Technological innovation in healthcare: challenges, opportunities and sustainability

FUNDACIÓN RAMÓN ARECES

Real Academia de Ingeniería

Technological innovation in healthcare: challenges, opportunities and sustainability

María Vallet Regi[1,2,3]
Manuel Doblare[4,5,12]
José Antonio Garrido[6,13]
Almudena Fuster-Matanzo[7]
Ángel Alberich-Bayarri[7]
María Elena Hernando[8,2]
Cecilia E. García Cena[9,10]
Marie Destarac Eguizabal[11,12]
Emilio Bouza[1,3]

[1] Universidad Complutense de Madrid (Spain)
[2] Instituto de Investigación Sanitaria Hospital 12 de Octubre, CIBER-BBN, Madrid (Spain)
[3] Fundación Ramón Areces, Madrid (Spain)
[4] Instituto Universitario de Investigación en Ingeniería de Aragón (I3A), Universidad de Zaragoza (Spain)
[5] Instituto de Investigación Sanitaria Aragón (IISA). CIBER-BBN (Spain)
[6] ICREA, Barcelona (Spain)
[7] Quibim S.L, Valencia (Spain)
[8] Centro de tecnología Biomédica. Universidad Politécnica de Madrid (Spain)
[9] Universidad Politécnica de Madrid. Escuela Técnica Superior de Ingeniería y Diseño Industrial (Spain)
[10] Centro de Automática y Robótica (ETSIDI-UPM-CSIC)
[11] OWSD Guatemala (Organization for Women in Science for the Developing World)
[12] ABB (Spain)
[13] Catalan Institute of Nanoscience and Nanotechnology (ICN2), CSIC and The Barcelona Institute of Science and Technology, Barcelona (Spain)

Abstract

Technological innovation is transforming healthcare by improving diagnostic precision, optimizing treatment strategies, and contributing to consolidate personalized medicine. This review explores key advancements in medical technology, focusing on their impact on healthcare delivery, system sustainability, and patient empowerment, especially in the European/Spanish context. The integration of innovative technologies, such as artificial intelligence and digital health tools has not only improved clinical workflows but also facilitated remote monitoring and predictive analytics, enabling earlier interventions and better resource allocation. However, the adoption of these technologies faces challenges related to regulatory compliance, data security, patient adoption and clinician training to cite some. The disparities in regulatory frameworks between Europe, the United States, and China further influence market accessibility and the speed of implementation. Beyond regulatory hurdles, technology transfer remains a critical bottleneck, hindered by limited investment and significant differences in funding and innovation infrastructure across countries. Many promising medical technologies struggle to transition from research to clinical application due to financial constraints and fragmented collaboration between Academia, industry, and healthcare systems. Additionally, the role of public-private collaborations is highlighted as a key driver for fostering innovation, enabling efficient technology transfer, and lowering barriers to adoption in clinical practice. As digital health continues to evolve, it is crucial to balance technological progress with ethical considerations, patient safety, and equitable access to innovations. This review provides a comprehensive analysis of these aspects, offering insights into how emerging technologies are reshaping the future of healthcare systems globally.

Introduction

Throughout history, technology has been a key driver of progress, enhancing efficiency across every domain where it has been applied. In healthcare, its impact is particularly significant, not only improving the quality of medical care but also optimizing resource use and accelerating responses to emerging challenges. From process automation to the application of artificial intelligence (AI) in diagnostics, technological innovation continues to reshape the foundation of modern medicine.

The convergence of technology and healthcare is no longer a futuristic promise, but a transformative reality that shapes medical practice, patient wellbeing and the management of healthcare systems on a global scale, generating a positive impact on people's quality of life. Until now, the diagnosis and treatment of disease had been largely based on clinical observation and a variety of diagnostic tests, including blood- and urine-derived biomarkers and histopathological analysis. The advent of advanced medical imaging techniques (such as magnetic resonance imaging and computed tomography), genomics and medical informatics, however, has enabled earlier and more precise diagnosis, as well as increasingly personalized treatments.

The exponential growth of technologies applied to healthcare is evidenced in the investment and rapid adoption of innovative solutions in hospitals, healthcare centers and even in patients' homes. The global digital health market was valued at $288.55 billion in 2024, and is projected to reach $946.04 billion by 2030, with a compound annual growth rate of 22.2%[1]. Likewise, investment in research and development in this field is growing steadily. Emerging technologies such as telemedicine, AI, new medical imaging techniques, organ preservation, enhancement devices, new biomaterials, tissue engineering systems, controlled drug delivery systems, and digitized systems for the management of healthcare systems, to name just a few of the many examples, are poised to radically reshape the practice in medicine.

Within this context, this article discusses the main technological advances in the healthcare sector, their development cycle from conceptualization to regulatory certification and commercialization, and their impact on the sustainability of the healthcare system, with special emphasis on the European context, particularly the Spanish ecosystem. Likewise, the ethical and regulatory challenges associated with data management and AI, along with patient empowerment through smart devices, will be also addressed.

The aim of this review is to provide a comprehensive overview of the present and future of technology in healthcare, highlighting its benefits, limitations and challenges for its effective integration into medical practice and healthcare systems. Through a critical analysis, solutions to overcome current barriers will be proposed while exploring the broader impact of technological innovation on the evolution and the sustainability of the healthcare system.

Technological advances in healthcare

Technological innovation has driven significant advances in medical care, giving rise to tools that improve diagnostic accuracy and optimize therapeutic interventions, contributing to the advancement of personalized and precision medicine. Some of the recent technologies[7] are transforming, or are set to transform, the healthcare sector and how they contribute to the sustainability of the healthcare system.

An example is telemedicine or virtual healthcare, which in recent years has revolutionized the doctor-patient relationship by allowing remote consultations, continuous follow-up and emergency care in health crises such as the COVID-19 pandemic. Telemedicine has improved equity in access to healthcare, eliminating geographical barriers and facilitating communication between professionals and patients; although, according to a study by the World Economic Forum, over 97% of hospital-generated data is underutilized. This highlights an standing major gap between data production and its effective use in healthcare. The underlying technology has been instrumental for the management of chronic diseases, which require continuous monitoring for early detection of any change in the patient and improving patient access to healthcare services. Another example is AI, a technology implemented in multiple clinical applications, from the advanced analysis of diagnostic images —medical images analysis with AI confers speed and precision that surpasses human capabilities, enabling radiologists to detect anomalies earlier and more efficiently— to the identification of disease biological markers through analysis of genomic data analysis or the optimization of treatments. Likewise, the pharmaceutical industry is currently investing in AI to leverage the use of novel algorithms to shortening drug

development times. For instance, AI is allowing clinical trial optimization through the identification of control patients and the creation of synthetic control arms, and the generation of new drug candidates with greater therapeutic potential through the analysis of molecular databases. The use of these AI-based techniques accelerates and improves diagnostic accuracy, avoiding redundant tests and optimizing resources. As a result, the operating costs of the healthcare system are reduced. According to a report published by Frost & Sullivan, the use of AI could reduced costs up to 50% and other reports suggest it could save the US healthcare system more than $150 billion in 2026[3,4].

In this context, the integration of information and communication technologies in the healthcare sysem is having a huge impact in clinical processes. The implementation of interoperable electronic medical records, the automation of administrative processes and integration with telemedicine systems have enabled specialists to access key information in a faster and more structured manner. In addition, the development of advanced tools facilitates the generation of clinical reports by autocompleting data, identifying drug interactions and issuing automatic alerts when out-of-range values appear. These systems improve medical decision-making while reducing the administrative burden on professionals, allowing them to focus on patient care.

