Alliance for AI, IoT and Edge
Continuum Innovation

IoT, Edge Computing and AI supporting sustainable health systems in Europe

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Executive Summary

This paper examines the roles and integration of the Internet of Things (IoT), Edge Computing, and Artificial Intelligence (AI) within European healthcare systems, aiming for enhanced sustainability and improved health outcomes. It is structured around a series of analytical and informational objectives designed to provide a substantive overview of the current landscape, opportunities, and challenges associated with these technologies in healthcare.

The objectives are centred around the current status of technology and standards while showcasing studies and addressing challenges related to future applications.

This paper dives into an in-depth analysis of IoT, Edge Computing, and AI technologies, focusing on their applications in healthcare. The objective is to clarify these technologies' functionalities, benefits, and potential for innovation within Europe while reviewing the existing state of healthcare systems in Europe concerning IoT, Edge Computing, and AI. This includes evaluating infrastructures, policies, and ongoing initiatives influencing technology adoption in healthcare environments. The paper aims to encourage a concerted effort among stakeholders in European healthcare to embrace technology-driven solutions for achieving long-term sustainability and addressing the evolving health demands of the population.

Selected case studies from Europe will be highlighted to demonstrate the effective use of these technologies in healthcare, emphasising successful integration strategies and the observed benefits on system sustainability and patient care. Alongside the success stories, obstacles will be identified to adopting IoT, Edge Computing, and AI in healthcare, covering technical and infrastructural issues, regulatory concerns, and data privacy and ethical implications. Thus, the paper will outline potential future developments in healthcare influenced by these technologies, focusing on anticipated trends, innovations, and the importance of collaborative efforts in advancing healthcare sustainability.

Finally, the paper presents recommendations for policymakers, healthcare entities, and technology developers to facilitate technology adoption, address identified barriers and promote innovation within healthcare systems. This white paper is intended as a resource for stakeholders across the healthcare and technology sectors, offering a comprehensive examination of the intersection between IoT, Edge Computing, AI, and healthcare sustainability. It aims to provide a detailed, objective, and pragmatic overview to guide future initiatives and policy-making in the European healthcare landscape.

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1. Introduction

In recent years, the European healthcare landscape has faced escalating pressures from an ageing population, rising chronic disease prevalence, and escalating costs associated with advanced medical treatments. These challenges necessitate a shift towards more sustainable healthcare systems capable of delivering high-quality care in a cost-effective and resource-efficient manner. This white paper examines the pivotal roles of the Internet of Things (IoT), Edge Computing, and Artificial Intelligence (AI) technologies in driving this transformation. By integrating these technologies, European healthcare systems can enhance operational efficiencies, improve patient outcomes, and ensure long-term sustainability.

The objective of this document is to provide a comprehensive analysis of the current integration of IoT, Edge Computing, and AI within European health systems, highlight successful case studies, identify existing barriers, and offer actionable recommendations for stakeholders. This introduction sets the stage for a detailed exploration of how these technologies contribute to the development of sustainable healthy systems, addressing both their potential and the challenges they present.

1.1 Background on Sustainable Healthy Systems

Nowadays, healthcare systems across the world strive to provide safe, high-quality care and deliver the best possible health outcomes for the populations they serve. At the same time, fiscal constraints necessitate the delivery of healthcare in an efficient and cost-effective way. This creates a challenge to the sustainability of healthcare systems globally. Lead international agencies, including the World Health Organization[1], the Organisation for Economic Cooperation and Development and the World Economic Forum, have recently highlighted significant threats to the sustainability of healthcare system performance. Ageing populations and the rapidly increasing burden of chronic conditions also pose challenges to healthcare system sustainability. The introduction of new medical technologies based on edge computing and AI technologies gives the unique opportunities to concretely support the sustainability of EU healthcare systems.

In particular, sustainable healthcare systems are defined by their ability to meet present healthcare needs without compromising the ability of future generations to meet their own needs. This involves optimizing resource use, minimizing environmental impact, and ensuring equitable access to healthcare services. In the European context, sustainability also encompasses the financial viability of healthcare systems, given the diverse economic landscapes and healthcare funding mechanisms across the continent. The quest for sustainability in healthcare is driven by several factors. Firstly, demographic shifts, particularly the ageing population, are increasing the demand for healthcare services, while the prevalence of chronic diseases necessitates long-term care plans and continuous monitoring. Secondly, economic pressures are pushing healthcare systems towards more cost-effective models of care delivery. Thirdly, there is an increasing recognition of the environmental impact of healthcare operations, prompting a move towards greener and more energy-efficient practices.

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[1] World Health Organization. Everybody's business. Strengthening health systems to improve health outcomes. WHO's framework for action. Geneva, Switzerland: WHO, 2007. https://www.who.int/ healthsystems/strategy/everybodys_business.pdf

2 The Importance of IoT, Edge Computing, and AI in Modern Healthcare

Integrating IoT, Edge Computing, and AI technologies holds significant promise for addressing sustainability challenges in healthcare. These technologies offer innovative solutions for optimizing healthcare delivery, enhancing patient care, and reducing operational costs.

From a healthcare perspective, IoT devices, such as wearable sensors and remote monitoring tools, enable continuous patient monitoring outside traditional healthcare settings. This capability is crucial for managing chronic diseases, reducing hospital readmissions, and facilitating preventive care—all of which contribute to the sustainability of healthcare systems. Moreover, IoT applications in healthcare logistics, such as inventory management and asset tracking, can significantly reduce waste and improve the efficiency of healthcare operations.

