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Alliance for AI, IoT and Edge Continuum Innovation

The Role of remote monitoring sensors in health and well-being

Release 1.0

AIOTI WG Health

23 July 2025

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Executive Summary

In a world where healthcare is evolving from reactive treatment to proactive prevention, remote monitoring sensors are quietly revolutionising how we care for ourselves and others. These small, often wearable devices, equipped with cutting-edge sensors and enhanced by artificial intelligence (AI), are enabling a new era of health and well-being—one defined by continuous, personalised, and data-driven care.

From monitoring chronic conditions at home to predicting falls in elderly patients, these technologies offer real-time insights that empower individuals and caregivers alike. They are reshaping healthcare delivery, making it more accessible, adaptive, and intelligent. Elderly individuals can live more independently, patients recovering from surgery can be monitored from the comfort of home, and healthcare professionals can make better-informed decisions with real-time data at their fingertips.

This transformation is not happening in isolation. Across Europe, a tapestry of collaborative initiatives—such as ACTIVAGE, SHAPES, StrokeBack, and ENACT—are weaving together technology, clinical expertise, and user-centred design to ensure that these innovations are not only effective but also equitable and scalable. Meanwhile, European regulatory frameworks like the GDPR and the upcoming AI Act are setting the stage for responsible and ethical deployment of these systems.

However, this bright future comes with challenges. Questions of data privacy, technological readiness, and equitable access must be answered with as much ingenuity and urgency as the technologies themselves. But the promise is clear: remote monitoring sensors are not just tools—they are enablers of a healthier, more connected society where health and well-being are continuously supported, regardless of place, age, or ability.

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Introduction

Objectives

State-of-the-Art

Remote monitoring sensors have become pivotal in advancing healthcare and enhancing well-being by enabling continuous, real-time tracking of physiological and environmental parameters. These technologies facilitate early detection of medical conditions, personalized health interventions, and improved management of chronic diseases. Promoting inclusivity for aging populations requires the implementation of integrated service models. These models should address the development of both accessible physical and digital infrastructures, the provision of personalized support services, and the cultivation of societal attitudes that embrace diversity and individual needs. A number of initiatives across Europe have played a crucial role in driving progress toward these aims. Among them, the FIWARE platform has been pivotal in enabling the development of adaptable smart applications, applicable in areas such as urban planning and healthcare services. Similarly, the UniversAAL project offered an open-source framework that supported the creation of interoperable digital solutions to enhance elderly care and promote independent living. Recent advancements include the ACTIVAGE (GA N. 732679) project, which employed Internet of Things (IoT) technologies to build intelligent environments that help older adults maintain autonomy and enhance their well-being. Meanwhile, PlatformUptake.eu (2022 - GA N. 875452) focused on evaluating and encouraging the broad adoption of open service platforms in Europe, by conducting comprehensive assessments and establishing mechanisms to track platform usage and impact. Additionally, the Activage Association (https://activage-association.org/) works to support the broader implementation and scaling of solutions that encourage healthy and active living across all age groups in Europe. Another key actor, the European Association for Social Innovation, fosters collaborative networks that champion social innovation and the pursuit of creative solutions to societal challenges. Through cross-sector partnerships and a commitment to accessibility, these projects collectively aim to remove systemic barriers, allowing people with developmental challenges, autism, and older adults to engage fully in society—both through inclusive environments and technological innovation.

Wearable Health Monitoring Devices

Wearable devices equipped with various sensors can monitor and record real-time information about an individual's physiological condition and motion activities. These devices may include flexible sensors integrated into textiles, clothing, or elastic bands, or they may be directly attached to the human body. They are capable of measuring physiological signs such as electrocardiogram (ECG), electromyogram (EMG), heart rate (HR), body temperature, electrodermal activity (EDA), arterial oxygen saturation (SpO_2), blood pressure (BP), and respiration rate (RR). Additionally, micro-electro-mechanical system (MEMS)-based miniature motion sensors like accelerometers, gyroscopes, and magnetic field sensors are widely used for measuring activity-related signals.

Continuous monitoring of these physiological signals can aid in detecting and diagnosing various cardiovascular, neurological, and pulmonary diseases at their early onset. Real-time monitoring of motion activities is also useful in fall detection, gait and posture analysis, and sleep assessment.

These wearable health monitoring systems typically consist of electronic and MEMS sensors, actuators, wireless communication modules, and signal processing units. The data collected by sensors connected in a wireless Body Sensor Network (BSN) are transmitted to a nearby processing node using suitable communication protocols, such as Bluetooth, ZigBee, ANT, or Near Field Communications (NFC).

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The processing node, which could be a smartphone, computer, or custom-made module, runs advanced processing, analysis, and decision algorithms, and may also store and display the results to the user. It transmits the measured data over the internet to healthcare personnel, thus functioning as a gateway to remote healthcare facilities.

Advancements in Wearable Sensor Technology

Recent advancements in wearable sensor technology have led to the development of innovative devices aimed at improving health monitoring and disease management. For instance, researchers have developed washable smart garments capable of monitoring sleep disorders at home by incorporating fabric sensors that detect skin movements to monitor breathing, identifying various sleep states, including types of apnea and snoring, with high accuracy.

Integration with Artificial Intelligence

The integration of artificial intelligence (AI) with wearable sensors has further enhanced remote monitoring capabilities. In elderly care settings, AI-powered devices can predict falls, adjust air quality, and detect pain in dementia patients by analysing data from sensors that monitor residents' activities.

Conclusions

In conclusion, remote monitoring sensors represent a transformative approach in healthcare, offering continuous, real-time insights into individuals' health and well-being. As technology advances and integration with AI continues to evolve, these devices hold the potential to significantly enhance personalised healthcare, early intervention, and the management of chronic conditions.

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1. Opportunities and challenges

Despite the significant advancements, challenges remain in the widespread adoption of remote monitoring sensors. Issues such as data privacy, the need for consistent internet access, and the potential reduction of human interaction in care settings must be addressed. Additionally, the accuracy of wearable devices in unsupervised, real-world environments can be affected by variability in movement patterns and sensor noise, indicating the need for further optimization and validation.

Remote monitoring sensors have emerged as pivotal tools in enhancing health and well-being, particularly in the contexts of elderly care, home-based health management, and understanding the interplay between environmental factors and personal health. These technologies offer significant opportunities but also present notable challenges that warrant careful consideration.

1.1 Opportunities

The integration of remote monitoring sensors in elderly care facilitates continuous health assessment, enabling early detection of potential health issues and promoting independent living. Smart home health technologies, including wearable devices and ambient sensors, have been developed to monitor activities of daily living, cognitive functions, and physiological parameters in older adults. A systematic review highlighted that these technologies are instrumental in tracking conditions such as cognitive decline and heart diseases, thereby supporting aging in place for seniors with complex health needs.

For individuals managing chronic illnesses or recovering from medical procedures, remote monitoring sensors provide a means to track vital signs and health metrics within the comfort of their homes. This continuous data collection allows healthcare providers to tailor interventions promptly, potentially reducing hospital readmissions and improving patient outcomes. The COVID-19 pandemic has further accelerated the adoption of these technologies, emphasizing their role in delivering healthcare remotely.

Remote sensors also play a crucial role in assessing environmental factors that impact health and well-being. For instance, a study utilizing satellite data revealed elevated ammonia pollution levels from industrial swine facilities, disproportionately affecting communities of color in North Carolina. This underscores the potential of remote sensing technologies in identifying environmental health risks and informing public health interventions.

1.2 Challenges

1.2.2 Privacy and Ethical Concerns

The deployment of sensors for remote monitoring raises significant privacy issues, particularly regarding the collection and use of personal health data. Research involving semi-structured interviews with older adults and caregivers identified concerns across multiple dimensions of privacy, including physical, psychological, social, and informational aspects. Participants expressed apprehension about data misuse and the intrusive nature of constant monitoring, highlighting the need for stringent data protection measures and ethical guidelines.

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1.2.2 Technological Readiness and Adoption

Despite the potential benefits, the readiness level of remote health monitoring technologies remains relatively low. A systematic literature review indicated that while these technologies are promising, their adoption is hindered by factors such as user resistance, technical complexity, and lack of standardized protocols.

1.2.3 Equity and Accessibility

The implementation of remote monitoring technologies must address issues of accessibility and equity. Technological solutions should be designed to accommodate diverse populations, including those with limited technological literacy or access. Moreover, there is a risk that reliance on technology could reduce human interaction in caregiving, potentially impacting the quality of care. For instance, while AI-powered devices in care homes can predict falls and detect health issues, concerns have been raised about the reduction of human touch and the potential for technology malfunctions.

