ITEA4

PROFIT

PRocedure Optimization and data-driven eFficiency Improvement in healthcare environmenTs

DELIVERABLE D1.1
Use cases State-of-the-art description and Innovation

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PROFIT

HISTORY

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Deliverable review procedure:
- **3 weeks before due date**: deliverable owner sends deliverable –approved by WP leader– to Project Manager.
- **Upfront** PM assigns a co-reviewer from the PMT group to cross check the deliverable.
- **1 week before due date**: co-reviewer provides input to deliverable owner.
- **Due date:** deliverable owner sends the final version of the deliverable to PM and co-reviewer.

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Acronyms

Acronym	Description
ABAC	Attribute-based access control
AER	Automated Endoscope Reprocessor
AI	Artificial Intelligence
AIaMD	AI as medical device
API	Application Programming Interface
ASR	Automatic Speech Recognition
BERT	Bidirectional Encoder Representations from Transformers
BI	Business Intelligence
BLE	Bluetooth Low Energy
DECT	Digital Enhanced Cordless Telecommunications
EHR	Electronic Health Record
ERP	Enterprise Resource Planning
ERCP	Endoscopic Retrograde Cholangiopancreatography
FHIR	Fast Healthcare Interoperability Resources
GDPR	General Data Protection Regulation
GPS	Global Positioning System
GPT	Generative Pre-trained Transformer
HC	HealthCare
HLD	High Level Disinfection
HL7	Health Level Seven
ICER	Incremental Cost-Effectiveness Ratio
IHE	Integrating the Healthcare Enterprise
IT	Information Technology
KPI	Key Performance Indicator
LPWAN	Low-power wide-area network technology
MDRO	Multidrug-Resistant Organisms
ML	Machine Learning
NHB	Net Health Benefit
NLP	Natural Language Processing
NNT	Number Needed To Treat
OR	Operating Room
PROFIT	Procedure optimization and data-driven Operational eFficiency in healthcare environmenTs
QA	Quality Assurance
QR	Quick Response (Code)
QS	Quality Standard
RFID	Radio-Frequency Identification
RGB	Red, Green, Blue

RNN	Recurrent Neural Network
RTLS	Real-Time Location System
SotA	State-of-the-Art
UWB	Ultra-Wideband

PROFIT

1 Introduction

PROFIT will develop technologies and solutions for asset and personnel management, alarm response, context-aware information management, operational efficiency, and clinical assistance to reduce staff burden and optimize workflows in healthcare environments.

This deliverable describes the six Use Cases selected by the PROFIT project to capture a wide diversity of contexts where innovative technologies could bring significative benefits and added values. These Use Cases play a central role in the project, as they allow us to identify and address challenges, define requirements and needs of the relevant stakeholders, define strategies, provide inputs to the R&D activity and support in the demonstration and validation of the project's results. Five of the selected use cases address specific areas related to the hospital's workflow: alarm management (use case 1), deployment of AI-enabled solutions in healthcare (UC2), real-time asset tracking and sterilization process of medical diagnostic equipment (UC3), AI-aided management of the clinical documentation (UC5), orchestration of clinical services for optimized care pathways (UC6). The use case 5 (Digital home care) aims at extending digital health beyond the hospital's boundaries and at improving access to home-based primary care.

In all six use cases the final goal is to contribute to addressing the four societal challenges in the healthcare domain: better health outcomes, improved patient experience, improved staff experience, lower cost of care.

The deliverable D1.1 is devoted mainly to the description of the selected use cases and of the current practice, to the identification for each of them of weaknesses and the definition of solutions – enabled by advanced technologies – having the potential of filling in the existing gaps.

Available solutions and innovation beyond state-of-the art will be investigated and integrated to improve the workflow and provide an answer to the today's challenges.

D1.1 defines the inputs for the deliverables D1.2 and D1.3 that will address the use cases requirements from different perspectives: technical & functional (D1.2) and legal & ethical (D1.3).

The design of all Use Cases will greatly benefit from the active engagement of stakeholders and end-users; they helped and will help to define the most important aspects, questions to be addressed in each PROFIT Use Case. An active communication channel with stakeholders will be extensively used to discuss the results of the Use Cases and identify policy-relevant recommendations and approaches for a successful integration of the project's results into clinical practice.

The deliverable D1.1 serves as a starting point and as a basis for the R&D activities in WP2, WP3, WP4 and WP5 and provides inputs to WP6, where integrated demonstrators will be realized, shown to healthcare professionals to get feedback and validated also in terms of impact assessment.
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2 Use cases

2.1 Use Case 1: Smart alarm response and context-aware information management

2.1.1 Use case description and current practice

In hospitals, a significant amount of time is wasted in poor management of information and unplanned care services caused by a variety of alarms. Typically, information is difficult to acquire at the point of decision-making; hence, it is challenging to have the right resources in the right place at the right time to efficiently meet care needs.

Within a hospital ward, nurses receive alarms triggered by patients, telemetry devices and other systems. The current nurse call systems are statically assigned to certain devices, with no ability for nurses to reprogram the configuration. Such alarms are transferred to DECTs or mobile devices. The routing is static based on the building plan and average nurse-to-patient ratio. Nurses are assigned by their manager to patients in different rooms in an ad hoc manner based on time schedules and expected workload. Software solutions exist (e.g., IQMessenger[1], Televic[2]) to distribute the alerts, but they require manual effort and do not consider the actual situation at the unit at the time of an alarm. Instead, alarms coming from certain rooms are linked to a DECT phone and are seldomly changed, not to the number of patients, not to the number and qualifications of the nursing staff. In general, there is a lack of context and increased communication between staff, resulting in unnecessary disturbances and increased workload. In addition, some alarms do not require immediate attention, and time gets lost by first assessing the cause and severity thereby causing unnecessary interruptions in patient care. In addition, not all tasks need to be done by nurses and can be handled by other caregivers or supporting staff.

2.1.2 Workflow improvement

PROFIT aims to optimize information management and alarm response by taking the relevant context into account. Based on contextual data, incoming alarms and events will be efficiently scheduled and assigned to nurses improving outcomes and workload. Context includes information regarding both the conditions of a patient (e.g., health information, care needs, current location and activity, past interventions) and the expertise and status of healthcare staff (e.g., competence, current location and running activity, preferences). An accurate representation of the context in which both patients and nurses are when an alarm is triggered allows the allocation of the alarm to the most suited nurse and a prioritization of the delivered information by avoiding information overload.

PROFIT will acquire and integrate heterogeneous and multi-source data (data from human resource systems, nurse call equipment, sensors, and information from the hospital's information system) and apply AI algorithms to profile the relevant stakeholders (modelling their preferences, conditions, and workload). By building representations of the context in which patients & nurses are when an alarm is triggered, the smart alarm response system will determine what information to provide, to which caregiver, at which moment and under which form. Nurses will benefit from these innovations via new digital tools such as dashboards, mobile apps and patient terminals thereby reducing alarm fatigue, disturbances, and unnecessary communication between staff. AI-aided patient's information summary will allow

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[1] https://iqmessenger.com/en/

[2] https://www.televic.com/en/business-units/healthcare

a fast and easy detection of information and insights and will contribute to a timely intervention. The system includes AI-enabled solutions predicting nurse workloads based on patient data.

The ability to derive context information relies on data access. The increased volume of personal and sensitive data makes necessary the use of the cloud not just to store, but also to process data.

There is the need for suitable technologies for data privacy and protection, and this topic is becoming hot due to the upgrade of personal data protection in the new EU GDPR rules that prevent storing and processing in the cloud personal data that is not appropriately protected.

The use case on smart alarm response and context aware information management addresses specific areas of innovation:
1. Context representation and detection,
2. Knowledge propagation,
3. Proactive support delivery,
4. Workload prediction,
5. Privacy-aware outsourcing of storage and processing of sensitive data,
6. Access control on encrypted data.

2.2 Use Case 2: Deployment of AI-enabled solutions into clinical practice

2.2.1 Use case description and current practice

Significant investments have been made for developing a multitude of AI-based algorithms capable to improve the workflow in the hospital and support healthcare professionals in their critical tasks. A challenge is represented by the severe medical requirements for AIaMD (AI as medical device).

The use case addresses two key issues that slow down the deployment of AI in healthcare:
a. The inadequateness of consumer workstations, PCs and GPUs to fit for use in a clinical context (due e.g. to limited computing capabilities, limited lifetime support);
b. Complex, time consuming and costly process for getting the approval by the international regulatory bodies.

There has been little or no research on compute appliances and on QA frameworks that can ensure the reliable running of these algorithms.
Hospitals find it hard:
o to put these apps to use if they lack a common underlying platform that is integrated with their workflow at the point of care,
o to validate and deploy AI-based solutions without an appropriate quality assurance (QA) framework capable to verify and continuously monitor their performances and their safe and reliable execution.

Moreover, consumer devices often are unpredictably updated over time. Indeed, both software updates (e.g., because of bug fixes or cybersecurity issues), as well as hardware updates (e.g., other suppliers of certain chips such as memory or storage resulting in different hardware being shipped to customers over time), are applied to such consumer devices at random moments, often without even informing users. While for the consumer market this is often not a problem, it represents a huge issue for healthcare use. It is well known that changes in

software and changes in hardware components can influence the performance, correctness and reliability of algorithms running on those platforms.

An additional issue is represented by the lack of interoperability; in a sector as complex as healthcare, no individual player has all the solutions. Instead, the future of digital healthcare will be built in collaborative ecosystems, with solutions from multiple vendors working in concert on open and interoperable platforms.

2.2.2 Workflow improvement

PROFIT will introduce a healthcare compute platform and a QA framework allowing a constant monitoring of AI algorithms and their compliance with medical requirements and regulations when applied in so variable and complex contexts such as the healthcare ones. The proposed solution will facilitate the deployment of multivendor AI-based solutions.

New technologies and specifically AI-enabled solutions help in the move towards a "smart hospital" and more effective HC services (automation and increased operational efficiency, simplification of the workflow and support to medical professionals). PROFIT will develop a QA framework and methodologies facilitating the deployment of a variety of multivendor AI algorithms in the healthcare domain in a highly performant, safe, reliable, privacy preserving and regulatory compliant way.