Robotics is another area of technology with a growing impact on healthcare, with a market for robotic-assisted surgery expanding steadily, driven by advances in technology, the rising demand for minimally invasive procedures, and evidence of improved patient outcomes. This sector is projected to reach approximately USD 14 billion globally by 2026 with a compound annual growth rate of nearly 11%[5]. Medical robotics has optimized clinical outcomes with its application in high-precision surgery, rehabilitation and assistance to people with reduced mobility. Systems such as the Da Vinci surgical robot have improved the safety of interventions, reducing hospitalization time and improving postoperative recovery[6,7]. Similarly, the development of robots and exoskeletons for assisted rehabilitation offers new alternatives for patients with reduced mobility and the elderly to perform everyday tasks and furher maintain their autonomy. In recent years, we have also witnessed a widespread adoption of portable or wearable devices-such as smartwatches, rings and fitness bracelets – that enable constant monitoring of physiological health parameters, including heart rate, oxygen level, physical activity, and sleep patterns[8]. In addition, mobile health apps offer support tools for disease management allowing access to reliable medical information and the adoption of healthy habits. By encouraging informed self-care and early intervention, these digital technologies support measures that can prevent serious complications and, in the long term, ease the burden on the healthcare system.

Advances in 3D printing and bioprinting have revolutionized the manufacturing of personalized prostheses, surgical planning and the development of artificial tissues[9]. The ability to generate biocompatible structures opens the door to future applications in regenerative medicine, including bioprinting (printing of functional organs), which allows reproducing the geometry and positioning of cells in tissues and organs, simulating a real organism. These personalized solutions promise more effective treatments by adjusting to the needs of each patient, potentially reducing complications and the need for repeat surgery. The advent of novel biomaterials that can mimic real tissues and organs will circumvent issues with bank tissues samples. As these biomaterials are the basis of tissue engineering[10] to encapsulate cell and components essential for tissue regeneration, and even the biointegration of a complete organ, they have become a mainstay in nanomedicine, enabling precise drug delivery through the encapsulation and targeted controlled release of active ingredients, avoiding unwanted systemic[11,12]. These bioengineering innovations seek to improve clinical outcomes and avoid more invasive or costly procedures.

Big data allows the analysis of large volumes of information, which is partic ularly relevant in healthcare given the vast amount of medical data generated[13]. Big data in healthcare has enabled the creation of digital twins, which are highly complex predictive virtual models that faithfully reproduce the behavior of organs and even complete biological systems in silico and simulations for disease prediction, optimization of hospital resources and clinical risk assessment in specific populations[9]. The prognostic/predictive capacity of AI and big data facilitates patient segmentation[14], more proactive healthcare planning[15], guiding decision-making to avoid a collapse of the system and focusing preventive efforts where they are most needed[16].

Both virtual and augmented reality have been developed for medical training[17], medical skills evaluation[18], and rehabilitation therapies for complex procedures without any risk to patients, acting as simulators that recreate real clinical scenarios. Thus, recurrent training of healthcare professionals can equip them with skills and knowledge of new techniques and procedures.

Technological innovations have therefore profoundly reshaped medical practice, influencing not only clinical approaches but also the broader sustainability of the healthcare system. By enhancing service efficiency and accessibility, lowing costs, improving diagnosis and therapeutic accuracy, supporting preventive care, and strengthening the training of professionals, these innovations contribute to a more sustainable, equitable, and patient-centered healthcare model.

In summary, technology has become, and will increasingly remain, an indispensable ally in improving health across all its dimensions. Its capacity to drive efficiency, optimize resource use, and transform personalized and precision medicine is undeniable. However, realizing this potential fully will require strategic planning, robust regulatory frameworks, and a patient-centered approach. Continuous research and cross-sector collaboration will be key in shaping a more precise, accessible and personalized medicine.

Medical technology development cycle

One of the core pillars of medical regulation is guaranteeing patient safety and maintaining high standards of care. For medical devices —whether software, hardware, or a combination of both— regulation aims to ensure that these products are safe, effective, and perform as intended.

Devices are classified based on their risk level as i) Low-risk (Class I), ii) Moderate-risk (Class II), and iii) High-risk (Class III). The higher the risk level, the more stringent the regulatory requirements. Although the regulatory process is mandatory, it often involves lengthy and resource-intensive validation procedures. As a result, some safe and potentially beneficial products may face substantial delays —or may never reach the market at all— due to regulatory burdens.

Key stages: conceptualization, development, validation and certification

In general, the development of a medical technology consists of five phases, as described in Figure 1.

In any field, including healthcare, the technology advances through different stages increasing the technology readiness level (TRL)[19]. This development process is gradual, starting with concept validation (TRL 1-3), followed by laboratory validation (TRL 4-6) and subsequent validation in increasingly significant environments (from TRL 7 onwards)[20]. Although this scale may be linear for other technology fields, in healthcare technology, the term "polyhedral" is more appropriate, and often

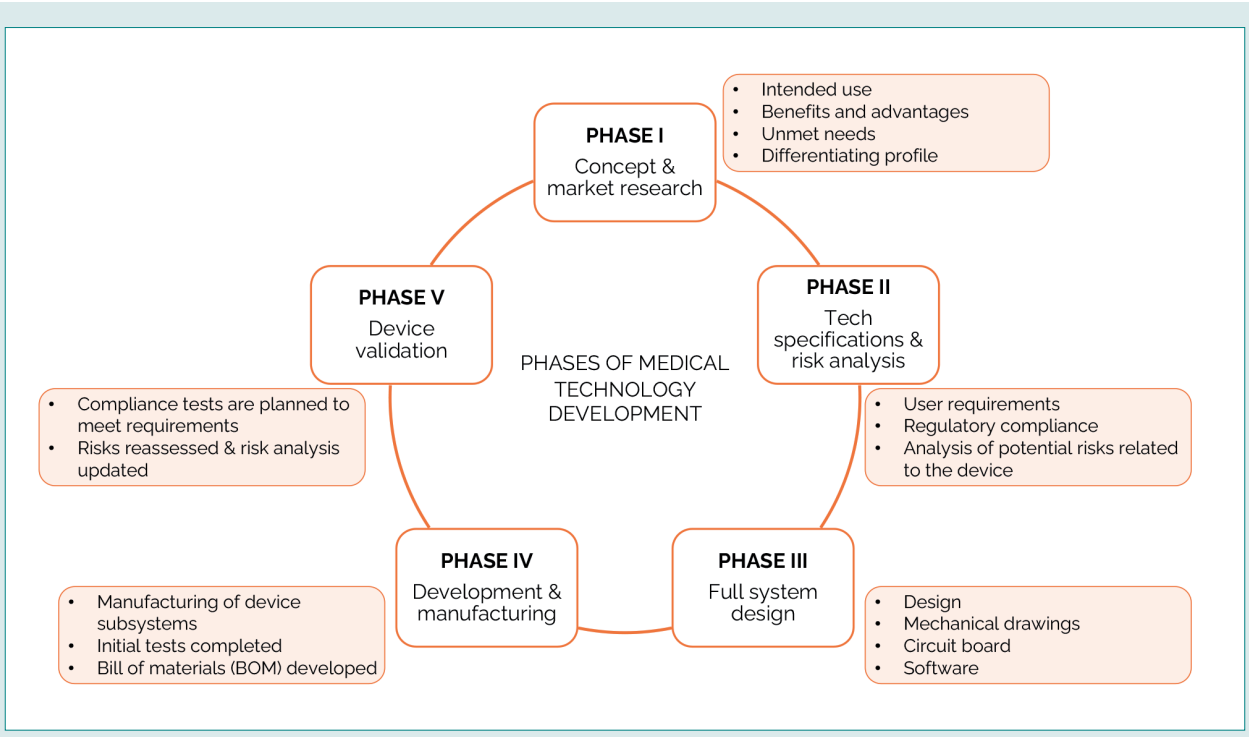

Figure 1. Phases for the development of a medical technology from inception to validation of final product.

depends on the regulatory framework, which may be different in each territory[21].