1.3 Conclusions

In conclusion, while remote monitoring sensors offer transformative opportunities in health and well-being, particularly for elderly individuals and home-based care, it is imperative to address the associated challenges. Ensuring privacy, enhancing technological readiness, and promoting equitable access are critical to the successful integration of these technologies into healthcare systems.

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2. Impact on users

The advent of remote monitoring sensors has revolutionized healthcare by significantly enhancing patient outcomes, operational efficiency, and preventive care strategies. These technologies, which leverage sensors to collect real-time physiological and environmental data, have proven indispensable for various stakeholders, including patients, healthcare providers, policymakers, and technology developers. Their impact extends beyond immediate clinical applications, influencing public health strategies, economic sustainability, and the broader societal approach to well-being.

The deployment of remote monitoring technologies affects a wide range of actors, including patients, caregivers, healthcare providers, insurers, policymakers, technology developers, and researchers. Indeed, the multifaceted impact of these systems spans from improving patient well-being to reshaping healthcare financing and influencing regulatory frameworks.

For patients, the impact of remote monitoring sensors is profound, as these devices enable continuous health tracking, early disease detection, and personalized care management. The ability to monitor physiological parameters such as heart rate, glucose levels, and oxygen saturation in real time reduces uncertainty and empowers individuals to take proactive steps toward managing their health (Dinesen et al. 2016, 200–202. https://doi.org/10.1177/1357633X15626884). This is particularly beneficial for patients with chronic illnesses, who often face the challenge of maintaining stable health conditions while minimizing hospital visits. Moreover, remote monitoring enhances adherence to treatment regimens by providing automated reminders and feedback, fostering greater patient engagement. However, challenges such as digital literacy, accessibility, and the psychological impact of continuous monitoring must be considered. Some patients may experience anxiety related to constant health tracking, while others may struggle to interpret the data without proper medical guidance.

For caregivers, particularly family members of elderly or chronically ill individuals, remote monitoring technologies serve as a crucial support system. These systems alleviate the burden of caregiving by providing real-time alerts and facilitating early interventions. For example, fall detection sensors and wearable ECG monitors can notify caregivers instantly in the event of an emergency, reducing response time and potentially preventing severe health deterioration. This not only improves patient safety but also provides peace of mind for caregivers, many of whom experience significant emotional and physical stress. However, the integration of such technologies into caregiving routines requires adequate training and support to ensure effective use.

For healthcare providers, including doctors, nurses, and allied health professionals, remote monitoring sensors significantly enhance clinical decision-making by offering continuous and real-time health data. These technologies shift healthcare from a reactive to a proactive model, where interventions can be implemented before conditions worsen. Predictive analytics, powered by artificial intelligence, enable clinicians to anticipate complications and optimize treatment plans (Garg et al. 2022, 143-145. https://doi.org/10.1007/s10198-022-01400-9). Additionally, remote monitoring helps in managing hospital resources more efficiently by reducing unnecessary visits and hospitalizations. However, challenges such as data overload, interoperability issues, and concerns regarding liability and accountability in remote care must be addressed. Physicians must be trained to interpret continuous data streams, and clear protocols should be established to determine when remote alerts warrant clinical intervention.

For insurers and healthcare payers, remote monitoring sensors offer a significant opportunity to improve cost-efficiency in healthcare systems. By enabling preventive care and reducing hospital admissions, these technologies help lower healthcare expenditures. Insurance companies are increasingly adopting value-based reimbursement models that incentivize the use of digital health solutions to improve patient outcomes.

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The ability to track patient health metrics in real time allows insurers to develop personalized health plans, adjusting premiums based on an individual's health status and adherence to recommended lifestyle changes (European Commission 2020, 5-7. https://doi.org/10.2777/63549). However, these benefits must be balanced with concerns regarding data privacy, potential discrimination based on health data, and the need for regulatory safeguards to ensure ethical use of patient information.

For policymakers and public health institutions, the large-scale implementation of remote monitoring technologies presents both opportunities and challenges. On the one hand, these systems contribute to population health management by enabling early detection of epidemics, chronic disease tracking, and health trend analysis at the community level. Governments and public health agencies can use aggregated health data to develop targeted interventions, allocate resources more effectively, and implement evidence-based policies. On the other hand, regulatory frameworks must be continuously updated to address data security, interoperability, and equitable access to technology. The European Union's approach to digital health, which includes regulatory measures such as the General Data Protection Regulation (GDPR), serves as an example of how policymakers are navigating these challenges while promoting innovation in health technology.

For technology developers and industry stakeholders, the rise of remote monitoring presents significant business opportunities and technical challenges. The success of these systems depends on the development of reliable, accurate, and user-friendly devices that integrate seamlessly with existing healthcare infrastructures. Innovations in wearable technology, artificial intelligence, and big data analytics are driving advancements in remote monitoring capabilities (Channa et al. 2021, 600-603. https://doi.org/10.1109/JBHI.2020.3014772). However, industry stakeholders must also address regulatory compliance, cybersecurity risks, and ethical considerations related to data ownership. The integration of blockchain technology, for instance, is being explored as a means to enhance data security and transparency in remote monitoring applications.

For researchers and academia, remote monitoring technologies open new avenues for studying patient behavior, treatment efficacy, and health interventions in real-world settings. Unlike traditional clinical trials, which often rely on controlled environments, remote monitoring allows researchers to collect longitudinal health data from diverse populations. This has significant implications for epidemiological research, precision medicine, and the development of personalized treatment approaches. However, ethical concerns regarding informed consent, data anonymity, and potential biases in data collection must be rigorously addressed.

But how it is really possible to assess the impact of remote monitoring on this pletora of heterogeneous stakeholders? In the socio and healthcare area there are different frameworks for accomplishing with such goal, such as the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) model providing a comprehensive method for measuring the effectiveness of health interventions in real-world settings thus ensuring that not only clinical efficacy but also patient engagement, scalability, and long-term sustainability are considered in the assessment process (Glasgow et al. 2019, 15-18. https://doi.org/10.1007/s13142-019-00479-0).

Additionally, the Health Technology Assessment (HTA) framework is often employed to evaluate cost-effectiveness, usability, and broader societal benefits of remote monitoring solutions. These evaluations consider direct and indirect economic impacts, ensuring that such technologies are both viable and beneficial for national healthcare systems.

A pertinent example of impact assessment in this domain is the Pharaon Horizon 2020 project, which focuses on integrating digital solutions to support aging populations.

From a methodological perspective, Pharaon adopts a multi-layered evaluation strategy that combines qualitative and quantitative analyses to measure both technological performance and user experience. The project emphasizes co-creation with end-users, ensuring that remote

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monitoring solutions align with the actual needs of older adults and caregivers. The impact assessment framework employed by Pharaon incorporates health-related quality of life indicators, cost-benefit analysis, and usability studies to generate a holistic understanding of these technologies' societal and economic benefits (Pharaon Consortium 2022, 10-12. https://doi.org/10.5281/zenodo.7316245).

Pharaon implements its impact assessment by deploying a structured mixed-methods approach that integrates real-world evidence from pilot studies with standardized impact measurement tools. These include validated clinical outcome metrics, user satisfaction surveys, and economic modelling to assess cost-effectiveness. The project also utilizes longitudinal data collection to track changes in patient well-being and healthcare resource utilization over time. By employing a participatory evaluation model, Pharaon ensures that insights from multiple stakeholders, including patients, caregivers, healthcare professionals, and policymakers, are incorporated into its assessment framework.

Additionally, Pharaon utilizes Social Return on Investment (SROI) analysis to quantify the broader social benefits of remote monitoring adoption. This method allows for an in-depth understanding of how digital health interventions contribute to economic sustainability by reducing hospitalization rates, enabling independent living for older adults, and improving caregivers' quality of life. The integration of key performance indicators (KPIs) specific to digital health interventions ensures that Pharaon's impact assessment remains adaptable to evolving healthcare needs.

Moreover, Pharaon aligns its evaluation methodologies with European regulatory frameworks and ethical guidelines, ensuring that data privacy and security concerns are addressed while maintaining transparency in reporting findings. By disseminating its impact assessment results through academic publications, policy recommendations, and stakeholder workshops, Pharaon plays a crucial role in shaping future best practices for evaluating remote monitoring technologies.

Ultimately, the role of remote monitoring sensors in health and well-being is transformative, bridging the gap between clinical environments and everyday life. Their impact spans multiple stakeholders, addressing fundamental needs such as accessibility, efficiency, and personalized care. The integration of rigorous evaluation frameworks ensures that these technologies not only meet current healthcare demands but also contribute to the evolution of future health systems in a sustainable and ethical manner. As the healthcare landscape continues to evolve, remote monitoring technologies will remain a cornerstone of digital health, fostering a paradigm shift toward more patient-cantered, data-driven, and efficient healthcare delivery.