Processing data is also a common topic, and Edge Computing describes processing data locally, near the source of data generation, which reduces the latency and bandwidth use associated with sending data to centralized data centres. This means faster and more reliable access to critical patient data in healthcare, enabling real-time decision-making and interventions. This capability is especially important in emergency situations and in remote areas where connectivity may be limited.

AI technologies, including machine learning algorithms and natural language processing, can analyze vast amounts of health data to identify patterns, predict health outcomes, and personalize patient care. AI can support clinical decision-making, streamline administrative processes, and contribute to research and development of new treatments. AI plays a crucial role in advancing healthcare sustainability by enhancing diagnostic accuracy, optimizing treatment plans, and improving operational efficiencies.

These technologies form a technological foundation for innovative healthcare solutions that are more efficient, effective, and sustainable. The following sections of this white paper will delve deeper into the applications, benefits, and challenges of these technologies in the European healthcare context, providing a roadmap for their successful integration into sustainable health systems.

3 Understanding IoT, Edge Computing, and AI: Definitions and Key Concepts

The integration of the Internet of Things (IoT), Edge Computing, and Artificial Intelligence (AI) has emerged as a pivotal advancement in the evolution of healthcare systems. The Internet of Things encompasses a vast network of interconnected devices, each embedded with sensors and software to facilitate data exchange over the Internet. This technological framework enables a seamless connection between various healthcare devices, ranging from wearable sensors to sophisticated diagnostic equipment, thereby creating an ecosystem that supports real-time monitoring and data-driven decision-making in healthcare.

Edge Computing represents a paradigm shift in data processing, focusing on handling data near its source at the network's edge. This approach significantly reduces latency and conserves bandwidth by minimizing the distance data travels for processing. In the context of healthcare, Edge Computing ensures that critical patient information is processed promptly and accurately, enabling immediate clinical decisions and interventions, which is crucial for emergency care and remote patient monitoring.

Artificial Intelligence, which can simulate human cognitive processes, plays a transformative role in healthcare. Through subsets such as machine learning and natural language processing, AI technologies analyse vast quantities of healthcare data to identify patterns, predict outcomes, and provide personalized care recommendations. This capability enhances diagnostic accuracy, optimizes treatment plans, and streamlines administrative processes, contributing to more efficient and effective healthcare delivery.

3.1 Interoperability across Computing Continuum

The Computing Continuum is a concept composed of diverse paradigms that have emerged over time. The notion refers to a framework that integrates three different paradigms: Cloud, Edge, and IoT to create a flexible infrastructure for processing data and executing tasks.

4. The Role of Each Technology in Healthcare

The application of IoT in healthcare, often referred to as the Internet of Medical Things (IoMT), revolutionizes patient care by enabling continuous, real-time monitoring. By equipping patients with wearable devices that track vital signs and other health metrics, healthcare providers can detect deviations from normal parameters early, allowing for timely interventions. This constant flow of patient data supports the shift towards preventive healthcare, where conditions can be managed proactively, and personalized care plans can be developed, ultimately leading to better health outcomes and reduced healthcare costs.

Edge Computing's role in healthcare is underscored by its ability to process data locally, which is especially critical in time-sensitive situations. For instance, in emergency care, where every second counts, Edge Computing ensures that data analysis and decision-making can occur almost instantaneously, without the delays associated with data transmission to and from distant servers. This capability is also vital in remote areas with limited connectivity, where Edge Computing can support local data processing, ensuring that patient care is not compromised.

Artificial Intelligence in healthcare extends beyond diagnostic support to include predictive analytics for patient care and operational efficiency. AI algorithms are capable of sifting through mountains of data to forecast patient admissions, potential outbreaks, and even the progression of diseases. This predictive capability enables healthcare providers to allocate resources more effectively, plan patient care more accurately, and adopt preventive measures to mitigate health risks. Furthermore, AI's role in automating routine administrative tasks frees up healthcare professionals to focus more on patient care, enhancing the overall efficiency of healthcare delivery.

4.1 IoT in Healthcare

IoT devices in healthcare (often referred to as the Internet of Medical Things, or IoMT) are revolutionizing patient care through real-time monitoring, improved accuracy of diagnoses, and enhanced treatment processes. Wearable devices monitor vital signs, smart inhalers track medication usage and connected insulin pumps adjust doses based on glucose levels. IoT enables a data-rich environment that supports preventive healthcare, early detection of abnormalities, and personalized patient care plans, leading to improved health outcomes and reduced healthcare costs.

The Internet of Things (IoT) refers to a network of physical objects embedded with sensors, software, and other technologies that connect and exchange data with other devices and systems over the Internet. These objects range from ordinary household items to sophisticated industrial tools.

Key Concepts:

- **Sensors and Actuators**: Devices that detect changes in the environment (sensors) and respond with actions (actuators).
- **Connectivity:** The means by which IoT devices communicate with each other and with centralized systems, utilizing various protocols and network technologies.
- **Data Processing:** The analysis and interpretation of data collected by IoT devices, often requiring significant computational resources.
- **Interoperability:** The ability of IoT devices and systems to work together despite differences in manufacturer, design, or function.

4.2 Edge Computing in Healthcare

In healthcare, Edge Computing could be applied in situations that require immediate data analysis and action, such as emergency response, remote patient monitoring, and surgical robotics. By processing data close to its source, edge computing ensures critical health applications function reliably and efficiently, even in environments with poor connectivity. It supports using AI algorithms on portable devices for quick diagnostics and decision-making, enhancing the quality of care delivered in real-time and ensuring patient data privacy and security.