In addition, the PROFIT solution will provide support during the full deployment phase of the AIaMD lifecycle:
- from ramp-up and pre-deployment in a hospital (where shadow monitoring helps assert that the AI algorithm is safe and effective on the patient population at hand);
- to post-market follow-up in the form of performance monitoring and tracking using real-world on-prem data for more effective subgroup performance analysis and bias detection.

In addition, PROFIT will foster the adoption of a regulatory "adaptive" approach for AI algorithms allowing the use of additionally collected field data, not only for the incremental fine-tuning of AI by means of (re)training and verification, but also for re-obtaining regulatory approval of the refined AI-algorithm and reducing the need to formally conduct new clinical trials in a hospital setting.

It will represent a change in the currently adopted regulation rules and a move from a "frozen approach" (that requires that AI algorithms in HC are not modified after the approval) towards an "adaptive approach". This change is in line with current debate in this sector. The further benefits of a continuous and configurable training and monitoring in AI for healthcare use will be a wider representativeness of the full population with a mitigation of the risk of biases.

2.3 Use Case 3: Asset tracking and reprocessing management system for the safe reuse of invasive medical diagnostic equipment

2.3.1 Use case description and current practice

Reusable hospital equipment used in invasive procedures require constant reprocessing, including microbiological validation, to ensure safe clinical use. Current practices require the implementation of several decontamination and cleaning steps to guarantee a high level of disinfection, followed by specific transport and storage procedures, to prevent pathogen

growth. Additionally, all devices are subject to traceability protocols, which can vary between institutions, devices and levels of digitalization. These protocols follow international guidelines to ensure consistency. However, the variations found are detrimental to efficiency and safety, and end-to-end traceability is often fragmented across systems. Additionally, microbiological contamination testing standards, although efficacious, are slow in high throughput, low resource settings. This can extend device downtime and contribute to scheduling disruptions, including procedure postponements and late cancellations. Thus, several improvements can be made in the lifecycle of reusable invasive medical devices.

This use case will assess, in a practical and measurable way, the use and efficiency of the lifecycle of reusable invasive devices, namely gastroenterological endoscopes. The focus will be on the entire equipment journey (Examination → Reprocessing → Storage → Examination), identifying bottlenecks, the factors involved, and how to improve efficiency without compromising patient safety. Additionally, this use case will also assess and develop solutions to enhance the speed and accuracy of microbiological screening compared to current gold standards. Improvements will be quantified through an explicit baseline and before-after evaluation of the selected Key Performance Indicators (KPIs).

2.3.1 Workflow improvement

PROFIT plans to implement a unified lifecycle view of reusable endoscopes, by consolidating status, reprocessing, and maintenance data. This will establish operational and reliability KPIs on a common foundation to support effective day-to-day decision-making. By deconstructing and analysing process inefficiencies and failures, predictive models and strategies will be developed to optimize reprocessing workflows, forecast failure risk, prioritize preventive maintenance, and reduce unplanned downtime. Baseline values for the selected KPIs will be established and used to quantify improvements over the project period.

An RGB camera-based computer vision system will be developed for the screening of the microbiological samples, to support earlier screening and prioritization and to reduce reliance on current manual visual inspections performed by clinical staff. Data-based approaches will be used to develop and implement models to detect early signs of bacterial growth to support an earlier and more consistent detection of positive microbiological tests, enabling earlier initiation of corrective actions, including renewed decontamination and follow-up testing when needed, while maintaining existing confirmation procedures. Precision and accuracy will be maximized by tuning decision thresholds during model tuning. Finally, this solution is expected to provide substantial time savings, reduce device downtime, improve efficiency and patient safety.

2.4 Use Case 4: Digital home care and preventive digital care

2.4.1 Use case description and current practice

The use case aims at expanding the boundaries of healthcare services beyond the hospital and at improving the access and the delivery of home-based primary care.

Digital home care services have gained a solid position and are expanding; in this regard, in Europe there is high expectation on the opportunities offered by advanced technologies, also in terms of preventive digital care services addressing frail persons such as old people living in nursing homes.

In Finland and in the Nordic countries, the digital home care sector is rising rapidly as an important component of the public care services and there is the request by the public service providers of enhancing and expanding the capabilities of this new approach in terms of improved workflow efficiency and quality and optimization of the care processes though automation and system integrations.

Currently, with no system integration or automation available, the whole process required to provide a single individual digital home visit includes several tasks that take unnecessarily large portion of the professionals worktime:

- Receiving the name of the next patient to be contacted (ERP) and the background information on his / her situation (EHR/ERP + other systems);
- Understanding the patient's health status and the overall situation (EHR/ERP + other systems);
- Contacting the patient;
- Providing the remote service by using also patient's data from other sources when needed.
- Logging (EHR): most of the digital home care service providers write the log during the digital home visit to the EHR and finalize the logging after the visit.

Health care professionals, mainly consisting of digital home care nurses, have to manually find and interpret customer data from several separate operational systems and this requires manual work and often the professionals don't have time to find and interpret the patient's data before and/or during each digital home visit. This represents a key issue; the current process, as described above, misses the potential a smart utilization of customer data has regarding the quality and effectiveness of the service. Today finding and interpreting the patient data and building a comprehensive understanding on the patient's situation is too laborious and time-consuming for the professionals. Consequently, they provide the service with limited situational knowledge, which can be expected to affect the service quality.

The average time reserved for each digital home visit is 15 minutes, out of which 12 minutes are reserved to the visit itself and 2-3 minutes for the logging. It can be expected that due to manual logging during the digital home visits these are longer than needed.

Public service providers in Finland are also looking for ways to offer preventive digital care to the elderly living outside home, e.g. in nursing homes. Even if preventive digital care services rely a lot on the service concept and technology already developed for the home care service, there are new requirements for the technical platform to be used.

In both applications PROFIT will take benefit of the experience gained by Oiva Health in this field and specifically in the Finnish context.

2.4.2 Workflow improvement

PROFIT will explore new solutions and approaches in digital home care by using Finland as first test case.

Significant and positive impacts are expected in the following areas:
- time-efficiency in the digital home care services.
- well-planned system integrations and usage of situational patient data,
- automation added to each part of the care process.

The newly developed solutions will take benefit of their integration into the Oiva Health's digital care platform that is the primary solution available in Finland. For health care professionals, the Oiva Care platform represents the primary tool in their everyday work and allows them an

effective communication with their patients. An additional advantage is the capability of collecting and presenting the relevant patients' data on the already available Oiva Health's user interface solution that medical professionals already use; it makes unnecessary the use of other systems during the contact with the patient.

In addition, the project aims at overcoming the current lack of BI solutions/dashboards for delivery, combination and visualization of the status of the service for each stakeholder (service provider's staff, service unit managers, directors, etc.) with all relevant data appropriately presented to meet the different information needs (patients, professional team, service unit, etc.).

The integration of the new digital home care system into the platform already used by the care provider organizations will open the potential for the development of new functionalities and added value capabilities such as for example:
- Automated calling and logging,
- Integration of multisource information of the patient including logging to EHR directly from Oiva Health's UI,
- Dashboard providing an overview on effectiveness, and services,
- AI supported Natural Language Processing solutions for automated logging,
- Automation of treatment and everyday support
- Support in decision-making and full AI supported automation.

In the PROFIT project these new capabilities will be evaluated together with public home care provider organizations. In addition, the integration with EHR and ERP systems is expected to create high added value for the health care professionals.

Efficiency gain will be a key objective; by taking into account the high volumes of digital home visits (in Finland over 2 million in 2024) it has been evaluated that process optimization can gain a great impact for the digital home care service providers.

2.5 Use Case 5: AI-enabled management of clinical documentation

2.5.1 Use case description and current practice

The integration of AI-driven tools can transform the current way how clinical documentation is managed, streamlining workflows across hospitals, home care, and elderly care facilities and enhancing patient's and healthcare professional's experience. In modern healthcare environments, clinical documentation is a core yet time-consuming component of patient care. As an example, healthcare providers (hospitals, outpatient clinics, and remote care services) face increasing demands to efficiently manage and document patient interactions while minimizing administrative burdens and healthcare professionals spend a significant portion of their time recording patient interactions in electronic health record (EHR) systems.

A typical workflow involves healthcare professionals collecting patient information during consultations or bedside interactions. This information is documented manually, often after the interaction, in free-text or structured formats within EHR systems. Administrative staff may assist in updating records, but the process remains largely manual and causes delays.

For remote care services and interdisciplinary team meetings, the documentation workflow becomes even more complex. Professionals rely on disparate systems to record and share notes, leading to fragmented data spread across multiple platforms. Social care information,

which plays a critical role in understanding a patient's context, is stored in entirely separate systems, creating silos that impede holistic decision-making.

This workflow has inefficiencies and bottlenecks, including:
- o Time-Intensive Documentation: Healthcare professionals must dedicate significant time to entering patient information manually, reducing the time available for direct patient care,
- o Fragmented information sources: The separation of social care data and clinical records prevents the construction of a comprehensive patient profile. It is missed a holistic approach that integrates social care information and EHR data allowing a comprehensive profile of the patient and his/her context and enabling informed and proactive decisions,
- o Inconsistent and incomplete records: Manual documentation often results in lack of accuracy, inconsistencies or incomplete updates, which can compromise care quality and regulatory compliance,
- o Limited automation in EHR systems: Existing systems lack robust automation capabilities, such as real-time voice-to-text transcription or context-aware summarization; it increases the administrative burden,
- o Minimal decision support: Current tools provide basic alerts but fail to offer advanced insights, such as predictive analytics or peer group comparisons, to guide proactive care planning,
- o Interoperability gaps: The lack of seamless data exchange between multivendor systems further hampers real-time collaboration and operational efficiency.

These inefficiencies highlight the urgent need for innovative, AI-driven solutions that can streamline documentation workflows, enhance situational awareness, and support proactive decision-making.