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3. Regulations, Standardisation and Interoperability

Regulations

Recent European legislative frameworks, notably the General Data Protection Regulation (GDPR, 2024) and the forthcoming Artificial Intelligence Act (AI Act), carry substantial consequences for initiatives that involve older adults or other vulnerable populations. The GDPR serves as the cornerstone of personal data protection in the EU, mandating rigorous standards for any organization that gathers, uses, or retains personal data, particularly when dealing with sensitive information related to at-risk individuals. The AI Act, nearing full legislative adoption, introduces the first overarching legal structure in the EU to govern artificial intelligence technologies. It categorizes AI applications according to risk levels, enforcing strict requirements for systems identified as "high-risk," especially when their deployment could affect fundamental rights. This is especially relevant for technologies aimed at individuals with disabilities or the elderly. Identifying and involving all relevant stakeholders early in the planning and implementation phases of such projects is vital. Doing so not only ensures compliance with legal standards like the GDPR and AI Act but also supports the ethical development of technologies, improves service relevance, and helps mitigate potential harms. Engaging diverse stakeholders, including end users, caregivers, and data protection experts, enhances project accountability and ensures that the solutions developed are transparent, respectful, and genuinely aligned with user needs. An often-underestimated aspect of these regulatory efforts lies in the distinction between legal definitions of privacy and how privacy is experienced or perceived by users. While GDPR provides a robust legal framework aimed at securing personal information and upholding citizens' rights, individual perceptions of privacy can diverge markedly due to cultural, psychological, or cognitive factors. For instance, in Active and Healthy Ageing (AHA) projects that involve surveillance systems or wearable technologies, even when full regulatory compliance is achieved, users may still feel uneasy or mistrustful. This disconnect can lead to reluctance in participation or reduced data quality. Factors such as unfamiliarity with the technologies, varying attitudes toward consent, and levels of trust in digital systems all contribute to a mismatch between regulatory intentions and user perceptions. Understanding and addressing this gap is crucial for the successful adoption of innovative health and care solutions.

Standardisation and Interoperability

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 [1]

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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) [1]

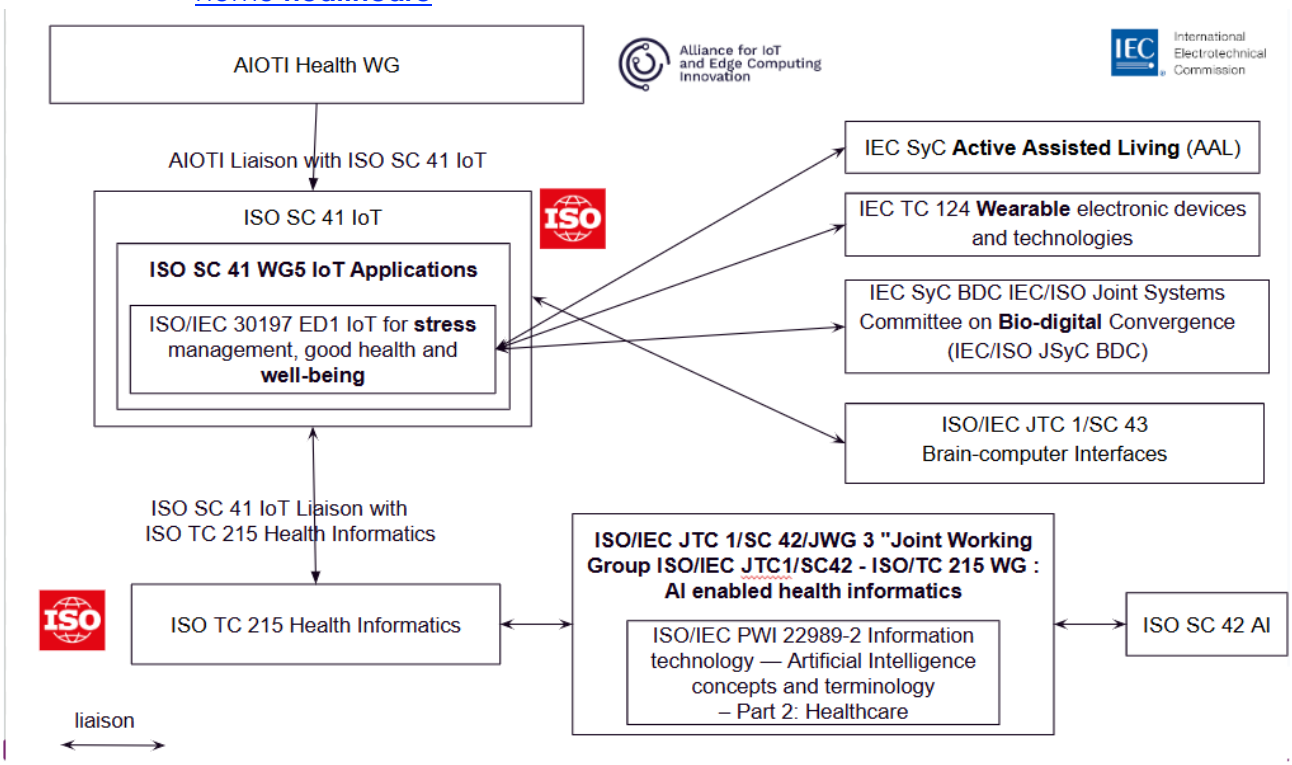
[1] Synergies Among Health Data Projects with Cancer Use Cases based on Health Standards. Stud Health Technol Inform. Gyrard A, Gribbon P, Hussein R, Abedian S, Bonmati LM, Cabornero GL, et al. In: Medical Informatics Europe 2024 (MIE 2024). In press. https://ebooks.iospress.nl/doi/10.3233/SHTI240649

Ongoing standards for well-being and home healthcare:

1. **ISO SC41 IoT WG5 IoT Applications**

   ISO/IEC 30197 ED1 Internet of Things (IoT) - IoT for **stress** management, good health and **well-being**

   ISO/IEC TR 30123 ED1 - Internet of Things (IoT) - Guidance on IoT application to home **healthcare**



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The adoption of the European Health Data Space (EHDS) regulation has made integrating health data critical for both primary and secondary applications. Primary use cases include patient diagnosis, prognosis, and treatment, while secondary applications support research, innovation, and regulatory decision-making. Additionally, leveraging large datasets improves training quality for artificial intelligence (AI) models, particularly in cancer prevention, prediction, and treatment personalization. The European Union (EU) has recently funded multiple projects under Europe's Beating Cancer Plan. However, these projects face challenges related to fragmentation and the lack of standardization in metadata, data storage, access, and processing. [Gyrard et al. JMIR 2025] examine interoperability standards used in six EU-funded cancer-related projects: IDERHA (Integration of Heterogeneous Data and Evidence Towards Regulatory and Health Technology Assessments Acceptance), EUCAIM (European Cancer Imaging Initiative), ASCAPE (Artificial Intelligence Supporting Cancer Patients Across Europe), iHelp, BigPicture, and the HealthData@EU pilot. These initiatives aim to enhance the analysis of heterogeneous health data while aligning with EHDS implementation, specifically for the EHDS for the secondary use of data (EHDS2). Between October 2023 and July 2024, we organized meetings and workshops among these projects to assess how they adopt health standards and apply Internet of Things (IoT) semantic interoperability. The discussions focused on interoperability standards for health data, knowledge graphs, the data quality framework, patient-generated health data, AI reasoning, federated approaches, security, and privacy. Based on our findings, we developed a template for designing the EHDS2 interoperability framework in alignment with the new European Interoperability Framework (EIF) and EHDS governance standards. This template maps EHDS2-recommended standards to the EIF model and principles, linking the proposed EHDS2 data quality framework to relevant International Organization for Standardization (ISO) standards. Using this template, we analysed and compared how the recommended EHDS2 standards were implemented across the studied projects. During workshops, project teams shared insights on overcoming interoperability challenges and their innovative approaches to bridging gaps in standardization.

With support from HSbooster.eu, we facilitated collaboration among these projects to exchange knowledge on standards, legal implementation, project sustainability, and harmonization with EHDS2. The findings from this work, including the created template and lessons learned, will be compiled into an interactive toolkit for the EHDS2 interoperability framework. This toolkit will help existing and future projects align with EHDS2 technical and legal requirements, serving as a foundation for a common EHDS2 interoperability framework. Additionally, standardization efforts include participation in the development of ISO/IEC 21823-3:2021—Semantic Interoperability for IoT Systems. Since no ISO standard currently exists for digital pathology and AI-based image analysis for medical diagnostics, the BigPicture project is contributing to ISO/PWI 24051-2, which focuses on digital pathology and AI-based, whole-slide image analysis. Integrating these efforts with ongoing ISO initiatives can enhance global standardization and facilitate widespread adoption across health care systems.