Edge Computing refers to processing data near the edge of the network, where it is generated, instead of in a centralized data-processing warehouse. This approach reduces latency, conserves bandwidth, and allows for more responsive data analysis and decision-making.

Key Concepts:

- **Latency Reduction**: The decrease in time it takes for data to be transferred from its source to the point where it is processed.
- **Local Data Processing**: The ability to process data on or near the device itself, reducing the need for data to be sent to distant servers.
- **Bandwidth Optimization**: Minimizing the amount of data that needs to be transmitted over the network, thus reducing network congestion and costs.
- **Security and Privacy**: Enhancing data security and privacy by processing data locally, thereby reducing exposure to vulnerabilities during transmission.

4.3 Interoperability in healthcare across Computing Continuum

In healthcare, the Computing Continuum could support applications such as remote patient monitoring, real-time diagnostics, or AI-assisted decision-making. Data from IoT devices (e.g., wearables) is processed locally at the edge for immediate insights, while more comprehensive analyses can be performed in the cloud.

In order to create such a framework, there is a question of interoperability between the three main paradigms. The integration of Cloud, Edge and IoT in healthcare opens up the potential for seamless and dynamic shifts in processing workloads.

Novelty could be introduced by creating systems or applications that distribute workloads across the continuum base of real-time needs optimizing resources and latency. For example, emergency diagnostics could be handled at the edge while non-urgent data analysis could be processed in the cloud.

Another potential scenario fit for Computing Continuum is that the edge devices could local process close to real-time data from wearable sensors from patients with “health sensible” conditions, but switch to Cloud for a more intricate analysis for anomaly detection for example.

4.4 AI in Healthcare

AI's role in healthcare is expansive and transformative. It includes diagnostic algorithms that detect diseases from imaging data with accuracy surpassing human experts, predictive analytics for forecasting outbreaks and patient admissions, and personalized medicine where treatments are optimized for individual genetic profiles. AI systems improve operational efficiencies by automating administrative tasks, predicting patient flows, and optimizing resource allocation.

They also play a crucial role in research, integrating and analyzing vast datasets from divergent data sources to uncover new insights into diseases, treatments, and patient care strategies and to capture all the health determinants of individuals.

Collectively, IoT, Edge Computing, and AI constitute a technological trifecta that is essential for the advancement of healthcare. They enable a shift towards more proactive, predictive, and personalized healthcare services, ultimately contributing to the sustainability and effectiveness of health systems. The integration of these technologies supports a seamless, efficient healthcare delivery model that is responsive to the needs of patients and healthcare providers alike, paving the way for a future where technology and healthcare are inextricably linked.

Artificial Intelligence (AI) encompasses a range of technologies that enable machines to simulate human intelligence processes such as learning, reasoning, problem-solving, and decision-making. AI systems can improve their performance over time as they are exposed to more data leading to the provision of enhanced and more personalized recommendations, prevention and intervention measures.

Key Concepts:

- **Machine Learning**: A subset of AI that involves the development of algorithms which can learn from and make predictions or decisions based on data.

- **Natural Language Processing (NLP)**: The ability of machines to understand and interpret human language, allowing for more natural interactions between humans and computers.

- **Computer Vision**: The field of AI that enables machines to interpret and make decisions based on visual data from the world around them.

- **Predictive Analytics**: The use of data, statistical algorithms, and machine learning techniques to identify the likelihood of future outcomes based on historical data.

5. Healthcare standards

Healthcare must meet several criteria that aim to ensure that all clinical information is collected, transmitted, and stored securely and understandably by any actor in the healthcare ecosystem. To comply with the imposed criteria, developing and making available healthcare standards was necessary.

Several standards have been developed over the years to allow the exchange and storage of clinical information, each with its own specificities. Within this set of standards, Health Level Seven (HL7) Clinical Document Architecture (CDA), HL7 Fast Healthcare Interoperability Resources (FHIR), Clinical Data Interchange Standards Consortium (CDISC), and openEHR stand out.

The development of Health Information Systems (HIS) involves the selection of interoperability standards suited to the desired characteristics and specificities. In the selection process, it is necessary to check the characteristics of the available standards, as an incorrect choice can generate development, maintenance and security problems.

It is important to find out whether the standard needs to provide all the specifications to develop a complete and shared EHR system, what formats of documents or objects are used in storing or transmitting data, the types of APIs supported, the security features they have, and whether they support control versioning and auditing. It is also important to consider the complexity of implementing each of the standards.

As an example, several European Health Data Space projects (e.g., IDERHA, EUCAIM, ASCAPE, iHELP, Bigpicture, and HealthData@EU pilot project) use health standards usage since they are involved or using standards, and/or designing health ontologies. Health-standardized models/ontologies/terminologies such as HL7 FHIR, DICOM, OMOP, ISO TC 215 Health Informatics, W3C DCAT, etc. used in those projects are compared[2].