2.5.2 Workflow improvement

PROFIT will propose a novel and integrated documentation approach, enabled by AI, that will produce and present context-aware and meaningful information for health and social care professionals. Novel speech-to-text solutions will be introduced to allow the collection of voice data and its integration (including social care data) into EHR system; in addition, easy-to-consult data summaries will be developed.

The system will incorporate decision support components that will visualize the individuals' situation in relation to their peer group and provide predictions of their health and wellbeing trends. These components will help professionals to make proactive care decisions and justify them to customers.

Innovative aspects include:
- - Voice-to-text and structured data generation allowing - during treatment encounters, remote consultations, or interdisciplinary meetings - to convert spoken interactions into structured entries within the EHR.
- - AI-driven tools for automated summarization e.g.:
    - o The creation of a concise, accessible record of each interaction with the patients by converting conversations with them into clear, structured text summaries,
    - o The generation of a quick review of patient histories and care needs, enabling more efficient care planning and situational awareness for healthcare teams,
    - o Bedside process optimization through the use of generative AI tools such as large language models; for example, the real-time conversion of speech into

structured text, enhancing bedside documentation processes across hospital and elderly care settings.
- A comprehensive validation of the newly developed solutions and the identification of adoption barriers through
  - o studies on the acceptability of these AI tools among healthcare professionals and on how well the tools integrate into daily workflow,
  - o studies assessing the impact of automated documentation and summarization in terms of time-savings, healthcare professional workload, operational efficiency,
  - o Model validation and clinical accuracy evaluation that will ensure that AI algorithms perform effectively and accurately across diverse healthcare scenarios, enhancing trust and safety.

We expect that:
a. Automated documentation will reduce the need for manual entries, will allow care providers to dedicate more time to patient care by reducing the administrative workload,
b. Automatically generated summaries and structured entries will support knowledge management, enabling healthcare professionals to prepare more effectively for patient encounters and deliver more streamlined care,
c. Optimized documentation will improve overall operational efficiency, will result in cost savings and more efficient resource utilization across healthcare environments,
d. Secure data management practices and - through the development of appropriate APIs - seamless integration between EHR systems, data analytics platforms, and stakeholder systems.

2.6 Use Case 6: Smart orchestration for optimized customer and care pathways

2.6.1 Use case description and current practice

In the healthcare landscape, patients often are confronted with fragmented and confusing care pathways, leading to inefficiencies and suboptimal outcomes. During recent decades advancements in technology have enabled the collection of vast amounts of data in healthcare, both in clinical and administrative contexts. The data has allowed the development of solutions for knowledge management and predictive medicine. Additionally, development of digitally enhanced services has widened the portfolio of health services from traditional face-to-face services to services which combine digital tools with traditional care.

However, in spite of these developments in healthcare, the users still face siloed services, inefficient care and gaps in the continuum of care. Patients lack the visibility of their journey, which may lead to unnecessary contacts with healthcare professionals burdening already overburdened services. As the HC services are fragmented, users might not find the correct care provider, which in turn can delay treatment. Particularly patients with multiple health conditions might have overlapping care processes which might even lead to conflicting care instructions. Additionally, patients lack personalized instructions, especially in digital services, which may decrease the adherence to care and lack of motivation for self-care.

The understanding of how patients navigate through various care pathways is limited, leading to increased costs and inefficiencies. This challenge is compounded by the proliferation of service channels within healthcare systems. Patients may interact with various departments, specialists, and healthcare providers, often with limited coordination and a lack of centralized

oversight. This fragmentation hinders the ability of healthcare professionals to capture and analyse comprehensive insights into individual patient journeys. Additionally, healthcare professionals operate within static organizational structures and systems, while patients lack a holistic view of their care journey. These results decrease efficiency and give suboptimal outcomes.

Health care organizations have defined treatment pathways for different health conditions. As an example, in Finland the Current Care Guidelines provide evidence-based guidelines for care pathways that describe the best practices for various health problems. However, it has been identified that organizations lack understanding of how these care pathways are implemented in practice or how they actually work in practice. The data collected might not provide needed visibility, or the data might be scattered to various systems, and it prevents objective monitoring and measuring of service delivery. Inability to identify overlapping care paths can lead to inefficiencies in care. Transitions between care organizations can lead to interruptions of care pathways, delays in care delivery while causing unnecessary suffering. Stiff organization-dependent care pathways do not adjust easily to individual needs of the patients, which decreases the user experience in health care services.

2.6.2 Workflow improvement

Intelligent orchestration of care pathways and services can enable the provision of timely care by leveraging insights into how patients and professionals utilize care processes and clinical workflows.

It is important to identify and address bottlenecks, limitations, overlaps, and delays in patient guidance and care processes. PROFIT plans to provide a framework for the analysis, optimization and smart orchestration of patients' journeys.

The framework will streamline customer and care pathways, and AI-driven solutions will be developed and implemented to enable real-time multichannel patient's journey analysis and intelligent orchestration. These solutions include, for example, voice bots that assist healthcare professionals with real-time information and guidance. AI can be leveraged to improve efficiency and personalize care. The underlying data challenges for journey analysis and orchestration are managed by defining a data model with key variables and relationships to mitigate the risk of poor data quality and availability.

With the provided AI-enabled technology, data models, framework and structured approach, it will be possible to:
- understand the problems with the current solutions and assess organisational readiness for smart orchestration by, for example, comparing the available data sources to pre-defined data model,
- Gain a data-driven understanding of the patient journey, including real-time feedback and patient inputs, to prioritize impactful process change,
- Provide patients and operators with notifications, alerts, guidance and functionalities based on the context,
- Orchestrate the journey in real time, for example with next best actions, and optimize individual journeys to deliver the best care and process outcomes,
- Deliver, deploy and maintain the orchestration technology efficiently, including components that need to comply with strict regulatory requirements (such as MDR and AI Act).

3 Technology domains and innovations

Based on the Use Case Description and current practice in the field, different technology domains were identified. The technical state-of-the-art and targeted innovations are described per common technology domain.

3.1 Context representation and detection

Applicable use cases
- *UC1*
- *UC4*
- *UC5*
- *UC6*

3.1.1 State-of-the-art

The accurate representation of the different parameters that constitute the context in which a patient or a healthcare worker is, and of the relationships between these parameters is a crucial step before being able to detect the current context of these users, and reason and appropriately react (and adapt) upon it. In recent years, semantic technologies have been increasingly used in the ubiquitous computing domain for realizing context-aware applications [1], [2]. Similar solutions have been proposed as well in the healthcare domain for patient monitoring [3]. Next to context representation, it is important to detect the different contexts that occur in the data. A large body of applicable knowledge is available regarding (sequential) pattern mining [4]. Interestingly, a pattern-based anomaly detection method (PBAD) has been recently proposed [5] that can handle time series data and mixed-type sequential data, i.e. time series data derived from heterogeneous data sources. In most cases, data has to be segmented. For temporal data, the easiest way is to use a sliding window. Within each window, raw data is pre-processed by employing different aggregation and dimensionality reduction strategies specific to the type of data, such as for example Symbolic Aggregate Approximation (SAX) for continuous sub-sequences [6]. After a suitable representation is found, existing clustering algorithms can be used to group similar records together. For example, in Inductive System Health Monitoring (ISHM) [7], these groups, or segments, represent a consistent set of (system) parameters characteristic of a class of nominal behaviour. Crucial to this grouping is how to measure similarity; SotA methods focus on a single type of data, whereas in a healthcare context data is of heterogeneous nature. Finally, the temporal evolution of these clusters can be monitored via split-and-merge techniques [8].

In the context of patient data, hypergraph clustering [9] can be an effective tool for uncovering meaningful patterns and subgroups within the data. For instance, nodes might represent patients, and hyperedges could represent shared features like similar symptoms, lab results, demographic factors, or treatment responses. By clustering the hypergraph, researchers can identify subgroups of patients who share important characteristics. These subgroups can reveal insights such as distinct disease subtypes, patterns of treatment response, or risk factors for disease progression. This makes hypergraph clustering particularly valuable in personalized medicine, where identifying smaller, more homogeneous patient groups can lead to better-targeted interventions and improved outcomes.

UC1 will characterize and model HC workers and patients and will build an accurate representation of the context in which both of them are when alarms and events are triggered. Context includes information such as the location of the different stakeholders at the moment an alarm is triggered, status of the stakeholders, health history and the updated list of activities performed or events related to a patient, the current workload of caregivers, the current status and location of necessary infrastructure and resources, etc.

For UC4 the state-of-the-art relates to the ability to use multimodal (sensory, questionnaire, natural language interpreted) data to construct a context and accumulate information about the care recipients' situation. In this, the ability to differentiate between context related changes and the care recipients' own actions is crucial. Hence, the ability to distinguish correlations between the modalities is highly relevant.

In the context of the use case 5 (UC5), context representation and detection play a crucial role in enabling AI-driven clinical documentation. The integration of advanced natural language processing (NLP) with contextual modelling allows for the automatic structuring of voice-transcribed text into meaningful data entries. Additionally, anomaly detection and sequential pattern recognition methods can help identify deviations in documentation patterns, improving the reliability and accuracy of AI-generated clinical summaries. The fusion of social care data with clinical records further benefits from ontology-based context modelling, enabling a more holistic view of patient status and care needs.

Considering the use case 6 (UC6), context-awareness is crucial for workflow optimization and patient journey orchestration. Recognizing the diverse factors that influence a patient's experience, from individual demographics and health literacy to real-time physiological data and social determinants of health, is crucial for tailoring interventions and support. Advanced technologies like AI and machine learning are essential for analysing this complex contextual information. Effectively representing this contextual information is equally important. Interactive patient journey maps that dynamically display relevant context can aid healthcare providers in making informed decisions. This information can also trigger automated actions, such as alerts to clinicians or personalized recommendations, optimizing workflows and resource allocation.