[Gyrard et al. JMIR 2025] Lessons Learned From European Health Data Projects With Cancer Use Cases: Implementation of Health Standards and Internet of Things Semantic Interoperability. Amelie Gyrard, Somayeh Abedian, Philip Gribbon, George Manias, Rick van Nuland, Kurt Zatloukal, Irina Emilia Nicolae, Gabriel Danciu, Septimiu Nechifor, Luis Marti-Bonmati, Pedro Mallol, Stefano Dalmiani, Serge Autexier, Mario Jendrossek, Ioannis Avramidis, Eva Garcia Alvarez, Petr Holub, Ignacio Blanquer, Anna Boden, Rada Hussein. Journal of Medical Internet Research (JMIR) 2025

The successful implementation of the European Health Data Space (EHDS) for the secondary use of data (known as EHDS2) hinges on overcoming significant challenges, including the proper implementation of interoperability standards, harmonization of diverse national approaches to data governance, and the integration of rapidly evolving AI technologies.

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We can these challenges by developing an interactive toolkit [Hussein et al. JMIR 2025] that leverages insights from 7 leading cancer research projects (Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance [IDERHA], European Federation for Cancer Images [EUCAIM], Artificial intelligence Supporting Cancer Patients across Europe [ASCAPE], Personalised Health Monitoring and Decision Support Based On Artificial Intelligence and Holistic Health Records [iHelp], Central repository for digital pathology [Bigpicture], Piloting an infrastructure for the secondary use of health data [HealthData@EU] pilot, and improving cancer diagnosis and prediction with AI and big data [INCISIVE]) to guide in shaping the EHDS2 interoperability framework. Building upon the foundations laid by the Towards the European Health Data Space (TEHDAS) joint action (JA) and the new European Interoperability Framework (EIF), the toolkit incorporates several key innovative features. First, it provides interactive and user-friendly entry modules to support European projects in creating their own interoperability frameworks aligned with the evolving EHDS2 requirements technical and governance requirements. Second, it guides projects in navigating the complex landscape of health data standards, emphasizing the need for a balanced approach to implementing the EHDS2 recommended standards for data discoverability and sharing. Third, the toolkit fosters collaboration and knowledge sharing among projects by enabling them to share their experiences and best practices in implementing standards and addressing interoperability challenges. Finally, the toolkit recognizes the dynamic nature of the EHDS2 and the evolving regulatory landscape, including the impact of AI regulations and related standards. This allows for continuous adaptation and improvement, ensuring the toolkit remains relevant and useful for future projects. In collaboration with HSbooster.eu, the toolkit will be disseminated to a wider audience of projects and experts, facilitating broader feedback and continuous improvement. This collaborative approach will foster harmonized standards implementation across projects that ultimately contribute to the development of a common EHDS2 interoperability framework.

[Hussein et al. JMIR 2025] Interoperability Framework of the European Health Data Space for the Secondary Use of Data: Interactive European Interoperability Framework–Based Standards Compliance Toolkit for AI-Driven Projects. Rada Hussein, Amelie Gyrard, Somayeh Abedian, Philip Gribbon, Sara Alabart Martínez. Journal of Medical Internet Research (JMIR) 2025

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4. Use cases/Examples

4.1 Remote Monitoring of Parkinson's Disease (Tyndall/UCC)

The growing field of wearable technology is transforming the remote monitoring of Parkinson's disease (PD), a neurodegenerative disorder affecting motor function and autonomic regulation. Tyndall/UCC focused on the development and evaluation of wearable sensor systems to continuously track PD symptoms in real-world settings, supporting objective assessment, treatment optimization, and clinical decision-making.

In the WESAA (Wearable Sensor-based Assessment and Analysis system) project, Tyndall/UCC introduced a novel multi-sensor wearable platform designed for the continuous home monitoring of PD symptoms[1]. The system consists of two compact devices worn on the wrist and ankle, integrating tri-axial accelerometers, gyroscopes, photoplethysmography (PPG), and electrocardiography (ECG) sensors. These sensors provide comprehensive physiological and motion data to assess:

- Motor symptoms (e.g., tremor, bradykinesia, dyskinesia)
- Gait abnormalities (e.g., gait speed, freezing of gait episodes)
- Sleep-wake cycles (for evaluating sleep disturbances in PD)
- Cuffless blood pressure monitoring (to assess autonomic dysfunction, such as orthostatic hypotension)

The project took into consideration system requirements, industrial design, ergonomics, user experience, and preliminary validation results, showing that the sensor data aligns with gold-standard techniques. Given PD's complex symptomatology, WESAA presents a promising tool for continuous symptom tracking, helping clinicians tailor treatment strategies and optimise medication timing based on real-world patient data.



In the same project, Tyndall/UCC investigated the feasibility of machine learning (ML) models trained on wearable sensor data from the WESAA device to classify PD motor symptoms such as tremor, bradykinesia, and dyskinesia[2].

The models were trained using data collected from scripted lab-based activities where participants performed predefined movements, with symptoms rated by clinicians using video recordings. The system achieved high accuracy in the lab:

[1] https://ieeexplore.ieee.org/abstract/document/10466549

[2] https://ieeexplore.ieee.org/abstract/document/10711881

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- Tremor detection: 83% accuracy
- Bradykinesia detection: 75% accuracy
- Dyskinesia detection: 81% accuracy

However, when the same models were tested on unscripted, at-home patient data, accuracy dropped significantly (to approximately 63%–67%) when compared to self-reported symptom diaries. This highlights the challenges of generalizing AI models trained in controlled conditions to real-world settings, where variability in movement patterns, sensor noise, and contextual differences impact performance. Additionally, ankle-worn sensors improved dyskinesia detection but did not provide significant advantages for tremor and bradykinesia assessment. These findings emphasize the need for further optimization of sensor placement and ML model adaptation to real-world environments.

Finally, Tyndall/UCC also focused on non-invasive blood pressure (BP) monitoring[3], addressing a lesser-known yet critical aspect of PD: autonomic dysfunction and blood pressure instability. Many PD patients experience orthostatic hypotension, leading to dizziness, fainting, and increased fall risk. Existing BP measurement methods rely on cuff-based devices, which are cumbersome and impractical for continuous monitoring. This research presents a cuffless BP monitoring solution using PPG and ECG signals, processed through a Random Forest machine learning model. Using a combination of data publicly available as well as new lab-recorded measurements from PD patients using the WESAA device, the model achieved a Mean Absolute Error (MAE) of 7.84 ± 8.12 mmHg (systolic BP) and MAE of 7.51 ± 6.16 mmHg (diastolic BP). These results meet clinical standards and suggest that integrating real-time BP monitoring into wearable PD management systems could significantly improve patient care. Since fluctuating BP symptoms can mimic dopaminergic deficiencies, real-time BP tracking can help distinguish between PD-related symptoms and cardiovascular issues, ultimately supporting better medication adjustments and reducing fall risk.

These studies underscore the transformative potential of wearable technology and AI-driven analytics in PD management. The WESAA system provides a holistic approach to remote symptom tracking, while ML-based symptom detection and non-invasive BP monitoring enhance real-time clinical assessments.

4.2 ACCRA EU Project (robots for ageing)

Social companion robots are getting more attention to assist elderly people to stay independent at home and to decrease their social isolation. When developing solutions, one remaining challenge is to design the right applications that are usable by **elderly people**. Co-creation methodologies involving multiple stakeholders and a multidisciplinary researcher team (e.g., **elderly people**, medical professionals, and computer scientists such as roboticists or **IoT engineers**) are designed within the ACCRA (Agile Co-Creation of Robots for Ageing) EU project (https://www.accra-project.org/en/sample-page/) (2016-2020).

How can Internet of Robotic Things (IoRT) technology and co-creation methodologies help to design emotional-based robotic applications? This is supported by the ACCRA project that develops advanced social robots to support active and healthy ageing, co-created by various stakeholders such as **ageing people** and physicians. We demonstrate this with three robots, Buddy, ASTRO, and RoboHon, used for daily life, mobility, and conversation.

The three robots understand and convey emotions in real-time using the **Internet of Things and Artificial Intelligence** technologies (e.g., knowledge-based reasoning). ACCRA project (robotics

[3] https://ieeexplore.ieee.org/abstract/document/10253995

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for Ageing). Knowledge Engineering Framework for IoT Robotics Applied to Smart Healthcare and Emotional Well-Being.

Amelie Gyrard, Kasia Tabeau, Laura Fiorini, Antonio Kung, Eloise Senges, Marleen De Mul, Francesco Giuliani, Delphine Lefebvre, Hiroshi Hoshino, Isabelle Fabbricotti, Daniele Sancarlo, Grazia D'Onofrio, Filippo Cavallo, Denis Guiot, Estibaliz Arzoz-Fernandez, Yasuo Okabe, Masahiko Tsukamoto. International Journal of Social Robotics 2021. Springer Nature.