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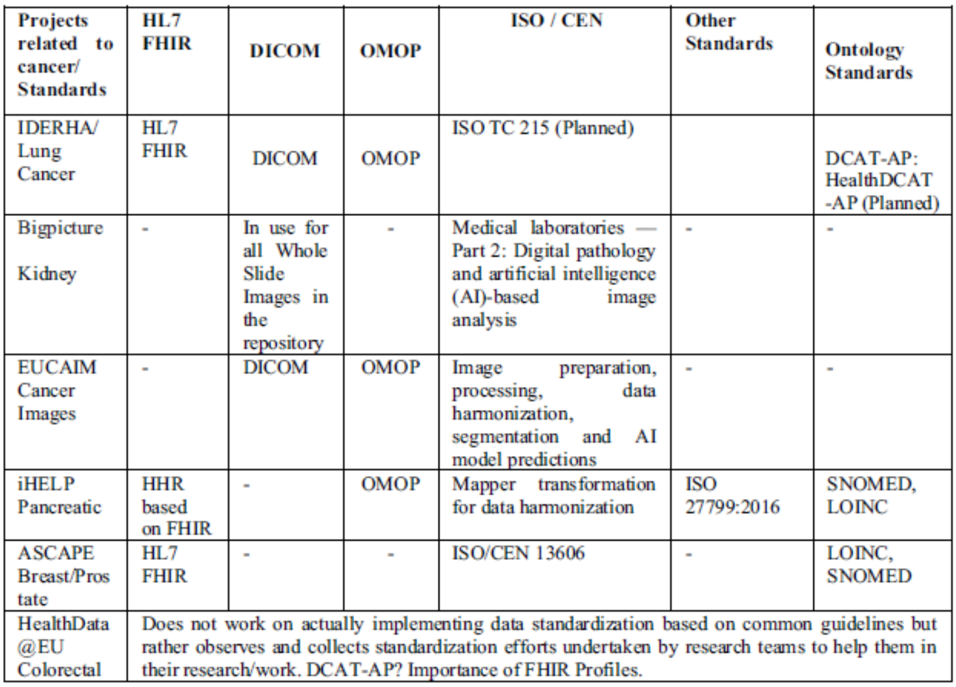
[2] Synergies Among Health Data Projects with Cancer Use Cases based on Health Standards. Stud Health Technol Inform. Gyrard A, Gribbon P, Hussein R, Abedian S, Bonmati LM, Cabornero GL, et al. In: Medical Informatics Europe 2024 (MIE 2024). In press. https://ebooks.iospress.nl/doi/10.3233/SHTI240649



Projects related to cancer/ Standards	HL7 FHIR	DICOM	OMOP	ISO / CEN	Other Standards	Ontology Standards
IDERHA/ Lung Cancer	HL7 FHIR	DICOM	OMOP	ISO TC 215 (Planned)		DCAT-AP: HealthDCAT -AP (Planned)
Bigpicture Kidney	-	In use for all Whole Slide Images in the repository	-	Medical laboratories — Part 2: Digital pathology and artificial intelligence (AI)-based image analysis	-	-
EUCAIM Cancer Images	-	DICOM	OMOP	Image preparation, processing, data harmonization, segmentation and AI model predictions	-	-
iHELP Pancreatic	HHR based on FHIR	-	OMOP	Mapper transformation for data harmonization	ISO 27799:2016	SNOMED, LOINC
ASCAPE Breast/Prostate	HL7 FHIR	-	-	ISO/CEN 13606	-	LOINC, SNOMED
HealthData @EU Colorectal	Does not work on actually implementing data standardization based on common guidelines but rather observes and collects standardization efforts undertaken by research teams to help them in their research/work. DCAT-AP? Importance of FHIR Profiles.					

Figure 1: Health standards used in Health Data Space EU Projects (IDERHA, EUCAIM, ASCAPE, iHELP, Bigpicture, and HealthData@EU pilot) [see last footnote]

5.1 Health Level Seven Clinical Document Architecture (HL7 CDA)

HL7 CDA provides a model for exchanging clinical documents to obtain Electronic Medical Records (EMR). A CDA document is a defined and complete information object that must be stored and managed in a document management system (not covered by the specification) and can be sent within an HL7 message. It allows text, images, sounds, and other multimedia content to be incorporated (in the form of external references).

It uses XML, the HL7 Version 3 standard, and encoded vocabularies. These are machine—and human-readable, which means they can be processed electronically for decision support but are easily used by users and professionals who need them in the process of providing healthcare. The CDA architecture allows representing the complexity of a document that should correspond to the complexity of the material to be transported.

It is often used in conjunction with the HL7 FHIR standard or others, which allow easier instantiation of entities participating in the healthcare environment, such as patients or medicines, but FHIR is gradually replacing it.

HL7 Version 3 is a standard developed for exchanging information through messages between health information systems. It adopts an object-oriented approach using the Unified Modeling Language (UML) principles, is based on the HL7 Referenced Information Model (RIM), is implemented in XML and typically uses the SOAP protocol to exchange messages. HL7 messages are generally used to support a continuous real-time process, transmitting status information and updates related to the same dynamic business object.

HL7 messaging standards must be implemented following the HL7 Reference Information Model (RIM) guidance, which provides instructions for database design and software engineering. RIM supports creating a single messaging environment that can be shared by all healthcare institutions and defines a set of pre-defined attributes for each class, and these are the only ones allowed in HL7 messages. Each attribute has a specified data type, and these attributes and data types become tags in XML HL7 messages.

5.2 Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR)

It is a next-generation standard that combines the best features of previous HL7 standards (HL7 v2, HL7 v3 and HL7 CDA). It can be used in mobile phone applications, cloud communications, EHR-based data sharing, communication with servers at large institutional healthcare providers, etc. With a focus on speed and ease of implementation, several implementation libraries are available; the basic "FHIR resources" can be used as is or can be adapted; it is presented as an evolution of HL7 Version 2 and CDA, uses web standards such as XML or JSON. Features an easy-to-understand specification and a human-readable serialisation format. FHIR contains two main components at its core, resources and APIs.