3.1.2 Technological innovation

Related to UC1, PROFIT intends to (1) explore the usage of semantic technologies to construct an accurate standard representation of the context in which both a patient and a healthcare worker can be, enabling to reason upon it in view of alarm resolution, (2) research how relevant domain knowledge can be captured and modelled in the form of semantic rules supporting context-aware rule-based reasoning, and (3) research (semi-)supervised and adaptive approaches to detect the current context in (near) real-time, able to deal with the heterogeneous type of data available in a healthcare context.

Technological innovation in UC4 for context representation and detection relates to the information system's ability to better construct intuitive context representations and the care recipients' own action types. This can be done by developing further tooling that enables automated multimodal data clustering and user interfaces that assist the professional in either defining these clusters further or providing their own grouped correlation functions.

The use case 5 (UC5) builds on the existing scientific advancements to address the specific needs of healthcare environments by providing state-of-the-art tools and capabilities for context representation and detection. By integrating health and social care data into a unified contextual model, the project overcomes existing silos and provides a comprehensive view of the patient. The integration allows healthcare professionals to take into account both clinical data and social determinants of health, enabling better-informed, proactive care decisions.

The UC5 employs real-time context detection during clinical interactions, using dynamic data inputs such as voice-to-text transcriptions and updates from electronic health records (EHRs). By combining these heterogeneous data streams, the system ensures a more accurate and up-to-date understanding of the user's context. This dynamic representation is particularly

relevant for healthcare professionals working in time-critical and information-intensive environments.

Another UC5 key innovation lies in the ability to provide context-enriched summaries, enabling professionals to quickly grasp a patient's overall situation. Summaries include not only historical trends and anomalies but also relevant comparisons to peer groups, aiding in situational awareness and decision-making. Temporal pattern detection, powered by advanced clustering and anomaly detection algorithms, adds predictive capabilities to the system. By monitoring trends and identifying deviations in patient data, the system can flag potential health risks, enabling early interventions.

Decision-support components are tightly integrated into the system, visualizing health trajectories and offering actionable recommendations based on a patient's context and peer group comparisons. These components help clinicians optimize care planning, anticipate future needs, and confidently justify interventions, fostering more proactive and effective care delivery.

Through these innovations, the project sets a new standard in context representation and detection by addressing the complexity and heterogeneity of healthcare data, while empowering professionals with predictive insights and actionable knowledge.

Use case 6 (UC6) aims to integrate data from various sources which enables a holistic understanding of the patient's situation. AI algorithms can identify patterns and undocumented care paths, and personalize interventions, while Natural Language Processing (NLP) techniques can extract valuable insights from unstructured data like clinical notes and patient feedback.

3.2 Knowledge propagation

Applicable use cases
- *UC1*
- *UC5*

3.2.1 State-of-the-art

Most of the real-world data is not consistently labelled, i.e. there is no explicit indication of when relevant events have occurred. Data labelling is mostly done manually; this is, however, labour-intensive, time-consuming, and very expensive. Label propagation is a data enrichment method that assigns new labels to unannotated data by recognizing underlying patterns in the data. These patterns are learned from annotated datasets, based on the underlying assumption that similar patterns are likely to have the same labels. Therefore, the task of propagating labels is usually converted into *classification of the unlabelled data*. For example, Wang and Zhang [10] use linear neighbourhood propagation and Nie et al. [11] expand this approach by developing a method that also discovers latent normal classes in the data, which may not be labelled by the user. Annotated datasets that are used to learn signature patterns for each label can consist of a subset of the data (which may be confined to a time period). If no annotated dataset exists, a semi-automatic process involving the evaluation of a small number of events by a human expert can be adopted [12] This approach identifies a subset of events (different approaches can be used, such as random selection, event saliency selection and frequent event selection) that can be manually annotated in a short amount of time by the human expert. Label propagation is a data-driven approach, which makes it difficult to apply in application contexts which suffer from lack of good quality data to train and validate advanced models ("cold start problem"). Transfer learning methods are an alternative

approach consisting in improving the learning performance from one domain by transferring information from another domain. Four different transfer learning strategies have been considered in the literature [13]. Namely, transfer learning through instance transfer, by re-weighting some labelled data in the source domain to adapt it to the target domain; feature transfer, by finding the feature representation that minimizes the difference between the source and target domains; parameter transfer, by discovering shared parameters and priors between the two domains; and relation transfer, by defining the relationships between the domains [14] through second-order Markov logic.

3.2.2 Technological innovation

PROFIT intends to (1) explore how (semi-)automatic label propagation techniques can alleviate manual data labelling by enabling the sharing of labels between similar contexts, (2) research how algorithms trained on previously characterized situations can be used to label new data (as it is safe to assume that in the healthcare domain similar events share comparable characteristics in similar contexts), and (3) investigate how transfer learning techniques can support knowledge propagation across multiple data sources; in particular, how feature-based techniques can support direct model bootstrapping and transfer from one source to another.

In UC1, Knowledge representation methods (such as ontologies) for modelling the different context parameters and their relationships; semi-supervised knowledge propagation techniques to transfer previously identified contextual information to new, previously unseen data; and semi-supervised context detection techniques able to operate on (near) real-time on heterogeneous healthcare data will be explored and used. All the above-mentioned activities will allow to best address an alarm or event and to provide relevant and specific support to healthcare workers

Building on these advancements in the use case 5 (UC5), the project applies label propagation and transfer learning techniques to improve clinical documentation and decision support in social and healthcare environments. AI-driven tools will generate structured data entries from voice interactions, ensuring that key medical and social care insights are captured and stored within the EHR in an accessible format. By applying advanced label propagation techniques, the system will be able to automatically categorize, and structure information extracted from patient interactions, reducing the manual effort required for annotation and improving consistency in documentation.

Furthermore, transfer learning will be used to adapt AI models across different social and healthcare settings, ensuring robust performance even in cases where limited labelled data is available. This will be particularly useful for automated summarization, where AI models trained on one type of clinical setting (e.g., hospitals) can be fine-tuned to work effectively in home care and elderly care environments. By leveraging semi-supervised learning, the project aims to refine these models using a small set of manually validated annotations, ensuring high accuracy while minimizing the need for extensive human intervention.

Additionally, the project will introduce context-aware decision support tools that enhance proactive care planning. By detecting patterns in patient histories and peer-group comparisons, the system will provide actionable insights for healthcare professionals. These capabilities will not only streamline workflows but also improve patient outcomes by enabling timely interventions based on structured, high-quality clinical documentation.

3.3 Proactive support delivery

Applicable use cases

- *UC1*
- *UC4*
- *UC5*
- *UC6*

3.3.1 State-of-the-art

In many real-world situations work professionals need to take decisions under stressful, sometimes life-threatening situations, while having to consider a multitude of information coming from several sources. To avoid information overload and facilitate both decision making and the interaction between such professionals and a supporting computer system, such systems should prioritize the information to deliver and proactively provide the most relevant one based on the current situation. In the context of UC1, Tsiporkova et al. [15] propose a semantic modelling framework for multimodal interface design, composed of a hierarchical ontological model capturing key concepts and knowledge, their applicability, and recommendations for dynamic interface adaptation, and incorporating reasoning capabilities. The authors illustrate its potential in an emergency dispatching context and a manufacturing process context. In view of learning a user's preferences and adapt the delivery policy accordingly, Lei et al. [16] propose a system for proactively delivering information to mobile phone users, funnelling the user's responses through a reinforcement learning engine. In the healthcare domain, however, the use of these techniques is focused on the detection of relevant events in the context of patient monitoring (see [1]) and appears underexploited for delivering feedback to health professionals. The delivery of proactive support is still hampered today by the use of individual devices mostly unaware of each other. As a result, relevant data is fragmented, which limits the construction of complete user profiles, the derivation of context-specific insights, and the delivery of personalized feedback. In addition, most solutions on the market are of reactive nature and provide feedback based on past activities and predefined objectives; to the best of our knowledge, literature solutions trying to deliver a more proactive support remain limited to use case specific and in-the-lab scenarios, and this in fields other than healthcare.

Current state of the art for UC4 relates to the ability to indicate trends in low-dimensional data. For example, the ability to note that a care recipients activity monitoring is steadily declining and invoking possible responses to negate this trend.

Considering the use case 5 (UC5), proactive support delivery is crucial in optimizing clinical workflows and enhancing healthcare decision-making. By integrating AI-driven tools, UC5 enables real-time, context-aware documentation and decision support. Advanced voice-to-text solutions convert spoken interactions into structured EHR entries, while AI-powered summarization generates concise and relevant patient overviews, reducing cognitive load for healthcare professionals. Additionally, predictive analytics and peer-group comparisons provide proactive insights into patient health trends, enabling earlier interventions. Seamless integration of health and social care data further ensures a holistic view of the patient, allowing for informed and timely decision-making. By addressing existing gaps in proactive support, UC5 contributes to a more efficient and intelligent healthcare system, reducing administrative burdens and improving patient outcomes.

In the context of use case 6 (UC6), proactive customer (incl. patients and healthcare providers) support is essential for optimal journey orchestration. This involves understanding the care path holistically, from initial contact to treatment and follow-up care, and providing timely interventions to address the specific needs. Research highlights the importance of seamless

communication among healthcare providers, particularly during transitions between care settings. A robust communication platform that facilitates information sharing and strengthens the patient-provider relationship is crucial, especially in complex cases. Such platforms empower patients by making them active participants in their care.

3.3.2 Technological innovation

PROFIT intends to make significant steps to further extend and bring the solutions available in the academic state-of-the-art closer and usable in a healthcare context. For UC1, reasoning upon the triggered alarm or event and, based on the associated relevant context information, to provide proactive support and actionable information to healthcare workers for efficiently and effectively addressing the alarm / event is essential. Such a proactive form of information delivery entails determining which information needs to be provided to whom, at what moment in time, and under which form (e.g. text notification on a smartphone, audio notification using the infrastructure in a room), based on the HC worker's preferences.

Technological innovation in UC4 for proactive support delivery allows the whole context to be taken into account. This means that all trends (with their trust levels) are presentable, all possible proactive support mechanisms are associated to relevant trends and finally each of these associations and their interactions are intuitively addressable by the care giving professionals.