4.3 ENACT EU Project[4] (Environmental Effect on Health Care and Wellbeing and Active Interventions)

Non-communicable diseases (NCDs) account for 80% of the disease burden as well as for most premature deaths in the EU; diminishing the citizens' quality of life, life expectancy and increasing the financial burden (from those affected to the health system). During the last 3 decades environmental stressors have been addressed through numerous studies, which have raised concerns about the detrimental effects of the environment on human health. Most evaluated environmental stressors are air temperature, particulate and gaseous air pollutants, urban noise, food pollutants and radiation. By end of 2022, air pollution was reported to be responsible of an excess mortality of 311.000 people per year in the UE-27[5], driving not only premature deaths but also an increased risk of NCDs such as vascular diseases (e.g., ischemic heart disease, stroke) and other non-vascular NCDs like chronic respiratory diseases or depression. Some newly considered stressors such as electromagnetic field, and light exposure are also implicated in human health (e.g., ocular and dermatological NCD diseases). For example, bright artificial light at night (particularly blue light emitted from electronic devices and outdoor lighting) is found to disrupt circadian rhythms, impact the natural sleep-wake cycle, and contribute to retinal damage and retinal degeneration[6]. Also, Ultraviolet (UV) radiation can damage DNA in cells, including in the retina, and lead to oxidative stress, inflammation, and cellular damage. UV radiation, especially UVB and UVA, can contribute to the production of free radicals and inflammation in the retina, potentially accelerating the progression of age-related macular degeneration. **Challenges and current limitations**: All these stressors share some common properties; all can promote both chronic and acute diseases and their health effects are related to the concentration of exposure, following a linear or a curvilinear dose-effect relationship. However, still several challenges need to be overcome for elucidating their role. In the case of fine particle pollutants or radiation for example, **there is no clear threshold of effect appearance**. In other cases, such as the ocular diseases, Ophthalmoscopy (Fundoscopy) and Optical Coherence Tomography (OCT) are the only ways to detect retinal damage only in progressive stage in a less invasive and more comfortable manner. However, current OCT devices and ophthalmoscopes are still invasive, and there have been concerns about their accuracy and cost. Similar is the case of dermatological diseases (biopsy and dermascopy still invasive). **Non-invasive measurement systems have not yet been achieved and there is a lack of representative data for Artificial Intelligence (AI) model training and retraining that address data security and privacy concerns**. In addition, even though the health effects of environment are well documented[7], the understanding of the effects of the environment on NCDs is limited and **a holistic and coordinated approach to prevention and care is still an underinvested area**[8]; this is potentially driven by several factors: i) most of the studies have focused on the effects of one single type of pollutant or stressor[9]. Consequently, the synergistic effects of exposure to multiple environmental stressors are

4 ENACT on Europa: https://cordis.europa.eu/project/id/101157151

5 Health impacts of air pollution in Europe, 2022, Web report, published 24 Nov 2022 - Last modified 13 Mar 2023. https://www.eea.europa.eu/publications/air-quality-in-europe-2022/health-impacts-of-air-pollution#:~:text=64%2C000%20premature%20deaths%20were%20attributable,above%2070%20%C2%B5g%2Fm3

6 Contin, M. A., Benedetto, M. M., Quinteros-Quintana, M. L., & Guido, M. E. (2016). Light pollution: the possible consequences of excessive illumination on retina. *Eye*, *30*(2), 255-263. https://pubmed.ncbi.nlm.nih.gov/26541085/

7 WHO, Compendium of WHO and other UN guidance on health and environment: version with International Classification of Health Intervention (ICHI) codes, ISBN 978-92-4-008806-1 2023

8 Chaudhry, Divya. "Environmental Pollutants and Climate Change: Mainstreaming the Discourse on Noncommunicable Diseases." *Sustainability and Climate Change* 17.1 (2024): 7-17.

9 Daiber, Andreas, et al. "The Exposome Concept: Description of Lifelong Environmental Exposure Effects on Metabolism, Health and Disease." *Environmental Stressors and OxInflammatory Tissues Responses*. CRC Press, 2024. 11-22.

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not enough addressed. ii) most of the scientific literature regarding the effects of air pollution and noise relies on a quantitative assessment, considering only the concentration of pollutants or the level of noise exposure[10]; iii) Very few studies have until now considered some possible predispositions to the effects of environment[11]; iv) there is still a lack of evidence on the environmental impact of the healthcare sector, and a lack of standard methods and reliable tools for collecting data on emissions, consumption, and waste generation. v) most technological tools for hospital management (e.g., patient workflow management, clinical engineering tools) do not account for analysing the environmental impact. vi) despite dedicated environmental policy interventions, their application is hampered by the lack of implementational protocols guiding healthcare decision-makers and operators in greening hospitals. While environmental management systems standards exist (e.g., ISO 14001:2015, ISO 14040:2016, etc), they are not compulsory for healthcare organizations. Overall, there is a global lack of communication and consensual approaches between experts in environmental sciences and policies and healthcare experts; and vii) Lastly, very few studies embodied a co-creation and a bottom-up approach capable of eliciting and understanding the real stakeholders' needs and expectations at their different levels to support a positive societal impact[12]. Currently, to reduce NCD risk main efforts are focused on achieving primary disease prevention. The current guidelines recommend the use of standardized risk estimation tools or calculators that are based on risk-scoring algorithms and estimate the 10-year risk of a first NCD event[13], enabling physicians to suggest lifestyle modifications to individuals at risk and guide preventive treatment. Although very beneficial, these **scoring tools suffer from several limitations,** the most important of which is their low sensitivity[14]. Another prime limitation of these tools is that the number of parameters they consider is very restricted. Most importantly, the current models are mainly directed at physicians and do not incorporate real-time data nor dynamic and/or interactive capabilities that could continuously assess NCD risk and inform both physicians/healthcare systems and individuals, or just individuals themselves, about their health risk.

10 Mahakalkar, Amruta Umakant, et al. "Geospatial analysis of short-term exposure to air pollution and risk of cardiovascular diseases and mortality–A systematic review." *Chemosphere* (2024): 141495.

11 Hahad, Omar, et al. "Supporting and implementing the beneficial parts of the exposome: The environment can be the problem, but it can also be the solution." *International journal of hygiene and environmental health* 255 (2024): 114290.

12 Draudviliene, Lina, et al. "Innovations strategy for moving from created regional clusters to co-creation in life sciences for health care and well-being ecosystems." *Environmental Science and Pollution Research* 28 (2021): 26215-26222.

13 https://pubmed.ncbi.nlm.nih.gov/34458905/

14 https://www.escardio.org/Journals/E-Journal-of-Cardiology-Practice/Volume-22/new-insights-in-cardiovascular-risk-estimation-and-stratification

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Hence, there is a pressing need to critically analyse environmental parameters and their influence on well-being, by addressing in a coupled manner their short-term and long-term effects on health, using cutting-edge strategies and techniques, and involving from the outset all levels of key stakeholders. As presented in detail in the following, the ENACT proposal has been designed to respond to these challenges looking at, firstly, complex interactions between pollutants and causalities acting at both the population and individual level, and secondly the link with individual medical and socioeconomic vulnerabilities. ENACT will use risk modelling based on the risk of hospitalization for acute states of NCDs while linking it with the environmental events, to capture through time how pollutants and environment affect important NCD states that need intervention.