Upon reaching TRL6, the technology must undergo testing to confirm safety and feasibility for a medical or hospital environment, including its use in patients and by the medical staff. To this end, validation and verification tests, including unitary tests of submodules, are required to be performed in a certified laboratory to ensure compliance with medical device regulations. These tests are destructive, as tested technology units will be subjected to deterioration cycles. This entails the manufacture of multiple units exclusively for safety testing, which will increase costs for its future adoption. In addition the development of new healthcare technologies carries a high level of risk. Many candidates must be abandoned at early stages due to viability constraints, which in turn raises the overall costs of those that eventually reach the market. To mitigate this impact, substantial investment in material, technological and organizational resources is essential. Equally important is the extensive prior application of predictive models, particularly digital twin-based virtual simulations

Once regulatory compliance is achieved, the device can proceed to clinical trials aimed at demonstrating its usability, reliability and safety. At this stage, careful consideration must be given to the number of participants required to validate the technology. If the trial results are favorable, the device's technical documentation and clinical evaluation are submitted to a notified body for assessment and certification.

When both validation and verification studies, including clinical trials, yield positive results, they provide assurance that the medical technology is safe and fulfills the intended requirements. The role of notified bodies is therefore crucial, not only in meeting regulatory compliance but also in verifying the adequacy of the manufacturing processes. Their certification ultimately enables the technology to enter the market and be deployed in the appropriate clinical setting.

The healthcare sector is one of the most highly regulated industries, and existing regulations strongly influence every stage of technology development; from preclinical and clinical validation to market launch, and eventual adoption in the healthcare practice (TRL ≥7; Figure 2). Key aspects such as functionality, efficacy, manufacturing processes, quality, and traceability are directly shaped by these regulations and must be carefully integrated into the design and development roadmap to optimize resources, including time as a critical factor.

The certification process tipically begins once technological development reaches approximately TRL 8. At this stage, compliance must be ensured not only with healthcare-specific requirements but also with other applicable regulations. This step, often considered the preclinical validation phase, which must be completed prior to the clinical evaluation. This is a resource-intensive

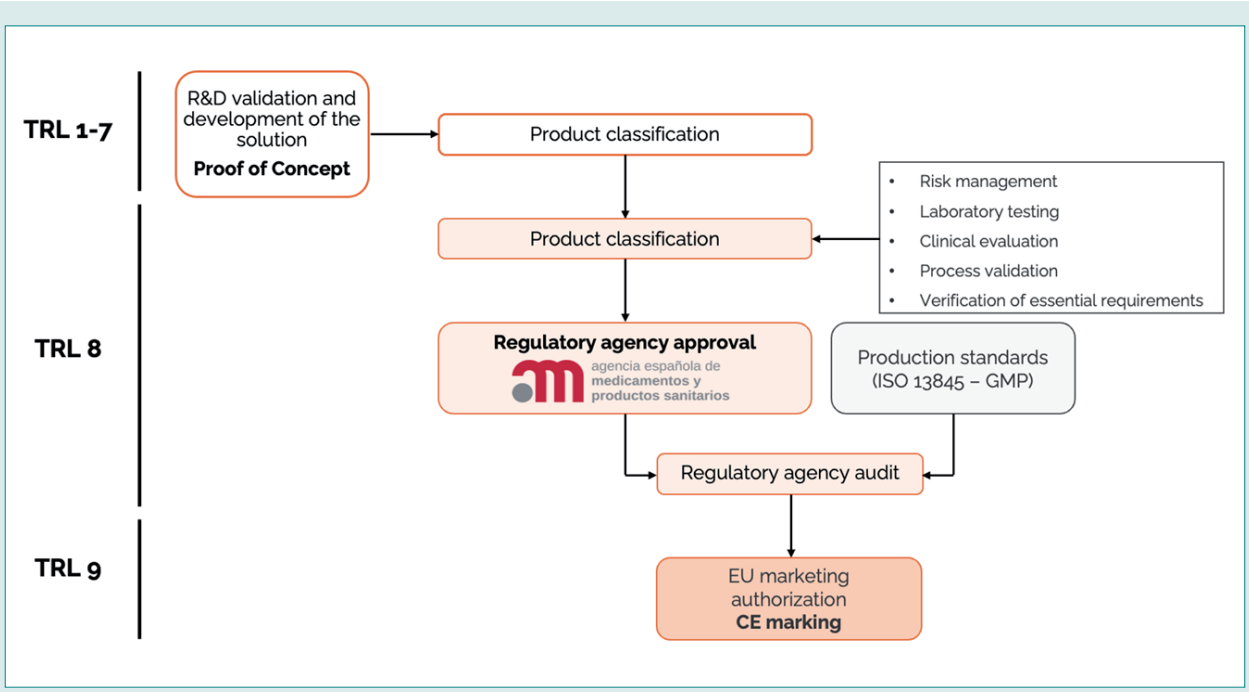

Figure 2. Example of the validation process starting from TRL 7 in Europe-Spain, when the Spanish Agency of Drugs and Medical Devices (AEMPS) acts as notified body.

and time-consuming process that may last longer than the product's actual development. Many technologies fail here —not due to lack of efficacy, but because available resources are exhausted. Ultimately, the outcome depends heavily on the decision of a third party, the notified body (NB). An NB is an organization designated by an EU country to assess the conformity of certain products before they can enter the market. These bodies are responsible for conducting conformity assessment in accordance with the applicable legislation, when a third party is required. The European Commission publishes and maintains the list of such notified bodies.

Under current regulations, each product (hardware, software, or a combination of both) is classified according to its risk profile, and this classification determines certification roadmap. This process may take years —often longer than the development of the technology itself. For disruptive or highly innovative medical devices, meaning they lack a clear predecessor or rely on novel technological tools or scientific discoveries, the certification pathway becomes even more complex and time-consuming.

Regulatory differences between regions

Medical device regulations differ significantly across regions. In Europe, the medical device regulation (MDR) sets strict requirements to ensure device safety and efficacy. However, the framework has also introduced certification delays and high compliance costs, particularly challenging startups and small and medium-size enterprises (SMEs). As a result, many companies now prioritize launching products in large or agile markets such as the U.S., where FDA approval can accelerate access, or China, which represents an attractive growth opportunity but where the certification of medical devices remains a complex process despite the market's potential. Additionally, the limited capacity of notified bodies has created bottlenecks in the certification process and unusual practices (such as the fast track or dedicated review system in some cases, where applications are prioritized for an additional fee), further slowing down innovation.

By contrast, both the U.S. and China are fostering innovation with more favorable regulatory frameworks and accelerator programs, which strengthen their global competitiveness. The US Food and Drug Administration (FDA, por sus siglas en inglés) has modernized its approach to medical device regulation, particularly for software as a medical device (SaMD). The FDA's Digital Health Innovation Action Plan includes initiatives such as the Precertification (Pre-Cert) Pilot Program, which evaluates the developer's organizational excellence rather than focusing exclusively on the product[22]. This approach aims to accelerate approvals for innovative digital health products while upholding safety and efficacy standards. Agile methodologies are also supported under the FDA framework[23,24]. For example, AAMI TIR45 provides guidance on integrating agile practices into regulatory compliance under FDA 21 CFR Part 820 and ISO 13485, enabling faster prototyping, testing, and iteration.