In the use case 5 (UC5), technological innovations focus on enhancing proactive support delivery for healthcare professionals through AI-driven automation and intelligent assistance. The integration of voice-to-text solutions with EHR systems ensures real-time, structured documentation, reducing the administrative burden on clinicians. AI-powered summarization tools generate concise and relevant overviews, enabling more efficient decision-making and reducing information overload. Additionally, predictive analytics and decision-support mechanisms allow for early identification of health risks and personalized care planning. By seamlessly integrating health and social care data, UC5 enables a more holistic understanding of patient needs, fostering proactive interventions and optimized care pathways. These advancements improve workflow efficiency, enhance clinical decision-making, and ultimately lead to better patient outcomes.

Use case 6 (UC6) aims to build on existing knowledge to research innovative ways to enhance proactive support delivery to enable better communication and customer engagement. Technological innovations empower patients with interactive platforms and self-management tools, enabling them to track their progress, access information, and communicate effectively with healthcare providers. AI-powered chatbots and virtual assistants can provide 24/7 support, answer questions, and triage symptoms, tailoring interactions to individual patient needs. In addition, personalized educational content and remote monitoring tools can proactively address patient needs and provide timely interventions. By integrating these technological advancements, healthcare organizations can deliver proactive, personalized support that enhances the patient experience and improves health outcomes.

3.4 Information Exchange and smart data management

Applicable use cases

- *UC1*
- *UC4*
- *UC5*
- *UC6*

3.4.1 State-of-the-art

Effective information exchange in healthcare is crucial for ensuring continuity of care, yet current systems face interoperability challenges due to fragmented data sources and vendor-specific solutions. Existing healthcare IT infrastructures often rely on standardized protocols such as HL7 FHIR and IHE frameworks to facilitate data sharing between disparate systems. However, these standards alone do not guarantee seamless data flow, as differences in implementation and lack of real-time integration continue to hinder efficient communication. Advances in secure data exchange mechanisms, including blockchain-based data sharing and federated learning approaches, aim to address privacy concerns while maintaining interoperability. Despite these advancements, real-world adoption remains slow due to regulatory barriers, complex legacy system dependencies, and varying levels of digital maturity among healthcare providers.

Current state-of-the-art in UC1 is very limited as nurse call systems are often isolated systems. They communicate events over serial protocols such as ESPA to alarms servers. No actual data exchange of patient data from the EHR is happening today.

Current state of the art for UC4 relates to the ability to use general protocols like HL7 FHIR to interchange data in a smart manner, retaining its structure. Information exchange relates to the ability to transfer data from master and auxiliary systems to operational systems in order to maintain representativeness and efficiency. Certain minimum context transfers (e.g. opening same patient page) have been done, but this does not offer any additional logic to ensure the previous matters taking place also.

In the context of the use case 5 (UC5), smart data management is very important for integrating structured data generated from voice-to-text solutions with existing EHR systems and social care records. By employing automated data classification and contextual tagging, UC5 ensures that critical medical and social information is efficiently organized and readily accessible. Additionally, real-time data harmonization across various healthcare environments allows for seamless updates and reduces discrepancies between data sources. The use of AI-driven data validation and error detection enhances data accuracy and reliability, supporting informed clinical decision-making. Prioritizing secure, standards-compliant APIs, UC5 also enables trustworthy data sharing across different platforms, fostering better collaboration among healthcare professionals and improving overall patient care.

The challenge lies in integrating social care data with traditional healthcare records to enable a more holistic patient view. Currently, social care information is often stored in separate databases or paper-based systems, making it difficult for healthcare professionals to access comprehensive patient insights. Efficient and standardized mechanisms for merging these data sources are necessary to improve care coordination and informed decision-making.

Smart data management, which emphasizes the efficient handling of data across various healthcare systems, is particularly vital in the context of use case 6 (UC6). The orchestration of patient journeys involves integrating diverse data sources, ensuring data security, and leveraging advanced analytics to provide personalized care. The advanced analytics includes, for example, predictive modelling and real-time decision support to personalize interventions.

3.4.2 Technological innovation

The PROFIT project aims to bridge the gap between health and social care data by implementing AI-driven interoperability solutions that facilitate seamless, real-time data exchange.

In UC1, ADT will be integrated to include the patient trajectory in the hospital and FHIR will be investigated to transfer actual patient data to enrich the smart alarming system. Furthermore, the semantic data model of FHIR will be used as a starting point for AI drive decision making.

Innovation for UC4 relating to information exchange needs to make sure that between all possible information systems and between all possible roles (both professional and care recipient) are complete. This means that the systems must retain and communicate data integrity, including the source and destination systems representations of data and ensure that all modifications continuously ensure this representation is propagated to the connected systems and roles regardless of place of observations or modification. Context needs to allow all users with proper credentials to commit changes in the systems they are operating from, regardless of the source and destination of the data.

In the use case 5 (UC5), AI-driven smart data management focuses on real-time structuring and classification of unstructured voice and text data. Advanced natural language processing (NLP) and contextual tagging methods ensure that voice-to-text outputs are automatically categorized and stored in the correct sections of EHR systems. Additionally, ontology-based data integration facilitates the seamless merging of clinical and social care data, allowing for a more holistic patient view. Automated data summarization further enhances usability by transforming lengthy consultation records into concise, structured summaries, improving efficiency for healthcare professionals. The implementation of secure, standardized data exchange protocols (e.g., HL7 FHIR) ensures interoperability between different healthcare systems, supporting better decision-making and collaboration.

Additionally, UC5 will leverage automated summarization and AI-driven decision-support tools to enhance the efficiency of information exchange. AI-powered data harmonization will standardize records across different platforms, ensuring consistency and reducing manual data reconciliation efforts. By implementing secure APIs aligned with FHIR standards, the solution will enable real-time, multi-system integration across hospitals, outpatient clinics, and social care services, improving collaboration and decision-making across sectors.

Furthermore, robust data management must prioritize patient privacy and security. This includes implementing strong data governance policies, utilizing de-identification techniques, and leveraging state-of-the-art technologies to ensure secure data sharing and transmission.

3.5 Voice-to-text and generation of structured data entries into the EHR systems

Applicable use cases
- *UC1*
- *UC4*
- *UC5*

3.5.1 State-of-the-art

Recent advancements in automatic speech recognition (ASR) and natural language processing (NLP) have enabled the development of voice-to-text solutions that assist healthcare professionals in documenting patient interactions. These technologies leverage deep learning models, such as recurrent neural networks (RNNs) and transformer-based architectures (e.g., BERT, GPT), to transcribe spoken language with high accuracy. While commercial ASR solutions, like those used in virtual assistants, perform well in general settings, their effectiveness in clinical environments is often limited due to domain-specific vocabulary, overlapping speech, and background noise.

In healthcare, medical speech recognition systems have been developed to enhance transcription accuracy by incorporating domain-adapted language models trained on clinical dialogues. Some state-of-the-art systems integrate context-aware NLP techniques to extract relevant medical concepts and convert unstructured text into structured formats suitable for electronic health records (EHRs). However, existing solutions often struggle with disambiguation, contextual inference, and structured data generation. Moreover, many current implementations require manual validation and correction, limiting their efficiency gains.

Another challenge is the integration of voice-generated data into EHR systems. While structured documentation tools exist, they typically rely on predefined templates and fail to capture the full clinical context dynamically. Research efforts have explored ontology-based approaches and knowledge graphs to improve structured data extraction, but their adoption in real-world healthcare settings remains limited. Regulatory compliance and data security also pose additional barriers, as speech-derived medical data must adhere to strict privacy and security standards.

Current state of the art for UC4 relates to basic use of voice-to-text translators that are superimposed on top of existing operational systems. These are used purely to produce translation to manually indicated slots in the operational system. This can be quite convenient but requires additional steps and technical knowledge to be proficient.

3.5.2 Technological innovation

To address abovementioned challenges, this project introduces an AI-powered voice-to-text system specifically designed for clinical documentation. The solution will employ advanced NLP models fine-tuned on medical speech data, ensuring high accuracy in transcription and context-aware structured data generation. Unlike conventional ASR tools, the proposed system will not only transcribe speech but also contextually interpret medical information, enabling seamless integration into EHR systems with minimal manual intervention.

One of the key innovations is the ability to generate structured data entries from spoken interactions. By leveraging semantic parsing and medical ontologies, the system will automatically identify relevant clinical terms, diagnoses, and treatment plans, structuring them in accordance with standardized healthcare data formats (e.g., FHIR). This will significantly reduce the documentation burden for healthcare professionals, allowing them to focus more on patient care rather than administrative tasks.

Additionally, the system will incorporate adaptive learning mechanisms, refining its performance over time by continuously adapting to specific user preferences and institutional documentation styles. The integration of real-time summarization capabilities will further enhance workflow efficiency, providing concise and structured summaries of patient interactions for quick review and decision-making.

To ensure widespread adoption, the project will prioritize interoperability with existing healthcare IT systems, enabling seamless data exchange between voice-to-text solutions, EHR platforms, and clinical decision support tools. By addressing the limitations of current ASR technologies and advancing the structured documentation process, this innovation will contribute to more efficient, accurate, and context-aware clinical documentation in hospitals, home care, and elderly care settings.

State-of-the-art for UC4 provides a seamless human-interface to operational systems in terms of spoken languages. The system must ingest, understand, and structure the spoken relevant

text so that the professional only needs to commit to the final stages of the process, submitting the details as his or her own contents.

Within UC1, voice-to-text in combination with LLM will be investigated in order retrieve the reason why a patient is making an alarm. From the spoken text, the LLM are able to make a summary. This summary can be included in the proactive delivery algorithm to classify alarms and retrieve the relevant information to appropriately handle the alarm.

3.6 Protecting personal data in AI-based model development

Applicable use cases
- *UC4*
- *UC6*

3.6.1 State-of-the-art

There is a substantial need to apply AI and data to address various challenges in the social and healthcare sector. AI and data have great potential to improve care delivery by enhancing the efficiency and effectiveness of healthcare services. Ensuring data privacy and security while integrating AI solutions into existing service workflows is crucial for realizing the full potential of these technologies. The challenges lie in accessing the necessary data, processing data to develop AI based models and deploy the models in operational care delivery processes.

