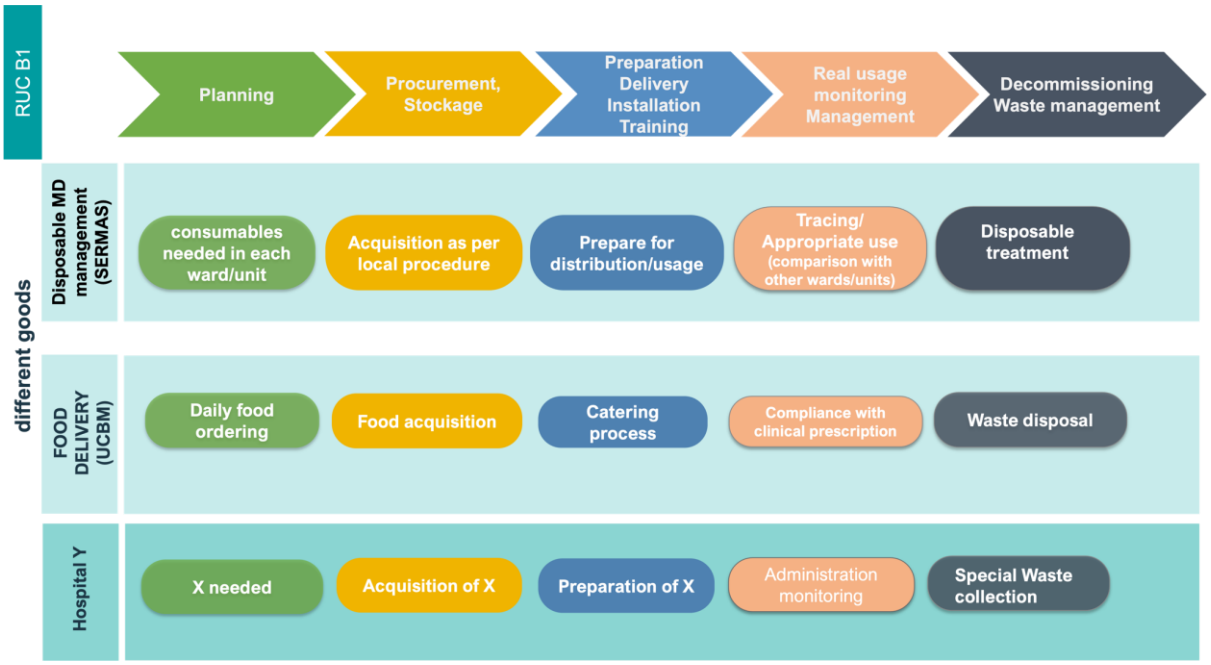

Figure 4 - RUC sub case B1 Navigation Diagram

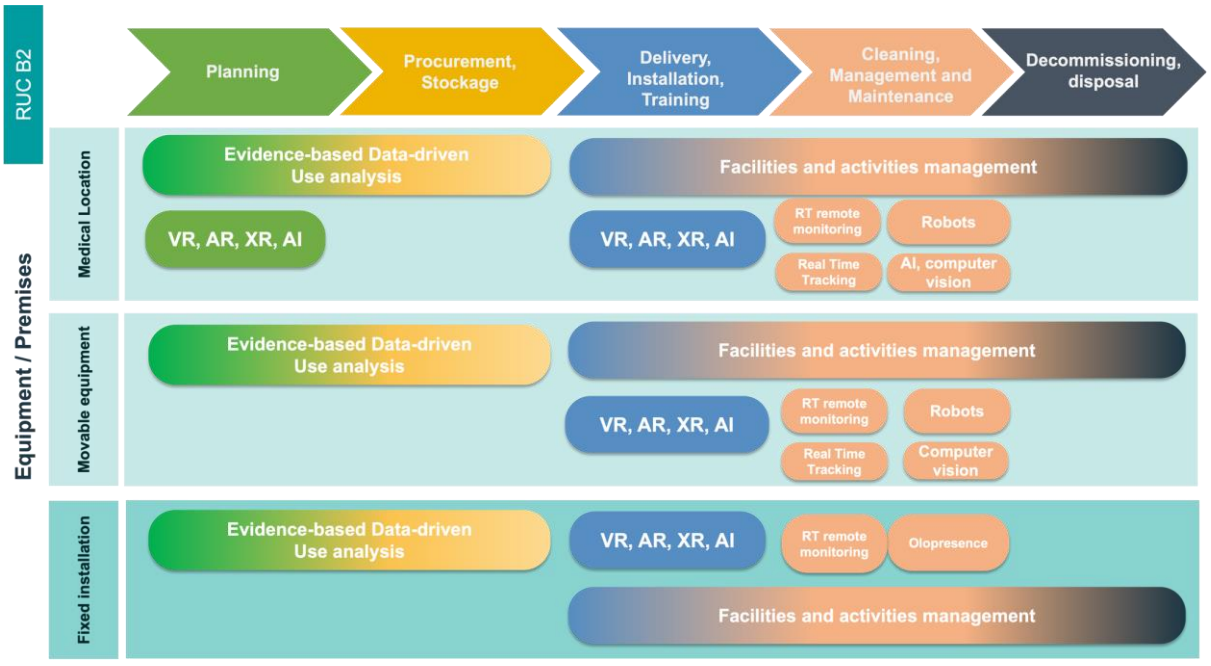

Figure 5 - RUC sub case B2 Navigation Diagram

6.2 RUC B Phases (overall and for each phase)

The first two defined use cases are covered in this RUC, which is relevant to the managerial area (RUC B1 - UC1, RUC B2 - UC2). It focuses on improving the design, programming, and execution of hospital logistics, clinical engineering, and medical device management using ODIN technology.

The first of these, RCU B1 - UC1, has been conceptualised as the entire process of procurement, storage, and distribution of various commodities in the hospital environment, with a focus on operations inside the hospital environment that are considered redundant, as specified by the DoA. (e.g., transport of consumables).

The other is RUC B2 - UC2 "Clinical Engineering, MD locations, real-time management," which focuses on the management of medical devices employing ODIN technology. This is especially essential because one of the main causes of adverse occurrences in the hospital environment is the current absence of real-time information transmission. The proper functioning and modification to this use case will allow for the optimisation of normal tasks as well as disaster preparedness, which will be covered in further depth in RUC C - UC7.

Here below, the phases of the RUC are briefly described.

Planning

Planning the changes to medical locations and to the electromedical equipment fleet to respond to health needs, based on evidence from needs assessment, current usage, analysis of faults and recalls, maintenance and real-world data (RWD)

Procurement, Storage

Defining a rational process for acquiring and stocking electromedical equipment

Delivery, installation, training

Planning delivery and installation steps which minimise the impact on the hospital processes. Performing effective and customised training to technical staff and healthcare staff

Cleaning, management, and maintenance

Managing the cleaning of spaces, their assignment to departments and operational units, plan and manage their maintenance.

Managing the maintenance of electro-medical devices with a data-driven evidence-based approach

Decommissioning, disposal

Managing the closure of medical locations and the transfers of activities and technology.

Managing the decommissioning and disposal of medical equipment

6.3 RUC B Goals (overall and for each phase)

This reference use case aims at maximising data-driven decisions and evidence-based management of processes.

Planning

Optimising the whole clinical engineering and medical locations management process

Procurement, Storage

Reducing time and maximising equipment availability

Delivery, installation, training

Innovating the way equipment is delivered and put in place, and the training to technicians and health personnel

Cleaning, management, and maintenance

Optimising medical locations and equipment management and maintenance

Decommissioning, disposal

Optimising closures and transfers

Optimising equipment decommissioning and disposal, in particular for fixed devices (e.g. MRI, CT, Radiology, etc.)

6.4 RUC B IA KPIs (for each phase)

Here below are reported the IA KPIs for RUC B summarised per each phase

The full experiment descriptions and the related, locally defined, KPIs are reported in the Appendix A.

Table 10 - RUC B KPIs

Phase	KPIs	Measure unit
Planning	Mean time to problem solution (MTPS)	[hours]
	Costs	[€]
	Operating time	[hours]
Procurement, Storage	Procurement time	[days]
	Backup appliances	[%]
	Storage costs	[€]
Delivery, installation, training	N. of non-conformities [#]	[#]
	Timeliness	[days]
	Training time	[hours]
	Training effectiveness	[scores TBD]
Cleaning, management, and maintenance	Cleanings costs	[€]

Phase	KPIs	Measure unit
	Medical location availability	[%]
	Equipment downtime	[%]
	Maintenance costs	[€]
Decommissioning, disposal	Medical locations closure and transfer time	[days]
	Decommissioning time	[days]
	Disposal costs	[€]

6.5 RUC B Sub Cases

6.5.1 RUC B1 UC1: Aided logistic support

This use case covers all the aspects about the hospital logistics, excluding patient experience part of RUC A

6.5.2 RUC B2 UC2: Clinical engineering and medical locations management

This use case covers aspects related to the exploitation of ODIN technologies for improving the clinical engineering, the management of medical locations and medical equipment.

6.6 Pilots implementing RUC B

Having defined, so far, the RUC B and its sub use cases RUC B1 and B2, ODIN pilots described their experiments as a specialisation of these models.

This resulted in the following ODIN RUC B table:

Table 11 - RUC B Pilots implementation

Use Case	Name	Pilot(s)
RUC B1 – UC1	Aided Logistic Support	SERMAS, UCBM
RUC B2 – UC2	Clinical engineering, MD locations, real-time management	SERMAS, MUL

Tables below summarises for each pilot the different implementation of RUC A. Full detailed pilots' experiments, where available, are reported in Appendix A.

6.6.1 SERMAS

Table 12 - RUC B SERMAS

Use Case	Name	Description	RUC B Phase (s)
RUC B1 – UC1	Aided Logistic Support	Monitor the use of consumables and their delivery within the hospital	Planning Procurement, Storage
RUC B2 – UC2	Clinical Engineering, MD Locations, Real-time Management	Consumable delivery automation	Delivery, installation, training Decommissioning, disposal

6.6.2 UCBM

Table 13 - RUC B UCBM

Use Case	Name	Description	RUC B Phase (s)
RUC B1 – UC1	Aided Logistic Support	Logistics of food delivery and environmental monitoring	Preparation, delivery, installation, training Real usage monitoring Management

6.6.3 MUL

Table 14 - RUC B - MUL

Use Case	Name	Description	RUC B Phase (s)
RUC B1 – UC1	Aided Logistic Support	Real time management of blood samples	Preparation, delivery, installation, training

7 Conclusions

This report included redefined version of the IA KPIs from the pilots' perspective to evaluate the impact of the designed experiments. Beside this, as declared in 4.2, we're deploying tools to actively monitor and support the ODIN experiment execution. From the next version we'll include details about the **Operative KPIs** and **Technical KPIs** defined in all the Work Packages 3, 4, 5, and 6; these new sets of KPIs together with the **IA KPIs** will build the full overview of the evolving **ODIN journey.**

This will pave the path to the **ODIN Impact awareness** framework and its foundational elements, introduced in this deliverable.

After defining the experiments with clear timelines and applying for the mandatory ethical approvals, pilots, performing the technology assessment, are in the full deployment phase, dealing with the technology partners and the procurement journey.

For the KPIs, we still referred to the **Impact Assessment KPIs** only and we used two levels of KPIs definitions: a general one, reported in sections 5 and 6, and the customised and locally defined KPIs, fully reported in the **Appendix A ODIN pilots experiments**.

In this appendix pilots also deepened and detailed their experiments design and implementation paths.

Starting from the next issue, we will introduce and describe in detail the adopted tools and indicators to also support and monitor the operational aspects of each pilot. This will give a full picture on how the ODIN experiments are evolving.

Appendix A ODIN pilots experiments

In this appendix there are briefly reported the experiments pilot per pilot, the goals and the IA KPIs so far defined including measurement tools.

Next releases of this report series will include the KPIs from the technical WPs together with the operative KPIs, in order to generate a global overview of the ODIN impact assessment framework.

Here below the experiment description per pilot,

A.1 CUB

A.1.1 Pilot Description

Charité University Hospital has 3,000 beds and 14,000 employees. It is distributed over 4 campuses in the city of Berlin. It is one of the largest hospitals in Europe with a strong focus on excellent patient care and research. The aim is to combine patient care, medical research, education to provide best practice for the future of medical services in Europe.

The sleep medicine centre is part of Charité, linked to the department of pneumology. The sleep medicine centre has 10 beds for patient care and 2 beds for research studies. We have about 3,000 sleep studies in the hospital with polysomnography (sleep recording) per year and about 5,000 home sleep studies (with fewer signals recorded) per year. The staff includes pneumologists, neurologists, ENT physicians, cardiologists, engineers, specialised medical technologists, and nurses.

A.1.2 Pilot Experiments

CUB will deploy the experiments according to the following table and described below

Table 15 – CUB Experiment

Use Case	Name	Description	RUC A Phase (s)
RUC A2 – UC4	Sleep disorders		Admission, Screening, Diagnosis, Monitoring

Sleep disorders are a medical problem with a very high prevalence and can have serious consequences for the health of those affected. As an example, approximately 1 billion people between the age of 30 and 69 years are estimated to have obstructive sleep apnoea (OSA) worldwide. Untreated OSA is associated with significant comorbidities, such as cardiovascular disease, metabolic disorder, stroke, and Alzheimer's disease. Consequences of unhealthy sleep have also a negative impact on the health system and economy due to productivity loss in the working population. Thus, the economic costs of sleep disorders are far-reaching, affecting the individual, family, and society directly and indirectly, in terms of productivity and public safety.