The overall objective of ENACT is twofold: first, to derive a model assessing the exposomic risk (risk score based on poli-environmental exposures) of hospitalization for acute vascular and non-vascular NCD across different populations and locales; second, to translate this risk from population to the individual level, predicting the risk of developing preclinical asymptomatic stages of disease. For this purpose, ENACT will develop fine scale spatiotemporal resolution data for environment and spatial factors linked with NCDs, delivering relevant and actionable information (pre-clinical markers) to allow the creation of non-invasive predictive AI-driven tools that support monitoring and prevention. ENACT will build a suite of services constituting a privacy-preserving platform using Federated and Distributed Ledger (DLT) Technologies. This will allow ENACT to overcome the data sharing barrier, enabling cross-border training of AI and data mining models over **an innovative, very large exposomic dataset**. The predictive score of the exposomic risk of different health NCD conditions**,** advanced analytics as well as decision making/recommendation and visualization tools will be integrated in the platform as a suite of services to **serve citizens/patients, city planners, public-health responders, EU, national and regional policymakers, clinicians, and hospitals,** for supporting predictive non-invasive approaches for NCD prevention and management. This will be performed at the **clinical and healthcare level** (supporting monitoring and thereby enabling clinicians to reduce NCD burden, while at the same time reducing the financial burden of hospitalization) **as well as at the prevention policy making and city planning guidelines level** (developing and validating new AI-based risk screening tools and providing **combined guidelines for environment, city planners and/or healthcare NCD policymaking).**

ENACT aims to implement a multisite randomized clinical study for validating an exposomic risk of hospitalisation for acute vascular and non-vascular diseases and development of pre-clinical markers of cerebral, respiratory and cardiovascular dysfunctions (ENACT validation study). The ENACT's multisite overall pilot aims at involving 10.000 users through 5 pilots in 5 EU countries (Belgium, Bulgaria, Ireland, Italy and Spain) comprising hospitals and cities (Similar protocol used for building the Belgium retrospective data). The study aims to go during two (2) years at the project's piloting phase, and to be extended to 4 years after the project end to support long-term data impact, further engaging new hospitals. The initial model coming from retrospective data, mapped to the baseline prevalence of the considered disease and pilot countries, linked with environmental data, will enable the predictive score of the exposomic risk (risk score based on poli-environmental exposures) of different health conditions driven framework for acute NCD vascular and non-vascular diseases. The validation prospective approach will validate and affine this model to predict earlier stages of the disease in a multisite prospective deployment focusing both on hospital admission rate, but also on underlying disease progression. Tech objective: validate at cross-pilot level the suite of service platform that operationalizes the exposomic risk calculator to be used as predictive non-invasive tool by clinicians, city planners and policy makers; as well as to evaluate a new generation of integrated and connected portable monitoring systems that can simultaneously assess exposure to noise, air and light pollution 24/7 and a continuous assessment of autonomic mediated variability of heart rate, respiratory rate and blood pressure.

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4.4 SHAPES EU Project[15] (Smart and Healthy Ageing through People Engaging in Supportive Systems)

The development of basic personas and general use cases including scenarios has been in accordance with the SHAPES strategic objectives: to build and deliver the innovative European-led SHAPES Platform, providing a broad range of interoperable solutions to improve the health, well-being and independence of older individuals, while enhancing the long-term sustainability of H&C systems in the EU. The development of basic personas and general use cases including scenarios is the first step towards the fulfilment of this goal since the targeting of the user´s attributes, attitudes, behaviours and characteristics prepare a suitable background for the subsequent identification of best practices focused on the elimination of psychological and physical effects of isolation, and loneliness in the elderly.

Furthermore, the development of basic personas and general use cases including scenarios also support the fulfilment of the objective to create, enlarge and consolidate the SHAPES Ecosystem for active and healthy ageing allowing stakeholders to exchange knowledge and expertise, identify current and future solutions for active and healthy ageing, provide mutual advice, training and support and exploit the collective knowledge for social and commercial purposes. The development of basic personas and general use cases is important also for another objective to promote the adoption of standards in the EU field of integrated care of older individuals, and the identification of standardization priorities to facilitate the deployment of open and interoperable Platforms.

Finally, 13 different general use cases have been developed. These general use cases are aimed to illustrate the breadth and variability of the technology used for the improvements of the quality of life of older adults, rather than specific use cases developed for designing concrete digital solutions (this will be done in subsequent stages of the SHAPES project, however). Thus, the final set of general use cases include:

- Assistive Technology for Reading
- Self-Management of Chronic Conditions
- Home Environment Monitoring
- In-Home Cognitive Training
- In-Home Glucose-Monitoring
- In-Home Self-Management Heart-Monitoring
- In-Home Post-Hospital Aftercare
- In-Home Video-Monitoring
- Location Tracking
- Meal Ordering
- Medication Reminder
- Motor Exercising with Robot
- Summarizer of Information from Internet

[15] SHAPES portal: https://shapes2020.eu

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How to understand personas and use cases in user experience design?

Persona, known also as "user persona", is a detailed description of a fictional person (often a composite of real individuals) used to communicate the key motivations, concerns, and interests of a user group (Bhattacharyya et al., 2019). Personas include fictitious characters described in narrative form in order to help solve design questions. Personas enable designers to better focus on primary users, especially on their behavioural patterns and user needs (Huh et al., 2016) and are widely used in system design organizations as a complement to individual or other user data. They provide a basic prototype of persons/users for the interaction of an individual with a product/digital solution.

A **use case** is generally a software and system engineering term that describes how a user uses a system to accomplish a particular goal. It is a methodology used in system analysis to identify, clarify, and organize system requirements. The use case is made up of a set of possible sequences of interactions between systems and users in a particular environment and related to a particular goal. A use case acts as a software modelling technique that defines the features to be implemented and the resolution of any errors that may be encountered. To represent an actor's participation in a system, all aspects of the interaction of a user with a product or service should be addressed in the use case. Use cases encompass human–computer interaction and address usability, usefulness, desirability, and optimal model of interaction with the focus placed on the quality of the user experience and other relevant solutions.

A use case generally comes as a list of actions, scenarios, or event steps defining the interactions between a role (known in the Unified Modelling Language as an actor) and a system to achieve a goal. The **actor** can be a human or other external system. Actors are roles that a user takes when invoking a use case specifying a role played by a user or any other system interacting with the subject. This simply means that the actor is a possible role of a future user. Different kinds of actors can be distinguished such as a receiving agent or registration operator.

The following personals have been developed (refer to SHAPES D2.7 for details) [16]:

1) Active, healthy older adults
2) Older adults with mild, but multiple chronic conditions
3) Older adults with chronic musculoskeletal disorders
4) Older adults with neurodegenerative diseases
5) Lonely and/or socially isolated older adults
6) Older adults with alcohol or drug dependency and severe chronic conditions non-complying to medical recommendations
7) Oldest old and frail
8) Older adults with deaf blindness (older adults with a dual sensory impairment)
9) Informal caregivers for the older adults with neurodegenerative disorders
10) Impact of the COVID 19 pandemics on the mental health and computer use of older adults

Connection to personas is as follows. Some of the general use cases are serviceable across most of the personas, e.g., Assistive Technology for Reading, Summarizer of Information from Internet, Meal Ordering, or Medication Reminder.

[16] SHAPES Deliverable 2.7
https://shapescdn.blob.core.windows.net/$web/deliverables/D2.7%20%E2%80%93%20SHAPES%20Personas%20and%20Use%20Cases_FINAL.pdf

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The general use case Self-Management of Chronic Conditions providing relatively broad and universal spectrum of assistive support, e.g., assisting in daily health and care activities, recommending appropriate dietary recommendations, etc., can also be serviceable across most personas, however, there is a requirement of the absence of neurodegenerative changes as these changes could possibly lead to ignoring or misleading of recommendations provided by the Self-Management of Chronic Conditions application.

Thus, this use case is not suitable for Persona 4. In contrast, merely use case In-Home Cognitive Training is supportive for this group of older adults (Persona 4), as well as their carers (persona 9) as it can support the possible improvement of the cognitive functions. For Persona 3 that is typical by various musculoskeletal problems, a general use case Motor Exercising with Robot is very useful as it can improve motoric abilities and flexibility of a body.

The development of the connections between the Personas and the Use Cases has been a complex task given the fact that there are no well-established methods for this task that would be recently available. Therefore, it was a big challenge for the SHAPES project to develop a method of building connections between the Personas and the Use Cases. There are several problems that we face at the beginning. All natural processes, including also the process of aging, are affected by intrinsic variation. One of the obstacles lies in these variations in the different characteristics of the Personas. This means that the Personas vary in their:

- health conditions
- perceptual and motor abilities
- degrees of cognitive decline
- health care requirements
- needs
- economical situations
- digital literacy
- health literacy
- affinity to ICT technologies

and many more characteristics or let say "parameters". Apparently, some degrees of these parameters may represent restraints or limitations for the technology use, and thus also for the suitability of the particular Use Case that could be potentially joined to the given Persona. For example, health care requirements cannot be the only criterion for the assessment of the suitability of the Use Case, because the given Persona may show insufficient perceptual or motor abilities for the technology use, insufficient digital literacy, or cognitive impairments that make the use of the particular technology impossible. Thus, the main problem to be solved was: How to develop connections between the Personas and the Use Cases when each Persona shows so many variations in their parameters? What parameter should be used for linking the Use Cases to the Personas?

Creating methods for the development of the connections between the Personas and the Use Cases requires a complex model that could explain the complexity and variations in the parameters of the Personas representing the different prototypes of older adults. But to our knowledge, recently there is no model of complex geriatric patients available. Therefore, the background used for the understanding variations in needs, health conditions, perceptual, motor and kinetic abilities, degrees of cognitive decline, health care requirements, economical situations, digital literacy, health literacy, affinity to ICT technologies, etc.