Health and social data are highly sensitive and, therefore, its access and safe processing is heavily regulated. The European Health Data Space (EHDS) regulation to enter into force by April 2025 will have a major effect to how existing data resources can be exploited in so called "secondary use" such as scientific research and AI model development. The regulation will also affect the information systems (e.g. EHR systems) through which new data driven innovations will be used by health and social care professionals. Additionally, the AI Act has recently entered into force and will affect AI driven software, for example software supporting medical and social care provision. Many of such software already fall under Medical Device Regulation (MDR) or In Vitro Diagnostic Regulation (IVDR) and from now on they are also regulated by the AI Act.

Healthcare organisations are increasingly implementing data lakes, with specific capabilities for integrating data resources and for using advanced data analytics to support management processes. Also closed secure processing environments (SPE) based on national or international (EHDS) regulation have been set up to enable data access aligned with secondary use regulation. A major challenge is the exporting of analysis results and AI models from SPE, as verifying the anonymity of results is challenging and in typically requires manual intervention. Manual intervention effectively prevents federated processing models where interim processing outputs (e.g. model training gradients) need to be transferred out from the SPE in real time.

Various technologies, such as anonymization, differential privacy, homomorphic encryption, and synthetic data generation, are being adopted to enable safe data outputs from SPEs. While these approaches are not new, there is limited evidence on their effectiveness. Evidence is needed both on their ability to safeguard privacy and on their impact on data utility. Many of these techniques inherently reduce data granularity, which may compromise the accuracy required for specific use cases.

The generation of synthetic data from EHRs presents a promising approach to balancing data utility with privacy protection, enabling AI-driven healthcare innovations. EHR data, primarily tabular and relational, contains complex, nonlinear interactions between diseases and correlated variables such as laboratory results. Traditional anonymization methods often struggle to maintain both privacy and analytical accuracy, necessitating advanced synthetization techniques. Standardized guidelines remain still lacking for evaluating synthetic data quality, effectiveness, and compliance.

3.6.2 Technological innovation

The PROFIT project contributes to the challenges highlighted above in the scope of use case 4. We will develop AI based models for analysing service pathways and predicting future service behaviour of health and social service customers. The modelling approach is based on using data resources of two different health and social service providers and Finland. The models will enable the service providers to predict the needs for services and thereby to enable accurate planning and management of resource usage. The models will also enable to carry out predictions pertaining to individual customers to support their care.

This model development activity is carried out in secure processing environments in compliance with the Finnish regulation on secondary use of health and social data. In this context, we will also investigate new approaches for ensuring the anonymity of the AI based models and for creating synthesized data. These approaches will enable efficient transfer of the data processing results into demonstration, piloting and deployment in healthcare settings.

We will particularly focus in validating the quality of the synthetization methods in terms of data protection and data utility, which is currently inadequately addressed. To address these challenges, various methodologies tailored for complex tabular data need to be explored, including rule-based techniques, statistical modelling, and deep learning approaches such as Generative Adversarial Networks (GANs). These methods aim to preserve essential data characteristics while preventing direct replication of real patient records. Ensuring both the quality and privacy of synthetic data is particularly critical in secure processing environments (SPEs), where verifying the anonymity of exported datasets is a key concern.

Robust quality metrics are essential to assess fidelity, differential privacy, and data utility. Synthetic data must retain statistical properties without exposing sensitive information. Validation methods, such as distribution matching, correlation preservation, and differential privacy safeguards, will ensure usability while maintaining strict privacy protections.

Within the PROFIT project, we will develop a framework for evaluating synthetic data quality, with consideration for privacy protection, fidelity, and utility. By defining clear validation metrics, we aim to support the responsible use of synthetic data in AI model development while ensuring compliance with regulatory requirements.

3.7 Privacy-aware outsourcing of storage and processing of sensitive data

Applicable use cases
- *UC1*
- *UC6*

3.7.1 State-of-the-art

Currently, various methods exist to ensure privacy-aware outsourcing of storage and processing of sensitive data to clouds, including data splitting, anonymization, and

cryptographic techniques [17]. These approaches aim to transform or remove sensitive information before storage, ensuring that the stored data reveals minimal or no sensitive details, and access to the original sensitive data is controlled and restricted. The challenge is balancing the preservation of cloud functionalities and data reliability while ensuring robust data privacy.

Data splitting fragments sensitive data and stores each fragment separately using mechanisms like RAID but faces challenges in preventing re-identification and collusion attacks. Data anonymization masks data to protect privacy but may result in approximate computation outcomes. Cryptographic solutions such as searchable encryption (SE), homomorphic encryption (HE), and secure multi-party computation (MPC) enable searching and computing on encrypted data, albeit with trade-offs in efficiency and complexity.

Research challenges include mitigating the limitations of these techniques, particularly when outsourcing large data volumes. Non-cryptographic solutions are generally more efficient but lack formal security guarantees, necessitating a trade-off between security and efficiency [18].

3.7.2 Technological innovation

Furthermore, robust data management must prioritize patient privacy and security. This includes implementing strong data governance policies, utilizing de-identification techniques, and leveraging state-of-the-art technologies to ensure secure data sharing and transmission.

In PROFIT, the focus is on investigating approaches suited to the identified use cases, i.e., UC1 and UC5, leveraging a hybrid solution employing both cryptographic and non-cryptographic techniques. Given the heterogeneous nature of healthcare data, an innovative strategy combining cryptographic solutions that enable secure computation on sensitive data with anonymization techniques such as tokenization is proposed. This hybrid approach ensures comprehensive data protection by safeguarding highly sensitive data with cryptographic methods while using non-cryptographic methods for less critical data segments. Additionally, to address the sensitivity of integrated data sources and extracted insights, PROFIT will explore secure data handling techniques ensuring privacy-respecting data manipulation. Considering the diverse responsibilities and authorization levels of hospital staff, multi-level security and fine-grained access control approaches will be developed. These approaches will ensure that authorized personnel, with varying security levels and degrees of trust, access only relevant information while maintaining compliance with privacy regulations such as GDPR. The proposed strategy will preserve data integrity and confidentiality, ensuring privacy-aware outsourcing of storage and processing operations.

Several technological innovations are transforming data management and analytics in the context of UC6. UC6 aims to research AI algorithms that are revolutionizing data integration by automating the process of mapping and harmonizing data from disparate sources, leading to a unified and comprehensive patient view. Federated learning is another key innovation, enabling collaborative model training on decentralized data sources while preserving privacy, allowing institutions to benefit from shared insights without compromising sensitive information. Furthermore, privacy-enhancing technologies like homomorphic encryption are gaining traction, allowing for data analysis and sharing while maintaining patient confidentiality.

3.8 Access control on encrypted data

Applicable use cases
- *UC1*

3.8.1 State-of-the-art

In addition to privacy-preserving computation, access control on protected data is essential for secure data management. Two primary user-centric access control mechanisms are Identity-Based Encryption (IBE) and Attribute-Based Encryption (ABE). ABE extends IBE by allowing decryption based on a set of attributes rather than a single identity, ensuring that only users satisfying a defined policy can access data.

There are two main types of ABE: Ciphertext-Policy ABE (CP-ABE) and Key-Policy ABE (KP-ABE). CP-ABE embeds policies in ciphertexts, allowing access based on user attributes, whereas KP-ABE embeds policies in users' secret keys, restricting access to encrypted data based on predefined rules. Recent advances include Multi-Level Security Attribute-Based Access Control (MLS-ABAC) [19], which integrates CP-ABE with multi-level security models, ensuring access based on both security level and attribute-based policies. While these approaches offer strong security guarantees, their reliance on pairing-based cryptography introduces performance bottlenecks due to the complex mathematical operations involved.

3.8.2 Technological innovation

PROFIT aims to design an advanced access control mechanism that provides multi-level security attribute-based access control for both encrypted and non-encrypted data. The approach will align with the National Institute of Standards and Technology (NIST) ABAC model while addressing challenges related to key management, efficiency, reliability, and completeness of access control policies.

The project will investigate the feasibility of optimizing Multi-Level Security ABAC by leveraging lightweight cryptographic algorithms to address the performance challenges of traditional ABAC solutions. The solution will support heterogeneous data and accommodate varying security and trust levels among multiple users in dynamic environments. Additionally, data lifecycle management solutions will be designed to ensure traceability and enforce data access policies, supporting further processing while maintaining privacy.

To enhance data confidentiality, integrity, and low-latency secure communication, PROFIT will adopt ASCON [20], a secure authenticated encryption with associated data (AEAD) scheme providing tamper resistance for data protection. This approach will support mutual authentication, secure key agreement, and authenticated encryption, offering a robust access control framework for healthcare data in compliance with regulatory standards.

Furthermore, this access control mechanism directly complements the privacy-aware data outsourcing strategies outlined in Section 3.7. By ensuring that only authorized personnel, classified by their security level and trust, can access relevant data, PROFIT will enable a cohesive security framework that integrates both secure storage and controlled access to sensitive information. This linkage between secure storage, processing (Section 3.7), and access control (Section 3.8) will ensure that privacy is upheld across the entire data lifecycle, maintaining GDPR compliance and enhancing hospital-wide data security practices.

3.9 Interoperability of Multivendor AI Algorithms

Applicable use cases
- *UC2*

3.9.1 State-of-the-art

Among the currently available AI algorithms each one addresses a narrow and very specific area, and the hospitals need a variety of algorithms and accompanying devices from different vendors. For each algorithm and device, the hospital faces integration costs with the existing ICT infrastructure; additionally, the interoperability of these algorithms and devices poses a complex challenge.