The goal is to identify patients at risk of sleep disorders. The most common groups of sleep disorders are insomnia and sleep-related breathing disorders (e.g., OSA). The third group in terms of prevalence is sleep-related movement disorders. Still, secondary sleep disorders are very common and should be recognised. However, they do not need an extra recording and treatment.

The reason why we want to diagnose these sleep disorders is to allow timely intervention, reduce the impact of proceeding daytime consequences, and to minimise complications if the sleep disorder is due to other medical conditions (e.g., longer duration of hospitalisation, complications during anaesthesia, staff problems, etc.). The goal is to minimise daily impact and make the patient aware of his or her condition and the means to deal with it.

A.1.3 RUC A2 – UC4

A.1.3.1 Description

This use case is based on validating new algorithm-based methods for the automated and remote diagnosing of sleep disorders. Up until now, overnight in-laboratory polysomnography (PSG) is the gold standard in sleep recording. It is a multiparameter diagnostic tool that monitors various body functions, i.e. brain activity, eye movements, muscle activity, and heart rhythm. However, in-laboratory PSG is labour-intensive, time-consuming, and expensive, which leads to long waiting lists for patients and high costs for the public health system. Manual sleep scoring by sleep technicians imposes a further impediment on the supply of staff given the current shortage in the number of sleep technicians, which is expected to worsen. Thus, reducing the level of burden on health personnel and the use of the hospital resources are required.

Wearable sleep monitor devices help to solve these issues. These devices meet the mobility requirements and are simple and lightweight, this allows self-application by the patient at home. Multiple parameters detection provides reliable monitory data and allows for automatic diagnosis which might obviate the need for manual scoring. However, these methods are to be validated and further developed in terms of validity relative to the PSG as the gold standard. While these wearable devices are already freely available, algorithms behind the automated diagnostic are still to be improved.

We are planning on two pilot studies on the validation of different wearable sleep tracking devices (Two wearable monitor devices that are worn on the finger, comparable to a ring):

A.1.3.2 Study 1

Automated analyses are expected to be the future of obstructive sleep apnoea (OSA) diagnosis and are likely to become part of the arsenal of practicing sleep physicians. One such method is based on cardiopulmonary coupling (CPC) analysis, which calculates coupled interactions between heart rate variability (HRV) and respiratory beats (electrocardiogram (ECG)-derived respiration, EDR) to automatically obtain multiple metrics for sleep quality assessment and sleep diagnosis. The latest wearable monitoring device (SleepImage Ring), based on CPC analysis, acquires both plethysmogram (PLETH) and SpO2 signals from a single photoplethysmogram (PPG) sensor. Thus, a software generated apnoea-hypopnea index (AHI) can be calculated by combining CPC output and PPG-derived hypoxic events. Previous research has accurate automated AHI can be derived from CPC and pulse oximetry from polysomnography (PSG). However, there are no studies that directly demonstrate the diagnostic performance of the SleepImage Ring device in adults with OSA.

This study aims to evaluate the diagnostic capabilities of a wearable monitoring device (the SleepImage Ring device) for OSA in adults using PSG as a reference standard.

Hypothesis:

The SleepImage Ring device will provide high sensitivity, specificity, and predictive values compared to PSG to identify OSA in adults at all thresholds of disease severity.

Protocol:

Overnight sleep recording by PSG and the SleepImage Ring device is planned simultaneously for each study participant.

Objective assessment of OSA severity by PSG used for routine sleep medicine diagnosis. In addition, the finger-worn SleepImage Ring provides objective parameters by which sleep quality, OSA severity, and blood oxygen saturation are recorded. Questionnaires are used for subjective surveys.

Questionnaires:

- ESS (Epworth Sleepiness Scale)
- STOP-Bang questionnaire
- Evening and morning questionnaire
-

A.1.3.3 Study 1 - Protocol Phases

Admission & Screening

Ethic application has already submitted and in minor revision by the local ethics committee.

All wearable devices are already acquired.

Patient recruitment starts as soon as final ethic approval is received.

Diagnosis

Embedded in daily hospital routine. When a patient is included in the study according to inclusion criteria, they undergo the overnight recording routine plus self-application of the wearable which is introduced by technical staff.

Monitoring

Following the standard clinical procedure, PSG data is collected and analysed by nurses and technical stuff. Data recorded by portal devices is analysed regarding different parameters and compared to PSG collected data by means of sensitivity and specificity.

A.1.3.4 Study 2

For some years now, apps for smartphones or wearables in the form of watches or rings have also promised to be able to determine a hypnogram. For different apps and the watches, it has been proven that the results vary and that the hypnogram of polysomnography cannot be replaced at present.

Nevertheless, the need is given, because simple and reliable home sleep measurements would significantly expand the diagnosis of sleep disorders and these measurements would then also be good for personal use. They would also have the advantage over polysomnography in that this measurement technique would not interfere.

Some commercial providers, such as the devices from "Oura" and "SleepOn" and "Circul" that we included in the study, offer so-called sleep trackers in ring format or based on an app-based contactless measurement. By measuring oxygen saturation, breathing rate, movement, pulse and activity, these devices evaluate sleep and breathing with proprietary algorithms and create a hypnogram.

Since these applications are very resource-saving and patient-friendly compared to conventional polysomnography, it is of particular interest to verify to what extent the measurements of polysomnography match those of sleep trackers. The quality of the collected parameters and the hypnograms evaluated by the apps of the respective measurement system will be investigated.

Aim of the study:

Primary endpoints:

The collected measurement values of the TST and WASO are to be collected and compared with the commercial sleep trackers and polysomnography.

Secondary endpoints:

The evaluated hypnograms of the commercial sleep-trackers are to be compared with those of the polysomnography

Hypotheses:

The measurements of TST and WASO collected by the commercial sleep-trackers are comparable to those of polysomnography.

The hypnogram produced by sleep trackers is comparable to the hypnogram produced by standard polysomnography.

A.1.3.5 Study 2 - Protocol phases:

Admission & Screening

Patient screening will be done initially in the clinical sleep facilities to assure inclusion criteria. The number of patients included in both studies is calculated by means of power calculation for sample sizes. In both studies, ethic applications will be collected prior to data collection. All patients will provide informed written consent about data collection, data analysis and data transfer between cooperation partners.

Diagnosis

Patients will undergo standardised sleep diagnostic by overnight PSG measurements. Those measurements will be compared to data derived from portable devices.

Monitoring

Following the standard clinical procedure, PSG data is collected and analysed by nurses and technical staff. Data recorded by portal devices is analysed regarding different parameters and compared to PSG collected data by means of sensitivity and specificity.

A.1.3.6 Side Project

Collaboration with Phillips

Furthermore, we are planning a cooperation with Philips with the goal of improving machine learning algorithms for the automatic classification and diagnosis of sleep data. In compliance with our ethics guidelines, we will provide Philipps with recorded PSG data from a European data base.

A.1.3.7 Timeline (overall and for each phase)

Both experiments will start in December 2022 and will stop in December 2023 with the following timeline:

Admission & Screening (Start approx. 1.12.2022)

Patient recruitment starts as soon as final ethic approval is received.

Diagnosis (Start approx. 1.02.2023)

The patient undergoes an overnight recording routine plus self-application of the wearable which is introduced by technical staff.

Monitoring (Start as soon as patient data is available, approx. 01.06.2023)

PSG data is collected and analysed.

Write-up & Dissemination (Approx. 01.07.2023 – 01.12.2023)

Writing up the final report and disseminating to all other partners. This will include tying up all loose ends and finalising all aspects of the project.

A.1.3.8 Technology acquisition

Study 1

The device used in this study is the SleepImage Ring device, we expect that it provides high sensitivity, specificity, and predictive values compared to PSG to identify OSA in adults at all thresholds of disease severity.

Study 2

We are using finger ring devices from the commercial providers: "Oura", "SleepOn", and "Circul". They offer so-called sleep trackers in ring format or based on an app-based contactless measurement. By measuring oxygen saturation, breathing rate, movement, pulse and activity, these devices evaluate sleep and breathing with proprietary algorithms and create a hypnogram.

We expect the following:

1. The measurements of TST and WASO collected by the commercial sleep-trackers are comparable to those of polysomnography.

2. The hypnogram produced by sleep trackers is comparable to the hypnogram produced by standard polysomnography.

A.1.3.9 Goal

Overall goal for both studies:

This use case aims to evaluate the diagnostic capabilities of a wearable monitoring device (the SleepImage Ring device) for OSA in adults. We will use PSG as a standard reference. If the finger ring's diagnostic abilities are similar to the gold standard PSG, it could be a very helpful alternative for diagnosis. Using devices like these could reduce waiting times whilst providing the most appropriate course of treatment to each patient due to results from validated devices.

Each Phase:

Admission & Screening

We aim to gather and screen the patients that fit our inclusion criteria in good time. By doing so will allow us to investigate the presence/absence of a sleep breathing disorder. This way we can determine the appropriate course of treatment.

Diagnosis

We aim to collect data in a standardised manner in order to produce a clean dataset which can be easily analysed.

Monitoring

We aim to analyse the data as soon as possible (once data collection has finished). This will indicate whether OSA is present and whether treatment is needed. Treatment is not part of these studies but will be provided by the physicians at the sleep medicine outpatient department after the study.

A.1.3.10 Impact Assessment KPIs

CUB will monitor the impact of the above described experiments with the following KPIs

Table 16 - CUB IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Admission & Screening	Patients enrolled: questionnaires (ESS, STOP-Bang questionnaire, evening and morning questionnaire) and appointment with nurse	Scores and qualitative report	report from nurses	
Diagnosis & Case Study	Patient's adherence	drop-out rate	report from nurses	
	Personalisation level	scores TBD	report from nurses	
	Data collection from both studies	Sleep recordings and questionnaires	Finger rings, PSG, questionnaires	

Phase	KPIs	Measure unit	Tool	Notes
Monitoring	Adherence to prescribed treatment: correct execution, specific KPIs, number of errors	Qualitative	Report about user experience with wearable device	
	Users' acceptance	Qualitative	Report about user experience with wearable device	
	Analysis and diagnosis of OSA	Quantitative	Report about the presence of OSA and the comparability between finger rings and PSG:	

Admission & Screening:

Questionnaires (ESS, STOP-Bang questionnaire, evening and morning questionnaire) and appointments with nurses

Expected outcome: determines whether a patient is suitable for either experiment

Diagnosis & Case Study:

Patient's adherence - expected outcome: determines how well the patient used the devices/ how often

Personalisation level - expected outcome: explains where each device was used on the body and if it needed to be calibrated in a certain way

Data collection from both studies - expected outcome: we expect a large clean dataset that measures the constructs of interest.

Monitoring

Adherence to prescribed treatment: correct execution, specific KPIs, number of errors - Expected outcome: report about user experience with wearable device

Users' acceptance - expected outcome: report about user experience with wearable device

Analysis and diagnosis of OSA - Expected outcome: Report about the presence of OSA and the comparability between finger rings and PSG.

A.1.3.11 Involved staff (overall and for each phase)

Admission and Screening:

Administrative, Physicians, Nurses

Diagnosis/Case Studies:

Physicians, nurses, scientific staff

Treatment:

Physicians

Monitoring:

Physicians, nurses

Follow up:

Administrative, Physicians, Nurses

A.2 MUL

A.2.1 Pilot Description

Medical University of Lodz (MUL) is a higher state school having over 70 years-long history. With its 5 faculties, 3 teaching hospitals and 80 clinics, 9,500 students, 1,000 foreign students and app. 1,600 academics, Medical University of Lodz belongs to the leading Polish medical universities. The University is strongly committed to scientific research in a number of health-related disciplines as well as national and international scientific cooperation. The University is considered a leader in the number of scientific publications and citations among medical schools in Poland. In 2022, MUL ranked 9th among Polish Universities, according to national 'High Schools Ranking Perspectives'. MUL's scientists conduct extensive basic and translational research. The Medical University of Lodz has reached the leading position in various research areas, and particularly in patient adherence and healthy ageing. In acknowledgment of these achievements, the Medication Adherence Research Centre (MARC) was founded in 2020 in MUL, headed by Prof. Przemyslaw Kardas.

MUL makes a substantial contribution to the development of the health care system by promoting modern standards of prophylaxis and treatment, and by building long-lasting cooperation with institutions realizing objectives of public health at regional, national and international levels. Last but not least, MUL is strongly committed to Silver Economy. Being formally recognised as the EIP on AHA Reference Site, MUL plays the key role in facilitation of collaboration between academia and industry, in order to change the demographic challenge into opportunity. Initiating creation of dedicated businesses cluster, MUL plays a role of pioneer and helps boosting of local economy.