The set of general use cases developed in SHAPES included various kinds of monitoring, Home Environment Monitoring, In-Home Glucose-Monitoring, In-Home Heart-Monitoring, In-Home Post-Hospital Aftercare, In-Home Video-Monitoring, and Location Tracking. These monitoring devices serve different functions. For example, Home Environment Monitoring is focused on the control and monitoring of home conditions like the regulation of the Self-Management temperature, light, or various daily used electric devices.

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This may help frailty people that are represented by Persona 7, but also people suffering from serious and chronic diseases - e.g., Persona 6, Persona 4 and also their carers (persona 9). In contrast, In-Home Video-Monitoring is much more focused on the detection of falls and the actual state of the clients that are at the risk of falls, i.e., Persona 7, Persona 5, Persona 3 and Persona 9. The general use case Location Tracking is specifically designed for Persona 4, i.e., demented people that are at a greater risk of being lost when they are travelling or moving uncontrollably from place to place. This use case will obviously also help the people who care for patients with dementia – Persona 9. Furthermore, the general use case Home Post-Hospital Aftercare is designed for the situation of post-hospital aftercare for in-home patients after a surgical operation or another serious medical intervention. Next all 13 general use cases are presented with detailed information about the contents of the considered use cases.

4.5 StrokeBack EU Project

Stroke is a disease with very high socio-economic impact. In average the healthcare expenditure cost for Strokes across different countries in Europe and USA is 3% of their entire healthcare expenditure. This includes inpatient treatment cost, outpatient hospital visits and long-term rehabilitation and care. Analysis showed that costs of long-term care have increased from 13% to 49% of overall costs in average in recent years. Therefore, there is an urgent need for devising an effective long-term care and rehabilitation strategy for Stroke patients, which involved the patients actively in the process while minimising costly human intervention. The StrokeBack project has developed an automated remote rehabilitation system by blending advances of ICT and practical clinical knowledge that empowers patients and their immediate carer for effective application of the rehabilitation protocol in home settings.

StrokeBack combined state-of-the-art monitoring devices forming a wireless Body Area Network that enable simultaneous measurement of multiple vital parameters and currently executed movements that are particularly of interest from a Stroke rehabilitation point of view. The measured parameters were fused using advanced feature extraction and classification algorithms processed on-body, which will denote the accuracy of the executed exercise. The training parameters along with vital data will be stored in a patient health record to which the responsible clinicians and therapists have access so that they can dynamically update the rehabilitation program. By employing manual intervention only when actually necessary, it eliminated costly human intervention and thereby significantly reduced the associated costs. The increased rehabilitation speed as well as the fact that the rehabilitation training can be done at home directly improves quality of life of patients. To sum up StrokeBack increased rehabilitation speed while reducing cost.

The StrokeBack concept puts the patient into the centre of the rehabilitation process. It aims at exploiting the fact the patients feel better at home, that it has been shown that patients train more if the training is combined with attractive training environments. Figure 1 illustrates how we think the vision of such a patient centric approach can come true. First the patients learn physical rehabilitation exercises from a therapist at the care centre or in a therapists' practice (left part of Figure 1). Then the patients do exercises at home (middle part of Figure 1) and the StrokeBack system monitors their execution and provide real time feedback on whether the execution was correct or not. In addition, it records the training results and vital parameters of the patient. These data are analysed by medical experts (lower right part of Figure 1) for assessment of the patient recovery. The patient gets midterm feedback on her/his personal recovery process. In order to ensure proper guidance of the patient also the therapist get information from the PHR to assess the recovery process and decide whether other training sequences should be used, which are then introduced to the patient in the practice again.

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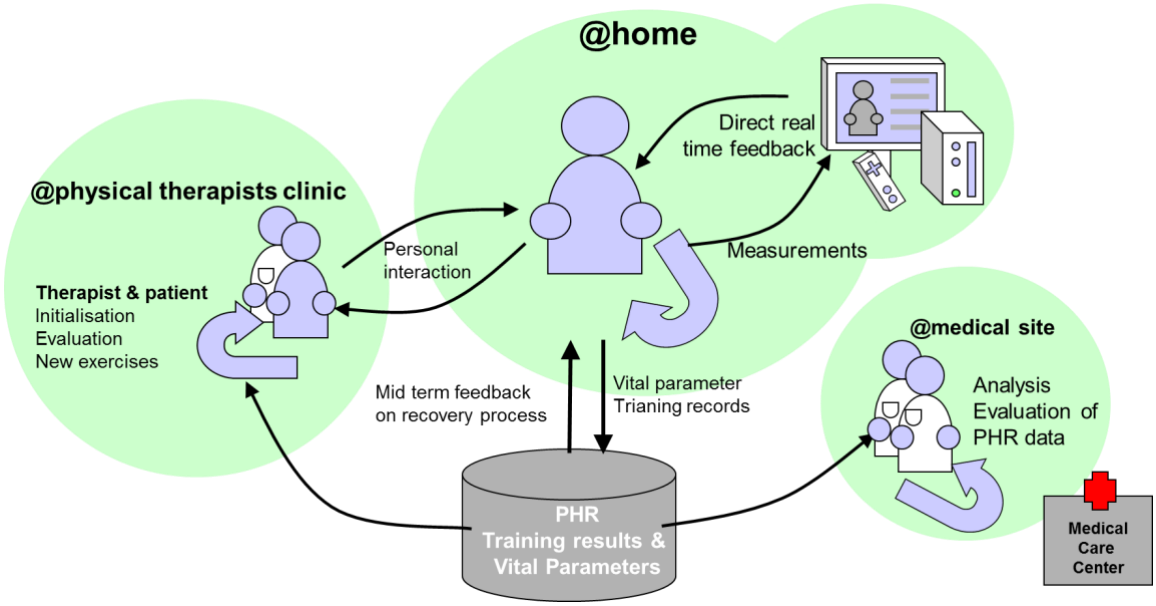


Figure 2: The StrokeBack Rehabilitation Cycle

The goal is achieved by investigating the following objectives:

- telemedicine supervision of rehabilitation exercise
- continuous monitoring of impact of the exercises also in "normal" life situations
- integration of telemedicine rehabilitation and Personal Health Records for improved long-term evaluation of patient recovery
- providing feedback to health care professionals on the impact of rehabilitation exercises

To provide remote rehabilitation exercises at gold standard level i.e. as good as in a face-to-face training with rehabilitation experts, we plan to exploit the advanced features of today's body area networks (BAN). A BAN attached to the patient enables permanent monitoring of patients' activity and vital parameters. We aim to monitor and record the patients' activity enabling them to regularly, maybe daily, exercise independently from the guidance of the physical therapist. With a correct instrumentation we expect to be able to detect also unwanted additional movements. In order to achieve a comparable monitoring by cameras at least two of them need to be deployed at the patient's home. This is a costly solution which also bears a privacy risk. Both issues can be solved with our BAN based solution.

As one possible application, the physical therapist has to look after the patient once a week only to exploit the level of rehabilitation, to analyse the results of last exercises based on recorded data and to take corrective action if necessary. Further, the physical therapist may show new exercises and configure a new exercise schedule. By that, we intend to boost the rehabilitation process at home.

The BAN can be worn by the patients throughout the whole day which enables us to compare actual movements in their daily life with the correct movement pattern define in rehabilitation exercises.

To simplify the configuration process of the system we will analyse and evaluate self-learning techniques for exercise recognition i.e. the StrokeBack system may learn the correct behaviour (patient's movements) when exercises are carried out under instruction of the physical therapist.

We will additionally evaluate the feasibility and requirements of using electronic personal health records to store and document recorded data and to remotely track the rehabilitation process, e.g., by the attending doctor. This includes the recordings done during rehabilitation exercises and during daily life. The recorded data will be stored and can then be processed by healthcare professionals.

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The evaluation can be used to deduce detailed information of effects of individual exercises. This feedback can be used to select exercises for other patients, to assess effectiveness of exercises for specific groups of patients etc. In addition, the vital parameters can be used to assess the healthiness of the patients which might even help to assess the probability of a further stroke.

To evaluate the effectiveness of the StrokeBack system, two types of use cases have been developed and evaluated, one Expert System Use Case and two ones for evaluating the Home-Based part of the system.

4.5.1 Expert system use case

The expert system is designed to be employed in a controlled environment under the supervision of a physiotherapist, or other appropriately qualified clinician, trained in its use. This will generally take place at the clinic although it could possibly be used within the home environment as well if suitable personnel are present.