FHIR "resources", are a collection of information models that define the data elements, constraints and relationships for “business objects”, such as “a patient”, “a procedure”, “an observation”, “an order”, etc.

It consists of a URL, a logical ID, meta-data (including version number), a base language, references to implicit rules (e.g., an implementation guide), and optional properties. A collection of ready-to-deploy “resources” is provided that cover most of the information models that make up an HIS. The “resource” sets are called a “bundle”.

The RESTful API only supports level 2 of the REST Maturity model, but it is possible to achieve level 3 compliance, defines the same set of interactions for all resource types, does not directly address authentication, authorisation or auditing, but recommendations are provided.

The FHIR includes the following components:

- Information Model - components related to creating FHIR “resources”;
- Constrains - components addressing constraints and validating;
- Terminology - components of clinical terminologies and ontologies;
- Usage - component that deals with the use of the FHIR in execution capacity.

The FHIR limitations are:

- Impossibility of duplicating information that is already in other resources;
- The granularity of resources varies;
- Lack of rules to achieve content granularity consistency across resources;
- Lack of strict rules about which resources should be referenced by other resources and under what circumstances (ambiguity, duplication, imprecision, and conflict);
- Constraints for element definitions are defined at design time, but with variable semantic constraints at runtime.

FHIR is easier to implement and maintain than openEHR due to its adherence to RESTful design principles.

5.3 FHIR integration with edge computing

Edge computing could reduce data transmission latency by enabling local processing. One idea is to implement FHIR in close to real-time scenarios. For example, the monitoring systems could be designed close to the sensor, bypassing the overhead of delivering data to the Cloud. This would involve ensuring that FHIR-compliant data is processed locally at the edge, minimising the network bandwidth and transmission times for faster response of computing operational agents like a decision agent. However, given that many IoT devices have limited processing power, optimizing FHIR for such environments by reducing its complexity while maintaining the desired performances is challenging. If the efforts lead to successful results, this approach could lead to a more scalable and practical implementation of IoT in healthcare, facilitating faster deployment in IoMT.

5.4 openEHR

OpenEHR consists of a set of components organized into three groups, which allow the implementation of an openEHR Health Computing Platform. It provides a complete architecture that is highly generic, archetype-based, and allows you to meet most eHealth requirements, including shared and integrated health records.

The specifications published by openEHR constitute the primary reference for all openEHR semantics. They do not follow any specific programming language but use various formalisms and illustrations appropriate to each topic, using texts and UML class diagrams and grammar files. However, most abstract specifications have concrete expressions in formalisms such as JSON, XML schema, openEHR BMM and REST APIs, which can be used in development.

The openEHR information models define information at various levels of granularity. Fine-grained structures such as data types or supporting components are used to build "top level" models (such as EHR, EHR Extract, Demographics models). These latter models define openEHR 'top level structures', which can be considered equivalent to separate documents in a document-oriented system. In openEHR information systems, it is usually the high-level structures that are of direct interest to users.

Major top-level structures include:

- Composition (the committal unit of the EHR);
- EHR Access (the EHR-wide access control object);
- EHR Status (the status summary of the EHR);
- Folder hierarchy (act as directory structures in EHR);
- Party (various subtypes including ACTOR, ROLE, etc. representing a demographic entity with identity and contact details);
- EHR Extract (the transmission unit between EHR systems, containing a serialization of EHR, demographic and other content).

All information conforming to the openEHR Reference Model is expressed in 'archetypes', which means that the creation and modification of content and the subsequent query of data are controllable by archetypes. Like the 'resources' in FHIR, there are also libraries of archetypes online, and often archetypes are deployed at runtime via templates that specify which archetypes are used for a particular purpose (e.g., registering a 'blood pressure measurement').

It presents information security measures, such as the separation of EHR records from demographic information (allows that, in the event of an EHR theft, there is no direct clue to the patient's identity), access control policies, versioning of objects, possibility commit and access audits, digital signatures and hashes (for example, to digitally sign each version in a versioned object). Furthermore, it has other important features, such as logical deletion (health record information cannot be deleted, it can only be made invisible) or the use of the configuration management paradigm (IEEE 828 standard).

Provides an architecture that allows meeting most of the requirements of shared health records, is the most complete in terms of security and can fully represent medical knowledge. Both openEHR and FHIR fully support EHR systems, although openEHR does so in a more complete way, which positions it as the best alternative for storing more complete clinical data, FHIR is easier to implement and more versatile.

5.5 Clinical Data Interchange Standards Consortium (CDISC)

The Clinical Data Interchange Standards Consortium develops standards for generating clinical research data, transforming incompatible formats or inconsistent methodologies. The organization brings together a global community of research experts who come from diverse disciplines and contribute to the development of standards that provide a common interoperable language across systems across the clinical research lifecycle. Its main objective is to help the clinical research industry to explore and develop its work, its standards allow data accessibility, interoperability and reusability and are suitable to be implemented in use cases that avail AI/Machine Learning, meta-analytics, and big data, providing well-defined secure datasets that adhere to a common framework.