With its own complete ecosystem of healthcare services, covering full range of healthcare system levels, from primary health centres to tertiary teaching hospitals, MUL is perfectly well-placed for the purpose of testing and implementation of novel health technologies. **Serving over 86,000 patients yearly**, MUL is also ono of the major local healthcare providers, active in each and every area of modern medicine. This potential will be of particular use within the framework of ODIN project.

A.2.2 Pilot Experiments

MUL will deploy the experiments according to the following table and described below

Table 17 - MUL Experiments

Use Case	Name	Description	RUC Phase (s)
RUC A2 – UC4	Blood samples transport	Robotic transportation of laboratory specimens from the Emergency Department to the Central Lab	All
RUC B2 – UC2	Clinical Engineering and Medical Locations Management	Support the execution of care and diagnostic procedures with AI-guided location identification	All

A.2.3 RUC A2 - UC4: Clinical Tasks and Patient experience

Intervention envisaged by MUL will adopt a principal objective of helping execution of care and diagnostic procedures with AI-guided robotic transportation employing IoT, using the use case of blood samples and other specimens' transportation from the Emergency Department to the Central Lab.

A.2.3.1 Description (overall and for each phase)

The clinical scenario that corresponds with this objective is the need to help execution of effortful care and diagnostic procedures in selected patients at the teaching hospital Emergency Unit. These procedures belong to the daily tasks of nursing stuff. The clinical basis for this is defined by the specific needs of certain clinical specimens (e.g. blood samples), that cannot be carried to the Central Lab with available pneumatic post due to their fragility toward shocks. With the mobile robotic delivery process, these effortful tasks needing a lot of physical help and staff time will be made easier for nursing staff. Moreover, the use of robotic staff will minimise the need of direct contact between nursing staff and the patient infected with dangerous pathogens, such as e.g., *Clostridium difficile*, or COVID-19. Thus, nurses will be safer, less tired, and could be more attentive and focused on over higher-level patients' needs, such as e.g. need for social interactions and emotional support in the stressful environment of Emergency Room. In consequence, the use of ODIN technology will have in these patients a positive impact on the quality of life of patients. Enabling patients to be tested, and diagnosed faster, the technology will have a positive effect on their overall wellbeing, as well.

Admission and Screening phase:

There is a need for identification of patients with a need for a specific lab test for the *Clostridium difficile* related infection, particularly those which require fast and safe delivery of the specimen to the Central lab. A robotic system available in stand-by mode is already available in point of care, i.e. at the Emergency Department, to be used by clinicians as soon as they assess there is a need for a dedicated test.

Diagnosis:

Healthcare providers, especially nurses are struggling with a lot of tasks in Emergency Department. It takes a lot of time and effort to carry the fragile specimens from this environment to the Central lab. This is of particular importance in the ED where the cases are acute and need fast decision-making and continuous support. Current gaps include lack of hospital staff (particularly nursing staff), and need for assistance in carrying of fragile samples, just to name the most important ones. At the top of this, patients suspected to be infected with *Clostridium difficile* create additional risk to the nursing staff, and need enhanced protective measures, which are both costly and effortful. Therefore, as soon as the patient who is already registered to the hospital system, and the need for lab tests is identified, a robotic system is ready to be employed.

Treatment:

Currently healthcare professionals in hospitals must often use their precious time to carry fragile samples to the Central Lab in person. Any help in this activities will enable healthcare professionals, especially nurses and paramedics, to save their time, and reschedule their valuable time to other duties. Current gaps include acute patients, especially unconscious ones, who need continuous help from healthcare staff at the ED. There is a need for new solutions supporting healthcare professionals in securing fast and reliable testing of these patients against life-threatening infections, such as those caused by *C. difficile*. According to fast and safe delivery of specimens to Central Lab, detailed diagnosis is taken faster, and the correct treatment may be initiated already in the Emergency department.

Monitoring:

Performance of robotic delivery system is monitored in real time, according to IoT. This enables clinicians to be absolutely sure at which stage of execution the process of delivery is at the moment. Data collected will be used retrospectively to fine-tune the algorithm employed, and train the AI system which guides the robot in real-life settings of ED.

At the top of this, a human factor needs to be carefully assessed, as well. Employing robotic solutions is a new idea for Polish hospital staff members. Therefore, there is a need to carefully monitor the performance of this new solution, satisfaction of end-users (nursing staff), safety of the specimens, as well as safety of the other patients in the Emergency Room, in order to secure accumulation of evidence, and future better acceptance of similar robotic solutions.

A.2.3.2 Timeline (overall and for each phase)

The experiment will start in January 2023 and will stop in December 2023 with the following timeline:

Phase 1 (January-June 2023): Feasibility study in the artificial environment: in this phase, the entire system will be tested in a safe laboratory environment, in order to prove correct functioning of its each and every individual part (Phase 1A, January-April 2023) and collaboration of all parts in cohesive system (Phase 1B, May-June 2023). In an iterative way, potential problems will be identified, solutions developed and implemented, and corrections will be made, until the fine-tuned system works smoothly.

Phase 2 (July-September 2023): Feasibility study in real-life environment: Fine-tuned system will be employed in real-life settings of Emergency Department, using a side part of it where the patient access is normally very limited. This will allow to test the system in close-to-normal scenario, and assess its usability under such circumstances, taking special care of staff safety, infectious safety (decontamination process), and the level of assistance the system needs at its current version. Couple rounds of testing will be organised, in various scenarios, to detect potential shortcomings, and iterative process of fine-tuning will be employed.

Phase 3 (October-December 2023): Pilot assessment in real-life environment: matured system will be employed in real-life settings of Emergency Department, with direct contact with patients. This will allow to test the system in the target scenario, and assess its usability under such circumstances, taking special care of both patients and staff safety, infectious safety (decontamination process), and finally, the effectiveness and cost-effectiveness of the system. Three rounds of testing will be organised, in various scenarios, to identify potential problems, and assess the performance of the system against the set of predefined criteria.

A.2.3.3Technology acquisition

The experiment will need the following key technologies to be acquired:

Robotic transportation system

Specialised specimen container.

RFID localisation system

Currently, the first model architecture of the system has been defined, and the target technologies have been provisionally detailed. According to the market search, and careful review of ODIN technology catalogue, the best available technologies have been identified. This process will be continued in order to inform the final decisions regarding system architecture and allow it to address well the need of the Use Case, as well as assure interoperability with the other ODIN Use Cases, and the ODIN platform. The final architecture of the system will be ready by the end of November 2022.

In order to secure compliance with national and internal procedures of MUL, as well as allow for guaranteeing best value for money, the process of acquisition of the technology will be organised according to the procurement process, whenever possible. However, if the final technologies are made available through the ODIN partners, or are unique to the market, a direct buy will be considered as an alternative approach. Finally, certain technologies may be enabled by other ODIN partners at no costs.

Declined into the experiment phases the technology will contribute as follows:

Overall strategy a cohesive system of screening-execution-monitoring will be secured with the use of relevant digital solutions and interlinked hardware/equipment; robotic carrier (e.g., Robotnik solution) equipped with dedicated smart boxes (e.g., SSSA solution)

Admission and Screening phase: initial screening of the need for specific lab test versus provisional diagnosis (employing HL7/FHIR).

Diagnosis & Case Study phase: robotic carrier (e.g., Robotnik solution) equipped with dedicated smart boxes (e.g., SSSA solution); AI component to allow for choosing the best path of specimen delivery in a potentially crowded environment of Emergency Room; RFID to locate the robot in the ED environment.

Treatment phase: same as above

Monitoring phase: same as above; data storage secured with SQL

A.2.3.4 Goal (overall and for each phase)

Overall goal of this Use Case is to help nursing staff in the execution of unsafe and time-consuming physical tasks, at the same time improving patient experience and safety in the environment of Emergency Department.

Admission and Screening phase: early enough identification of the patients with a need for specific lab tests, such as e.g. patients with a risk of *C. difficile* infection, etc.

Diagnosis & Case Study phase: final and sure validation of the advantage of robotic delivery of blood samples to the Central Lab; along with the assessment of time necessary to establish correct preliminary diagnosis in the patient.

Treatment phase: to replace physical work of nursing staff with robotic solutions.

Monitoring phase: assess HTA parameters describing performance of robotic solutions, and staff-reported parameters assessing end-users' satisfaction.

A.2.3.5 Impact Assessment KPIs

MUL will monitor the impact of the above described experiments with the following IA KPIs

Table 18 - MUL RUC A2 IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Admission & Screening	Ratio of patients qualified to robot intervention to patients not qualified	[percentage]	[report from admission/emergency ward]	
	Percentage of patients needing specific lab tests, identified at the admission.	[percentage]	[report from admission/emergency ward]	
Diagnosis & Case Study	Number of staff members trained in the usage of robot	[Number]	[hospital data]	
	Number of correct arrivals from the stopping point to the sampling point	[Number]	[operator's records]	
	Number of robot's interventions	[numbers]	[robot's report]	
	Number of failed deliveries	[percentage]	[robot's report/hospital data]	
Treatment	Number of blood samples delivered to laboratory	[numbers]	[report from emergency ward/robot and report from laboratory]	
	Ratio of samples delivered to laboratory to all collected samples	[%]	[report from emergency ward/robot and report from laboratory]	
Monitoring	Medical staff satisfaction of robot usage	[numbers 1-5]	[5-point Likert scale, online/paper survey]	
	Time spent by HCW in contagious area	[minutes]	[time measurements performed in emergency ward]	

Phase	KPIs	Measure unit	Tool	Notes
	Ratio of time spent by HCW in contagious area after robot deployment to before the robot deployment	[%]	[time measurements performed in emergency ward]	
Follow up	Time of average robot decontamination	[minutes]	[time measurement]	
	E-robots interventions	[number]	[internal robot report]	
	Percentage of safe interventions, without technical/medical interventions	[percentage]	[internal robot report]	
	Uninterrupted interventions in a row	[number]	[internal robot report]	

Overall strategy, a battery of various parameters, will be traced in order to assess solution feasibility, effectiveness and cost-effectiveness.

Admission and Screening phase:

Number of patients enrolled

Percentage of patients needing specific lab tests, identified at admission.

Diagnosis & Case Study phase:

Percentage of patients with lab tests performed correctly using the means of robotic delivery

Average transportation time from ER to Central Lab

Treatment phase:

Proxy for effectiveness – e.g., number of e-robots' interventions, nursing staff satisfaction parameters;

Proxy for safety – percentage of safe interventions, without technical/medical complications;

Unobtrusive performance of robotic delivery in real-world environment of Emergency Room;

Proxy for costs – nursing staff work time parameters.

Monitoring phase: the same as the ones employed in treatment phase, plus parameters assessing effectiveness of solution functioning in stand-by/active mode.

A.2.3.6Involved staff (overall and for each phase)

Involved staff will include target end-users – i.e. mostly nursing staff; as well as researchers involved in designing and executing the tasks (health scientists, IT specialists, etc.)

Admission and Screening phase: Emergency unit staff - mostly nurses, partly – medical doctors.

Diagnosis & Case Study phase: Emergency unit staff - mostly nurses, partly – medical doctors; IT specialists to monitor the work of the system

Treatment phase: Emergency unit staff - mostly nurses, partly – medical doctors.

Monitoring phase: Researchers – for monitoring.

A.2.4 RUC B2 - UC2 Clinical engineering

Intervention envisaged by MUL will adopt a principal objective of helping execution of care and diagnostic procedures with AI-guided location identification system employing IoT, using the use case of identification of the location of particular pieces of mobile equipment in the Emergency Department.

A.2.4.1 Description (overall and for each phase)

This MUL reference use case covers aspects related to the exploitation of ODIN technologies for improving the management of medical locations of medical equipment in the busy environment of the Emergency department of tertiary teaching hospital.

Planning:

This involves identification of core components of medical equipment which are subject to changing location (e.g. ECHO scanner) and are of potential need of emergency use depending on the conditions and provisional diagnosis established in a patient admitted to the Emergency Department. This process will be based on evidence from the assessment of the needs of both staff members and the patients, current usage patterns, analysis of faults and recalls, maintenance and real-world data (RWD).

Delivery, installation, training:

Currently, the items of medical equipment being used within the Emergency Department are taken to the room where they will be used by the staff members from their current location. Due to the various needs of individual patients, this location is changing asa consequence. Neither their current location, nor the information on the time of their use is currently traced and recorded in the hospital systems.

In order to change this, previously identified core components of medical equipment will be marked with unique digital identifiers, using RFID technology, allowing for their tracing. The technology used for this will secure their safe, resistant and unique identification without any negative consequences for their principal role (e.g., caused by electromagnetic fields

interferences, etc.). Existing infrastructure allowing for in-hospital localisation and navigation will minimise the negative impact of system installation over the performance of the staff in the real-world conditions. Minimal level of technical and healthcare staff training on the system use will be necessary to implement the system.

Cleaning, management, and maintenance:

Tagging RFID system applied in order to identify equipment location conforms with relevant cleaning techniques and standards. The use of a digitally-enhanced location system will help better adherence to the relevant cleaning procedures (e.g., UV irradiation).

Decommissioning, disposal:

Not applicable to MUL RUC B – relevant medical equipment items are in the continuous use in the Emergency Department.