The expert system will consist of a number of body worn wireless sensors (the expert BAN) and a PC based motion capture system (Kinect or ASUS). The choice of sensors used will be kinematic sensor modules (comprised of tri-axial accelerometers, tri-axial rate gyroscopes and tri-axial magnetometers, which when combined give 9 degrees of freedom in measurement), EMG sensors to monitor muscle activity in the biceps and triceps and an ECG sensor to monitor heart rhythm. The kinematic sensor modules will be positioned on the forearm just above the wrist, on the upper arm just above the elbow and on the sternum, though exact positioning will be determined through early-stage investigations. The motion capture system will be used to film the patient as they perform specific tasks and exercises, and the temporal film record will be used as a qualitative measure of patient rehabilitation progress.

Appropriate methods to provide secure and repeatable attachment of the sensors to the body will be investigated early in the research programme as well as the effects of sensor orientation and misalignment.

Assessment with the expert system will initially commence with a face-to-face dialogue between the patient and clinician. From this, the clinician will be able to establish the patient's level of impairment and the patient will be able to inform the clinician as to what their personal objectives from rehabilitation are. This will enable the clinician to decide which of a range of upper limb functional tasks and exercises are most appropriate for the patient. Following on from this dialogue the measurement phase commences with the patient encouraged to perform a subset of exercises and functional tasks from the WMFT collection, which will have been specifically selected by the clinician to suit the patient's objectives and perceived capabilities.

The motion capture system will record the patient's movements during the exercises. Through suitable signal processing, the motion capture system will produce temporal and spatial kinematic information including: limb segment position in space, limb segment velocity and acceleration, joint angles, and total time for individual task completion. Accordingly, the motion capture system can be considered as a 'standard' against which data derived from other sensor sources can be compared.

During the exercises data from the body-worn wireless sensors will also be directly transmitted to the host PC in real-time and processed in two different ways. Firstly, transformation algorithms will convert the raw sensor data to 3-dimensional spatial information which will be directly compared with the data generated from the motion capture system. This will serve as a simple check on the accuracy and robustness of the transformation algorithms. The second data processing strategy will involve searching for patterns within the sensor data that exhibit high correlation with specific movements of the upper limb or specific functional tasks being performed. These data patterns will be used by the home-based system as templates to determine whether such movements are being performed by the patient during normal activities of daily living. Other features of the data recorded (such features to be determined) will also be used as metrics to assess rehabilitation progress. For example, this might include calculating energy expenditure from EMG data or estimating metabolic rate from ECG data.

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The clinician will also assess the patient whilst they perform the prescribed exercises and use their professional judgement to rate the patient in accordance with the WMFT scoring system. This score will be entered into the PHR. All of the raw data collected from the body-worn wireless sensors and motion capture system as well as processed data will also be stored in the PHR.

Subsequent scheduled or ad hoc visits to the clinic will involve re-rating the patient's performance of their specific and prescribed subset of tasks from the WMFT, allowing a longitudinal measure of rehabilitation progress to be determined with clinical credibility.

4.5.2 Home-based system – Use Case #1

Because the home-based system is required to be used with non-professional intervention, it is less complex than the expert system and will involve fewer sensors. Specifically, EMG and ECG sensors will not be incorporated within the home-based BAN. Simplicity of use and ease of donning will, however, be of prime importance since the system is intended to be operated either solely by the patient or with the assistance of a carer or family member. Two different use cases are proposed for the home-based system, representing a short-controlled assessment phase and a longer uncontrolled assessment phase.

In the first use case, the home-based BAN was used in conjunction with a PC motion capture system within a controlled 'measurement zone' (*e.g.* at a work table with a customised interaction platform). Initially the patient was instructed to perform a number of simple tasks that effectively move the sensors through a number of predefined orientations whilst being filmed by the motion capture system. At the same time the sensors were transmitting their data to the host PC. By comparing the sensor data with that from the motion capture system it was possible to re-calibrate the sensors, accounting for any positional inaccuracies in sensor placement.

After this calibration phase, the patient was asked to perform repetitions of the specific WMFT exercises identified as being appropriate to them during initial assessment at the clinic. To keep the patient engaged with these motor function tests, motivational software games were developed that required the patient to move the upper limb in a manner that mimics the movement requirements of the specific exercises assigned to them. Data from the body worn sensors were transmitted in real-time to the PC through a wireless communication link and converted directly into time-stamped spatial coordinates that were used as the input controls to the PC games. As well as making the exercises more enjoyable, this also presented patient with real-time visual performance feedback.

Other relevant kinematic information was derived from the spatial coordinate data including body segment acceleration, body segment velocity, body segment angle, body segment tremor, etc., and these were all stored on the PC for post exercise analysis to yield quantitative measures of performance. Such performance indicators were presented to the patient in a suitable format at the end of the exercise session (*e.g.* graphs, road maps, etc.). In this manner, the patient felt a greater sense of involvement in their own rehabilitation. Raw sensor data, processed sensor kinematic data, motion capture kinematic data and processed sensor classifying data were all stored in the PHR through an internet connection to the patient's home PC, which could be accessed on demand (remotely) by clinicians to assess rehabilitation progress.

4.5.3 Home-based system – Use case #2

In this second use case, the home-based BAN was used to surreptitiously gather data from the patient during activities of daily living (ADLs). This removed the bias often encountered due to patients trying harder during exercises when they know that they are being assessed and therefore provides a more accurate measure of patient effort and progress. It is therefore of vital importance that the method by which the sensors are attached is both comfortable and non-intrusive to the patient and does not restrict normal activities or movements. Ideally the BAN garments might take the form of a simple wrist strap, upper arm strap and chest band.

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The home-based BAN also contained a processing hub with data storage facility and a wireless receiver. The BAN sensors at this stage have been re-programmed by the PC software to operate at a lower acquisition rate to prolong battery life. The hub processed the sensor data in real-time and perform data compression to reduce data storage requirements (thus helping to extend the BAN operational lifetime). Data was gathered by the BAN over a fixed period (battery life dependant) and at the end of a session this data was downloaded from the hub to a PC through a docking station. The data was then analysed to look for the classifying, characteristic patterns that are associated with particular movements or operations (as defined in the clinical assessment phase and daily PC gaming phase). Other patient activities not previously defined by data patterns may also be inferred, such as inactivity, lying down, sit-to-stand, stand-to-sit, and so on. Once these activities have been identified within the BAN data, they were presented to the patient in a meaningful format and also stored on the PHR for later analysis by clinicians. Presentation formats might for example simply convey information such as the patient performed 20 reach-and-grasp tasks during the monitoring period which revealed that the time to complete this task increased over the course of the day by 15% or the patient was inactive for 3 hours and 20 minutes during the monitoring period.

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5. Conclusions/Recommendations

Challenges:

Remote monitoring sensors are no longer fringe innovations confined to research labs or niche medical trials—they have entered the mainstream as one of the most transformative forces in modern healthcare. These technologies have redefined what it means to care, shifting the paradigm from reactive interventions to continuous, proactive, and personalised support. They give new meaning to the phrase "being present," allowing healthcare systems to monitor, understand, and respond to a person's needs in real time, wherever they are.

The promise is enormous: earlier detection of disease, better chronic condition management, reduced hospitalisations, and enhanced independence for older adults. They enable healthcare professionals to intervene before a crisis unfolds. They empower patients to become more active participants in their own care. And they offer caregivers—often family members—the confidence that their loved ones are supported, even when they can't be physically nearby.

But this promise is not without friction. As we welcome a future shaped by AI-enhanced, sensor-driven care, we must also confront profound questions of privacy, autonomy, and equity. Technologies that track our steps, heartbeats, or environmental exposures must be designed not just for efficiency, but for empathy. Trust cannot be an afterthought. The challenge lies in balancing innovation with responsibility—ensuring that remote monitoring empowers without surveilling, and supports without replacing the irreplaceable human touch.

Moreover, the path from pilot project to widespread adoption is often steep. While many European initiatives, such as SHAPES, ENACT, and StrokeBack, have demonstrated extraordinary potential, they also highlight systemic barriers: a fragmented regulatory landscape, lack of standardization, limited access to open standards, and digital divides that risk leaving behind the most vulnerable. Interoperability, both technical and institutional, remains a linchpin for success.

We must also acknowledge that real-world conditions are messier than laboratory scenarios. Models trained in controlled settings may falter in everyday environments. Devices may perform inconsistently, or generate overwhelming data that clinicians struggle to interpret. These are not reasons to retreat—but reminders that technology must evolve alongside human needs and healthcare practices.

Yet despite these hurdles, the momentum is undeniable. With the right mix of policy, investment, ethical oversight, and inclusive design, remote monitoring sensors can form the backbone of a truly patient-centred healthcare system. One where care is not something we wait for, but something that travels with us—anticipating, adapting, and responding.

In the end, the role of remote monitoring sensors is not just to collect data, but to tell meaningful stories about our health. Stories that help us age with dignity, live with agency, and heal with insight. As we look ahead, our task is to ensure that these stories remain grounded in the values that matter most: compassion, equity, privacy, and trust.

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