China's National Medical Products Administration (NMPA) has implemented reforms to streamline medical device approvals, particularly for innovative devices. The special review procedure for innovative medical devices and the priority approval procedure provide accelerated pathways for high-impact products in areas including rare diseases, AI diagnostics, and radiation therapy.

The NMPA's fast-track pathways are selective but have significantly reduced approval times for qualifying devices-for example, shortening average evaluations for innovative devices by 83 days, while aligning with international standards (e.g., ISO, FDA) and addressing national healthcare needs.

Recent regulatory updates under the new Medical Devices Administration Law further emphasize efficiency and innovation by enabling transferability of market authorization certificates and promoting local development through initiatives such as Made in China 2025[25].

To remain competitive, Europe must complement its strict regulatory requirements with incentives and supportive mechanisms that foster innovation and lower barriers for emerging companies (Table 1).

In the U.S., the FDA offers different certification pathways depending on the device's risk profile, including the 510(k) pathway for lower-risk devices and the Premarket Approval (PMA) for higher-risk or more disruptive innovations. In China, the NMPA enforces regulations that favor local manufacturers and requires domestic clinical trials even for devices already approved in other regions.

The regulatory differences across these regions shape the expansion strategies of companies and influence global adoption timelines for new technologies. While the U.S. and China have adopted mechanisms to accelerate innovation, Europe faces the challenge of preserving its leadership in safety standards while safeguarding the competitiveness of its tech companies.

Table 1. Comparison of the certification processes in Europe, China, and the U.S.

Aspect	Europe	U.S.	China
Law	Medical Device Regulation (MDR)[26]	Drugs and Cosmetics Act Title, 21-Code of Federal Regulations[27]	State Order No. 739 and other NMPA orders28
Classes	I, IIa, IIb, III	I, II, III	I, II, III
Approval time	Lengthy process with recent delays	Long but predictable process	Variable
Innovation support	Moderate (no specific certifications)	High (breakthrough device designation)	Evolving
Local market access	Strict procedural regulation	Competitive	Local pr otectionism
Regulatory body	Fragmented (notified bodies)	Single (FDA)	Single (NMPA)
Language of submission	Covering European Languages	English	Chinese
Quality Management System	ISO 13485	21 CFR 820	ISO 13485 or Chinese GMP
Validity	Depends on declaration of conformity	Unexpired	5 years (for class I unexpired)
Process on significant product change	Report to notified body with evidence	New 510k	New change registration
Costs	High	Very high	Medium

Innovation and sustainability

The role of innovation in ensuring the sustainability of healthcare systems

The capacity for innovation is critical not only for the long-term sustainability of healthcare systems but also for their ability to adapt to emerging challenges, such as population aging, the emergence of new diseases, and the rapid evolution of new technologies and therapies[29, 30]. Healthcare innovation improves service quality, stimulates research and drives the development of new therapeutic interventions, fostering a virtuous cycle that attracts both talent and resources, ultimately enhancing the healthcare system efficiency.

To illustrate its impact, key indicators of the 2024 European medical device market and Spain's position are outlined below[31]:

- The European medical device market represents 26% of the global share in 2024, with a total value of €160 billion. Spain ranks fifth with 6.3%, behind Germany (26.5%), France (14%), Italy (12.1%), and the United Kingdom (6.8%).
- The medical device sector employs 880,000 people, a figure comparable to the pharmaceutical industry (900,000). Spain accounts for 32,000 jobs, ranking seventh behind Germany (257,000), Italy (117,600), the United Kingdom (117,200), France (84,000), Switzerland (67,500), and Ireland (48,000).
- Of the 190,200 patent applications filed to the European Patent Office (EPO) in 2024, 16,000 pertain to medical devices, surpassing the pharmaceutical industry (9,300) and biotechnology (8,300). However, Spain lags in innovation, accounting for only 1% of patent applications, far behind Germany (12.5%), France (5.4%), Switzerland (4.7%), the Netherlands (3.5%), and Italy (2.5%).

These figures highlight the need to strengthen the innovation ecosystem in Spain and across Europe. Priority areas include:

- Healthcare system optimization: Innovation in healthcare contributes to improving efficiency, reducing long-term costs, and promoting preventive and personalized care models. The use of emerging technologies, such as AI and smart medical devices, optimizes patient management and resource allocation in hospitals, reducing unnecessary hospital admissions and wait times[32]. These tools also support early disease detection and

minimize the need for costly interventions, while enabling rapid response to health emergencies like pandemics.

- Talent attraction and retention: Investing in innovation not only elevates healthcare quality but also strengthens scientific and clinical research. Cutting-edge healthcare systems attract highly skilled researchers and clinicians by providing opportunities to apply the latest advances in diagnostics and treatment.
- Accessibility and inclusion: The adoption of new technologies should not only focus on improving treatments and diagnostics but also on ensuring equitable access to the entire population, especially for vulnerable groups such as the elderly, who require continuous monitoring for chronic conditions. Tools like remote monitoring devices and health apps improve medication adherence. Technologies also enable patients to report their data via questionnaires (PROMs: patient-reported outcomes measures) and participate in health prevention and promotion initiatives. However, to ensure usability, it is crucial that these technologies have accessible interfaces adapted to their needs. Voice recognition, natural language processing, and even brain-computer interfaces can facilitate interaction with medical devices for these populations.
- Healthcare professional training: Beyond regulatory or financial hurdles, one key challenge in adopting new technologies is training healthcare professionals. The integration of advanced tools into clinical practice requires doctors and specialists to understand device functionality, interpret their results and apply findings in clinical practice. yet, training gaps persist. Addressing this requires integration of medical device regulation and technology use into medical curricula and hospital training, alongside continuous education programs on AI, telemedicine, and data analysis. This training should not only focus on technical aspects but also on developing the skills necessary to interpret the data generated by these tools and use them critically. In this way, the effective integration of technology into clinical practice can be ensured without compromising patient safety or quality of care.
- Agility in adopting new therapies and technologies: Efficient clinical trial processes are crucial for evaluating new therapies, ensuring patient safety without generating unnecessary delays. The adoption of personalized therapies improves clinical outcomes and reduces costs but requires flexible and adaptive regulatory frameworks. For healthcare innovation to be truly effective, it is essential to have agile regulations that keep pace with technological evolution, allowing the incorporation of new solutions without compromising safety or ethical standards.
- Investment and public-private collaboration: Fostering innovation requires not only investment in R&D but also the implementation of public policies that facilitate technology transfer and collaboration with the private sector. Currently, the lack of dedicated funding in this process prevents many innovations developed in academic settings from reaching the market. To address this issue, it is crucial to increase resources for Technology Transfer Offices (TTOs) and entrepreneurship centers, aiming to accelerate the conversion of scientific developments into marketable products. Expanding public-private partnerships will accelerate the validation and integration of innovations into healthcare systems.

Academia plays a central role in developing new technologies, but without considering market needs, regulations, and usability, integration of these technologies into healthcare system is challenging. Many innovations reach technical feasibility in academic settings, but the process stagnates without adequate technology transfer mechanisms. Successful technology transfer demands strategic planning, market adoption strategies, and adequate funding. Disruptive technologies, in particular, require educational efforts and targeted communication to build trust and visibility among healthcare professionals.

Ultimately, the successful implementation of innovation relies more on long-term strategy and collaborative execution than on the technology itself. In Spain, science and innovation strategies are still insufficiently aligned with this approach. Without concrete measures to promote cross-sector collaboration and funding for technology transfer, the country risks falling behind. Often, researchers themselves must take on commercialization, sacrificing their scientific focus without adequate training or resources.