A.2.4.2 Timeline (overall and for each phase)

The experiment will start in November 2022 and will stop in September 2023 with the following timeline:

Phase 1 (November 2022-February 2023): Feasibility study in artificial environment: in this phase, the entire system will be tested in a safe laboratory environment, in order to prove correct functioning of its each and every individual part and collaboration of all parts in cohesive system. In an iterative way, potential problems will be identified, solutions developed and implemented, and corrections will be made, until the fine-tuned system works smoothly.

Phase 2 (March-June 2023): Feasibility study in real-life environment: Fine-tuned system will be employed in real-life settings of Emergency Department, using a side part of it where the patient access is normally very limited. This will allow to test the system in close-to-normal scenario, and assess its usability under such circumstances, taking special care of staff safety, infectious safety (decontamination process), and the level of assistance the system needs at its current version. Couple rounds of testing will be organised, in various scenarios, to detect potential shortcomings, and iterative process of fine-tuning will be employed.

Phase 3 (July-September 2023): Pilot assessment in real-life environment: Matured system will be employed in real-life settings of Emergency Department, with direct contact with patients. This will allow to test the system in target scenario, and assess its usability under such circumstances, taking special care of both patients and staff safety, infectious safety (decontamination process), and finally, the effectiveness and cost-effectiveness of the system. Up to 4 rounds of testing will be organised, in various scenarios, to identify potential problems, and assess the performance of the system against the set of predefined criteria.

A.2.4.3 Technology acquisition

The experiment will need the following key technologies to be acquired:

RFID localisation system

Healthcare staff interface

Currently, the first model architecture of the system has been defined, and the target technologies have been provisionally detailed. According to the market search, and careful review of ODIN technology catalogue, the best available technologies have been identified. This process will be

continued in order to inform the final decisions regarding system architecture and allow it to address well the need of the Use Case, as well as assure interoperability with the other ODIN Use Cases, and ODIN platform. The final architecture of the system will be ready by the end of September 2022.

In order to secure compliance with national and internal procedures of MUL, as well as allow for guaranteeing best value for money, the process of acquisition of the technology will be organised according to the procurement process, whenever possible. However, if the final technologies are available through the ODIN partners, or are unique to the market, a direct buy will be considered as an alternative approach. Finally, certain technologies may be enabled by other ODIN partners at no costs.

Declined into the experiment phases the technology will contribute as follows:

Planning

Big Data analysis, AI

CAFM (Computer Aided Facilities Management)

Semantic ontology

Delivery, installation, training

Big Data analysis, AI

CAFM (Computer Aided Facilities Management)

RFID tagging system

Cleaning, management, and maintenance

CAFM

Semantic ontology

Artificial Intelligence

A.2.4.4 Goal (overall and for each phase)

This reference use case aims at maximising data-driven decisions and management of diagnostic and treatment processes in Emergency Department.

Planning:

Optimising the whole clinical medical locations management process with the use of need-to-solution flow paradigm, starting with the identification of items needing support in their localisation management, through providing operational solution, up to extensive testing and evaluation

Procurement, Storage:

Reducing staff work time, maximising equipment availability and patient safety.

Delivery, installation, training:

Innovating the way the medical equipment is delivered and reused, and the training to technicians and health personnel on the use of the novel system.

Cleaning, management, and maintenance:

Optimising equipment cleaning due to shorter time use for location and transportation, and hence, longer time left to e.g., UV irradiation.

A.2.4.5 Impact Assessment KPIs

MUL will monitor the impact of the above described experiments with the following IA KPIs

Table 19 - MUL RUC B2 IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Admission & Screening	Patients qualified for use of located equipment	[numbers]	[report from platform]	
	Number of staff members trained in the location system use	[number]	[hospital data]	
	Ratio of episodes of equipment use with and without the use of digitally-enhanced location	[percentage]	[hospital data]	
Diagnosis & Case Study	Number of effective uses of located equipment	[number]	[hospital data]	
	Time to locate the equipment	[minutes]	[hospital data/ RFID data]	
	Equipment delivery time	[minutes]	[hospital data]	
Treatment	Time from localisation of equipment to its effective usage by clinical staff	[minutes]	[hospital data]	
Monitoring				
	Users' acceptance of localisation system	[points 1-5]	[5-point Likert scale]	
	Time saved on looking for equipment	[%]	[RFID data/clinical data]	
	Improvement of time-at-bed spend by	[%]	[hospital data]	

Phase	KPIs	Measure unit	Tool	Notes
	clinical staff with patients			
Follow up	Staff satisfaction	[points 1-5]	[5-point Likert scale]	
	Length of stay in hospital	[days]	[hospital data]	
	Hospitals readmissions	[%]	[hospital data]	
	Number of patients treated with localised equipment	[number]	[hospital records]	

A.2.4.6 Involved staff (overall and for each phase)

The involved staff for this reference use case spans from technical staff to healthcare personnel, clinical engineers, and manufacturers.

Planning

Technical managers

Health managers

Hospital epidemiology managers

Delivery, installation, training

Clinical engineers

Manufacturers

Emergency department megamenu

Healthcare staff (nurses, physicians)

Cleaning, management, and maintenance

Technical managers

Clinical engineers

Hospital epidemiology unit staff

A.3 SERMAS

A.3.1 Pilot Description

This pilot is going to take place in Hospital Clínico San Carlos. Three main departments are going to be involved: the Procurement Department, the Cardiovascular Institute and the Innovation Unit.

The Procurement Department is in charge of the supply and logistics distribution of the medical equipment and consumable materials inside the hospital, being a key player in the smooth development of all clinical processes and procedures. This department has transversal action, so the problems we want to tackle affect the performance of the entire hospital.

The Cardiovascular Institute (ICV) represents around 48% of the total hospital's expenditure in medical equipment and consumables. Inside the ICV, the therapeutic areas dedicated to Hemodynamic and Electrophysiology have high impact equipment and some of the best-described pathways for consumables provision.

Finally, the Innovation Unit is the hospital team that is part of the ODIN Consortium. It will act as a bridge between the ODIN partners and the hospital staff.

A.3.2 Pilot Experiments

This pilot will deploy the experimentations within the RUC B as the detailed in the table below:

Table 20 - SERMAS Experiments

Use Case	Name	Description	RUC X Phase (s)
RUC B1 – UC1	Aided logistic support	Monitor the use of consumables	Planning, procurement, storage
RUC B2 – UC2	Clinical engineering, MD locations, real-time management	Consumable delivery automation	Delivery, installation, training, decommissioning, disposal

A.3.3 RUC B1 UC 1

A.3.3.1 Description (overall and for each phase)

This use case has as its objective the development of a dashboard to monitor the use of consumables in the hospital and their future procurement. For this use case, we are going to focus on a single consumable related to the Cardiology service: stents.

Planning

The consumable acquisition of the different hospital services needs to be planned in advance. The hospital has no stock management system implemented right now. The prediction of the needed consumables is done based on historic data, but also on the particular demands of each service based on the procedures scheduled for the near future. The historic data concerning consumptions and purchases is obtained by the Procurement Department on a monthly basis, in the form of excel/txt files.

Procurement, Storage

The same stent can be purchased from several different vendors. There is the possibility that a vendor is chosen based solely on the preference of individual clinicians. There is currently no objective metric with which to compare the different vendors. For example, the time that elapses between making and order and the product arriving to the hospital is not recorded. In fact, the entire delivery process is transparent to us.

Right now, there is little control over the inventory. The number of units left of each consumable is obtained periodically by counting them by hand. Several persons go through the different storage rooms and count by hand the number of items that are stored. Purchase orders are then made in accordance with this counting.

A.3.3.2 Timeline (overall and for each phase)

The implementation of UC1 will start in June 2022 and will stop in August 2024, with the end of the ODIN project. UC1 will have the following timeline:

Data set batch 1 preparation (June 2022 – July 2022)

SERMAS team will gather the data from the different hospital sources and will assemble the data sets needed to develop the UC1 algorithm. The data gathered for these data sets will comprise the year 2021. SERMAS team will also anonymize these data sets and write a report describing the process, which will be forwarded to the ODIN Consortium. The data sets will be delivered to FORTH for the development of the algorithm.

Algorithm development (July 2022 – January 2023)

FORTH team will develop the AI algorithm to predict the use of consumables. An analysis of the vendors will also take place, with the objective of finding out if the high number of vendors is necessary or it can be narrowed down.

Data set batch 2 preparation (January 2023 – February 2023)

The process carried out for the first batch of data sets will be repeated with the data of the year 2022.

Algorithm tuning (March 2023 – June 2023)

FORTH team will adjust the developed algorithm with the new information of 2022.

Hospital implementation (June 2023 – August 2024)

The last phase is the implementation of the algorithm in the daily activity of the Procurement Department. The Innovation team will guide the Procurement Department in the use of the dashboard and will help to determine if the predictions made by the algorithm are accurate and if the vendor list can be reduced.

A.3.3.3 Technology acquisition

For the development of this use case, it is not necessary to acquire any technology since the ODIN platform will be used with a module ad hoc developed by the technological partners of the consortium.

A.3.3.4 Goal (overall and for each phase)

UC1 aims at maximising data-driven decisions and evidence-based management of processes.

Planning

The goals would be to improve stock management (number of units, time, costs) and being able to predict accurately the number of units needed for each consumable. It would also be interesting to know, when considering buying a new consumable, if there is already one with the same specifications, despite of being from a different brand, already in the catalogue, to make the purchase process more efficient.

Procurement, Storage

In terms of procurement, the objective would be to be able to select vendors based on objective metrics: clinical outcomes associated to a certain consumable, number of delays, number of errors, delivery time, cost, etc. It would also be interesting to optimise and homogenize the catalogue of consumables. Having the same item from different brands is not necessary nor efficient.

Concerning storage, the goal would be to have registered how many units are left of each item automatically. That is, to know in real time when new units of a certain consumable are stored in the storage room and when are they retrieved.

A.3.3.5 Impact Assessment KPIs

SERMAS is going to measure the impact of the above described experiments with the following IA KPIs

Table 21 - SERMAS RUC B1 - IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Planning	Difference between the number of consumable units predicted as needed and the real needs	[%]	AI-empowered interactive dashboard	
Procurement, Storage	Objective metrics to evaluate the different vendors: Difference in clinical outcomes	[Readmission %]	AI-empowered interactive dashboard	
	Delivery time, delays, errors	[hours/days required for delivery] [Delivery delays/errors %]		
	Costs	[€]		
	Number of consumable units stored in the storage room	[# units]	AI-empowered interactive dashboard	

Planning

Difference between the number of consumable units predicted as needed and the real needs: This KPI will measure how accurate the algorithm is when predicting the future needs of the Procurement Department concerning stents. Being able to measure it is fundamental to evaluate the performance of the algorithm and the positive impact it can have on the efficiency of the Department. It should be able to anticipate the need for stents and not run out of them nor hoard more than necessary.

Procurement, Storage

Difference in clinical outcomes. This KPI will measure the impact each stent model has in the patient prognosis. If the same stent model is available from different vendors, then the model associated with better clinical outcomes should be kept and the rest, discarded. This should be done to both improve the patient care and simplify the stent catalogue.

Delivery time, delays, errors. Measuring these metrics will allow evaluating the different vendors and selecting the ones who perform the best, resulting in a more efficient procurement process.

Costs. Measuring the costs is a key element in deciding which stent models should be prioritised, as the Cardiovascular Institute represents around 48% of the total hospital's expenditure in medical equipment and consumables.

Number of consumable units stored in each storage room. Knowing where the different units are stored will allow to see if there is a correct relationship between the stents that are being marked as consumed and the number of units that are really being consumed. It will also help to distribute the stents in a more efficient way.

A.3.3.6 Involved staff (overall and for each phase)

The involved staff for this reference use case spans from technical staff to healthcare personnel and clinical engineers.

Planning

Procurement Department: They provide part of the data necessary to develop the algorithm and contribute with their knowledge to the design of the dashboard. They also are responsible for using the dashboard during its implementation.

Innovation Unit staff: They gather and anonymize the data from the Procurement Department and the rest of the hospital sources. They process the data and send it to the ODIN Consortium. They act as an intermediary between the Procurement Department and the ODIN Consortium. They will guide the Procurement Department in the use of the dashboard.

Wardens: They check that the number of units available according to the dashboard correspond with the units stored in each storage room.

Procurement, Storage

Procurement Department: They are responsible for using the dashboard during its implementation. They will determine if the predictions made by the algorithm are accurate and if the vendor list can be reduced

Innovation Unit staff: They will act as intermediaries between the ODIN Consortium and the Procurement Department. They will guide the Procurement Department in the use of the dashboard.

Wardens: They check that the number of units available according to the dashboard correspond with the units stored in each storage room.

A.3.4 RUC B2 UC 2

A.3.4.1 Description (overall and for each phase)

This use case has as objective the use of a robot to automatically transport consumables from the storage room to certain destination. This use case will be focused on the same consumable as UC1, stents, and will take place in the Haemodynamic Room area.

Delivery, installation, training

At the present moment, consumables are both manually retrieved and taken to the room where they will be used. Consumables are withdrawn from the storage rooms without this action being registered. There is no information about the moment a consumable leaves the storage room or when it arrives to its destination. There is no control over the stent journey inside the hospital.