CDISC standards can be organized into four classes:

- The Foundational Standards - support end-to-end clinical and non-clinical research processes. They include models, domains, and specifications for representing data.
- Data Exchange Standards - facilitate the sharing of structured data between different information systems. May be used by information systems that do not implement the CIDISC Core Standards, e.g., legacy data, academic studies.
- Therapeutic Area (TA) Standards - extend Foundational Standards to represent data pertaining to specific disease areas (e.g., Acute Kidney Injury, Alzheimer's, and Asthma), include specific metadata, examples, and standards implementation guidance.
- Controlled Terminology (CT) - is the set of standard expressions or values developed or adopted by the CDISC used in data sets defined by the CDISC.

As they are entirely focused on clinical research, they present major limitations in terms of interoperability with EHR, EMR or clinical decision support systems, requiring mappings to and from other standards, in different situations.

Key Concepts:

- **Healthcare data standards**: encompasses methods, protocols, terminologies, and specifications for the collection, exchange, storage, and retrieval of information associated with health care applications, including medical records, medications, radiological images, payment and reimbursement, medical devices and monitoring systems, and administrative processes.

6. The European Context

Europe's healthcare landscape is characterized by its diversity, with systems that vary significantly across nations regarding structure, funding, and access to care. Despite these differences, European healthcare systems share common goals: improving health outcomes, ensuring access to care, and maintaining sustainability in the face of demographic changes and rising healthcare costs. The integration of Internet of Things (IoT), Edge Computing, and Artificial Intelligence (AI) technologies is increasingly viewed as essential to achieving these goals. These technologies promise to enhance the efficiency of healthcare delivery, improve patient outcomes, and support the development of more sustainable healthcare systems.

In the context of IoT, Edge Computing, and AI, Europe has been at the forefront of adopting technological innovations in healthcare. IoT devices are widely used for patient monitoring in clinical settings and remotely, enabling continuous care and early detection of potential health issues. Edge Computing has found application in emergency care and remote patient monitoring, where rapid data processing can be critical to patient outcomes. AI is increasingly used in diagnostic processes, patient data analysis, and predicting patient flows within healthcare facilities, contributing to more personalized and efficient care.

6.1 Initiatives

Current initiatives and policies within Europe reflect a strong commitment to leveraging technology in healthcare. The European Commission has launched several initiatives to foster digital innovation in healthcare. For example, the Digital Single Market strategy aims to open up digital opportunities for people and businesses, with a significant focus on health. The strategy includes actions to promote health data sharing and infrastructure, support digital health innovation, and ensure cybersecurity in health data handling. Policies such as the General Data Protection Regulation (GDPR) provide a robust framework for protecting patient data and addressing privacy concerns related to digital health technologies.

Moreover, the European Union (EU) has emphasized the importance of research and innovation in health technologies through funding programs such as Horizon 2020, which supports research projects in health, demographic change, and wellbeing. These initiatives drive technological advancements and facilitate cross-border collaboration, sharing best practices, and the development of standards for digital health technologies across Europe.

The findings presented in the European context underscore the potential of IoT, Edge Computing, and AI to transform healthcare. These technologies enable more proactive and preventive healthcare models, enhance the precision of diagnostics and treatments, and improve the efficiency of healthcare operations. However, the findings also highlight challenges, including the need for robust data protection measures, interoperability standards to ensure seamless integration of technologies, and the ongoing requirement to address the digital divide within and between European countries to ensure equitable access to digital health innovations.

6.2 European healthcare landscape

In Europe's healthcare landscape, the IoT, Edge Computing, and AI present the potential to address some of the most pressing challenges faced by healthcare systems. Current initiatives and policies clearly recognise this potential, coupled with a commitment to addressing the associated challenges. As Europe continues to navigate its digital health transformation, the focus will be on harnessing these technologies to create healthcare systems that are more efficient, effective, equitable, and sustainable.

Integrating IoT, Edge Computing, and AI technologies into Europe's healthcare systems has led to the implementation of several innovative tools and equipment. These technologies enhance healthcare delivery and create new opportunities for patient care, operational efficiency, and data management.

AI's role in analyzing complex datasets transcends human capabilities, identifying patterns and predictions that inform clinical decisions, public health strategies, and operational efficiencies. AI-powered diagnostic tools augment the capabilities of healthcare professionals, enabling them to diagnose conditions more accurately and at earlier stages. Supporting AI, Edge computing further reduces latency in data processing, which is crucial for time-sensitive medical interventions. Enabling local data analysis ensures that healthcare decisions are made swiftly and based on the most current patient data, even in resource-limited settings.

These technologies strengthen healthcare services by improving the accuracy of diagnoses, enhancing the efficiency of care delivery, and personalizing patient care. For instance, wearable health monitors and remote patient monitoring systems ensure that patient data is continuously collected and analysed, leading to more timely and informed healthcare decisions. Smart inhalers and portable diagnostic devices empower patients and healthcare providers with immediate insights into health conditions, improving disease management and treatment outcomes.

Europe's healthcare systems enhance patient care, operational efficiency, and data-driven decision-making. improving health outcomes, ensuring access to care, and maintaining the sustainability of healthcare systems in the face of evolving challenges.

6.3 Case study: Artificial Intelligence’s role in Sustainable Health Systems

DeepHealth (Horizon 2020 project) aims to create Machine Learning libraries for specialized for biomedical applications and to explore these libraries in a set of 15 use-cases to support new and more efficient ways of diagnosis and treatment of disease. The project used state-of-the-art techniques in Deep Learning and Computer Vision to expand knowledge of the possible ways of using Artificial Intelligence in the medical field.