3.9.2 Technological innovation

In PROFIT a novel medical-grade compute platform will be designed; composed by hardware and software layers, it will allow a variety of multi-vendor AI algorithm to be integrated into the hospital ICT infrastructure and run without any degradation of their performances. In addition, the platform will enable interoperability and the programming of a cascade of algorithms that sequentially perform multiple different tasks. The SW layer includes a QA service suited to constantly monitor the correct operation of the algorithm and its regulatory compliance over time. Moreover, the QA layer and the developed tools make the regulatory compliant integration easier both for the AI vendors and the hospitals, facilitating a faster time-to-market and reduced integration costs.

3.10 Performance Metrics for AI Algorithms in Healthcare

Applicable use cases
- *UC2*
- *UC4*

3.10.1 State-of-the-art

The methodologies related to the modelling and monitoring of the performance of AI-based algorithms have been mostly designed for use with high-latency, low-bandwidth applications. Very little research has been done with regard to methodologies suitable for low-latency, time-critical contexts such as the operating room in a hospital. We miss a robust matrix of insights for the different stakeholders, based on clinically relevant performance metrics for AI algorithms in real-world, time-critical environments.

Current technology measuring AI performance in relation to work on UC4 analyses miss-rates for low dimensional / low enrichment use cases. This means that AI systems are analysed as decision support systems and the human is able to clearly dictate if the AI result (e.g. spoken vs AI-written word are the same or self-measured trend is same as AI-indicated correlation in data). These are very efficient performance measures as they immediately allow the adjustment of underlaying AI system but are uncapable of receiving and assessing models for more complex AI decision systems.

3.10.2 Technological innovation

PROFIT will fill in the current gap by developing advanced performance metrics and QA framework for AI algorithms capable to:
- consider multiple performances rather than just a single feature as in current solutions (e.g., using accuracy only in the assessment of diagnostic AI algorithms); in such way the model will fit with the enormous complexity and variability of the healthcare ecosystem;
- address subgroups of diseases, patients and users (e.g. different ages, different geographical areas, different clinical applications (diagnosis, therapy, screening, etc.))

on the contrary of the current performance models that are based on the paradigm of "a single metrics overall performance model",

- detect sources of heterogeneity in real world data, including data and usage drift,
- indicate confidence intervals providing bounds on what performance we can expect, taking into account the on-prem real-world data,
- detect subpopulations for which AI was insufficiently trained.

Preliminary research on a "verification & validation" methodology for AI algorithms in healthcare was already initiated by BARCO in previous projects (e.g. in the PENTA/VLAIO project VIVALDY mostly focused on detection and classification tasks for dermatology). In PROFIT the research work will be continued by moving to a more robust software library and by linking the QA functionality with the algorithms. The objectives are:

- extending towards other types of applications and other types of algorithms that require new types of metrics and QA methods (e.g. combination of tracking and segmentation and instance detection, cascading of AI tasks with accompanying confidence interval propagation),
- allowing real-time applicability through minimal latency and minimal impact on system resources,
- safeguarding both patient and physician privacy and data security,
- finding sets of metrics to enable new and improved ways of patient informedness, engagement and acceptance of new technologies such as AI-enabled solutions.

Technological innovation in AI-performance metrics in relation to UC4, allows professionals to operate the AI systems, receive intuitive performance data (e.g. used vs assessed progress of events e.g. in proactive intervention models applied for the care recipient) and then take corrective action as a change to the entire operated, multidimensional or -modal AI-decision-making and AI-proposal-systems within the operational systems.

3.11 Regulatory Approval for AI Algorithms in Healthcare

Applicable use cases
- *UC2*

3.11.1 State-of-the-art

Obtaining regulatory clearance for medical solutions and particularly for AI-enabled algorithms could represents a true challenge and could cause delay in the introduction of innovative and effective solutions. Often the regulatory approval is a complex, time consuming and costly process that becomes prohibitive for SMEs and startups that are the main developers of AI algorithms. This negatively impact the time-to-market.

An additional issue it that the HC regulatory rules (e.g. FDA and EU MDR) currently require that AI algorithms are not modified after approval (a "locked approach" with a rigorous clinical study protocol conducted within the confines of a limited set of healthcare facilities where data is collected on a relatively small patient population). Unfortunately, locked models are liable to decay in performance over time in consideration of the highly dynamic healthcare environment, e.g. through data and usage drift. There is the need of a new approach based on a continuous post-market monitoring. Recently FDA recognized that its current paradigm impedes innovation in digital healthcare and is researching new regulatory approaches. In the EU, the focus is more on extended monitoring plans to help guaranteeing the safety and effectiveness of the AI algorithm, e.g. through bias and drift detection and mitigation plans, as indicated in the EU MDR and EU AI Act. In both cases (FDA and EU regulations), a configurable and highly performant, privacy-preserving AI performance monitoring mechanism

is needed using on-prem data, which is currently lacking and limiting the adoption of AI in the medical sector.

3.11.2 Technological innovation

The continuous performance monitoring in real life context assured by the PROFIT QA framework allows regulatory compliant and privacy-preserving monitoring of AI algorithms in HC during the full lifecycle, i.e. from regulatory submission where monitoring plans are described, ramp-up deployment using shadow monitoring and up to continuous monitoring and supporting the update management during the post-deployment phase.

By using configurable and updateable monitoring plans, the needed granularity and flexibility for bias, data drift and usage drift detection can be attained. It will require tracking and evaluating a smart combination of multiple performance indicators, meta-data fields and on-prem specifics, at various levels and timeframes. Such monitoring plans will help the initial regulatory submission and review.

Additionally, the project proposes a new regulatory "adaptive" approach and the use of additionally collected field data, not only for the incremental fine-tuning of AI-algorithms themselves by means of (re)training and verification, but also for re-obtaining regulatory approval of the refined AI-algorithm; it will reduce the need to formally conduct clinical trials in a hospital setting. The further benefits of this "decentralized clinical trial" will be a wider representativeness of the full population with a mitigation of the risk of biases, and better insights for notified bodies to assess and compare the current state-of-the-art performances of AI algorithms at subpopulation level. In this context, the regulatory world fragmentation, and the fact that the AI regulatory ecosystem is in a transition phase represent challenging aspects.

3.12 Data modelling for efficient medical device lifecycle management

Applicable use cases

- *UC3*

3.12.1 State-of-the-art

Gastrointestinal endoscopy is a fundamental resource for both diagnoses and treatment; however, the literature demonstrates a persistent risk of procedure-associated infections. This problem is particularly noticeable in highly complex interventions, such as Endoscopic Retrograde Cholangiopancreatography (ERCP), with reported rates of up to 0,8%, frequently involving multidrug-resistant organisms (MDROs), namely *Pseudomonas aeruginosa* and carbapenem-resistant *Enterobacteriaceae* strains [21]. This vulnerability arises mainly from biofilm formation within internal channels (including dry biofilms that are difficult to remove) and structural constraints inherent to devices. Features such as long, narrow lumens or complex parts (such as duodenoscope elevator) create protected bacterial reservoirs that can persist even when High Level Disinfection (HLD) protocols are strictly followed [21,22,23,24,25]. Outbreak reports consistently demonstrate a link between device integrity and protocol effectiveness, with structural damage (cracks, worn seals), insufficient maintenance and human error during the reprocessing emerging as the main precursors of these transmissions [26,27,28].

The recommended reprocessing protocol comprises successive stages – initial pre-cleaning, leak testing, manual cleaning with enzymatic detergent, HLD in an automated endoscope reprocessor (AER) or sterilization, followed by thorough drying and controlled storage – with the drying phase and storage quality representing the most critical links in the chain, crucial to

ensure the absence of biofilms and prevent persistent bacterial colonization [21,26,27]. Although HLD typically provides a 6-log reduction in microbial load, fulfilling the requirements for semi-critical devices, several studies suggest that this safety margin is insufficient for endoscopes with complex geometries. The presence of residual contamination in duodenoscopes classified as "ready for use" is a documented finding, highlighting the vulnerability of current protocols in high-demand technical settings [21,27]. Consequently, there is growing support for terminal sterilization (such as vaporized hydrogen or ethylene oxide) or the use of disposable devices for high-risk instruments. These strategies are frequently assessed using cost-effectiveness models that incorporate the financial impact of MDRO infections, drawing on metrics such as ICER, NHB, NNT, and operational cost per cycle [21,27,29].

At the same time, traceability systems have shifted from manual paper records to digital platforms using RFID, barcodes, or QR codes. This evolution enables detailed mapping of each procedure, linking the device and user to the full reprocessing history in order to monitor critical variables such as temperature, cycle times, and disinfectant efficacy. The implementation of these technologies has shown tangible benefits, namely improved inventory accuracy, reduced time spent retrieving records, mitigation of adverse events, and enhanced adherence to safety and quality standards [30,31,32]. However, most current implementations remain confined to reprocessing safety and short-term logistical management. There is a clear gap in the connection between usage data, maintenance and physical degradation metrics and reliability indicators: as a result, measures such as mean time between failures (MTBF), mean time to repair (MTTR), usable lifecycle and cleaning failure rates remain underexploited [28,31]. In practice, this fragmentation limits the ability to anticipate endoscope unavailability, plan preventive maintenance, and optimize device allocation across clinical demand.

The PROFIT project is positioned precisely at this intersection by linking digital traceability with predictive maintenance and wear metrics, which may include, for example, cumulative cycle counts, recurrent failure patterns, repair history, and other proxies of device degradation captured in routine operations. The initiative proposes the convergence of currently siloed data flows and the definition of KPIs focused on operational efficiency, with the central aim of shifting from reactive management models to a data-driven and predictive strategy applied to the lifecycles of reusable medical devices.

3.12.2 Technological innovation

The PROFIT project focuses on the traceability and lifecycle management of reusable medical devices, specifically in gastroenterology departments. The innovation lies in the systematic acquisition and aggregation of data throughout the entire endoscope journey, such as clinical use, reprocessing, waiting times, failures and maintenance interventions, with the goal of integrating currently siloed data sources (clinical records, AER logs, inventory, maintenance) into a unified view aimed at identifying operational bottlenecks and process irregularities and inefficiencies.