Although the action of withdrawing consumables from the storage room is not recorded, information about which items have been used is however registered. That is, if an item is withdrawn from its shelf and not used, it could be placed back in that shelf or simply kept in the destination room for later use. However, if the item has been used, this action is registered in a database as this information is used to justify costs and plan procurement.

Decommissioning, disposal

The packaging of the consumables that have been used is returned to the storage room, where one person has to manually enter the stent code in a database. This action registers the item as used. Afterwards, the packaging is thrown away.

A.3.4.2 Timeline (overall and for each phase)

The implementation of UC2 started in June 2022 and will stop in August 2024, with the end of the ODIN project. UC2 will have with the following timeline:

Trajectory definition (November 2021 – December 2021)

SERMAS team received the visit of a member of SSSA (26/11/2021), who studied the Hemodynamic Room area and the possible trajectories that could be followed by the robot and their constraints. SSSA also inspected the storage room and the candidate consumables. This helped SSSA team to define the characteristics of the robot.

Robot development (January 2022 – September 2022)

SSSA will work in the development of the robot and it will be tested in simulated environments. Meetings will be held between SSSA and SERMAS to discuss technical details. SERMAS will send the plans of the hospital area where the robot will be deployed.

Robot installation and testing (September 2022 – December 2022)

The robot is expected to arrive to the hospital in September 2022. It will then be deployed in the Haemodynamic area and its behaviour will be tested. SSSA will teach SERMAS team how to operate the robot and, if needed, adjustments will be made on the hardware and software.

Staff training (January 2023 – March 2023)

SERMAS team will train the wardens and nurses in the use of the robot.

Hospital implementation (April 2023 – August 2024)

Finally, the robot will be tested in a real environment. Feedback will be periodically gathered from the users.

A.3.4.3 Technology acquisition

The deployment of internet antennas and switches will be acquired through a public tender. The robot will be supplied by SSSA.

A.3.4.4 Goal (overall and for each phase)

RUC B2 UC2 aims at maximising data-driven decisions and evidence-based management of processes.

Delivery, installation, training

The goal would be to measure when an item leaves the storage room and when it reaches its destination point. If the item has not been used, it should be known when it is returned to the storage room. This is key to being able to have control over the inventory.

Decommissioning, disposal

The main goal would be to automatise the process of registering used goods. If possible, avoiding taking their packaging back to the storage room.

A.3.4.5 Impact Assessment KPIs

SERMAS is going to measure the impact of the above described experiments with the following IA KPIs

Table 22 - SERMAS RUC B1 - IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Delivery, Installation, Training	Stents 1) withdrawn from the storage room, 2) correctly delivered to the target destination, 3) stents not used and returned to the storage room,	[%]	Robot	

Phase	KPIs	Measure unit	Tool	Notes
	4) stents not used and not returned			
	Consumable delivery time	[seconds]	Robot	
	Feedback from the clinical staff	[score]	TAM, SUS	
Decommission, Disposal	Monthly time saved by automatising the disposal process	[hours]	Manually	

Delivery, Installation, Training

Stents 1) withdrawn from the storage room, 2) correctly delivered to the target destination, 3) stents not used and returned to the storage room, 4) stents not used and not returned:

Recording the result of each stent journey provides information about the performance of the robot but also about how the medical staff use the stents.

Consumable delivery time: The time required by the robot to deliver the stent is an indicator of its performance. Ideally, the shortest, the better. However, constraints must be taken into account (robot stability, medical staff safety, etc.).

Feedback from the clinical staff: Feedback from the medical staff interacting with the robot will be gathered periodically. At the end of the day, the robot needs to be a tool accepted by the clinicians and easy to use. Questionnaires will be employed to obtain this information.

Decommission, Disposal

Monthly time saved by automatising the disposal process: The robot will register the used stents and will remove the need of bringing its packaging back to the storage room for someone to register it manually. Being able to measure the time saved in this process can provide another reason to support the adoption of this technology in the hospital.

A.3.4.6 Involved staff (overall and for each phase)

As in UC1, the involved staff for UC2 spans from technical staff to healthcare personnel and clinical engineers.

Delivery, Installation, Training

Procurement Department: They will oversee the installation process.

Innovation Unit staff: They will oversee the installation process and test the robot. They will be in charge of placing the RFID tags on the stents or registering the bar codes. They will train the hospital staff in its use.

Nurses and wardens: They will be trained in the use of the robot. Feedback will be periodically collected from them to assess their acceptance of the new technology and see if adjustments should be made.

Decommission, Disposal

Procurement Department: They will receive the data about stent consumption from the robot. They will review this information and check that it corresponds with the real use of stents.

Innovation Unit staff: They will run tests to check that the robot is performing the decommission phase correctly.

Nurses: They are responsible for loading the used stents or their packaging inside the robot to initiate the decommission phase. They will be trained on how to do so.

A.4 UCBM

A.4.1 Pilot Description

Università Campus Bio-Medico di Roma (UCBM) is a young, yet rapidly developing, private academic institution, devoted to undergraduate and postgraduate education, advanced research, and third mission. Established in 1992, today the University runs the School of Medicine and Surgery, the School of Engineering, the School of Science and Technology for Humans and the Environment and PhD in "Integrated Biomedical Sciences and Bioethics", "Science and Engineering for Humans and the Environment" and the National PhD in Artificial Intelligence – area: Health and Life Sciences". The University hosts 51 multidisciplinary Research Units. In Italy, UCBM has been systematically top-ranked for the quality of the education provided to a selected group of students. The institution has increasing:

i) scientific production per year (more than 900 papers, 4500+ ISI cumulative impact factor in 2021);

ii) funding raised from competitive sources in Italy, Europe and worldwide (70+ research projects ongoing in collaboration with large companies and SMEs);

iii) technology transfer activities (18 patents families owned/co-owned and 8 spin-off companies from 2015).

An outstanding network of national and international key scientific and educational partners, including 200+ national and international partner, has been continuously developed and consolidated with specific collaboration agreements over the years.

UCBM has devolved at the end of 2021 the Policlinico Universitario Campus Bio-Medico business unit to the Fondazione Policlinico Universitario Campus Bio-Medico (FPUCBM). FPUCBM is a not-for-profit institution pursing the aim of protecting and promoting the human person in the field of healthcare, training, scientific research and innovation in the biomedical and health fields, both clinical and translational. From January 1st 2022, all clinical activities as well as clinical and

translational research are carried out by FPUCBM. It is hosting 60 Research Operative Units and 10+ laboratories. Scientific production of the researchers of FPUCBM includes 700 papers in indexed journals with 3000+ normalized cumulative impact factor. At the present FPUCBM has more than 15 research active projects (40% as coordinator) funded under competitive calls and commissioned research contracts and more than 100 active clinical trials (profit). From January 2022, more than 45 projects under competitive calls have been submitted and are currently under evaluation.

Within FPUCBM, the Geriatrics Unit conducts research activities in the following areas:

i) evaluation of the elderly patient health condition, with particular focus on multidimensional evaluation techniques in various disorders or multimorbidity pattern;

ii) evaluation of respiratory functions, with particular focus on the interpretation of spirometry results in elderly patients; study of diagnosis/prognosis properties of breath volatile organic compounds in the following disorders: heart failure, chronic obstructive bronchitis, obstructive sleep apnoea syndrome, diabetes mellitus, liver diseases;

iii) development and application of remote telemonitoring systems for patients with chronic diseases;

iv) pharmacoepidemiologic and epidemiologic geriatric research.

The Unit research activity can make use of a wide range of equipment for functional evaluations. It also has epidemiologic and statistical competences for the designing, planning, execution and analysis of interventional and observational epidemiological studies.

A.4.2 Pilot Experiments

With reference to the selected RUCs, the planned experiments at UCBM are overviewed in the following table and described below.

Table 23 - UCBM – Experiments.

Use Case	Name	Description	RUC A Phase (s)
RUC A2.1 – UC4	Clinical Tasks and Patient Experience	Monitoring of food assumption to prevent malnutrition	Treatment, Monitoring
RUC A2.2 – UC4	Clinical Tasks and Patient Experience	Rehabilitation to prevent loss of mobility	Treatment, Monitoring
RUC A3 – UC5	Automation of Clinical Workflows	Monitoring of oxygen therapy to prevent hypoxia complications	Monitoring
RUC B1 – UC1	Aided Logistic Support	Logistics of food delivery	Preparation, delivery, installation, training Real usage monitoring Management

A.4.3 RUC A2.1 UC 4: Clinical Tasks and Patient experience – Monitoring of food assumption to prevent undernutrition

A.4.3.1 Description (overall and for each phase)

Malnutrition is a highly prevalent condition in older hospitalised patients and associates with an increased risk of prolonged hospitalisation and mortality. Inpatients usually present undernutrition, which is promoted by an energy expenditure exceeding energy intake, and/or micronutrient-related malnutrition (i.e. lack of important vitamins and minerals). Nutritional support is effective in improving body weight, fat and fat-free mass, hence a timely recognition of an unbalance between energy expenditure and intake is pivotal to minimise the risks of adverse outcomes. Although there exist formulas to easily predict the energy expenditure of hospitalised patients, the estimation of energy intake requires to quantify food assumption, a burdensome activity for nurses, that is performed only in a selected population, leading to an underestimation of patients at risk for undernutrition.
Furthermore, malnutrition recognises several causes but one of the most common is dysphagia, a condition that increases the risk of pulmonary aspiration and aspiration pneumonia. Screening is therefore crucial at hospital admission, particularly in older patients.

Admission and Screening (screening of patients at risk of undernutrition and dysphagia): Acute diseases requiring hospitalisation increase the risk of undernutrition, an independent risk factor for morbidity and mortality, particularly in the older and more frail adults. Indeed, these individuals, aside a higher energy expenditure due to the multimorbidity, experience a lower energy intake due to the loss of appetite, dental disorders and cognitive impairment that affect their ability to feed autonomously. One of the most common causes of undernutrition is dysphagia, a difficult swallowing increasing the risk of pulmonary severe complications. Screening of dysphagia and undernutrition is therefore mandatory in all patients at admission and is usually performed by nurses and doctors. Several questionnaires and tests are available in the literature, among which it is worth to cite the 3-oz water swallow test for dysphagia and the Mini Nutritional Assessment for malnutrition. Patients that are considered at risk are then addressed to a specialised evaluation to confirm the diagnosis.

Diagnosis/Case Studies (diagnosis of undernutrition and dysphagia and diet prescription): Once patients have performed screening tests and result at risk of dysphagia and malnutrition, they undergo a specialised assessment which is performed by the nutritionist and speech therapist (or otorhinolaryngologist), respectively. Nutritionists evaluate patient weight and body composition (e.g. bioimpedance analysis or DeXa scan), estimate energy expenditure using predicting formulas (e.g. Harris-Benedict, Angelillo-Moore, etc.) and calculate food intake using food intake diaries. Speech therapists evaluate vocal cords using and endoscope and quantify the risk of aspiration using coloured boli. Once the diagnosis has been confirmed, specialists prescribe the treatment, which mainly consists of speech exercises and detailed diet (i.e. calories, consistency, etc.).
Treatment (meal assumption): Meal is delivered by nurses and healthcare providers and respects the nutritionist and speech therapist indications in terms of consistency and calories. This helps to get the required energy intake and to minimise the risk of pulmonary aspiration.

Monitoring (compliance with clinical prescription): Nurses and doctors daily overview whether and to which extent patients are feeding, quantifying the food assumption. Errors, as well as no willingness to accomplish the prescription are detailed and reported to the specialist. Patients are motivated to follow their prescription.

Follow-up (check for improvements in reducing undernutrition): Specialists reassess patients during hospitalisation in order to evaluate the goodness of fit to their prescription and patient short-term improvements, if any. This allow to stop the treatment in case the problem is solved or to modify the schedule of exercises or diet to reach the goal.

A.4.3.2Timeline (overall and for each phase)

The experiment will start in March 2023 and will stop in July 2023 with the timeline reported in the following table:

Table 24 UCBM RUC A2.1 UC4 - Timeline.

Task	M25	M26	M27	M28	M29
Preliminary functionality tests in UCBM laboratory					
Tests on healthy subjects at UCBM					
Tests on selected geriatric patients at FPUCBM for preliminary validation					
Full experiments on geriatric patients at FPUCBM					

A.4.3.3 Technology acquisition

It is not necessary to acquire any additional technologies except for oximeters able to exchange data with TIAGo robot.
The technologies for this UC include:

TiAGo robot: already available at UCBM

Wearable sensors (RGB-D camera, Heart Rate and Respiration Rate sensors): already available at UCBM

Oximeter: to be acquired

AI software modules: to be developed in the ODIN consortium

Barcode/Tag module for patient/meal matching: to be developed within the ODIN consortium

A.4.3.4 Goal (overall and for each phase)

Admission and Screening (screening of patients at risk of undernutrition and dysphagia): The goal is to identify patients at risk of dysphagia and undernutrition to refer to a further specialised assessment.
Diagnosis/Case Studies (diagnosis of undernutrition and dysphagia and diet prescription): The goal is to diagnose dysphagia and undernutrition to allow a timely intervention to minimise complications (e.g. aspiration pneumonia, low of muscle mass, low of exercise capacity, etc.).