In the coming years, new European guidelines are expected to support the integration of innovation into healthcare. For Spain to remain competitive, it must adopt similar strategies that facilitate technology transfer and accelerate the adoption of innovations in the healthcare sector.

Innovation ecosystem in Spain and Europe

Historically, the U.S. has led global investment in healthcare innovation. However, recent years have shown sustained growth in Europe and Spain, marked by the emergence of specialized funds in deep tech, healthcare, and diagnostics. This evolution reflects a growing interest to compete globally in digital health and AI-based solutions. Investment vehicles such as Asabys, Sofinnova, Buenavista Partners, Ysios, Columbus VC, Amadeus Capital, K-Fund, Adara, APEX, and Partech, among others, have begun channeling resources into startups and innovative companies, enabling projects that previously relied heavily on U.S. capital. Additionally, the European Union has strengthened its support for innovation through initiatives such as Horizon Europe and the European Innovation Council (EIC), which allocate substantial funding to disruptive technologies, including AI applied to healthcare.

Although the total investment volume in Europe still lags behind the U.S. and China, the growing specialization of European funds and their focus on strategic sectors have enabled the region to enhance its competitive position. These investments are promoting solutions that comply with rigourous quality and regulatory standards while adderssing both local and global market needs. However, to consolidate this trend, it is crucial to strengthen technology transfer mechanisms, ensuring that innovations reach the market efficiently.

The creation of technology-based companies is one of the main cpathways for transferring innovation in the healthcare sector. When the technology developed is protected through patents, it can subsequenetly be licensed by universities to third parties. However, recent evidence reveals certain challenges in this process. According to the University and Technology Transfer Report (2021) [33], while the number of patent applications has continued to rise (Figure 3), the creation of spin-offs has declined (Figure 4) and the number of contracts and licenses derived from technological innovation has remain stagnant (Figure 5).

This situation is partly due to the lack of specific support aimed at technology transfer, which prevents innovations developed in academic settings from effectively reaching the industrial sector. Moreover, investment vehicles that support intermediate development phases —still considered high risk and typically requiring between €3-10 million— remain scarce. This funding gap often leads spin-off companies

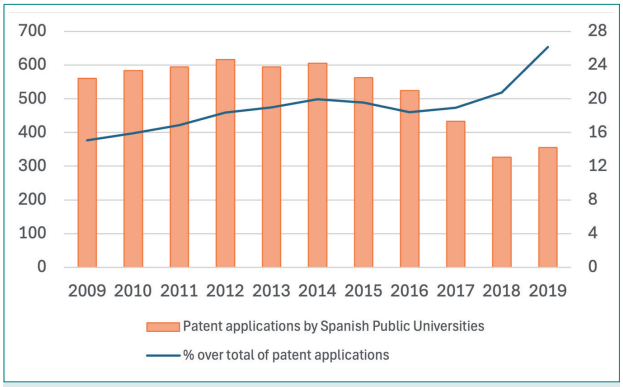

Figure 3. Evolution of national patent applications filed by Spanish public universities as a percentage of the total in Spain (2009-2019). Data obtained from the Spanish Patent and Trademarks Office (OEPM) using number of national patent application.

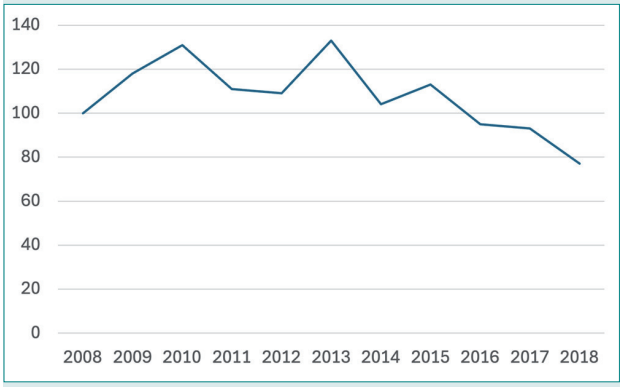

Figure 4. Evolution of spin-off creation (2008-2018). Data obtained from Conference of Presidents of Spanish universities.

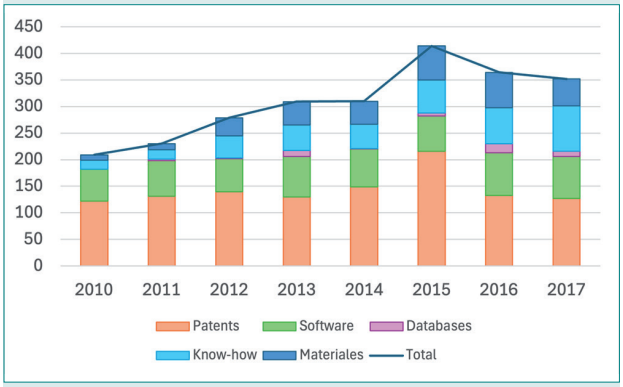

Figure 5. Distribution of the number of licenses by type of innovation (2010-2017).

to shut down within 3-5 years, without the opportunity to scale and advance to the next stage of growth.

In the digital health and AI sector, investors consistently highlight the importance of both the idea and the team behind it. However, in this highly dynamic and regulated field, the team is often prioritized over the idea. This is because, throughout the development process, ideas frequently evolve or even transform completely due to factors such as technological advancements, regulatory barriers, or market changes. Therefore, the resilience and execution capacity of the team are crucial aspects for the scalability of the project and its long-term viability.

That said, the idea remains a fundamental factor in capturing investors' attention. To be compelling it must address a clinically meaningful or economically impactful problem, be supported by solid data, and have a clear implementation plan. Ultimately, securing investment in digital health and AI requires a balanced combination of a strong, multidisciplinary team and a well-founded idea, as this balance not only attracts funding but also maximizes the impact on the healthcare system and competitiveness in the global market.

Public-private collaboration

To foster healthcare innovation, continuous investment in professional training and the establishment of supportive public policies are essential. Public-private partnerships play a decisive role in accelerate innovation by funding research projects and overcoming regulatory barriers. These collaborations have helped consolidate more sustainable innovation models in other countries and may be key to ensuring that healthcare innovations effectively reach patients.

In this context, European funding calls for Research and Innovation Action (RIA) projects have played a key role in integrating the various actors of the innovation ecosystem. These calls have begun to balance the weight between research and innovation, promoting broader consortia that include diverse stakeholders, such as academic institutions, end users, and industry, which in the past tended to play only a marginal role. Additionally, key actors such as law firms and consulting firms specialized in business development have been integrated to ensure a clear path to market translation. Nonetheless the lack of targeted support continuos to limit the real impact of these initiatives on the industry, underscoring the need for more robust R&D investment strategies and effective support mechanisms.

Moreover, public-private collaboration must extend beyond project funding to include the implementation of innovation models that accelerate the adoption of new technologies. For Spain and Europe to compete on equal terms with the U.S. and China, it is essential to strengthen technology transfer mechanisms and facilitate the implementation of more flexible and effective collaboration models. This involves improving regulations, simplifying administrative processes, and offering incentives that encourage private sector participation in healthcare innovation.

Data management and ethics

Use of AI and big data in healthcare

The digitalization of the healthcare sector has enabled a convergence between AI, big data, and medical care, facilitating more personalized and efficient healthcare. One of the main drivers of this transformation is the use of mobile devices (mHealth), enabling real-time data collection, benefiting both patients and healthcare professionals. The widespread use of these devices has allowed the deployment of applications for managing appointments, accessing medical records, test results, and medical images. They also facilitate citizen interaction with professionals through telemedicine systems, in which home monitoring devices can be integrated.