Building on this integrated data layer, the project will define and model KPIs directly associated with the unavailability of endoscopes and their efficiency of use. Additionally, a predictive model for maintenance needs is expected to be developed. By combining specific lifecycle KPIs with failure prediction, the aim is to shift equipment management from a reactive towards a data-driven and predictive model, supporting decisions on logistics and maintenance and creating a methodology that can be transferred to other settings involving reusable medical devices, particularly other invasive devices with analogous reprocessing and maintenance workflows.

3.13 Computer vision based early microbiological detection

Applicable use cases

- *UC3*

3.13.1 State-of-the-art

Endoscope microbiological contamination analysis procedures are based on bacterial cultures [33], which can take over 48h to perform and take place in intervals no longer than 3 months, leaving the endoscopes inoperative for eight days in a year, assuming device quarantine during testing. Microbiological testing failure extends downtime considerably, requiring re-decontamination and re-testing. These additional procedures entail the cancellation of appointments with minimal forewarning, which burdens patients and medical staff alike, with unnecessary travel and procedure delays for the former and inefficient time use, with possible cramped rescheduling, for the latter. New microbiological detection technologies have been developed since, which although not being strictly recommended, show great potential in achieving a more sensitive and faster detection when compared to bacterial cultures. Biosensor based systems [34,35,36], immune detection [37,38,39,40,41], physical and light scattering-based systems [42,43,44,45,46,47,48,49,50], among other specialized systems all have key limitations: they require the acquisition of expensive equipment, additional consumables and specialized staff training. The increased detection capabilities come at an increased cost.

However, novel methods have been developed which could theoretically improve the outcomes and celerity of the biological analyses, while at the same time retaining mostly the same testing workflow without increasing the laboratory's recurring costs, requiring minimal additional training. This could be done with the development of computer vision analysis of bacterial cultures using machine learning and AI based systems. These have proven to be potential candidates for the specific use case of early bacterial detection (less than 8 hours when compared to the standard 48h) [51], while only requiring the initial acquisition/development of the detection systems. These systems rely on the already existing workflow (culture media and related apparatus and incubators) and could therefore serve as a cheap and simple augmentation for endoscope reprocessing quality control and early detection of contamination of any sampleable equipment. These methodologies have been tested for water quality control and in the food industry and have not thus far been tested in the context of healthcare, motivating validation in a clinical quality-control context.

3.13.2 Technological innovation

PROFIT aims to develop a computer vision and machine learning based system for the use case of early bacterial detection. The innovation is the introduction of an RGB imaging layer on top of an already established microbiological culture workflow, enabling earlier screening of culture evolution without changing culture media, incubators, or routine laboratory handling. In this use case, it applies to endoscope reprocessing quality control, to reduce endoscope downtime, reduce running costs, improve detection accuracy, and ultimately improve efficiency and patient safety.

The system is intended to support earlier screening and prioritization, while positive or uncertain findings will continue to follow existing confirmation procedures, and decision thresholds will be tuned to maximize accuracy and precision. Nevertheless, once in place, it could be used to rapidly detect contamination in a vast array of reusable devices which require serial decontamination and analysis.

4 Summary of technological innovation per UC

The table below shows a clear overview of the technological innovation by referring to the results and identified gaps in the State-of-the-Art analysis and by indicating the novelty beyond this SotA.

Table 1. Research areas and innovations proposed by PROFIT.

Research area	Current SotA	Proposed Innovation in PROFIT
Context modelling and AI techniques		
Context representation and detection	Heterogeneous and multi-source data in the healthcare domain, making real-time adaptation difficult.	Semi-supervised and adaptive approaches to detect the current context in (near) real-time.
Knowledge propagation	A semi-automatic process allowing a human expert to label a small subset, which helps in learning signature patterns for label propagation. Other methods use transfer learning methods to enable knowledge transfer from one domain to another.	Explore (semi-)automatic label propagation and transfer learning techniques to reduce manual data labelling, improve clinical documentation, and enhance decision support in healthcare. By leveraging AI-driven tools and context-aware decision support, the project aims to generate structured data from voice interactions, adapt models across different care settings, and provide actionable insights for healthcare professionals.
Proactive support delivery	Different devices are unaware of each other, resulting in data fragmentation, incomplete user profiles, limited insights, and limited personalization.	Proactive information delivery to healthcare professionals, building upon heterogeneous data acquisition and integration, accurate user profiles, AI aided documentation, context modelling and reasoning.
Data management, exchange and interoperability		
Information exchange	Lack of healthcare architecture models for the integration of AI-based solutions.	Development of a platform for AI deployment in clinical practice that integrates multiple solutions, assures quality and compliance and meets the needs of stakeholders. It will also provide a testing environment for new AI algorithms.

Research area	Current SotA	Proposed Innovation in PROFIT
Smart data management	AI algorithms for healthcare applications are increasingly available and evolving, but each product focuses on a narrow, highly specific area of the overall healthcare workflow.	The vendor-neutral AI platform developed in PROFIT will allow the integration of various 3rd party AI solutions and to program a cascade of algorithms that sequentially perform multiple different tasks.
Voice-to-text and generation of structured data entries into the EHR systems	Not available even if natural language processing is an area attracting the attention of the research community. ASR and NLP are used but require manual validation and integration.	Data about patient / customer can be easily collected and enriched by using AI-based solutions for transforming voice data into structured text-data and by creating data summaries. A next step will be advance in text-to-speech techniques such as voice control for EHR and application in intuitive and innovative user interfaces.
Data protection and privacy techniques		
Protecting personal data in AI-based model development	Data is protected through rigorous access data processes and requirement to process data only in isolated secure processing environments (SPEs). The challenge is to verify the anonymity of ML models and anonymized data sets so that they could be exported out from isolated environments.	Provide methods for creating synthetic data with verified utility, fidelity and privacy. This will enable health and social data to be used in test and operative service settings and to create privacy preserving ML models.
Privacy-aware outsourcing of storage and processing of sensitive data	Various privacy-preserving techniques such as data splitting, anonymization, and cryptographic methods exist, but they pose trade-offs in security, efficiency, and scalability.	A hybrid approach combining cryptographic solutions for secure computation on sensitive data with anonymization techniques such as tokenization for less critical data. This enables privacy-aware outsourcing of heterogeneous healthcare data while ensuring security, efficiency, and compliance with GDPR.

Research area	Current SotA	Proposed Innovation in PROFIT
Access control on encrypted data	Existing approaches, such as Attribute-Based Encryption (ABE) and Multi-Level Security (MLS) models, provide secure access control but face challenges in key management, efficiency, reliability, completeness of access policies, and handling heterogeneous data with varying security and trust levels.	Design of a NIST-aligned multi-level security access control model for fine-grained control over encrypted and non-encrypted data. It addresses key management, efficiency, and policy completeness while supporting heterogeneous data in dynamic environments. Integration with AEAD schemes ensures tamper resistance, confidentiality, and traceability across the data lifecycle.
Deployment of AI as a medical device		
Interoperability of multivendor AI algorithms	There is a lack of HC compute platforms capable to run multivendor medical applications and specifically AI algorithms. Interoperability of these algorithms and devices represents a complex challenge.	A novel medical-grade compute framework (HW & SW layers) allowing integration of various 3rd party AI solutions into the hospital ICT infrastructure and to program a cascade of algorithms that sequentially perform multiple and different tasks.
Performance metrics for AI algorithms in healthcare	Very little research has been done with reperformance modelling and monitoring of AI algorithms mainly in time-critical context and applications requiring low latency.	Performance metrics and QA framework for AI algorithms with advanced features such as: a. multiple performances metrics; b. differentiation on the basis of subgroups of diseases, patients and users; c. definition of confidence intervals for the expected performances; d. detection of subpopulations for which AI was insufficiently trained; e. detection of heterogeneity in real world data.
Regulatory approval for AI algorithms in HC	A "locked approach" based on a limited quantity of data collected on a relatively small patient population and asking for a new approval with a new clinical study protocol in case of retraining of the algorithms.	A continuous post-market monitoring in a real-life context during the full lifecycle assured by the PROFIT QA framework (an "adaptive" approach); reduction of the need to formally conduct clinical trials in a hospital setting through a "decentralized clinical trial" with the additional benefit of a wider representativeness of the population and a mitigation of the risk of biases.
Lifecycle management and optimization of invasive medical diagnostic equipment		

Research area	Current SotA	Proposed Innovation in PROFIT
Data modelling for efficient medical device lifecycle management	In gastrointestinal endoscopy, digital traceability mainly supports infection control and documentation. Data on use, reprocessing, downtime and repairs remain fragmented across systems and are rarely combined into lifecycle, availability or reliability KPIs for reusable medical devices.	By integrating data across clinical use, reprocessing, storage, maintenance, and repairs, PROFIT will deliver a clearer end-to-end view of the endoscope lifecycle and enable more transparent monitoring of each device's status over time. This common data layer will support actionable operational and reliability KPIs and predictive maintenance models to reduce unplanned downtime, optimize reprocessing capacity, and improve device allocation.
Computer vision based early microbiological detection	Current gold standard is slow; new methodologies are expensive and require additional skills.	An RGB camera-based system for the analysis of bacterial cultures will be developed, alongside the creation of a machine learning model for pattern recognition and early detection. This will improve detection speed and accuracy in a low cost, low staff burden fashion.

5 Conclusion

This deliverable describes the six Use Cases identified by the PROFIT project and intended to capture a wide diversity of contexts where innovative technologies could bring relevant benefits and added values.

For each use case the deliverable provides a short description, the practices currently adopted and the plan for addressing existing challenges and improving the workflow.

The use cases will serve to demonstrate and validate the project innovations and to assess the impact of the developed solutions.

The deliverable provides an overview of the technological scenario related to the selected use cases; describes the state-of-the-art of different and relevant technology domains and in some of them the project promises to bring advances beyond the state-of-the art.

The validation of the results in each specific use cases will also explore the scalability of the solutions and their adaptability to other clinical applications.

Some of the technologies and of then newly developed solutions are used in more use cases; it will give the opportunity of an intense collaboration between the Partners jointly developing the solutions and the Partners who will integrate them in the project's use cases.

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