Treatment (meal assumption): The goal is to reach the required energy intake to avoid weight and muscle mass loss, to minimise the risk of aspiration and treat dysphagia. The use of the TIAGo robot is expected to identify problems of undernutrition and avoid complications.

Monitoring (compliance with clinical prescription): The goal is to verify that patient is following correctly the diet prescribed in order to timely modify the intervention. We aim at monitoring meal assumption that normally is not performed in the normal clinical routine. An accurate monitoring can provide the patient with several benefits and robotic intervention can reduce the time spent by healthcare operators in monitoring patients.

Follow up (check for improvements in reducing undernutrition): The goal is to verify the overall efficacy of the treatment for nutrition improvement and swallowing and stop it in case of solution or to redefine the prescription to improve its effectiveness.

A.4.3.5 Impact Assessment KPIs

UCBM is going to measure the impact of the above described experiments with the following IA KPIs

Only **treatment** and **monitoring** phases will be interested by the use of ODIN technologies.

Table 25 - UCBM RUC A2.1 - IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Treatment	Energy intake	[kcal]	TIAGo camera with AI algorithm	
	Percentage of macronutrients	[%]		
Monitoring	Correct head position while eating	[rad]	Kinect camera with algorithm for skeleton reconstruction	
	Meal intake time	[min]	TIAGo text-to-speech module	The patients interact verbally with TIAGo
	Number of oxygen desaturation events	[#]	Oximeter connected with TIAGo	Indicator of severe aspiration

A.4.3.6 Involved staff (overall and for each phase)

Admission and Screening (screening of patients at risk of undernutrition and dysphagia):
Doctors and nurses.

Diagnosis/Case Studies (diagnosis of malnutrition and dysphagia and diet prescription):
Nutritionists and speech therapists (or otorhinolaryngologists).

Treatment (meal assumption and speech exercises):
Doctors and nurses.

Monitoring (compliance with clinical prescription):
Doctors and nurses.

Follow up (check for improvements in reducing malnutrition):
Doctors and nurses.

A.4.4 RUC A2.2 - UC4: Clinical Tasks and Patient experience – Rehabilitation to prevent loss of mobility

A.4.4.1 Description (overall and for each phase)

World Health Organisation defines rehabilitation as “a set of interventions designed to optimise functioning and reduce disability in individuals with health conditions in interaction with the environment” . From a general point of view, motor rehabilitation aims at recovering patient motor skills following an injury, trauma and/or pathology and can involve both upper and lower limbs. In case of elderly, rehabilitation aims recovering the highest possible level of self-sufficiency (especially to carry out activities such as eating, dressing, washing, moving from bed to chair, going to the bathroom, checking the function of the bladder and intestine) and avoid loss of mobility.
Moreover, the importance of movement in elderly patients, while not being among the priorities in the acute phase of any disease, should not be underestimated because the restoration of motor functions becomes problematic, complex and sometimes completely impossible. Hospitalised patients may have reduced mobility and potential consequent risks and can strongly benefit from rehabilitation in terms of active mobilisation and motor recovery.

Admission and Screening (screening based on the risk of reduced mobility):

The admission phase is focused on the screening of hospitalised patients with possible long time of reduced mobility and potential consequent risks with the final aim to avoid prolonged bed rest syndromes.

Diagnosis/Case Studies (motor assessment and rehabilitation prescription):

The rehabilitation treatment is preceded by an evaluation phase of the patient, which is fundamental for both the therapist/nurse and the patient, as it allows the identification of the treatment to be performed and, at the same time, validated clinical scales are generally administered, in order to assess the state of the patient at the beginning and at the end of the rehabilitation treatment, in order to guarantee a targeted treatment outcome.

This phase ends with identification of rehabilitation exercises (bed mobilisation, sit-to-stand exercises, bed positioning and repositioning, stand, short walk, ADLs, etc.) and the prescription

of the exercises to be performed with passive and/or active mobilisation, potentially in an autonomous way.

Treatment (in-hospital rehabilitation):

During the rehabilitation treatment, the patient is asked to perform exercises aimed at improving mobility. The recovery of the muscular characteristics from the structural and functional point of view is a long and difficult process, which can last even a few months.

For collaborative patients, the treatment is active and the patient is able to (at least partially) autonomously move or support himself/herself, with or without the assistance of a physiotherapist. For uncollaborative patients, the treatment is passive and the presence of the physiotherapist, who guides the execution of the task, is strictly necessary.

Monitoring (monitoring of compliance prescription, correctness, and risks):

The aim of this phase is to monitor the patient in performing physical exercises and verify their correctness, compliance with prescription and risks of injuries.

During the rehabilitation treatment it is necessary to optimise the involvement of the physiotherapist, who should support the patient's movement only when strictly necessary and, if not, favour the patient's autonomous movement in order to guarantee the maximum effectiveness and autonomy of the treatment. In the worst case, the therapist monitors the subject and encourages him to carry out the assigned motor task correctly.

Follow up (short-term post-rehabilitation assessment):

The aim of this phase is the motor assessment and the valuation of benefits of mobilisation, in order to evaluate of effectiveness of rehabilitation treatment in short term.

A.4.4.2 Timeline (overall and for each phase)

The experiment will start in August 2023 and will stop in January 2024 with the timeline reported in the following table

Table 26 UCBM RUC A2.1 UC4 - Timeline.

Task	M30	M31	M32	M33	M34	M35
Preliminary functionality tests in UCBM laboratory						
Tests on healthy subjects at UCBM						
Tests on selected geriatric patients at FPUCBM for preliminary validation						
Full experiments on geriatric patients at FPUCBM						

A.4.4.3 Technology acquisition

It is not necessary to acquire any additional technologies.
The technologies for this UC are already available/will be developed within the ODIN consortium.

TiAGo robot: already available at UCBM
Wearable sensors (RGB-D camera, EMG sensors, Heart Rate and Respiration Rate sensors): already available at UCBM

AI software modules: to develop in the ODIN consortium

Barcode/Tag module for patient matching: to develop in the ODIN consortium

A.4.4.4 Goal (overall and for each phase)

The objectives of the treatment are many, including certainly the recovery of flexibility and range of motion, the recovery of strength and muscle tone and mass, the reduction of pain, risk of blood clot formation, the improvement of fitness and balance.

Admission and Screening (screening based on risk of reduced mobility):

The goal of this phase is to identify hospitalised patients at risks of mobility loss that require to perform (possibly autonomously) rehabilitation exercises.

Diagnosis/Case Studies (motor assessment and rehabilitation prescription):

The objective of this phase is to collect the greatest number of relevant clinical information, to exclude the presence of contraindications for the rehabilitation treatment, to confirm the initial diagnostic hypothesis, identify risk factors, preserve and possibly improve the original motor functions and avoid loss of exercise capacity in bedridden patients secondary to acute diseases.

Treatment (in-hospital rehabilitation):

The goal of the treatment phase is to improve patients' mobility and reduce consequences of limited mobilisation, providing continuous support to rehabilitation with reduced involvements of the clinical staff.

Monitoring (monitoring of compliance prescription, correctness and risks):

The goals of monitoring phase are the continuous assessment of the adherence to the prescription for each task, providing an effective feedback and prompting of the patients to correctly execute the assigned task.

Follow up (short-term post-rehabilitation assessment):

The aim of the follow up phase is to check the motor functions of the patient, to estimate the benefits and the efficacy of rehabilitation in comparison with his/her initial condition.

A.4.4.5 Impact Assessment KPIs

UCBM is going to measure the impact of the above described experiments with the following IA KPIs

Table 27 - UCBM RUC A2.2 - IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Treatment	Presence/Absence of immobilisation-related lesions	[#]	Clinical operators	
	Percentage of function preservations (trunk control)	[%]		
	Time spent in performing autonomous exercises	[min]	TIAGo + Kinect	
	Number of vocal robotic interventions	[#]	TIAGo	
	Number of physical robotic interventions	[#]		
Monitoring	Success rate	[%]	TIAGo + Kinect	
	Execution time	[min]		
	Number of repetitions	[#]		
	Number and type of errors	[#]		
	Number of requests to stop the therapy	[#]		
	Number of anomalous movements from the patient	[#]		

A.4.4.6 Involved staff (overall and for each phase)

Admission and Screening (screening based on risk of reduced mobility):
Physician and nurses.

Diagnosis/Case Studies (motor assessment and rehabilitation prescription):
Specialist in physiotherapy.

Treatment (in-hospital rehabilitation):
Physiotherapist and nurses.

Monitoring (monitoring of compliance prescription, correctness and risks):
Physician, physiotherapist and nurses.

Follow up (short-term post-rehabilitation assessment):
Specialist in physiotherapy.

A.4.5 RUC A3 - UC5: Automation of Clinical Workflows - Monitoring of oxygen therapy to prevent hypoxia complications

A.4.5.1 Description (overall and for each phase)

Respiratory failure is a syndrome in which the respiratory system is unable to correctly perform gas exchange: arterial blood oxygenation and carbon dioxide elimination. It is possible to recognise two types of respiratory failure based on the underpinning mechanism: lung failure, or type I failure, when ventilation, and thus carbon dioxide elimination, is preserved but the impaired lung function leads to hypoxia, and pump failure, or type II failure, when ventilation is impaired (i.e. neurological and/or muscle and/or chest disorders) and hypoxia develops together with hypercapnia. In the first case the therapy is the supplementation of oxygen through different devices according to the severity and patient's characteristics, in the latter ventilation is needed. Hypoxia and hypercapnia are usually symptomatic (i.e. confusion, dyspnoea, etc.), however older patients are often asymptomatic or develop geriatric syndromes, like delirium, which are totally nonspecific, delaying the diagnosis and increasing the occurrence of complications.

Admission and Screening (screening of patients requiring oxygen):

Acute respiratory failure is one of the leading causes of hospitalisation in geriatric patients, particularly during the COVID-19 pandemic. Hypoxia consists in the lack of arterial blood oxygen to deliver to peripheral tissues for the production of energy and increases the risk of complications, even severe. Symptoms of hypoxia may attract the attention, however older patients may be totally asymptomatic or have nonspecific reactions that can delay the diagnosis and therapy.

Diagnosis/Case Studies (patient assessment and oxygen therapy prescription):

Once the patient is considered at risk of respiratory failure, it is mandatory to confirm the diagnosis and classify the underpinning mechanism to timely start the required treatment, which entails oxygen supplementation in case of lung failure and ventilation in case of pump failure. Furthermore, the diagnosis of respiratory failure compels to search the disease responsible for the organ failure to start a treatment. Symptoms and signs are pivotal, but additional investigations (e.g. imaging, echocardiography, etc.) help to address the diagnosis.

Treatment (in-hospital therapy):

Once the diagnosis has been confirmed and the type of respiratory failure identified, oxygen therapy or ventilation is prescribed. Prescription is performed by hospital doctors and takes into account several aspects other than blood gas analysis. Oxygen can be supplemented through nasal prongs, venture mask or high-flow nasal cannula and the treatment can be prescribed during the whole day or only during the night according to patient needs.

Monitoring (monitoring of compliance with prescription and correctness of therapy):

Once oxygen therapy has been prescribed, the correctness of the therapy and patient's compliance should be monitored. Indeed, older patients, particularly those with dementia or with hospital-induced delirium, do not perform the therapy correctly and are less compliant, reducing the benefits of the therapy and increasing side-effects. It is therefore mandatory to check that oxygen supplementation is ongoing and that it is performed with the correct device and for the right time to foster healing.

Follow up (short-term assessment):

Oxygen supplementation is not a causative therapy, and its prescription is aimed only at avoiding the risk of developing hypoxia complications until the causative disease has been treated. It is therefore clear that patients should be regularly evaluated to define whether respiratory failure has improved, worsened or resolved to timely stop or increase/decrease the treatment.

A.4.5.2 Timeline (overall and for each phase)

The experiment will start in February 2025 and will stop in June 2024 with the timeline reported in the following table:

Table 28 UCBM RUC A3 UC5 - Timeline.

Task	M36	M37	M38	M39	M40
Preliminary functionality tests in UCBM laboratory					
Tests on healthy subjects at UCBM					
Tests on selected geriatric patients at FPUCBM for preliminary validation					
Full experiments on geriatric patients at FPUCBM					

A.4.5.3 Technology acquisition

It is not necessary to acquire any additional technologies.
The technologies for this RUC are already available/will be developed within the ODIN consortium. Oximeter and Camera are to be acquired.

TiAGo robot: already available at UCBM

Wearable sensors (RGB-D camera, Heart Rate and Respiration Rate sensors): already available at UCBM

Oximeter: to be acquired.

Camera: to be acquired.

AI software modules: to be developed in the ODIN consortium

Barcode/Tag module for patient matching: to develop in the ODIN consortium

A.4.6 Goal (overall and for each phase)

Admission and Screening (screening of patients requiring oxygen):

Prompt identification of patients at risk of respiratory failure.

Diagnosis/Case Studies (patient assessment and oxygen therapy prescription):

Diagnosis of respiratory failure, classification and stratification of severity.

Treatment (in-hospital therapy):

Oxygen supplementation according to patient's needs.