One of the use cases of the DeepHealth project tackles diagnosing cancer tumours on kidneys and adrenal glands based on medical imaging. It uses current research into use of Convolutional Neural Networks in Computer Vision to predict if a kidney or adrenal gland has a tumour and to highlight to tumour in the image if one is indeed present. In essence, the use case addressed 2 classical problems in Computer Vision: classification and segmentation. Classification was used to determine if a patient is healthy or has a tumour on their kidneys or adrenal glands, while segmentation was used to delineate the tumour in the CT scan images.

Artificial Intelligence has the potential to completely revolutionize the field of medical diagnostics. The biggest advantage of using AI-assisted tools in diagnostics is the time saved. Artificial intelligence improves the diagnostic due to the automatic nature of the process. In the Urology example of the DeepHealth project, the time to diagnose a patient dropped from 420 seconds by manual inspection of an expert to 12 seconds using the assistance of an AI tool. Most of the time is used in developing the model, gathering suitable data, and the trial-and-error process to get good results. However, this time is only spent once and the resulting application can be used repeatedly in the future, vastly saving time for expert physicians.

Treatment and patient care can also be improved using Artificial Intelligence methods. Faster diagnosis can lead to optimized treatment and patient care, but AI tools are also available to support creating semi-automatic treatment plans based on the effectiveness of past treatments on different types of patients.

Data analysis can be substantially enhanced using Artificial Intelligence to complement classical statistical methods for analysing data. One important factor is time saving; Artificial Intelligence can greatly reduce the time to study a research population. For example, in the Urology use-case of the DeepHealth project, the time to study a population was reduced from 117600 seconds to 3360 seconds. Additionally, Artificial Intelligence can highlight errors in the way data was gathered or labelled if it does not fit with the predictions realized by Artificial Intelligence. Moreover, using AI tools can underline the critical aspects of a dataset and make further research focus more on the relevant aspects.

Another important aspect to consider for the data analysis is that Artificial Intelligence needs large amounts of data for accurate predictions. Research projects in the medical field can gather the necessary data for their own research goals and increase the general knowledge in the field. For example, the DeepHealth project developed several Open-source datasets in various medical topics that can be further used in other research endeavours.

6.4 Case study: Artificial Intelligence and Holistic Health Records (HHRs) towards the realisation of Sustainable Health Systems

iHELP (Horizon 2020 project) seeks to unpack a comprehensive approach fostering improved exploitation of clinical and real-world data using powerful tools such as AI and High-Performance Computing to improve e-health, decision support systems, telemedicine, remote monitoring systems, health data access and health data exchange. The analysis of these data using advanced AI techniques seeks to draw adaptive learning models that are used to provide decision support in the form of early risk predictions and personalised prevention and intervention measures delivered through user-centric mobile and wearable applications. In that context, the project realizes the interconnection and integration of advanced AI models coupled with Holistic Health Records (HHRs). The project validates its results and robust approach in five different pilot sites, within and across Europe (i.e., Spain, Italy, Bulgaria, UK, and Taiwan), and five different types of cancer, i.e., pancreatic, liver, prostates, anal canal, and breast, demonstrating the great potential that the utilization of AI tools pose in the modern healthcare domain.

One of the project’s key propositions is the development of an AI-based Decision Support System (DSS) offered to healthcare professionals to improve clinical care and the knowledge of healthcare professionals as concerns the risk factors and health determinants of individuals. One important factor towards introducing AI-based solutions in clinical settings is enhancing healthcare professionals' awareness and digital literacy. Key aspects of this direction are the improved usability, explainability, and transparency of the tools. Through a systematic assessment, the project evaluates the utilization of its AI-based solutions and explores its impact in five different use cases to unveil improved and more personalized approaches to the early detection and risk identification diagnosis and treatment of disease. Key findings of this impact assessment approach are that after utilising the DSS, 81% of the clinical experts participating in the project reported a better understanding of key risks and underlying factors through its (near) real-time delivery and monitoring mechanisms.

One of the key reasons for this high acceptance is the integration of the project's DSS with powerful and adaptive AI models that are integrated with improved eXplainable AI (XAI) techniques, producing user-friendly explainable dashboards. Improved explainability and interpretability of the final results of the AI systems are crucial in the healthcare domain in order for the AI decision support systems to act as valuable tools and assistants for healthcare professionals. Considering clinical interoperability through the use of clinical annotations and concepts enhances the integration of AI models within existing healthcare systems, making them more user-friendly and better interpreted by clinicians. In the context of the project, this is translated into 78% of the participating clinicians who reported that the AI systems provide clear, understandable explanations of how decisions are made, enhancing their trust and confidence in the systems.

Moreover, another key outcome is the improved user engagement and monitoring that has been achieved through the integration of the DSS with the project's wearables, mobile application and Virtual Coach. The latter is supported by two different outcomes. On one hand the 80% of the healthcare professionals have reported that the iHELP AI-based DSS replaced many of their time-consuming tasks of communication, monitoring, and follow-up of their participants. While at the same time, 90% of the participants reported that their behavioural habits and everyday activities were closely monitored and timely reminders were sent to them when they had not completed certain activities recommended by their healthcare professionals. These alerts/reminders were reported as very useful towards achieving their goals, fostering behavioural change and healthier habits and improving their Quality of Life (QoL). On top of this, about 70% reported that the iHELP project has made an impact on health behavior overall and a 72% responded that the project increased their knowledge on ways to change their health habits. Finally, the participants in two specific pilot studies reported that almost 90% of their responses, in the context of questionnaires related to their QoL, have been provided because of these reminders. The latter showcases improvement on the provision of patient reported outcomes and relevant information (e.g., sleep quality, pain scales etc.), as well as a wider adoption of the AI-based solutions and a greater adherence to their utilization.