However, to ensure structured and efficient access to data is crucial for these digital tools to have a real impact on health. Major challenges remain around data governance, structure, and availability. Patients should be recognized as the true owners of their data, with the ability to transparently decide how and with whom to share it. Currently, most health data is fragmented across hospitals and research centers, hindering interoperability between systems and slowing the development and implementation of AI-based health solutions. Clinical information is not always available in a standardized and reusable format, which creates barriers to data integration across institutions. To address this issue, it is necessary to promote open standards that facilitate data integration across different institutions while ensuring data quality and integrity.

A major challenge in modern healthcare is the fragmentation of data and formats, which hinders their effective use in both clinical practice and biomedical research. In response to this issue, data federation technologies offer a solution by enabling the analysis

of decentralized data without requiring data transfer, safeguarding patient privacy. This approach facilitates the integration of large datasets, especially when hospitals, research centers, startups, and tech companies collaborate. Projects such as clinical data biobanks, medical imaging repositories, population cohort data platforms, and public-private access programs such as the UK Biobank or the U.S. TCIA have proven to be successful models for leveraging healthcare data without compromising privacy or citizen's rights. In this regard, the implementation of common regulatory frameworks —such as those proposed by the European Union with the European Health Data Space (EHDS)— would further enable efficientcross-border data exchange, facilitating research while ensuring strong protection for individual rights.

Ensuring a secure, privacy-preserving data management model is essential to build trust among patients and professionals in these new technologies. Technological tools such as dynamic consent management platforms will allow patients to grant or revoke data usage permissions easily and with full traceability. Securing anonymization and data aggregation through techniques such as homomorphic encryption and data federation ensure that patient privacy is preserved while making datasets accessible to rsearchers and companies.

Drawing inspiration from established practices, such as organ or blood donation, the concept of the "data donor" has emerged. This enables citizens to support scientific progress and AI-based healthcare under ethical, secure, and transparent conditions. As with traditional donations, it is crucial to establish clear mechanisms for informed consent, ensuring that donors understand how their data will be used. Additionally, privacy and security guarantees must be provided, with audits to prevent misuse or unauthorized commercialization, as well as non-monetary incentives, such as social recognition or benefits derived from the use of their data, like personalized check-ups.

Beyond healthcare management, the reuse of health data creates significant value for biomedical research by generating real-world evidence (RWE). To date, the evaluation of new treatments is conducted through randomized controlled trials (RCTs), which, while being the gold standard in biomedical research, require substantial financial resources and limit the number of participating patients and the duration of follow-up periods. This creates a gap between results obtained in RCTs and the real-world effectiveness of treatments when applied to the general population.

One alternative to expand the evidence base is the extraction of real world data (RWD) from clinical health systems or existing repositories. RWD allows for the personalization of therapies and supports clinical decision-making with information based on everyday clinical practice. Additionally, clinical trials often include highly selective populations that do not accurately reflect the diversity of real-world patients, resulting in limited applicability of the results. To overcome these limitations, there are national and European Union initiatives aimed at creating shared data spaces that facilitate the extraction of clinical evidence and research, recognizing the value of health data as a public good and balancing its use with respect for privacy and the confidentiality of personal information.

Data ownership and patient empowerment

Patient empowerment refers to patients playing an active role in decisions about their health, including how they participate in managing their treatments. With the digitalization of medicine, this concept has gained renewed relevance, supported by health training and education —both for specialists and the general public— which are essential to fully harness the potential of new health technologies. As medicine advances towards more digital, personalized, and participatory models, technological competencies and patient empowerment enable an optimize medical care enhances individual autonomy in managing personal health.

A central aspect of empowerment is granting patient access to their own health data. As discussed earlier, new wearable and portable monitoring systems now provide real-time information on health status and therapy, allowing them to track their progress and engage more actively in decision-making. Thanks to technological advances, this possibility is increasingly within reach, offering greater control and autonomy in managing their health. Advances in AI and implantable medical devices extende these possibilities by supporting continuous and personalized supervision, facilitating early detection of changes and dynamically adjusting treatment. Implantable devices such as brain-computer interfaces (BCIs) can stream real-time data, such as brain activity[34,35], heart rate[36], or glucose levels, to external systems, which can generate personalized alerts recommending therapy adjustments when the data suggests reduced treatment effectiveness. Some devices, such as the neural stimulator for pain managemen, can

even adapt therapy dynamically modify the intensity of stimulation based on signals from the patient's own nervous system, allowing it to adapt to changes in their condition without medical intervention.

Additionally, these technologies would enable remote treatment management by healthcare providers after receiving healthcare updates on the patient's condition. For cardiac implants, studies predict that quarterly check-ups could be spaced out to every 3 to 24 months[36]. This would optimize healthcare system efficiency, enable rapid intervention, and reduce hospital admissions. Improved remote care will be further enhanced through integration with telemedicine platforms that enable virtual connections between patients and healthcare professionals for evaluations and treatment adjustments.

AI further enables early detection of potential complications and anomalies through real-time monitoring of patient data, allowing for quick intervention before the condition worsens and lowering the burden on emergency visits and hospitalizations. The continuous analysis of an evolving condition enables real-time therapy adjustments and integration of patient-reported information[35]. This evolution in clinical management is a major advancement in precision medicine by enabling truly individualized and dynamic treatment. Patients may also have the option to actively adjust therapeutic parameters —such as frequency or intensity of stimulation— in the treatment of conditions, such as epilepsy or Parkinson's disease, in accordance with pre-established safety protocols[37]. An illustrative example is a Parkinson's patient with a deep brain stimulation implant who co-authored a scientific article describing their lived experience with the technology-highlighting how empowered patients can actively contribute to innovation[38]. Patients must trust the transparency of AI systems and how they operate to access information to fully leverage thir value towards decision-making for clinical conditions. Educating patients is crucial to ensure they understand how these tools work and how they impact their medical care.

Patient engagement

The involvement of healthcare professionals in patients' digital education can significantly improve acceptance and effective use of these technologies. At the same time, data privacy and security remain fundamental concerns, as the collection and sharing of real-time information require strict safeguards. These technologies could also offer patients personalized educational content about their condition and treatment, along with practical advice and guidance on when to seek medical help or adjust daily habits.

An informed and engaged patient can make more conscious decisions about their health, collaborate actively with healthcare professionals, and contribute to the development of more preventive and personalized medicine. In this model, patients shifts from being passive recipients of care to becomes active participants in the prevention, follow-up, and treatment of their condition. This transformation strengthens the efficiency and sustainability of the care model. Technology facilitates this shift by providing direct communication channels, real-time monitoring tools, and systems that ensure transparent and secure access to their data, enabling a more efficient, accessible, and person-centered model of care.

Ethical, technical, and regulatory challenges

The adoption of AI-guided medical therapies introduces multiple ethical, technical, and regulatory challenges that vary by application. From AI models used for diagnostic support to advanced medical devices such BCIs, each type of technology introduces particular issues. Systems designed to provide adaptive or personalized therapies, and those that operate without human supervision, pose additional dilemmas requiring careful consideration.

Among the most relevant ethical challenges is informed consent. The functioning of AI systems is complex, which can make it difficult for patients to fully understand how decisions about their treatment are made. In the case of technologies like BCIs, this issue is amplified, as the interaction between system and patient is direct and continuous. Patient autonomy is also at stake: to what extent can the system's decisions replace those of the physician or the user themselves? Moreover, responsibility in the event of adverse outcomes is another unresolved issue: should accountability fall on the treating physician, the algorithm developers, or the AI system itself? Other ethical dilemmas include data biases and fairness in access to these technologies. If AI models have been trained on poorly representative datasets, there is a risk that AI-based treatments will be less effective or even inappropriate for certain underrepresented groups. This issue affects diagnostic algorithms as well as advanced devices like BCIs, where poor programming may result in suboptimal therapy for

some patients. Likewise, data privacy and security are critical concerns —especially in the case of neurodata generated by BCIs, which can be extremely sensitive and vulnerable to misuse. Data ownership and permitted uses also complicate the landscape, as it is unclear who has the right to access it and for what purposes (medical, insurance, research, etc.).