Monitoring (monitoring of compliance with prescription and correctness of therapy):

Prompt identification of scarce compliance to oxygen therapy and/or erroneous supplementation.

Follow up (short-term assessment):

Identification of patients that have recovered from those who still need oxygen and reassessment of oxygen needs.

A.4.6.1 Impact Assessment KPIs

UCBM is going to measure the impact of the above described experiments with the following IA KPIs

Table 29 - UCBM RUC A3 - IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Monitoring	Device correctness	[Boolean]	TIAGo camera	
	Air flow	[l/min]	Flowmeter	
	Fraction of oxygen	[%]		
	Therapy duration	[min]	External camera	
	Correct device positioning	[Boolean]		
	Correct therapy duration	[min]		
	Number of robotic interventions	[#]	TIAGo	
	Oxygen saturation	[%]	Oximeter connected with TIAGo	

A.4.6.2 Involved staff (overall and for each phase)

Admission and Screening (screening of patients requiring oxygen):

Doctors, nurses and caregivers.

Diagnosis/Case Studies (patient assessment and oxygen therapy prescription):

Doctors.

Treatment (in-hospital therapy):

Doctors.

Monitoring (monitoring of compliance with prescription and correctness of therapy):

Doctors, nurses and caregivers.

Follow up (short-term assessment):

Doctors.

A.4.7 RUC B1 - UC1: Aided logistics support – Logistics of food delivery

Hospital foodservice is complex and can be considered as one of the most complicated systems in the hospitality sector with many interrelated factors. The layout of hospital wards, often at considerable distances from the kitchen, adds an additional logistics burden, and as a consequence, a long stream of possible delays between production, service, delivery and consumption. The goals of a hospital foodservice are to provide inpatients with nutritious meals that are beneficial for their recovery and health, and also to give them an example of healthy nutrition with menus tailored to patients' specific health conditions. When meals are carefully planned and customised to meet patients' specific needs, and when patients consume what they are served, these goals can be considered as achieved. Meal consumption by inpatients is related to nutritional status and satisfaction with the foodservice, along with other factors such as health status, medical conditions, appetite, the eating environment and dentition. It is widely recognised that food and other aspects of foodservice delivery are important elements in patients' overall perception of their hospital experience and that healthcare teams have a daily commitment to deliver appropriate food to patients. Moreover, among many difficulties that can potentially arise in the phase of meal distribution, the patient-meal match is an issue that can both burden clinical staff and also have negative effect on patients' care and experience.

This UC will address the problem of improving the process of delivering the right meal to the right patients (food delivery process in the following sub-sections) based on the clinical prescription and on the daily special requests.

Planning (food ordering):

Any hospital menu planning and food-based criteria aims to ensure that differing dietary needs are catered for and thus maximising opportunities to ensure nutritional needs can be achieved. Hospital menu requirements are informed by assessment of local patient population needs which require to be regularly reviewed. The hospital menu typically provides for breakfast, lunch, and evening meal and can include two additional substantial snacks throughout the day. It enables the range of energy and protein requirements of patients to be met i.e. 'nutritionally well' and 'nutritionally vulnerable'. Effective menu planning is essential to meet the dietary and nutritional needs of the hospital population and requires the collection of a wide range of information and input from numerous groups. Before considering menu planning or development of a recipe database, menu planning groups need to consider the wider issues that can affect patient food choice and hence food intakes. Gathering of information about the differing dietary needs of different hospital patient groups can help menu planners develop an appropriate food service that is in a form that is familiar to patients.

Preparation, delivery, installation, training (food delivery process):

Meal distribution represents a repetitive and elementary task that burdens nurses and healthcare workers but is not free of risks. Indeed, the delivery of food to allergic patients can lead to adverse and even severe events, and the delivery of food to patients fasting for a procedure can raise the costs for the healthcare system. Most of the activities related to food delivery must be carried out at least twice a day, to ensure lunch and dinner for each hospitalised patient, as well as breakfast and a possible afternoon snack. Moreover, the perfect synchronization of all the involved resources (not just human: from dieticians to cooks, from drivers to bedside delivery operators) is absolutely necessary. In this context, there are different aspects from a logistic point of view that can be optimised to make a critical service such as that of hospital catering contributing to the improvement of patient health.

Real usage monitoring management (compliance with clinical prescription):

The monitoring of food assumption can have different final aims:

i) to check for the proper nutrition of patients;

ii) to identify compliance with clinical prescription;

iii) to identify possible needs for changes of the patients' diet;

iv) to provide feedback on the food planning and delivering;

v) to identify possible food waste.

A wide literature has been produced on all these different topics; anyhow, the focus of the UCBM UC is to compare the diet prescription with the actual delivery of the food. This aspect is also strictly related to the activity carried out within the RUC A2.1 (Monitoring of food assumption to prevent undernutrition) where the aim is to check possible problems of undernutrition.

A.4.7.1 Timeline (overall and for each phase)

The experiments will run in parallel to those of RUCA2.1, thus is scheduled as follows.

The experiment will start in March 2023 and will stop in July 2023 with the timeline reported in the following table:

Table 30 UCBM RUC B1 UC1 - Timeline.

Task	M25	M26	M27	M28	M29
Preliminary functionality tests in UCBM laboratory					
Tests on healthy subjects at UCBM					
Tests on selected geriatric patients at FPUCBM for preliminary validation					
Full experiments on geriatric patients at FPUCBM					

A.4.7.2 Goal

Planning (food ordering):

Menu planning groups need to:

i) recognise the often complex needs of specific patient populations to be cared for including 'nutritionally vulnerable' patients and those on specialised therapeutic diets;

ii) provide a choice of foods for individuals who require or would benefit from following a diet based on 'healthy eating' principles enabling them to meet their nutritional requirements;

iii) ensure provision is made for a choice of foods for individuals with poor appetites or increased requirements to enable them to meet their nutritional requirements;

iv) ensure that the dietary needs of individuals who follow diets for cultural or religious reasons are met (e.g. vegetarian diet, vegan diet).

It is important to remember that the menu should be reviewed and updated regularly in order to continue to meet the dietary needs of a potentially changing hospital.

Preparation, delivery, installation, training (food delivery process):

The objective of this phase of the UC is to introduce technologies to:

Monitor and support the delivery of the right meal to the right patient (to avoid any issues related to specific prescriptions or diet constraints);

Improve safety for patients during food assumption (to prevent risky assumption of wrong dangerous food);

Improve working conditions of the healthcare operators (to re reduce the time spent in checking meal-patient correspondence and possibly adopt corrective actions);

Increase hospital efficiency and workflow (to avoid time loss and inefficiencies due to erroneous meals delivery).

The intervention not only directly impact on patient health but also will soothe the burden for nurses and healthcare workers.

Real usage monitoring management (compliance with clinical prescription):

The goal of this phase, at least in the UCBM UC, is to verify the compliance of the food assumption with clinical prescription. This is also strictly related with the goals presented in the RUC A2.1 of UCBM, where a timely intervention on undernutrition is targeted. This phase is strictly interwoven with the previous one and technology/KPIs, presented hereafter, will be shared among the two phases.

A.4.7.3 Impact Assessment KPIs

UCBM is going to measure the impact of the above described experiments with the following IA KPIs

Table 31 - UCBM RUC B1 IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Preparation, delivery, installation, training (food delivery process)	Success rate in verifying patient-meal matching	[%]	TIAGo camera	
	Success rate in delivering food (right food to the right patient)	[%]	TIAGo camera	
Real usage monitoring management (compliance with clinical prescription)	Number of warnings detected by robotic platform	[#]	TIAGo and its HMI module	

A.4.7.4 Technology and its contribution

Preparation, delivery, installation, training (food delivery process) and real usage monitoring management (compliance with clinical prescription):

A robotic system will deliver the meal to the patient checking the congruity between patient records on the meal and that on patient bracelet. Moreover, the robotic platform verifies the correspondence between the assigned meal and patient's special requests (allergies, pathologies, daily needs, etc.). The robot is also able to deliver the meal and check the percentage of correct intake by providing alerts (if necessary). The system needs to be equipped with:

Navigation capabilities to reach the bed of the correct patient;

Multisensory system and intelligent algorithms for patient recognition;

AI capabilities to monitor food assumption (shared with UCBM RUC A);

Communication system to provide alerts to the healthcare staff.

It is not necessary to acquire any additional technologies.
The technologies for this UC are already available/will be developed in the ODIN consortium.
More in detail, the following hardware/software modules will be adopted for this UC:

TiAGo robot: already available at UCBM

Wearable sensors (RGB-D camera, Heart Rate and Respiration Rate sensors): already available at UCBM

AI software modules: to develop in the ODIN consortium

Barcode/Tag module for patient matching: to develop in the ODIN consortium

A.4.7.5 Involved staff

Preparation, delivery, installation, training (food delivery process)

Doctors, nurses.

Real usage monitoring management (compliance with clinical prescription):

Doctors, nurses.

A.5 UMCU

A.5.1 Pilot Description

The University Medical Center Utrecht (UMCU) is one of the leading and largest medical centres in the Netherlands and ranks among the best European academic hospitals in international rankings. Core business of UMCU is to provide healthcare for which special knowledge is required, provide leading research and offer excellent education to students, medical doctors, researchers and other healthcare providers. UMCU has a strong track record in both pre- and clinical research and forges strong links with companies and scientific institutions across the world.

UMC Utrecht's research focusses on six strategic themes, the ODIN projects fall into the Circulatory Health theme. Healthcare is divided over ten divisions, ODIN falls into the Division Laboratories, Pharmacy and Biomedical Genetics division, where the Central Diagnostic Laboratory is located. CDL's translational subunit ARCADIA (Academic Research for Clinical Applications of DIAgnositcs) hosts the Utrecht Patient Oriented Database (UPOD).

Established in 2003, UPOD provides access to the comprehensive and complete electronic health record information of all patients that visited the UMC Utrecht since the 1990's. Overall, 650k individual patients have been included that have been hospitalised. Including out-patients, UPOD comprises more than 2.4 million individuals. The UPOD group in brief aims to improve clinical diagnostics using routine care data and is involved in efforts to turn the UMC Utrecht into a learning healthcare system.

The UMCU ODIN project members will work in close collaboration with the recently established (2020) UMCU department of Digital health, which is located in the corporate staff.

All projects within the UMCU use case will take place in the strategic theme Circulatory health. Within this area, UMCU has established a Center for Circulatory Health where a multidisciplinary team sees every patient with a cardiovascular disease. The Circulatory health strategic area includes a long-standing research cohort (Utrecht Cardiovascular Cohort) that already encompasses 13,000+ patients. Combining the Center for Circulatory Health and Utrecht Cardiovascular Cohort efforts has led to the first steps towards transitioning patient care for cardiovascular disease patients into a learning healthcare system. Within this system we are currently developing (clinical decision) support systems. This is where ODIN has its home.

A.5.2 Pilot Experiments

With reference to the selected RUCs, the planned experiments at UMCU are reported in the following table and described below.

Table 32 - UMCU - Experiments

Use Case	Name	Description	RUC X Phase (s)
RUC A1 - UC3	AI for Diagnosis	AI tools to improve Personalisation and efficiency of CVD diagnostic pathways outpatient clinic setting	Diagnosis
RUC A2 – UC4	Clinical tasks & patient experience	Automatically identify new patients eligible for CVD learning healthcare system	Admission & Screening
RUC A4 – UC6	Telemonitoring	Post-operative home-tele monitoring of cardiovascular patients.	Monitoring, Follow up

A.5.3 RUC A1 UC 3 – AI for Diagnosis

A.5.3.1 Description (overall and for each phase)

The right treatment starts with the right diagnosis. Diagnostic trajectories can be straightforward, short and inexpensive, but in specialised medical centres can become difficult, long, expensive and cumbersome for patients. Most diagnostic pathways are well defined within protocols, and this implicates simplicity. However, patients that are referred to the UMC Utrecht Cardiovascular health centre (= cardiovascular outpatient clinic) can be referred by general practitioners or other medical specialists in secondary or tertiary care.

Cardiovascular diagnostics can be broad, as atherosclerosis, the underlying culprit disease, can manifest itself in multiple ways. Especially in patients that present with atypical complaints, this can result in a series of diagnostic tests before a diagnosis is given. At the same time, some diagnostics are redundant (e.g. sometimes MRI or angiography can replace CT, yet MRI is more expensive and angiography is more invasive) for some specific patients and diagnostic modalities can replace each other. Furthermore, choices are made based on availability of diagnostic tools. This availability can be in terms of whether or not a specific machine is available in a hospital, but also in terms of whether the agenda indicates availability of the machine within a certain period of time, or even in terms of where the machine is within the hospital. This leads to inefficient diagnostic pathways.

The above culminates into the following conclusion:

in the UMC Utrecht Cardiovascular health centre, diagnostic pathways for complicated diagnostic problems are not Personalised and the location and availability of diagnostic tools are not considered in planning.

For this use case, we want to include patient characteristics, location and availability of the diagnostic devices to make the diagnostic process in the UMC Utrecht Cardiovascular health centre more efficient. We will start with the diagnostic process in patients that visit the cardiovascular surgery department, as these patients vary the most in terms of patient characteristics, diagnostic trajectories and diagnostic modalities used.