Another key proposition of the project is that it facilitates the integration, harmonization, and management of different data sources, including biobanks, cohorts, medical records, longitudinal observational studies, real-world data about patients, as well of alternative data sources, such as IoT, sensors, wearables and mobiles in a standardized structure called HHRs. The latter is supported by a 71% of the clinical experts reporting usefulness and effectiveness of iHELP integrated HHR solution on the cancer research. At this point, it should be noted these integrated data are coded based on the HL7 FHIR format leading to improved interoperability with other systems and compliance of the data models in a harmonized format.

Finally, in alignment with the previous presented endeavour and use case, i.e., DeepHealth, also the iHELP project has publicly published an open-source synthetic dataset that has been synthesized from primary and secondary data collected during the implementation of one of its pilots and the corresponding pancreatic cancer program. In addition, the project has created a pancreatic-specific ontology that if foreseen to be made also available in the research and healthcare communities until the end of 2024 fostering the wider exploitation of its outcomes.

7. Strategies for Implementation and Scale

The wider adoption of AI is hindered by some associated risks preventing the full trust by its users. In particular, the main associated risks are variegated but can be summarised as follow.

- **Lack of transparency and trust:** lack of understanding and trust in AI,
- **AI algorithms errors due to for example:** data shift between AI training data and real-world data, unexpected variations in clinical contexts and environments,
- **Privacy and security issue:** risk of data being exposed, shared without any consent, re-purposing, etc.,
- **Misuse of medical AI tools:** lack of training, lack of digital literacy among patients, etc.,
- **Gaps in AI accountability:** Legal gaps in current regulations, lack of ethical and legal governance for AI,
- **Obstacles in AI's implementation into real-world healthcare:** limited data quality, lack of clinical & technical integration and interoperability of AI with existing clinical workflows.

Various strategies could be implemented in order to smooth these risks and to favour the trust toward AI and to support its impact assurance.

In particular, what is relevant is to start from the needs and to analyse a possible solution in terms of: feasibility, available resources, acceptance from users' standpoint, management and sustainability elements.

In accordance to a **Responsible Research in Health (RRH)** approach, a concrete strategy to support implementation, sustainability and scale up of AI and Edge Computing based technology in the healthcare domain should be based on the constitution of a collaborative endeavour wherein stakeholders are committed to clarify and meet a set of ethical, economic, social and environmental principles, values and requirements when they design, finance, produce, distribute, use and discard sociotechnical solutions to address the needs and challenges of health systems in a sustainable way. According to this, collaboration among different stakeholders (e.g. investors, technology developers, providers, managers and users of health services, regulators, policy-makers, etc.) is fundamental overcome some innovation adoption barriers such as users' lack of trust. Collaboration among these groups is certainly fraught with tensions because dominant settings of research, production and sale are not necessarily aligned with all of the many settings of adoption, adaptation and use of health innovations. Nevertheless, collaboration is essential not only from a normative procedural standpoint, but also because the development of innovations must tap into the complementary (and at times conflicting) expertise, know-how and experience these stakeholders possess as they handle different aspects of health innovations (e.g. financing, design, production, regulation, reimbursement, use, etc.).

Table below reports the key values and key attributes that should be considered when an innovative solution is developed in the healthcare domain in order to support its sustainability and replicability potential.

Value domain	Attribute
Population Health	**Health relevance**: Does the innovation address a relevant health problem? **Ethical, legal, and social issues**: Was the innovation developed by seeking to mitigate its ethical, legal or social issues? **Health equity**: In what ways does the innovation promote health equity?
Health System	**Health relevance**: Does the innovation address a relevant health problem? **Ethical, legal, and social issues**: Was the innovation developed by seeking to mitigate its ethical, legal or social issues? **Health equity**: In what ways does the innovation promote health equity?
Economic	**Frugality**: Does the innovation deliver greater value to more people using fewer resources?
Organizational	**Business model**: Does the organization that produces the innovation seek to provide more value to users, purchasers, and society?
Environmental	**Eco-responsibility**: Does the innovation limit its negative environmental impacts throughout its lifecycle as much as possible?

Table 1: The key values and attributes considered when an innovative solution is developed in healthcare

In healthcare systems v, various stakeholders must be involved in innovative services, solutions, and development to support their sustainability and replicability in the medium and long run. RIH provides them with a novel lens to examine the value different innovations may bring to health systems, and it opens up new managerial avenues to better harness innovation towards sustainable health systems.

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About AIOTI

AIOTI is the multi-stakeholder platform for stimulating AI, IoT and Edge Continuum Innovation in Europe, bringing together small and large companies, academia, researchers, policy makers, end-users and representatives of society in an end-to-end approach. We strive to leverage, share and promote best practices in the AI, IoT and Edge Continuum ecosystems, be a one-stop point of information to our members while proactively addressing key issues and roadblocks for economic growth, acceptance and adoption of the AI, IoT and Edge Continuum Innovation in society. AIOTI contributions go beyond technology and address horizontal elements across application domains, such as matchmaking and stimulating cooperation by creating joint research roadmaps, defining policies and driving the convergence of standards and interoperability.