A central challenge of AI in healthcare is its interpretability and reliability. Many AI models function as "black boxes," making it difficult for doctors and patients to understand how they reach certain conclusions. This generates distrust and may hinder adoption in clinical practice. In the case of BCIs, this problem is even more critical, since real-time decision-making depends on interpreting extremely complex brain signals. Additionally, AI technologies must be robust and safe, minimizing the possibility of errors or malfunctions. Cybersecurity is key, as network-connected medical devices can be vulnerable to cyberattacks, compromising patient data privacy and safety. As medical devices become more connected, cybersecurity threats have also increased. In 2023, 92% of medical institutions in the U.S. reported experiencing some form of cyberattack, highlighting the scale of the problem[14]. Depending on the type of medical technology, it must comply with safety standards established by regulatory agencies. However, beyond regulations, strict governance and control protocols must be implemented to minimize security risks. In general, any device that connects to a network and collects patient data should incorporate multiple layers of cybersecurity to avoid vulnerabilities[39].

At the regulatory level, the lack of clear and standardized guidelines hinders the approval of new AI-based technologies. Agencies such as the FDA and EMA are making progress in developing specific frameworks, but approval timelines remain long and are not always adapted to the fast pace of technological evolution. In the case of advanced medical devices like BCIs, these processes are even more complex due to the risks associated with implantation and the need to ensure long-term safety and efficacy. Clinical validation remains a major hurdle, as clinical trials must demonstrate that the AI works correctly while ensuring that decisions are safe and replicable across different clinical settings. In any case, the physician remains ultimately responsible for the patient's diagnosis and treatment, meaning that the physician retains ultimate responsibility for clinical decisions. Currently, AI in medicine is used as a support tool and not as a substitute for clinical judgment. Therefore, if the professional uses AI outside its approved scope ("off-label use") or fails to verify the results, their liability increases. To avoid problems, it is essential that physicians receive proper training in using these tools and that clear protocols exist for integrating AI results into clinical decision-making.

Conversely, the manufacturer of an AI solution also assumes direct responsibility for the design, development, and validation of the software, ensuring its compliance with safety and efficacy regulations. To this end, the manufacturer must clearly define system specifications and limits of use, provide clinical evidence of its performance, and ensure the software functions reliably and consistently. In addition, post-market monitoring must be carried out to detect potential failures and address them in a timely manner. If an AI system malfunctions due to design flaws or is used outside approved parameters, liability rests with the manufacturer.

Ultimately, the distribution of responsibilities in the use of AI in healthcare depends on multiple factors, including professional training, regulatory compliance by developers. Establishing a robust ethical, technical, and secure regulatory framework is essential to enable the implementation while minimizing risks, protecting patients, and fostering public trust.

Conclusion

Medicine today —and increasingly so in the future— is inseparable from the advancement and adoption of new technologies. These innovations are already essential for improving prevention, enabling early detection of risk factors through real-time monitoring and AI, which allows for timely interventions before disease manifests. They are also transforming predictive capabilities, with algorithms that analyze lifestyle habits and identifying patterns linked to chronic conditions or acute events such as heart attacks and strokes. In the realm of personalization, the adoption of genetic sequencing, imaging biomarkers, and clinical data analysis makes it possible to tailor treatments to each patient's unique profile, improving efficacy and reducing side effects. Moreover, digital platforms, telemedicine, and remote monitoring devices foster greater patient engagement by improving access to information and supporting informed, shared decision-making. Together, these advances embody the principles of 4P Medicine: predictive, preventive, personalized, and participatory.

The implementation of technology also contributes significantly to the sustainability of the healthcare

system. By reducing unnecessary clinical visits, enabling earlier diagnoses, and automating routine tasks personalized such as image analysis —technology tools streamline workflows and improve physician-patient communication.

In addition, health technologies support healthcare professionals not only by saving time through automation of repetitive tasks and process optimization —as seen with AI in medical image review or clinical data management— but also by improving clinical accuracy and reducing diagnostic errors through evidence-based decision support systems. As a result, clinicians can devote more time to high-value activities, including the diagnosis of complex cases and the delivery of personalized care. However, for these innovations to be effective, it is crucial to ensure their proper integration into clinical workflows by providing specific training to healthcare professionals and ensuring interoperability across information systems.

The adoption of these technologies also raises regulatory and ethical challenges, such as data privacy, equitable access to care, and the governance of AI in medicine. Collaboration between regulatory agencies, technology developers, and healthcare professionals will be key to establishing frameworks that promote innovation while safeguarding patient safety and user trust.

Perhaps the most striking paradox of technology in healthcare is that, while it enhances system efficiency, it also makes care more human. By relieving professional of routine burdens, it allows them to focus on what truly matters: connecting with understanding and supporting patients throughout their health journey. To fully realize this potential, it is imperative to foster public-private collaboration, promote technology transfer, and invest in research and development. Innovation must move beyond pilot projects to generate measurable improvements in healthcare delivery. Only through effective implementation —not just development— can these advances translate into meaningful benefits for patients. In this way, the continued integration of health technologies will not only improve care quality but also contribute to a more efficient, sustainable, and patient-centered healthcare system.

References

[1] https://www.grandviewresearch.com/industry-analysis/digital-health-market

[2] https://www.weforum.org/impact/how-digital-healthcare-tools-cut-costs-boost-outcomes/

[3] https://www.frost.com/news/press-releases/600-m-6-billion-artificial-intelligence-systems-poised-dramatic-market-expansion-healthcare/

[4] Collier M, Fu R, Yin L. Artificial intelligence: healthcare's new nervous system. Accenture plc. 2017. URL: https://www.accenture.com/_acnmedia/PDF-49/Accenture-Health-Artificial-Intelligence.pdf

[5] Oliver Wyman. (2023). Positioning the industry for growth in robotic surgery. Oliver Wyman Health. https://www.oliverwyman.com/our-expertise/perspectives/health/2023/august/positioning-the-industry-for-growth-in-robotic-surgery.html

[6] Z. Liu *et al.*, "Clinical efficacy of enhanced recovery surgery in Da Vinci robot-assisted pancreatoduodenectomy," *Sci Rep*, vol. 14, no. 1, p. 21539, 2024, doi: 10.1038/s41598-024-72835-9.

[7] F. Celotto *et al.*, "Da Vinci single-port robotic system current application and future perspective in general surgery: A scoping review," *Surg Endosc*, vol. 38, no. 9, pp. 4814-4830, 2024, doi: 10.1007/s00464-024-11126-w.

[8] C. Wall, V. Hetherington, and A. Godfrey, "Beyond the clinic: the rise of wearables and smartphones in decentralising healthcare," *NPJ Digit Med*, vol. 6, no. 1, p. 219, 2023, doi: 10.1038/s41746-023-00971-z.

[9] T. Sun, X. He, X. Song, L. Shu, and Z. Li, "The Digital Twin in Medicine: A Key to the Future of Healthcare?," *Front Med (Lausanne)*, vol. 9, Jul. 2022, doi: 10.3389/fmed.2022.907066.

[10] John P. Fisher and Antonios G. Mikos and Joseph D. Bronzino, *Tissue Engineering*, 1st ed., vol. 1. CRC Press, 2007.