Diagnosis

Once the patient has been referred to the UMCU cardiovascular surgery department, it is needed to determine what kind of diagnostic tests the patients should undertake. This can be determined by evaluating the patient characteristics (Personalising the diagnostic process). Thereafter, using data on the availability and the location of the medical devices within the hospital, we can make the diagnostic workflow more efficient, as it enables prioritisation within the workflow. For example; if a patient requires both an ECG and an MRI, but the ECG is further away than the MRI and only available in an hour, we could advise the patient to first take the MRI and later-on the ECG.

A.5.3.2 Timeline (overall and for each phase)

The experiment will start in January 2023 and will stop in January 2024.

This experiments takes place in one of the phases only (diagnosis). However, within the experiment we will be starting small and are planning to gradually expand the model.

First, we will build a model to predict the kind of diagnostic test needed solely based on the patient characteristics. Then, we will add the availability of the diagnostic modality to the model, based on agenda data from the electronic health record (EHR). Thereafter, we will incorporate the location of the modalities by using the data coming from the IoT platform, enabling us to determine and prioritise the diagnostic workup. At last, we will incorporate alternative pathways, in which some diagnostic modalities are replaced by others, if possible and if it would make the diagnostic workup more efficient.

Preliminary timeline:

Ethical approval: July 2022

Description of current and alternative diagnostic pathways: June 2022 – August 2022

Model 1: August 2022 - January 2023

Model 2: February 2023 – June 2023

Model 3 : July 2023 – December 2023

Evaluation/validation of the final model: January 2024 – August 2024

A.5.3.3 Technology acquisition

The experiment will need the following technology to be acquired: sensors, tags, gateways

The process of acquisition will be through a procurement technology partnership already in place. Currently the IT department of the UMCU is establishing a network of sensors, tags and gateways that enabling localisation and availability of medical devices and other modalities. At the moment of writing, several discussion have taken place. This ODIN use case could be used as a clinical use case for the IT department. Therefore, further acquisition will not be needed.

A.5.3.4 Goal (overall and for each phase)

Diagnosis

To make the diagnostic workflow more efficient by;

(1) Personalising the diagnostic process, and

(2) including location and availability of the medical devices.

A.5.3.5 Impact Assessment KPIs

UMCU is going to measure the impact of the above described experiments with the following IA KPIs

Table 33 - UMCU - RUC A1 IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Diagnosis & Case Study	Time to diagnosis	[days]	Measured by validating the model against manual planning done in 2019	-

Diagnosis

Time to diagnosis (in days). We expect to decrease the time to diagnosis, as by including the location and availability of the devices, we will be able to suggest a more time efficient diagnostic workup/planning. Furthermore, we will also determine the diagnostic tests needed based on patient characteristic, making the diagnostic process more Personalised.

A.5.3.6 Involved staff (overall and for each phase)

Diagnosis

IT department: The IT department will help us during the experiments by setting up the whole IoT landscape. They will put the sensors/tags on the medical devices needed and provide the data from those devices.

Datamanagers: The UPOD datamanagers will be involved during the entire process. They will provide us the necessary data from the electronic health records to build the model. In addition, the IT department will send the data from the sensors/tags to the datamanagers.

Physicians, nurses and administrative staff will be consulted to plot the current diagnostic pathway and underlying assumptions, and, in addition, possible alternative pathways.

A.5.4 RUC A2 UC 4 – Clinical tasks & patient experiences

A.5.4.1 Description (overall and for each phase)

Cardiovascular risk management has since the Framingham risk score was published been established as the best way to manage cardiovascular risk. The Framingham risk score has since then been updated and refined into cardiovascular risk management guidelines, that each physician needs to follow when treating at-risk patients. These guidelines include measuring blood pressure and BMI, draw blood to perform laboratory testing including lipid levels, assessing cardiovascular history and family history and behavior such as smoking and physical exercise. We know that cardiovascular risk management attainment is generally poor, i.e. not all patients that are entitled to it, get it.

Therefore, the UMCU initiated a cardiovascular learning healthcare system (LHS) to improve uniform assessment and registration of cardiovascular indicators in all patients referred to the UMCU that are entitled to cardiovascular risk management (e.g. for cardiovascular evaluation, either because they are at risk for cardiovascular disease (primary prevention) or because they already got it (secondary prevention)). Within this LHS, we regularly assess fields in our electronic health record system where the above risk factors need to be filled in (laboratory results, measurements, etc.). To close the LHS loop, each department received monthly feedback reports consisting of feedback on data quality and completeness so they can improve their cardiovascular risk management attainment and provide better care according to state-of-the-art guidelines that benefit the patients.

However, these reports only include this valuable information for the patients that are included into the LHS. Currently, these patients are manually included into the LHS by medical staff and research nurses. They screen appointments and referral letters in outpatient clinics for diagnoses and measurements that indicate cardiovascular risk. However, this identification method is very time-consuming and has proven to be unsustainable. For example, during the COVID-19 pandemic, inclusion of patients into the LHS stopped completely, as it dropped on the priority list. There was no time or resources left to include patients into the cardiovascular LHS. Additionally, after evaluation we saw that a lot of patients that actually should have been included into the LHS were missed because of time constraints/non-structured data that is not easily visualised in the

EHR is needed to identify them. A patient selection based on simple rule-based methodology and structured data (e.g. appointmentcodes/billingcodes) is will still miss patients and make our cardiovascular risk management suboptimal, which is not right for patients.

Therefore, we would like (1) to develop a patient selection tool for the cardiovascular LHS which includes the appropriate patients based on structured and unstructured routinely available electronic health record data. We then want to (2) provide reports to the treating physicians including visualisations and data quality feedback of the cardiovascular risk profile of their patients in order to close the LHS loop.

Admission & Screening

This use case only falls in the screening phase. Patients that visit outpatient clinics for cardiovascular evaluation for the first time will be included in the LHS based on structured and unstructured routine care electronic health record (EHR) data. Of these patients, baseline cardiovascular risk management indicators are extracted from the EHR and the completeness thereof is reported back to physicians through dashboards, aiming to improve the quality of care.

A.5.4.2 Timeline (overall and for each phase)

At the moment of writing, we already have developed a patient inclusion system/algorithm. However, this current system is solely based on structured data fields from the EHR (part 1). We have also developed the PowerBI dashboards. Both the inclusion systems and the dashboards are continuously being improved based on feedback we receive from the physicians. In 2023 we are planning an evaluation of this approach. In 2023 we will start incorporating AI into the algorithm (part 2) and this approach will be evaluated in 2024.

Timeline:

Submission of documents for ethical approval: October 2021

Part 1:

Development of patient inclusion algorithm without AI: November 2021 – December 2022 (iterative process)

Development of PowerBI reports regarding data quality for all departments: January 2022 – February 2023 (iterative process)

Send first monthly dashboards to the departments: March 2022

Submit data request to evaluate the new procedure: March 2023

Evaluation of the patient inclusion system: April 2023 – September 2023

Part 2:

Incorporation of AI within the patient inclusion algorithm: September 2023 – March 2024

Evaluation of patient inclusion system including AI: April 2024 – August 2024

A.5.4.3 Technology acquisition

The experiment will need the following technology: AI technology & PowerBI

We have had a discussion with Philips regarding the AI part of this use case. By using AI, such as NLP, we would be able to expand our algorithm and also select patients for the CVD LHS based on unstructured text fields from the EHR.

PowerBI will be used to create dashboards providing feedback on data quality to the departments. No further acquisition is needed for this. The dashboards are continuously being improved a tailored to match the wishes of the departments (as long as it is within the scope of UCC-CVRM).

A.5.4.4 Goal (overall and for each phase)

This use case aims to develop an AI-based system that is able to identify patients for the cardiovascular healthcare system and extracting data on cardiovascular risk indicators that, according to (inter)national guidelines should be registered yearly in the EHR. To close the LHS-loop we will provide dashboards on data quality, enabling improvement of care.

Admission & Screening

To develop an AI-based system that, based on extractable data from the electronic health record (EHR) automatically identifies new patients that are eligible for CVD learning healthcare system and creates reports for the LHS.

A.5.4.5 Impact Assessment KPIs

UMCU is going to measure the impact of the above described experiments with the following IA KPIs

Table 34 - UMCU - RUC A2 IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Admission & Screening	Percentage of (rightfully) included into the LHS	[%]	Measured by, for example, validating the to be developed patient inclusion model against historical data.	The model should at least identify all patients that were manually included into the LHS at that time.
	Number of included patients into LHS1	[number]	Comparison with inclusion rates of 2019	We have data regarding the monthly inclusion rates of 2019

Admission & Screening

Patients enrolled in the platform [number]

(Rightfully) included patients [%]

By measuring these we will have insight in the performance of the model compared to the manual and unsustainable inclusion procedure we had in the past. We expect the algorithm to be a lot more inclusive than the manual inclusion procedure was. Ultimately leading to improved care for cardiovascular patients, as cardiovascular risk indicators are monitored more closely.

A.5.4.6 Involved staff (overall and for each phase)

Admission & Screening

Nurses and physicians of all participating department of the UMCU are involved. They will need to provide us with the information needed to be able to select the correct patients for the LHS. For example, by pointing us towards structured and unstructured data that are able to identify of patients (-patient groups) that they want us to include into the LHS. This will be an iterative process.
UPOD data managers are consulted to extract data of all eligible patients.

A.5.5 RUC A4 UC 6

A.5.5.1 Description (overall and for each phase)

Many patients spend unnecessary time in hospitals for post-operative monitoring purposes leading to higher costs and a higher burden for the patient. COVID-19 helped to implement the concept of telemonitoring into the UMCU. However, telemonitoring hasn't been implemented yet for all. Patients that had a carotid endarterectomy in which blood pressure needs to be monitored multiple times a day to prevent major post-operative complications (e.g. cerebral hyperperfusion syndrome) could benefit from telemonitoring and are currently monitored while admitted to the hospital. The UMCU already has a telemonitoring app (e-Health, Luscii) to monitor blood pressure in high risk obstetric patients that need blood pressure monitoring and otherwise would visit the obstetrics outpatient clinic 3 times a week. This application could potentially be also useful in vascular surgery patients. However, obstetric patients are usually younger tech-savvy patients whereas vascular surgery patients are considerably older. Furthermore, the at-risk pregnancy is different from post-operative monitoring in terms of risk. Therefore, we would like to establish a workflow that incorporates remote monitoring of patients with mitigated remaining risks and trains both nurses and patients to use and adhere to the monitoring protocols.

Monitoring

Each patient is monitored while, in parallel, data is collected and analysed in real time. Patients will have the opportunity to monitor their blood pressure at home and at the same time healthcare professionals will have more time to treat other patients in the hospital. Thanks to the algorithm of the application and platform, the medical team will only receive notifications when abnormalities occur resulting in a decrease in workload.

A.5.5.2 Timeline (overall and for each phase)

Ethical submission of documents: January 2023 – February 2023

Clinical study: March 2023 – August 2024. Preliminary timeline:

Start including patients in clinical study: March 2023

Data collection on ease of use, usability of the workflow and usability of the device:

August 2023 – December 2023

Data analyses: January 2024 – May 2024

A.5.5.3 Technology acquisition

The experiment will need the following technology to be acquired: e-Health application and companying home monitoring platform (Luscii) that interacts with the EHR.

The technology partnership already in place. This technology is currently used in the obstetrics departments of the UMC Utrecht. We will expand this to the vascular surgery department.

A.5.5.4 Goal (overall and for each phase)

The overall goal is to reduce the number of days that patients have to stay in the hospital for monitoring.

Monitoring

Expanding our (already used by the obstetrics department) telemonitoring platform to enable post-operative home-monitoring of vascular surgery patients.

Establishing a workflow that accurately mitigates remaining risks, incorporating training of patients and nurses to use and adhere to the monitoring protocol using the app.

A.5.5.5Impact Assessment KPIs

UMCU is going to measure the impact of the above described experiments with the following IA KPIs

Table 35 - UMCU - RUC A4 IA KPIs

Phase	KPIs	Measure unit	Tool	Notes
Monitoring	Ease of use	[1-7 Likert scale]	Survey	We will enrol patients into a clinical study
	Usability of the workflow	-	Interviews	Doctors/nurses and patients
	Usability of the device	-	Interviews	Doctors/nurses and patients

Monitoring

We expect that after thorough training of the patients and healthcare providers usability of this application and platform will be rates as high. This will have several impacts. First of all, patients

will be able to measure their blood pressure at home in a comfortable environment, which will probably increase patient satisfaction. Secondly, the healthcare provider's workload will lower, as it is not needed to measure the patient's blood pressure multiple times a day. Thirdly, as a direct consequence of the earlier hospital discharge, there is room to treat multiple patients.

A.5.5.6 Involved staff (overall and for each phase)

Monitoring:

UPOD data managers to extract data from the EHR. UPOD is a large patient database containing all data from the electronic health record (EHR) of all patients in the UMCU.
nurses and doctors will need to be involved to increase the adoption and adherence of the technology
Nurses and doctors to help monitor the values obtained from the home monitoring devices
PhD candidate and/or research nurse and/or master student to set up a clinical study and include 100 patients and perform data analyses.