[11] Q. Zhao, N. Cheng, X. Sun, L. Yan, and W. Li, "The application of nanomedicine in clinical settings," *Front Bioeng Biotechnol*, vol. 11, Jun. 2023, doi: 10.3389/fbioe.2023.1219054.

[12] J. K. Patra et al., "Nano based drug delivery systems: recent developments and future prospects," *J Nanobiotechnology*, vol. 16, no. 1, p. 71, Dec. 2018, doi: 10.1186/s12951-018-0392-8.

[13] Pastorino, R., De Vito, C., Migliara, G., Glocker, K., Binenbaum, I., Ricciardi, W., & Boccia, S. (2019). Benefits and challenges of Big Data in healthcare: An overview of the European initiatives. *European Journal*

of Public Health, 29(Suppl_3), 23-27. https://doi.org/10.1093/eurpub/ckz168

[14] Somolinos-Simón, F. J., García-Sáez, G., Tapia-Galisteo, J., Corcoy, R., & Hernando, M. E. (2024). Cluster analysis of adult individuals with type 1 diabetes: Treatment pathways and complications over a five-year follow-up period. *Diabetes Research and Clinical Practice*, 215, 111803. https://doi.org/10.1016/j.diabres.2024.111803

[15] Bragazzi, N. L., Dai, H., Damiani, G., Behzadifar, M., Martini, M., & Wu, J. (2020). How Big Data and artificial intelligence can help better manage the COVID-19 pandemic. *International Journal of Environmental Research and Public Health, 17*(9), 3176. https://doi.org/10.3390/ijerph17093176

[16] Danielle, R., & Muin, K. (2022). Artificial intelligence in medicine and public health: Prospects and challenges beyond the pandemic. *Genomics and Precision Health, Centers for Disease Control and Prevention*, 1-7. https://doi.org/10.1109/ICCTCT.2018.8550857

[17] Izard, S. G., Juanes, J. A., García-Peñalvo, F. J., Estella, J. M. G., Ledesma, M. J. S., & Ruisoto, P. (2018). Virtual reality as an educational and training tool for medicine. *Journal of Medical Systems, 42*(3), 50. https://doi.org/10.1007/s10916-018-0900-2

[18] Rodríguez-Matesanz, M., Guzmán-García, C., Oropesa, I., Rubio-Bolivar, J., Quintana-Díaz, M., & Sánchez-González, P. (2022). A new immersive virtual reality station for cardiopulmonary resuscitation objective structured clinical exam evaluation. *Sensors, 22*(13), 4913. https://doi.org/10.3390/s22134913

[19] EIT Health. (n.d.). A framework for innovation in healthcare. Retrieved October 2025, from https://eithealth.eu/a-framework-for-innovation-in-healthcare/

[20] R. R. Seva, A. L. S. Tan, L. M. S. Tejero, and M. L. D. S. Salvacion, "Multi-dimensional readiness assessment of medical devices," *Theor Issues Ergon Sci*, vol. 24, no. 2, pp. 189-205, Mar. 2023, doi: 10.1080/1463922X.2022.2064934.

[21] Y.-J. Chen, C.-M. Chiou, Y.-W. Huang, P.-W. Tu, Y.-C. Lee, and C.-H. Chien, "A Comparative Study of Medical Device Regulations: US, Europe, Canada, and Taiwan," *Ther Innov Regul Sci*, vol. 52, no. 1, pp. 62-69, Jan. 2018, doi: 10.1177/2168479017716712.

[22] U.S. Food and Drug Administration. (2022). *The Software Precertification (Pre-Cert) Pilot Program: Tailored total product lifecycle approaches and key findings*. U.S. Department of Health and Human Services. https://www.fda.gov/media/161815/download

[23] Deloitte. (n.d.). *Reimagining digital health regulation: An agile model for regulating software in health care*. https://www2.deloitte.com/content/dam/Deloitte/us/Documents/public-sector/reimagining-digital-health-regulation.pdf

[24] Greenlight Guru. (2025). *The ultimate guide to agile design and development for medical devices* (Bogdanowicz, L. & Mastroianni, M.). https://www.greenlight.guru/downloads/agile-design-development-medical-devices

[25] Daxue Consulting. (2025, March 27). *China's medical device regulations*. Retrieved April 7, 2025, from https://daxueconsulting.com/china-medical-device-regulations/

[26] European Union. (2017). *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*. Official Journal of the European Union, L117, 1-175. https://eur-lex.europa.eu/eli/reg/2017/745/oj

[27] U.S. Food and Drug Administration. (2024). *Title 21-Food and Drugs: Code of Federal Regulations (CFR)*. U.S. Government Publishing Office. https://www.ecfr.gov/current/title-21

[28] National Medical Products Administration. (2021). *Regulations on the supervision and administration of medical devices (State Council Order No. 739)*. State Council of the People's Republic of China. https://www.nmpa.gov.cn/xxgk/fgwj/flxzhfg/20210318145936136.html

[29] Gocke, D., Johnston-Webber, C., McGuire, A., Wharton, G., & PHSSR (2023). *Building sustainable and resilient health systems* (Partnership for Health System Sustainability and Resilience). World Economic Forum. https://www3.weforum.org/docs/WEF_PHSSR_Building_Sustainable_and_Resilient_Health_Systems_2023.pdf

[30] Fundación IDIS. (2022). *El camino a la innovación tecnológica: Cartera de servicios y guías de práctica clínica*. https://www.fundacionidis.com/uploads/informes/20221017_INFORME_V1_El_camino_a_la_innovacin_tecnolgica_Cartera_de_Servicios_y_Guas_de_Practica_Clnica.pdf

[31] MedTech Europe. (2024). *MedTech Europe's facts & figures 2024*. https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europes-facts-figures-2024.pdf

[32] Alowais, A., *et al.* (2023). BMC Medical Education, 23, 689. https://doi.org/10.1186/s12909-023-04698-z

[33] Spanish University Data. La Universidad Española en Cifras 19-20. Conferencia de Rectores de Universidades Españolas, CRUE. ISBN 978-84-09-71085-0 https://www.crue.org/publicacion/espanola-en-cifras/

[34] K. M. Patrick-Krueger, I. Burkhart, and J. L. Contreras-Vidal, "The state of clinical trials of implantable brain-computer interfaces," *Nature Reviews Bioengineering*, vol. 3, no. 1, pp. 50-67, Sep. 2024, doi: 10.1038/s44222-024-00239-5.

[35] J. Herron *et al*., "The convergence of neuromodulation and brain–computer interfaces," *Nature Reviews Bioengineering*, vol. 2, no. 8, pp. 628-630, Apr. 2024, doi: 10.1038/s44222-024-00187-0.

[36] N. Varma *et al*., "Remote monitoring of cardiac implantable electronic devices and disease management," *Europace*, vol. 25, no. 9, Aug. 2023, doi: 10.1093/europace/euad233.

[37] A. R. Merner *et al*., "Changes in Patients' Desired Control of Their Deep Brain Stimulation and Subjective Global Control Over the Course of Deep Brain Stimulation," *Front Hum Neurosci*, vol. 15, Feb. 2021, doi: 10.3389/fnhum.2021.642195.

[38] M. D. McAuley, "Deep brain stimulation for Parkinson's disease: A case for patient empowerment," *Brain Stimul*, vol. 16, no. 1, pp. 97-99, Jan. 2023, doi: 10.1016/j.brs.2023.01.840.

[39] P. Williams and A. Woodward, "Cybersecurity vulnerabilities in medical devices: a complex environment and multifaceted problem," *Medical Devices: Evidence and Research*, p. 305, Jul. 2015, doi: 10.2147/MDER.S50048.